



# Investor Presentation

Bell Potter Healthcare Conference

November 2021

# Investment highlights

## Novel Technology: WiSE®

- WiSE® is the world's smallest inside-the heart wireless cardiac pacing device
- WiSE® is the only way to provide leadless Cardiac Resynchronization Therapy (CRT)
- EBR's patent portfolio, which includes 53 issued US patents and 44 issued patents outside the US (OUS), provides strong competitive protection for EBR's WiSE® system

## Large Addressable Market

- EBR is initially targeting patients who cannot receive CRT from existing devices, or are at high risk for conventional upgrades, which represents an addressable market of ~US\$2.1 billion
- The WiSE® technology platform can be leveraged and extended into other patient groups, expanding EBR's market opportunity to ~US\$7.1bn.

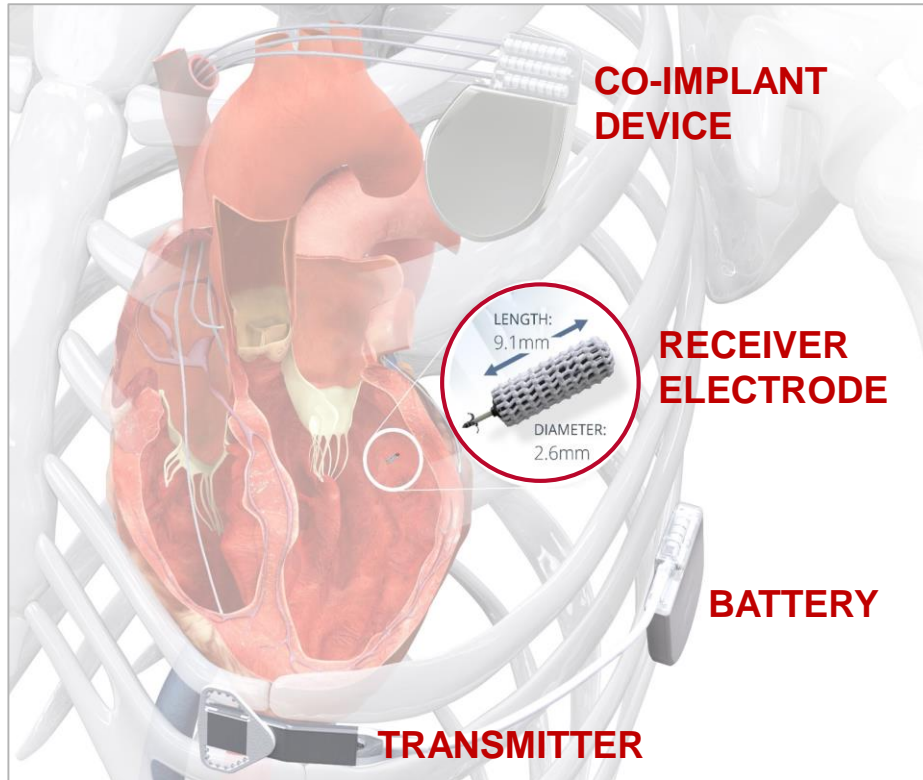
## Excellent, reproducible clinical results

- 94% of patients who failed conventional CRT achieved cardiac resynchronization at 6-months with WiSE® in earlier trials
- WiSE® is currently in the final stage of a pivotal clinical trial (SOLVE) which will complete enrolment in H1 2022
- Previous studies have exceeded the Performance Goals (Endpoints) set for the SOLVE trial

## Rapid path to commercialisation

- WiSE® has been awarded FDA Breakthrough Device Designation which provides greater access to the FDA and initial multi-year payment coverage
- EBR is targeting FDA approval and US commercial launch in H2 2023 with initial adoption from sites participating in the clinical trial for currently untreatable patients
- Established relationships and increased adoption of leadless CRT expected to drive rapid commercialisation in the US and OUS following FDA approval

# EBR has a leadless solution for heart failure patients



- Heart failure is a major medical and economic problem
- Many patients with heart failure require CRT treatment (Cardiac Resynchronisation Therapy)
- CRT uses cardiac pacing devices to coordinate the beating of the left and right sides of the heart
- CRT has been shown to significantly improve the health and quality of life for heart failure patients
- However, many patients are unable to receive CRT because their anatomy or disease condition prevents placing a lead to stimulate the left side of their heart
- EBR's wireless WiSE® can be used in these patients to stimulate the left side of the heart and, in conjunction with a right-side pacer, deliver CRT

# WiSE® technology overview

**WiSE™**  
CRT SYSTEM

Caution: Not commercially available in the United States

# Cardiac rhythm management is going leadless

WiSE® is the **only** leadless solution for left ventricle pacing and CRT

## Major players have introduced leadless pacing technology

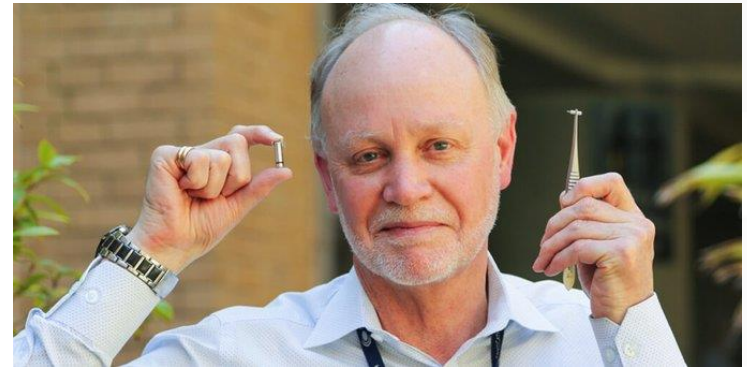
- Medtronic reported US\$400m annual sales run rate for Micra® for the March Quarter 2021
- Micra® grew a further 30%-35% in the June Quarter 2021

## However, the size of leadless pacemakers restricts use to right ventricle (RV) and right atrium (RA) bradycardia pacing

- Too large to completely endothelialise (0.80-1.0cc)
- Interference with valves if placed basally
- Risk of blood clots and size prohibit LV placement

## WiSE® is the **only** leadless solution for LV pacing including CRT and only leadless conduction system pacing (CSP):

- 0.05cc in volume (5% to 6% the volume of other leadless pacemakers)



Dr. Jeffrey Alison, Monash Hospital, Melbourne  
Micra on the left, WiSE® held by tweezers on the right.

# Extensive clinical experience in multiple trials

Human Feasibility: WiSE CRT = **13 pts**

CE Study: SELECT-LV = **35 pts**

Post-CE Mark Registry & SAS > **170 pts**

SOLVE-CRT Roll-in Study = **31 pts**

SOLVE-CRT Pivotal Study = **128 pts**

**>350**  
patients

Total human  
experience to date

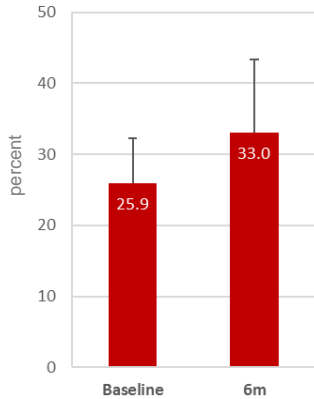
# SELECT-LV | WiSE<sup>®</sup> benefits in failed conventional CRT

94%

OF PATIENTS WHO FAILED CONVENTIONAL CRT ACHIEVED CARDIAC RESYNCHRONISATION AT 6-MONTHS<sup>1</sup>

## LV Ejection Fraction

Baseline and 6m

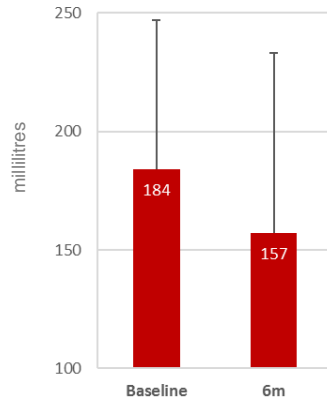


+7.1 ± 8.0%, p = 0.001

Proportion of blood which is pumped out of heart - efficiency

## End Systolic Volume

Baseline and 6m

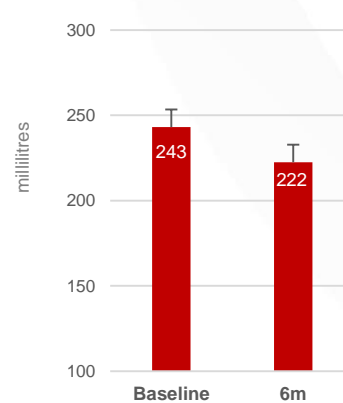


-26.8 ± 45.1 ml, p = 0.007

Volume of blood in heart after a contraction - ability of heart to pump

## End Diastolic Volume

Baseline and 6m

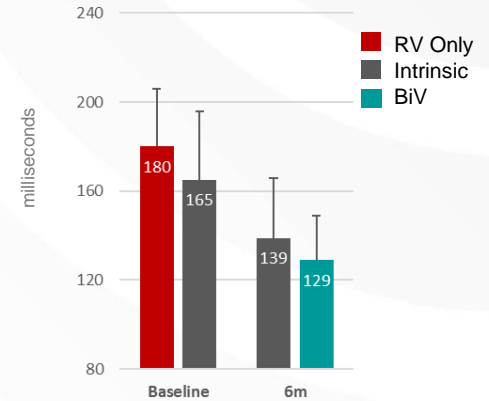


-20.6 ± 41.5 ml, p = 0.02

Volume of blood in heart before a contraction - extent of enlargement

## QRS Duration

Baseline and 6m



SELECT-LV: QRS decrease of 51 ms (180 to 129 ms or 28% reduction. N=20)

Timing between different parts of the contraction process

# Registry | Improves heart function in real world setting

Data from 90-patients in the European WiSE® Post Market Surveillance Registry<sup>1</sup>

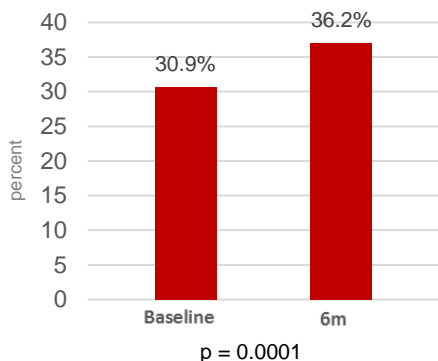
90 PATIENTS

14 CENTERS

94.4% BIVENTRICULAR PACING AT 6 MONTHS

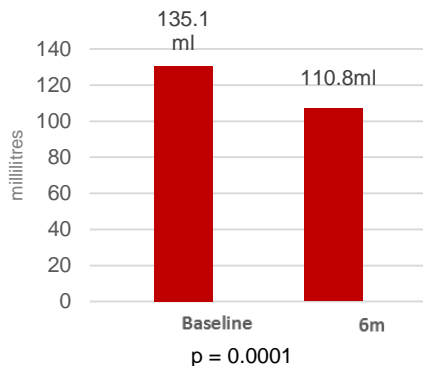
## LV Ejection Fraction

Baseline & 6m (n=43)



## End Systolic Volume

Baseline & 6m (n=43)



*“Our results suggest that endocardial CRT pacing with this novel pacing system is an effective treatment for a high-risk group of patients with heart failure...”<sup>1</sup>*

Proportion of blood which is pumped out of heart - efficiency

Volume of blood in heart after a contraction – ability of heart to pump

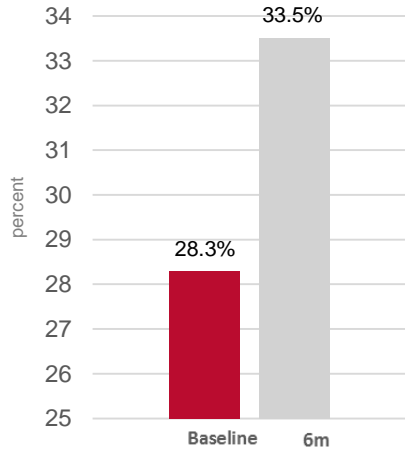


# SOLVE Roll-in Study | Evidence of cardiac remodeling

Data from 31-patients in the Roll-in study for the pivotal SOLVE clinical trial<sup>1</sup>

## LV Ejection Fraction

Baseline and 6m

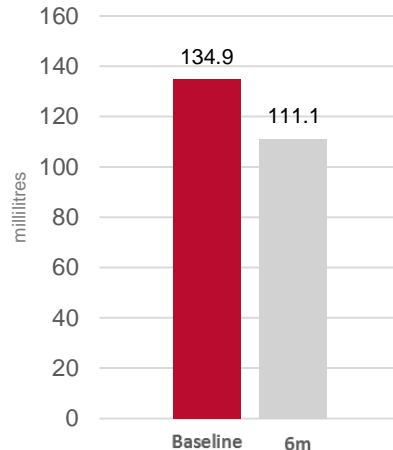


+5.3 ± 5.8%, p < 0.001

Proportion of blood which is pumped out of heart - efficiency

## End Systolic Volume

Baseline and 6m

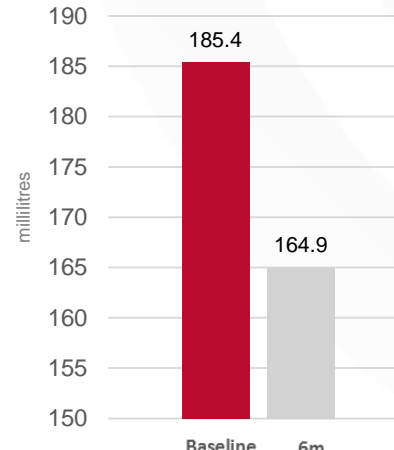


-23.7 ± 31.7 ml, p = 0.004

Volume of blood in heart after a contraction – ability of heart to pump

## End Diastolic Volume

Baseline and 6m

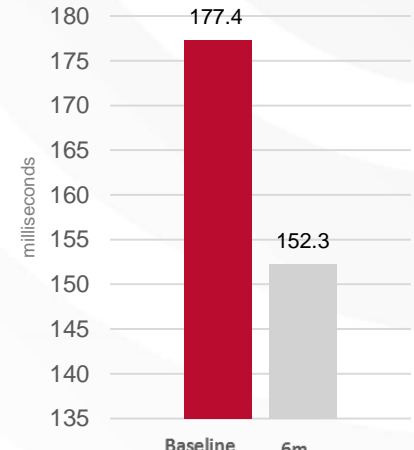


-20.5 ± 31.9 ml, p = 0.0017

Volume of blood in heart before a contraction – extent of enlargement

## QRS Duration

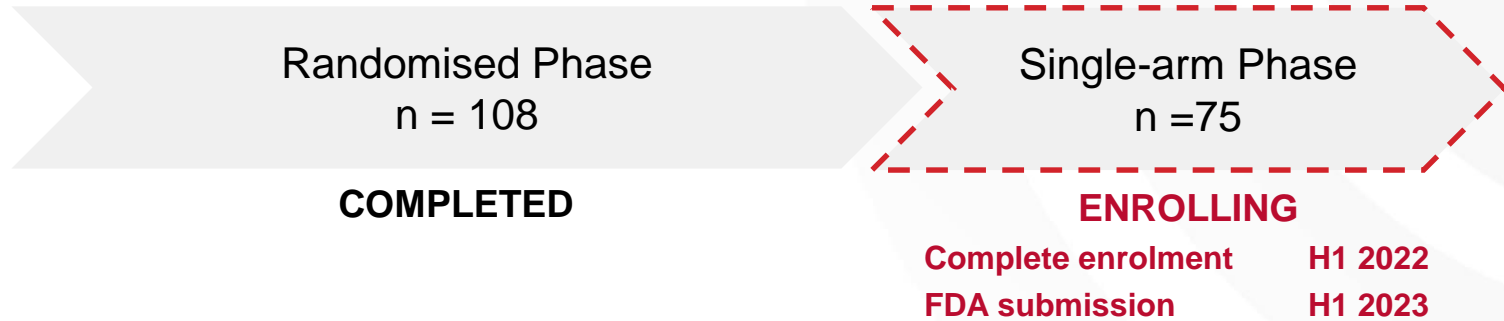
Baseline and 6m



-25.1 ± 30.0 ms, p = 0.0002

Timing between different parts of the contraction process

# SOLVE Pivotal Study | Currently underway



**Purpose:** Assess the safety and effectiveness of the WiSE® System

**Design:** International, multi-center study following initial 31-patient US roll-in study (completed and published)<sup>1</sup>

**Population:** Acute lead failures, chronic lead failures, high risk upgrades

**Single-arm Phase:** single arm, open label targeting enrolment complete H1 2022 and headline data H2 2022

**Primary Efficacy Endpoint:** >9.3% improvement in heart function measured by reduction in left ventricular end systolic volume

**Primary Safety Endpoint:** <30% patients with device or procedure-related complications

<sup>1</sup> Modified design of Stimulation Of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy (SOLVE-CRT) in non-responders, previously untreatable and high-risk upgrade patients trial, J.P. Singh et al (2021), Am. Heart J. 235:158-162

# SOLVE Pivotal Study | Endpoints achieved previously

*Previous studies have exceeded the pre-specified Performance Goals (Endpoints) set for the SOLVE trial*

<b>Efficacy</b>	<b>Lead Failures &amp; High-Risk Upgrades</b> (patients in subgroup)	<b>End Systolic Volume<sup>1</sup></b> (% chg in subgroup)
Select-LV	18 / 35	-19.9%
Post Market Surveillance Registry	47 / 90	-20.9%
SOLVE Roll-in study	15 / 31	-18.5%
<b>Combined Clinical Trials</b>	<b>80 / 156</b>	<b>-20.2%</b>
<b>SOLVE Trial Performance Goal</b>		<b>-9.3%</b>

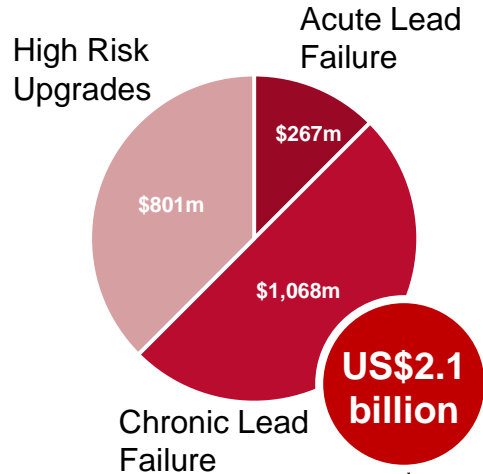
<b>Safety</b>	<b>Freedom from Type I Complications Rate</b>
SOLVE Roll-in (N = 31 all patient relevant for safety evaluation)	90.3% (28/31)
<b>SOLVE Trial Performance Goal</b>	<b>70.0%</b>

<sup>1</sup> Sub-group analysis conducted by EBR on relevant patients (i.e., acute lead failures, chronic lead failures and high-risk upgrade patients) that will be assessed in the SOLVE clinical trial for the US PMA application

# Market expansion opportunity

*The WiSE® technology platform can be expanded into other patient groups, increasing EBR's market opportunity and driving sales growth*

## Initial Addressable Market



Strong market growth for leadless CRM Devices

Additional Clinical Applications

## Expansion Opportunity

### New Patient Groups, Indications & Geographies

- First-line CRT treatment
- De novo implants for bradycardia and chronic atrial fibrillation
- International expansion

**US\$7.1 billion**

# Commercial strategy

## Pre-Commercial 2021 & 2022

- Complete SOLVE IDE pivotal trial enrolment in H1 2022
- Continue to support clinical sites and patient implants
- Presentations at high profile cardiology conferences and multiple publications in medical & scientific journals
- Expand payment and reimbursement coverage for WiSE

## Initial Commercial Late 2023

- Initial focus on sites with WiSE® experience through clinical trials
- Fast growth opportunities via an expanded direct sales force penetrating high-volume accounts in U.S. Targeting top 200-250 sites that account for 50% of U.S. CRT market
- Launch in select OUS markets as reimbursement coverage is secured
- Initial focus on key opinion leaders at high volume sites in each market

## Expansion 2024 & beyond

- Expand use of WiSE® beyond initial target of Lead Failure and High-Risk Upgrade patients
- Leverage growth opportunities from increasing adoption of leadless pacemakers
- Geographic expansion into other markets using distributors

# US sales and distribution platform

*Established relationships and infrastructure in US to drive strong initial sales growth*

## Clinical trial sites to drive sales

**Targeting 45 sites in the US IDE trial. Capitalise on existing partnerships with these top CRT sites**

- Expansion will target top 200-250 sites, representing > 50% US CRT market
- Top 100 sites in EBR's target OUS markets represent ~40% of the OUS CRT market

## Unmet need and strong data

**Creation of demand and market awareness in the US from:**

- Unmet need underscored by FDA Breakthrough Device designation for WiSE®
- Extensive body of clinical evidence
- Utilise final SOLVE Roll-in results (HRS LBCT & Publication) to drive further demand and awareness
- Well known technology globally with the support of Key Opinion Leaders (KOLs)

## Reimbursement & high ASP

**Reimbursement - New Technology Add-on Payment (NTAP) expected post FDA approval**

- High ASPs
- US WiSE® US\$35,000<sup>1</sup>
- RoW WiSE® CRT US\$20,000<sup>2</sup>

## Specialist sales force established

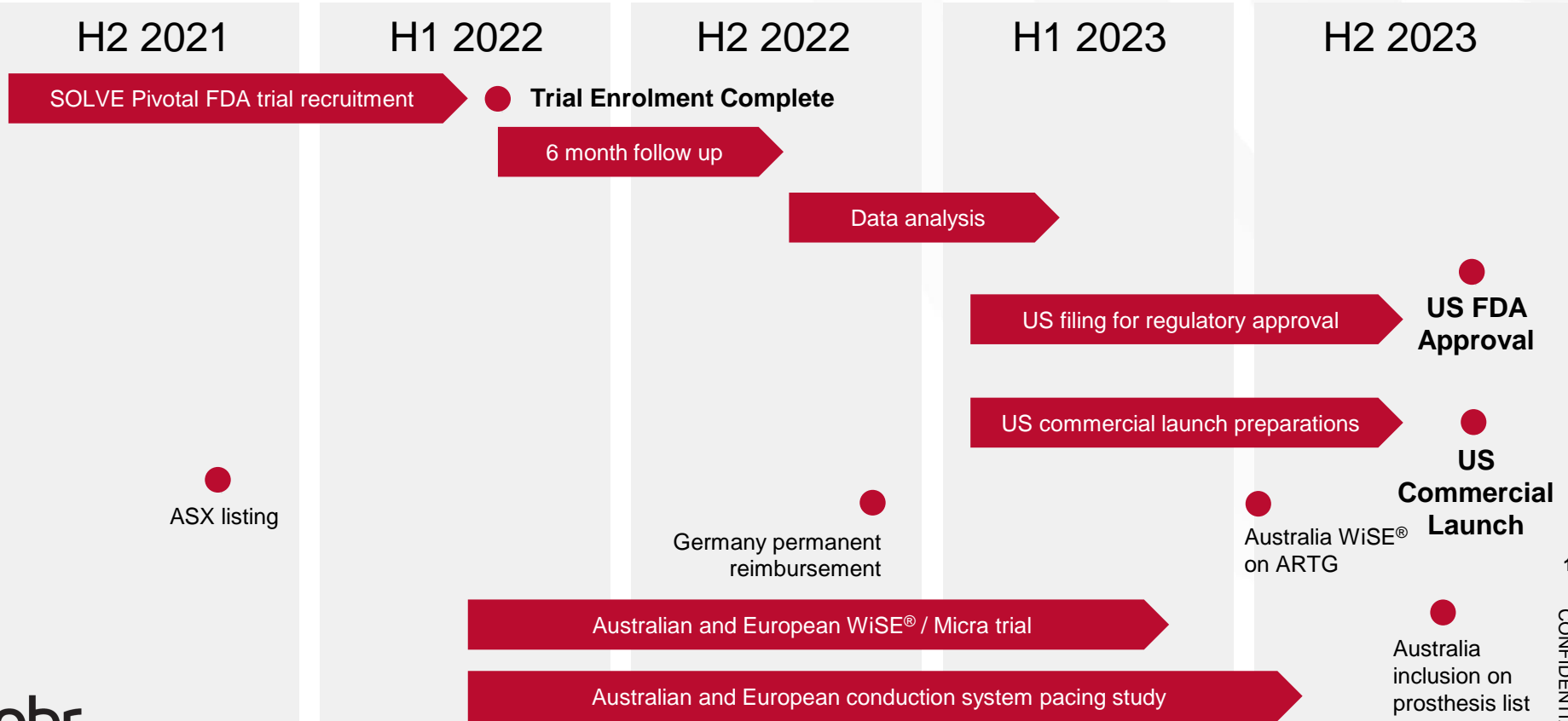
**Strong execution of commercial launch supported by specialised direct sales force**

- 8 FT field staff in place with strong clinical and technical expertise of WiSE® System
- Target growth to 35 sales territories by end of 2025

## Low hospital adoption barriers

**Low barrier for opening new accounts – no capital equipment required and hospital-favorable reimbursement available post-approval**

# Regulatory and commercial pathway



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