

# ASX ANNOUNCEMENT

# 29 August 2023

# EBR Half-Year Results 2023 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 2023, together with a securityholder update.

During the half-year, EBR:

- Achieved primary efficacy and safety endpoints in its pivotal SOLVE-CRT trial ("SOLVE"), paving the way to FDA approval by the end of 2024
- Successfully completed a US\$21.6m/A\$32.7m<sup>1</sup> capital raise to support regulatory activities and commercial launch
- Unlocked and completed drawdown of US\$20.0m/A\$30.2m<sup>2</sup> from the second tranche of EBR's growth capital facility with Runway Growth Capital based upon successful achievement of clinical trial endpoints
- Strengthened management team with the appointment of Dr. Rick Kuntz as consulting Chief Scientific Officer
- Maintained a strong cash position of ~US\$84.8m/A\$128.1<sup>2</sup> m at 30 June 2023, which includes cash and cash equivalents of US\$51.6/A\$77.8<sup>2</sup> million and short-term investments of US\$33.2/A\$50.3<sup>2</sup> million

## **Operating and Financial Review**

#### Financial performance

For the half-year ended 30 June 2023, the Company's net loss is US\$15.6m/A\$23.6<sup>2</sup>

(30 June 2022: US\$15.6m/A\$23.6<sup>2</sup>).

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

- Operational expenses of US\$15.6m/A\$16.5m<sup>2</sup>, a decrease of US\$0.9m/A\$1.5m<sup>2</sup> compared to prior corresponding period (pcp) driven by a US\$1.3m/A\$1.9m<sup>2</sup> reduction in research and development materials, a US\$0.7m/A\$1.1m<sup>2</sup> reduction in clinical trial expenses, and offset by a US\$0.9m/A\$1.3m<sup>2</sup> increase in salaries, payroll taxes and employee related benefits.
- 1% increase in net cash used in operating activities compared to pcp, to US\$15.6m/A\$23.5m<sup>2</sup>.
- Strong cash position of US\$84.8m/A\$128.1m<sup>2</sup> at 30 June 2023.

To view the Half-Year Report, please click:

https://announcements.asx.com.au/asxpdf/20230829/pdf/05t6m51pcrgl7m.pdf

<sup>&</sup>lt;sup>1</sup> Assumes an average exchange rate of A\$:US\$0.6605

<sup>&</sup>lt;sup>2</sup> Assumes an exchange rate of A\$:US\$0.66229

#### Obtained positive results in pivotal SOLVE-CRT trial

In May, EBR achieved a major milestone by announcing positive top-line data from its pivotal SOLVE-CRT trial at the 2023 Heart Rhythm Society ("HRS") Conference in New Orleans. The trial met both primary endpoints demonstrating clinically significant improvement in heart function (a 16.4% reduction in heart volume compared to a 9.3% benchmark), with more than 80.9% of patients free from device or procedure-related complications (compared to a 70% benchmark). The trial evaluated the safety and efficacy of WiSE<sup>®</sup> in heart failure patients whose conditions were classified as acute lead failures, chronic lead failures, high-risk upgrades, or leadless upgrades. The outcome validates the WiSE<sup>®</sup> device as a safe and efficacious CRT treatment, representing a significant breakthrough in the treatment of cardiac arrhythmia. Following the positive trial results, EBR will submit a manuscript to a medical journal for peer-review and publication.

#### Secured funding for regulatory activities & initial commercial launch

In June, EBR successfully raised A\$30.0m via an Institutional Placement ("Placement") and launched its Security Purchase Plan ("SPP") for eligible shareholders, which closed after the half-year raising ~A\$2.7m. Both the Placement and SPP issued new CDIs at an issue price of A\$0.91 per CDI, ranking equally with all existing CDIs on issue. The Placement was strongly supported by institutional and sophisticated investors and proceeds from the raise will support EBR's regulatory approval activities and commercialisation strategy, including finalising pre-market approval ("PMA") submission to the FDA, manufacturing scale up and development of sales and marketing capabilities for initial commercial launch.

Subsequent to the half-year, EBR also announced its successful draw down of US\$20.0m after unlocking the second tranche of the Company's growth capital facility with Runway Growth Capital on 6 June 2023 based upon achieving the SOLVE pivotal trial endpoints. The second tranche of the facility provides additional nondilutive funding flexibility and further supports EBR's regulatory activities and initial commercial launch.

#### Continued engagement with the FDA

EBR is utilising a modular submission for US Food and Drug Administration ("FDA") approval, with three out of the five modules having already been submitted. The fourth module will be submitted in Q3 2023, with the final module scheduled to be submitted early 2024. EBR expects full FDA approval by the end of 2024. The Company has a successful track record of engagement with the FDA spanning multiple years and looks forward to continuing to engage with the regulatory body during the final stages of the approval process.

#### Identified expanded market opportunities

EBR remains focused in progressing its commercialisation strategy, subject to regulatory approval. Focusing initially within the US CRT market, the Company will leverage its established clinical partnerships to drive initial sales growth, with sales expected by H1 2025. EBR's significant clinical relationships with sites in the US have been developed over the course of the SOLVE-CRT trial and will be a valuable network for commercial launch. EBR targets an initial addressable market of US\$2.6bn in 2024 and estimates the addressable market to grow by an additional US\$4.2bn in the near-term, led by growth in the Totally Leadless CRT (TLC) market. The TLC market consists of patients with a leadless right ventricle pacemaker who subsequently develop pacing induced heart failure, who receive an upgrade to CRT with the WiSE System; and new patients with an indication for CRT who receive a WiSE System in combination with a leadless pacemaker as first-line therapy. Expanded use cases of WiSE into new patient groups and geographies enables the Company to target a long-term addressable market opportunity of US\$9.6bn

## **Appointed Chief Scientific Officer**

In February, EBR strengthened its management team with the appointment of Dr. Rick Kuntz as consulting Chief Scientific Officer, whose 15 years of experience in the medical industry will be invaluable as the Company executes on its regulatory and commercialisation strategy. Dr. Kuntz formerly occupied the positions of Senior Vice President, Chief Medical and Scientific Officer of Medtronic and founding CEO of the Harvard Clinical Research Institute.

#### **Investor Relations**

During the half-year, EBR also continued to feature in the media and at high-profile conferences, having presented virtually to Wholesale Investor's 30,000+ investor network across Australia, New Zealand, Singapore, and the UK.

#### ENDS

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

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#### 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<sup>®</sup>) 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<sup>®</sup> 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<sup>®</sup> 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, 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. 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.