



Capital Raising Presentation

Through FDA approval & into Commercialisation

September 2024

personal use only

Important Notices and Disclaimer

Introduction

- THIS DOCUMENT IS NOT FOR DISTRIBUTION OR RELEASE IN THE UNITED STATES OR TO ANY U.S. PERSONS, OR IN ANY OTHER JURISDICTION WHERE SUCH DISTRIBUTION OR RELEASE IS UNLAWFUL.
- This presentation is dated 18 September 2024 and has been prepared and authorised by EBR Systems, Inc. (ASX:EBR) (ARBN 654 147 127) ("**EBR**" or "the **Company**") in connection with EBR's proposed capital raising (the "**Capital Raise**"), comprising:
 - a placement of new CHESS Depositary Interests ("**New CDIs**") to certain institutional and sophisticated investors (the "**Placement**"); and
 - an accelerated non-renounceable pro-rata entitlement offer of New CDIs to all eligible securityholders in Australia and New Zealand, as well as certain other jurisdictions for institutional securityholders ("**Entitlement Offer**").
- By accepting this presentation, you acknowledge and agree to the terms set out below.

Summary information and not financial product advice

- The material contained in this presentation is a presentation of general information about the EBR and its subsidiaries ("**Group**") and their activities current as at the date of this presentation. It should be read in conjunction with EBR's periodic and continuous disclosure announcements filed with the Australian Securities Exchange, available at www.asx.com.au.
- The information in this presentation is provided in a summary form, does not purport to be complete and should not be relied upon as advice for investment purposes. This presentation is for information purposes only and is not financial product advice or a recommendation to acquire EBR securities. This presentation does not take into account the investment objectives, financial position or needs of any particular investor. Independent advice should be sought before making any investment decision.
- The information in this presentation has been prepared by EBR in good faith and with

due care, but the EBR does not make any representation or warranty, express or implied, as to the fairness, accuracy, correctness, reliability or completeness of the information, opinions or conclusions contained in this presentation. Certain information in this presentation has also been sourced from publicly available sources that have not been independently verified. This presentation is current as at the date of this presentation and is subject to change without notice and unless required by law, EBR assumes no obligation to update this presentation or its contents for any matter arising or coming to EBR's notice after the date of this presentation.

- None of EBR, its officers, directors, employees or agents, nor any other person makes any representation or warranty, express or implied, as to, or endorsement of, EBR, the accuracy or completeness of any information, statements or representations contained in this presentation and none of them accepts any responsibility or liability for any errors or omissions in this presentation whatsoever.

Investment risk

- An investment in EBR is subject to known and unknown risks, some of which are beyond the control of EBR and its directors. EBR does not guarantee any particular rate of return in relation to EBR securities or the performance of the Group.
- Refer to "Risk factors" on pages 33 to 43 of this presentation for a non-exhaustive summary of certain key business, offer and general risk factors that may affect EBR.
- EBR recommends that potential investors consult their professional advisors as an investment in EBR is subject to investment and other known and unknown risks, some of which are beyond the control of EBR or its directors and therefore any investment is considered to be speculative in nature. Cooling off rights do not apply to the acquisition of New CDIs.

Important Notices and Disclaimer

Forward-looking statements

- Certain statements in this presentation may constitute forward-looking statements or statements about future matters that are based on management's current expectations and beliefs (being statements about matters that are not historical facts), including but not limited to, statements related to EBR's financial performance, business strategy and goals, plans and prospects, potential benefits of EBR's products and technology, product development, timing of international regulatory approvals, market size, commercial success and future financial performance. EBR uses words such as 'will', 'seeks', 'would', 'should', 'may', 'could', 'believes', 'estimates', 'expects', 'anticipates', 'intends', 'probability', 'risk', 'aim' and other similar words to identify forward looking statements. These statements are subject to risks and uncertainties that are difficult to predict and are based on assumptions as to future events that may not prove accurate. Actual results may differ materially from what is expressed in this presentation.
- Any such statements, opinions and estimates in this presentation speak only as of the date hereof and are based on assumptions and contingencies subject to change without notice, as are statements about market and industry trends, projections, guidance and estimates. Forward-looking statements are provided as a general guide only. The forward-looking statements contained in this presentation are not indications, guarantees or predictions of future performance and involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of the Group, and may involve significant elements of subjective judgement and assumptions as to future events which may or may not be correct. Forward-looking statements may also assume the success of the Group's business strategies. The success of any of these strategies is subject to uncertainties and contingencies beyond EBR's control, and no assurance can be given that any of the strategies will be effective or that the anticipated benefits from the strategies will be realised in the period for which the forward-looking statements may have been prepared or otherwise.
- To the maximum extent permitted by law, no responsibility for any loss arising in any way (including by way of negligence) from anyone acting or refraining to act as a result of this presentation or its contents is accepted by EBR or any of its officers, employees

or agents.

Past performance

- Past performance, including the pro-forma historical information in this presentation is given for illustrative purposes only and should not be relied on, and is not, and an indication of future performance including future security price information. Historical information in this presentation relating to EBR is information that has been released to the market. For further information, please see past announcements released to ASX. Nothing contained in this presentation nor any information made available to investors or potential investors is, or shall be relied upon as, a promise, representation, warranty or guarantee, whether as to the past, present or future.
- Past performance is not necessarily a guide to future performance and no representation or warranty is made as to the likelihood of achievement or reasonableness of any forward-looking statements or other forecast.

Not an offer

- This presentation is for information purposes only and is not a prospectus, disclosure document, product disclosure statement or other offering document under Australian law or any other law (and will not be lodged with the Australian Securities and Investments Commission ("ASIC")). This presentation is not and should not be considered an offer or an invitation to acquire the New CDIs or any other financial products and does not and will not form any part of any contract for the acquisition of the New CDIs.

Important Notices and Disclaimer

- The retail component of the Entitlement Offer will be made on the basis of the information contained in the Retail Offer Booklet (“**Retail Offer Booklet**”) to be prepared for eligible retail securityholders in Australia and New Zealand and made available following its lodgement with ASX. Any eligible retail securityholder in Australia or New Zealand who wishes to participate in the Entitlement Offer should consider the Retail Offer Booklet before deciding whether to apply for New CDIs under the Entitlement Offer. Anyone who wishes to apply for New CDIs under the Entitlement Offer will need to apply in accordance with the instructions contained in the Retail Offer Booklet.
- The distribution of this presentation outside of Australia may be restricted by law and any such restrictions should be observed. Any failure to comply with such restrictions may constitute a violation of applicable securities laws. In particular, this Presentation may not be released or distributed to, or relied upon by, any person in the ‘United States’ or any ‘US Person’, each as defined in Regulation S under the United States Securities Act of 1933, as amended.
- This presentation does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States or any other jurisdiction where it would not be lawful to make such an offer.
- Refer to pages 44 to 46 of this presentation for further details about international offer restrictions.

Financial data

- Investors should note that this presentation may contain unaudited financial information that has been prepared by EBR’s management. EBR’s results are reported under US GAAP. Certain financial data in this presentation is “non-IFRS financial information” under Regulatory Guide 230 (Disclosing non-IFRS financial information) published by ASIC. All values are stated in U.S. dollars unless otherwise stated.

Foreign ownership restriction

- EBR’s CDIs are traded on ASX in reliance on the safe harbour provisions of Regulation

S under the US Securities Act of 1933, as amended, and in accordance with the procedures established pursuant to the provisions of a no-action letter dated 7 January 2000 given to ASX by the staff at the US Securities and Exchange Commission. The relief was given subject to certain procedures and conditions described in the no-action letter. One of the conditions is that the issuer provides notification of the Regulation S status of its securities in communications such as this presentation.

Disclaimer

- The Capital Raise will be joint lead managed by Bell Potter Securities Limited (ACN 006 390 772, AFSL 243480) (“**Bell Potter**”), E&P Capital Pty Limited (ACN 137 980 520) and Morgans Corporate Limited (ACN 010 539 607) (together, the “**Joint Lead Managers**”) and will be fully underwritten by Bell Potter.
- To the maximum extent permitted by law, the Company and the Joint Lead Managers and their respective related bodies corporate and affiliates, and their respective officers, directors, employees, agents and advisers (in respect of the Joint Lead Managers, **JLM Parties**): (i) disclaim all responsibility and liability (including, without limitation, any liability arising from fault, negligence or negligent misstatement) for any loss (including consequential or contingent loss or damage) arising from this presentation or reliance on anything contained in or omitted from it or otherwise arising in connection with this presentation; (ii) disclaim any obligations or undertaking to release any updates or revision to the information in this presentation to reflect any change in expectations or assumptions; and (iii) do not make any representation or warranty, express or implied, as to the accuracy, reliability, completeness of the information in this presentation or that this presentation contains all material information about the Company, the Offer or that a prospective investor or purchaser may require in evaluating a possible investment in the Company or acquisition of shares in the Company, or likelihood of fulfilment of any forward-looking statement or any event or results expressed or implied in any forward-looking statement.

Important Notices and Disclaimer

- The JLM Parties take no responsibility for the Capital Raise and make no recommendations as to whether any person should participate in the Capital Raise nor do they make any representations or warranties (express or implied) concerning the Capital Raise, and they disclaim (and by accepting this presentation you disclaim) any fiduciary relationship between them and the recipients of this presentation, or any duty to the recipients of this presentation or participants in the Capital Raise or any other person. The JLM Parties have not authorised, permitted or caused the issue, submission, dispatch or provision of this presentation and, for the avoidance of doubt, and except for references to their name, none of the JLM Parties makes or purports to make any statement in this presentation and there is no statement in this presentation which is based on any statement by any of them. The JLM Parties may rely on information provided by or on behalf of institutional investors in connection with managing, conducting and underwriting the Capital Raise and without having independently verified that information and the JLM Parties do not assume any responsibility for the accuracy or completeness of that information. The JLM Parties may have interests in the securities of the Company, including by providing corporate advisory services to the Company. Further, the JLM Parties may act as market maker or buy or sell those securities or associated derivatives as principal or agent. The Joint Lead Managers will receive fees for acting in its capacity as joint lead managers to the Capital Raise and Bell Potter will receive fees for acting in its capacity as underwriter to the Capital Raise.
- You acknowledge and agree that determination of eligibility of investors for the purposes of the Capital Raise is determined by reference to a number of matters, including legal and regulatory requirements, logistical and registry constraints and the discretion of the Company and the Joint Lead Managers and each of the Company and the Joint Lead

Managers (and their respective related bodies corporate, affiliates, officers, directors, employees, agents and advisers) disclaim any duty or liability (including for negligence) in respect of the exercise or otherwise of that discretion, to the maximum extent permitted by law.

Acknowledgement and representation and warranty

- By receiving this presentation, you acknowledge and agree that you understand the contents of this notice and that you agree to abide by its terms and conditions. By receiving this presentation, you further agree, irrevocably and unconditionally, to submit to the non-exclusive jurisdiction of the courts of Victoria, in respect of any disputes, actions, suits or proceedings arising out of, or relating to, this presentation.

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 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

- Recently submitted final PMA module to the FDA and now has a clear pathway to achieve FDA approval (expected in Q1 CY2025)
- 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\$3.6bn 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 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

Capital raising details

- A fully underwritten capital raising of approximately A\$50.0 million which comprises:
 - An institutional Placement of approximately A\$37.4 million ("**Placement**"); and
 - A 1 for 20 pro-rata accelerated non-renounceable Entitlement Offer to eligible securityholders of EBR to raise approximately A\$12.6 million ("**ANREO**").
- New CHESS depositary interests over shares of common stock ("**New CDIs**") under the Placement and ANREO will be issued at a price of A\$0.82 per New CDI, representing a discount of approximately 15.9% to the last close of A\$0.975¹
- Funds raised will be used to support of commercialisation, manufacturing scale up, R&D, and general working capital
- Post completion of the capital raise, EBR will have a pro forma cash balance of ~US\$88.1m / ~AUD\$129.6m²



¹ As at close 17 September 2024.

² Pro-forma based on cash balance of US\$54.1m as reported June 30, 2024, and completion of the US\$34.0m raise derived above – it is nonreflective of cash consumed since June 30, 2024

Investment highlights

Developer of the world's first and only leadless pacemaker for heart failure

High value market opportunity



Unique solution

No competition as the WiSE CRT system is complementary to other leadless devices. It is the only leadless device to deliver CRT



Large markets

Targeting an initial addressable market of US\$3.6bn



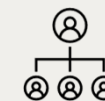
Positive results

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



Clear pathway to FDA approval

Final PMA module submitted to FDA. Approved expected in Q1 2025.



Clear commercial strategy in place

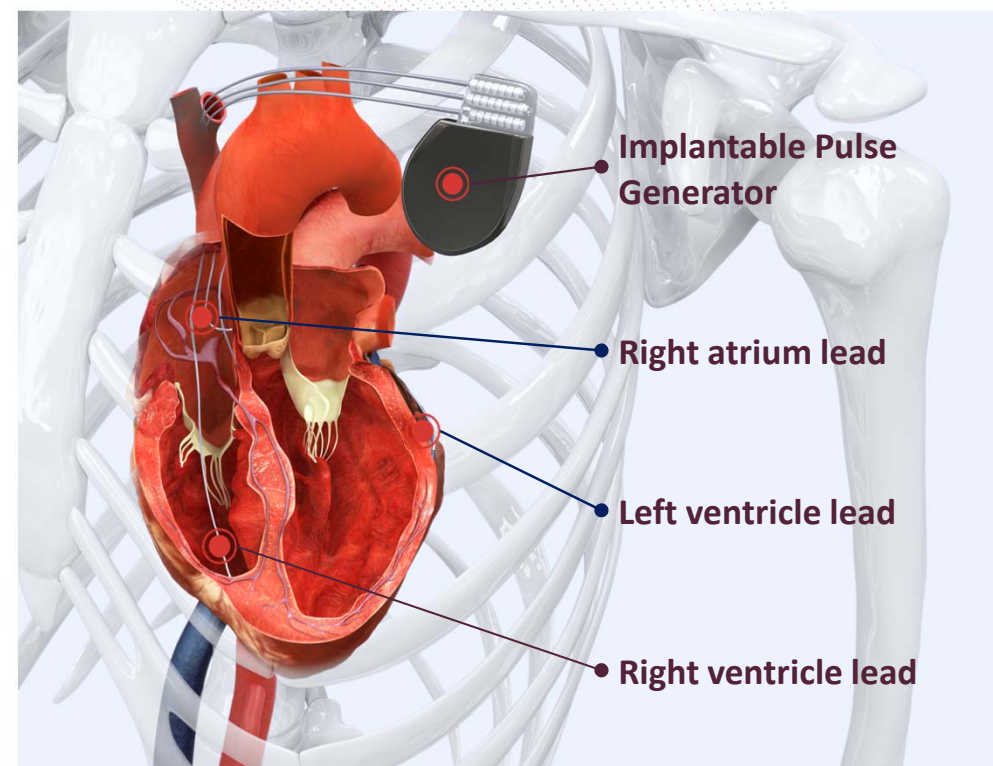
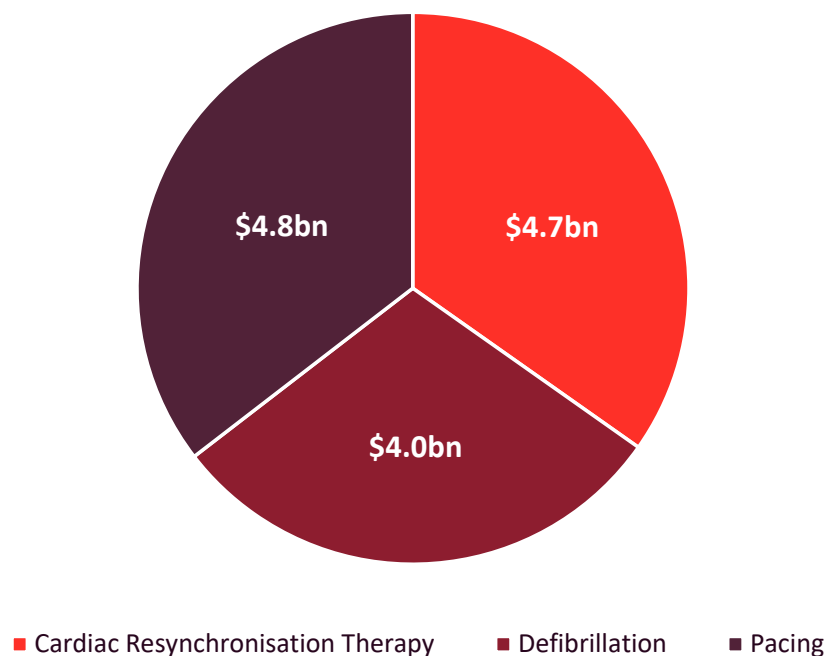
Progressing commercialisation activities to initial revenue in CY2025 by targeting high-volume sites in the US

Funded through initial commercialisation with pro forma cash balance of ~US\$88.1m / ~AUD\$129.6m¹

Cardiac Rhythm Management Market

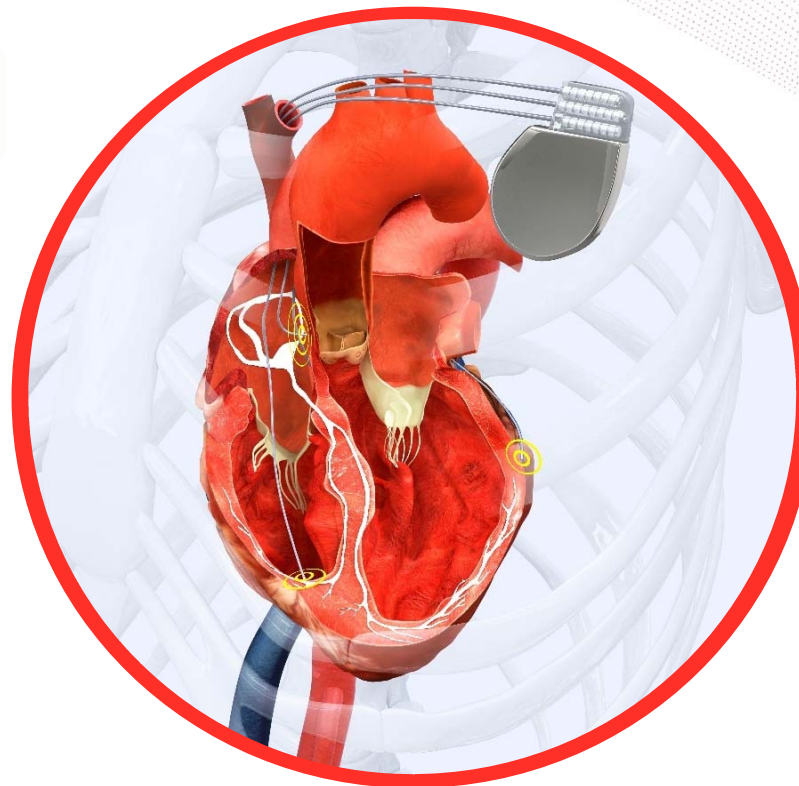
Three key segments driving growth in the global cardiac rhythm management market

Worldwide CRM Market (~US\$13.6bn)¹



Traditional CRT systems are suboptimal

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



Leads can migrate and sometimes fracture



Leads can become a way for pathogens to reach the myocardium



Difficult to place



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



Coronary Sinus limits Left Ventricle (LV) lead placement locations



Leads can be associated with phrenic nerve stimulation

EBR has a wireless solution for the heart

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

WiSE CRT System fills the gap

The only leadless solution for left ventricle (LV) pacing

Other wireless pacemakers are too big for LV pacing

Their size 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 ventricle¹



EBR Systems
WiSE CRT System

Right ventricle / atrium¹



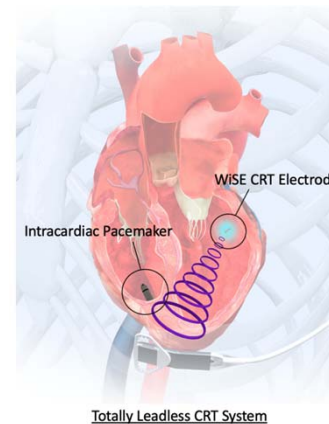
Medtronic
Micra®



Boston
Scientific
Empower®



Abbott
Aveir®



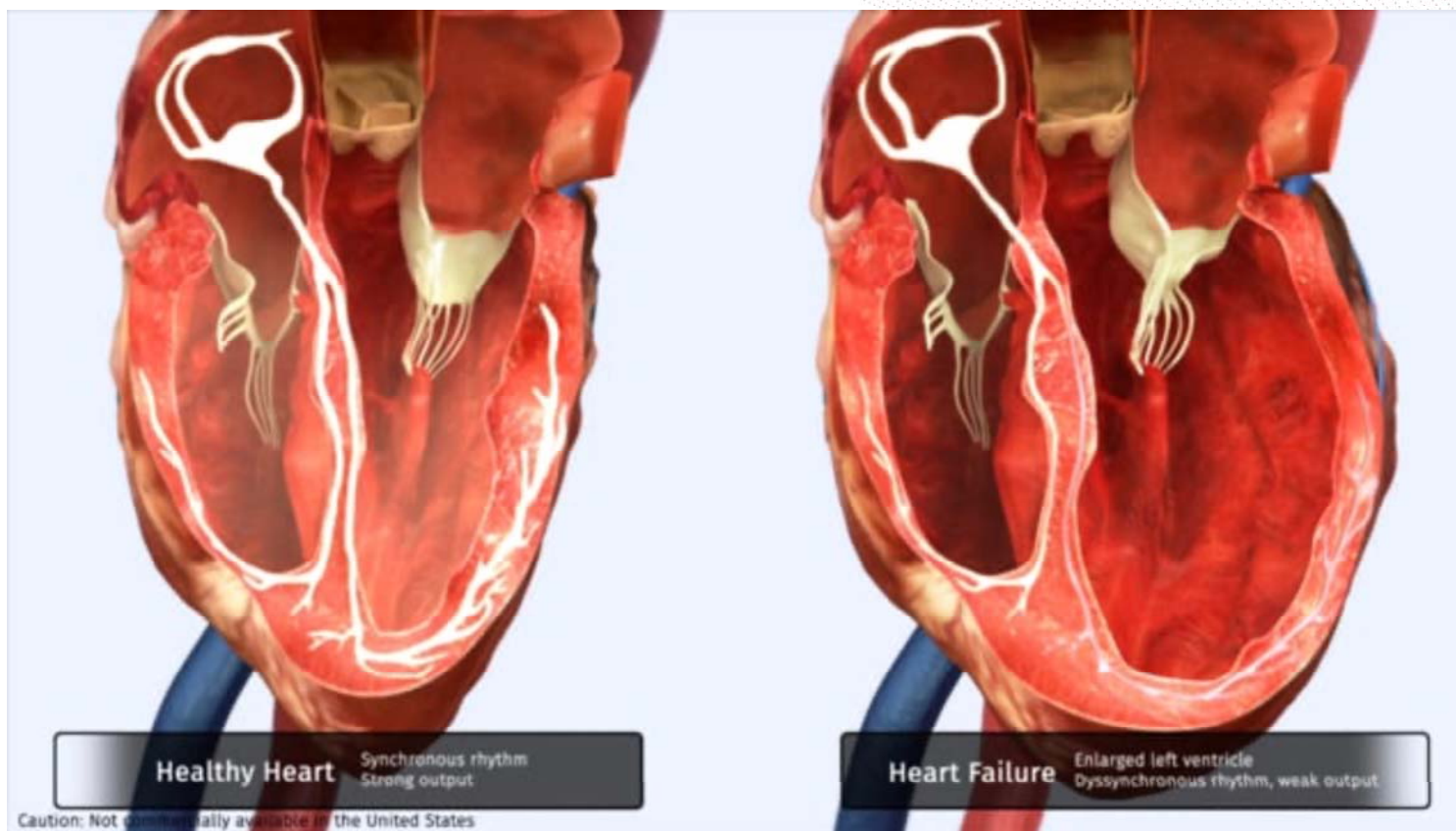
Boston
Scientific
Emblem®



Medtronic
Aurora®

WiSE CRT Technology Overview

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



Pivotal SOLVE-CRT Study met all endpoints

Positive results confirm WiSE CRT System as a highly effective treatment option for patients with heart failure¹

Primary efficacy endpoint met

-16.4%

p = 0.003

Decrease 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 SoC²

Studies using SoC treatment for CRT upgrades have shown 81.3% freedom from device & procedure related complications³



Other key data

Observed complication rates decreased over time with experience

Strong Support from Global Key Opinion Leaders



Jagmeet P. Singh M.D., Ph.D.
Cardiologist & Electrophysiologist,
*Harvard Medical School,
Massachusetts General Hospital,
Boston, Mass*

"This study opens the window for the future care of patients who require CRT. By pacing endocardially, this allows us to explore individual treatment strategies to provide more physiologic treatment of patients with heart failure. What I'm also really excited about is the potential to achieve totally leadless CRT by pairing WiSE with leadless pacemakers."



Prash Sanders, MBBS, PhD, FHRS
Cardiologist & Electrophysiologist,
*University of Adelaide,
Adelaide, Australia*

"EBR Systems' WiSE technology is the future of CRT and pacing. Today it allows us to treat previously failed patients. WiSE also has a unique opportunity to enable Leadless Left Bundle Branch Pacing or Conduction System Pacing, and down the road, act as a standalone system."



Timothy Betts, MD, MBChB, FRCP
Cardiologist & Electrophysiologist
*Oxford University Hospitals NHS
Foundation Trust, Oxford, UK*

"The WiSE CRT system has enabled me to successfully treat many patients who had previously failed treatment with conventional CRT devices. Without WiSE, these heart failure patients would be relegated to progressive deterioration of their condition and repeated hospitalizations."

Commercialisation pathway

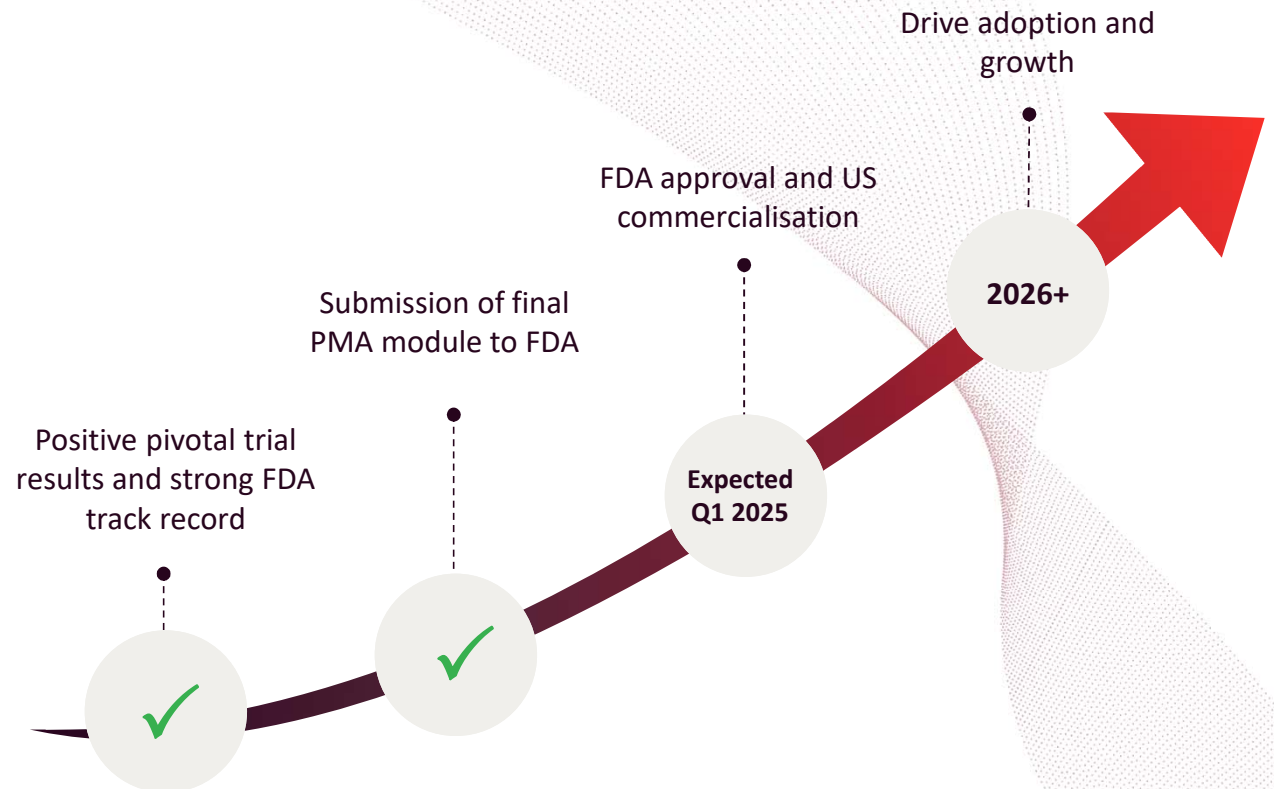
Positive pivotal trial results and strong track record with the FDA provide a clear pathway to approval and commercialisation

FDA approval process underpinned by positive pivotal trial results and a track record of successful engagement with the FDA resulting in:

- Award of Breakthrough Device Designation
- Approval of pivotal study re-design
- Approval of leadless pacemakers as a co-implant in pivotal study

EBR has finalised its PMA submission to the FDA. Breakthrough Device Designation ensures prioritised review process:

- Filing acknowledgement
- Biomedical Monitoring audit (BIMO)
- Pre-Approval Inspection (PAI)
- 100-day meeting



Favourable US market dynamics

Market dynamics in the US support initial adoption of the WiSE CRT System



Market validation

- Support of Key Opinion Leaders (KOLs)
- Unmet need underscored by FDA Breakthrough Device designation
- CRT market is highly concentrated - targeting high-volume CRT procedure sites



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 ASP¹

- CMS¹ recently updated WiSE specific CPT¹ codes (e.g. 0515T, 0522T)
- CPT¹ codes already assigned to interim APC¹ codes (e.g. 5231, 5741)
- Clear pathway to NTAP¹ and TPT¹ reimbursement schemes post FDA approval
- Defined process to reassign APC codes based on actual claims data
- WiSE CRT System target US ASP: US\$45,000²

Initial commercialisation strategy

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



Clinical trial sites to drive initial sales

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



Direct, specialist sales force

- Execution of commercial launch supported by specialised direct sales force to target high volume sites
- SOLVE-CRT core team in place with clinical and technical expertise of WiSE CRT System
- Grow initial sales and expand into new areas with sales force expansion over time



Manufacturing capabilities

- Manufacturing capabilities in place with capability to meet early demand
- Expand in-house manufacturing facility to meet future demand

US\$3.6bn initial addressable market

At commercial launch, EBR estimates an initial addressable market of ~US\$3.6bn

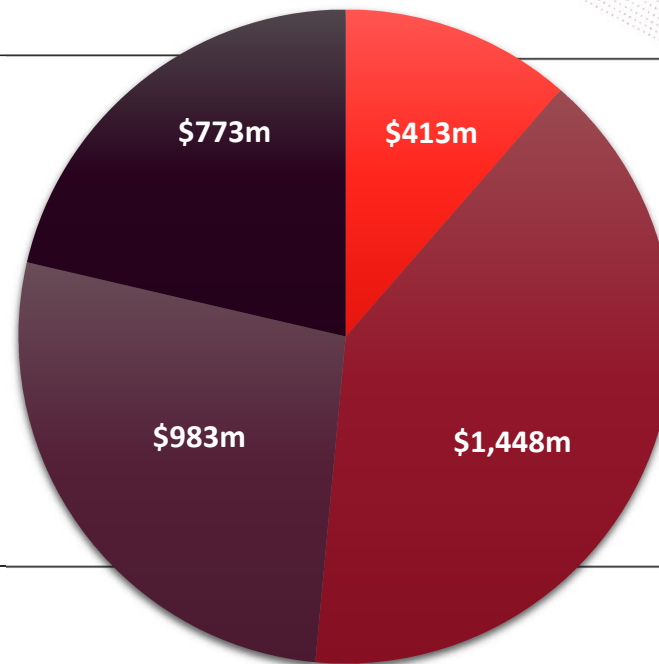
Leadless Upgrades

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

Further growth potential – see next slide

High Risk Upgrades

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



Acute Lead Failure

Unable to implant CRT wire in a new CRT patient.

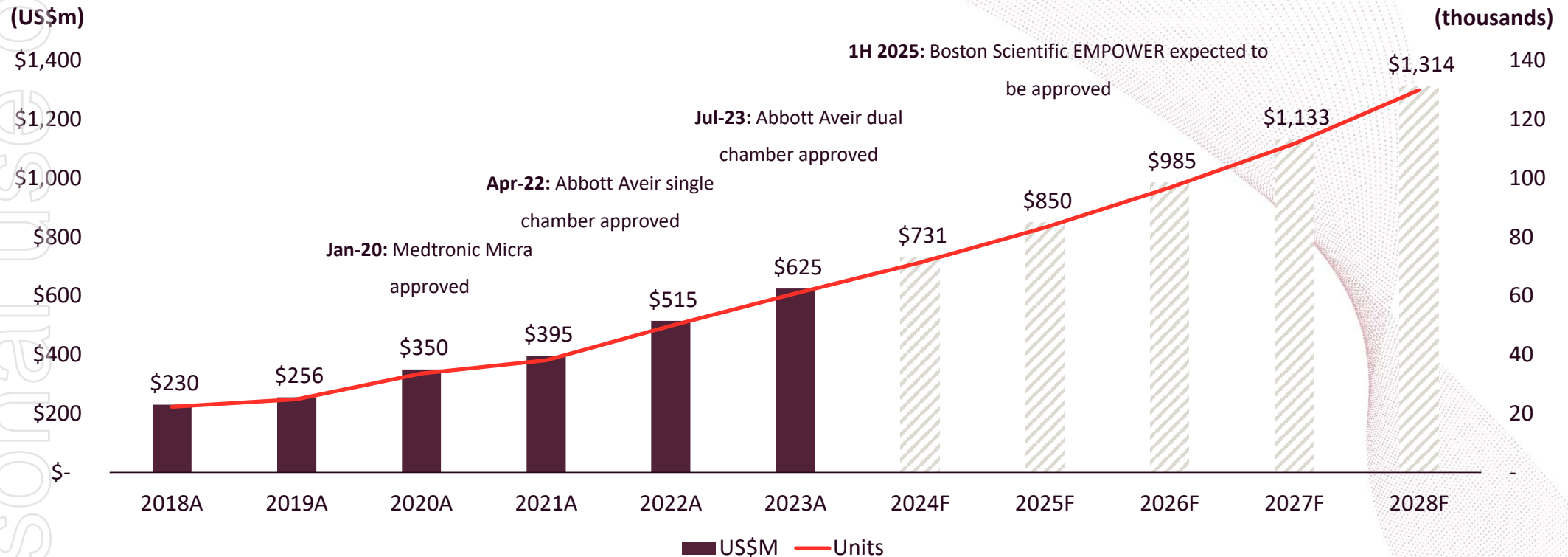
Chronic Lead Failure

Traditional CRT system implanted but has ceased to provide effective CRT

Totally Leadless CRT grows the market

Continued global growth and adoption of leadless RV pacemakers significantly expands EBR's market opportunity

Global Leadless RV Pacemaker Market Revenue and Unit Growth



Long term growth strategy

Long term growth opportunity targeting new patient groups, indications and geographies



Pursue new indications

Progress clinical studies to expand indications and diversify product applications, opportunity to build a new market as first-line-therapy



Product development

Grow addressable market through product development initiatives including a rechargeable battery



Expand internationally

Launch in select OUS¹ markets as regulatory and reimbursement coverage is secured using US market entry as a template for success

Clinical development: Totally Leadless CRT

EBR is actively progressing activities to initiate studies to support expanded indication

Commercial benefits

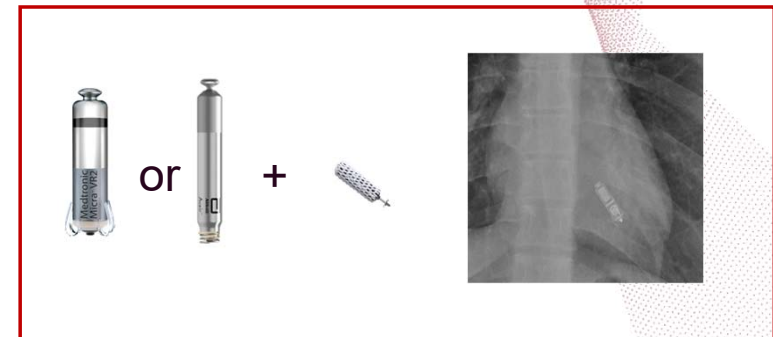
- Increased adoption of leadless pacemakers expands the need for WiSE, including upgrading dual chamber leadless pacemakers
- Opportunity to build a new market as first-line therapy with de novo totally leadless CRT

Patient benefits

- Avoid complications associated with lifelong implant of transvenous pacing leads
- More physiological pacing therapy

Development status

- Initiate the TLC-AU study in Australia in early 2025



Product development: Rechargeable battery

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

Commercial benefits

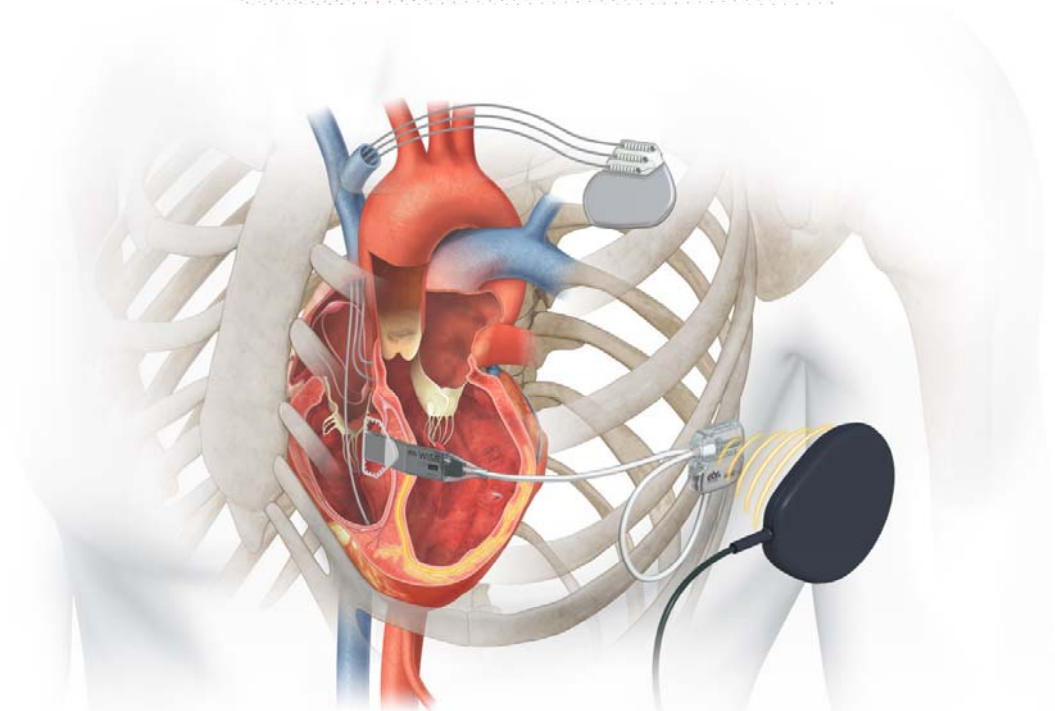
- Drives higher uptake by removing barriers to adoption
- Potential to become a first-line therapy option
- Diversifies applicability of the WiSE CRT System and grows the addressable market

Patient benefits

- Reduces need for future battery replacement surgery
- Recharge interval once per week¹
- 66% reduction in size from current battery

Development status

- Specifications and initial design completed
- Regulatory and commercial timing to be announced as project progresses



EBR's rechargeable battery will charge using a patch and external device to provide non-invasive, wireless charging

Upcoming milestones

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

Delivered

- ✓ SOLVE-CRT 6 Month follow up completed for final patient
- ✓ Headline data released at Heart Rhythm Society conference
- ✓ Randomised data presented at industry conferences including Asia-Pacific Heart Rhythm Society
- ✓ Publication of manuscript in a peer reviewed medical journal
- ✓ Additional sub-studies published using SOLVE-CRT dataset
- ✓ Final PMA module submitted to the FDA

Near term

- ❑ FDA approval in the US
- ❑ Commercial launch in the US
- ❑ Continued clinical publications
- ❑ Initiate ACCESS and TLC studies

Next steps

- ❑ Expand manufacturing facility
- ❑ Expand use of WiSE CRT System into new patient groups
- ❑ Drive adoption in US
- ❑ Clinical study of rechargeable battery

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.



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.



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.



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.



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 Health¹.



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



Gary Doherty
Chief Financial Officer

Mr. Doherty has over 30-years of experience across technology, healthcare and finance with a proven track record of developing high performing finance functions and medical device companies including his previous role as CFO of Acutus Medical (NASDAQ:AFIB). Prior to this, he held key positions at Volcano Corporation.



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.



Erik Strandberg
Chief Commercial Officer

Mr. Strandberg has over 20 years in the medical device sales industry and has demonstrated exceptional leadership in strategic planning and operational oversight. He was previously Sr. Vice President of Hybrid Therapies at AtriCure. Prior to that he worked at Boston Scientific, St Jude Medical and Guidant.



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 25 years of medical device experience and has led the successful commercialisation of new technologies and products working in corporate, start-up and distributor settings.

Summary

EBR remains driven to deliver superior treatment for patients suffering from cardiac rhythm diseases



Developer of the world's first and only leadless pacemaker for heart failure



EBR's WiSE® CRT System has no direct competitors and is complementary to other pacemaker technologies



Positive pivotal trial results de-risk the regulatory pathway and validate the device as safe and highly effective



Clear commercial strategy in place focusing on high-volume procedure sites in the US, minimising execution risk



Significant market opportunity with an initial addressable market of US\$3.6bn and potential for further growth



Post completion of the capital raise, EBR will have a pro forma cash balance of ~US\$86.2m / ~AUD\$126.8m¹



(1) Pro-forma based on cash balance of US\$54.1m as reported June 30, 2024, and completion of the US\$32.1m raise derived above – it is nonreflective of cash consumed since June 30, 2024

Capital Raise

Offer Summary

Fully Underwritten Institutional Placement to raise ~A\$37.4 million and an Entitlement Offer to raise up to ~\$12.6m

Offer Structure	<p>A fully underwritten Offer of approximately A\$50.0 million which comprises:</p> <ul style="list-style-type: none"> A 1 for 20 pro-rata accelerated non-renounceable Entitlement Offer to eligible securityholders of EBR to raise approximately A\$12.6 million ("ANREO or Entitlement Offer"); and an institutional Placement ("Placement") of approximately A\$37.4 million The Entitlement Offer is non-renounceable & entitlements will not be tradeable or otherwise transferable <p>Approximately 61 million New CDIs to be issued under the Offer, representing approximately 19.8% of existing CDIs and shares on issue in EBR</p>
Offer Price	<ul style="list-style-type: none"> The Offer will be conducted at a fixed price of A\$0.82 per New CDI (Offer Price) which represents: <ul style="list-style-type: none"> A discount of 15.9% to the last close of A\$0.975 on 17 September 2024 A discount of 14.0% to the 5-day VWAP of A\$0.953 up to and including 17 September 2024 A discount of 13.6% to the TERP¹
Institutional Offer	<ul style="list-style-type: none"> The institutional component of the Entitlement Offer and the Placement will be conducted on Wednesday, 18 September 2024 and Thursday, 19 September 2024 (Institutional Entitlement Offer) Entitlements not taken up and those of securityholders who are ineligible to participate in the Institutional Entitlement Offer will be sold at the Offer Price
Retail Entitlement Offer	<ul style="list-style-type: none"> The retail component of the Entitlement Offer will open on Tuesday, 24 September 2024 and will close at 5.00pm on Wednesday, 9 October 2024 (Retail Entitlement Offer) The retail component of the Entitlement Offer will include a 'top-up' Facility under which Eligible Retail Securityholders who take up their entitlement in full may also apply for additional New CDIs representing up to 100% of their entitlement (Top-Up Facility) Only eligible securityholders of EBR with an address on the EBR CDI register in Australia or New Zealand on the Record Date may participate in the Retail Entitlement Offer
Record Date	<ul style="list-style-type: none"> 7.00pm (Sydney, Australia time) on Friday, 20 September 2024
Ranking	<ul style="list-style-type: none"> New CDIs issued under the Entitlement Offer and Placement will rank pari passu with existing CDIs from their date of issue
Joint Lead Managers and Underwriters	<ul style="list-style-type: none"> Bell Potter Securities Limited, Morgans Corporate Limited and E&P Capital Pty Limited are Joint Lead Managers and Bookrunners. Wilsons Corporate Finance Limited is a Joint Lead Manager. The capital raise is fully underwritten by Bell Potter.

Indicative timetable

Event	Date
Trading halt and announcement of underwritten offer (including release of ASX announcement, Appendix 3B, cleansing notice and investor presentation)	Wednesday, 18 September 2024
Complete Institutional Offer (Placement and Institutional Entitlement Offer) bookbuild	Thursday, 19 September 2024
Announcement of completion of Placement and Institutional Entitlement Offer and recommence trading	Friday, 20 September 2024
Record date for Entitlement Offer (7.00pm Sydney)	Friday, 20 September 2024
Retail Entitlement Offer documentation despatched and Retail Entitlement Offer opening date	Tuesday, 24 September 2024
Settlement of shares issued under the Placement and Institutional Entitlement Offer	Wednesday, 25 September 2024
Allotment of shares issued under the Placement and Institutional Entitlement Offer	Thursday, 26 September 2024
Retail offer close date (5.00pm Sydney)	Wednesday, 9 October 2024
Announcement of results of Retail Entitlement Offer	Monday, 14 October 2024
Settlement of Retail Entitlement Offer	Tuesday, 15 October 2024
Allotment of shares under the Retail Entitlement Offer	Wednesday, 16 October 2024
Normal Trading of Retail Entitlement Offer shares	Thursday, 17 October 2024

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 & Uses of Funds

Funding to support the commercialisation, manufacturing scale up, R&D, and general working capital

Sources	AU\$m	US\$m
Placement	37.4	25.4
ANREO	12.6	8.6
Total	\$50.0m	\$34.0m

Uses	AU\$m	US\$m
Sales and Marketing	11.6	7.9
Manufacturing Scale Up (including initial tooling)	8.4	5.7
Research and Development	10.4	7.1
General Administrative, Working Capital and Offer Costs	19.6	13.3
Total	\$50.0m	\$34.0m

- Post completion of the capital raise, EBR will have a pro forma cash balance of ~US\$88.1m / ~AUD\$129.6m⁽¹⁾
- The proceeds will be used to support the commercialisation and manufacturing scale up of EBR's WiSE CRT system in anticipation of receiving FDA approval in early CY2025.

**Assumes FX rate of .68 USD/AUD*

(1) Pro-forma based on cash balance of US\$54.1m at June 30, 2024, and completion of the US\$34.0m raise derived above – it is nonreflective of cash consumed since June 30, 2024

Appendix

Patient success story – Richard

EBR has allowed the patient to once again partake in all the activities he enjoyed before his heart failure

Pre heart failure

US Marine and Vietnam war veteran who enjoyed a very active and outgoing lifestyle

"Sport was a very big part of my life."

"I was an active person."



On-set of heart failure

Heart failure materially impacted the patient's quality of life

2014

Pacemaker implanted in 2014, due to collapsing from a low heart rate

2016

Developed pacing induced heart failure. Conventional lead-based CRT implanted. Multiple lead failures.

2017

Rapid deterioration

"I couldn't walk up a flight of stairs. I couldn't work, I couldn't do anything. I was just existing."

Post-WiSE CRT implant

Post WiSE CRT implant, the patient has been able to enjoy many activities that he used to do

"I was energised immediately. I could now take out the bins and walk up a flight of stairs."

"I was able to resume daily walks and open water swimming. Got stronger and lost 20kg."

"I'm happy, extremely happy. It's given me my life back!"

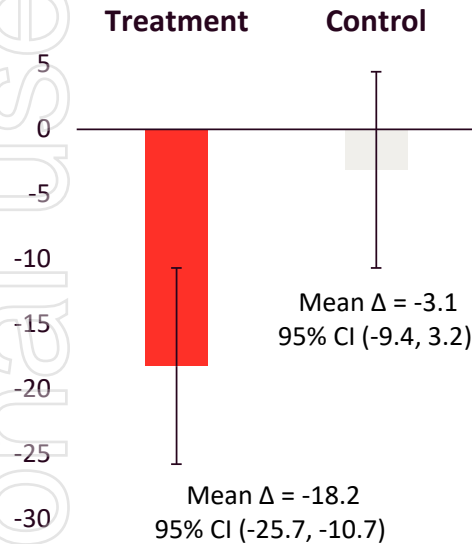


Randomised sub-study supports primary results

The WiSE CRT System demonstrates clinically and statistically significant evidence of reverse remodelling and electrical response within previously untreatable and high-risk patients

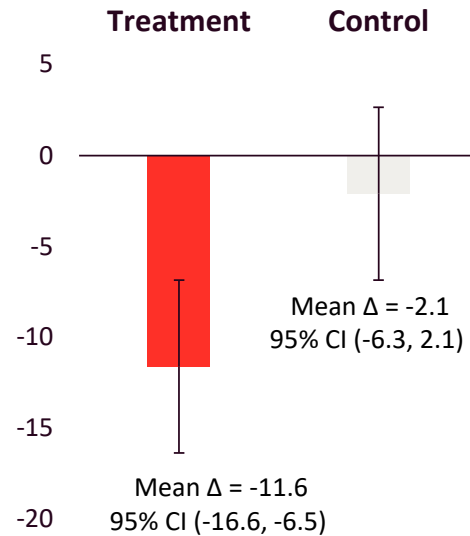
LVESV (%)

$p = 0.002^{\dagger}$



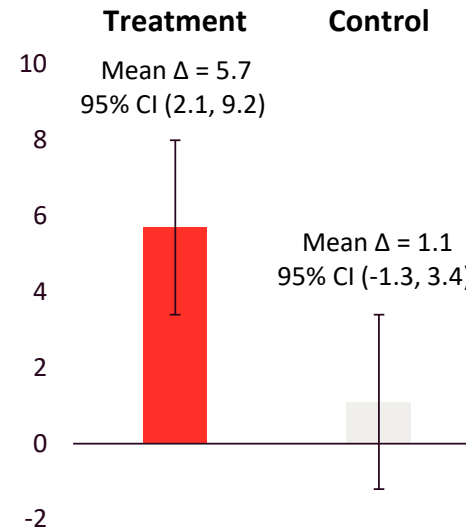
LVEDV (%)

$p = 0.004^{\ddagger}$



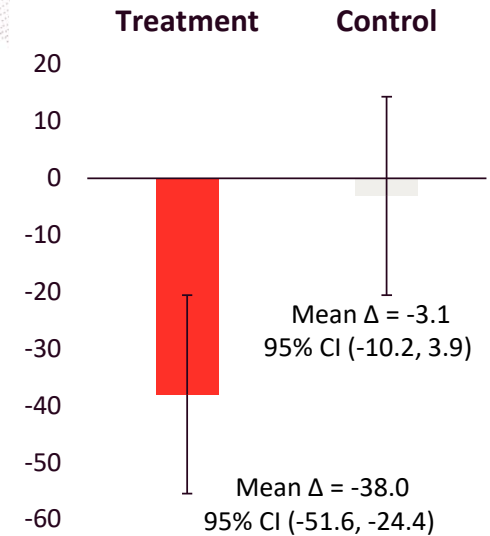
LVEF (%)

$p = 0.025^{\dagger}$



QRS (ms)

$p < 0.001^{\ddagger}$



Control n = 29, Treatment n = 22

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 the 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 market.

The Company recently submitted its final PMA module to the FDA. 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 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 approval or notified body certification in other jurisdictions, and cannot predict with certainty the timelines for such approvals or certifications, 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 or notified body certification in some jurisdictions before EBR may sell the revised product.

Reimbursement for EBR's products in the United States and in key international 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.

Key risk factors

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, the demand for the Company's products and its revenues will be adversely affected.

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, or that there will be broad market acceptance, 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.

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 Q1 of CY2025, 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.

Key risk factors

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 CRT and the assumed prices at which EBR can sell products for markets that have not been definitively 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.

Reliance on key suppliers for product components

EBR's products include components that are manufactured and supplied by third parties, some of which are single-source suppliers. 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.

Key risk factors

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.

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.

Key risk factors

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.

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.

Key risk factors

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 2027. If the Company gains significant market share over and above its current short-term expectations and, in any case, from 2027 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.

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.

Key risk factors

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.

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.

Key risk factors

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.

Healthcare policy changes

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

Various healthcare FCPA 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.

Key risk factors

Defects or failures, and product liability claims

EBR's business is subject to significant risks associated with the manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could also result in the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, EBR's products and could result in significant costs, negative publicity, and adverse competitive pressure.

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.

The impact of the 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 United Kingdom has devised a new route to market culminating in a UKCA Mark. The UK government also plans to introducing new legislation governing medical devices to apply from 1 July 2025. EBR cannot be sure that future UK legislation governing medical devices will not diverge substantially from that applicable in the E.U., preventing EBR from relying on data and materials developed as part of MDR assessment in the E.U. to support an application for a UKCA Mark.

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.

Key risk factors

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.

Requirements of being an SEC registrant

EBR filed a Form 10 Registration Statement with the U.S. Securities and Exchange Commission (**SEC**) in July 2024, which it expects will become effective by the end of September 2024. The Company will be required to comply with SEC rules and regulations from that point onwards. As an SEC registrant, EBR will be subject to the reporting and corporate governance requirements of the U.S. Securities Exchange Act of 1934. Compliance with these rules and regulations will increase EBR's legal and financial compliance costs, make some activities more difficult and time-consuming and increase demand on EBR's systems and resources.

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 Capital Raise 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 Chess Depositary Interests (“CDIs”) representing shares of common stock 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 to the public within New Zealand other than to existing securityholders of the Company with registered addresses in New Zealand to whom the offer of these securities is being made in reliance on the Financial Markets Conduct (Incidental Offers) Exemption Notice 2021.

Other than in the entitlement offer, the CDIs may only be offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) 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.

Foreign offer restrictions

United Kingdom

Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the CDIs.

The CDIs may not be offered or sold in the United Kingdom by means of this document or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This document is issued on a confidential basis in the United Kingdom to “qualified investors” within the meaning of Article 2(e) of the UK Prospectus Regulation. This document may not be distributed or reproduced, in whole or in part, nor may its contents be disclosed by recipients, to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the CDIs has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (“relevant persons”). The investment to which this document relates is available only to relevant persons. Any person who is not a relevant person should not act or rely on this document.

Summary of Underwriting Agreement

Underwriting Agreement

EBR entered into an underwriting agreement with Bell Potter Securities Limited (**Bell Potter**), Morgans Corporate Limited and E&P Capital Pty Ltd (the **Joint Lead Managers**) in respect of the Capital Raise on 18 September 2024 (**Underwriting Agreement**). Pursuant to the Underwriting Agreement, the Joint Lead Managers have agreed to act as joint lead managers and bookrunners of the Capital Raise and Bell Potter has agreed to fully underwrite both the Capital Raise.

Key Terms of the Underwriting Agreement

The Joint Lead Managers' obligations under the Underwriting Agreement are conditional on certain matters, including, but not limited to, certain Offer Documents (defined below) being released within the required timeframes and certain other diligence-related deliverables being provided within the required timeframes.

If certain conditions are not satisfied or certain events occur, a Joint Lead Manager may terminate the Underwriting Agreement. Termination of the Underwriting Agreement would have a material adverse impact on the total amount of proceeds that could be raised under the Capital Raise, which in turn would have a material adverse impact on EBR's financial position.

The events which may trigger termination of the Underwriting Agreement include (but are not limited to) the following:

- failure to satisfy a condition precedent to Bell Potter's underwriting obligations within the required timeframe;
- a statement contained in the disclosure materials for the Capital Raise (**Offer Documents**) does not comply with the Corporations Act, including if a statement in any of the Offer Documents or in certain public information is or becomes misleading or deceptive in a material respect or is likely to mislead or deceive in a material respect, including by omission, or a material matter, required to be included is omitted from an Offer Document;
- a cleansing notice is or becomes defective or EBR gives or is required to give a corrective statement under the Corporations Act and, in each case, that defective cleansing notice or corrective statement is adverse from the point of view of an investor;
- EBR is prevented from issuing the New CDIs within the time required by the ASX Listing Rules, applicable laws, an order of a court of competent jurisdiction or a government agency;
- EBR withdraws the Capital Raise or any part of it;

Summary of Underwriting Agreement

- EBR or a group member is insolvent or there is an act or omission which may result in EBR or a group member becoming insolvent;
- other than as permitted by the Underwriting Agreement, EBR alters its capital structure or constituent documents without the prior written consent of the Joint Lead Managers;
- any statement in a certificate is untrue, inaccurate, incomplete or misleading or deceptive;
- a contravention by EBR or a group member of the Corporations Act, its constituent documents, the ASX Listing Rules or any other applicable law;
- hostilities not presently existing commence (whether war has been declared or not) or a major escalation in existing hostilities occurs (whether war has been declared or not) involving any one or more of the United States, Australia, Russia, Ukraine, New Zealand, the United Kingdom, North Korea, South Korea, the People's Republic of China, Japan, Singapore, Iran, Israel or a member state of the European Union or the declaration by any of these countries of a national emergency or war or a major terrorist act is perpetrated anywhere in the world;
- EBR fails to perform or observe any of its obligations under the Underwriting Agreement;
- a representation or warranty made or given by EBR under the Underwriting Agreement proves to be, or has been, or becomes, untrue or incorrect;
- a change in the Chief Executive Officer, the Chief Financial Officer, or the Senior Vice President (Business Development) of EBR or in the board of directors is announced or occurs without the Joint Lead Managers' prior written consent;
- any adverse change occurs, or there is a development involving a prospective adverse change, in the assets, liabilities, financial position or performance, profits, losses or prospects of the Group from those respectively disclosed in any Offer Document or the public information or from those respectively disclosed to ASX by EBR prior to the date of the Underwriting Agreement; and
- the due diligence committee report or any other information supplied in writing by or on behalf of EBR to the Joint Lead Managers in relation to the group or the Capital Raise is misleading or deceptive (including by omission).

Summary of Underwriting Agreement

The ability of a Joint Lead Manager to terminate the Underwriting Agreement in respect of some events will depend on whether the Joint Lead Manager has reasonable grounds to believe that the event:

- has, or is likely to have, a material adverse effect on the success, marketing or settlement of the Capital Raise, the value of the CDIs or the willingness of investors to subscribe for New CDIs or the performance of the secondary trading market of the New CDIs;
- leads or is likely to lead to:
 - a contravention by the Joint Lead Manager of, or the Joint Lead Manager being involved in the contravention of, the Corporations Act or any other applicable law; or
 - a liability of the Joint Lead Manager under the Corporations Act or any other applicable law.

For details of the fees payable to the Joint Lead Managers, see the Appendix 3B released to ASX on 18 September 2024.

EBR also gives certain representations, warranties and undertakings to the Joint Lead Managers and indemnifies the Joint Lead Managers and certain affiliated parties subject to certain carve-outs. As part of the undertakings, EBR has agreed to not for a certain period of time, without the prior written consent of the Joint Lead Managers, allot or agree to allot any CDIs of EBR or other securities that are convertible or exchangeable into equity, subject to certain exceptions.

Any shortfall under the Capital Raise may, subject to the terms of the Underwriting Agreement, be allocated to Bell Potter or to third party investors as directed by Bell Potter.



Contact us

Company

John McCutcheon

President & CEO

P: +1 408 720 1906

E: info@ebrsystemsinc.com

Investors

Joel Seah

Vesparum Capital

P: +61 3 8582 4800

E: EBRSystems@vesparum.com