



# Canaccord Growth Conference Investor Presentation

**John McCutcheon**  
**President and CEO**  
**August 2025**

# Pillars of Success

*Developer of the world's first and only leadless pacemaker for heart failure  
Listed on ASX (symbol EBR) since 2021 and SEC registrant since 2024*

## Significant Growth Potential



### Unique solution

WiSE System is complementary to other cardiac pacing devices and is the only leadless device that can pace the left ventricle for heart failure



### Large market opportunity

Targeting an initial addressable market of US\$3.6bn in the US

## Barriers Removed



### FDA approved

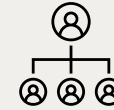
US FDA approval received 11 April 2025 supported by Breakthrough Device Designation and compelling clinical data



### Strong reimbursement

Inpatients: CMS approved NTAP add-on payments commencing Oct 2025  
Outpatients: CMS has granted preliminary approval for TPT payment expected to commence Oct 2025

## Poised to Scale



### Clear commercial strategy

Pilot launch underway. Limited Market Release (LMR) to commence Q4 2025 to coincide with reimbursement add-on payments



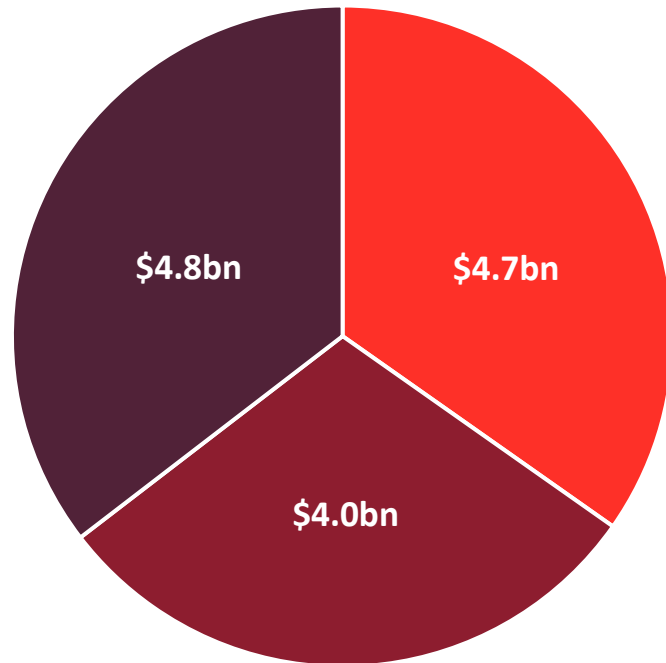
### Manufacturing facilities in place

New facility under construction to support commercial growth and scale  
Expect full transition to new facility by the end of H1 2026

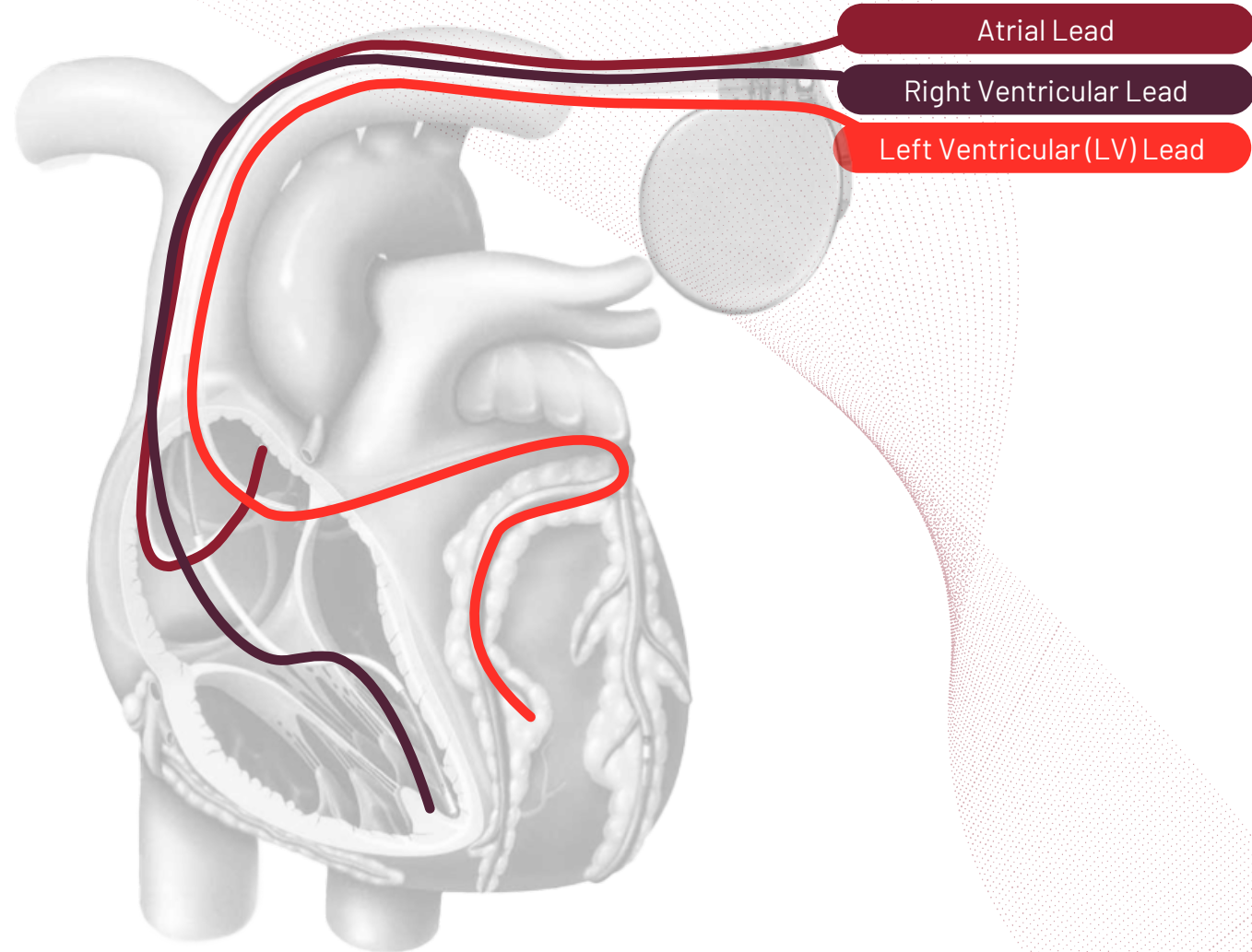
# Cardiac Rhythm Management Market

*Comprised of three key segments*

**Worldwide CRM Market (~US\$13.6bn)<sup>1</sup>**

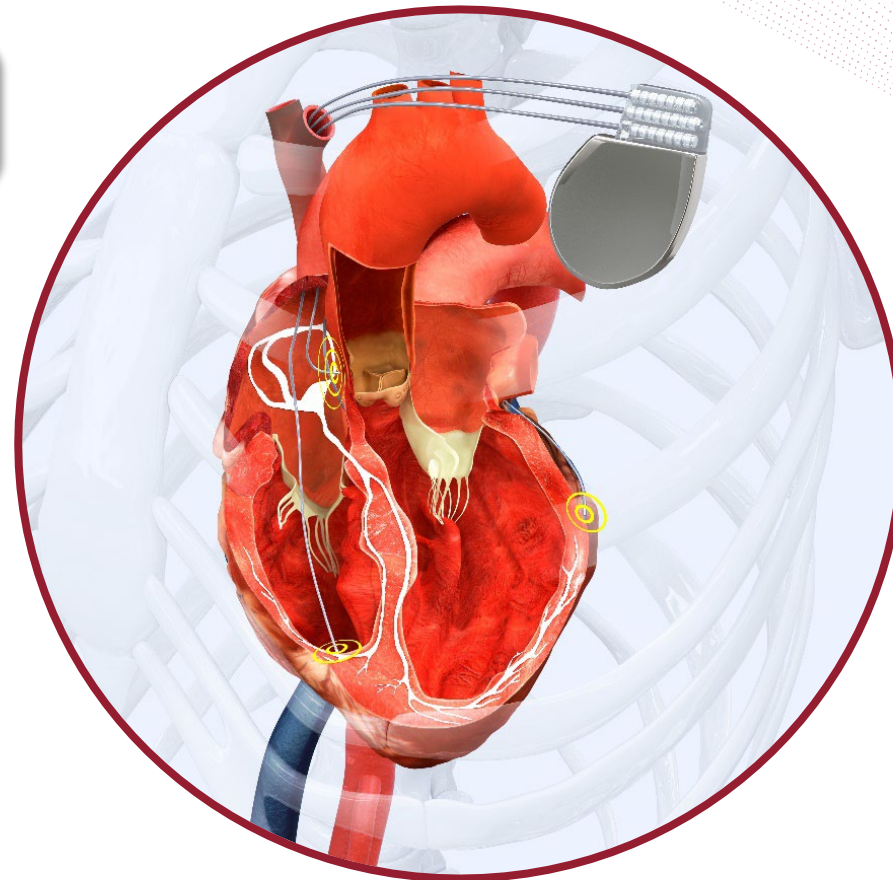


- Cardiac Resynchronisation Therapy (CRT)
- Implantable Cardioverter Defibrillation (ICD)
- Pacemakers



# Leads – The Achilles' Heel of Cardiac Rhythm Management

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



Leads can migrate and fracture



Leads can become infected - a pathway for pathogens to reach the myocardium



Cannot be placed inside (endocardially) the left ventricle



Left Ventricle (LV) lead must be placed outside the heart to avoid blood clots



Higher risk of complications with a lead-based upgrade to CRT



Risks increase as the number of leads increases

# Market is Rapidly Adopting Leadless Devices as Standard

*EBR's WiSE System is the only leadless device that can deliver leadless left ventricle pacing for cardiac resynchronization therapy*

## WiSE System fills the gap

The only leadless solution for left ventricle (LV) endocardial 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 System can be used in conjunction with leadless pacemakers to deliver totally leadless CRT

## Strong competitive protection

WiSE System is protected by over 97 issued patents globally

### Left ventricle<sup>1</sup>



EBR Systems  
WiSE Electrode



### Right ventricle / atrium<sup>1</sup>



Medtronic  
Micra®



Boston  
Scientific  
Empower®



Abbott  
Aveir®

### Extravascular / Subcutaneous ICD<sup>1</sup>



Boston  
Scientific  
Emblem®

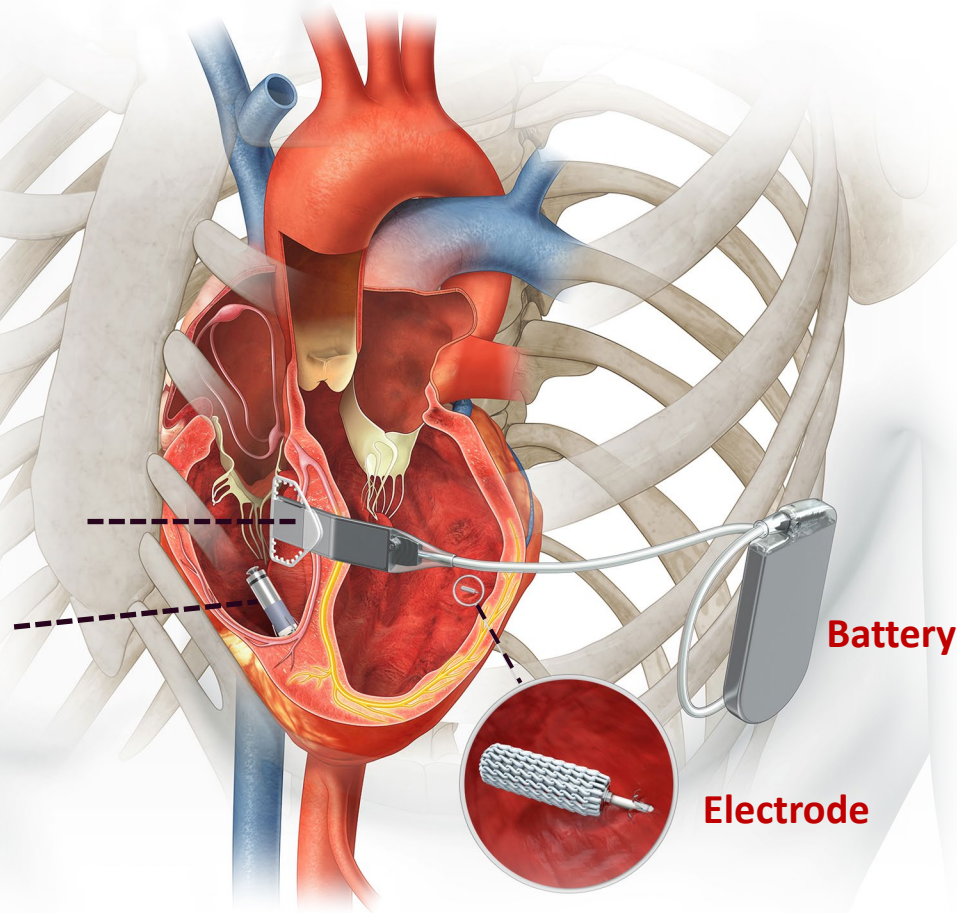


Medtronic  
Aurora®

# WiSE System for Heart Failure Patients

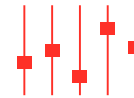
*Designed to overcome the limitations of conventional lead-based CRT*

For personal use only



## Leadless

Ultra-compact device removes constraints of lead-based pacing systems



## Versatile

Open platform synchronizes with a range of existing pacing devices



## LV Endocardial Pacing (LVEP)

Directly stimulates the heart's natural conduction system

# Targeting a \$3.6bn Total Addressable Market

Total addressable market represents patients with limited or no other options

Total Addressable market (~\$3.6bn)<sup>2</sup>

## Leadless Upgrades (~17K patients/yr)

- Patients with a leadless right ventricle pacemaker can only upgrade with WiSE CRT System to receive effective CRT
- WiSE CRT System paired with leadless pacemakers\*

*Rapidly growing segment*

## High Risk Upgrades (~20K patients/yr)

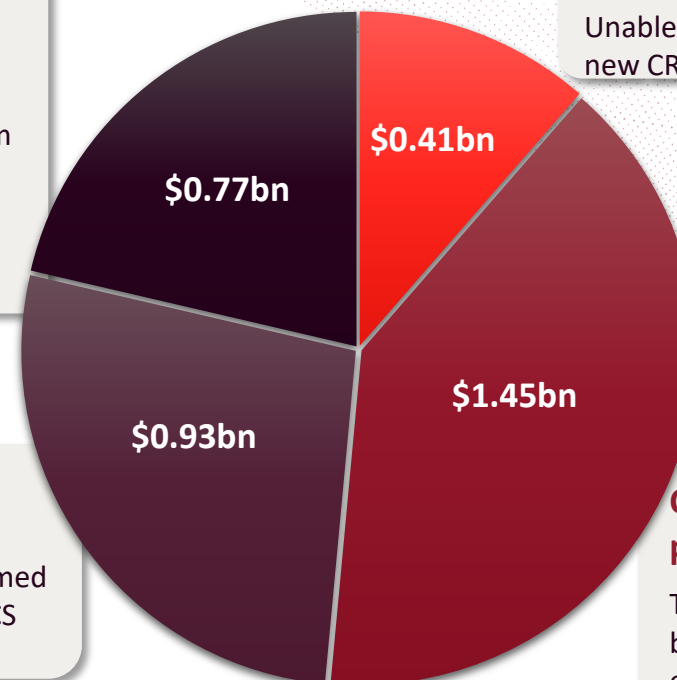
Patient requiring CRT, but is deemed too high risk for a conventional CS lead placement

## Acute Lead Failure (~11K patients/yr)

Unable to implant CRT wire in a new CRT patient.

## Chronic Lead Failure (~32K patients/yr)

Traditional CRT system implanted but has ceased to provide effective CRT



\*Medtronic's Micra leadless pacemaker has been qualified for use with WiSE CRT.  
Abbott's Aveir leadless pacemaker has not yet been qualified for use with WiSE CRT, but testing conducted by EBR is in progress.

Upgrade of a leadless pacemaker with WiSE to provide totally leadless CRT

# Executing a Clear Commercialization Strategy

## Reimbursement provides significant tailwinds

- ✓ Inpatient New Technology Add-on Payments (NTAP<sup>1</sup>) approved by CMS commencing October 1, 2025
- ✓ Outpatient Transitional Pass-Through (TPT<sup>1</sup>) payments pending final ruling, expected to commence October 1, 2025
- ✓ First technology accepted into the Transitional Coverage for Emerging Technologies (TCET) program for transitional national coverage decision;

## Disciplined approach to commercialization, limiting execution risk

- ✓ First sales achieved in 2Q '25 during pilot phase
- ✓ Limited Market Release (LMR) beginning 4Q '25 coinciding with initiation of add-on and pass-through payments
- ✓ Focused subset of strategic hospitals to be targeted
- ✓ Significant support and advocacy from US physicians

## Continued investment in expanding commercial leadership team and sales force

- ✓ Investment into leadership team including appointment of Chief Commercial Officer and 2 VPs of Sales and a VP of Marketing
- ✓ Direct sales force with 8 territories in place by year end 2025, each consisting of a sales rep and a clinical / technical specialist

# WiSE Reimbursement

*As a new medical device, EBR's WiSE System has unprecedented access to reimbursement*

## Medicare In-patient Payment

### New Technology Add-On Payment (NTAP)

- CMS has approved the NTAP payment for WiSE
- NTAP payments to commence October 2025
- Add-on payments based on \$63,300 ASP

#### Benefits of NTAP:

- Designed to cover the increased cost of important new technologies
- Reduced financial barriers for sites and improves access
- Validates the technology's innovation and clinical benefit

## Medicare Out-patient Payment

### Transitional Pass-Through (TPT) Payment

- CMS has recommended approval for WiSE up to \$63,300 ASP
- Expected to commence October 2025

#### Benefits of TPT:

- Covers cost of WiSE system
- Reduced financial barriers for sites and improves access
- External validation that the technology represents a meaningful clinical advancement

## Medicare Coverage

### Transitional Coverage of Emerging Technologies (TCET)

- WiSE is **first** technology to be accepted into the TCET program
- Developing Coverage with Evidence (CED) protocol

#### Benefits of TCET:

- Early CMS engagement for an efficient review process
- Transitional NCD for up to 5 years
- Expedited Medicare coverage

# World Class Manufacturing Facility

*EBR has secured a new state-of-the-art facility to support long-term commercial growth and scale*

## Significant Facility Expansion:

- New 11-year lease secured for 51,000 sq ft (4,751 sqm) facility
- Expansion of capability from critical manufacturing processes to manufacture of complete units
- Expands EBR's manufacturing capacity to accommodate future growth and demand for WiSE

## Phased Financial Commitment:

- Rent payments deferred until January 2026
- Gradual space occupancy and rent scaling up annually to full occupancy by year four
- Landlord to finance approximately US\$4m in tenant improvements

## Timing:

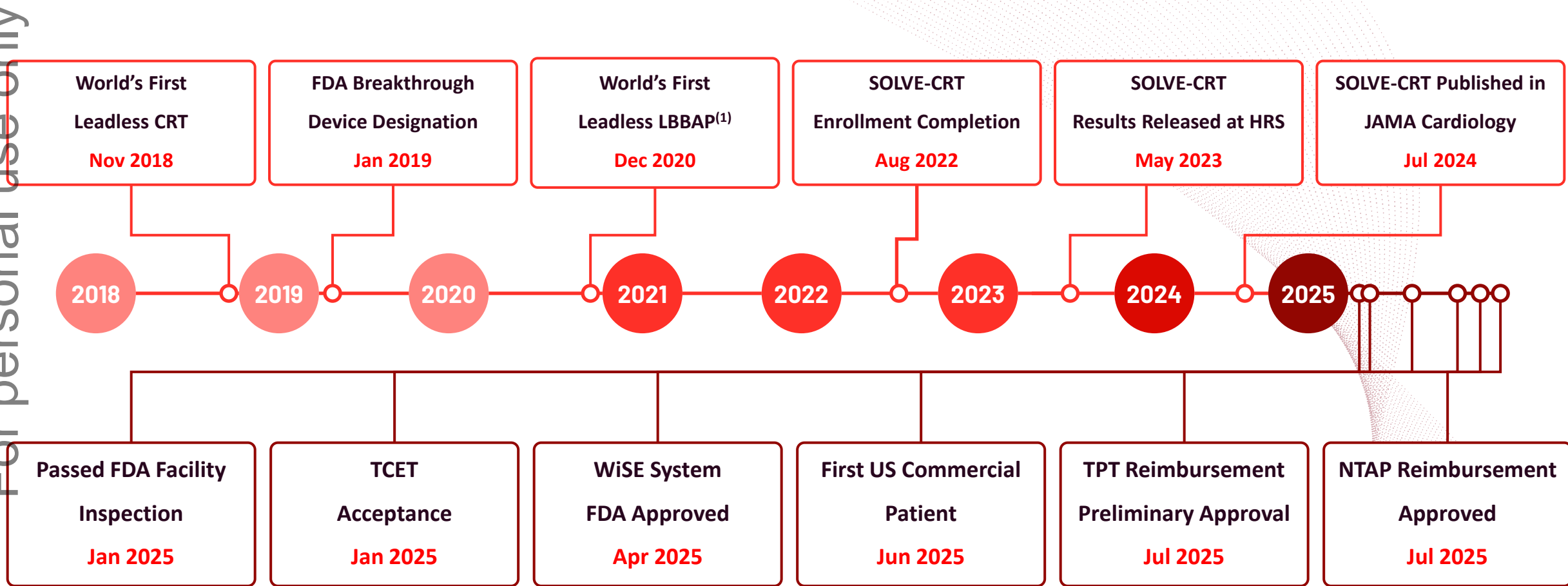
- Facility upgrades and qualifications to be completed progressively over the next year, with full transition to the new facility expected in H1 2026



*State-of-the-art facility in Santa Clara, California*

# Major Milestones

*Proven track record of achieving major clinical, regulatory, and reimbursement milestones*



# Leadership Team



**John McCutcheon**  
PRESIDENT & CHIEF  
EXECUTIVE OFFICER

- CEO since 2019
- 40+ years of sales, marketing and leadership experience in med device
- Lengthy CEO and M&A background



**Gary Doherty**  
CHIEF FINANCIAL OFFICER

- CFO since 2023
- 35+ years of finance and accounting experience
- Led 2020 Nasdaq IPO for Acutus Medical



**Erik Strandberg**  
CHIEF COMMERCIAL  
OFFICER

- CCO since 2024
- Over two decades of med device sales experience and related leadership
- Strategic planning and product portfolio management



**Michael Hendricksen**  
CHIEF OPERATING OFFICER

- COO since 2021
- Extensive product development and manufacturing experience, scaling and integrating operations



**Pharoah Garma**  
CHIEF REGULATORY  
OFFICER

- CRO since 2024
- Sr. FDA Reviewer prior to leadership roles at various startups and multinationals.
- COO at Boomerang Medical



**Spencer H. Kubo, M.D.**  
MEDICAL MONITOR

- CMO 2019-2025
- Lengthy experience as CMO, in clinical trial oversight, and in various academic roles



**Andrew Shute**  
CHIEF CORPORATE  
DEVELOPMENT OFFICER

- SVP Global Field Ops / CCDO since 2015
- Strong clinical training and sales experience
- Integral role in investor relations



**N. Parker Willis**  
CHIEF TECHNOLOGY  
OFFICER

- CTO since 2011
- Extensive signal processing experience in medical devices and development for novel cardiac EP



Board of Directors:	Allan Will	Bronwyn Evans, Ph.D.	Christopher Nave, Ph.D.	Karen Drexler	Trevor Moody	David Steinhaus, M.D.	John McCutcheon
	EXECUTIVE CHAIRMAN	DIRECTOR	DIRECTOR	DIRECTOR	DIRECTOR	DIRECTOR	DIRECTOR, PRESIDENT & CEO

# Summary

*EBR is poised for success to deliver superior treatment for patients suffering from cardiac rhythm diseases*



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



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



FDA approved and reimbursement in place supporting attractive ASP



Significant market opportunity with an initial addressable market of \$3.6bn



Disciplined commercialization strategy in place focusing on high-volume sites in the US, minimizing execution risk



# Thank You

[www.ebrsystemsinc.com](http://www.ebrsystemsinc.com)