

# Capital Raising Presentation

**EBR funded into commercialisation**

June 2023

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- a placement of new CHES Depositary Interests in EBR ("New CDIs") to certain institutional and sophisticated investors (the "Placement"); and
- an offer of New CDIs under a security purchase plan to eligible CDI holders in Australia and New Zealand ("Security Purchase Plan" or "SPP").

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# Disclaimer

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# Executive Summary

## Novel technology

- The WiSE® CRT System is the world's smallest inside-the-heart wireless cardiac pacing device, and the only way to provide leadless Cardiac Resynchronization Therapy (CRT)
- There are no direct competitors for the WiSE CRT System, the technology and other leadless pacemakers are complementary

## Clinically de-risked

- Primary safety and efficacy endpoints met for recently completed SOLVE-CRT trial demonstrating improved heart function and fewer complications
- Results confirm that the WiSE CRT System is a safe and highly effective treatment for patients suffering from heart failure

## Clear path to Commercialisation

- Clear pathway to FDA approval with final PMA submission to the FDA expected in Q1 2024
- Breakthrough Device Designation to support and expedite the FDA review process
- Strategy in place to prepare for commercial launch, targeting initial adoption from sites participating in the clinical trial

## Significant market opportunity

- Initially targeting US\$2.6bn market opportunity including patients who cannot receive CRT from existing devices, are at high risk for conventional upgrades, or require CRT upgrades from leadless pacemakers
- Opportunity to expand the addressable market to US\$9.6bn by targeting new patient groups, indications and geographies
- 20+ years of R&D and an extensive portfolio of 97 patents provides a substantial economic moat for EBR<sup>1</sup>

## Capital raising details

- Placement and SPP to raise up to approximately A\$35m: Placement of approximately A\$30m and SPP to eligible CDI holders to raise up to a further A\$5m
- New CHESS depositary interests over shares of common stock ("New CDIs") under the Placement will be issued at a price of A\$0.91 per New CDI, representing a discount of approximately 7.1% to the last close of A\$0.980<sup>1</sup>, and 12.6% to the 10-day VWAP of A\$1.041<sup>1</sup>
- In addition to the Capital Raising Proceeds, EBR intends to draw down on Tranche Two of the Runway Growth Capital debt facility of US\$20m before 30 June 2023
- Funds raised will be used to expand sales team and inventory (working capital) for commercial launch
- Post completion of the capital raise, EBR will have a pro forma cash balance of A\$127.9m / US\$87.0m<sup>2</sup>

<sup>1</sup> As at close 21 June 2023.

<sup>2</sup> Based on cash balance as at 31 March 2023, estimated Q2 2023 expenditure, and assuming completion of a capital raising of A\$30m and US\$20m drawdown of Tranche 2 of Runway debt facility, and capital raising costs. Excludes proceeds raised under the SPP.

# Traditional pacemakers are suboptimal

Traditional pacemakers use wires or leads to deliver energy to the heart, which can lead to many problems



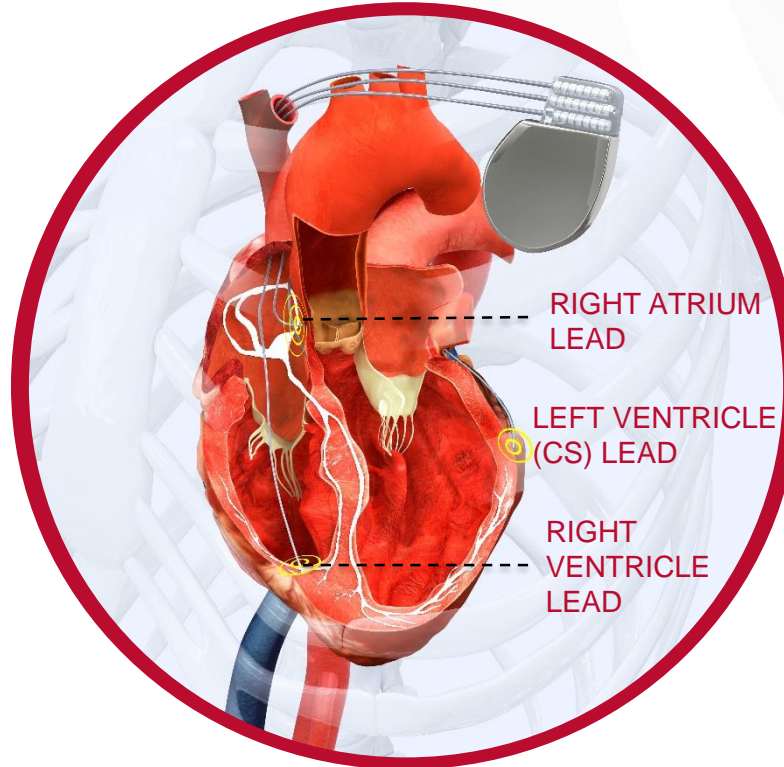
Coronary Sinus limits  
Left Ventricle (LV) lead  
placement locations



Pathway for  
pathogens to  
myocardium



Associated with  
phrenic nerve  
stimulation



Can migrate and  
sometimes fracture



Difficult to place



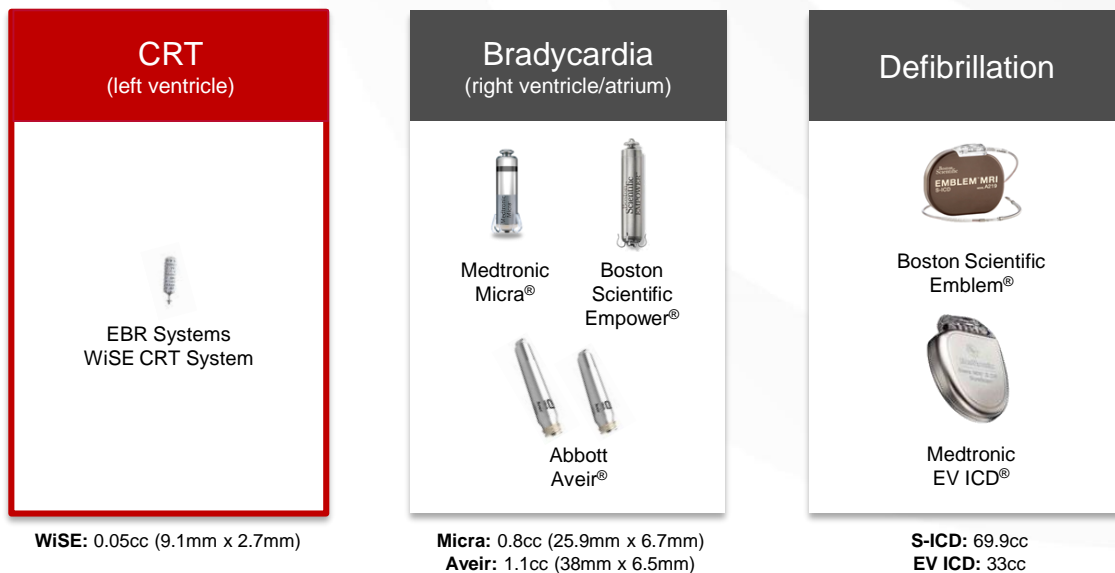
LV lead must be  
placed outside the  
heart to avoid blood  
clots

# No direct competitors

EBR's WiSE CRT System is the only wireless device that can deliver cardiac resynchronisation therapy

- There are several wireless cardiac rhythm management products in the market
- Patients with heart failure require a therapy called Cardiac Resynchronisation Therapy (CRT) which uses cardiac pacing devices to **stimulate the left ventricle** and coordinate the left and right sides of the heart
- WiSE CRT System is the **only wireless device small enough to stimulate the left side of the heart** and therefore deliver CRT

## Wireless cardiac rhythm management landscape<sup>1</sup>



<sup>1</sup>Illustrative sizing (not to scale)



# EBR has a wireless solution for heart failure patients

EBR's WiSE CRT System and other leadless pacemakers are complementary

## WiSE CRT System fills the gap

Currently the only leadless solution globally for LV pacing including CRT.

## Other wireless pacemakers are too big for LV pacing

This increases the risk of blood clots, restricting their use to right ventricle (RV) and right atrium (RA) pacing only.

## Complementary solution

WiSE CRT System can be used in conjunction with wireless RV/RA pacemakers to deliver CRT.

## Strong competitive protection

WiSE CRT System is protected by over 97 issued patents globally.

### Left ventricle



EBR Systems  
WiSE CRT System

### Right ventricle/atrium



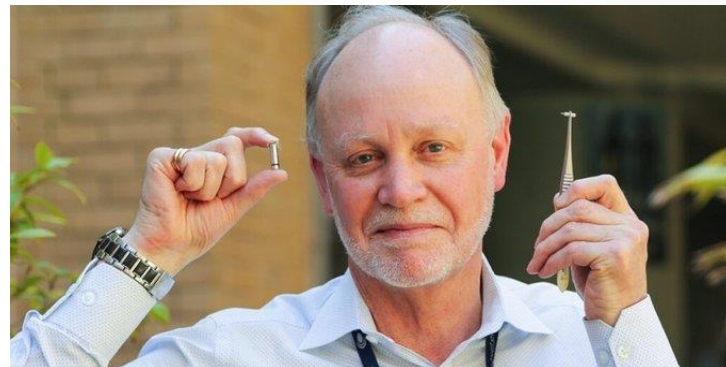
Medtronic  
Micra®



Boston  
Scientific  
Empower®



Abbott  
Aveir®



Dr. Jeffrey Alison, Monash Hospital, Melbourne.

*Micra on the left, WiSE CRT device held by tweezers on the right.*

Note: Illustrative sizing (not to scale)



# Pivotal SOLVE-CRT Study meets all endpoints

Positive results confirm WiSE CRT System as a highly effective treatment option for patients with heart failure

## Primary efficacy endpoint met

**-16.4%**

$p = 0.003$

Decrease in in left ventricular end systolic volume  
**vs -9.3% target**, showing improved heart function



### Success in high-risk patients

SOLVE-CRT patient pool consists of patients who have failed conventional CRT



### Other key data

All data analysed to date shows consistent, positive results in reversing heart failure symptoms and physiology

## Primary safety endpoint met

**80.9%**

$p < 0.001$

Patients free from type I complications **vs 70% target**



### Safety profile comparable to SoC

Other studies using standard of care (SoC) treatment for CRT upgrades have shown 81.3% freedom from device & procedure related complications<sup>1</sup>



### Other key data

Observed complication rates were higher in early phases and decreased with experience

Note: see "CEO Presentation on SOLVE-CRT Pivotal Trial Top-line Data" ASX release on 22 May 2023

<sup>1</sup> Poole, J. E., et al. (2010). Circulation 122(16): 1553-1561

# Broad support from patients and KOLs

Positive data welcomed by key industry leaders, patients and the industry



## Professor Prash Sanders

Director of Cardiac Electrophysiology and Pacing at the Royal Adelaide Hospital

*"The WiSE CRT device represents a major advancement in cardiac pacing technology. This technology is life changing for heart failure patients who do not respond to traditional therapy."*



## Brian Oakley

Scout leader and avid Melbourne FC fan, unable to walk up MCG stairs due to pacing induced heart failure

*"I can do all the things that I could do prior to developing heart failure. I would definitely recommend other patients consider the WiSE CRT device if they were in a similar situation."*

## Clinical coverage

Coverage by major healthcare publications and conferences<sup>1</sup>

**A leadless pacemaker the size of a grain of rice delivers cardiac resynchronization therapy**

BREAKING NEWS

David Forrester **Heart Rhythm 2023: World's Smallest Leadless Pacemaker Shows Clinical Benefits**

A leadless pacemaker can deliver cardiac resynchronization therapy to patients unable to be treated with conventional CRT and epicardial leads.

MEDICAL RESEARCH

**EBR Systems' Pivotal SOLVE-CRT Trial Meets Endpoints: Excellent Interim Analysis Results Lead to Early Trial Halt for Success**

PRNewswire | May 22, 2023

*Heart Rhythm Society represents medical, allied health, and science professionals from more than 90 countries who specialise in cardiac rhythm disorders*



**World's Smallest Leadless Pacemaker Shows Clinical Benefits in Patients with Previous CRT Failure**

<sup>1</sup> Cardiovascular Business – May 22 2023, Medical Product Magazine Outsourcing – May 24 2023, PR Newswire – May 22 2023

# Clear regulatory pathway

EBR's track record of successful engagement underpins confidence for FDA approval process

● 2019

## **FDA granted Breakthrough Device Designation to WiSE CRT System**

Provides EBR with interactive and timely access to and input from the FDA during premarket development phase, and a prioritised review of regulatory submissions filed with the FDA.

● 2020

## **FDA approved trial re-design of pivotal study**

Pivotal study was redesigned with the FDA to be completed with a single-arm, treatment only phase. This was underpinned by extensive clinical experience with >450<sup>1</sup> patients treated with WiSE CRT System to date.

● 2022

## **FDA approved leadless pacemakers as a co-implant in pivotal study**

FDA approval to include leadless pacemakers as a co-implant in the pivotal SOLVE-CRT trial. If approved during the PMA submission, this would potentially expand EBR's addressable market by ~US\$550m.

● 2023+

## **Clear pathway to approval with modular submission approach**

EBR has already submitted three out of five modules to the FDA. The fourth module is scheduled to be submitted by the end of 2023 and the final module by end of Q1 2024. EBR is targeting FDA approval by the end of Q4 2024.

**On track to finalise PMA submission to the FDA by end of Q1 2024, with FDA approval expected by H2 2024**

# Focused commercialisation strategy

EBR will leverage its established partnerships and presence in the US to drive initial sales growth, targeting initial sales in H1 2025



## Clinical trial sites to drive initial sales

- CRT market is concentrated - targeting high-volume CRT procedure sites
- 2025: Targeting US sites that have participated in the SOLVE-CRT trial and other high-volume sites with Key Opinion Leaders (KOLs)
- 2026-2027: Target top 200 to 250 clinical sites, representing >50% US CRT market



## Specialist sales force established

- Execution of commercial launch supported by specialised direct sales force to target high volume sites
- SOLVE-CRT team in place with clinical and technical expertise of WiSE CRT device
- Grow from an initial 7 sales territories to 35 sales territories by the end of 2027

# Strategy enhanced by market factors

EBR's commercialisation strategy is underpinned by 3 distinctive features



## Low hospital adoption barriers

- Low barrier for opening new accounts
- No capital equipment required and reimbursement available post-approval
- Proven and refined implanter training program



## Reimbursement & High ASP

- New Technology Add-on Payment (NTAP) and Transitional Passthrough Payment (TPT) expected post FDA approval
- WiSE CRT System ASP:
  - US: US\$35,000<sup>1</sup>
  - OUS: US\$20,000<sup>2</sup>



## Unmet need & strong data

- Unmet need underscored by FDA Breakthrough Device designation
- Support of Key Opinion Leaders (KOLs)
- Low barrier to transition to become first-line therapy

Note: ASP: Average Selling Price

<sup>1</sup> U.S. pricing with New Technology Add-on Payment (NTAP) post-approval

<sup>2</sup> Initial Phase "OUS Markets" limited to AU, UK, Germany, France, BeNSca

# Product development

EBR is developing a new rechargeable battery that will support WiSE CRT System in becoming a first-line therapy option and treat a broader suite of patients

## Background

EBR is developing a rechargeable battery and wireless charging system based on feedback from implanters and patients

## Benefits

- Reduces the need for future battery replacement surgery
- Recharge interval once per week<sup>1</sup>
- 66% reduction in size from current battery

## Development status

- Specifications and initial design completed
- First working product for testing expected in H1 2024
- Regulatory and commercial timing to be announced as project progresses



**EBR's new rechargeable battery charges uses a patch and external device to provide non-invasive, wireless charging**

<sup>1</sup> 95% of patients will only need to recharge once per week

# Clinical development: totally leadless CRT

EBR is currently progressing planning activities for studies to expand indications

## Totally leadless CRT

- WiSE CRT System can pair with a leadless RV pacemaker to achieve totally leadless CRT
- Increased adoption of leadless pacemakers expands the need for WiSE CRT System
  - Approximately 30% of these patients will need CRT within 4 years
  - WiSE CRT System provides the only means to upgrade leadless pacemakers to CRT
- Opportunity to build a new market as first-line-therapy with de novo totally leadless CRT
  - Avoid issues associated with implant of transvenous pacing leads
- Initiating TLC Study in H2 2024, the study is physician-initiated and includes long-term follow-up on existing patients





# US\$2.6bn initial addressable market

At commercial launch, EBR estimates to have an initial addressable market of ~US\$2.6bn

## Leadless Upgrades

- Patients with a leadless right ventricle pacemaker can only upgrade with WiSE CRT System to receive effective CRT
- WiSE CRT System used in conjunction with the Medtronic Micra (single chamber) or Abbott Aveir (single chamber) device



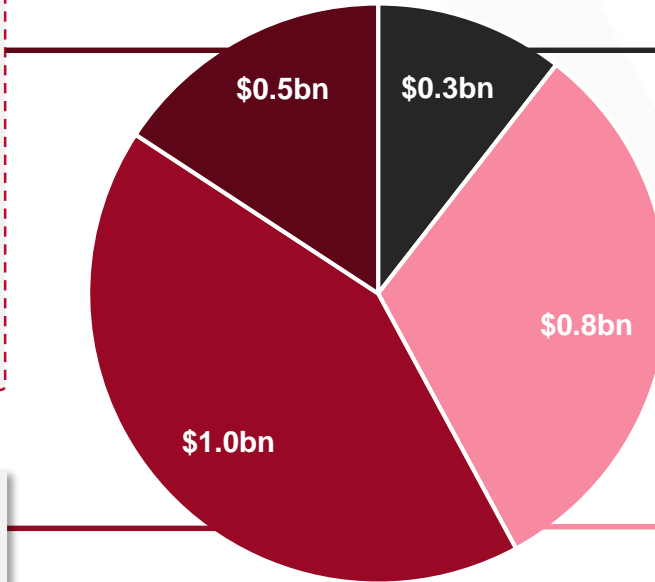
*Near term upside potential – see slide 15*

## Chronic Lead Failure

Traditional CRT system implanted but has ceased to provide effective CRT

## Acute Lead Failure

Unable to implant CRT wire in a new CRT patient



## High Risk Upgrades

Patient requiring CRT, but is deemed too high risk for a conventional CS lead placement

# Totally Leadless CRT is a growth market

The Totally Leadless CRT (TLC) market has the potential to grow by an additional US\$4.2bn

## Upgrading dual chamber leadless

WiSE CRT System used in conjunction with the Abbott Aveir dual chamber device, estimated to launch late 2023

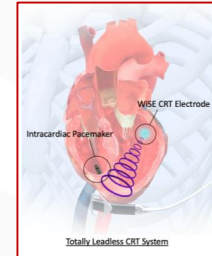


**\$2.2bn** segment TAM

*Near term expansion opportunity (3-4 years)*

## TLC as first-line therapy

WiSE CRT System used in conjunction with any leadless device

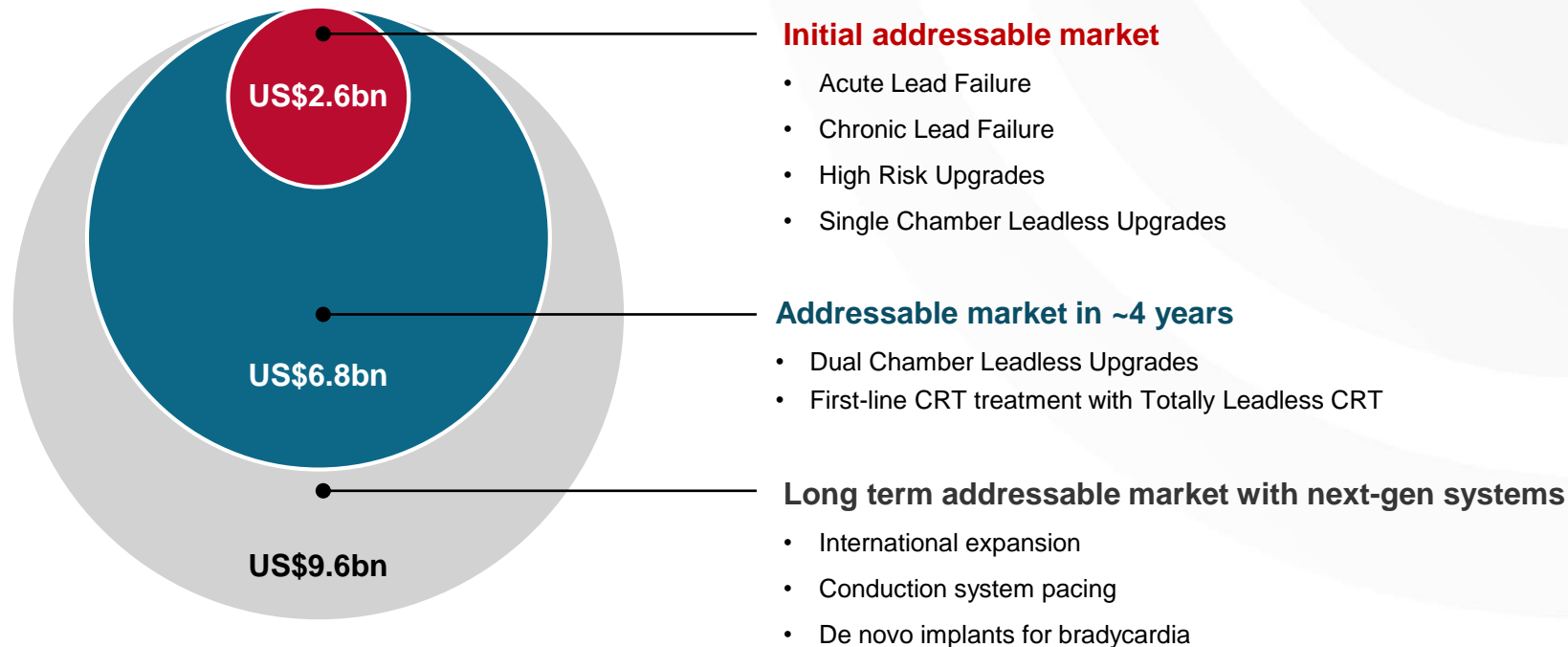


**\$2.0bn** segment TAM

*Near term expansion opportunity (~4 years)*

# Market expansion opportunity

The WiSE CRT System can be expanded for use in other patient groups, indications and geographies, increasing EBR's market opportunity and underpinning future growth



Note: Expanding into any additional clinical indications and/or patient groups may require supporting data from clinical studies, additional regulatory approvals, and establishing payment coverage or reimbursement.

# Upcoming milestones

EBR continues to achieve significant value catalysts and pave the way to future value creation

2023

- ✓ SOLVE-CRT 6 Month follow up completed for final patient in February 2023
- ✓ **Headline data released at Heart Rhythm Society conference**
- ✓ **Positive trial data unlocks second tranche of growth capital facility**
- ❑ Publication of manuscript in a peer reviewed medical journal
- ❑ Submit Clinical Module for PMA application to the FDA
- ❑ Present at industry conferences including APHRS<sup>1</sup>

2024

- ❑ Submit Final PMA Module including transmitter upgrades
- ❑ Production of working rechargeable batteries for design verification testing
- ❑ Additional sub-studies published using SOLVE-CRT dataset
- ❑ Initiate ACCESS and TLC studies
- ❑ FDA approval in the US

2025+

- ❑ Commercial launch in the US
- ❑ Launch in select markets OUS<sup>2</sup> as reimbursement and regulatory coverage is secured
- ❑ Expand use of WiSE CRT System into new patient groups and geographies
- ❑ Launch of rechargeable battery

<sup>1</sup> Asia Pacific Heart Rhythm Society

<sup>2</sup> OUS: Outside the US

# Investment highlights

EBR is focused on executing its clear and targeted commercialisation strategy to deliver shareholder value

## High value market opportunity



### Unique solution

No competition as the WiSE CRT system is complementary to other leadless devices



### Large markets

Targeting initial addressable market of US\$2.6bn with expansion opportunity up to US\$9.6bn



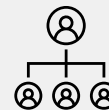
### Positive results

Safety and efficacy endpoints met for SOLVE-CRT trial and Breakthrough Device Designation granted



### Focused strategy

Clear pathway to achieve FDA approval and progress commercialisation activities to achieve first sales



### Strong team

Experienced management team with significant clinical development and commercial expertise

# Capital raise



# Capital raising overview

Institutional Placement to raise ~A\$30 million and Security Purchase Plan to raise up to ~A\$5 million

## Offer structure and size

- Placement to raise approximately A\$30 million through the issue of ~33.0 million new CHESS depositary interests over shares of common stock ("**New CDIs**") (representing ~12.2% of EBR's currently issued capital) ("**Institutional Placement**")
- Security Purchase Plan to eligible CDI holders in Australia and New Zealand, under which eligible CDI holders have an opportunity to subscribe for up to A\$30,000 of New CDIs ("**Security Purchase Plan**" or "**SPP**")
- The SPP will raise up to approximately A\$5 million. EBR may (in its absolute discretion) decide to increase or decrease the amount to be raised under the SPP or scale back applications at its discretion

## Offer price

- Offer price of A\$0.91 per New CDI issued under the Institutional Placement and SPP ("**Offer Price**"), which represents a:
  - 7.1% discount to the last closing price of A\$0.980 on 21 June 2023
  - 12.6% discount to the 10-day Volume Weighted Average Price ("**VWAP**") of A\$1.041 to 21 June 2023

## Institutional Placement

- The Institutional Placement was conducted on 22 June 2023

## Security Purchase Plan

- EBR intends to offer eligible CDI holders an opportunity to subscribe for up to A\$30,000 of New CDIs under the SPP at a price per New CDI equal to the Offer Price
- The SPP will raise up to approximately A\$5 million. EBR may (in its absolute discretion) decide to increase or decrease the amount to be raised under the SPP or scale back applications at its discretion

## Ranking

- New CDIs issued under the Institutional Placement and SPP will rank pari passu with existing CDIs from their date of issue

## Joint Lead Managers

- Wilsons Corporate Finance Ltd, Bell Potter Securities Ltd and Morgans Corporate Ltd are Joint Lead Managers to the offer



# Indicative timetable

Event	Date
Trading halt	Thursday, 22 June 2023
Institutional Placement bookbuild conducted	Thursday, 22 June 2023
Record date for SPP	7:00pm (AEST) Thursday, 22 June 2023
Trading halt lifted, announce Completion of Institutional Placement	Friday, 23 June 2023
Settlement of new CDIs issued under the Tranche 1 Placement	Wednesday, 28 June 2023
Allotment and trading of new CDIs issued under the Tranche 1 Placement	Thursday, 29 June 2023
SPP offer booklet dispatched, SPP offer period opens	Friday, 30 June 2023
Settlement of new CDIs issued under the Tranche 2 Placement	Friday, 7 July 2023
Allotment and trading of new CDIs issued under the Tranche 2 Placement	Monday, 10 July 2023
SPP offer period closes	Wednesday, 19 July 2023
SPP completion announcement	Tuesday, 25 July 2023
Allotment of new CDIs issued under the SPP	Tuesday, 25 July 2023
Commencement of normal trading in new CDIs issued under the SPP	Wednesday, 26 July 2023

*The above timetable is indicative only. The Company or Joint Lead Managers may vary any of the above dates without notice, subject to the Corporations Act, the ASX Listing Rules and other applicable law.*

# Sources and Use of funds

Funds raised will be used to advance EBR's progress towards commercialisation and strengthen EBR's balance sheet

Sources	A\$m	Uses	A\$m
Equity Raising	30.0	Manufacturing (capital expenditures and operations)	6.6
		Sales and marketing	8.2
		Regulatory and clinical	3.0
		Research and development	5.4
		General administrative	4.7
		Offer costs	2.1
Total	30.0	Total	30.0

- EBR intends to drawdown US\$20m from Tranche 2 of its Runway Capital debt facility by 30 June 2023
- Post completion of the capital raising, EBR will have a pro forma cash balance of ~A\$127.9 / US\$87.0m<sup>1</sup>
- EBR will be fully funded for its pathway to FDA approval and commercial launch, through to Q3 2025

<sup>1</sup> Based on cash balance as at 31 March 2023, estimated Q2 2023 expenditure, and assuming completion of a capital raising of A\$30m and US\$20m drawdown of Tranche 2 of Runway debt facility, and capital raising costs. Excludes proceeds raised under the SPP.

# Appendix



# Growth capital facility with Runway Growth Capital

EBR has unlocked the second tranche of up to US\$20m following positive SOLVE-CRT results

## Key facility terms

<b>Financier:</b>	Runway Growth Finance Corp. (Runway)
<b>Facility size:</b>	Up to US\$50,000,000
<b>Tranches:</b>	<p><b>Tranche 1:</b> US\$20,000,000 available immediately (subject to satisfaction of customary conditions precedent)</p> <p><b>Tranche 2:</b> Up to US\$20,000,000 available through 30 June 2023, with a minimum draw of US\$15,000,000 – contingent on positive data from the pivotal SOLVE trial (sufficient to proceed with PMA submission to FDA)</p> <p><b>Tranche 3:</b> Up to US\$20,000,000 available through 30 June 2024, with a minimum draw of US\$10,000,000 (and subject to overall US\$50,000,000 maximum facility size) – contingent on FDA approval</p>
<b>Total term:</b>	60 months
<b>Repayment:</b>	Interest-only payments made monthly and the entire principal amount outstanding will be due at maturity
<b>Interest rate:</b>	The Wall Street Journal Prime Rate (floating, subject to floor of 4.00%) + margin (4.90%)
<b>Covenants:</b>	EBR to maintain unrestricted cash and cash equivalents of US\$2,500,000 plus other customary affirmative and negative covenants.
<b>Collateral:</b>	First ranking security over all assets of EBR and subsidiaries
<b>Fees:</b>	A success fee of 3.00% of principal funded is to be paid to Runway if there is a liquidity event in respect of EBR (which includes a merger or sale of EBR). Other customary fees apply (e.g., for early prepayment).
<b>Events of default:</b>	Customary events of default, including a failure to make a payment under the facility when due and payable, subject, in certain instances, to a grace period.

# Experienced Board

Experienced board with a proven track record



**Allan Will**  
Executive Chairman

Mr. Will is an operating executive with extensive experience founding, funding, operating, and selling medical device companies. Prior to EBR, as chairman of Ardian, he led negotiation of the company's acquisition by Medtronic for over US\$800m.

Mr. Will was also founding Managing Director of Split Rock Partners' Silicon Valley office, focusing on therapeutic medical devices. He was founder, chair and CEO of the Foundry, co-founding 11 companies there, including:

- Evalve Inc., which was acquired by Abbott Laboratories for US\$450m
- Concentric Medical Inc., which was acquired by Stryker Corp for US\$135m

Mr. Will is an inventor on more than 30 issued patents.



**John McCutcheon**  
President & CEO

Mr. McCutcheon has over 35 years of sales, marketing, and general management experience in medical devices. Previously he served as the President and CEO of Ceterix Orthopaedics Inc. He has also held CEO roles at Ventus Medical and Emphasys Medical.



**David Steinhaus, MD**  
Independent Non-exec Director

Dr. Steinhaus was formerly VP and GM of the Heart Failure Business for the Cardiac Rhythm and Heart Failure Division at Medtronic plc, after 20 years of cardiology (electrophysiology) practice. He is currently the Executive Chairman of the board of Enopace Biomedical Ltd.



**Trevor Moody**  
Independent Non-exec Director

Mr. Moody recently served as Medical Device Partner at M.H. Carnegie & Co, where he made investments in medical device companies. He was previously General Partner at Frazier Healthcare Ventures, a large U.S. based venture capital and private equity firm.



**Karen Drexler**  
Independent Non-exec Director

Ms. Drexler is a serial entrepreneur with expertise in the fields of digital health, medical devices, and diagnostics. She currently serves on the boards of three other public companies, Resmed, Outset Medical, and Tivic Health.



**Bronwyn Evans, PhD AM**  
Independent Non-exec Director

Dr. Evans is an experienced leader and CEO with a broad technical background across multiple sectors including medical technology, manufacturing and technical regulation & standards. She is the current Chair of Building 4.0 CRC is a Director at ACOR Consultants and GME.



**Christopher Nave, PhD**  
Non-exec Director

Dr. Nave is a Founder and Managing Director of Brandon Capital Partners and the CEO of the Medical Research Commercialisation Fund. Dr Nave previously served as the Director of Commercialisation at the Baker Heart Research Institute.

# Senior management team

Highly qualified senior management team to drive commercial strategy



**Frank Hettmann**  
Chief Financial  
Officer

Mr. Hettmann has over 25 years of experience in senior and executive positions in finance, operations and administration within medical device and technology companies. He was previously CFO of Avenu Medical Inc. and Neology Inc.



**Parker Willis, PhD**  
Chief Technology  
Officer

Dr. Willis is an electrical engineer and has worked in medical devices for over 25 years, all in technical leadership capacities for the development of novel technologies in cardiac electrophysiology. He previously held a senior position at Boston Scientific Corporation (NYSE: BSX).



**Michael Hendricksen**  
Chief Operating  
Officer

Mr. Hendricksen has over 25 years of medical device product development and manufacturing experience. He was previously COO at Ceterix Orthopaedics. Prior to Ceterix, he was VP of R&D at Foundry NewCo XI.



**Steve Sandweg**  
Chief Commercial  
Officer

Mr. Sandweg has 30 years of sales experience in Fortune 500 medical technology companies, primarily within cardiovascular and structural heart space. Previously he served as General Manager for Keystone Heart, a Venus Medtech Company.



**Madhuri Bhat**  
Chief Regulatory  
Officer

Ms. Bhat has over 20 years of experience in public affairs, public policy, clinical, quality assurance and regulatory roles. She led several successful pivotal clinical trials and secured regulatory approvals in the US and internationally for Class II and III cardiovascular systems.



**Spencer Kubo, MD**  
Chief Medical  
Officer

Dr. Kubo has extensive experience developing innovative cardiovascular devices including neuromodulation, mitral regurgitation and cardiac support.



**Andrew Shute**  
Senior VP of Global  
Business  
Development

Mr. Shute has over 20 years of medical device experience and has led the successful commercialisation of new technologies and products working in corporate start-up and distributor settings.

# Key risk factors

## 1. Company Specific Risks

In addition to the general risks noted in this Presentation, investors should be aware of the specific risks of an investment in EBR. These specific risks include, but are not limited to, those risks referred to below.

### Regulatory approvals to market its WiSE® CRT System technology

Until FDA approval is received, EBR does not have regulatory approval to market WiSE® CRT System in the United States and it will be unable to generate revenue in the United States. EBR's business model and growth strategy is dependent on obtaining FDA approval as well as approvals from regulatory bodies in other key jurisdictions, including the Australian, UK and European markets.

The Company's SOLVE-CRT trial recently met its safety and efficacy endpoints, and the Company expects to submit its final PMA module to the FDA in Q1 of 2024. This module includes the proposed transmitter upgrades to prevent battery depletion. EBR has no reason to believe that FDA approval will not be granted, however, it can give no assurance as to the outcome of the FDA approval process once the final PMA module is submitted and has no control over the timing of that process. The FDA may require further information or data from EBR which requires EBR to expend additional costs and time. If FDA approval is not received within the expected timeframe, or not received at all, EBR will be unable to implement its business model.

Furthermore, even if EBR receives FDA approval, it is not assured of receiving future regulatory approvals for other indications or in other jurisdictions and cannot predict with certainty the timelines for such approvals, or other requirements that may be imposed by regulatory authorities (e.g., further clinical trials (if required) or other requirements to prove the safety and effectiveness of its products). In addition, future changes or updates to EBR's products, which affect their safety or efficacy, may require new regulatory approvals in some jurisdictions before EBR may sell the revised product.

### Reimbursement for EBR's products in the United States and in key European jurisdictions

The Company expects to derive its revenue in the United States from sales to hospital and medical centres, which typically bill all or a portion of the costs and fees associated with the Company's products to various third-party payers, including Medicare, Medicaid, private commercial insurance companies, health maintenance organisations and other healthcare-related organisations, and then bill patients for any applicable deductibles or co-payments. As a result, access to adequate coverage and reimbursement for the Company's products by third-party payers is essential to the acceptance of the Company's products by its customers.

However, in the United States, there is no uniform policy of coverage and reimbursement for medical device products and services among third-party payers, so coverage and reimbursement can differ significantly from payer to payer, and each coverage decision and level of reimbursement is independent. As a result, third-party reimbursement may not be available or adequate for the Company's products, and there is no guarantee that the Company will be able to achieve adequate reimbursement for using EBR's products.

Further, payers continually review new technologies for possible coverage and can, without notice, deny coverage for products and procedures or delay coverage approval until further clinical data is available. As a result, the coverage determination process is often a time-consuming and costly process that may require the Company to provide scientific and clinical support for the use of its products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained. If third-party reimbursement is not available or adequate for the Company's products, or if there is any decline in the amount that payers are willing to reimburse customers, new customers may not adopt, or may reduce their rate of adoption of, the Company's products and EBR could experience additional pricing pressure, any of which could have a material adverse effect on the Company's business, financial condition and results of operations.

If sufficient levels of coverage and reimbursement are not available for WiSE® CRT System, in either the United States or internationally, particularly in key European jurisdictions targeted by the Company, the demand for the Company's products and its revenues will be adversely affected.



# Key risk factors

## **Market adoption of WiSE® CRT System**

EBR's business model depends on hospitals and clinics in markets where it obtains the required regulatory approvals adopting WiSE® CRT System for the treatment of heart failure with CRT. However, there can be no guarantee that all or any of these sites will adopt WiSE® CRT System if FDA approval or other applicable regulatory approval is granted. Even if a site does adopt WiSE® CRT System, the site may not adopt WiSE® CRT System at the levels required to support EBR's business model and growth strategy. If EBR's technology is not increasingly adopted or favoured by hospitals, clinics and physicians, EBR's ability to achieve its growth strategy and generate revenue will be significantly impaired.

## **The impact of the new E.U. Medical Device Regulation**

In 2017, the new E.U. Medical Device Regulation (**MDR**) came into force, which replaced the E.U.'s Medical Device Directive. EBR will not market WiSE® CRT System in the E.U. until it has been certified under the MDR. The MDR assessment and certification process is a lengthy and arduous process that requires tremendous time and resources and may prove to be costly and disruptive to EBR's business. The MDR will also be required for the UK as of May 2024.

## **Cyber security breaches, loss of data and other disruptions**

In the ordinary course of the Company's business, it may become exposed to, or collect and store sensitive data, including procedure-based information and legally protected health information, insurance information and other potentially personally identifiable information. The Company also stores sensitive intellectual property and other proprietary business information. Although EBR takes measures to protect sensitive information from unauthorised access or disclosure, its information technology may be vulnerable to cyber-attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

The Company is investing in protections to reduce these risks and continue to monitor its systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that these efforts will prevent breakdowns or breaches to the Company or its third-party providers' databases or systems that could materially and adversely affect the Company's business, financial condition and results of operations.

## **Market size for EBR's current and future products**

The Company's estimates of the annual total addressable markets for WiSE® CRT System is based on internal and third-party estimates, including, without limitation, the number of patients with heart failure requiring cardiac resynchronisation therapy and the assumed prices at which EBR can sell products for markets that have not been established. While EBR considers the assumptions and the data underlying its estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting its assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, the Company's estimates of the annual total addressable market for its current or future products may prove to be incorrect. If the actual number of patients who would benefit from EBR's products, the price at which EBR can sell future products, or the annual total addressable market for EBR's products is smaller than the Company has estimated, it may impair EBR's sales growth and have an adverse impact on its business.

# Key risk factors

## **Reliance on key suppliers for product components**

EBR's products include components that are manufactured and supplied by third parties. The products are then assembled, validated and tested by these third parties or at the Company's headquarters in California. There are inherent risks in relying on third-party suppliers for the Company's product components, especially since any change to the manufacturing process of an approved medical device requires significant documentation and, in many cases, supplemental testing. A disruption at a key supplier could cause a substantial delay in the availability of EBR's products, leading to a potential loss of sales.

## **Management resources and attracting and retaining skilled staff**

EBR's long term growth and performance is dependent on attracting and retaining highly skilled staff. Despite having structured incentive programs, there is a risk that EBR will be unable to attract and retain the necessary staff to pursue its business model. In particular, if Mr John McCutcheon, EBR's CEO, was to leave EBR, it would lose significant technical and business expertise and EBR may not be able to find a suitable replacement. This would affect how efficiently EBR operates its business, and its future financial performance could be impacted.

## **New or competing technologies or products**

EBR expects to generate the vast majority of its revenue going-forward from the sale of WiSE® CRT System. The medical device industry is competitive, subject to rapid change and significantly affected by new product introductions. Although the Company believes that there are currently no products or technologies that are commercially comparable to WiSE® CRT System, there are a number of other products and devices on the market which are commonly used to perform conventional CRT procedures. To this end, EBR may compete with larger companies who manufacture and sell CRT products, including Abbott Laboratories Inc., Boston Scientific Inc., and Medtronic plc. If competitors develop new products (which could include devices or drugs) or technologies that offer better combinations of price and performance than the Company can offer for the treatment of certain types of heart failure, EBR's products or future products may become obsolete or not competitive, which would have a significant negative effect on the Company's business and financial position.

## **Continued research and development costs**

Developing medical devices and related technologies is expensive and the investment in the development of these product offerings often involves an extended period of time to achieve a return on investment. An important element of EBR's business strategy is to continue to make investments in innovation and related product opportunities. EBR believes that it must continue to dedicate resources to its innovation efforts to develop product offerings in order to achieve a competitive position and expand the total addressable market opportunity. EBR may not, however, receive significant revenues from these investments for several years, or at all.

# Key risk factors

## Transition to commercialisation phase

EBR is currently at the pre-commercialisation phase. The Company intends to move into the initial commercial phase after it receives FDA approval of WiSE® CRT System, which is currently expected in the H2 of 2024, subject to the risks discussed above. As is common with companies with a limited operating history, EBR has incurred net losses since its inception, has never been profitable and can give no assurance that the Company will be profitable or cash-flow positive in the future. In assessing EBR's business prospects, you should consider the various risks encountered by companies early in their commercialisation, particularly companies that develop and sell medical devices. These risks include EBR's ability to:

- transition into a commercialisation-stage company, and implement and execute its business strategy;
- increase awareness of its brand and market acceptance of its products;
- obtain future regulatory registrations and market approvals;
- manage expanding operations; and
- respond effectively to competitive pressures and developments.

## Sales and marketing resources

The Company currently has limited sales and marketing resources. In order to successfully launch its CRT products commercially, it will need to, among other things, expand its sales team. There is a risk that the Company will be unable to develop sufficient sales and marketing capabilities to effectively commercialise its products.

## Relationships with physicians

The research, development, marketing and sale of EBR's products and potential new and improved products depend upon EBR maintaining working relationships with physicians. EBR relies on these professionals to provide it with considerable knowledge and experience regarding the development, marketing and sale of EBR's products. Physicians assist EBR in clinical trials, marketing, and as researchers, product consultants and public speakers. If EBR cannot maintain its strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of its products could suffer, which could have a material adverse effect on its business, financial condition and results of operations.

At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General (the **OIG**), the U.S. Department of Justice (the **DOJ**), U.S. state attorneys general and other foreign and domestic government agencies. The Company's failure to comply with requirements governing the industry's relationships with physicians or an investigation into its compliance by the **OIG**, the **DOJ**, state attorneys general and/or other U.S. or foreign government agencies, could have a material adverse effect on its business.

# Key risk factors

## Physician training

The success of EBR's products depends in part on hospitals' and physicians' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by the Company. However, physicians rely on their previous medical training and experience, and EBR cannot guarantee that all such physicians will have the necessary skills or training to effectively utilise WiSE® CRT System. If physicians use the Company's products in a manner that is inconsistent with their labelled indications, with components that are not compatible with EBR's products or without adhering to or completing the requisite training sessions, their patient outcomes may not be consistent with the outcomes achieved by other physicians or in EBR's clinical trials. This result may negatively impact the perception of patient benefit and safety and limit adoption of EBR's products.

## Future clinical trials and long-term effects of WiSE® CRT System

Although the SOLVE-CRT trial was executed and completed successfully, it may not necessarily be predictive of the results of future clinical trials that may be needed to be conducted to support regulatory approval in other jurisdictions.

WiSE® CRT System is a relatively new solution for treating heart failure with CRT. The long-term effects of using WiSE® CRT System have not been studied and the results of short-term clinical use do not necessarily predict long-term clinical benefits or reveal long-term adverse effects.

## Pricing and margins

The Company can give no assurance that it will be able to achieve satisfactory prices for its products or maintain prices at the initial levels it achieves. Any decline in the amount that payors reimburse EBR's customers for procedures involving the use of the Company's products could make it difficult for customers to continue using, or to adopt, EBR's products and could create additional pricing pressure for EBR.

## Capital requirements

EBR may require substantial additional funds which may be dilutive or that may not be available to EBR on favourable terms, or at all. EBR cannot guarantee the future availability of funds. If EBR requires additional funding and is unable to raise these funds, it could adversely impact EBR's business.

## Managing growth

The Company expects that its current manufacturing capabilities will be sufficient to support its projected growth profile only through to the end of 2025. If the Company gains significant market share over and above its current short-term expectations and, in any case, from 2025 onwards, it will need to expand its manufacturing capacity, including additional facilities, and invest in systems and processes to support the development of the business. The failure of the Company to address projected growth in a timely and efficient manner may negatively impact the Company's financial performance.

# Key risk factors

## **Regulatory requirements for manufacturing facilities**

The manufacturing facilities for EBR's products must meet stringent quality standards. Any failure to comply with the applicable regulatory requirements could result in, among other things, temporary manufacturing shutdowns, product recalls, product shortages, bans on imports and exports and a damaged brand name.

## **Protection and enforcement of intellectual property rights**

The protection of the intellectual property relied upon by EBR is critical to its business and commercial success.

EBR has an extensive patent portfolio. Though a patent may be issued, there can be no assurance that the patent is valid and enforceable. However, it should be noted in the U.S., a patent granted by the U.S. Patent and Trademark Office is presumed to be valid in court proceedings. In addition, there can be no assurance that any of the Company's pending patent applications will result in the issuance of a patent, or that the scope of protection provided by any patent that is granted will be identical to the scope of the application as originally filed. There is a risk that the Company's competitors may be able to compete with EBR by designing around the claims of EBR's patents, or by otherwise using products and techniques that are outside the scope of EBR's patents.

## **Third party intellectual property rights disputes**

EBR does not believe that its activities infringe any third party's intellectual property rights. However, in the future the Company may be subjected to infringement claims or litigation arising out of patents and pending applications of third parties. Intellectual property authorities may also re-examine the patentability of licensed or owned patents. The defence and prosecution of intellectual property claims can be costly and time consuming to pursue, and their outcome is uncertain. If EBR is determined to have infringed the rights of third parties, the Company could be prevented from selling some of its products, which would have a significant negative effect on the Company's business and financial position. The Company has not budgeted for potential legal costs of intellectual property claims and significant legal costs would have a negative effect on the Company's financial position.

## **FCPA and similar worldwide anti bribery laws and any investigation**

The U.S. Foreign Corrupt Practices Act (**FCPA**) and similar worldwide anti-bribery laws prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. Due to the significant role government entities play in the administration and regulation of many foreign healthcare markets, the Company may be exposed to heightened FCPA and similar risks arising from its efforts to promote and sell its products and to seek regulatory approval of and reimbursement for its products in such countries. In the future, the Company also may operate in parts of the world that have experienced governmental corruption to some degree. EBR cannot assure investors that its internal control policies and procedures will protect it from improper acts committed by its employees or agents. Violations of these laws, or allegations of such violations, could significantly disrupt the Company's business and have a material adverse effect on its business and brand.

# Key risk factors

## **Regulatory registrations or market approvals**

The manufacture, testing, labelling, sale and marketing of medical devices are subject to extensive regulation in the U.S., Europe, UK, Australia and other countries. Regulatory registrations or market approval of products can subsequently be withdrawn for a variety of reasons, including failure to comply with manufacturing regulatory requirements by the Company or any third-party contractors engaged by EBR to manufacture its products. Regulators have the power to ban products sold by EBR as well as to require the recall, repair, replacement or refund of such products. Further, regulators may change their approval policies or impose additional regulatory requirements on the Company that could increase its compliance costs, restrict its ability to maintain its current regulatory registrations or market approvals, prevent or delay approval of future products under development or impact its ability to modify its currently cleared products. EBR cannot guarantee that it will successfully maintain the registrations and approvals it obtains.

## **Healthcare fraud and abuse laws and other healthcare laws and regulations**

Healthcare providers, including physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any products for which EBR obtains marketing approval. EBR's current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject it to various U.S. federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, EBR's clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, EBR may be subject to patient privacy laws by both the federal government and the states in which EBR conducts or may conduct its business.

Efforts to ensure that EBR's business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against EBR for violation of these laws, even if EBR successfully defends such actions, could cause EBR to incur significant legal expenses and divert EBR's management's attention from the operation of the Company's business. If the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to the Company, EBR may be subject to significant monetary penalties, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of EBR's operations, any of which could harm the Company's business.

# Key risk factors

## Healthcare policy changes

Many countries have instituted healthcare policy changes in an attempt to bring increasing spending on healthcare under control.

Various healthcare reform proposals have also been proposed by U.S. federal and state governments and other national governments that may subject the Company to additional U.S. or foreign regulatory requirements. EBR cannot predict whether future healthcare initiatives will be implemented in or outside of the U.S., or the effect any future legislation or regulation will have on the Company. The expansion in any government's regulation of the healthcare industry may result in decreased profits to EBR and reduced medical procedure volumes, all of which may adversely affect the Company's business and financial position.

## Product liability claims

The medical device industry is subject to substantial litigation, and EBR will face an inherent risk of exposure to product liability claims in the event that the use of EBR's products results or is alleged to have resulted in adverse effects to a patient. Although EBR maintains product liability insurance, the Company cannot assure you that the scope or coverage limits of its insurance policies will be adequate, or that insurance will be available to it on acceptable terms, if at all. A product liability or other claim with respect to uninsured liabilities or in excess of the Company's insurance coverage would materially impact EBR's business, financial condition and operating results.

## International operations

EBR will, subject to regulatory approvals, seek to sell its products in the U.S., the E.U., UK and Australia. The sale of its products outside of the U.S. exposes it to national trade laws, regulatory rules, as well as customs regulations and other laws and regulations discussed above. In some jurisdictions there can be high compliance costs associated with these laws, rules and regulations, and failure to comply with any applicable law or regulatory requirement could result in penalties and enforcement action.

## Changes in U.S. and non-U.S. tax laws

The rules dealing with U.S. and non-U.S. tax matters are constantly under review by persons involved in the legislative, judicial, administrative, regulatory and related governmental processes and authorities. Changes to tax laws or the interpretation and application thereof (which changes may have retroactive application) could adversely affect the Company or the holders of CDIs. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. and non-U.S. tax laws could have a material adverse effect on the Company's business, cash flow, financial condition or results of operations.

## Dividends

The ability of EBR to pay any dividend is dependent on many factors including the outcome of EBR commercialisation activities. Many of the factors that will affect EBR's ability to pay dividends and the timing of those dividends will be outside the control of EBR and its directors. No assurance can be given regarding the payment of dividends in the future.

# Key risk factors

## 2. General risks

There are risks associated with any stock market investment. Some of these risks are listed below.

### Stock market fluctuations

Stock market fluctuations in Australia and other stock markets around the world may negatively impact the CDI price. Factors that may influence the investment climate in stocks (which may not relate to actual performance of EBR) include general economic outlook, movements in commodity prices, exchange rate movements, interest rates, inflation and political developments.

### General economic conditions

Australian, U.S., and world economic conditions may negatively impact EBR's financial performance. These factors may include fluctuations in inflation, interest rates, rate of economic growth, taxation laws (and the application of existing laws by the courts or taxation authorities), consumer spending, unemployment rates, government fiscal, monetary and regulatory policies and consumer and business sentiment. Other factors include acts of terrorism, cyber hostilities, pandemics, outbreaks of international hostilities, fire, floods, earthquakes, labour strikes, natural disasters, outbreaks of disease or other natural or manmade events or occurrences that may have an adverse demand for EBR's products or EBR's ability to conduct business. A prolonged deterioration in economic conditions could be expected to have a material adverse impact on EBR.

## 3. Other

Other risks include those normally found in conducting business, including litigation resulting from breach of agreements or in relation to employees or any other cause.

The above list of risk factors should not be taken as exhaustive of the risks faced by EBR or by investors in EBR. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of EBR and the value of the CDIs.

Therefore, the CDIs to be issued pursuant to the Placement carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those CDIs.



# Foreign offer restrictions

## International Offer Restrictions

This document does not constitute an offer of CDIs of the Company in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the CDIs may not be offered or sold, in any country outside Australia except to the extent permitted below.

### Hong Kong

**WARNING:** This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the "SFO").

Accordingly, this document may not be distributed, and the CDIs may not be offered or sold, in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the CDIs has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to CDIs that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted CDIs may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

# Foreign offer restrictions

## New Zealand

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the “FMC Act”).

The CDIs are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

## Singapore

This document and any other materials relating to the CDIs have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of CDIs, may not be issued, circulated or distributed, nor may the CDIs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the “SFA”) or another exemption under the SFA.

This document has been given to you on the basis that you are an “institutional investor” or an “accredited investor” (as such terms are defined in the SFA). If you are not such an investor, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the CDIs being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire CDIs. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.



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