



# Annual Report

2022



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EBR Systems is driven to deliver superior treatment for millions of patients suffering from cardiac rhythm diseases by developing safe, clinically superior, cost-effective and reliable therapies using wireless cardiac stimulation.

# Executive Chairman and CEO Letter



Dear Shareholders,

It is our pleasure to present EBR Systems' 2022 Annual Report. In what has been a busy year for the Company, we have made tremendous strides towards completing our operational milestones. Our pivotal SOLVE trial results will be released mid-year and 2023 aims to be transformative for the Company as we continue our quest to improve the lives of millions of patients suffering from heart failure.

We are delighted to have completed interim enrolment for our SOLVE trial during the year, representing a major milestone for the Company. Final patient follow-ups were completed subsequent to year end, which will culminate in sharing the results in the very near term. This is the accumulation of more than 10 years of clinical development. We remain confident that we will achieve the primary endpoints as outcomes from the previous clinical trials of WISE have exceeded the performance endpoints.

During the year, we strengthened our financial position by securing a growth capital facility with leading provider, Runway Capital. This provides additional balance sheet flexibility to support EBR as we progress toward our clinical and commercial milestones. Importantly, this method of funding is non-dilutive to shareholders and promotes financial stability in otherwise turbulent market conditions. We feel fortunate to have secured this facility before markets further deteriorated.

We are honoured to have been recently featured in many high-profile journals and leading clinical conferences, validating our technology and extending our engagement with the broader scientific community. In the last 12 months, the WISE system has been featured in the leading peer-reviewed Heart Rhythm Journal, which is the official journal of the Heart Rhythm Society, the Cardiac Electrophysiology Society, and the Paediatric & Congenital Electrophysiology Society.

Subsequent to the year end, we strengthened the management team with the addition of Dr Rick Kuntz as consulting Chief Scientific Officer. Dr Kuntz brings extensive experience overseeing numerous clinical trials and has a strong background across many different areas of healthcare. His guidance will prove invaluable as EBR progresses through the final stages of the SOLVE trial and FDA review.

Looking ahead, we are focused on completing our analysis of the SOLVE trial data and are excited to be releasing the results at the prestigious Heart Rhythm Society conference in the high-profile Late Breaking Clinical Studies section. We remain focused on delivering our goals, driving clinical development and pre-commercialisation activities.

On behalf of the Board, we would like to thank our shareholders for the ongoing support as we move toward commercialisation. We would also like to take this opportunity to thank our fellow Board members and the entire EBR Systems team for their hard work and contributions. We look forward to achieving further success in 2023.

Sincerely,

**ALLAN WILL**  
Executive Chairman  
EBR Systems Inc

**JOHN McCUTCHEON**  
President and CEO  
EBR Systems Inc

# Operational Highlights

Operating expenses

**US\$34.0m**

Cash position

**US\$64.5m**

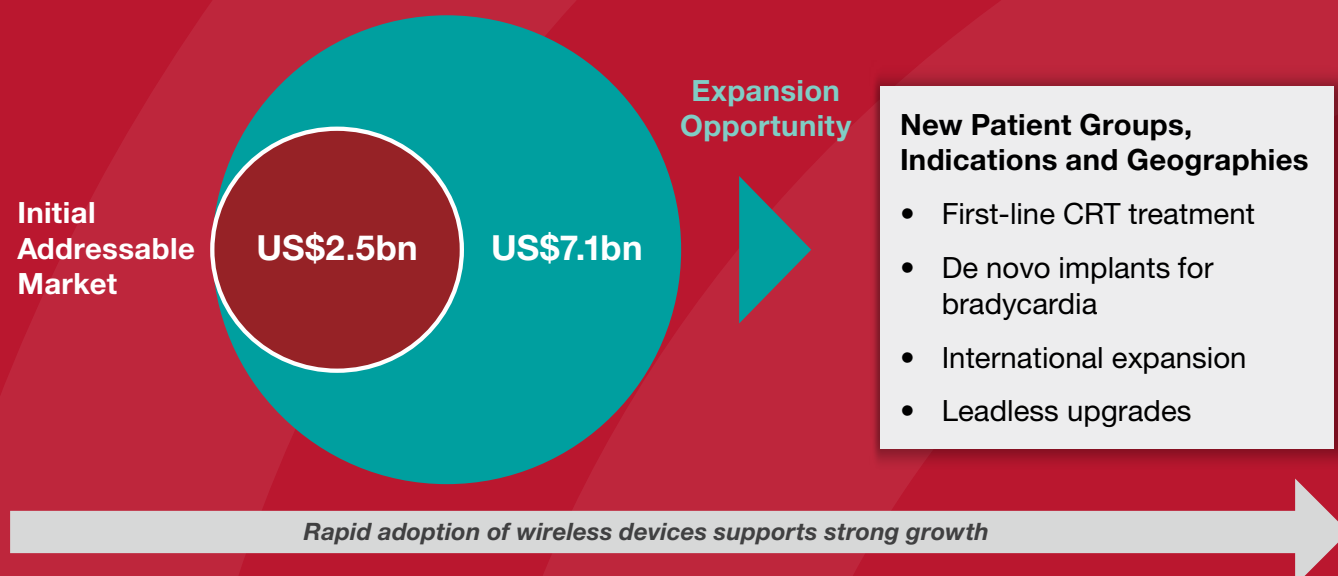
(at 31 Dec 2022)

Net cash used in operating activities

**US\$30.4m**

## Market expansion opportunity

The WiSE® technology platform can be expanded for use into other patient groups, increasing EBR's market opportunity and underpinning future growth.



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





# Operational Review 2022

## Strategic focus

- Completing final data analysis and certifying results for the pivotal SOLVE trial
- Presenting the full SOLVE trial results at the 2023 Heart Rhythm Society conference in May
- Resolving a transmitter issue that caused an increased rate of battery depletion in a small number of devices
- Exploring product improvement opportunities with a longer lasting rechargeable battery

## Finalising data analysis of the recently completed SOLVE trial

During the year, EBR successfully completed its interim enrolment of 183 patients in the pivotal SOLVE-CRT (**SOLVE**) trial of WiSE. After completing a 6-month check up on final patients, data analysis and cleansing is currently underway with the Company expecting to release full trial results at the Heart Rhythm Society conference in May 2023, followed by the submission of a pre-market approval (**PMA**) application to the FDA in the second half of 2023.

The single-arm pivotal trial assesses the safety and efficacy of the WiSE System in patients with acute lead failures, chronic lead failures and high-risk upgrades. The primary efficacy endpoint for the trial is a greater than 9.3% improvement in heart function measured by a reduction in left ventricular end systolic volume, and the primary safety endpoint is less than 30% of patients with a device or procedure-related complication. EBR is confident that the SOLVE trial will meet the key primary endpoints based off its previous clinical study, the SELECT-LV study, having exceed both endpoints.

## Presenting at premier global conferences and distinguished events

The Company's trial abstract titled "*Safety and Efficacy of a Leadless Ultrasound-Based Cardiac Resynchronisation Pacing System in Heart Failure – Results from the SOLVE-CRT Study*", has been accepted at the prestigious 2023 Heart Rhythm Society (**HRS**) conference. The presentation will be delivered by Dr Jagmeet Singh, MD, DPhil, the Co-Principal Investigator. The Heart Rhythm Society's annual meeting is the largest gathering of heart rhythm professionals globally and EBR's inclusion is a testament to the importance of the Company's technology.

Over the last 12 months, EBR's WiSE technology was also featured at the 15th Asia Pacific Heart Rhythm Society (**APHRS**) Scientific Session in Singapore, the 2022 European Heart Rhythm Association, and the 2022 HRS conference in San Francisco, highlighting the Company's position at the frontier of scientific breakthrough and innovation in the cardiac rhythm management landscape. The combined network of these global events provides EBR with an opportunity to connect with thousands of medical, allied health, and science professionals from up to 100 different countries.

## Implementing changes to rectify battery transmitter issue

During the year, EBR identified an increased rate of battery depletion caused by the transmitter in a subset of WiSE devices. The issue was picked up as part of ongoing technical assessments and subsequently, EBR issued a notification to customers in line with regulations and industry best practice.

The Company is confident that the issue will not impact the headline data or timing of the SOLVE trial. Affected devices were able to continue functioning normally and deliver biventricular pacing until the battery was depleted. The Company has actively been working toward a solution which will be completed prior to PMA submission to the FDA in the second half of 2023.

## Continuing rigorous R&D and innovation

During the period, EBR continued its research into optimising the WiSE battery performance and lifetime. The objective of the R&D project is to substitute the existing battery with a smaller and rechargeable one that can last up to 20 years; charged through the skin for approximately one hour per week using inductive charging. Similar technology is already being used in implantable devices for heart failure and neuromodulation and EBR is collaborating with a well-established vendor that supplies similar batteries to other medical device firms.

## Growth opportunities

- FDA submission and eventual approval
- Robust commercialisation strategy for geographic expansion and distribution
- Future expansion of total addressable market supported by three key areas:
  - Increasing uptake of leadless pacemakers
  - Upgrading patients with leadless pacemakers
  - Furthering clinical applications using WiSE

## Strategic commercialisation plan

EBR expects to commence its commercialisation activities in the US, following successful trial data and FDA approval. The strategy is underpinned by two key elements: targeting clinical trial sites and utilising a specialised sales force. The Company has a plan to leverage established partnerships with ~45 US sites that have participated in previous clinical trials to drive initial sales growth. Each site has been considered due to its captive market as a high-volume site. Once established, the Company aims to use a specialist sales force to accelerate its growth profile. EBR will also seek to expand its outreach to high volume sites outside the US, following regulatory approvals and reimbursement coverage.

## Burgeoning market potential

EBR has focused primarily on targeting patients in the U.S. who require CRT treatment but are either unable to use conventional lead-based systems, or those who are considered at risk for a CRT upgrade. EBR estimates to have an initial addressable market opportunity of approximately US\$2.5 billion, targeting the U.S., Germany, France, the U.K., Australia, Benelux and Scandinavia. The Company aims to expand its total addressable market to US\$7.1 billion by focusing on new patient groups and indications, while expanding internationally using EBR's global distribution platform.

In addition, EBR expects to benefit from the rapid growth and strong demand for leadless pacemakers (PPMs), led by Medtronic's Micra and Abbott's Aveir. WiSE can capitalise on the opportunity to provide entirely leadless CRT through two avenues:

- **De novo leadless CRT patients:** patients who have been newly implanted with a leadless pacemaker in the right ventricle and WiSE in the left ventricle to deliver biventricular pacing
- **Leadless upgrade patients:** patients who already have a leadless pacemaker in the right ventricle but have developed heart failure and need to upgrade.

## Corporate update

- Appointed industry expert Dr Kuntz as consulting Chief Scientific Officer, who brings extensive experience leading clinical trials and a deep understanding of the broader healthcare industry
- Dr Kuntz's experience will prove invaluable to the team as the SOLVE trial nears completion

## Strengthened management team

During the year, EBR strengthened the Company's management team with the appointment of Dr Rick Kuntz as consulting Chief Scientific Officer. Dr Kuntz has a broad background across multiple areas of healthcare with extensive experience in clinical trials. He previously served as Senior Vice President, Chief Medical and Scientific Officer of Medtronic overseeing health policy, reimbursement of clinical research activities and corporate technology. Throughout his career, Dr Kuntz has directed numerous multicentre clinical trials, has authored more than 250 original publications and was founding CEO of the Harvard Clinical Research Institute. Dr Kuntz will play an essential role in helping EBR navigate SOLVE through its final stages and engagement with regulatory bodies.

## Financial update

- Successfully executed an agreement for a 5 year US\$50 million growth capital facility
- Provides financial stability and is non-dilutive to shareholders

## Secured US\$50 million growth capital facility

The Company executed an agreement for a 5-year US\$50 million growth capital facility with leading venture debt provider, Runway Growth Capital, LLC. The agreement provides EBR with additional balance sheet flexibility, non-dilutive capital, and protection from volatile macroeconomic conditions as the company advances towards its clinical and commercial goals.

The facility is structured such that EBR can immediately withdraw US\$20 million in its 1st tranche and may choose to draw on subsequent tranches conditional upon achieving significant milestones. As at 31 December 2022, EBR had withdrawn US\$20 million with the remaining US\$30 million available in future tranches.

## Outlook

EBR is expected to complete the data analysis from its SOLVE trial and plans to unveil the full results during the Heart Rhythm Society's late breaking clinical trial session on 21 May 2023. The Company intends to submit a PMA application for U.S. FDA approval later this year and plans to execute on its robust commercialisation strategy following FDA approval in 2024.





WiSE is the  
world's first and  
only leadless  
inside-the-heart  
pacemaker for  
heart failure



# WiSE® Technology Overview

## Introduction

EBR is a United States-based company developing and commercialising WiSE, an implantable, cardiac pacing device able to provide stimulation to endocardial (inside the heart) heart tissue for the correction of heart rhythm conditions without requiring the use of leads.

EBR has initially developed WiSE for use in conjunction with another implanted pacemaker to provide cardiac resynchronisation therapy (**CRT**) to patients who are unable to receive CRT from a traditional lead-based system or are at high risk of complications from an upgrade procedure. EBR estimates this initial application has an addressable market of US\$2.5 billion in the Company's major target markets of the U.S., Germany, France, the U.K., Australia and other select E.U. countries. In the future, and subject to supporting clinical data and regulatory approvals, the use of WiSE may be broadened to include other CRT patient groups or cardiac pacing applications.

EBR completed interim enrolment in the pivotal SOLVE study in June 2022 and results will be released during the Heart Rhythm 2023 meeting in May 2023, in support of an application for FDA approval in the U.S. of WiSE. The Company is anticipating WiSE will receive FDA approval in 2024 and launch commercially in the U.S. soon after. The Company plans to commercialise the device in Australia and certain European countries following its initial launch in the U.S. and upon local regulatory approvals.

## Heart Failure

The market for EBR's leadless WiSE device is for use in patients with moderate to severe heart failure who require CRT. The initial market for WiSE is for use in patients who are not able to receive, or who are at high risk to receive, CRT using existing lead-based devices because of potential complications from the use of leads due to their anatomy or disease condition, or for use in patients in whom the CRT lead has failed.

### Prevalence and Incidence of Heart Failure

Heart failure belongs to a group of diseases called cardiovascular diseases. Heart failure is a complex clinical syndrome that results from functional or structural impairment of the heart that results in the dysfunction of the left ventricle (**LV**).

Heart failure is a significant public health problem with an estimated prevalence in 2020 of 6.9 million people in the U.S., and around 64 million people worldwide. It is expected that 8.5 million people in the United States will suffer heart failure by 2030, and it is the leading cause of hospitalisation in the U.S. in people over age 65. Approximately 30–40% of patients with heart failure have a history of hospitalisation which is linked with worse health and clinical outcomes.

Over 850,000 new cases of heart failure are diagnosed in the U.S. each year. It is estimated that approximately 20% of heart failure patients are classified as having moderate to severe disease. Around 10% of all heart failure patients in the U.S. meet the criteria for CRT, due to the ventricles of the heart contracting at slightly different times (dyssynchronous contractions).

### Healthcare Burden of Heart Failure

Heart failure is a major and growing medical and economic problem, with high prevalence and incidence rates worldwide.

The economic burden of heart failure on healthcare systems is considerable and is expected to increase as its prevalence grows.

An analysis in 2012 estimated the global cost of heart failure to be US\$108 billion per annum, with US\$65 billion attributed to direct costs (e.g., treatments, hospitalisations, drugs and devices) and US\$43 billion to indirect costs (e.g., transportation, allied healthcare provision and rehabilitation). In the U.S., approximately 1% to 2% of the total U.S. healthcare budget is spent on heart failure. The total U.S. cost of care (direct and indirect costs) for heart failure in 2020 was estimated to be US\$43.6 billion. Without improvements in outcomes, the annual total cost of care for heart failure patients in the U.S. is projected to increase to US\$69.7 billion by 2030.

## Drivers of Heart Failure

The risk of developing heart failure increases with age. There are several factors that increase the risk of developing heart failure including:

- high blood pressure (hypertension);
- coronary heart disease (CHD);
- previous heart attack;
- family history; and
- diabetes.






In addition to ageing, the prevalence of heart failure in the population is expected to continue to increase, driven by factors including:

- poor diet and nutrition;
- insufficient activity and exercise;
- increasing levels of obesity; and
- smoking.

## Cardiac Rhythm Management Devices

The first cardiac pacing device was developed in the 1950s and formed the foundation for the medical device company, Medtronic plc. Since then, cardiac pacing devices have continued to play a key role in the clinical management of patients with heart disease.

### History of cardiac pacing devices

1950s	1950s	1958	2015	2016
AC-powered pacemakers tethered to an extension cord (Furman)	Battery-powered transistorised “wearable” pacemakers (Lillehei/Bakken)	First fully implantable pacemaker (Elmqvist/Senning)	Implantable pacemaker – basic system had not evolved significantly	Leadless pacemaker – the entire device is placed within cardiac chambers
				

	1950s	1980s	1990s
CRM Applications	Pacing – Pacemakers	Implantable Cardiac Defibrillation – ICDs	Cardiac Resynchronisation Therapy – CRTs

Source: adapted from S.K. Mulpuru et al (2017), J. Am. Coll. Cardiol. 69:189–210.

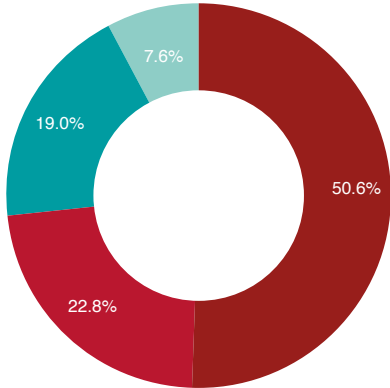
Cardiac rhythm management (CRM) devices are devices that monitor a patient's heart rhythm and normalise different types of irregularities by delivering small, electrical shocks to the heart tissue. The three most common therapeutic CRM devices are:

- **Pacemakers:** which stimulate contractions of the heart if it slows or becomes irregular;
- **Defibrillators:** which deliver an electric shock to reset the heart rhythm when certain types of cardiac arrhythmia occur; and
- **CRT devices:** which synchronise the contraction of the left and right sides of the heart.



Based on reported sales from the relevant company segments for Medtronic, Abbott and Boston Scientific and shares of the CRT market, EBR has estimated the total market for CRM devices in 2020 was US\$7.5 billion – US\$8.5 billion.

## Estimated Global Market for CRM devices

Sales FY20 <sup>1</sup> (US\$)	Company	Company Reporting Segment	CRT Market share 2015–2018 <sup>3</sup>
\$5.1 billion	Medtronic	Cardiac Rhythm & Heart Failure <sup>2</sup>	
\$1.9 billion	Abbott	Rhythm Management	
\$1.7 billion	Boston Scientific	Cardiac Rhythm Management	

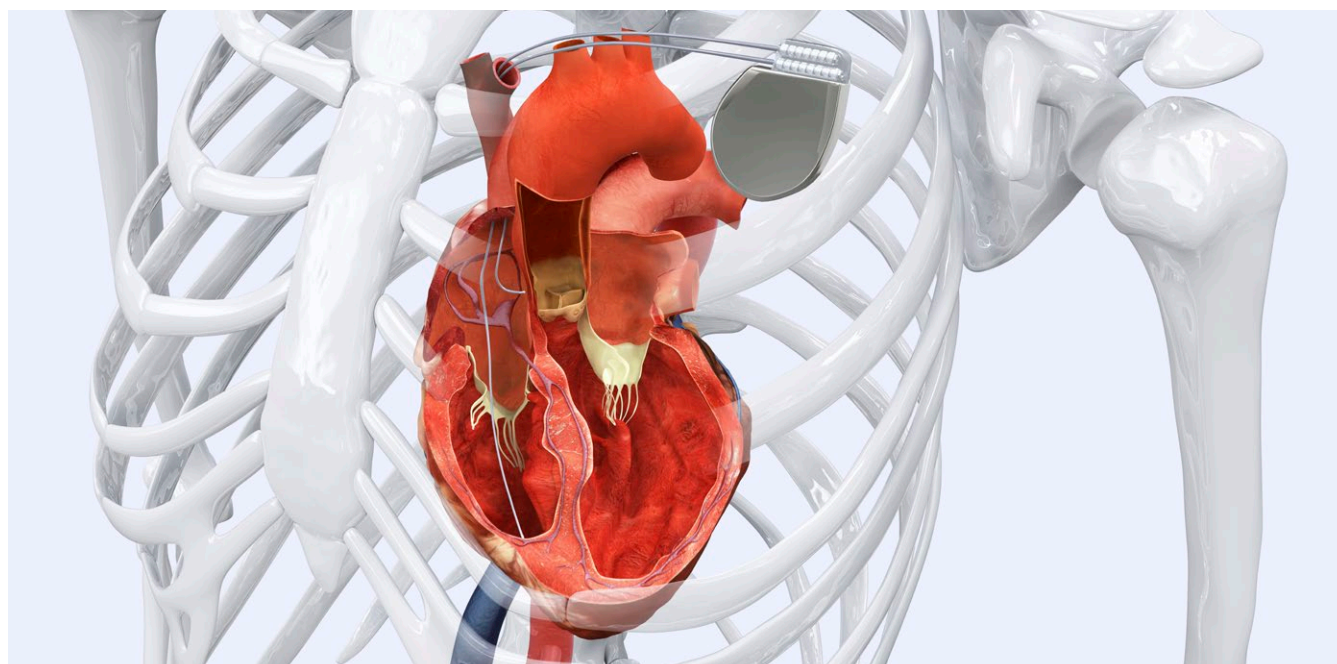
Based on CRT market share estimates and reported segment numbers, CRM devices in 2020 is estimated at US\$7.5 billion – US\$8.5 billion.

1. Reported financials from annual reports for fiscal 2020.
2. Includes ablation, pumping and monitoring products as well as CRM devices. Split not reported.
3. MarketsAndMarkets: Cardiac Resynchronisation Therapy Market Report.

## Pacemakers

Due to disease, tissue damage or medication, the heart rate of some patients may tend to slow. This condition is called bradycardia (slowing of the heart). Permanently implanted pacemakers (PPMs) detect if the beating of the heart becomes slow or irregular and corrects it using small, electrical impulses to stimulate contractions.

### Diagram showing an implanted permanent pacemaker (PPM)



The pattern of pacing required is controlled by an implantable pulse generator (IPG) and can be adjusted over time as a patient's needs change. Some patients are entirely dependent on their pacemakers to make their heart beat, while others are paced occasionally and only when required.

### (a) Implantation of PPMs

The chambers of the heart where the pacing electrodes are placed may also vary:

- **single lead** (single chamber pacing) – in the right ventricle or right atrium;
- **two leads** (dual chamber pacing) – in the right ventricle and right atrium;
- **leadless pacemaker** – direct implant into the right ventricle to treat bradycardia.

Each year, it is estimated that over 200,000 pacemakers are implanted in U.S. patients with bradycardia. Estimates for the number of individuals around the world who are living with an implanted pacemaker range from 1.25 million to 3 million people.

### (b) Leadless Pacemakers

The most recent advance in the evolution of pacemakers has been the advent of leadless cardiac pacing systems. The most frequent complications with pacemakers are usually associated with their leads. To overcome this, leadless pacing systems have recently been developed in which the IPG and stimulating electrode are combined into a single unit that can be fully implanted inside the heart chamber. The three leading CRM device companies (Medtronic plc, Boston Scientific, and Abbott) have each developed such leadless cardiac pacemakers.

### Increasing use of leadless pacemakers

Major players have introduced leadless pacing technology:

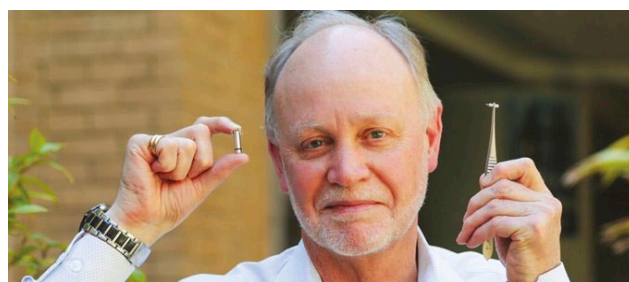
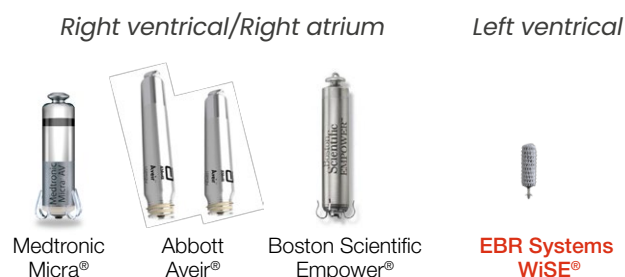
- Medtronic reported mid-teen growth for Micra five years after launch during their Q3 2023 quarter.
- Abbott received FDA approval for their single chamber Aveir device during the second quarter 2022. Their dual-chamber leadless pacemaker is currently in clinical trials.

However, the size of leadless pacemakers restricts use to right ventricle (RV) & 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 cardiac resynchronisation therapy (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.

Leadless devices are expected to play an increasingly important role in the future pacemaker market. This expectation is supported by the rapid growth in sales of Medtronic's Micra device since its approval by the FDA in 2016.

WiSE is not currently being clinically investigated for conventional pacing of the heart.

## Defibrillators (ICDs)

Implantable cardioverter defibrillators, or ICDs, are implantable devices that deliver an electrical shock to the heart when certain types of abnormal heart rhythm (also called 'cardiac arrhythmias') are detected to prompt the heart to return to its normal rhythm.

Two cardiac arrhythmias that ICDs are used to correct are ventricular tachycardia (speeding up of the heart) and ventricular fibrillation (rapid twitching of the heart muscle). If these arrhythmias are left untreated and allowed to progress, they can result in cardiac arrest, and potentially death. The electrical shock delivered by an ICD is designed to interrupt the progression of these arrhythmias and prompt the heart to return to its normal rhythm.

ICD devices have a very similar design to pacemaker devices and comprises an IPG, a lead responsible for stimulation implanted in the right ventricle, and up to two additional leads for stimulating other chambers of the heart. As well as managing arrhythmias, an ICD may also provide pacing activity for the heart.

ICDs are typically implanted in patients who have survived a cardiac arrest attributable to ventricular tachycardia or ventricular fibrillation and are at high risk of experiencing additional cardiac arrhythmias in the future.

Approximately 150,000 ICDs are implanted in the U.S. each year. Multiple clinical studies have demonstrated that ICDs improve clinical outcomes and significantly reduce mortality in patients with heart failure.

## Cardiac Resynchronisation Therapy

Cardiac Resynchronisation Therapy (**CRT**) refers to the use of implanted pacemakers to synchronise the contractions of the left and right sides of the heart.

In addition to the usual PPM or ICD leads implanted in the right ventricle and/or right atrium, CRT requires an additional lead to stimulate the left ventricle. Due to the risk of thromboembolism (formation of blood clots) this lead is not usually implanted inside the left side of the heart, but instead is implanted in the coronary sinus (**CS**) which is a vein on the outside of the heart.

### What is CRT?

Many patients with heart failure have an enlarged left ventricle which can delay its contraction. When this happens, the right and left ventricles contract at slightly different times (dyssynchronous) and effectively work against each other, making the heart less efficient.

CRT refers to the use of electrical stimulation to synchronise the contractions of the right and left ventricles. When CRT is used in this manner, it is referred to as biventricular pacing (**BiV pacing**). This is the first application for which WiSE has been developed.

### How does CRT work?

CRT uses electrical stimulation to coordinate the contractions of the right and left ventricles of the heart. This is achieved using an IPG with electrodes placed to stimulate the right and left ventricles. Implanted CRT devices may also provide pacing alone (referred to as **CRT-P**) or pacing and defibrillation (referred to as **CRT-D**), depending on a patient's requirements.

CRT requires electrical stimulation to be delivered to the left ventricle. Unlike the right side of the heart, leads cannot be placed on the inside of the left side due to the risk of clot formation. To avoid this, a stimulating lead for the left side is usually placed in a blood vessel called the CS that runs on the outside surface of the left ventricle. While this traditional placement can provide adequate left ventricular pacing in many patients, procedural limitations can result in suboptimal lead placement. In some patients, placement of a lead in the CS is not an option due to their anatomy or disease condition. Furthermore, pacing from the epicardial surface is not physiologic (i.e. normal) since normally stimulation progresses from the inside of the heart to the outside (i.e., from the endocardium to the epicardium).

When CRT is required in patients who already have an implanted PPM or ICD, WiSE provides an alternative option for upgrading to CRT. WiSE may be particularly helpful for patients whose anatomy or disease condition puts them at a high risk from the procedures for placing a lead in the coronary sinus (**CS**). Another advantage of WiSE is that it provides stimulation of the left ventricle from the inside endocardial surface thereby utilising the native conduction system more normally.



## Therapeutic Benefits of CRT

CRT has been demonstrated to improve clinical outcomes in multiple clinical trials. A meta-analysis of nearly 100 studies which included over 9,000 patients reported that CRT provides significant benefits to patients including:

- a 41% reduction in the risk of heart failure events;
- 59% of CRT recipients demonstrating functional improvement at six months;
- a 37% decrease in hospitalisations;
- a 22% reduction in all-causes mortality;
- improved heart function; and
- improved quality of life.

In patients who receive effective CRT, reverse remodelling is also observed. Reverse remodelling refers to structural changes in the heart muscle that reverse the enlargement of the left ventricle that is responsible for the heart failure. Reverse remodelling is considered a positive indication of underlying clinical improvement.

In addition to improving clinical outcomes, several studies have shown that the reduced healthcare costs arising from lower hospitalisation rates and ongoing clinical management requirements can make CRT a cost-effective intervention.

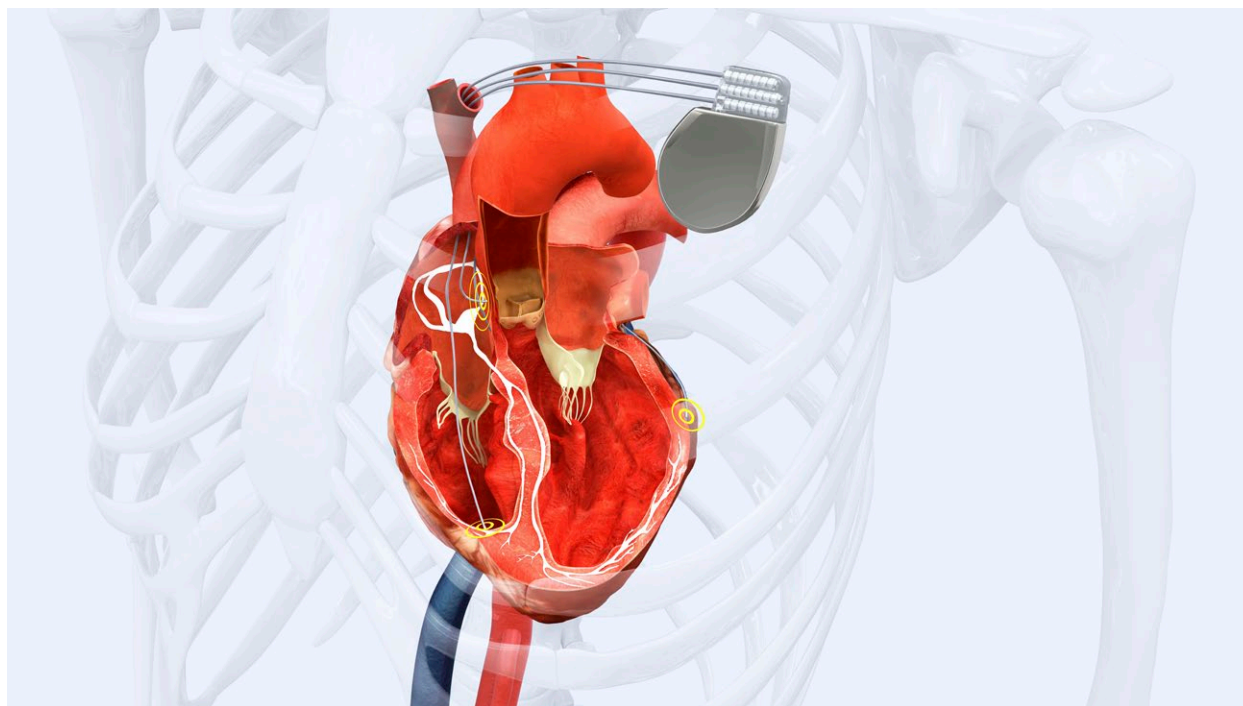
## Current Limitations to Providing CRT

### (a) Inability to Provide CRT

Most of the limitations that prevent patients from being provided with effective CRT arise from the use of leads. Specifically:

- The successful placement of an effective lead in the CS is not achieved in at least 5% of patients due to the patient's anatomy or disease condition;
- Each year 2%-6% of patients who initially received effective CRT have their leads subsequently fail, move position, or develop other chronic problems.

### *Placement of leads for lead-based CRT systems*



Without a functional CS lead to stimulate the left ventricle, these patients are unable to receive effective CRT using existing devices. These patients represent a key target patient population for WiSE.

## (b) High Risk for Conventional Upgrade

Patients with pacemakers and defibrillators can progress to develop heart failure that requires BiV pacing. It is estimated that up to 60% of patients who require an upgrade from an existing pacemaker are at greater risk of complications from a lead-based CRT device due to potential problems arising from their anatomy or disease condition. These patients provide an opportunity for WiSE to be marketed as an alternative approach that is able to overcome these limitations.

## (c) Upgrade Leadless Pacemaker to CRT

Patients with a leadless pacemaker are also at risk of developing pacing induced heart failure. Approximately 30% of pacemaker patients develop this within 4 years. Patients with a leadless pacemaker do not have an option to upgrade to CRT with a traditional pacing lead in the coronary sinus. The only means to provide CRT in conjunction with a leadless pacemaker is with the WiSE System.

## (d) Failure to Respond

Approximately 30% of patients implanted with a CRT are classified as 'non-responders' (NR) to CRT. Non-response to CRT may occur due to multiple factors. However, the technical constraints of traditional, transvenous epicardial CRT mean those factors can be challenging to overcome. A recent study looking at healthcare expenditure associated with NRs, identified there are additional healthcare costs associated with this group.

In EBR's SELECT-LV clinical trial, 85% of patients improved based on cardiac health metrics.

While WiSE has been able to provide clinically effective CRT in some patients previously classified as NR, based on the patient inclusion criteria agreed with the FDA, this patient group will not be included in the Company's PMA submission for FDA approval.

## (e) Endocardial Stimulation More Physiologic

With conventional CRT devices, the lead to stimulate the left ventricle cannot be placed inside the heart chamber for endocardial pacing due to the risk of clot formation, which can cause a heart attack or stroke. For this reason, this lead is normally placed in the CS where it stimulates the ventricle from outside the chamber. This is called 'epicardial' pacing.

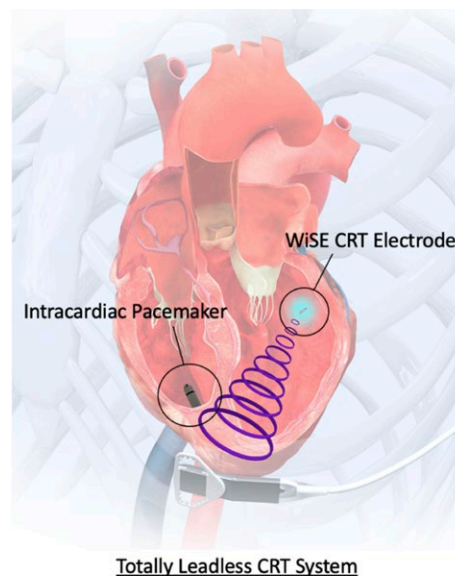
Stimulation from inside the heart chamber, or endocardial pacing, is more like normal conduction (i.e., more physiologic). Endocardial pacing has been shown to improve both left and right ventricular function. While there are a few techniques for delivering left ventricular endocardial pacing using leads, these are highly invasive and usually not considered suitable for routine or long-term use.

Due to its small size (slightly larger than a grain of rice), the WiSE electrode can be safely implanted inside the left ventricle to deliver endocardial pacing. Furthermore, because the options for its placement are not confined by the heart vasculature, it can be placed in a more optimal position based upon the physiological responsiveness of different sites.

## Future Directions in Cardiac Pacing

Significant advances in pacing technology have been made over the last 50 years including: multi-chamber pacing, improved rate responsiveness, device size reduction, internet-based remote monitoring, and marked increases in battery longevity. However, the basic system format of using an IPG connected to one or more leads to stimulate the heart muscle tissue, has remained unchanged over this time.

Many pacemaker-related complications arise from this basic design, in particular from the use of leads. This has driven the recent evolution of pacemaker systems which do not require leads.

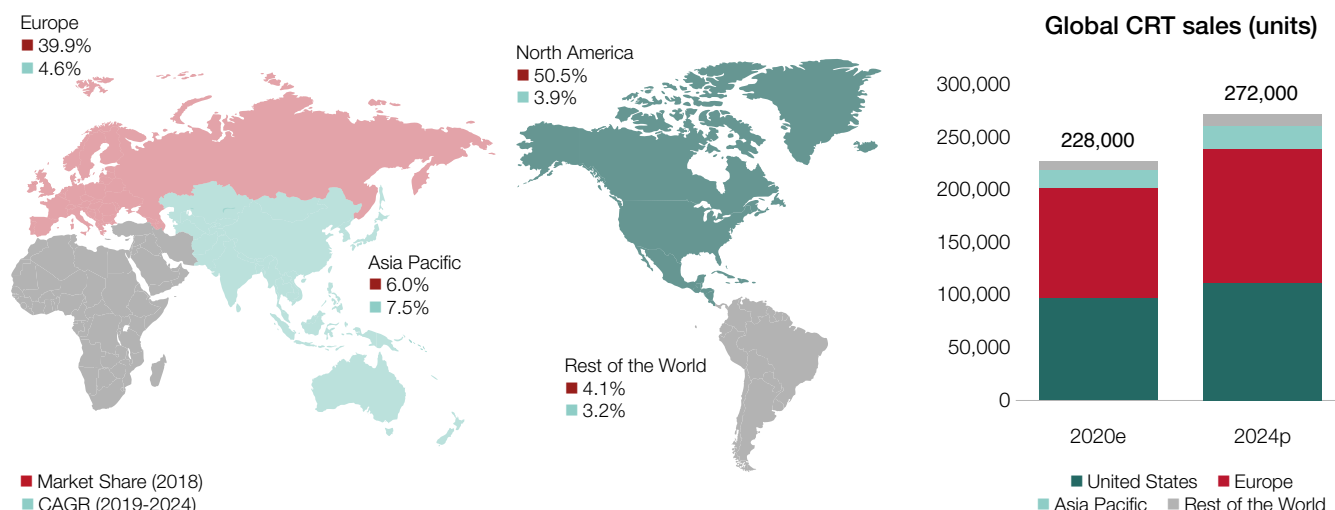


Apart from WiSE, the leadless pacemakers which have been developed are all single component systems. In such systems, the entire device is placed within the cardiac chamber. Advantages of this approach over lead-based systems include greater energy efficiency, system simplicity, and ease of implantation. However, these systems also have certain limitations, including the need to retrieve the device in future years due to battery depletion, risk of cardiac perforation and uncertain thrombus and infection risk. Additionally, because of their size and thrombogenicity (tendency to generate and release clots that might cause heart attack or stroke) they cannot be used within the left ventricle.

## Overview of the CRT market

The global CRT market is expected to reach US\$5.1 billion by 2024, from an estimated US\$4.1 billion in 2019, representing a compound annual growth rate (CAGR) of 4.4% during the forecast period.

### Overview of the Global CRT Market



Source: MarketAndMarkets: Cardiac Resynchronisation Therapy Market (2019), Global Forecast to 2024.

The growth of the CRT market is mainly driven by the increasing incidence of heart failure and the ageing of the population. Technological advancements and increasing standards of healthcare also contribute to the growth of the market for devices to treat heart failure.

North America is the largest market for CRT and accounts for 50% of global sales. Countries in Europe account for nearly 40% of global sales, of which 50% are from Germany, France and the U.K. (i.e., combined these countries account for 20% of the global market).

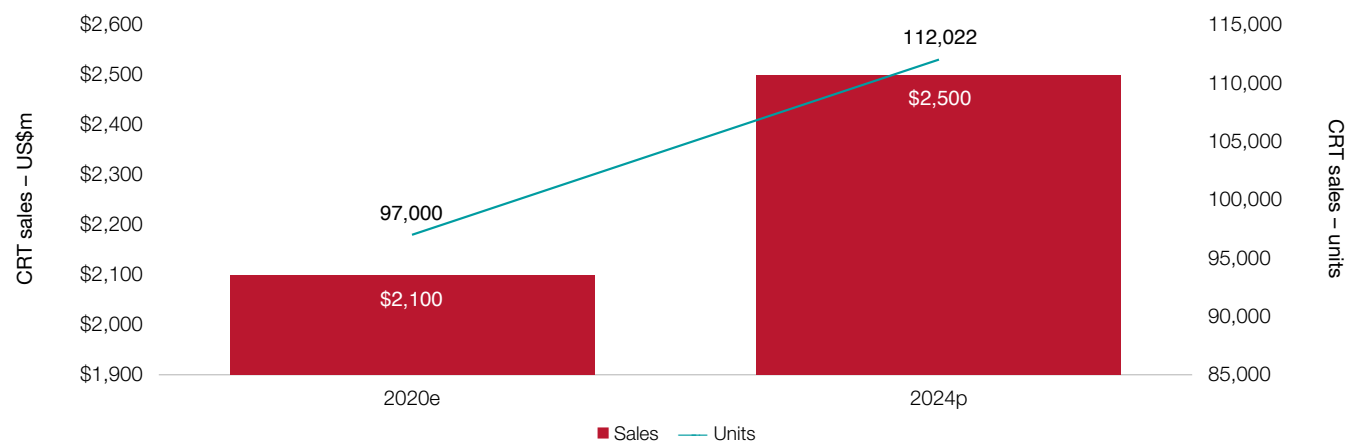
The CRT market is dominated by three companies: Medtronic plc (Ireland), Abbott Laboratories (U.S.), and Boston Scientific Corporation (U.S.). These companies accounted for over 90% of the global CRT market in 2018.

### CRT Market – North America

North America accounted for 50% of the global CRT market in 2018. The North American market is projected to reach US\$2.5 billion by 2024 from US\$2.1 billion in 2019, equating to a CAGR of 3.9%.



## CRT sales in North America

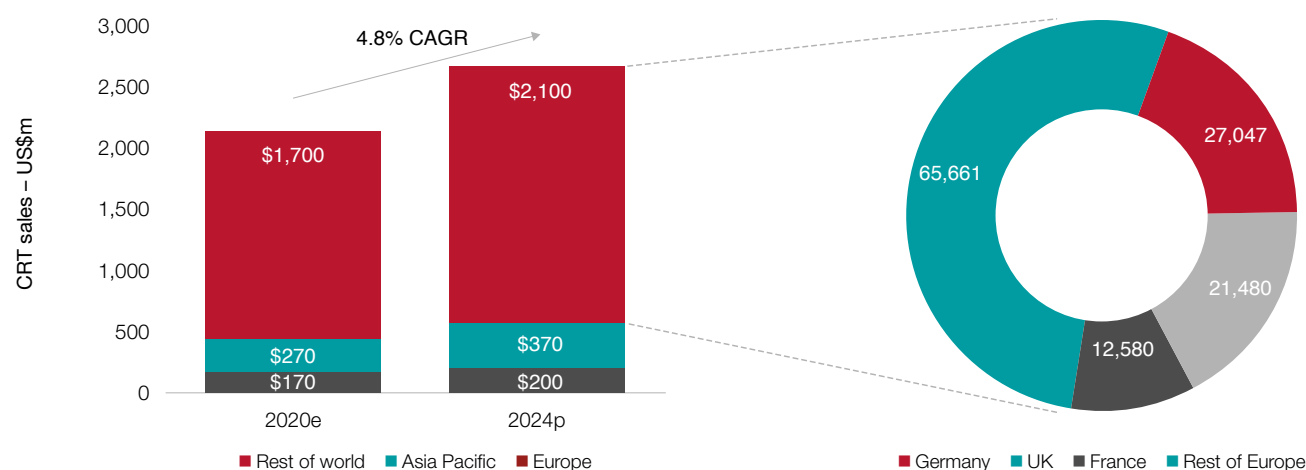


Source: MarketAndMarkets: Cardiac Resynchronisation Therapy Market (2019), Global Forecast to 2024.

## CRT Market – Outside United States (OUS) Market

Outside of the U.S., the CRT market is dominated by European countries. The European market accounts for nearly 40% of global CRT sales and 80% of OUS sales.

### CRT Sales Outside U.S. Market



Source: MarketAndMarkets: Cardiac Resynchronisation Therapy Market (2019), Global Forecast to 2024.

EBR is targeting select OUS markets for the initial commercial launch of WiSE based on:

- volume of CRT procedures;
- concentration of high-volume accounts;
- supportive regulatory and reimbursement frameworks; and
- strong clinician engagement.

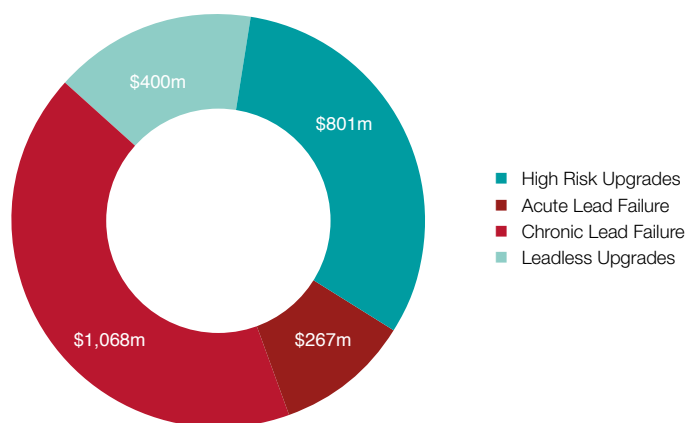
The large OUS markets that EBR intends to initially target are Germany, France and the U.K. Based on data from MarketsAndMarkets, approximately 49,000 CRT devices were implanted in patients in these select OUS markets in 2019 and this is projected to increase to approximately 61,000 units by 2024.

EBR also intends to launch WiSE in Australia and other select E.U. countries (Benelux, and Scandinavia). Based on hospital CRT implantation data compiled by the Company, EBR estimates that these combined markets may represent the implantation of an additional 10,000 CRT units per year.

## Target markets for WiSE

The initial target patient group for WiSE is patients who are unable to receive CRT with the existing lead-based systems, and for patients who are considered at risk for a CRT upgrade from a previously implanted PPM or ICD. EBR estimates this has an addressable market opportunity of approximately US\$2.5 billion in the Company's initial target markets of the U.S., Germany, France, the U.K., Australia, Benelux and Scandinavia.

### Initial Addressable Market



### Initial Target Patient Groups for WiSE

The three key patient profiles that comprise the initial target patient group for WiSE are:

- (a) Acute Lead Failures (LF – acute);
- (b) Chronic Lead Failures (LF – chronic);
- (c) High risk upgrades (HRU); and
- (d) Leadless upgrades (LU).

#### (a) Lead Failures – acute

In at least 5% of patients, placement of an effective lead in the CS is not achieved due to the patient's anatomy or disease condition. These patients are referred to as "LF – acute" patients. Based on the estimated size of this patient group, EBR believes the addressable market of LF – acute patients is approximately 5% of new CRT implants.

#### (b) Lead failures – chronic

"LF – chronic" patients have a CRT system that has had the lead to the left heart switched off or the lead has become otherwise ineffective. This may be for many reasons, but often relates to the lead failing or not functioning properly. Reported lead failure rates for CRT range from 2% – 6%. Based on this, EBR believes the annual addressable market for LF – acute patients may be approximately 4% of patients living with an implanted CRT device.

As the median survival time for a patient after being implanted with a CRT device is five years, EBR estimates that the number of patients living with an implanted CRT device may be approximated as five times the estimated annual implantation rate.

#### (c) High Risk Upgrades

Patients with pacemakers and defibrillators can develop heart failure that requires BiV pacing. These patients are referred to as HRUs if they have a high risk of complications from upgrading to a lead-based CRT device. Approximately 25% of CRT implants are upgrades from other cardiac pacing devices (PPMs and ICDs). It is estimated that up to 60% of patients who require an upgrade from an existing pacemaker are at greater risk due to potential complications arising from their anatomy or disease condition.

On this basis, EBR estimates approximately 15% of CRT implants are for HRU patients who may benefit from the use of WiSE rather than a lead-based CRT device.

## (d) Leadless Upgrades

Patients with leadless pacemakers are also at risk of developing pacing induced heart failure and subsequently require BiV pacing. Unlike a conventional pacemaker, it is not possible to implant a CS lead to pace the left ventricle. The only means to provide these patients with BiV pacing is with the WiSE System. Based on the current implant rate of leadless pacemakers and published rate of pacing induced heart failure, EBR estimates initial market opportunity at launch of US\$400 million, which will continue to increase as adoption of leadless pacing continues.

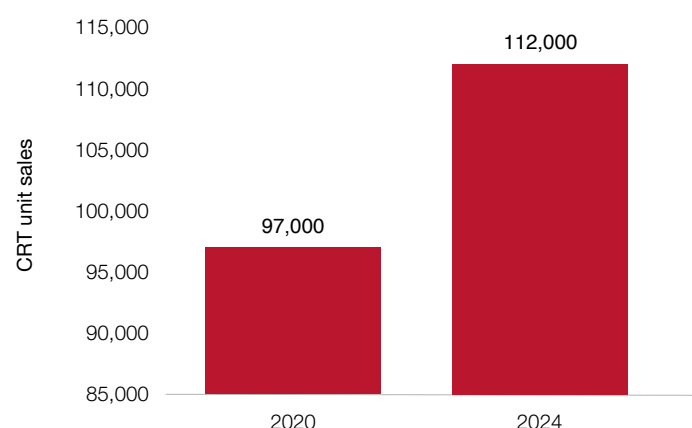
### a. Initial U.S. Target Market for WiSE

MarketsAndMarkets has projected there will be approximately 112,000 CRT implants in the U.S. by 2024.

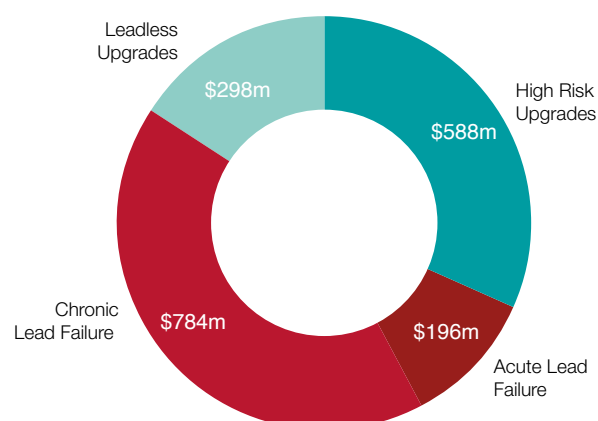
EBR will initially target LF-acute, LF-chronic, HRU and LU patients. The projected CRT implantation rates provide a basis for estimating the number of patients that may be able to receive CRT using WiSE.

In the U.S., EBR is targeting an Average Selling Price (ASP) for WiSE of approximately US\$35,000. Based on this ASP, EBR estimates that the initial U.S. addressable market opportunity for WiSE is approximately US\$1.866 billion and accounts for 73% of EBR's total initial target addressable market.

#### U.S. Addressable Market Opportunity for WiSE



#### US Market Breakdown



Source: Company estimates, MarketAndMarkets: Cardiac Resynchronisation Therapy Market (2019), Global Forecast to 2024.

Based on data compiled by the Company on CRT implantation rates at different hospitals, EBR estimates that approximately 50% of procedures are performed at 250 hospitals in the U.S. Many of these high-volume sites are participating in the SOLVE-CRT trial.

### b. Initial Outside the U.S. (OUS) Target Market for WiSE

MarketsAndMarkets has projected there will be a total of approximately 61,000 CRT units implanted per annum in Germany, France, and the U.K. by 2024. These are the three largest OUS country markets that EBR intends to target for the initial commercialisation of WiSE.

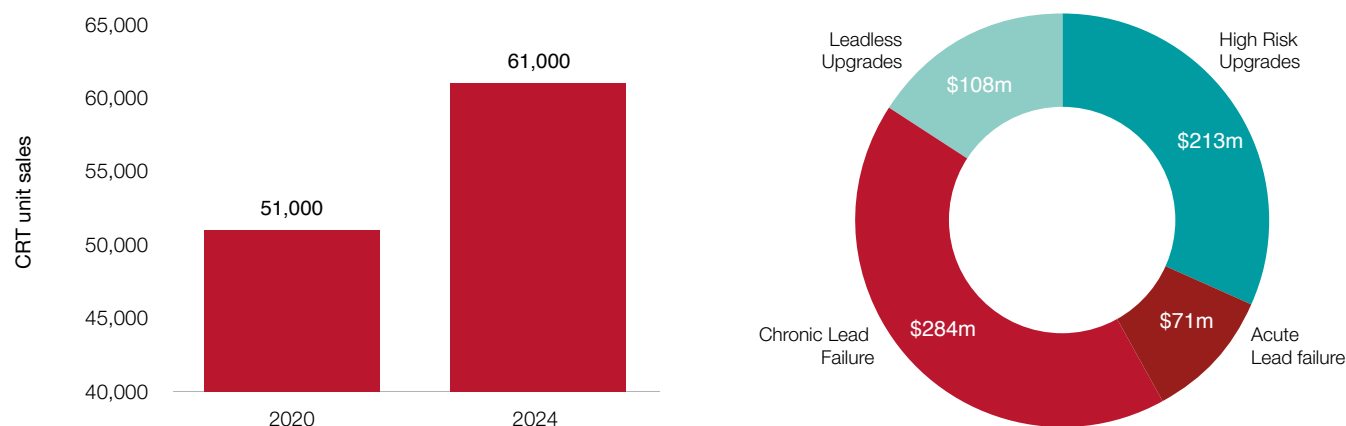
In addition to Germany, France and the U.K., EBR intends to target Australia, Benelux (Belgium, The Netherlands, and Luxembourg), and Scandinavia (Denmark, Sweden, Norway and Finland) for the initial commercialisation of WiSE. Based on hospital CRT implantation rate data compiled by the Company, EBR has estimated that, in combination, these additional markets may account for approximately additional 10,000 CRT implants each year.

### c. Medical devices typically sell for lower prices outside the U.S.

EBR has used an ASP of US\$20,000 for WiSE to estimate the addressable OUS market. On this basis, EBR estimates that the initial OUS addressable market opportunity for WiSE is approximately US\$676 million, which will account for 27% of EBR's estimated initial target addressable market. The actual ASP in each market, and the blended ASP once WiSE is made commercially available in multiple OUS target markets, may differ from this initial estimate.



## Addressable market opportunity for WiSE in key OUS markets      OUS Market Breakdown



Source: Company estimates, MarketAndMarkets: Cardiac Resynchronisation Therapy Market (2019), Global Forecast to 2024.

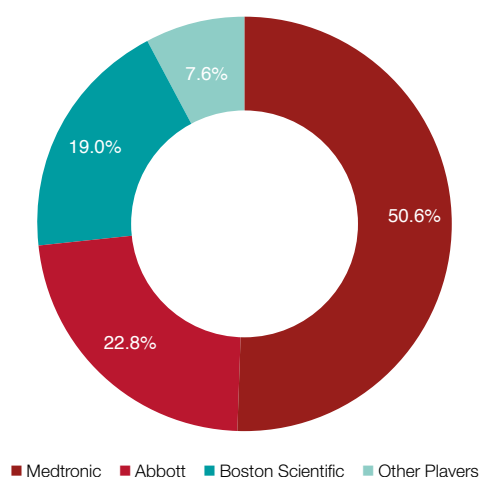
Based on CRT implantation data compiled by the Company regarding the markets of Germany, France and the U.K., around 50% of CRT implantations are conducted by 50–80 hospitals in each of the large OUS countries (i.e., 150–240 sites in total). In the other OUS country markets, around 50% of CRT implantations are conducted by 10–30 hospitals.

In the future, EBR may increase the addressable market it is targeting by broadening its OUS market outside its initial target country markets. EBR may also expand the use of WiSE into other applications by undertaking additional clinical studies and securing the required regulatory approvals.

## Key market players in CRT

The CRT market is highly consolidated with a small number of players dominating the market. In 2018, Medtronic (Ireland), Abbott (U.S.), and Boston Scientific Corporation (U.S.) were the key players in the CRT market and accounted for 92.4% of the market. Other prominent players include Biotronik (Germany), MicroPort Scientific Corp (China), and Medico S.p.A (Italy).

### Market share by key player (2015–2018)



Source: Company estimates, MarketAndMarkets: Cardiac Resynchronisation Therapy Market (2019), Global Forecast to 2024.

## Medtronic

In 2018, Medtronic held the leading position in the CRT market with a share of 50.6%. The company offers a wide range of products for the treatment of heart failure. The company offers CRT devices under brand names such as Claria MRI CRT-D Surescan, Amplia MRI CRT-D Surescan, Compia MRI CRT-D Surescan, Viva CRT-P, Consulta CRT-P, and Syncra CRT-P, among others.

## Abbott

Abbott Laboratories accounted for a market share of 22.8% of the CRT market in 2018. The company is engaged in the research, development, production, and distribution of a diversified range of healthcare products, including drugs, diagnostics, branded generics, vascular, and nutritional products. Abbott offers CRT devices for the treatment of heart failure under the brand names — Quadra Allure MP CRT-P, Allure RF, Unify Assura, and Promote Plus CRT-D, among others.

## Boston Scientific

Boston Scientific Corporation accounted for a market share of 19.0% of the CRT market in 2018. The company offers CRT devices through the CRM subsegment under the brand names— Visionist X4 CRT-P, Valitude X4 (CRT-P), Momentum CRT-D, Resonate X4 CRT-D, and Vigilant X4 CRT-D, among others.

## Emerging leadless market for cardiac pacing

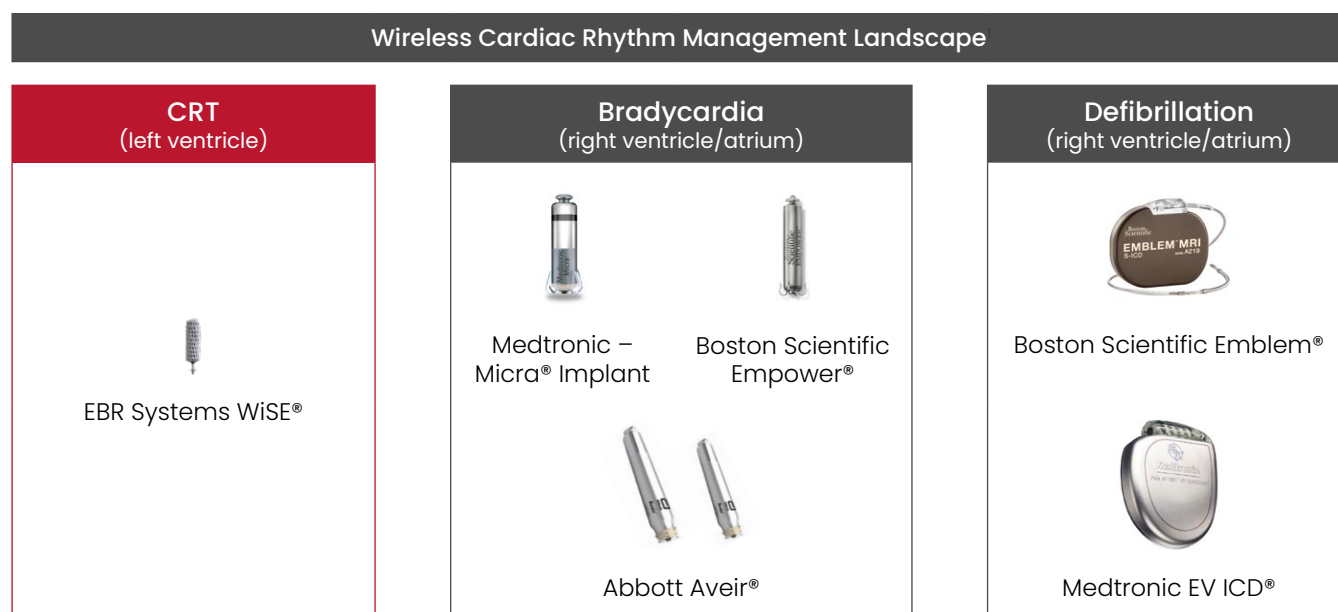
The most recent advance in the evolution of pacemakers has been the advent of leadless cardiac pacing systems. Most of the complications associated with pacemakers have been due to the leads. Leadless pacing systems have the pulse generator and the stimulating electrode in a single unit that can be fully implanted inside the heart chamber.

## Overview of Leadless Pacemakers for Cardiac Pacing

The three major CRM device companies (Medtronic plc, Boston Scientific, and Abbott) have each developed leadless cardiac pacemakers that can be implanted in the right ventricle.

Leadless devices are expected to play an increasingly important role in the future pacemaker market. This has been reflected in the rapid growth of sales demonstrated by Medtronic's Micra<sup>®</sup> device since it received FDA approval in 2016.

## Leadless Pacemakers for Cardiac Pacing



Medtronic's Micra implant is one of the two leadless pacemakers that are currently commercially available. In 2020, the FDA approved a second leadless pacemaker for Medtronic, Micra AV, that is also implanted in the right ventricle but has an additional capability of being able to sense the contraction of the right atrium to create atrioventricular synchrony. Both versions of Micra can only be implanted in the right ventricle due to their size. In February 2023, five years after its launch, Medtronic reported mid-teen growth rate for Micra.

### Abbott – Aveir® Implant

Abbott's Aveir VR single chamber leadless pacemaker received FDA approval in April 2022. As with Micra, the Aveir VR can only be implanted in the right ventricle due to its size. The Aveir DR dual chamber leadless pacemaker is currently in a 550-patient clinical trial that is scheduled to complete in 2023. As dual chamber pacing makes up approximately 80% of the pacing market, the entry of the Aveir DR has the potential to expand the entire leadless pacing market.

### Boston Scientific – Empower® Implant

Boston Scientific's leadless Empower pacemaker is currently in a 300-patient clinical trial with a primary completion data scheduled for 202. As with the other leadless pacemakers, Empower can only be implanted in the right ventricle due to its size.

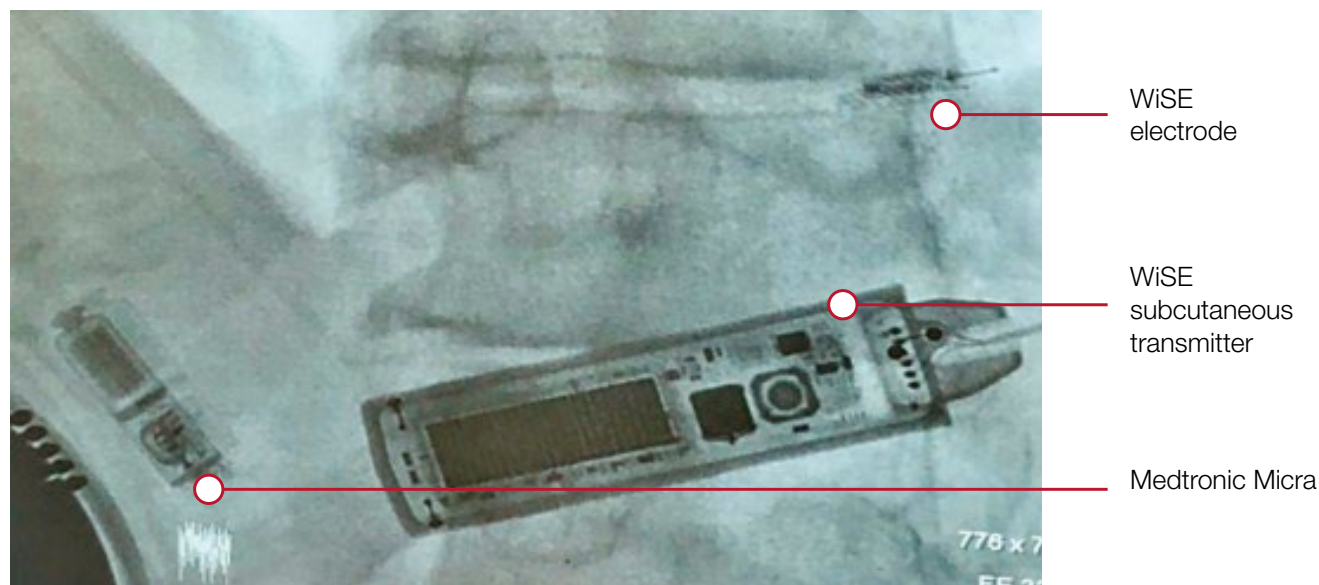
### Opportunity for WiSE

While the only leadless pacemakers currently on the market are for right ventricle bradycardia, it is anticipated that the eventual entry of Abbott's Aveir DR dual chamber device could further increase the adoption of leadless pacemakers.

It has been reported that up to 30% of patients with pacemakers develop pacing-induced heart failure within four years. Thus, many of the patients implanted with leadless pacemakers (such as Micra) may require an upgrade to CRT at a later date.

A 14-patient clinical study, presented during Asia-Pacific Heart Rhythm Society meeting in 2022, demonstrated that WiSE is able to work in conjunction with Medtronic's Micra to provide BiV pacing and an entirely leadless option for upgrading these patients. Only WiSE can provide these patients an entirely leadless upgrade solution.

### *X-Ray From Patient Receiving Leadless CRT Using Micra and WiSE*





# Initial Addressable Market

At commercial launch, EBR estimates to have an addressable market of ~US\$2.5bn initially.



EBR initially targeting patients unable to receive CRT from existing devices, those at high risk from conventional upgrades, or where CRT has failed.



Without effective CRT, these patients have poor clinical prognosis, poor quality of life and reduced life expectancy.

CRT results in 41% reduction in the risk of heart failure events, a 22% reduction in all-causes mortality and a 37% decrease in hospitalisation.

## Target patient groups

### Acute Lead Failure

Unable to implant CRT wire in a new CRT patient

### High Risk Upgrades

Patient has another implanted device but has developed heart failure and requires CRT

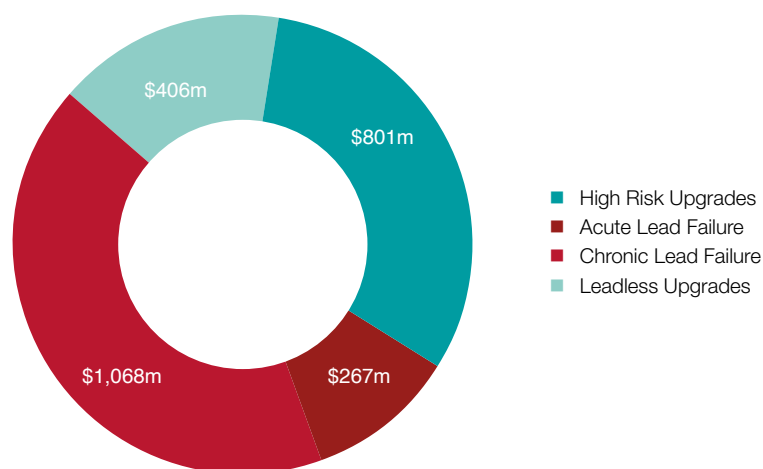
### Leadless Upgrades

Patient has a leadless pacemaker but has developed heart failure and requires CRT

### Chronic Lead Failure

Traditional CRT system implanted but has ceased to provide effective CRT

## Initial Addressable Market (US\$)







EBR Systems

ARBN 654 147 127

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# Directors' Report and Financial Statements – 31 December 2022



# Remuneration Report

EBR Systems is a Delaware domiciled company that is listed on the Australian Securities Exchange and as such is subject to remuneration disclosure requirements that are suitable for reporting in both in Australia and the United States.

This remuneration report provides details of the remuneration arrangements for EBR System's key management personnel (KMP):

- Non-executive directors (NEDs)
- President and Chief Executive Officer (CEO), John McCutcheon; and
- Chief Financial Officer (CFO), Frank Hettmann.

KMP are those persons who, directly and indirectly, have authority and responsibility for planning, directing and controlling the major activities of the Company.

## Role of the Board and Nomination and Remuneration Committee

The Board and its Nomination and Remuneration Committee (established in October 2021) are responsible for reviewing and approving remuneration and incentive policies and practices. The Company has a clear distinction between the structure of non-executive directors' remuneration and that of the President and CEO, John McCutcheon and CFO, Frank Hettmann.

The primary purpose of the Nomination and Remuneration Committee is to support the Board in relation to:

- a. Board composition, competencies and diversity;
- b. Board succession planning generally;
- c. establishing processes for the identification and recruitment of suitable candidates for appointment to the Board;
- d. establishing and implementing processes for reviewing the performance of individual directors, the Board as a whole, and Board committees;
- e. determining the executive remuneration policy;
- f. determining the non-executive director remuneration policy;
- g. reviewing all equity based incentive plans and making recommendations to the Board regarding their adoption and implementation; and
- h. ensuring that the remuneration policies of EBR are balanced and do not reward behaviour that is inconsistent with its values.

The Nomination and Remuneration Committee is composed of four non-executive directors: Karen Drexler (Chair), Allan Will, Chris Nave and Trevor Moody. The Nomination and Remuneration Committee Charter is available on the Company's website <https://ebrsystemsinc.com/investors/>

## Use of external remuneration policies

From time to time the Nomination and Remuneration Committee may, at its discretion, appoint external advisors or instruct management to compile information as an input to decision making.

## Principles of compensation

The remuneration framework of EBR Systems is designed to support and reinforce its principal strategic objectives. The purpose is to create a reward and incentive framework that produces remuneration outcomes that are aligned to corporate financial and operation performance, as well as the interest of stockholders, having regard to high standards of corporate governance.

The Company aims to reward executives with a level and mix of remuneration appropriate to their position, experience and responsibilities, while being market competitive and enabling the Company to structure awards that may conserve cash reserves due to the current stage of development.



## Remuneration structure

EBR Systems' executive compensation packages include a mix of fixed and variable compensation, and short and long term performance based incentives.

### Employment arrangements with President and Chief Executive Officer

Mr McCutcheon commenced his employment as President and Chief Executive Officer on 17 June 2019.

Mr McCutcheon is entitled to a base annual salary of US\$475,000 (subject to annual review). Mr McCutcheon is also eligible for an annual incentive bonus of up to 50% of his base salary based on annual performance targets determined by the Board. Mr McCutcheon must be employed by the Company at the time of the bonus determination to qualify for payment.

Mr McCutcheon is eligible for the Company's standard benefits which are offered to all employees, including medical insurance, paid-time off and reimbursement of reasonable business expenses incurred in performing duties (e.g. travel expenses).

Mr McCutcheon did not receive Option grants in 2022.

Mr McCutcheon's employment is on an "at-will" basis and may be terminated at any time, with or without cause or advanced notice, at the option of either the Company or Mr McCutcheon. Mr McCutcheon and the Company have also entered into a Severance and Change of Control Agreement, under which Mr McCutcheon may be entitled to certain additional benefits if his employment terminates involuntarily in connection with a change of control of the Company.

### Employment arrangements with Chief Financial Officer

Frank Hettmann has been employed as the Company's Chief Financial Officer since 4 May 2021. Mr Hettmann is entitled to a base annual salary of US\$340,000 (subject to annual review). Mr Hettmann is also eligible for an annual incentive bonus of up to 40% of his base salary in cash based on annual performance targets determined by the Board. Mr Hettmann must be employed by the Company at the time of the bonus determination to qualify for payment.

Mr Hettmann is eligible for the Company's standard benefits which are offered to all employees, including medical insurance, paid leave and reimbursement of reasonable business expenses incurred in performing duties (e.g. travel expenses).

Mr Hettmann did not receive Option grants in 2022.

Mr Hettmann's employment is on an "at-will" basis and may be terminated at any time, with or without cause or advanced notice, at the option of either the Company or Mr Hettmann. Mr Hettmann and the Company have also entered into a Severance and Change of Control Agreement, under which

Mr Hettmann may be entitled to certain additional benefits if his employment terminates involuntarily in connection with a change of control of the Company.

### Other employment arrangements with Key Managers

The other Key Managers are generally employed on an at-will basis and may be terminated at any time, with or without cause or advanced notice, at the option of either the Company or the employee. Key Managers and the Company have also entered into Severance and Change of Control Agreements, under which Key Managers may be entitled to certain additional benefits if their employment terminates involuntarily in connection with a change of control of the Company. The offer letters provide for a fixed cash compensation and an initial grant of Options and in certain cases, the ability to earn an annual bonus. Each employee is eligible for the Company's standard benefits.

# Remuneration Report

## Employment arrangements with Executive Chair

Allan Will is engaged as the Executive Chair of EBR and the terms of his engagement are contractually governed by letter agreement with EBR. Mr Will's role includes consulting and advisory meetings with the CEO and the senior management team.

Mr Will's compensation from Listing is US\$5,200 per month (equivalent to US\$62,400 on an annualised basis).

Mr Will did not receive Option grants in 2022.

Mr Will is eligible for the Company's standard benefits which are offered to all employees, including medical insurance, paid-time off and reimbursement of reasonable business expenses incurred in performing duties (e.g. travel expenses).

Mr Will and the Company have also entered into a Severance and Change of Control Agreement, under which Mr Will may be entitled to certain additional benefits if his employment terminates in connection with a change of control of the Company.

## Change of Control Agreements

The Company has entered into Severance and Change of Control Agreements with Allan Will and certain of the Key Managers (including Mr McCutcheon and Mr Hettmann) providing for certain benefits in the event that they are involuntarily terminated in connection with a change of control transaction.

The benefits include:

- six (6) to twelve (12) months base salary (at the rate in effect at the time of such termination)
- and in some cases, one-half (1/2) of the employee's target bonus for the year in which the termination occurred;
- six (6) months of continued health insurance; and
- any outstanding options become fully vested and exercisable, and if the employee holds any restricted stock, any repurchase right shall lapse.

The above benefits are only triggered if the Company or its assets are sold (including a merger or consolidation into another corporation where the Shareholders do not hold more than 50% of the voting power) and the relevant employee is terminated without cause, or the employee resigns following a material change in his or her position (including a material reduction in the nature or scope of employee's authority, duties or responsibilities and a reduction in the employee's then-current compensation by more than 5% (excluding across-the-board reductions)).

## Non-Executive Directors' fees and appointment letters

Under the Company's Bylaws, the directors decide the total amount paid to all directors as remuneration for their services as a director of EBR. However, under the Listing Rules, the total amount paid to all directors (excluding the salary of any executive director) for their services must not exceed in aggregate in any financial year the amount fixed by EBR in a general meeting. This amount has been fixed at US\$800,000.

The cash fees to be paid by EBR to each non-executive director are US\$40,000 per annum. In the case of the Australian non-executive directors, this amount is inclusive of statutory superannuation.

In addition, each Chair of a Board committee will receive an annual fee of US\$15,000 (inclusive of statutory superannuation, if applicable) for his/her services as Chair of that committee. Directors will receive an additional annual fee of US\$7,500 (inclusive of statutory superannuation, if applicable) for being a member of a Board committee (other than the Chair).

Dr Nave has directed the Company to pay his director fees to BCP3 Pty Ltd, a company in which Dr Nave is managing director and a shareholder.

Each of the non-executive directors of the Company (or in the case of Dr Nave, those directors' nominees) may also receive future grants of securities subject to the Listing Rules and Board approval. The non-executive directors of the Company did not receive Option grants in 2022.

Directors may be reimbursed for travel and other expenses incurred in attending to EBR's affairs.

Each non-executive director has entered into an appointment letter with EBR, confirming the terms of their appointment, roles and responsibilities and EBR's expectations of them as directors.

## Restrictions on EBR's U.S. Directors and Officers Buying CDI's on the ASX

The outstanding CDI's traded on ASX bear a "FOR US" designation, which currently prevents any U.S. persons from buying CDI's on the ASX. This designation is intended to fulfill a condition of a no-action letter issued by the U.S. Securities and Exchange Commission to enable EBR's Initial Public Offering on the ASX in November 2021. As a result, EBR's U.S.-based directors and officers are restricted from buying CDI's on the ASX.

## Share options

### Options granted

The following options were granted during FY22:

- 3,667,500 options with exercise price of US\$0.49, expiring 23 February 2032
- 1,593,250 options with exercise price of US\$0.42, expiring 10 May 2032
- 774,500 options with exercise price of US\$0.46, expiring 22 August 2032
- 330,000 options with exercise price of US\$0.33, expiring 28 November 2032.



## Board of Directors

The Board of Directors of the Company comprise the following Directors:

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**Allan Will**

*Executive Chair  
(Age: 67)*

*Joined the Board in  
May 2003*

Mr Will served as the CEO of the Company from 2011 until 2019, and has served in the role of Executive Chair since 2019.

Mr Will is a seasoned executive with extensive experience founding, funding, operating, and selling medical device companies. In addition to his role with the Company, Mr Will currently serves as chair of the boards of Fractyl Health, Inc. and SetPoint Medical Corporation, and a director of Fogarty Innovation, a not-for-profit institute promoting innovation in medical technology founded by Dr Thomas J Fogarty.

Previously, as chair of Ardian, Inc., Mr Will led negotiations of the company's acquisition by Medtronic Inc. for over US\$800 million. Mr Will was also founding Managing Director of Split Rock Partners' Silicon Valley office, focusing on therapeutic medical devices, having joined Split Rock Partners' predecessor entity St. Paul Venture Capital (SPVC) in 2002. Mr Will was founder, chair and CEO of The Foundry, co-founding 11 companies there, including Ardian, Evalve, Inc. (acquired by Abbott Laboratories for US\$450 million) and Concentric Medical Inc (acquired by Stryker Corp for US\$135 million).

Mr Will is an inventor on more than 30 issued patents, is a University of Maryland Distinguished Alumnus and a recipient of the ASTIA/Deloitte Excellence in Mentoring Women Executives Award. He served on the MIT Entrepreneurship Center Shareholders' Board and the University of Maryland President's Committee on Innovation and Entrepreneurship.

Mr Will earned a B.S. degree in Zoology from the University of Maryland and his Master's degree in Management from the Massachusetts Institute of Technology.

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**John McCutcheon**

*President, Chief  
Executive Officer (CEO)  
and Executive Director  
(Age: 61)*

*Joined the Board in  
June 2019*

Mr McCutcheon has served as President and CEO of EBR since June 2019 and is responsible for the overall management and strategic direction of EBR.

Mr McCutcheon has over 35 years' experience in sales, marketing, and management of medical device companies. Prior to joining EBR, Mr McCutcheon was the President and CEO of Ceterix Orthopaedics, Inc. for nine years from 2010 to 2019. He also held CEO roles at Ventus Medical, Inc. (2009-2010) and Emphasys Medical, Inc. (2000-2009).

Mr McCutcheon holds a B.A. in Economics and Psychology from the University of California, Los Angeles and an M.B.A. from the UCLA Anderson Graduate School of Management.

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**Christopher Nave, PhD**  
Non-executive Director  
(Age: 46)

*Joined the Board in  
October 2017*

Dr Nave has served as a Director of EBR since 2017.

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.

Dr Nave is currently a director of The Australian Investment Council, Azura Ophthalmics, Inc., Certa Therapeutics Pty Ltd, Global Kinetics Corporation Ltd, OccuRx Pty. Ltd., Osprey Medical, Inc. (ASX:OSP), PolyActiva Pty Ltd and Que Oncology, Inc. Dr Nave was chairperson of Fibrotech Therapeutics Pty Ltd at the time of its successful sale to Shire Plc and a director of Spinifex Pharmaceuticals, Inc. at the time of its sale to Novartis International AG.

Dr Nave holds a B.Sc. (Honours) from the University of Melbourne and a PhD in Endocrinology and Physiology for the University of Melbourne.



**Trevor Moody**  
Non-executive Director  
(Age: 56)

*Joined the Board  
initially from May 2003  
to April 2010. Current  
tenure commenced in  
October 2017*

Mr Moody has served as a Director of EBR since 2017.

Mr Moody recently served as Medical Device Partner at M.H. Carnegie & Co. (from 2013 to 2022), where he made investments in medical device companies. He has also served since January 2010 as President of TM Strategic Advisors LLC, a management consultancy. Mr Moody was previously a General Partner at Frazier Healthcare Ventures, a large U.S. based private equity and venture capital firm.

Mr Moody is currently a director of electroCore, Inc. (NASDAQ: ECOR), Cardiac Dimensions Pty Ltd, Renew Medical Pty Ltd, The Brain Protection Company Pty Ltd, and CurvaFix, Inc. Mr Moody also serves on the board of Angel Flight West, a not-for-profit that provides free air transport for patients requiring long distance travel for medical treatment. Mr Moody was a director of Simplify Medical Pty Ltd at the time of its sale to NuVasive, Inc. (NASDAQ: NUVA).

Mr Moody holds a B.Eng. from the University of Southern Queensland, and a M.S. in Management from the Massachusetts Institute of Technology (Sloan School).



**Bronwyn Evans,  
PhD AM**  
Non-executive Director  
(Age: 61)

*Joined the Board in  
October 2021*

Dr Bronwyn Evans AM, who joined the Board in October 2021 is an experienced Director and CEO with a broad technical background across multiple industry sectors including medical technology, manufacturing and technical regulation and standards.

Dr Evans currently holds board roles as the Chair of Building 4.0 CRC, a Director of ACOR Consultants Pty Ltd and a Director at GME Pty Ltd. Dr Evans has previously held positions as CEO of Engineers Australia and CEO of Standards Australia. She has also previously held positions in innovation initiatives, including as Chair of MTPConnect (the Industry Growth Center for Medical Technologies and Pharmaceuticals) and was a member of the Industry 4.0 Advanced Manufacturing Forum Leadership group. She has also held various senior engineering roles, including at Cochlear and GE Healthcare.

Dr Evans holds a BE (Honors I) and a Ph.D. in Electrical Engineering from the University of Wollongong. She also has an Honorary Doctorate from Swinburne University and is an Honorary Fellow of the University of Wollongong, an Honorary Fellow of Engineers Australia and a Fellow of the Australian Academy of Technological Sciences and Engineering. In 2021, she received an AM in the Queen's Birthday honours for significant service to engineering, to standards, and to medical technology.

Dr Evans also serves as Chair of the Audit and Risk Committee and is considered to be an independent director.

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## Board of Directors



**David Steinhaus, MD**  
*Non-executive Director*  
(Age: 69)

*Joined the Board  
in October 2021*

Dr Steinhaus retired in 2019 as Vice President and General Manager of the Heart Failure Business for the Cardiac Rhythm and Heart Failure Division at Medtronic plc (NYSE:MDT).

Dr Steinhaus joined Medtronic in 2005, after 20 years of cardiology (electrophysiology) practice. Dr Steinhaus' responsibilities at Medtronic included bringing the physician voice to CRHF, identifying future opportunities in new product development, and serving as a liaison to government agencies, professional societies and medical groups.

Dr Steinhaus has been closely associated with research and academia, performing extensive clinical studies in implantable cardiac devices and leads. He served as Chair of the Department of Cardiology, and Director of the Electrophysiology Department at the Mid America Heart Institute and St. Luke's Hospital and Director of the Electrophysiology Fellowship Program at the University of Missouri at Kansas City School of Medicine, and has instructed students in medicine since 1982.

Since leaving Medtronic, he has served as a consultant and board member to multiple established and early stage medical device companies. He is currently the Executive Chairman of the board of Enopace Biomedical Ltd., a company which produces therapeutic neuromodulation devices for the treatment of heart failure.

A 1973 magna cum laude graduate of Harvard College, Dr Steinhaus received his medical doctorate from Harvard Medical School as part of the Harvard-M.I.T. program in Health Sciences and Technology, with AOA honours.



**Karen Drexler**  
*Non-executive Director*  
(Age: 62)

*Joined the Board  
in October 2021*

Ms Drexler is a serial entrepreneur with expertise in the fields of digital health, medical devices, and diagnostics.

Ms Drexler serves on the boards of three other public companies, Resmed, Inc. (NYSE, ASX:RMD), where she serves on the compensation and nominating and governance committees, Outset Medical Inc. (NASDAQ: OM), where she serves on the compensation and nominating and governance committees, and Tivic Health Systems (NASDAQ:TIVC) where she chairs the compensation and nominating and governance committees.

Ms Drexler is also on the board of two private companies: VIDA Diagnostics Inc., an artificial intelligence powered lung imaging solutions company, and HUMA.ai, a leading generative AI platform for life science.

Ms Drexler also acts as a senior strategic advisor for other early-stage companies, and spent 11 years on the board of the Keller Center for Innovation in Engineering Education at Princeton University.

Ms Drexler is an active mentor and advisor with Astia, a global nonprofit that supports high-potential female founders. She is a founding member of Astia Angels, a network of individual investors who fund such founders, and a lead mentor with StartX, the Stanford University incubator. She is also on the Life Science and Women's Health Councils for Springboard, an accelerator for women-led technology-oriented companies. Ms Drexler graduated magna cum laude with a B.S.E. in Chemical Engineering from Princeton University, and earned an MBA with honors from the Stanford University Graduate School of Business.



## Consolidated Balance Sheets

		December 31,	
	Notes	2022	2021
<b>ASSETS</b>			
Current assets			
Cash and cash equivalents	3	\$ 15,456,338	\$ 78,242,340
Marketable securities	3	48,073,019	-
Non-trade receivables and unbilled reimbursements, net	5	443,919	966,123
Prepaid expenses		2,004,441	1,716,878
Other current assets		607,543	173,882
Total current assets		66,585,260	81,099,223
Property and equipment, net	5	1,577,044	1,743,704
Right of use operating lease asset	6	1,941,138	2,143,481
Marketable securities	3	985,957	-
Other assets		589,624	437,660
<b>TOTAL ASSETS</b>		<b>\$ 71,679,023</b>	<b>\$ 85,424,068</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities			
Accounts payable		\$ 2,092,474	\$ 1,710,855
Accrued expenses and other liabilities	5	3,470,107	2,726,024
Interest payable	7	99,167	282,256
Operating lease liability	6	216,817	185,707
Current portion of notes payable, net	7	51,590	2,410,496
Total current liabilities		5,930,155	7,315,338
Other liabilities		482,448	-
Operating lease liability	6	1,921,106	2,137,923
Notes payable, net	7	19,396,221	73,085
Total liabilities		27,729,930	9,526,346
Commitments and contingencies (Note 16)			
<b>STOCKHOLDERS' EQUITY</b>			
Convertible preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2022 and 2021			
	11	-	-
Common stock, \$0.0001 par value; 600,000,000 shares authorized, 270,752,201 and 267,985,340 shares issued and outstanding at December 31, 2022 and 2021, respectively			
	12	27,077	26,800
Additional paid-in capital		320,749,696	319,378,429
Accumulated deficit		(277,622,520)	(244,534,315)
Accumulated other comprehensive income		794,840	1,026,808
Total stockholders' equity		43,949,093	75,897,722
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>		<b>\$ 71,679,023</b>	<b>\$ 85,424,068</b>

The accompanying notes are an integral part of these consolidated financial statements.

## Consolidated Statements of Operations

		Twelve Months Ended December 31,	
	Notes	2022	2021
Operating expenses:			
Research and development		\$ 13,228,782	\$ 7,232,171
Sales and marketing		8,107,645	6,814,151
Clinical and regulatory		7,283,693	5,588,249
General and administrative		5,406,095	3,139,286
Total operating expenses		34,026,215	22,773,857
Loss from operations		(34,026,215)	(22,773,857)
Other income (expense)			
Interest expense	7 & 8	(1,525,795)	(19,009,916)
Other income	2	2,464,922	1,379,860
Gain on sale of equipment		-	3,639
Gain on forgiveness of debt	7	-	1,255,912
Gain on change in fair value of derivative liability	9	-	1,394,000
Gain/(loss) on foreign currency	2	483	(2,085,007)
Total other income (expense)		939,610	(17,061,512)
Loss before income tax		(33,086,605)	(39,835,369)
Income tax expense	15	(1,600)	-
Net loss		<u>\$ (33,088,205)</u>	<u>\$ (39,835,369)</u>
Net loss per common share:			
Basic and diluted	14	<u>\$ (0.12)</u>	<u>\$ (0.95)</u>
Weighted-average number of shares outstanding:			
Basic and diluted	14	<u>269,608,916</u>	<u>42,122,436</u>

The accompanying notes are an integral part of these consolidated financial statements.

## Consolidated Statements of Comprehensive Loss

		Twelve Months Ended December 31,	
	Notes	2022	2021
Net loss		\$ (33,088,205)	\$ (39,835,369)
Other comprehensive income / (loss):			
Change in unrealized (losses) on marketable securities	3	(118,218)	-
Foreign currency translation adjustments		(113,750)	1,114,645
Other comprehensive (loss) income		(231,968)	1,114,645
Comprehensive loss		<u>\$ (33,320,173)</u>	<u>\$ (38,720,724)</u>

The accompanying notes are an integral part of these consolidated financial statements.

# Consolidated Statements of Stockholders' Equity

Notes	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value				
Balance at December 31, 2020	84,856,456	\$ 8,486	13,190,604	\$ 1,320	\$ 166,278,889	\$ (203,851,437)	\$ (87,837)	\$ (37,650,579)
Issuance of stock warrants	10	-	-	-	3,123,094	-	-	3,123,094
Exercise of stock options	13	-	5,375,911	538	828,484	-	-	829,022
Stock-based compensation	13	-	-	-	459,180	-	-	459,180
Derivative liabilities settled to equity	9	-	-	-	11,979,000	-	-	11,979,000
Convertible notes payable converted		-	-	-	-	-	-	-
into stockholders' equity	8	62,710,518	6,271	-	60,719,203	-	-	60,725,474
Convertible preferred stock converted	11	(147,566,974)	(14,757)	14,757	-	-	-	-
into common stock	10	-	-	-	1,096,452	(847,509)	-	248,943
Issuance of common stock, net of issuance costs	12	-	101,851,851	10,185	74,894,127	-	-	74,904,312
Net loss	-	-	-	-	-	(39,835,369)	-	(39,835,369)
Other comprehensive income	-	-	-	-	-	-	1,114,645	1,114,645
Balance at December 31, 2021	-	-	267,985,340	26,800	319,378,429	(244,534,315)	1,026,808	75,897,722
Exercise of stock options	13	-	2,766,861	277	421,317	-	-	421,594
Stock-based compensation	13	-	-	-	869,557	-	-	869,557
Adjustment to common stock issuance costs	12	-	-	-	80,393	-	-	80,393
Net loss	-	-	-	-	-	(33,088,205)	-	(33,088,205)
Other comprehensive loss	-	-	-	-	-	-	(231,968)	(231,968)
Balance at December 31, 2022	-	\$ -	270,752,201	\$ 27,077	\$ 320,749,696	\$ (277,622,520)	\$ 794,840	\$ 43,949,093

The accompanying notes are an integral part of these consolidated financial statements.



## Consolidated Statements of Cash Flows

	Notes	Twelve Months Ended December 31,	
		2022	2021
<b>Cash flows from operating activities:</b>			
Net loss		\$ (33,088,205)	\$ (39,835,369)
Adjustment to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	4	652,432	384,022
Amortization of deferred loan costs and discount on notes payable	7 & 8	210,137	16,901,371
Lease amortization	6	413,518	-
Change in fair value of derivative	9	-	(1,394,000)
Stock-based compensation	13	869,557	459,180
Convertible notes payable issued for services		-	33,935
Gain on forgiveness of debt	7	-	(1,255,912)
Gain on disposal of property and equipment		-	(3,639)
Provision for doubtful accounts	5	(3,685)	-
Accretion of discount on marketable securities	2	(559,563)	-
Effect of exchange rate changes on monetary assets and liabilities			
denominated in non-functional currency		-	1,451,778
Changes in operating assets and liabilities:			
Non-trade receivables and unbilled reimbursements		507,323	(692,819)
Prepaid expenses		(288,603)	(983,584)
Other assets		(452,964)	(100,045)
Accounts payable		726,456	721,097
Accrued expenses and other liabilities		1,237,650	333,197
Interest payable		(183,089)	1,836,673
Operating lease liability	6	(396,882)	(5,279)
Net cash used in operating activities		(30,355,918)	(22,149,394)
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	5	(730,179)	(912,009)
Proceeds from sale of property and equipment		-	5,200
Purchase of marketable securities	3	(50,617,631)	-
Maturities of marketable securities	3	2,000,000	-
Net cash used in investing activities		(49,347,810)	(906,809)
<b>Cash flows from financing activities:</b>			
Repayment of notes payable	7	(2,400,000)	(2,404,299)
Proceeds from notes payable	7	20,000,000	-
Proceeds from convertible notes	8	-	22,424,554
Payments of deferred loan costs	7 & 8	(794,317)	(289,913)
Proceeds from exercise of stock options	13	421,594	829,022
Proceeds from initial public offering	12	-	80,099,614
Payment of offering costs	12	(213,326)	(4,901,583)
Net cash provided by financing activities		17,013,951	95,757,395
Effect of exchange rate change on cash		(96,225)	(337,133)
Net (decrease) increase in cash and cash equivalents		(62,786,002)	72,364,059
Cash and cash equivalents, beginning of the period		78,242,340	5,878,281
Cash and cash equivalents, end of the period		\$ 15,456,338	\$ 78,242,340

The accompanying notes are an integral part of these consolidated financial statements.

## Consolidated Statements of Cash Flows

	Notes	Twelve Months Ended December 31,	
		2022	2021
<b>Supplemental disclosure of cash flow information</b>			
Cash paid for interest expense		\$ 1,498,747	\$ 371,223
Cash paid for income taxes		\$ 1,600	\$ -
<b>Non-cash financing activities</b>			
Issuance of detachable warrants	10	\$ -	\$ 3,123,094
Derivative liabilities settled to equity	9	\$ -	\$ 11,979,000
Convertible notes payable and accrued interest converted to equity	8	\$ -	\$ 60,725,474
Warrant modifications	10	\$ -	\$ 847,509
Accrued financing costs		\$ -	\$ 293,719

The accompanying notes are an integral part of these consolidated financial statements.

# Notes to Consolidated Financial Statements

## **Note 1 - Business and organization**

### ***Business overview***

EBR Systems, Inc. and subsidiaries (“EBR” or the “Company”) is a United States-based company dedicated to the superior treatment of cardiac rhythm disease by providing physiologically effective stimulation through leadless endocardial pacing. The Company is in the final phase of its U.S. pivotal trial and expects to release results in 2023.

The Company completed its initial public offering of CDIs (“CHESS Depositary Interests”) and began trading on the Australian Securities Exchange (“ASX”) on November 24, 2021 under the symbol “EBR”.

The Company operates wholly-owned foreign subsidiary entities in Australia, EBR Systems (AUST) Pty Ltd (“EBR-AU”), and the United Kingdom, EBR Systems (UK) Limited (“EBR-UK”), which establish clinical trials in Australia and the United Kingdom, respectively, and work on intellectual property development and on Food and Drug Administration (“FDA”) approval. EBR-AU was incorporated on February 23, 2017 and EBR-UK was incorporated on July 31, 2015.

## **Note 2 - Summary of significant accounting policies**

### ***Basis of presentation***

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”).

### ***Principles of consolidation***

The consolidated financial statements include the Company’s accounts and those of its wholly-owned foreign subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

### ***Foreign currency translation***

The functional currencies of our foreign subsidiaries are their local currencies. Accordingly, the Company translates the foreign currency financial statements into US Dollars using the reporting period-end or average exchange rates. Assets and liabilities of these subsidiaries were translated at exchange rates as of the balance sheet dates. Revenues and expenses are translated at average rates in effect for the periods presented. The cumulative translation adjustment is included in the accumulated other comprehensive income / (loss) within stockholders’ equity (deficit). Gains and losses arising from the settlement and remeasurement of monetary assets and liabilities denominated in currencies other than a subsidiary’s functional currency are included in “Gain/(loss) on foreign currency” in the period in which they occur.

### ***Use of estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates, judgments, and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. Significant estimates and assumptions made by management include the estimated

## Notes to Consolidated Financial Statements

lives of long-lived assets, the fair value of stock-based awards issued, clinical trial accrual, fair value of derivative liability, fair value of warrants, and the valuation allowance on deferred taxes.

### ***Employee benefits***

The Company maintains an employee retirement/savings plan (the “Retirement Plan”) that permits participants to make tax-deferred contributions by salary reductions pursuant to Section 401(k) of the Internal Revenue Code. The Company may make discretionary contributions. For the twelve-month period ended December 31, 2022, the Company did not make any contributions. For the twelve-month period ended December 31, 2021, the Company made a contribution of \$357,736.

### ***Segment information***

Operating segments are defined as components of an entity for which discrete financial information is available that is regularly reviewed by the Chief Operating Decision Maker (“CODM”) in deciding how to allocate resources to an individual segment and in assessing performance. The Company’s Chief Executive Officer is the CODM. The CODM reviews financial information presented on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. As such, management has determined that the Company operates as one operating segment that is focused exclusively on the advancement of the Company’s wireless cardiac pacing system. Net assets outside of the U.S. were less than 10% of total net assets as of December 31, 2022 and 2021.

### ***Cash and cash equivalents***

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash. Cash equivalents are reported at fair value.

### ***Marketable securities***

Marketable securities, all of which are available-for-sale, consist of U.S. treasury bonds, U.S. government notes, and corporate debt securities. Marketable securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income (loss), except for losses from impairments which are determined to be other-than-temporary. For the twelve-month periods ended December 31, 2022 and 2021, there were no losses from impairments. Realized gains and losses and declines in value judged to be other-than-temporary are included in the determination of net loss and are included in other income. Interest and dividends on available-for-sale securities are included in other income. See Note 3, “Cash, cash equivalents, and marketable securities” for additional disclosure on marketable securities.

### ***Derivative liability***

The Company’s 2019 and 2021 convertible notes payable issued contain certain features that meet the definition of being embedded derivatives requiring bifurcation from the 2019 and 2021 convertible notes payable as a separate compound financial instrument. The derivative liability is initially measured at fair value on issuance and is subject to remeasurement at each



reporting period with changes in fair value recognized in other income (expense) in the accompanying consolidated statements of operations. See Note 9, “Derivative liabilities” for additional disclosure on derivative liabilities.

### ***Concentration of credit risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company’s cash and cash equivalents are primarily held at one U.S. financial institution that management believes is of high credit quality. Such deposits exceed federally insured limits.

### ***Non-trade receivables and unbilled reimbursements***

Non-trade receivables are recorded for amounts due to the Company related to reimbursements of clinical trials expenses based upon contracted terms. Unbilled reimbursements represent amounts for services that have been rendered but for which reimbursements have not been billed. See Note 5, “Consolidated balance sheet components” for additional information on non-trade receivables and unbilled reimbursements.

### ***Property and equipment***

Property and equipment is carried at acquisition cost less accumulated depreciation. The cost of normal, recurring, or periodic repairs and maintenance activities related to property and equipment are expensed as incurred.

Depreciation is computed using the straight-line method based on the estimated useful lives of the related assets. The estimated useful lives by asset classification are generally as follows:

Equipment	3 - 8 years
Computer software	3 years
Leasehold improvements	Lesser of 15 years or the remainder of the lease

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group be tested for potential impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that carrying value exceeds fair value. Fair value is determined using various valuation techniques, including discounted cash flow models, quoted market values, and third-party independent appraisals, depending on the nature of the asset. For the twelve-month periods ended December 31, 2022 and 2021, the Company did not recognize any impairment charges associated with long-lived assets.

### ***Leases***

At the inception of a contract, the Company determines whether the contract is or contains a lease based on all relevant facts and circumstances. Leases with a term greater than 12 months are recognized on the balance sheet date as right of use (“ROU”) assets and current and

## Notes to Consolidated Financial Statements

non-current lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically includes lease renewals in the assessment of the lease arrangement, unless there is reasonable certainty that the Company will not renew.

Lease liabilities and the corresponding right of use assets are recorded based on the present value of lease payments to be made over the lease term. The discount rate used to calculate the present value is the rate implicit in the lease, or if not readily determinable, the Company's incremental borrowing rate. The Company's incremental borrowing rate is the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right of use asset may be required for items such as initial direct costs or incentives received. Lease payments on operating leases are recognized on a straight-line basis over the expected term of the lease. Lease payments on financing leases are recognized using the effective interest method. See Note 6, "Leases" for additional disclosure on leases.

For all asset classes of its leases, the Company has elected to account for the lease and non-lease components together for existing classes of underlying assets.

### ***Revenue Recognition***

To date the Company's sole product is in the late stages of FDA approval, as such no revenue has been recorded from the sale of products. Once the Company receives FDA approval, revenue from product sales will be recognized upon the transfer of control, which is generally upon shipment or delivery, depending on the delivery terms set forth in the customer contract. Provisions for discounts, rebates and sales incentives to customers, and returns and other adjustments will be provided for in the period the related sale is recorded.

### ***Research and development***

Research and development costs are expensed when incurred. Research and development costs include costs of other research, engineering, and technical activities to develop a new product or service or make significant improvement to an existing product or manufacturing process.

### ***Stock-based compensation***

The Company recognizes stock-based compensation expense related to employees over the requisite service period based on the grant-date fair value of the awards. The fair value of options granted is estimated using the Black-Scholes option valuation model. The Company recognizes the grant-date fair value of an award as compensation expense on a straight-line basis over the requisite service period, which typically corresponds to the vesting period for the award. The Company elects to account for forfeitures as they occur and, upon forfeiture of an award prior to vesting, the Company reverses any previously recognized compensation expense related to that award. See Note 13, "Stock-based compensation" for additional details.

### ***Other Income***

The Company periodically receives reimbursements of clinical trial expenses, which are recorded as other income in the accompanying consolidated statements of operations. During the twelve-month periods ended December 31, 2022 and 2021, the Company recorded reimbursements of \$842,551 and \$1,378,908, respectively. During the twelve-month period ended December 31, 2022, the Company received refundable tax incentives from the Australian Taxation Office of \$504,207, which are recorded as other income in the accompanying consolidated statements of operations. The Company earned interest income, including accretion of discount, from investments in marketable securities of \$1,118,163 and \$952, which is also included in other income for the twelve-month periods ended December 31, 2022 and 2021, respectively.

### ***Income taxes***

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities reflect the tax effects of net operating losses, tax credits, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These are determined using enacted tax rates in effect for the year in which such temporary differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the period that includes the enactment date.

The Company records deferred tax assets to the extent the Company believes these assets will more likely than not be realized. In making such determination, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies and recent financial operations. When we establish or reduce the valuation allowance against our deferred tax assets, our provision for income taxes will increase or decrease, respectively, in the period that determination to change the valuation allowance is made.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements on a particular tax position are measured based on the largest benefit that has a greater than a 50% likelihood of being realized upon settlement. The amount of unrecognized tax benefits is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to unrecognized tax benefits in the provision for income taxes.

## Notes to Consolidated Financial Statements

### ***Earnings per share***

Basic income or loss per share is determined by dividing net income or loss by the weighted average common shares outstanding during the period. Diluted income or loss per share is determined by dividing net income by diluted weighted average shares outstanding during the period. Diluted weighted average shares reflect the dilutive effect, if any, of potential common shares. To the extent their effect is dilutive, employee equity awards and other commitments to be settled in common stock are included in the calculation of diluted income or loss per share based on the treasury stock method. Potential common shares are excluded from the calculation of diluted weighted average shares outstanding if their effect would be anti-dilutive at the balance sheet date based on a treasury stock method or due to a net loss.

### ***Recently adopted accounting pronouncements***

In August 2020, Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*. This ASU is intended to simplify the accounting for certain convertible instruments with characteristics of both liability and equity. This ASU removes certain accounting models which separate the embedded conversion features from the host contract for convertible instruments. As a result, after the adoption of this guidance, an entity’s convertible debt instrument will be wholly accounted for as debt. This ASU also expands disclosure requirements for convertible instruments and simplifies areas of the guidance for diluted earnings-per-share calculations by requiring the use of the if-converted method. This ASU is effective for fiscal years beginning after December 15, 2023, with early adoption permitted for fiscal years beginning after December 15, 2020 and can be adopted on either a fully retrospective or modified retrospective basis. An entity should adopt the guidance at the beginning of its annual fiscal year. The Company has elected to early adopt this standard on January 1, 2021, on a modified retrospective basis, and it did not have a material effect on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses*, which introduced new guidance for an approach based on expected losses to estimate credit losses on certain types of financial instruments. It also modifies the impairment model for available-for-sale debt securities and provides for a simplified accounting model for purchased financial assets with credit deterioration since their origination. Instruments in scope include loans, held-to-maturity debt securities, and net investments in leases as well as reinsurance and trade receivables. In November 2018, the FASB issued ASU 2018-19, which clarifies that operating lease receivables are outside the scope of the new standard. The Company has adopted this standard on January 1, 2021. There was no material impact on the consolidated financial statements.

### ***Recently issued accounting pronouncements***

In March 2022, FASB issued Accounting Standards Update (“ASU”) 2022-02, *Troubled Debt Restructurings and Vintage Disclosures*. This ASU eliminates the requirement for creditors



to recognize and measure certain modifications as troubled debt restructuring, enhances the disclosures by creditors for certain modifications of receivables to debtors experiencing financial difficulty, and requires public companies to disclose current-period write-offs by year of origination for the related financing receivables and net investments in leases. This ASU is effective for fiscal years beginning after December 15, 2022. The Company believes that adoption of ASU 2022-02 will not have a material impact on the Company's consolidated financial statements.

### Note 3 – Cash, cash equivalents and marketable securities

Cash, cash equivalents, and marketable securities consisted of the following at December 31, 2022 and 2021:

	2022	2021
Cash and cash equivalents:		
Cash	\$ 332,255	\$ 78,242,340
Money market funds	15,124,083	-
Total cash and cash equivalents	\$ 15,456,338	\$ 78,242,340
Marketable securities, short-term:		
US Treasury securities	\$ 12,341,584	\$ -
Corporate bonds	10,023,089	-
Commercial Paper	23,808,415	-
Asset backed securities	1,899,931	-
Total marketable securities, short-term	\$ 48,073,019	\$ -
Marketable securities, long-term:		
Asset backed securities	\$ 985,957	\$ -
Total marketable securities, long-term	\$ 985,957	\$ -
Total cash, cash equivalents, and marketable securities	\$ 64,515,314	\$ 78,242,340

During the year ended December 31, 2022, marketable securities matured for proceeds of \$2,000,000 with no gain or loss realized. During the year ended December 31, 2021, no marketable securities matured. See Note 4, "Fair Value Measurements" for additional information regarding the fair value of cash equivalents and marketable securities.

The following table summarizes the unrealized gains and losses related to the Company's available-for-sale marketable securities, by major security type, as of December 31, 2022:

## Notes to Consolidated Financial Statements

Marketable securities	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
US Treasury securities	\$ 12,382,149	\$ -	\$ (40,565)	\$ 12,341,584
Corporate bonds	10,068,768	-	(45,679)	10,023,089
Commercial paper	23,808,415	-	-	23,808,415
Asset backed securities	2,917,862	-	(31,974)	2,885,888
Total marketable securities	\$ 49,177,194	\$ -	\$ (118,218)	\$ 49,058,976

The following table shows the unrealized losses and fair values for those marketable securities that were in an unrealized loss position as of December 31, 2022, aggregated by major security type and the length of time the marketable securities have been in a continuous loss position:

	In Loss Position for Less Than 12 Months		In Loss Position for 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
US Treasury securities	\$ 12,341,584	\$ (40,565)	\$ -	\$ -	\$ 12,341,584	\$ (40,565)
Corporate bonds	10,023,089	(45,679)	-	-	10,023,089	(45,679)
Asset backed securities	2,885,888	(31,974)	-	-	2,885,888	(31,974)
Total	\$ 25,250,561	\$ (118,218)	\$ -	\$ -	\$ 25,250,561	\$ (118,218)

The contractual maturities of the Company's marketable securities as of December 31, 2022, were as follows:

	Fair Value
One year or less	\$ 48,073,019
One year to two years	985,957
Two years to three years	-
Total	\$ 49,058,976

#### Note 4 – Fair value measurement

The fair value measurement guidance establishes a fair value hierarchy which requires the Company to maximize the use of observable inputs when measuring fair value. The following levels of inputs may be used to measure fair value:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Management's assessment of the significance of a particular input to the fair value measurement requires judgement and may affect the valuation of financial assets and liabilities and their placement within the fair value hierarchy. The Company's financial assets that are accounted for at fair value on a recurring basis are presented in the table below:

Fair Values as of December 31, 2022				
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ 15,124,083	\$ -	\$ -	\$ 15,124,083
Marketable securities				
US Treasury securities	-	12,341,584	-	12,341,584
Corporate bonds	-	10,023,089	-	10,023,089
Commercial paper	-	23,808,415	-	23,808,415
Asset backed securities	-	2,885,888	-	2,885,888
Total	\$ 15,124,083	\$ 49,058,976	\$ -	\$ 64,183,059

In the Company's consolidated balance sheets, the carrying values of non-trade receivables, other assets, accounts payable and accrued expenses approximated their fair values due to the nature and relatively short maturities. The fair value of debt approximates its carrying value as it is variable rate debt or has relatively short maturities. The fair value measurements of the Company's derivative liability were considered Level 3 measurements under the fair value hierarchy. See Note 9 "Derivative liabilities" for additional disclosure on derivative liabilities.

#### Note 5 – Consolidated balance sheet components

*Non-trade receivables and unbilled reimbursements, net*

## Notes to Consolidated Financial Statements

Non-trade receivables and unbilled reimbursements include reimbursement of clinical trial expenses incurred. Non-trade receivables and unbilled reimbursements consisted of the following as of December 31, 2022 and 2021:

	2022	2021
Non-trade receivables	\$ 280,457	\$ 233,158
Unbilled reimbursements	265,143	843,879
Non-trade receivables and unbilled services	545,600	1,077,037
Less: allowance for doubtful accounts	(101,681)	(110,914)
Non-trade receivables and unbilled services, net	<u>\$ 443,919</u>	<u>\$ 966,123</u>

During the twelve-month periods ended December 31, 2022 and 2021, provision for doubtful accounts totaled \$3,685 and \$110,914, respectively.

### *Property and equipment, net*

Property and equipment consisted of the following as of December 31, 2022 and 2021:

	2022	2021
Equipment	\$ 2,981,787	\$ 2,439,709
Computer software	572,180	477,685
Leasehold improvements	415,590	415,590
Construction in progress	-	153,548
	3,969,557	3,486,532
Less accumulated depreciation and amortization	(2,392,513)	(1,742,828)
Total property and equipment, net	<u>\$ 1,577,044</u>	<u>\$ 1,743,704</u>

Depreciation and amortization expense on property and equipment was \$652,432 and \$384,022 for the twelve-month periods ended December 31, 2022 and 2021, respectively.

### *Accrued expenses and other liabilities*

Accrued expenses and other liabilities consisted of the following at December 31, 2022 and 2021:

	2022	2021
Accrued compensation and related liabilities	\$ 1,980,453	\$ 1,628,316
Accrued development expenses	697,908	663,288
Accrued warranty reserve	734,400	325,612
Accrued other expenses	57,346	108,808
Accrued expenses and other liabilities	<u>\$ 3,470,107</u>	<u>\$ 2,726,024</u>

### **Note 6 – Leases**

The Company determined that it held an operating lease for its corporate headquarters and laboratory space, located in Sunnyvale, California. The lease expires June 30, 2024, with an option to extend the lease an additional sixty-months, which was used in the calculation of the right of use asset and lease liability. The Company held no other lease agreements.



Future lease payments for non-cancellable operating leases as of December 31, 2022, were as follows:

Years Ended December 31,	
2023	\$ 408,786
2024	421,050
2025	433,682
2026	446,692
2027	460,093
Thereafter	714,346
Total undiscounted lease payments	2,884,649
Less: effects of discounting	(746,726)
Total operating lease liabilities	<u>\$ 2,137,923</u>

Amounts reported in the consolidated balance sheet for operating leases in which the Company is the lessee as of December 31, 2022 and 2021, were as follows:

	2022	2021
Right of use asset	\$ 1,941,138	\$ 2,143,481
Lease liability, current	216,817	185,707
Lease liability, noncurrent	1,921,106	2,137,923
Remaining lease term	6.50 years	7.50 years
Discount rate	10.00%	10.00%

Operating lease costs for the twelve-month periods ended December 31, 2022 and 2021 was \$413,518 and \$380,041, respectively. Short-term lease costs for the twelve-month periods ended December 31, 2022 and 2021 was \$570 and \$2,415, respectively. Cash paid for operating lease liabilities for the twelve-month period ended December 31, 2022 and 2021 was \$396,882 and \$385,320, respectively.

#### **Note 7 - Notes payable**

##### ***Runway Growth Finance Corp***

On June 30, 2022, the Company entered into a loan and security agreement with Runway Growth Finance Corp. The loan agreement provides three term loan tranches. Term A loan was made available to the Company at the inception of the loan agreement in an aggregate amount of \$20,000,000. Term B loan provides a minimum of \$15,000,000 and a maximum of \$20,000,000. The Term B draw period commences on the date the Company has received positive interim analysis data, sufficient to proceed with the clinical trial and premarket approval submission to the FDA, with respect to the Company's pivotal clinical trial for the WiSE CRT System and ends on June 30, 2023. Term C loan provides a minimum of \$10,000,000 and a maximum of \$20,000,000. The Term C draw period commences on the date the Company has received approval from the FDA for the WiSE CRT System and ends on June 30, 2024. All term loans may not exceed \$50,000,000. At December 31, 2022, the Company has not drawn the Term B or Term C loans as the company has not met the required milestones.

## Notes to Consolidated Financial Statements

Interest on the term loan accrues on the principal amount outstanding at a floating per annum rate equal to the greater of the rate of interest noted in The Wall Street Journal Money Rates section, as the “Prime Rate” or 4.00% plus a margin of 4.9% and is payable monthly in arrears and shall be computed on the basis of a 360-day year for the actual number of days elapsed. The Company is required to make interest only payments from July 2022 to May 2027. The note payable has a maturity date of June 15, 2027, at which time any unpaid interest, outstanding principal balance, and a final payment of 4.5% of the original principal amount borrowed shall be due in full. The Company has accounted for the final payment of \$900,000 as a discount of the note that will be amortized over the life of the loan using the effective interest method. Amortization of the discount was \$89,693 during the twelve-month period ended December 31, 2022. This amount was recorded as additional interest expense in the accompanying consolidated statements of operations. If the Company repays the loan prior to maturity, the Company will be required to pay a prepayment fee of 2% - 0.5% if the outstanding principal balance. The Company is also required to pay a 3% success fee of the funded principal amount of the term loan at the time of a liquidity event, as defined in the loan and security agreement. The success fee is enforceable within 10 years from the execution date of the agreement.

The Company incurred loan costs of \$794,317, which are being amortized over the life of the loan using the effective interest method. As of December 31, 2022, the note has been shown net of unamortized loan costs of \$714,968.

The debt is secured against substantially all assets of the Company, except for the Company’s intellectual property but includes all proceeds from the sale of intellectual property.

The Company is subject to customary financial and reporting covenants under the loan and security agreement. As of December 31, 2022, the Company was in compliance with all debt covenants.

### ***Bank of America Leasing & Capital, LLC***

In May 2021, the Company entered into an equipment purchase agreement for the purchase of certain software totaling \$128,974. The purchase agreement requires 30 equal payments of \$4,299 beginning December 1, 2021 through May 1, 2024. At December 31, 2022 and 2021, the outstanding principal balance was \$73,086 and \$124,675, respectively, of which \$51,590 was included in the current portion of notes payable at December 31, 2022 and 2021.

### ***Paycheck Protection Program***

On May 20, 2021, the entire principal balance of \$1,242,525 and accrued interest of \$13,387 was forgiven and accounted for as a gain on extinguishment of debt during the twelve-month period ended December 31, 2021.

### ***Silicon Valley Bank – 2020***

In March 2020, the Company entered into a loan and security agreement with Silicon Valley Bank and other lenders party thereto. The loan agreement provides for a term loan facility that includes three tranches in a principal amount of \$3,000,000, which if drawn would

result in an aggregate outstanding principal amount of \$9,000,000. As of December 31, 2021, the Company had borrowed \$6,000,000 of the \$9,000,000 available under the March 2020 loan agreement. As of December 31, 2022, the Company has repaid the outstanding principal balance under the loan agreement. At December 31, 2021, the outstanding principal balance under the loan agreement was \$2,400,000.

Interest on the term loan accrues on the principal amount outstanding at a floating per annum rate equal to the greater of 7.25% or 2.50% above the Prime Rate and is payable monthly in arrears. The Company is required to make interest only payments from April 2020 to June 2020. Thereafter, thirty monthly principal payments of \$200,000 per month plus interest commencing July 2020 and continuing until the maturity of the note in December 2022.

During the twelve-month periods ended December 31, 2022 and 2021, the Company recorded interest expense of \$61,424 and \$256,892, respectively, which is included in the accompanying consolidated statements of operations. Additionally, the Company was required to make a final payment of \$420,000 at the time the term loan was paid in full. This amount was recorded as additional interest expense over the life of the term loan. During the twelve-month periods ended December 31, 2022 and 2021, the Company recorded interest expense of \$152,727 and \$152,727, respectively, which is included in the accompanying consolidated statements of operations.

The debt is secured against substantially all assets of the Company, except for the Company's intellectual property but includes all proceeds from the sale of intellectual property.

The Company incurred loan costs of \$83,114, these costs are being amortized over the life of the loan. Amortization of the loan costs was \$30,245 and \$30,246 during the twelve-month periods ended December 31, 2022 and 2021, respectively, which is included in interest expense in the accompanying consolidated statements of operations.

The note payable described above was issued with fully vested detachable warrants. The note has been discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. As of December 31, 2021, the note has been shown net of the unamortized discount of \$10,848 on the accompanying consolidated balance sheets. Amortization of the discount was \$10,848 in both twelve-month periods ended December 31, 2022 and 2021, which is included in interest expense in the accompanying consolidated statements of operation.

At December 31, 2022 and 2021, notes payable consisted of the following:

	2022	2021
Current portion of notes payable	\$ 51,590	\$ 2,451,589
Long-term portion of notes payable	20,921,496	73,085
Less: unamortized deferred loan costs	(714,968)	(30,245)
Less: unamortized discount	(810,307)	(10,848)
Notes payable, net	<u>\$ 19,447,811</u>	<u>\$ 2,483,581</u>

## Notes to Consolidated Financial Statements

The following table presents information regarding the Company's notes payable principal repayment obligations as of December 31, 2022:

Years Ended December 31,	
2023	\$ 51,590
2024	21,496
2025	-
2026	-
2027	20,900,000
Total minimum payments	<u>\$ 20,973,086</u>

### Note 8 – Convertible Notes Payable

The Company had no outstanding convertible notes payable as of December 31, 2022 and 2021. All previously issued convertible notes payable were converted to equity in 2021. As a result of the Company's Initial Public Offering ("IPO"), as discussed in Note 12, "Common Stock", all warrants issued previously in connection with convertible notes payable transactions are now exercisable for the Company's common stock.

#### *Convertible Notes Payable – 2021*

In June 2021, the Company issued the first tranche ("tranche one") of convertible notes payable in the amount of \$8,712,277. In October 2021, the Company issued the second tranche ("tranche two") of convertible notes payable in the amount of \$8,712,277. The convertible notes payable has a maturity date of December 2022. The notes have a stated rate of 10% per annum.

In November 2021, the convertible note holders elected to convert the aggregate principal balance and accrued interest from the tranche one and tranche two convertible notes payable. The principal balance of \$17,424,544 and accrued interest of \$460,677 converted into 21,692,195 shares of the New Series B Convertible Preferred Stock.

As part of the agreement, in June 2021, the Company issued fully vested detachable warrants to purchase 3,111,787 shares of the New Series B Convertible Preferred Stock at \$0.8245 per share to the tranche one convertible note payable holders. On September 26, 2021, the Company amended the tranche one warrants and reduced the exercise price to \$0.589113 per share. In October 2021, the Company issued fully vested detachable warrants to purchase 3,111,787 shares of the New Series B Convertible Preferred Stock at \$0.589113 per share. Both tranches of warrants have an exercise period of 10 years. The Company has classified the warrants as equity. The convertible notes have been discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. Accordingly, the fair value of the tranche one and tranche two warrants at the time of issuance was \$1,128,927 and \$1,369,186, respectively. See Note 10 "Warrants", for additional information regarding the warrants.

In the event the Company raises \$40,000,000 of equity financing, not including the conversion of the notes, then the entire principal amount and accrued interest shall be converted into the qualified financing shares at 80% of the lowest price per share paid by a third party. If a



qualified financing event is not triggered, the principal amount and accrued interest shall be converted into the New Series B Convertible Preferred Stock at a price per share of \$0.8245. The Company analyzed the conversion feature of the agreement for derivative accounting consideration under FASB ASC Subtopic 815, *Derivatives and Hedging*, and determined that the embedded conversion features should be classified as a derivative liability because the exercise price of these convertible notes are subject to a variable conversion rate. The Company has determined that the conversion feature is not considered to be solely indexed to the Company's own stock and is therefore not afforded equity treatment, as such, the Company has bifurcated the conversion feature of the note and recorded a derivative liability for tranche one and tranche two of the convertible note. See Note 9 "Derivative liabilities", for additional information regarding the derivative liability.

The embedded derivative for the note is carried on the Company's accompanying consolidated balance sheets at fair value. The derivative liability is marked-to-market each measurement period and any unrealized change in fair value is recorded as a component of the consolidated statements of operations and the associated fair value carrying amount on the accompanying consolidated balance sheets is adjusted by the change. The Company measures the fair value of the embedded derivative using the Monte Carlo simulation. The aggregate fair value of the derivative at the issuance date of tranche one and tranche two was \$2,926,000 and \$2,611,000, which was recorded as a derivative liability and debt discount at the time of issuance. Amortization of the discount was \$5,537,000 during the twelve-month period ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations.

### ***Convertible Notes Payable – 2019***

In August 2019, the Company issued the first of three tranches ("tranche one") of convertible notes payable in the amount of \$12,500,000. In March 2020, the Company issued the second of three tranches ("tranche two") of convertible notes payable in the amount of \$12,458,890. In February 2021, the Company issued the third and final tranche ("tranche three") of the convertible notes payable in the amount of \$5,000,000. The convertible notes payable has a maturity date of December 2021. The notes had a stated rate of 10% per annum.

In May 2021, the convertible note holders elected to convert the aggregate principal balance and accrued interest from the tranche one, tranche two and tranche three convertible notes payable. The principal balance of \$29,958,890 and accrued interest of \$3,860,764 converted into 41,018,323 shares of the New Series B Convertible Preferred Stock.

As part of the agreement, the Company issued fully vested detachable warrants to the tranche one, tranche two, and tranche three convertible note payable holders to purchase 4,438,437 shares, 4,423,389 shares, and 1,732,123 shares, respectively, of the New Series B Convertible Preferred Stock at \$0.8245 per share. The warrants have an exercise period of 10 years. The Company has classified the warrants as equity. The convertible notes have been discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. Accordingly, the fair value of the tranche one, tranche two, and tranche three warrants at the time of issuance was \$1,329,621, \$1,526,399, and \$624,981, respectively.

## Notes to Consolidated Financial Statements

Amortization of the discount was \$2,042,378 during the twelve-month period ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations. On September 26, 2021, the Company amended the tranche one, tranche two, tranche three warrants and reduced the exercise price to \$0.589113 per share. See Note 10 “Warrants”, for additional information regarding the warrants.

In the event the Company raises \$20,000,000 of equity financing, not including the conversion of the notes, then the entire principal amount and accrued interest shall be converted into the qualified financing shares at 80% of the lowest price per share paid by a third party. If a qualified financing event is not triggered, the principal amount and accrued interest shall be converted into the New Series B Convertible Preferred Stock at a price per share of \$0.8245. The Company analyzed the conversion feature of the agreement for derivative accounting consideration under FASB ASC Subtopic 815, *Derivatives and Hedging*, and determined that the embedded conversion features should be classified as a derivative liability because the exercise price of these convertible notes is subject to a variable conversion rate. The Company has determined that the conversion feature is not considered to be solely indexed to the Company’s own stock and is therefore not afforded equity treatment, as such, the Company has bifurcated the conversion feature of the note and recorded a derivative liability. See Note 9 “Derivative liabilities”, for additional information regarding the derivative liability.

The aggregate fair value of the derivative at the issuance date of tranche one, tranche two, and tranche three was \$3,027,459, \$5,105,000, and \$984,000, respectively, which was recorded as a derivative liability and debt discount at the time of issuance. Amortization of the debt discount was \$5,157,443 during the twelve-month period ended December 31, 2021, which is recorded as interest expense in the accompanying consolidated statements of operations.

### ***Convertible Note Payable – 2017***

In October 2017, the Company issued a convertible promissory note for a principal amount of \$9,020,589, with a maturity date of April 2028. The note has a stated interest rate of 8% per annum and is convertible into 12,445,334 New Series B Convertible Preferred Stock. Interest is only due and payable in the event the Company declares a dividend on the New Series B Convertible Preferred Stock. As no such dividends have been declared to date there has been no accrued interest recorded on this convertible note. In connection with the convertible note payable, the Company issued fully vested detachable warrants to purchase 1,950,607 shares of common stock at \$0.41225 per share. The warrants have an exercise period of 10 years. The Company has classified the warrants as equity. The note was discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. The notes were converted in November 2021. Amortization of the discount was \$193,833 for the twelve-month period ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations.

A beneficial conversion feature discount of \$1,240,800 was recorded at the issuance of the convertible promissory note. The beneficial conversion feature is being amortized as interest expense over the term of the convertible note payable. Amortization of the beneficial conversion

feature was \$864,851 during the twelve-month period ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations.

#### **Note 9 – Derivative liabilities**

In June 2021, the 2019 convertible notes payable, which contained an embedded derivative liability, were converted into convertible preferred stock. In November 2021, the 2021 convertible notes payable, which contained an embedded derivative liability were converted into common stock. At the time of the conversions the related derivative liabilities were settled into equity.

A summary of the activity related to derivative liabilities for the twelve-month period ended December 31, 2021, is as follows:

Balance at January 1, 2021	\$ 6,852,000
Issued during the year	6,521,000
Change in fair value recognized in operations	(1,394,000)
Derivative liabilities settled into equity	(11,979,000)
Balance at December 31, 2021	<u>\$ -</u>

#### **Note 10 – Warrants**

##### ***Equity classified common stock warrants***

The Company has issued the following warrants to purchase shares of its common stock, which are outstanding as of December 31, 2022 and 2021. These warrants are exercisable any time at the option of the holder until their expiration date.

	Number of Shares	Weighted average exercise price	Weighted average remaining contractual term
Balance at January 1, 2021	11,855,331	\$ 0.75	8.42
Issued	7,955,697	0.73	9.85
Exercised	-	-	-
Modification	-	(0.24)	-
Expired/forfeited	-	-	-
Balance at December 31, 2021	19,811,028	0.58	8.27
Issued	-	-	-
Exercised	-	-	-
Expired/forfeited	(21,649)	11.50	-
Balance at December 31, 2022	<u>19,789,379</u>	<u>\$ 0.57</u>	<u>7.28</u>

##### ***Warrant Modifications***

On September 26, 2021, Company amended certain warrants issued in connection with convertible preferred stock as described in Note 8 and reduced the exercise price to \$0.589113 per share as consideration for the waiver of certain antidilution provisions by holders of the

## Notes to Consolidated Financial Statements

warrants. The Company accounted for the modification of the warrants in accordance with ASC 815-40, *Contracts in Entity's Own Equity*. The additional fair value attributed to the warrants related to outstanding convertible notes payable was \$248,943 at the modification date and reflected as an additional discount on the related convertible notes payable. The additional fair value attributed to the warrants related to convertible notes that had previously been converted to preferred stock was \$847,509 at the modification date and reflected as a deemed dividend.

### Note 11 – Convertible preferred stock

In connection with the Initial Public Offering (“IPO”), as discussed in Note 12, “Common Stock”, all shares of convertible preferred stock then outstanding were automatically converted into 147,566,974 shares of common stock on a one-for-one basis. As of December 31, 2022 and 2021, 10,000,000 shares of convertible preferred stock were authorized, of which no shares were issued or outstanding.

### Note 12 – Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company’s stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company’s board of directors. As of December 31, 2022 and 2021, no dividends have been declared.

As of December 31, 2022 and 2021, 600,000,000 shares were authorized, of which 270,752,201 shares and 267,985,340 shares, respectively, were outstanding.

The ASX uses an electronic system called CHESS for the clearance and settlement of trades on the ASX. The State of Delaware does not recognize the CHESS system of holding securities or electronic transfers of legal title to shares. To enable companies to have their securities cleared and settled electronically through CHESS, CDIs are issued. CDIs are units of beneficial ownership in shares and are traded in a manner similar to shares of Australian companies listed on the ASX. The legal title to the shares are held by a depository, CDN, which is a wholly-owned subsidiary of the ASX, and is an approved general participant of ASX Settlement. The equity capital raise consisted of 101,851,851 CDIs representing the same number of shares of common stock at \$1.08 Australian dollars per share, for total proceeds of \$74,984,705, net of \$5,114,909 of related offering costs.

Additionally, the Company has reserved the following shares of common stock for issuance as of December 31, 2022:

Conversion of Common Stock warrants	19,789,379
2013 Equity Incentive Plan	24,242,643
2021 Equity Incentive Plan	36,573,978
Total shares of Common stock reserved for issuance	<u>80,606,000</u>

### Note 13 – Stock-based compensation

The Company and its stockholders adopted an equity incentive plan (the “2013 Plan”) in 2013, which reserved shares of the Company’s common stock for the granting of incentive and nonqualified stock options to employees, directors, and consultants. On October 14, 2021, the

Company replaced the 2013 Plan with the 2021 Plan, as the 2013 Plan was expiring. Under the 2021 Plan, 36,573,978 shares of common stock are reserved. The Company may grant options to purchase common stock, stock appreciation rights, restricted stock awards and other forms of stock-based compensation. Stock options generally vest over four years and expire no later than 10 years from the date of grant. The Board of Directors has the authority to select the employees to whom options are granted and determine the terms of each option, including i) the number of shares of common stock subject to the option; ii) when the option becomes exercisable; iii) the option exercise price, which must be at least 100% of the fair market value of the common stock as of the date of grant and iv) the duration of the option, which may not exceed 10 years.

As of December 31, 2022, options to purchase a total of 7,975,284 shares of common stock remained outstanding and 28,598,694 shares remain available for grant under the 2021 Plan. As of December 31, 2022, options to purchase a total of 24,242,643 shares of common stock remained outstanding under the 2013 Plan. As of December 31, 2022, no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the twelve-month period ended December 31, 2022, was as follows:

	Shares	Weighted Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)
Outstanding at January 1, 2022	30,708,618	\$ 0.19	7.59
Granted	6,365,250	0.46	
Cancelled	(2,089,080)	0.28	
Exercised	(2,766,861)	0.15	
Outstanding at December 31, 2022	<u>32,217,927</u>	<u>\$ 0.24</u>	<u>7.15</u>
Vested and expected to vest at December 31, 2022	32,217,927	\$ 0.24	7.15
Exercisable at December 31, 2022	23,951,977	\$ 0.17	6.59

The fair value of the options granted to employees is estimated on the grant date using the Black-Scholes option valuation model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the volatility of the Company's common stock, an assumed risk-free interest rate and expected dividends. The Company uses the simplified calculation of expected life and volatility is based on an average of the historical volatilities of the common stock of several publicly traded entities with characteristics similar to those of the Company. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The Company uses the straight-line method for expense attribution. The weighted-average grant-date fair values of stock



## Notes to Consolidated Financial Statements

options granted during the twelve-month periods ended December 31, 2022 and 2021, was \$0.29 per share and \$0.17 per share, respectively.

The following assumptions were used to calculate the grant-date fair value of employee stock options granted during the twelve-month periods ended December 31, 2022 and 2021:

	2022	2021
Expected term (in years)	7.00	7.00
Expected volatility	58.38% - 79.90%	47.52% - 53.09%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	1.94% - 3.49%	0.75% - 1.55%

The following table presents classification of stock-based compensation expense within the accompanying consolidated statements of operations for the twelve-month periods ended December 31, 2022 and 2021:

	2022	2021
Research and development	\$ 261,577	\$ 96,835
Sales and marketing	174,799	48,659
Clinical and regulatory	64,024	50,792
General and administrative	369,157	262,894
Total	<u>\$ 869,557</u>	<u>\$ 459,180</u>

At December 31, 2022, there was \$2,223,398 of unamortized stock-based compensation cost, respectively, related to unvested stock options which is expected to be recognized over a weighted average period of 2.80 years.

### Note 14 – Net loss per share

The following tables sets forth the computation of basic and diluted net loss per share attributable to common stockholders at December 31, 2022 and 2021:

	2022	2021
<b>Numerator – basic &amp; diluted:</b>		
Net loss attributable to common stockholders, basic and diluted	<u>\$ (33,088,205)</u>	<u>\$ (39,835,369)</u>
<b>Denominator:</b>		
Weighted-average number of shares outstanding, basic and diluted	<u>269,608,916</u>	<u>42,122,436</u>
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.12)	\$ (0.95)

The following potentially dilutive shares were not included in the calculation of diluted shares outstanding for the periods presented as the effect would have been anti-dilutive at December 31, 2022 and 2021:

	2022	2021
Outstanding warrants	19,789,379	19,811,028
Outstanding stock options	32,217,927	30,708,618
Total dilutive shares	52,007,306	50,519,646

#### Note 15 – Income taxes

The Company did not record any income tax expense for the twelve-month periods ended December 31, 2022 and 2021. The Company has historically incurred operating losses and maintains a full valuation allowance against its net deferred tax assets.

The Company's effective tax rate of 0.01% and 0.00% for the twelve-month periods ended December 31, 2022 and 2021, respectively, differs from the statutory U.S. federal rate as follows:

	2022	2021
Statutory tax rate	\$ (6,973,527)	\$ (8,365,182)
R&D credit generation	(370,183)	(49,341)
State and foreign tax benefit	(6,463,619)	(1,162,345)
Other non-deductible expenses	1,554,541	3,451,555
Change in valuation allowance	12,254,388	6,125,313
Effective tax rate	\$ 1,600	\$ -

The tax effects of temporary differences that give rise to significant components of the deferred tax assets are as follows:

	2022	2021
Deferred tax assets:		
Net operating loss	\$ 48,332,000	\$ 40,097,000
Other accruals	829,000	267,000
Stock based compensation	249,000	111,000
Credit carryforwards	1,967,000	1,531,000
Research & development capitalization	2,686,000	-
Intangible assets	13,409,000	13,202,000
Total deferred tax assets	67,472,000	55,208,000
Deferred tax liability		
Fixed assets	(9,000)	-
Total deferred tax liability	(9,000)	-
Net deferred tax asset before valuation allowance	67,463,000	55,208,000
Valuation allowance	(67,463,000)	(55,208,000)
Net deferred tax assets	\$ -	\$ -

As of December 31, 2022, the Company recorded the portion of its deferred tax assets that was determined to meet the more likely than not threshold. Significant judgment is required in determining the Company's provision for income taxes, recording valuation allowances against

## Notes to Consolidated Financial Statements

deferred tax assets and evaluating the Company's uncertain tax positions. Due to net losses since inception and the uncertainty of realizing the deferred tax assets, the Company has a full valuation allowance against its net deferred tax assets. To the extent that the Company generates positive income and expects, with reasonable certainty, to continue to generate positive income, the Company may release all, or a portion of, the valuation allowance in a future period. This release would result in the recognition of all, or a portion of, the Company's deferred tax assets, resulting in a decrease to income tax expense for the period such release is made. As of December 31, 2022, the Company's valuation allowance was \$67,463,000 which increased by approximately \$12,255,000 for the twelve-month period ended December 31, 2022.

On August 16, 2022, the United States enacted the Inflation Reduction Act ("IRA"), which introduces, among other items, an excise tax that would impose a 1% surcharge on stock repurchases, net of stock issuances beginning in 2023. The IRA also introduces a 15% book minimum tax on adjusted financial statement earnings beginning in fiscal 2024. These provisions are not expected to impact the Company based on the Company's current financial positions but will be considered in future years.

Net operating loss ("NOL") carryforwards and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and may become subject to annual limitation due to ownership changes that have occurred previously or that could occur in the future under Section 382 of the Internal Revenue Code, as amended and similar state provisions. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed, and any limitation is known, no amounts are being presented as an uncertain tax position.

As of December 31, 2022, the Company had federal NOL carryforwards of \$164,381,569, available to reduce taxable income, of which \$45,825,483 expire beginning 2023 and \$118,556,086 do not expire. The Company had state NOL carryforwards of \$129,028,475 available to reduce future state taxable income, as of December 31, 2022, which expire beginning 2028.

As of December 31, 2022, the Company had federal and state research and development credit carryforwards of \$1,318,411 and \$1,254,827, respectively. The federal research and development credit carryforwards expire beginning in 2035 and the state credit carryforwards do not expire.

The Company files income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. In the normal course of business, the Company is subject to examination by taxing authorities throughout the world. Due to NOL carryforwards not being utilized, all periods are open to potential examinations.

The Company's policy is to classify interest and penalties related to unrecognized tax benefits, if and when required, as a component of interest expense, in the accompanying consolidated statements of operations. The Company had not recorded any interest or penalties for the twelve-month periods ended December 31, 2022 and 2021.

As of December 31, 2022, the Company's uncertain tax positions totaled \$1,012,850, which are netted against the underlying deferred tax assets. The entire balance in uncertain tax positions would cause a decrease in the effective income tax rate upon recognition, but that decrease would be offset by a change in the valuation allowance given the full valuation allowance position of the Company.

The following is a roll-forward of the Company's liability related to uncertain tax positions at December 31:

	2022	2021
Balance at January 1	\$ 656,159	\$ 619,152
Increase for current period tax positions	309,267	41,222
Increase/(decrease) for prior period tax positions	47,424	(4,215)
Balance as December 31	<u>\$ 1,012,850</u>	<u>\$ 656,159</u>

## **Note 16 – Commitments and contingencies**

### ***Purchase commitments***

The Company purchases raw materials, manufacturing equipment, and various services from a variety of vendors. During the normal course of business, in order to manage manufacturing lead times and help ensure an adequate supply of certain items, we enter into agreements with suppliers that either allow us to procure goods and services when we choose or that establish purchase requirements over the term of the agreement. In certain instances, our purchase agreements allow us to cancel, reschedule, or adjust our purchase requirements based on our business needs prior to firm orders being placed. Consequently, only a portion of our purchase commitments are firm and noncancelable. As of December 31, 2022, the Company's obligations under such arrangements were \$2,538,451.

### ***Contingencies***

The Company is party to various legal proceedings from time to time. A liability is accrued when a loss is both probable and can be reasonably estimated. Management believes that the probability of a material loss with respect to any currently pending legal proceeding is remote. However, litigation is inherently uncertain, and it is not possible to definitively predict the ultimate disposition of any of these proceedings. The Company does not believe that there are any pending legal proceedings or other loss contingencies that will, either individually or in

## Notes to Consolidated Financial Statements

the aggregate, have a material adverse impact on the Company's consolidated financial statements.

### **Note 17 – Related Party Transactions**

In October 2017, the Company entered into a services agreement with a stockholder of the Company. Under the terms of the agreement the stockholder of the Company agreed to provide services including: a) advising on the Australian regulatory, business and healthcare environment; b) advising on the establishment of operation in Australia; c) assisting in the recruitment of key employees; and d) supporting clinical trial operations. In lieu of payment for services received, the Company will remit 10% of the gross Australian R&D Incentive Proceeds, net of accounting fees, to the stockholder of the Company. On October 30, 2021, the Company terminated this agreement. As of December 31, 2022 and 2021, there was no outstanding liability for amounts due to the stockholder of the Company.

### **Note 18 – Subsequent Events**

The Company has evaluated subsequent events that have occurred through February 27, 2023, which is the date that the consolidated financial statements were available to be issued and determined that there were no subsequent events or transactions that required recognition or disclosure in the consolidated financial statements.



# Independent Auditor's Report



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## INDEPENDENT AUDITOR'S REPORT

To the Audit and Risk Committee of EBR Systems, Inc.:

### Opinion

We have audited the consolidated financial statements of EBR Systems, Inc. and subsidiaries (the "Company"), which comprise the consolidated balance sheet as of December 31, 2022, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the year then ended, and the related notes to the consolidated financial statements (collectively referred to as the "financial statements").

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year then ended in accordance with accounting principles generally accepted in the United States of America.

### Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in the United States of America (GAAS). Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### Predecessor Auditor's Opinion on 2021 Financial Statements

The financial statements of the Company as of and for the year ended December 31, 2021 were audited by other auditors whose report, dated February 24, 2022, expressed an unmodified opinion on those statements.

### Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are issued.

# Independent Auditor's Report

## Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and, therefore, is not a guarantee that an audit conducted in accordance with GAAS will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with GAAS, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control-related matters that we identified during the audit.

*Deloitte & Touche LLP*

February 27, 2023



## INDEPENDENT AUDITOR'S REPORT

To the Board of Directors and Stockholders  
of EBR Systems, Inc.

### Opinion

We have audited the accompanying consolidated financial statements of EBR Systems, Inc. and Subsidiary, (collectively, "the Company") (a Delaware, USA corporation), which comprise the consolidated balance sheet as of December 31, 2021, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the year then ended, and the related notes to the consolidated financial statements.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of EBR Systems, Inc. as of December 31, 2021, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Consolidated Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities in accordance with the relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### Responsibilities of Management for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are available to be issued.

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## Independent Auditor's Report

### Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with generally accepted auditing standards will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the consolidated financial statements.

In performing an audit in accordance with generally accepted auditing standards, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the consolidated financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control related matters that we identified during the audit.

*Price Kong & Co. C.P.A.'s P.A.*

Price, Kong, & Co., C.P.A.'s, P.A.  
Phoenix, Arizona  
February 24, 2022

We have served as the Company's auditor since 2021. In 2022, we became the predecessor auditor.

# Shareholder Information

## Overview

The Company has CHESS Depositary Interests (**CDIs**) quoted on the Australian Securities Exchange (**ASX**) trading under the symbol EBR. Each CDI represents an interest in one share of common stock of the Company (**Share**). Legal title to the Shares underlying the CDIs is held by CHESS Depositary Nominees Pty Ltd (**CDN**), a wholly owned subsidiary of the ASX.

Except where noted, all information provided below is current as at 12 April 2023. To avoid double-counting, the holding of Shares by CDN (underpinning the CDIs on issue) have been disregarded in the presentation of the information below, unless otherwise stated.

The Company's share capital was as follows:

Type of Security	Number of Securities
Total number of issued CDIs/Shares <sup>1</sup>	270,838,632
Total number of issued Options	31,479,006
Total number of issued Warrants <sup>2</sup>	19,789,379

1. Includes Shares held by CDN.

2. Including 3,032,515 warrants issued by EBR Systems (Aust) Pty Ltd which on exercise, are automatically exchanged for the issue of new Shares in the Company.

## Substantial Holders

The names of substantial holders in the Company and their respective stock holdings (to the best of the Company's knowledge) follow below:

### Hesta

Holder of Relevant Interest	Registered Holder	Person entitled to be Registered Holder	Nature of Relevant Interest	Class and Number of Securities	Person's Votes
MRCF3 Services (H) Pty Ltd ATF MRCF3 (H) Trust	MRCF3 Services (H) Pty Ltd	MRCF3 Services (H) Pty Ltd	Registered Holder	23,118,914 CDIs	8.54%
H.E.S.T. Australia Limited as Trustee of Health Employees Superannuation Trust Australia (HESTA)	MRCF3 Services (H) Pty Ltd	MRCF3 Services (H) Pty Ltd	Power to Control Voting and Disposal of Securities	15,875,392 CDIs	5.86%
Brandon Capital Partners	MRCF3 Services (H) Pty Ltd	MRCF3 Services (H) Pty Ltd	Power to Control Voting and Disposal of Securities	7,243,522 CDIs	2.67%
<b>Total</b>					<b>17.07%</b>



## Shareholder Information

### Hostplus

Holder of Relevant Interest	Registered Holder	Person entitled to be Registered Holder	Nature of Relevant Interest	Class and Number of Securities	Person's Votes
MRCF3 Services (HP) Pty Ltd ATF MRCF3 (HP) Trust/ MRCF3 (HP) Pty Ltd ATF MRCF3 Part C Trust	MRCF3 Services (HP) Pty Ltd/MRCF3 (HP) Pty Ltd	MRCF3 Services (HP) Pty Ltd/MRCF3 (HP) Pty Ltd	Registered Holder	23,472,085 CDIs	8.67%
Host – Plus Pty Ltd as Trustee of Hostplus Pooled Superannuation Trust (Hostplus)	MRCF3 Services (HP) Pty Ltd/MRCF3 (HP) Pty Ltd	MRCF3 Services (HP) Pty Ltd/ MRCF3 (HP) Pty Ltd	Power to Control Voting and Disposal of Securities	21,056,885 CDIs	7.77%
Brandon Capital Partners	MRCF3 Services (HP) Pty Ltd/MRCF3 (HP) Pty Ltd	MRCF3 Services (HP) Pty Ltd/ MRCF3 (HP) Pty Ltd	Power to Control Voting and Disposal of Securities	2,415,200 CDIs	0.89%
<b>Total</b>					<b>17.33%</b>

### Brandon Capital Partners

Holder of Relevant Interest	Registered Holder	Person entitled to be Registered Holder	Nature of Relevant Interest	Class and Number of Securities	Person's Votes
Brandon Capital Partners	MRCF3 Services (H) Pty Ltd	MRCF3 Services (H) Pty Ltd	Power to Control Voting and Disposal of Securities	7,243,522 CDIs	2.67%
	MRCF3 (HP) Pty Ltd/ MRCF3 Services (HP) Pty Ltd	MRCF3 (HP) Pty Ltd / MRCF3 Services (HP) Pty Ltd	Power to Control Voting and Disposal of Securities	2,415,200 CDIs	0.89%
	MRCF3 Services Pty Ltd	MRCF3 Services Pty Ltd	Power to Control Voting and Disposal of Securities	7,243,522 CDIs	2.67%
	MRCF3 Services (SW) Pty Ltd	MRCF3 Services (SW) Pty Ltd	Power to Control Voting and Disposal of Securities	2,415,200 CDIs	0.89%
	MRCF3 Services (CSL) Pty Ltd	MRCF3 Services (CSL) Pty Ltd	Power to Control Voting and Disposal of Securities	1,557,250 CDIs	0.57%
	MRCF3 Pty Ltd	MRCF3 Pty Ltd	Power to Control Voting and Disposal of Securities	48,432 CDIs	0.02%
<b>Total</b>					<b>7.73%<sup>1</sup></b>

1. The total percentage of votes held by investors advised or managed by Brandon Capital Partners is 27.76% (inclusive of the votes outlined above).

## M.H. Carnegie Funds

Holder of Relevant Interest	Registered Holder	Person entitled to be Registered Holder	Nature of Relevant Interest	Class and Number of Securities	Person's Votes
Carnegie Healthcare Fund, LP	Carnegie Healthcare Fund, LP	Carnegie Healthcare Fund, LP	Registered Holder	14,952,663 CDIs	5.52%
Carnegie Innovation Fund NO.2, LP	Carnegie Innovation Fund NO.2 LP	Carnegie Innovation Fund NO.2 LP	Registered Holder	14,162,839 CDIs	5.23%
MHC Fund Services 2A Pty Ltd ATF Carnegie Private Opportunities Fund No. 2A	MHC Fund Services 2A Pty Ltd	MHC Fund Services 2A Pty Ltd	Registered Holder	3,323,193 CDIs	1.23%
MHC Fund Services B Pty Ltd ATF MHC Hostplus Co Investment Trust	MHC Fund Services B Pty Ltd	MHC Fund Services B Pty Ltd	Registered Holder	7,833,287 CDIs	2.89%
<b>Total</b>					<b>14.87%</b>

## Split Rock Partners

Holder of Relevant Interest	Registered Holder	Person entitled to be Registered Holder	Nature of Relevant Interest	Class and Number of Securities	Person's Votes
SPVC VI, LLC	SPVC VI, LLC	SPVC VI, LLC	Registered Holder	6,996,473 CDIs	2.58%
Split Rock Partners, LP	Split Rock Partners, LP	Split Rock Partners, LP	Registered Holder	19,732,458 CDIs	7.29%
<b>Total</b>					<b>9.87%</b>

## Distribution of CDIs<sup>1</sup> and Shares

Range	Number	% of issued capital	No. of holders
1 – 1,000	167,115	0.06	240
1,001 – 5,000	2,587,896	0.96	770
5,001 – 10,000	4,607,996	1.69	531
10,001 – 100,000	29,323,171	10.75	959
100,001 and over	234,152,454	86.54	123
<b>Total</b>	<b>270,838,632</b>	<b>100.00</b>	<b>2,623</b>

1. The below holdings do not include CDN.

## Shareholder Information

### Unmarketable parcels

Based on the market price on 12 April 2023, there were 107 security holders holding less than a marketable parcel (i.e. a parcel of securities of less than \$500).

### Distribution of Options

Range	Number	% of Options Issued	No. of Holders
1 – 1,000	500	0.00	1
1,001 – 5,000	10,000	0.03	2
5,001 – 10,000	47,000	0.15	5
10,001 – 100,000	2,367,603	7.52	46
100,001 and over	29,053,903	92.30	29
<b>Total</b>	<b>31,479,006</b>	<b>100.00</b>	<b>83</b>

### Distribution of Warrants

Range	Number	% of Options Issued	No. of Holders
1 – 1,000	720	0.00	1
1,001 – 5,000	17,605	0.09	7
5,001 – 10,000	5,872	0.03	1
10,001 – 100,000	383,205	1.94	9
100,001 and over	19,381,977	97.94	22
<b>Total</b>	<b>19,789,379</b>	<b>100.00</b>	<b>40</b>

## Top 20 Holders of CDIs and Shares

Set out below is a schedule of the 20 largest holders of quoted securities in the Company, including the number and percentage of securities held by those holders as at 12 April 2023. (Related but separate legal entities are not aggregated for the purposes of the table below.)

	<b>Name of Registered Holder</b>	<b>No. of CDIs and Shares held</b>	<b>% of total of CDIs and Shares</b>
1	Split Rock Partners LP	19,732,458	7.29
2	MRCF3 Services (H) Pty Ltd <MRCF3 (H) A/C>	18,480,532	6.82
3	MRCF3 Services (HP) Pty Ltd <MRCF3 (HP) A/C>	16,823,969	6.21
4	Carnegie Innovation Fund No 2 LP	14,162,839	5.23
5	CHV III LP	12,818,782	4.73
6	Argo Investments Limited	9,782,633	3.61
7	MRCF3 Services Pty Ltd <MRCF3 (AS) A/C>	8,782,983	3.24
8	Carnegie Healthcare Fund LP	8,776,909	3.24
9	Emergent Medical Partners II LP	8,479,871	3.13
10	SPVC VI LLC	6,996,473	2.58
11	MHC Fund Services B Pty Ltd <MHC Hostplus Co-Invt A/C>	6,615,306	2.44
12	Carnegie Venture Captial Pty Ltd <Carnegie Healthcare F/LP A/C>	6,175,754	2.28
13	MRCF3 Services (SW) Pty Ltd <MRCF3 (SW) A/C>	6,161,947	2.28
14	MRCF5 Services (TS) Pty Ltd <MRCF5 (TS) A/C>	6,111,111	2.26
15	Mr Allan Will <AR Will U/A DT 6/14/12 A/C>	5,827,224	2.15
16	MRCF3 Services (HP) Pty Ltd <MRCF3 (HP) A/C>	4,709,239	1.74
17	MRCF3 Services (H) Pty Ltd <MRCF3 (H) A/C>	4,638,382	1.71
18	MRCF3 Services (SW) Pty Ltd <MRCF3 (SW) A/C>	4,629,630	1.71
19	BMYG Capital Pty Ltd <BMYG Paramount Fund A/C>	3,316,650	1.22
20	OKS-Clear Ltd	3,286,270	1.21
<b>Total CDIs and Shares held by top 20</b>		<b>176,308,962</b>	<b>65.10</b>
<b>Total CDIs and Shares held by all other holders</b>		<b>94,529,670</b>	<b>34.90</b>
<b>Total</b>		<b>270,838,632</b>	<b>100.00</b>

# Shareholder Information

## Restricted Securities

### ASX Restrictions

The following table shows the number of securities subject to ASX restrictions and the applicable restriction periods. Some of the securities listed in the following table are also subject to the voluntary escrow described below.

<b>Last day of ASX</b>	<b>Number of restricted CDIs</b>	<b>Number of restricted Options</b>	<b>Number of restricted Warrants</b>
23 November 2023	5,785,188	11,546,742	1,104,030
<b>Total</b>	<b>5,785,188</b>	<b>11,546,742</b>	<b>1,104,030</b>

### Voluntary Escrow

The following table shows the number of securities subject to voluntary escrow and the applicable escrow periods. Some of the securities listed in the following table are also subject to the ASX restrictions described above.

<b>Last day of voluntary escrow</b>	<b>Number of escrowed CDIs</b>	<b>Number of escrowed Options</b>	<b>Number of escrowed Warrants</b>
23 November 2023	114,221,926	21,997,408	18,486,748
<b>Total</b>	<b>114,221,926</b>	<b>21,997,408</b>	<b>18,486,748</b>

### Voting Rights

Every holder of Shares present in person or by proxy is entitled to one vote for each Share held on the record date for the meeting on all matters submitted to a vote of Shareholders.

CDI holders may attend and vote at the Company's general meetings. The Company must allow CDI holders to attend any meeting of Shareholders unless relevant US law at the time of the meeting prevents CDI holders from attending those meetings.

In order to vote at such meetings, CDI holders may:

- instruct CDN, as the legal owner, to vote the Shares underlying their CDIs in a particular manner. A voting instruction form will be sent to CDI holders with the notice of meeting or proxy statement for the meeting and this must be completed and returned to the Registry before the meeting;
- inform the Company that they wish to nominate themselves or another person to be appointed as CDN's proxy for the purposes of attending and voting at the general meeting; or
- convert their CDIs into a holding of Shares and vote these at the meeting. Afterwards, if the former CDI Holder wishes to sell their investment on the ASX it would need to convert the Shares back to CDIs. In order to vote in person, the conversion from CDIs to Shares must be completed before the record date for the meeting.

One of the above steps must be undertaken before CDI holders can vote at Shareholder meetings.

Proxy forms, CDI voting instruction forms and details of these alternatives will be included in each notice of meeting or proxy statement sent to CDI holders by the Company.

Holders of issued but unexercised options and warrants are not entitled to vote.



## Australian Corporate Governance Statement

The Board of Directors has confirmed that the Company's corporate governance framework complies in almost all respects with the ASX's Corporate Governance Council's *Corporate Governance Principles and Recommendations* (4th Edition) (**Recommendations**) and that where it does not comply, it is due to the current relative size of the Company, its stage of development, and the scale and nature of its operations.

The Company's Corporate Governance Statement and further details in relation to the Company's governance framework are set out in a dedicated corporate governance information section of the Company's website <https://ebrsystemsinc.com/investors/>. This section of the Company's website contains copies of all of the corporate governance policies and Board Committee charters.

## Required Statements

- a. There is no current on-market buy-back of the Company's securities.
- b. The Company is incorporated in the state of Delaware in the United States of America.
- c. The Company is not subject to Chapters 6, 6A, 6B and 6C of the *Corporations Act 2001* (Cth) dealing with the acquisition of shares (ie, substantial holdings and takeovers).
- d. The Company's securities are not quoted on any exchange other than the ASX.
- e. Under the Delaware General Corporation Law, shares are generally freely transferable subject to restrictions imposed by US federal or state securities laws, by the Company's certificate of incorporation or bylaws, or by an agreement signed with the holders of the shares at issue. The Company's amended and restated certificate of incorporation and bylaws do not impose any specific restrictions on transfer. The Company's CDIs were issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (**US Securities Act**) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of the Company's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the US Securities Act or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a "FOR US" designation on the ASX. This designation restricts any CDIs from being sold on the ASX to US persons. However, you still may freely transfer your CDIs on the ASX to any person other than a US person. In addition, hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.
- f. Since the Company's listing on ASX in November 2021, it has used the cash it had at the time of admission in a way consistent with its business objectives.
- g. The name of the Australian Company Secretary is Brendan Case. The name of the US Company Secretary is John Sellers.
- h. The address and telephone number of the Company's registered office in Australia is:  
Level 13, 41 Exhibition Street  
Melbourne, Victoria 3000  
+ 61 410 442 393

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# Corporate Directory

## Board of Directors and Secretaries

Allan Roger Will,  
Executive Chair

John Graham McCutcheon,  
President, CEO and executive director

Christopher Dean Nave,  
non-executive director

Trevor John Moody,  
non-executive director

Bronwyn Joy Evans,  
non-executive director

David Mark Steinhaus,  
non-executive director

Karen Ruth Drexler,  
non-executive director

Brendan Case,  
Australian Company Secretary

John H. Sellers,  
United States Company Secretary

## Executive Team

Allan Roger Will,  
Executive Chair

John Graham McCutcheon,  
President, CEO and director

Frank Hettmann,  
Chief Financial Officer

## Company – US Office & Headquarters

480 Oakmead Parkway,  
Sunnyvale, CA 94085,  
United States  
Tel: +1 (408) 720-1906

Website ERL: <https://ebrsystemsinc.com/>

## Company Address of Registered Office

251 Little Falls Drive,  
Wilmington, DE 19808,  
County of New Castle,  
USA

## Company – Registered Office in Australia

Level 13, 41 Exhibition Street  
Melbourne, Victoria 3000  
Tel: + 61 410 442 393

## US Auditor

Deloitte & Touche LLP  
100 South Mill Avenue  
Suite 1800  
Tempe, AZ 85281-2904  
USA

Tel: +1 602 234 5100  
[www.deloitte.com](http://www.deloitte.com)

## Name of Securities Registry

### CDI Registry:

Computershare Investor Services Pty Limited  
GPO Box 2975  
Melbourne, Victoria 3001  
Australia

### Share Registry:

Computershare Trust Company, N.A.  
150 Royall Street  
Canton, Massachusetts 02021  
USA

### Computershare Investor Services Pty Limited:

Tel: 1300 850 505 (within Australia) or  
Tel: +61 3 9415 4000 (outside Australia)

## Investors Relations

Joel Seah  
Vesparum Capital  
Tel: (61) 3 8582 4800  
[EBRSystems@vesparum.com](mailto:EBRSystems@vesparum.com)

## ASX Code

EBR

## Annual Meeting of Stockholders Date and Place

The Annual Meeting of stockholders will be held as a virtual meeting on Tuesday, 23 May 2023 at 9:00am Australian Eastern Standard Time (Monday, 22 May 2023 at 4:00pm U.S. Pacific Daylight Time).

