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Annual Report

2021



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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.

Letter from the Executive Chair



On behalf of the Board of Directors and management of EBR Systems, Inc (), I am excited to present EBR's first public annual report for the 2021 financial year.

EBR is focused on the development of WiSE® – the world's first and only inside-the-heart leadless cardiac pacing device for heart failure. Most patients with heart failure require a treatment called cardiac resynchronisation therapy (CRT), to stimulate the left ventricle and coordinate the beating of the left and right sides of the heart. Traditional CRT devices use leads (wires) to deliver energy to the heart; however, many patients are unable to receive effective CRT because their anatomy or disease prevents the use of leads. Our WiSE® device provides an alternative solution by providing leadless CRT to patients who would otherwise suffer poor prognosis. In 2022, we received FDA approval for the inclusion of other commercially available leadless pacemakers in the SOLVE-CRT pivotal trial which increased our initial addressable market by ~US\$400m, taking us to a US\$2.5bn¹ annual addressable market in 2024.

EBR made headway late last year with its admission to the official list of the Australian Securities Exchange (ASX) on 24 November 2021. This was underpinned by a successful A\$110m Initial Public Offering (IPO), which was strongly supported by our earlier venture investors including M.H Carnegie & Co, Brandon Capital and superfunds Australian Super, HESTA, Hostplus and Statewide Super, who collectively contributed more than A\$30m. We received significant investor interest and were pleased to welcome a host of other institutional and retail shareholders to the register. The funds raised will be allocated towards the Company's SOLVE-CRT pivotal trial, pursuing FDA approval, and to support commercialisation of WiSE® in the U.S. and other initial target markets.

The market has indeed been turbulent since we became public. Nonetheless, we have remained resilient and continue to be on track to meet our goals as outlined in the prospectus, with the Company rapidly embracing virtual and remote working practises operationally. The pandemic has had no material impact on SOLVE-CRT pivotal trial recruitment, which is still scheduled to complete by the first half of 2022. EBR is led by a highly experienced management team with significant expertise in the development, scale and commercialisation of medical device technologies. I have the highest confidence in this team's ability to advance WiSE® from development through to commercialisation and ultimately help patients suffering from heart failure.

Currently, our key focus areas are completing the SOLVE-CRT pivotal trial, research and development, and preparing for commercialisation. We continue to expand and establish our internal sales force with the aim of targeting high volume CRT procedure sites in the US and key target markets. This will be supported by the relationships we have fostered with clinical sites who have historically participated in our clinical trials. In addition to this, we have a comprehensive regulatory strategy and have a well-established and open line of communication with the FDA with priority review of regulatory submissions due to our Breakthrough Device Designation.

I would like to take this opportunity to thank my fellow Board members, our CEO and President John McCutcheon, and the entire EBR Systems team for their continuous devotion and determination. We also welcomed three new Board members in 2021: Dr Bronwyn Evans, Dr David Steinhaus and Ms Karen Drexler, who bring a wealth of clinical and commercial experience across the healthcare industry, which are of significant value to EBR. Their guidance and leadership will be critical as EBR embarks on its next growth phase. I would like to finally thank our shareholders, for their extensive and ongoing support. We look forward providing further updates on the Company's progress.

Yours sincerely,

A handwritten signature in black ink that reads "Allan Will". The signature is written in a cursive, slightly slanted style.

ALLAN WILL
Executive Chair, EBR Systems Inc.

1. Other pages in this document contain references to EBR Systems' initial addressable market pre-FDA approval for the inclusion of other leadless pacemakers, which is US\$2.1bn annually.

Letter from the CEO



Last year was a defining year in EBR Systems, Inc's (EBR) trajectory, with its transformation from a private company to a publicly listed company on the Australian Stock Exchange. I feel privileged to lead the Company during such an exciting and pivotal period, and I am committed to see WiSE[®] through to becoming an accessible, commercially available product for people who are unable to receive effective cardiac resynchronisation therapy (CRT). The first clinical trial for WiSE[®] was conducted in 2011 and today we are conducting our final pivotal study and are well positioned to commercialise our proprietary technology by the end of 2023.

During the year, our operating expenses reached US\$22.8m, an increase of US\$2.2m compared to the prior year. This was underpinned by an increase in field expenses to continue the SOLVE-CRT pivotal trial and to increase the number of clinical sites participating in the trial. We ended the year with a cash position of US\$78.2m, strengthened significantly by the IPO.

Our key focus has been progressing the SOLVE-CRT pivotal trial. The randomised phase (first phase) of the SOLVE-CRT pivotal trial was completed in 2020 and the single-arm phase (second phase) is currently recruiting patients and is set to finish enrolment for interim analysis by the first half of 2022. Previous clinical trials of WiSE[®] exceeded the efficacy and safety performance goals set for the current pivotal trial, and the FDA has provided extensive guidance with regards to the trial design, de-risking the clinical and regulatory pathways to commercialisation.

Our current initial addressable market is US\$2.5bn¹ annually, which we estimate will grow to approximately US\$7.1bn by expanding the use of WiSE[®] into other patient groups and geographies. To support this growth potential, EBR continued its collaboration on two other, investigator-initiated clinical projects which may lead the way to expanded indications.

The first is the Totally Leadless CRT trial which pairs WiSE[®] with a leadless intracardiac pacemaker, and the second is the Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT) study which will evaluate the ability to activate the heart's native conduction system with WiSE[®]. These additional studies address patient groups outside the current core focus of lead failures and upgrades, which pave the way for WiSE[®] to become a de-novo treatment option for heart failure patients.

On top of this, we strengthened our management team with the appointment of Mr Michael Hendricksen as Chief Operating Officer, Mr Steve Sandweg as Chief Commercial Officer and the promotion of Ms Madhuri Bhat to Chief Regulatory Officer. I am extremely proud of the team's achievements over 2021 and I believe the senior management team is best placed to deliver on our goals and drive clinical development and commercialisation activities forward.

I would like to thank the Board, for their ongoing counsel, the EBR team, for their hard work and dedication, and our shareholders for their optimism and support. We are committed to building a sustainable company that delivers better and safe treatment options for patients.

Yours sincerely,

JOHN McCUTCHEON

President & CEO, EBR Systems Inc.

1. Other pages in this document contain references to EBR Systems' initial addressable market pre-FDA approval for the inclusion of other leadless pacemakers, which is US\$2.1bn annually.

Operational Highlights

FY21 Financials

Operating expenses

US\$22.8m

Cash position

US\$78.2m

(at 31 Dec 2021)

Net cash used in operating activities

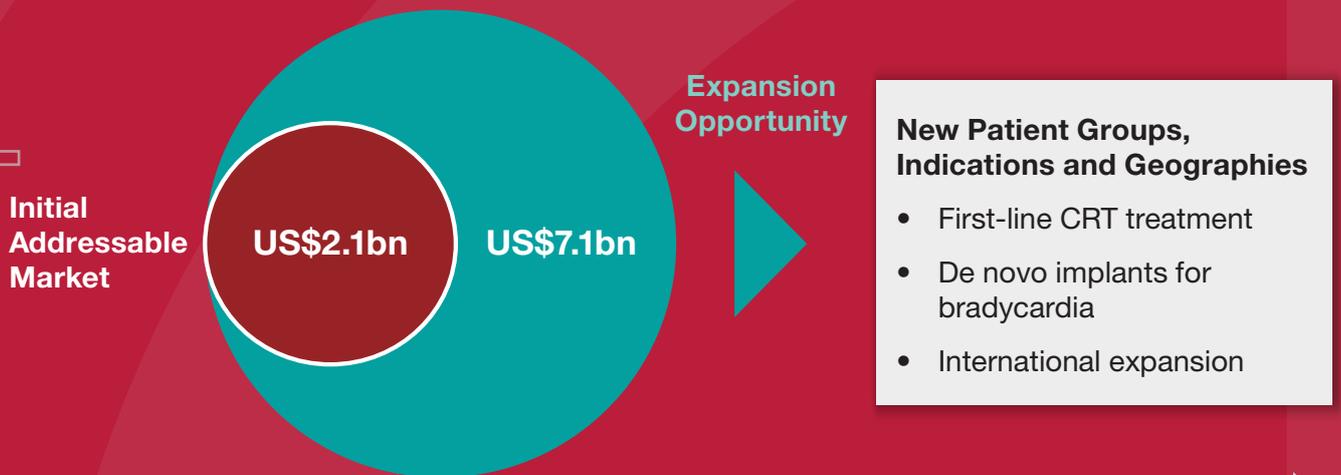
US\$22.2m

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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



Rapid adoption of wireless devices supports strong 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 2021

Operational milestones:

- Performed world's first leadless left bundle branch area pacing implant utilising WiSE CRT System
- Successful completion of a A\$110m initial public offering on the ASX in November 2021
- Advanced recruitment for SOLVE-CRT pivotal trial, with enrolment expected to complete in H1 2022
- Received FDA approval to include other commercially available leadless pacemakers in the SOLVE-CRT pivotal trial
- Continued execution of commercial strategy and fostering relationships with US clinical sites
- Progressed preparation activities for investigator-initiated studies in expanded indications: the Totally Leadless CRT (TLC) study and the Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT) study
- Strengthened management team by the appointment of Mr Steve Sandweg as Chief Commercial Officer, Mr Michael Hendricksen as Chief Operating Officer and promotion of Ms Madhuri Bhat to Chief Regulatory Officer
- Featured clinical studies in several peer-reviewed publications, including results from part 1 of SOLVE in the Heart Rhythm Journal
- Appointed industry experts Dr Bronwyn Evans, Dr David Steinhaus and Ms Karen Drexler to the Board of Directors as Independent Non-Executive Directors

Successful A\$110 million IPO on the ASX: In November 2021, EBR Systems listed on the Australian Securities Exchange (ASX) following the successful completion of an initial public offering ("IPO") that raised approximately A\$110 million through the offer of 101,851,851 CDIs at the offer price of A\$1.08. The IPO was strongly supported by institutional and sophisticated investors, including existing Australian shareholders such as M.H. Carnegie & Co, Brandon Capital and superfunds AustralianSuper, HESTA, Hostplus and Statewide Super, who collectively contributed more than A\$30 million, in addition to a broad range of new institutional and high net worth investors.

Proceeds raised will be primarily used to provide EBR with funding to support its growth strategies, including the clinical development of EBR's proprietary Wireless Stimulation Endocardially ("WiSE") device, expanding EBR's sales and marketing resources, manufacturing capacity, and investment into research and development to improve EBR's technologies.

World's first leadless LBBAP: Over the last 12 months, Professor Pascal Defaye, Head of Rhythmology and Cardiac Stimulation Unit, CHU de Grenoble-Alpes, France, performed the world's first successful leadless Left Bundle Branch Area Pacing (LBBAP) implant utilising the WiSE CRT System. The implant marks a significant achievement in the approach to physiological conduction system pacing. LBBAP pacing has been proposed as a strategy to achieve physiological pacing by utilising the heart's native conduction system, allowing faster left ventricular activation time. LBBAP has potential

For personal use only applications in both traditional bradycardia pacing and as an alternative approach to Cardiac Resynchronisation Therapy (CRT). Until now, LBBAP has required use of a conventional pacing lead, driven deep into the ventricular septum, which can be technically challenging. Leadless LBBAP has the potential to provide superior resynchronisation versus conventional CRT in select patients.

Progress in the SOLVE-CRT Pivotal trial: 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. EBR estimates that these indications have an initial addressable market of US\$2.1 billion in the Company's initial target markets of US, Germany, France, UK, Australia, Benelux and Scandinavia. 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 performance goal is less than 30% of patients with device or procedure-related complications. Such results were achieved and exceeded in a previous clinical study conducted by EBR, the SELECT-LV study, that was used to gain CE Mark approval Recruitment for final efficacy.

In March 2022, EBR received US FDA approval to include commercially available leadless pacemakers as co-implants for the WiSE® CRT System in the pivotal trial. This update meets a significant unmet clinical need by providing a solution to patients requiring CRT with leadless pacemakers who have no other upgrade options. This expands EBR's initial addressable market by US\$400m with further growth potential as other leadless pacemakers come to market. The timing and funding requirements for the pivotal trial will not be impacted by this and interim safety results in the pivotal trial is scheduled to complete as expected in H1 2022 with headline results expected 3-4 months post follow-up completion.

Advancement towards US Commercialisation: Throughout 2021, EBR focused on advancing its pivotal trial to target US FDA PMA submission in H1 2023. For its initial commercial launch, EBR will focus on driving adoption of WiSE at key, high-volume, luminary sites within the US followed by select, high-volume outside-of-US (OUS) sites. Initial adoption will be from sites who have participated in the EBR's clinical trials, which is expected to involve up to 45 US sites. EBR has fostered strong relationships with these sites, all of which are leaders in cardiac medicine and will assist with promoting and building credibility for WiSE.

Expansion of clinical portfolio and new indications: During the 12 months, EBR continued its collaboration on two other, investigator-initiated clinical projects: Totally Leadless CRT (TLC) and Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT). TLC is expected to add to EBR's already published experience of pairing the leadless WiSE with a leadless intracardiac pacemaker, which has previously demonstrated strong safety and efficacy results. ACCESS-CRT will evaluate the ability to activate the heart's native conduction system with

WiSE. EBR hopes that these prospective, non-randomised studies could lead the way to expanded indications. The two studies are expected to commence in H1 2022 in Australia and Europe.

Clinical studies in publications: The Heart Rhythm Journal featured EBR's initial experience and results from part 1 of the SOLVE-CRT pivotal study (roll-in phase), which demonstrated favourable clinical responses in heart failure symptoms and significant left ventricle reverse remodelling, as well as a high success rate of WiSE endocardial placement in centres with no prior implanting experience. In addition, a smaller study which confirmed the technical feasibility of delivering leadless LBBAP using the WiSE-CRT system was published in the European Heart Journal. The European Society of Cardiology also published a paper which found that WiSE-CRT upgrades had high rates of procedural success and similar improvements compared to coronary sinus upgrades in clinical composite score and a left ventricle remodelling.

Corporate Update: In 2021, EBR appointed Mr Michael Hendricksen as Chief Operating Officer ("COO") and Mr Steve Sandweg as Chief Commercial Officer ("CCO") and promoted Ms Madhuri Bhat to Chief Regulatory Officer ("CRO"). Michael has over 25 years of experience in product development and manufacturing of medical devices and previously served as COO at Ceterix Orthopaedics (Ceterix). Steve has 30 years of sales and commercialisation experience in Fortune 500 medical technology companies, having recently served as General Manager for Keystone Heart. Madhuri was promoted to CRO from her previous position as Senior Vice President of Regulatory & Compliance, Quality, and Clinical for EBR.

EBR also made several appointments to the Board following the departures of Mr Dave Stassen and Dr Leighton Reed. EBR welcomed Dr Bronwyn Evans, Dr David Steinhaus and Ms Karen Drexler to EBR's Board as independent Non-Executive Directors.

Outlook: EBR is in its final phase of recruitment for the SOLVE-CRT pivotal study, with completion of recruitment expected in H1 2022. EBR expects to announce headline data for the trial in H2 2022 and submit a PMA application in H1 2023 for U.S. FDA approval expected in H2 2023.

Pacing induced heart failure is an unresolved problem which results in poor patient outcomes and potentially severe heart complications. EBR provides the only wireless solution as it has been clinically tested to show effective synchronisation of the left ventricle to the pacing pulse of any pacing system. Overall, EBR faces an initial \$2.1 billion dollar market opportunity and is committed to expanding its reach globally to provide leadless CRT.

EBR remains focused on supporting clinical sites and patient implants and will continue its ongoing business activities including presentations at high profile cardiology conferences, investor conferences and multiple publications in medical & scientific journals.

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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\$2.1 billion in the Company's major target markets of the U.S., Germany, France, the U.K., Australia and other select E.U. countries (see also Section 4.2.6). 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 is conducting a pivotal clinical study that is expected to complete patient recruitment in H1 2022 and will provide headline data in H2 2022 in support of an application in H1 2023 for FDA approval in the U.S. of WiSE[®]. The Company is anticipating WiSE[®] will receive FDA approval in H2 2023 and launch commercially in the U.S. soon after. WiSE[®] has already received CE Mark approval and the Company plans to commercialise the device in Australia and certain European countries following its initial launch in the U.S.

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.

WiSE® Technology Overview

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:

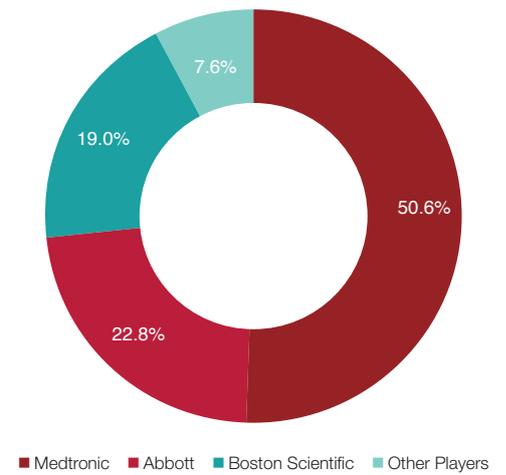
- **Pacemakers:** which stimulate contractions of the heart if it slows or becomes irregular;
- **Defibrillators:** which deliver an electric shock to reset the heart rhythm when certain types of cardiac arrhythmia occur; and
- **CRT devices:** which synchronise the contraction of the left and right 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 ¹ (US\$)	Company	Company Reporting Segment
\$5.1 billion	Medtronic	Cardiac Rhythm & Heart Failure ²
\$1.9 billion	Abbott	Rhythm Management
\$1.7 billion	Boston Scientific	Cardiac Rhythm Management

CRT Market share 2015-2018³



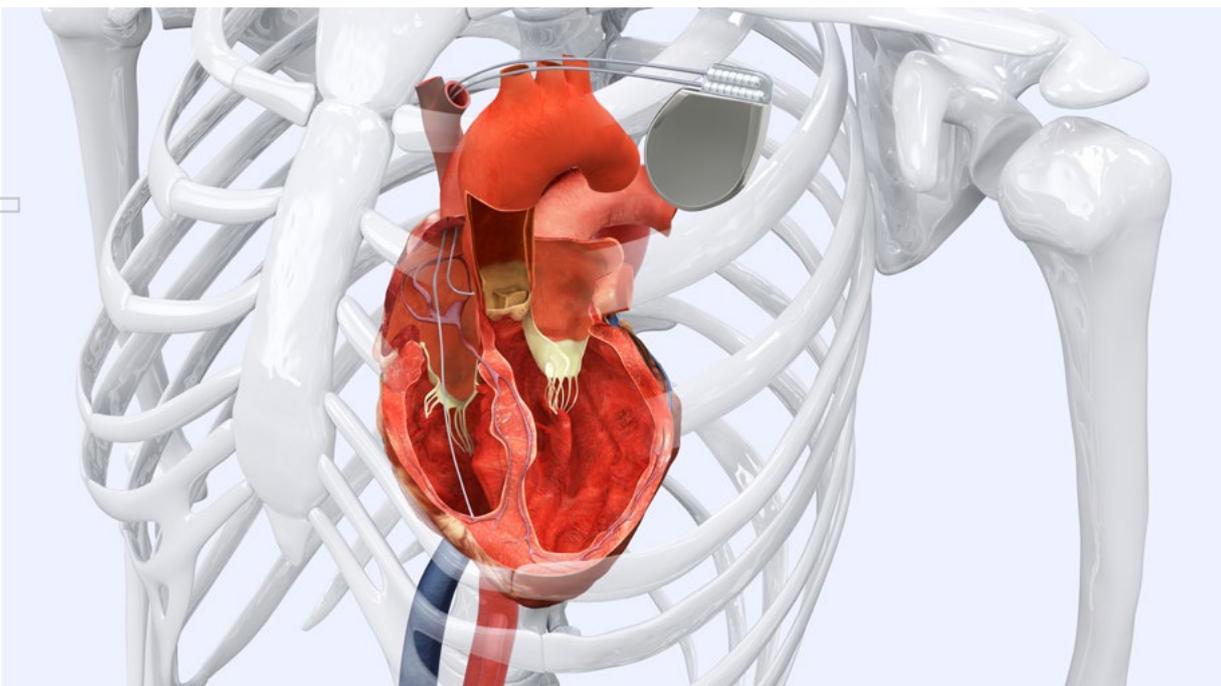
Based on CRT market share estimates and reported segment numbers, CRM devices in 2020 is estimated at US\$7.5 billion – US\$8.5 billion.

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)



WiSE® Technology Overview

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. See Section 2.7 for an overview of the key players and their products in the leadless market for cardiac pacing.

Increasing use of leadless pacemakers

Major players have introduced leadless pacing technology:

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

However, the size of leadless pacemakers restricts use to right ventricle (RV) & 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. See Section 2.8.1 for further details.

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.

WiSE® Technology Overview

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.

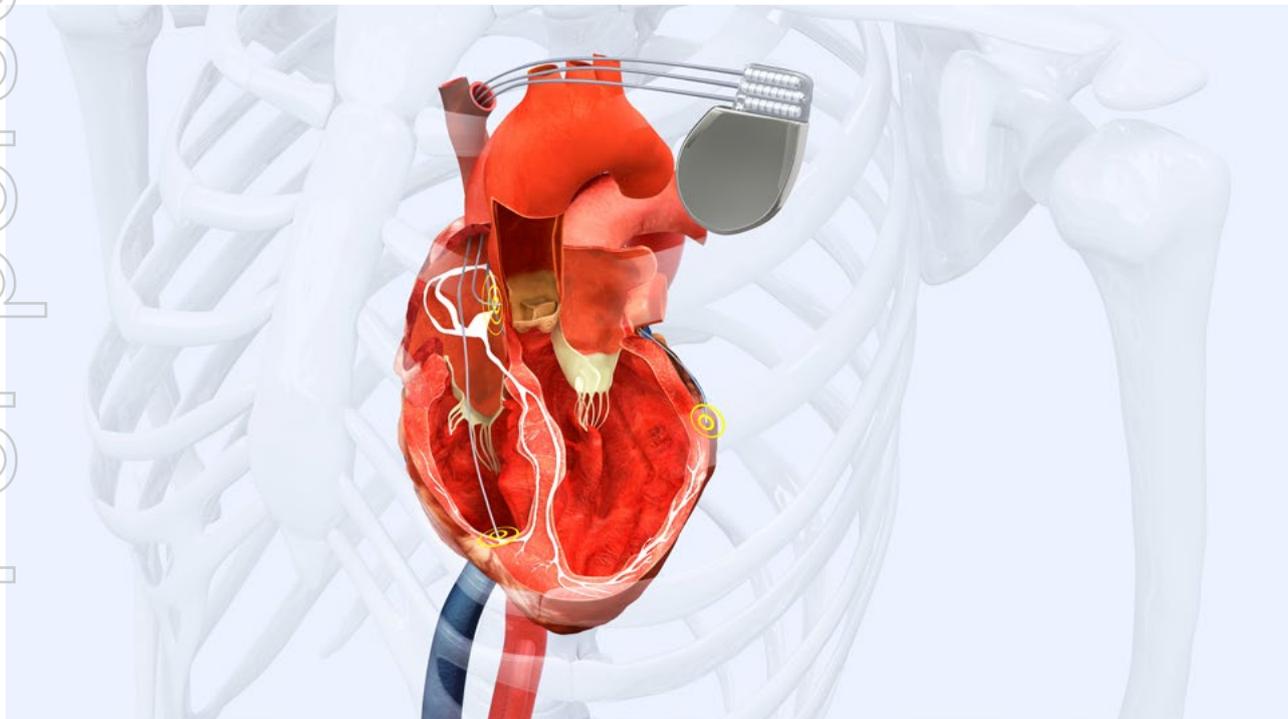
Current Limitations to Providing CRT

(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

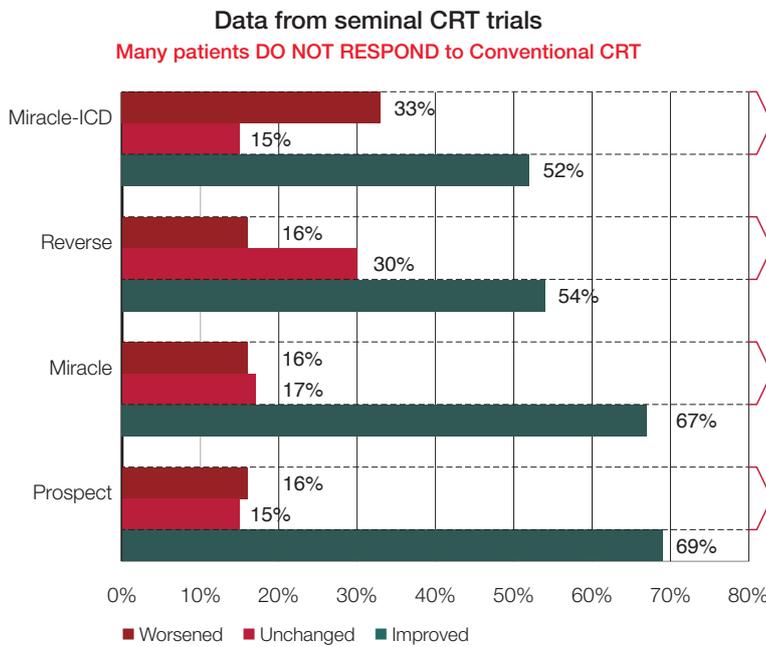
Patients with pacemakers and defibrillators can progress to develop heart failure that requires BiV pacing. It is estimated that up to 60% of patients who require an upgrade from an existing pacemaker are at greater risk of complications from a lead-based CRT device due to potential problems arising 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) Failure to Respond

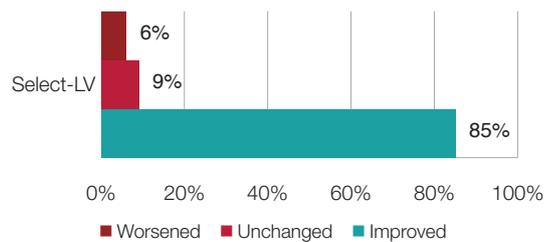
Approximately 30% of patients implanted with a CRT are classified as ‘non-responders’ (NR) to CRT. Non-response to CRT may occur due to multiple factors. However, the technical constraints of traditional, transvenous epicardial CRT mean those factors can be challenging to overcome. A recent study looking 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.

Delivering CRT to Non-Responders Using WiSE®



Data from 35-patient SELECT-LV clinical trials
WiSE® in Failed, Conventional CRT (N=35)



85%
of patients experienced persistent
Clinical benefits at 6-months
(N=33)

Source: EBR, Reddy et al (2017) J. Amer. Coll. Cardiol. 17:2119-29

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. See Section 3.5.1 for further details.

(d) 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.

WiSE® Technology Overview

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.

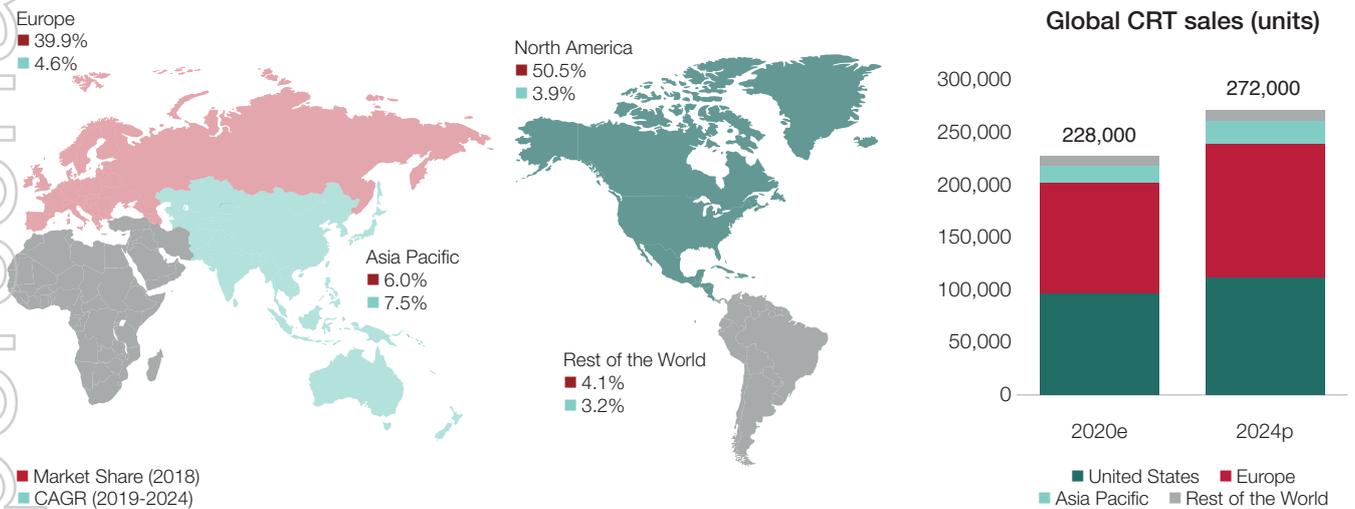
Many pacemaker-related complications arise from this basic design, in particular from the use of leads. This has driven the recent evolution of pacemaker systems which do not require leads.

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).

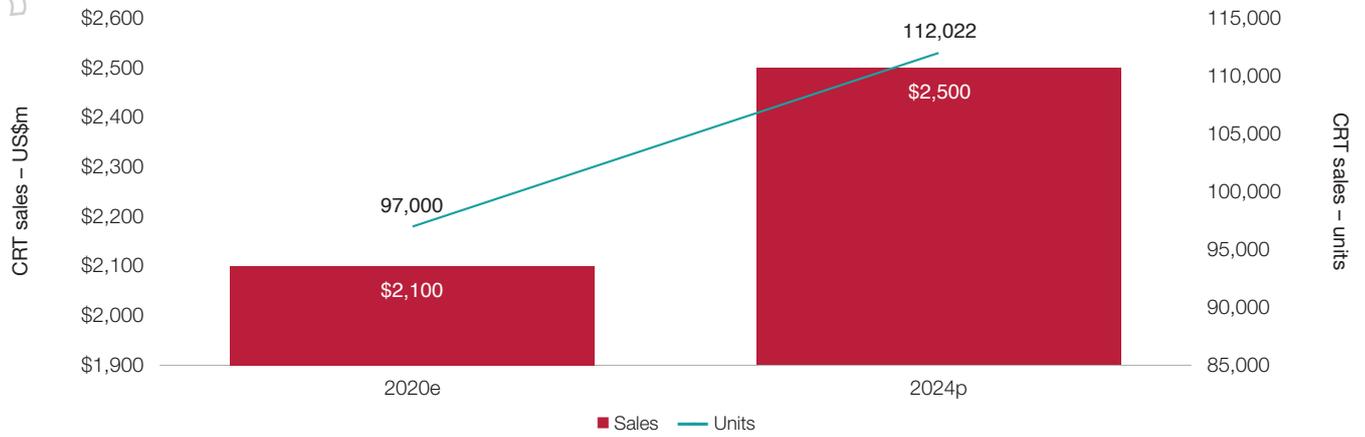
The CRT market is dominated by three companies: Medtronic plc (Ireland), Abbott Laboratories (U.S.), and Boston Scientific Corporation (U.S.). These companies accounted for over 90% of the global CRT market in 2018.

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%.

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CRT sales in North America

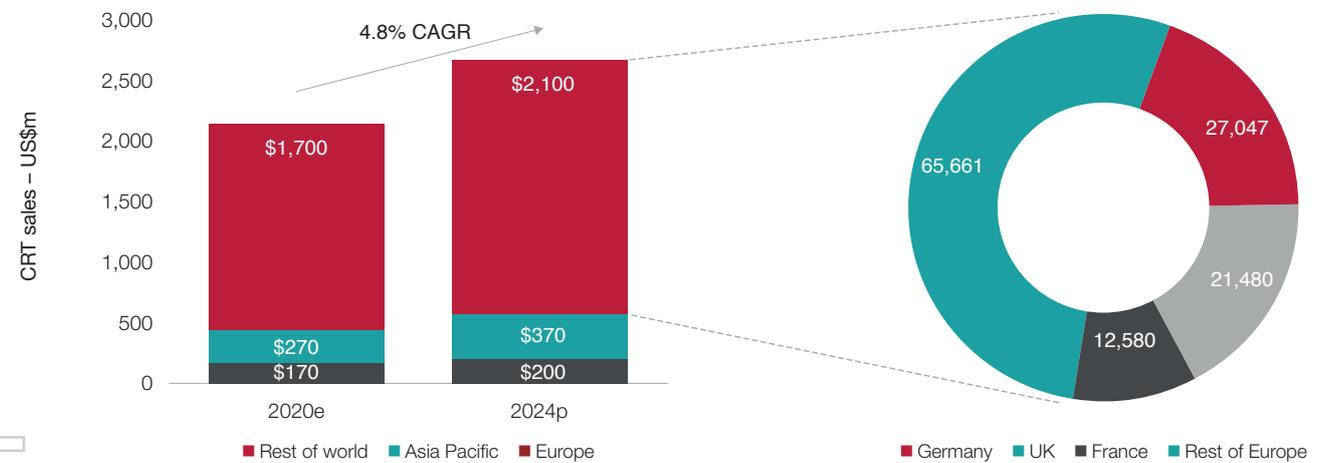


Source: MarketAndMarkets: Cardiac Resynchronisation Therapy Market (2019), Global Forecast to 2024.

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.

WiSE® Technology Overview

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\$2.1 billion in the Company's initial target markets of the U.S., Germany, France, the U.K., Australia, Benelux and Scandinavia (see also Section 4.2.6).

Initial Target Patient Groups for WiSE®

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

- Acute Lead Failures (**LF – acute**);
- Chronic Lead Failures (**LF – chronic**); and
- High risk upgrades (**HRU**).

(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.

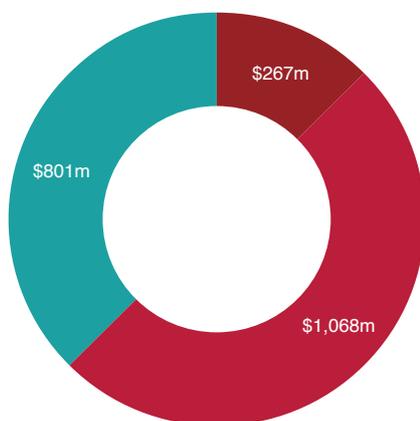
(c) High Risk Upgrades

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.

Initial addressable market for WiSE®

EBR estimates that the value of its initial addressable markets for WiSE® in 2024 will be approximately US\$2.1 billion, as described in further detail below (see also Section 4.2.6).



■ Acute Lead Failure ■ Lead Failure – Chronic ■ High Risk Upgrades

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

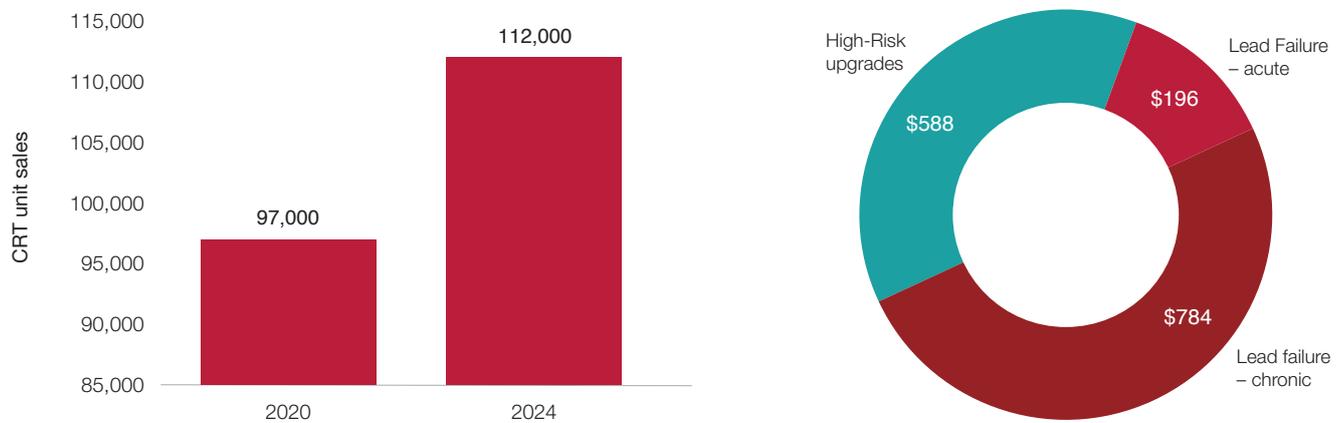
(a) Initial U.S. Target Market for WiSE®

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, and HRU 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\$1.568 billion and accounts for 73% of EBR's total initial target addressable market.

U.S. Addressable Market Opportunity for WiSE®



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 (discussed in detail at Section 3.4.2).

(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®.

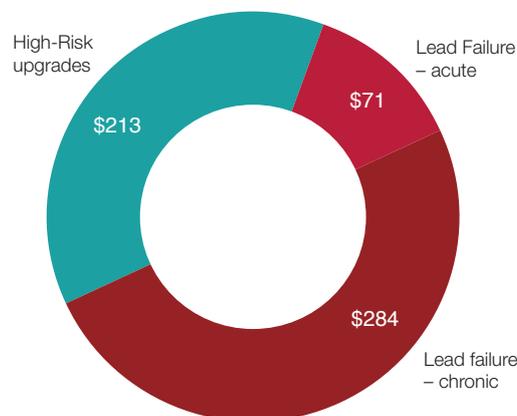
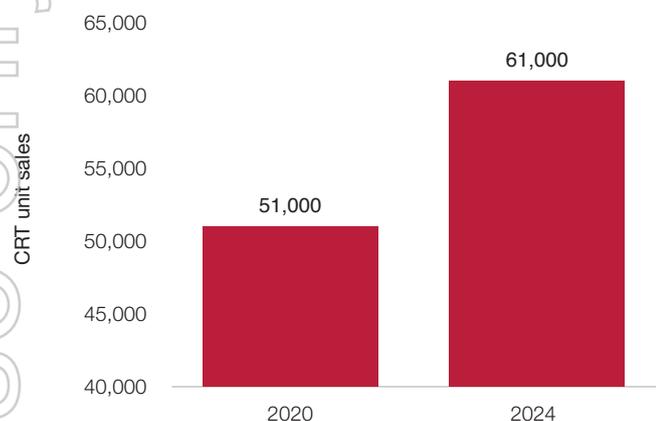
In addition to Germany, France and the U.K., EBR intends to target Australia, Benelux (Belgium, The Netherlands, and Luxembourg), and Scandinavia (Denmark, Sweden, Norway and Finland) for the initial commercialisation of WiSE®. Based on hospital CRT implantation rate data compiled by the Company, EBR 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\$568 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.

WiSE® Technology Overview

Addressable market opportunity for WiSE® in key OUS markets



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

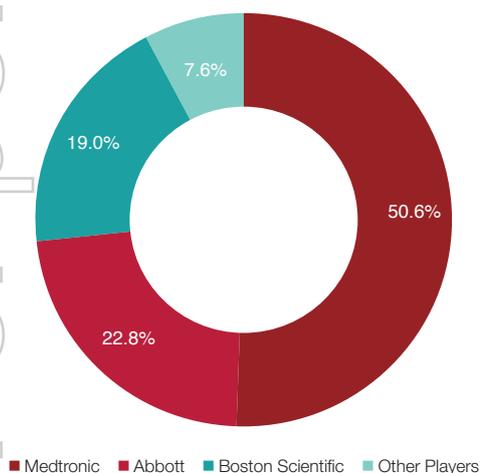
Based on CRT implantation data compiled by the Company regarding the markets of Germany, France and the U.K., around 50% of CRT implantations are conducted by 50-80 hospitals in each of the large OUS countries (i.e., 150-240 sites in total). In the other OUS country markets, around 50% of CRT implantations 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® device since it received FDA approval in 2016.

Leadless Pacemakers for Cardiac Pacing

<p>IPG DEVICE</p> <p>RA LEAD</p> <p>LV (CS) LEAD</p> <p>RV LEAD</p>	<p>Bradycardia <i>RV and RA Pacing only</i></p>  <p>Medtronic Micra®</p>  <p>Boston Scientific Empower®</p>  <p>Abbott Aveir®</p>
	<p>Sudden Cardiac Death Risk <i>Defibrillation</i></p> <div style="display: flex; justify-content: space-around;"> <div style="background-color: #008080; color: white; padding: 5px; text-align: center;">image to find?</div> <div style="background-color: #008080; color: white; padding: 5px; text-align: center;">image to find?</div> </div> <p>Boston Scientific Emblem®</p> <p>Medtronic EV ICD®</p>
	<p>Heart Failure <i>CRT and Septal Pacing</i></p>  <p>EBR Systems WiSE®</p>

WiSE® Technology Overview

Medtronic – Micra® Implant

Medtronic's Micra® implant is the only leadless pacemaker that is 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.

Medtronic announced that the quarterly sales of Micra® in the March 2021 quarter had grown by 74% and were annualised at US\$400 million. For the June 2021 quarter, Medtronic reported Micra® sales had increased by over 30% from the preceding quarter.

Abbott – Aveir® Implant

Abbott's Aveir® leadless pacemaker is currently in a 615-patient clinical trial that is scheduled to complete in 2022. This leadless pacemaker is based on the NanoStim™ pacemaker that was acquired in 2013 by St Jude Medical which Abbott later acquired in 2017. NanoStim received conditional approval from the FDA in 2013 but was withdrawn from the market in 2016 due to issues with its battery. As with Micra®, Aveir® can only be implanted in the right ventricle due to its size.

Boston Scientific – Empower® Implant

Boston Scientific's leadless Empower® pacemaker is currently in a 500-patient clinical trial with a primary completion data scheduled for 2023. As with the other leadless pacemakers, Empower® can only be implanted in the right ventricle due to its size.

Opportunity for WiSE®

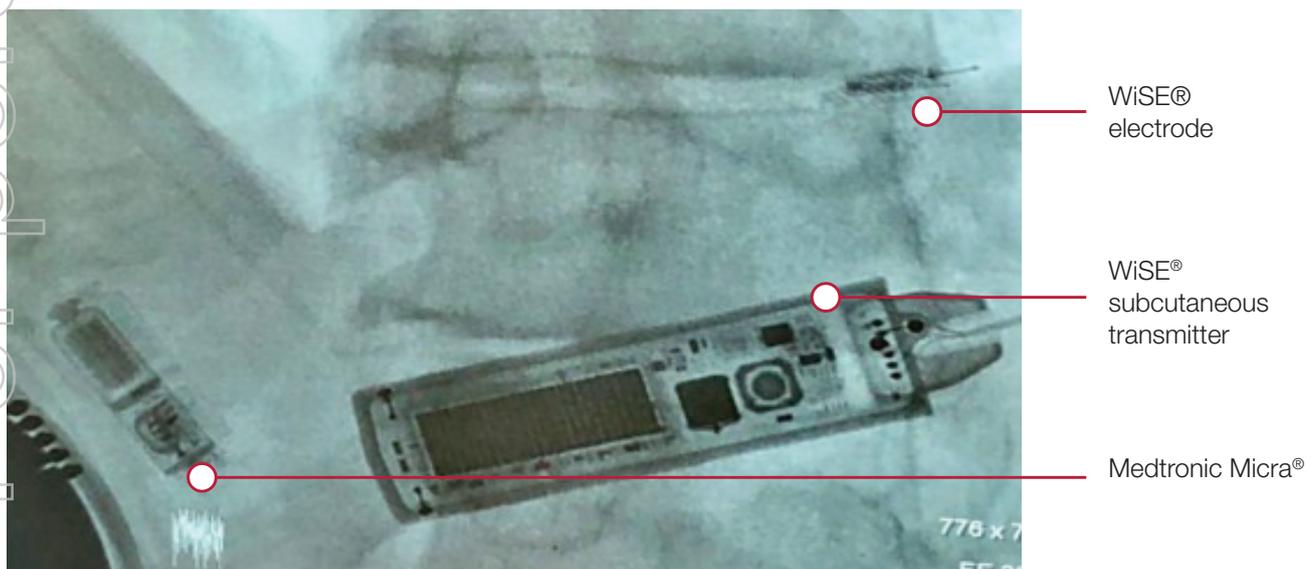
While Medtronic's Micra® is the only leadless pacemaker for right ventricle bradycardia pacing currently on the market, it is anticipated that the eventual entry of Abbott and Boston Scientific could further increase the adoption of leadless pacemakers.

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.

An 8-patient clinical study has 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\$2.1bn initially.



EBR initially targeting patients unable to receive CRT from existing devices and 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.

CTR 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 patients group

Acute Lead Failure

Unable to implant CRT wire in a new CRT patient

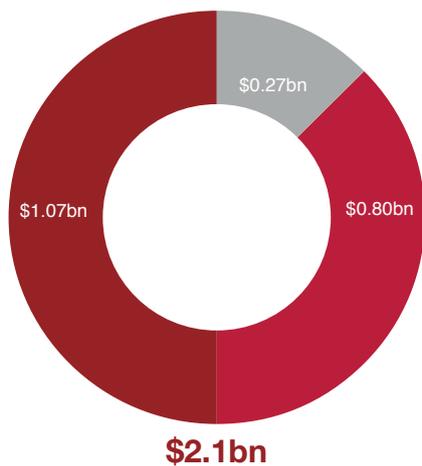
High Risk Upgrades

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

Chronic Lead Failure

Traditional CRT system implanted but has ceased to provide effective CRT

Initial Addressable Market (US\$)



■ Acute Lead Failure ■ High Risk Upgrades ■ Chronic Lead Failure



EBR Systems

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Directors' Report and Financial Statements – 31 December 2021

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.

Remuneration Report

Employment arrangements with President and Chief Executive Officer

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

Following the Company's listing, 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 has previously been granted Options under the Company's 2013 Plan (further details follow in the table below).

Mr McCutcheon's was granted a total of 304,719 Options in FY21 (further details follow below).

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 is employed as the Company's Chief Financial Officer. Following the Company's listing, 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 has been granted a total of 1,916,640 Options under the Company's 2013 Plan.

Mr Hettmann was granted a total of 1,916,640 Options in FY21.

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.

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\$4,853.33 per month (equivalent to US\$58,240 on an annualised basis). Following completion of the Offer, the Company granted Mr Will Options. Details of Mr Will's holding of Options are set out below.

Mr Will has previously been granted Options under the Company's 2013 Plan (further details follow in the table below).

Mr Will was granted a total of 171,121 Options in FY21 (further details follow in the table below).

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).

Mr Moody has directed the Company to pay his director fees to Australian Medtech Services Pty Ltd, a company in which Mr Moody is a director and shareholder (through TM Strategic Advisors LLC). 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 and Mr Moody, those Directors' nominees) receive a grant of Options following completion of the Offer. The Non-executive Directors may also receive future grants of securities subject to the Listing Rules and Board approval.

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.

Directors' interests in securities

The table below sets out the direct and indirect interests of the Directors in the securities of EBR as at the date of this Prospectus and following completion of the Offer and U.S. Private Placement, including the fully diluted percentage holdings these interests represent at Listing.

Remuneration Report

The terms of the grants are described below:

Grant date	22 November 2021
Recipients	Each Director individually except for Dr Nave and Mr Moody. The Options for Dr Nave will be issued to MRCF BTF Service (BCPIT) Pty Ltd as trustee for the MRCF BTF Service (BCPIT) Pty Ltd and the Options for Mr Moody will be issued to Australian Medtech Services Pty Ltd (AMS).
Number	<ul style="list-style-type: none"> • Allan Will – 171,121 Options • John McCutcheon – 304,719 Options • Each Non-executive Director (or their nominee, as applicable) – 100,100 Options
Consideration for grant	Nil
Exercise price	The U.S. dollar equivalent of A\$1.08 (being the Offer Price)
Vesting conditions	<p>In respect of Dr Bronwyn Evans, Dr David Steinhaus and Ms Karen Drexler, one-third of the Options will vest on the first anniversary of their commencement date as a Director and the remainder will vest in equal monthly instalments over the subsequent two years at a rate of 1/36th of the total Options per month.</p> <p>In respect of the other Directors (or their nominees), one-third of the Options will vest on the first anniversary of the date of Listing and the remainder will vest in equal monthly instalments over the subsequent two years at a rate of 1/36th of the total Options per month.</p>
Deadline for exercise of any vested Options	If the Director ceases to be an employee, Director or consultant of the Company (as the case may be), he or she (or the relevant nominee holder, as applicable) must exercise any vested Options within three months after termination, unless such termination is due to his or her death or disability, in which case any vested Options will be exercisable for one year after he or she ceases to be an employee, Director or consultant. Notwithstanding the foregoing, the term of the Options will be no more than ten years after the grant date.
Treatment in a “Change in Control” (as defined in the 2021 Plan)	In respect of Mr Will’s Options, 100% of the then-unvested Shares subject to any outstanding Options will accelerate and become fully-vested.
Other information	<ul style="list-style-type: none"> • The Options are being granted under the 2021 Plan, except for the Options to be granted to MRCF BTF Service (BCPIT) Pty Ltd as trustee for the MRCF BTF (BCP Investment) Trust and AMS, which are outside of the 2021 Plan, but subject to the terms and conditions of the 2021 Plan. A summary of the material terms of the 2021 Plan is set out in Section 7.7.1. • Options were chosen to be issued to the Directors in order to align the interests of the Directors with the interests of Shareholders and CDI Holders, and to provide an opportunity for the Directors to acquire CDIs. • For the Options issued to: <ul style="list-style-type: none"> – the Non-executive Directors, the Board based the number of Options to be issued on a value of US\$80,000 or A\$108,108.11, and divided such value by the Offer Price of A\$1.08; – Mr Will, the Board based the number of Options to be issued on a value of US\$136,759.90 or A\$184,810.68 and divided such value by the Offer Price of A\$1.08; and – Mr McCutcheon, the Board based the number of Options to be issued on a value of US\$243,531.43 or A\$329,096.52 and divided such value by the Offer Price of A\$1.08. • No loans will be provided to the Directors by the Company in relation to the exercise of the Options. • Allan Will and John McCutcheon have previously been granted Options under the 2013 Plan. Those Options were issued for nil cash consideration and have exercise prices of US\$0.16 and US\$0.14 for Mr Will and US\$0.14 and US\$0.12 for Mr McCutcheon. The details of the Directors’ Option holdings are set out above.

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Share options

Options granted

The following options were granted during FY21:

- 1,190,184 options with exercise price of US\$0.12, expiring 27 January 2031
- 180,000 options with exercise price of US\$0.12, expiring 05 April 2031
- 2,871,640 options with exercise price of US\$0.10, expiring 31 August 2031
- 2,182,947 options with exercise price of US\$0.7992, expiring 21 November 2031.

Board of Directors

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



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.



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.



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 currently serves as Medical Device Partner at M.H. Carnegie & Co. (since October 2013), where he makes 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), Australian Medtech Services Pty Ltd, Cardiac Dimensions Pty Ltd, Renew Medical Pty Ltd, Serene Medical Pty Limited, 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 Evans AM is an experienced leader and CEO with a broad technical background across multiple industry sectors including medical technology, manufacturing, power generation and distribution and technical regulation and standards.

Dr Evans is currently the CEO of Engineers Australia, the Chair of Building4.0 CRC, and the Director at GME Pty Ltd. Prior to her role with Engineers Australia, Dr Evans was the CEO of Standards Australia.

Dr Evans has previously held positions in innovation initiatives, including as Chair of MTPConnect (the Industry Growth Centre 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 has been recognised as one of Australia's 100 most influential engineers and recognised as a 100 Women of Influence.

Dr Evans holds a B.E (Honours I) from the University of Wollongong and a PhD 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 and Engineers Australia and a Fellow of the Australian Academy of Technological Sciences and Engineering.

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 two other public companies, Resmed, Inc. (NYSE, ASX:RMD), where she serves on the compensation and nominating and governance committees, and Outset Medical Inc. (NASDAQ: OM), where she chairs the compensation committee and serves on the nominating and governance committee.

Ms Drexler is also on the board of three private companies: Bone Health Technologies Inc., a medtech company focused on treating osteoporosis and its precursor, osteopenia, VIDA Diagnostics Inc., an artificial intelligence powered lung imaging solutions company, and Tivic Health Systems, Inc., a bioelectric medicine company focused on relief of congestion and sinus pain.

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 M.B.A. with honors from the Stanford University Graduate School of Business.

Consolidated Balance Sheets

	Notes	December 31,	
		2021	2020
ASSETS			
Current assets			
Cash and cash equivalents		\$ 78,242,340	\$ 5,878,281
Non-trade receivable and unbilled reimbursements	3	966,123	273,304
Prepaid expenses		1,716,878	848,220
Other current assets		173,882	72,295
Total current assets		81,099,223	7,072,100
Property and equipment, net	3	1,743,704	887,341
Right of use operating lease asset	6	2,143,481	-
Other assets		437,660	439,202
Total assets		\$ 85,424,068	\$ 8,398,643
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)			
Current liabilities			
Accounts payable		\$ 1,710,855	\$ 903,720
Accrued expenses and other liabilities		2,726,024	2,099,108
Interest payable	4	282,256	2,665,867
Operating lease liability	6	185,707	-
Current portion of notes payable, net of discounts and deferred loan cost	4	2,410,496	2,401,432
Current portion of convertible notes payable, net of discounts and deferred loan costs	5	-	19,248,821
Total current liabilities		7,315,338	27,318,948
Operating lease liability, net of current portion	6	2,137,923	-
Interest payable, net of current portion		-	114,545
Notes payable, net of current portion, discounts and deferred loan costs	4	73,085	3,558,906
Convertible notes payable, net of current portion, discounts and deferred loan costs	5	-	8,019,395
Derivative liabilities - fair value of warrants	7	-	6,852,000
Other long-term liabilities		-	185,428
Total liabilities		9,526,346	46,049,222
Stockholders' equity (deficit)			
Convertible preferred stock (new series A and new series B), \$0.0001 par value, 278,523,428 shares authorized, no shares issued and outstanding at December 31, 2021; 198,523,428 shares authorized, 84,856,456 shares issued and outstanding at December 31, 2020	9	-	8,486
Common stock, \$0.0001 par value; 600,000,000 shares authorized, 267,985,340 shares issued and outstanding at December 31, 2021; 240,000,000 shares authorized, 13,190,604 issued and outstanding at December 31, 2020	10	26,800	1,320
Additional paid-in capital		319,378,429	166,278,889
Accumulated deficit		(244,534,315)	(203,851,437)
Accumulated other comprehensive income (loss)		1,026,808	(87,837)
Total stockholders' equity (deficit)		75,897,722	(37,650,579)
Total liabilities and stockholders' equity		\$ 85,424,068	\$ 8,398,643

See accompanying notes to consolidated financial statements.

Consolidated Statements of Operations and Comprehensive Loss

	Notes	Twelve Months Ended December 31,	
		2021	2020
Operating expenses:			
Research and development		\$ 7,232,171	\$ 8,006,044
Sales and marketing		6,814,151	4,799,427
Clinical and regulatory		5,588,249	5,440,677
General and administrative		3,139,286	2,334,787
Total operating expenses		<u>22,773,857</u>	<u>20,580,935</u>
Loss from operations		(22,773,857)	(20,580,935)
Other income (expense)			
Interest expense	4 & 5	(19,009,916)	(7,861,576)
Other income	2	1,379,860	642,279
Gain on sale of equipment		3,639	-
Gain on forgiveness of debt	4	1,255,912	-
Gain on change in fair value of derivative liability	7	1,394,000	1,381,364
Gain (loss) on foreign currency	2	(2,085,007)	2,790
Total other income (expense)		<u>(17,061,512)</u>	<u>(5,835,143)</u>
Loss before income taxes		(39,835,369)	(26,416,078)
Income tax benefit		-	697,752
Net loss		<u>\$ (39,835,369)</u>	<u>\$ (25,718,326)</u>
Net loss per common share:			
Basic and diluted		\$ (0.95)	\$ (1.95)
Weighted average shares outstanding			
Basic and diluted		42,122,436	13,158,279
Other comprehensive income (loss):			
Foreign currency translation adjustments		<u>\$ 1,114,645</u>	<u>\$ (87,837)</u>
Comprehensive loss:		<u>\$ (38,720,724)</u>	<u>\$ (25,806,163)</u>

See accompanying notes to consolidated financial statements.

Consolidated Statements of Stockholders' Equity (Deficit)

	Notes	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Equity (Deficit)
		Shares	Par Value	Shares	Par Value				
Balance at December 31, 2019		84,856,456	\$ 8,486	13,120,274	\$ 1,313	\$ 164,297,586	\$ (178,133,111)	\$ -	\$ (13,825,726)
Issuance of stock warrants	8	-	-	-	-	1,549,357	-	-	1,549,357
Exercise of stock options	11	-	-	70,330	7	11,246	-	-	11,253
Stock-based compensation	11	-	-	-	-	420,700	-	-	420,700
Net loss		-	-	-	-	-	(25,718,326)	-	(25,718,326)
Foreign currency translation adjustment		-	-	-	-	-	-	(87,837)	(87,837)
Balance at December 31, 2020		84,856,456	\$ 8,486	13,190,604	\$ 1,320	\$ 166,278,889	\$ (203,851,437)	\$ -	\$ (37,650,579)
Issuance of stock warrants	8	-	-	-	-	3,123,094	-	-	3,123,094
Exercise of stock options	11	-	-	5,375,911	538	828,484	-	-	829,022
Stock-based compensation	11	-	-	-	-	459,180	-	-	459,180
Derivative liabilities settled to equity	7	-	-	-	-	11,979,000	-	-	11,979,000
Convertible notes payable converted into stockholders' equity	5	62,710,518	6,271	-	-	60,719,203	-	-	60,725,474
Convertible preferred stock converted into common stock	9	(147,566,974)	(14,757)	147,566,974	14,757	-	-	-	-
Warrant modifications	8	-	-	-	-	1,096,452	(847,509)	-	248,943
Issuance of common stock, net of issuance costs	10	-	-	101,851,851	10,185	74,894,127	-	-	74,904,312
Net loss		-	-	-	-	-	(39,835,369)	-	(39,835,369)
Foreign currency translation adjustment		-	-	-	-	-	-	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

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows

	Notes	Twelve Months Ended December 31,	
		2021	2020
Cash flows from operating activities:			
Net loss		\$ (39,835,369)	\$ (25,718,326)
Adjustment to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	3	384,022	246,403
Amortization of deferred loan costs and discount on notes	4 & 5	16,901,371	5,017,796
Change in fair value of derivative liability	7	(1,394,000)	(1,381,364)
Stock-based compensation	11	459,180	420,700
Convertible notes payable issued for services		33,935	64,432
Gain on forgiveness of debt	4	(1,255,912)	-
(Gain) loss on disposal of property and equipment		(3,639)	5,674
Effect of exchange rate changes on monetary assets and liabilities denominated in non-functional currency		1,451,778	(92,126)
Changes in operating assets and liabilities:			
Non-trade receivable		(692,819)	207,715
Inventory		-	2,840,195
Prepaid expenses		(983,584)	(612,691)
Other assets		(100,045)	163,801
Accounts payable		721,097	(479,013)
Accrued expenses and other liabilities		333,197	(454,991)
Interest payable		1,836,673	2,224,731
Operating lease liability		(5,279)	-
Net cash used in operating activities		(22,149,394)	(17,547,064)
Cash flows from investing activities:			
Purchase of property and equipment	3	(912,009)	(265,300)
Proceeds from sale of property and equipment		5,200	-
Net cash used in investing activities		(906,809)	(265,300)
Cash flows from financing activities:			
Repayment of notes payable	4	(2,404,299)	(3,200,000)
Proceeds from notes payable	4	-	7,242,525
Proceeds from convertible notes	5	22,424,554	12,458,890
Payments of deferred loan costs		(289,913)	(107,522)
Proceeds from exercise of stock options	11	829,022	11,253
Proceeds from initial public offering	10	80,099,614	-
Payment of offering costs	10	(4,901,583)	-
Net cash provided by financing activities		95,757,395	16,405,146
Effect of exchange rate change on cash		(337,133)	-
Net increase in cash and cash equivalents		72,364,059	(1,407,218)
Cash and cash equivalents, beginning of the period		5,878,281	7,285,499
Cash and cash equivalents, end of the period		\$ 78,242,340	\$ 5,878,281

See accompanying notes to consolidated financial statements.

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	<u>Notes</u>	Twelve Months Ended December 31,	
		2021	2020
Supplemental disclosure of cash flow information			
Cash paid interest		\$ 371,223	\$ 619,049
Cash received from income tax benefit		\$ -	\$ 697,752
Non-cash financing activities			
Issuance of warrants for deferred loan costs	8	\$	\$ 24,499
Issuance of detachable warrants	8	\$ 3,123,094	\$ 1,524,858
Derivative liabilities settled to equity	7	\$ 11,979,000	\$ -
Convertible notes payable and accrued interest converted to equity	5	\$ 60,725,474	\$ -
Warrant modifications	8	\$ 847,509	\$ -

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

Note 1 - Business and organization

Business overview

EBR Systems, Inc. (“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. In 2015, the Company received European CE Mark approval for the world’s first wireless cardiac pacing system for heart failure. In 2016, EBR announced its first commercial implants of its wireless cardiac pacing system.

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 establishes clinical trials in Australia and the United Kingdom, respectively, and works 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”).

Reclassification

Certain comparative figures have been reclassified to conform to the current year presentation. These reclassifications had no effect on the reported results of operations. An adjustment has been made to the Consolidated Balance Sheets to reclassify property, plant and equipment, and to reclassify deferred loan costs.

Principles of consolidation

The consolidated financial statements include the Company’s accounts and those of its wholly owned subsidiary: EBR Systems (AUST) Pty. Ltd., incorporated in Australia. All significant intercompany balances and transactions have been eliminated in consolidation.

Foreign currency translation

The Company translates the foreign currency financial statements into US Dollars using the reporting period-end or average exchange rates in accordance with the requirements of the Financial Accounting Standards Board (“FASB”) Accounting Standard Codification (“ASC”) subtopic 830-10, *Foreign Currency Matters*. 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 gain / (loss) within stockholders’ equity (deficit).

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 lives of long-lived assets, the fair value of stock-based awards issued, clinical trial accruals, and the valuation of the derivative liability.

Fair value of financial instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

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.

Our financial instruments include cash equivalents, non-trade receivables, other assets, accounts payable, accrued expenses and derivative liabilities. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgement and therefore cannot be determined with precision. The carrying amount of cash equivalents, non-trade receivables and unbilled reimbursements, other assets, accounts payable and accrued expenses are generally considered to be representative of their respective values because of the short-term nature of those instruments. The fair value of the Company's embedded derivative liability was valued using the Monte Carlo Simulation (Level 3).

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 and comprehensive loss.

Beneficial conversion feature

From time to time, the Company may issue convertible notes that may have conversion prices that create an embedded beneficial conversion feature pursuant to FASB ASC Subtopic 470-20, *Debt with Conversion and Other Options*. A beneficial conversion feature ("BCF") exists on the date a convertible note is issued when the fair value of the underlying common stock to which the note is convertible is in excess of the conversion price. In accordance with this guidance, the intrinsic value of the BCF is recorded as a debt discount with a corresponding amount to common stock. The debt discount is amortized to interest expense over the life of the note.

Notes to Consolidated Financial Statements

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 may, at times, exceed federally insured limits.

Cash and cash equivalents

EBR considers all highly liquid instruments with an initial maturity date of 90 days or less when purchased to be cash equivalents. All investments are considered cash equivalents.

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 3, "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 period ended December 31, 2021 and 2020, the Company did not recognize any impairment charges associated with long-lived assets.

Right of use assets and lease liabilities

In connection with the adoption on July 1, 2021, the Company follows the provisions of FASB ASC Topic 842, "Leases" ("ASC 842"). At the inception of a contract, the Company determines whether the contract is or contains a lease based on all relevant facts and circumstances. For contracts that contain a lease, the Company identifies the lease and non-lease

components, determines the consideration in the contract and recognizes the classification of the lease as operating or financing. At the commencement date of the lease, the Company recognizes a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term.

The Company has elected the package of practical expedients to not reassess its prior conclusions about lease identification, lease classification and indirect costs and to not separate lease and non-lease components. The Company has also elected not to recognize leases with a term less than one year on the balance sheet.

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.

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 in the accompanying consolidated statements of operations and comprehensive loss for all stock-based payments to employees, non-employees and directors. The Company records compensation expense over an award's requisite service period, or vesting period, based on the award's fair value at the date of grant. Awards generally vest over four years for employees. The Company generally uses the Black-Scholes option-pricing model to determine the fair value of each option grant as of the date of grant. The Black-Scholes option pricing model requires inputs for risk-free interest rate, dividend yield, expected stock price volatility and expected term of the options. The fair value of the options is recognized as expense on a straight-line basis over the requisite service period. The Company recognizes the impact of forfeitures on stock-based compensation expense as

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forfeitures occur. The Company applies the straight-line method of expense recognition to all awards with only service-based vesting conditions. See Note 11, “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 and comprehensive loss. During the twelve-month period ended December 31, 2021 and 2020, the Company recorded reimbursements of \$1,378,908 and \$624,361, respectively. Interest income of \$952 and \$17,918 is also included in other income for the twelve-month period ended December 31, 2021 and 2020, respectively.

Income taxes

The asset and liability approach is used for the financial reporting for income taxes. Deferred income balances reflect the effects of temporary differences between the financial reporting and income tax bases of the Company’s assets and liabilities and are measured using enacted tax rates expected to apply when taxes are actually paid or recovered. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses, or NOLs, and research and development credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse.

A valuation allowance is provided against deferred tax assets if it is more likely than not that some portion or all of the deferred tax asset will not be realized. In making such determination, the Company considers all available positive and negative evidence, including taxable income in available carryback periods, future reversals of existing taxable temporary differences, tax planning strategies, and future taxable income exclusive of reversing temporary differences and carryforwards.

Recently adopted accounting pronouncements

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* (“ASU 2021-04”). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. Early adoption is permitted for all entities, including

adoption in an interim period. If an entity elects to early adopt ASU 2021-04 in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company has elected the early adoption of ASU 2021-04. See Note 5, “Convertible notes payable” and Note 8 “Warrants” for additional details.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, which amended revenue recognition guidance to clarify the principles for recognizing revenue from contracts with customers. The guidance requires an entity to recognize revenue in an amount that reflects the consideration to which an entity expects to be entitled in exchange for the transfer of goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The Company adopted this guidance using the modified retrospective method in the first quarter of fiscal year 2020. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Note 3 – Consolidated balance sheet components

Non-trade receivable and unbilled reimbursements

Non-trade receivable and unbilled reimbursements include reimbursement of clinical trial expenses incurred. Non-trade receivable and unbilled reimbursements consisted of the following as of December 31, 2021 and 2020:

	2021	2020
Non-trade receivable	\$ 233,158	\$ 273,304
Unbilled reimbursements	843,879	-
Non-trade receivable and unbilled services	1,077,037	273,304
Less: allowance for doubtful accounts	(110,914)	-
Non-trade receivable and unbilled services, net	<u>966,123</u>	<u>273,304</u>

During the twelve-month period ended December 31, 2021, bad debt expense totaled \$110,914. During the twelve-month period ended December 31, 2020, there was no bad debt expense.

Property and equipment, net

Property and equipment consisted of the following as of December 31, 2021 and 2020:

	2021	2020
Equipment	\$ 2,439,709	\$ 1,725,043
Computer software	477,685	49,589
Leasehold improvements	415,590	301,060
Construction in progress	153,548	173,349
	<u>3,486,532</u>	<u>2,249,041</u>
Less accumulated depreciation and amortization	(1,742,828)	(1,361,700)
Total property and equipment, net	<u>\$ 1,743,704</u>	<u>\$ 887,341</u>

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Depreciation and amortization expense on property and equipment was \$384,022 and \$246,403 for the twelve-month period ended December 31, 2021 and 2020, respectively.

Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following at December 31, 2021 and 2020:

	2021	2020
Accrued compensation and related liabilities	\$ 1,628,316	\$ 1,098,954
Accrued development expenses	663,288	755,573
Accrued other expenses	434,420	244,581
Accrued expenses and other liabilities	<u>\$ 2,726,024</u>	<u>\$ 2,099,108</u>

Accrued other long-term liabilities

At December 31, 2020, other long-term liabilities consisted of deferred rent of \$185,428. See Note 6, "Lease liability" for additional disclosure of leases at December 31, 2021.

Note 4 - Notes payable

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, 2021, the outstanding principal balance was \$124,675, of which \$51,590 was included in the current portion of notes payable.

Paycheck Protection Program

In April 2020, the Company received loan proceeds in the amount of \$1,242,525 under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amount up to 2.5 times of the average monthly payroll expense of the qualifying business. The loan and accrued interest is forgivable after the earlier of (i) 24 weeks after the loan disbursement date and (ii) December 31, 2020, as long as the borrower uses the loan proceeds for eligible purposes including payroll, benefits, rent and utilities, and it maintains its payroll levels.

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. The Company used a portion of the proceeds of the initial tranche of term loans to

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fully repay its outstanding term loan under the 2018 loan and security agreement with Silicon Valley Bank. As of December 31, 2021 and 2020, the outstanding principal balance under the loan agreement was \$2,400,000 and \$4,800,000, respectively.

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.

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. As of December 31, 2021 and 2020, the note has been shown net of unamortized loan costs of \$30,245 and \$60,491, respectively. Amortization of the loan costs was \$30,246 and \$22,623 during the twelve-month period ended December 31, 2021 and 2020, respectively, which is included in interest expense in the accompanying consolidated statements of operations and comprehensive loss.

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 and 2020, the note has been shown net of the unamortized discount of \$10,848 and \$21,696, respectively, on the accompanying consolidated balance sheets. Amortization of the discount was \$10,848 during the twelve-month period ended December 31, 2021 and 2020, which is included in interest expense in the accompanying consolidated statements of operations and comprehensive loss. See Note 8 for additional information regarding the warrants.

Silicon Valley Bank – 2018

In April 2018, the Company and Silicon Valley Bank, entered into a loan and security agreement to provide a term loan in the principal amount of \$3,000,000. The term loan under the loan agreement was secured by substantially all of the Company's assets, other than intellectual property, but included proceeds from the sale of intellectual property. During 2020, the Company used a portion of the proceeds from the 2020 Silicon Valley Bank note payable to repay the outstanding balance. In connection with the term loan, the Company issued Silicon Valley Bank fully vested detachable warrants to purchase 234,176 shares of New Series B Convertible Preferred Stock. The note was discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. Amortization of the discount was \$47,885 during the twelve-month period ended December 31, 2020, which is included in interest expense in the accompanying consolidated statements of operations and comprehensive loss.

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At December 31, 2021 and 2020, notes payable consisted of the following:

	2021	2020
Current portion of notes payable	\$ 2,451,589	\$ 2,442,525
Long-term portion of notes payable	73,085	3,600,000
Less: unamortized deferred loan costs	(30,245)	(60,491)
Less: unamortized debt discount	(10,848)	(21,696)
Notes payable, net	<u>\$ 2,483,581</u>	<u>\$ 5,960,338</u>

The following table presents information regarding the Company's notes payable principal repayment obligations as of December 31, 2021:

Twelve-months ended December 31,	
2022	\$ 2,451,589
2023	73,085
Total minimum payments	<u>\$ 2,524,674</u>

Note 5 – Convertible Notes Payable

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. 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. Amortization of the discount was \$2,498,113 during the twelve-months ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations and comprehensive loss.

On September 26, 2021, Company amended the tranche one warrants and reduced the exercise price to \$0.589113 per share. The Company elected to account for the modification of the warrants under ASU 2021-04. Accordingly, the Company recognized the effect of the modification as a change in the discount on the convertible notes. The Company evaluated the

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difference between the fair value of the modified warrant and the fair value of the warrant immediately before it was modified. The Company accounted for the difference of \$248,943 as an additional discount on the convertible notes payable. Amortization of the additional discount was \$248,943 during the twelve-months ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations and comprehensive loss. See Note 8 “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 7 “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 comprehensive loss 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-months ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations and comprehensive loss.

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 have 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

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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. As of December 31, 2020, the note has been shown net of the aggregate unamortized discount of \$1,417,397 on the accompanying consolidated balance sheets. Amortization of the discount was \$2,042,378 and \$1,248,137 during the twelve-months ended December 31, 2021 and 2020, respectively, which is included in interest expense in the accompanying consolidated statements of operations and comprehensive loss. See Note 8 “Warrants”, for additional information regarding the warrants.

On September 26, 2021, the Company amended the tranche one, tranche two and tranche three warrants and reduced the exercise price to \$0.589113 per share. The Company elected to account for the modification of the warrants under ASU 2021-04. Accordingly, the Company recognized the effect of the modification as a dividend because the convertible notes had previously been converted in the New Series B Convertible Preferred Stock. The Company evaluated the difference between the fair value of the modified warrant and the fair value of the warrant immediately before it was modified. The Company accounted for the difference of \$847,509 as a dividend declared. See Note 8 “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 7 “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 comprehensive loss 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, 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. At December 31, 2020, the unamortized debt discount was \$4,173,443. Amortization of the debt discount was \$5,157,443 and \$3,526,522 during the twelve-month period ended December 31, 2021 and 2020, respectively, and is recorded as interest expense in the accompanying consolidated statements of operations and comprehensive loss.

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. As of December 31, 2020, the convertible note has been shown net of the unamortized discount of \$193,833. The notes were converted in November 2021. Amortization of the discount was \$193,833 and \$54,489 for the twelve-month period ended December 31, 2021 and 2020, which is included in interest expense in the accompanying consolidated statements of operations and comprehensive loss.

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 and \$118,738 during the twelve-month period ended December 31, 2021 and 2020, which is included in interest expense in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2020, the unamortized beneficial conversion feature amounted \$864,851.

At December 31, 2021 and 2020, convertible notes payable consisted of the following:

	2021	2020
Current portion of convertible notes payable	\$ -	\$ 24,924,955
Long-term portion of convertible notes payable	-	9,020,589
Less unamortized discounts	-	(6,456,231)
Less unamortized deferred loan costs	-	(221,096)
Convertible notes payable, net	<u>\$ -</u>	<u>\$ 27,268,217</u>

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Note 6 – Lease liability

The Company adopted ASC 842 on July 1, 2021 using the modified retrospective approach and elected to apply the transition method that allows companies to continue applying guidance under the lease standard in effect at that time in the comparative period financial statements and recognize a cumulative-effect adjustment to the balance sheet on the date of adoption. The Company has also elected the package of practical expedients to not reassess its prior conclusions about lease identification, lease classification and indirect costs and to not separate lease and non-lease components. With the adoption of ASC 842, the Company's balance sheet now contains line items for right of use asset, current lease liability and noncurrent lease liability.

The Company determined that it held an operating lease for its office and laboratory space as of July 1, 2021, which expires June 30, 2024. The Company held no other lease agreements. The Company leases the office and laboratory space for its corporate headquarters and primary research facility in Sunnyvale, California. On July 1, 2021, the Company recorded a right of use asset of \$2,238,387 and a corresponding lease liability of \$2,406,288.

The Company also has the option to extend the term of the lease an additional sixty-months. As the Company cannot provide reasonable assurance at this time that the Company will not elect to exercise the option to extend the lease, the lease term, as per ASC 842, currently only takes into consideration the additional five years.

Additionally, the lease agreements did not contain information to determine the rate implicit in the lease. As such, the Company calculated its incremental borrowing rate based on what the Company would have to pay to borrow on a collateralized basis over the lease term for an amount equal to the remaining lease payments taking into consideration such assumptions as, but not limited to, the U.S. treasury yield rate and borrowing rates from a creditworthy financial institution using the above lease factors.

Future lease payments for non-cancellable operating leases as of December 31, 2021 were as follows:

Twelve-months Ended December 31,	
2022	\$ 396,882
2023	408,786
2024	421,050
2025	433,682
2026	446,692
Thereafter	1,174,439
Total undiscounted lease payments	3,281,531
Less: effects of discounting	(957,901)
Total operating lease liabilities	\$ 2,323,630

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

Right of use asset	\$ 2,143,481
Lease liability, current	185,707
Lease liability, noncurrent	2,137,923
Remaining lease term	7.50
Discount rate	10.00%

Total rent expense for the twelve-month period ended December 31, 2021 and 2020 was \$380,041 and \$346,564, respectively.

Note 7 – Derivative liabilities

The Company determined the conversion feature of the convertible notes, which contain a variable conversion rate, represented an embedded derivative since the notes were convertible into a variable number of shares upon conversion. Accordingly, the convertible notes are not considered to be conventional debt under FASB ASC Topic 815, *Derivatives and Hedging*, and the embedded conversion feature was bifurcated from the debt host and accounted for as a derivative liability.

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. At December 31, 2020, the Company valued the derivative liability at \$6,852,000. The Company used the Monte Carlo simulation valuation model with the following assumptions as of December 31, 2020, risk-free interest rate of 0.10% and volatility of 63.0%.

A summary of the activity related to derivative liabilities for the twelve-month period ended December 31, 2021 and 2020, is as follows:

Balance at January 1, 2020	\$ 3,128,364
Issued during the twelve-month period	5,105,000
Change in fair value recognized in operations	<u>(1,381,364)</u>
Balance at December 31, 2020	6,852,000
Issued during the twelve-month period	6,521,000
Change in fair value recognized in operations	(1,394,000)
Derivative liabilities settled into equity	<u>(11,979,000)</u>
Balance at December 31, 2021	<u>\$ -</u>

Note 8 – Warrants

The Company follows FASB ASC Subtopic 815-40, *Contract in an Entity's Own Equity*, as it relates to outstanding warrants. Additionally, the Company follows ASU 2021-04, *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*, as it relates to modification of outstanding warrants.

In connection with the tranche two of the 2021 convertible notes payable as discussed in Note 5 "Convertible notes payable", which occurred in October 2021, the Company issued

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warrants to purchase 3,111,787 shares of New Series B Convertible Preferred Stock at an exercise price of \$0.589113 per share. These warrants are exercisable, in whole or in part at any time up until the expiration of the warrant agreement on October 4, 2031. The aggregate fair value attributed to these warrants was \$1,369,186 at the grant date. These warrants are classified as equity in the accompanying consolidated balance sheets.

The fair value for the warrants issued was calculated using the Black-Scholes model with the following assumptions:

Dividend yield	0.00%
Volatility	35.2%
Risk free interest rate	1.44%
Expected life	10 yrs.

In connection with the tranche one of the 2021 convertible notes payable as discussed in Note 5 “Convertible notes payable”, which occurred in June 2021, the Company issued a warrant to purchase 3,111,787 shares of New Series B Convertible Preferred Stock at an exercise price of \$0.8245 per share. These warrants are exercisable, in whole or in part at any time up until the expiration of the warrant agreement on February 12, 2031. The aggregate fair value attributed to these warrants was \$1,128,927 at the grant date. These warrants are classified as equity in the accompanying consolidated balance sheets.

On September 26, 2021, Company amended the tranche one warrants and reduced the exercise price to \$0.589113 per share. The Company elected to account for the modification of the warrants under ASU 2021-04. Accordingly, the Company recognized the effect of the modification as a change in the discount on the convertible notes. The Company evaluated the difference between the fair value of the modified warrant and the fair value of the warrant immediately before it was modified. The additional fair value attributed to the warrants was \$248,943 at the modification date.

The fair value for the warrants as originally issued and as modified was calculated using the Black-Scholes model with the following assumptions:

	As originally issued	As modified
Dividend yield	0.00%	0.00%
Volatility	48.90%	34.20%
Risk-free interest rate	1.29%	1.44%
Expected life	7	9.75

In connection with the tranche one, tranche two and tranche three of the 2019 convertible notes payable as discussed in Note 5 “Convertible notes payable”, which occurred on August 2019, March 13, 2020, and February 12, 2021, respectively, the Company issued warrants to purchase 4,438,389 shares, 4,423,389 shares and 1,732,123 shares, respectively, of New Series B Convertible Preferred Stock at an exercise price of \$0.8245 per share. The warrants have an exercise period of 10 years and are exercisable in whole, or in part at any time up until the expiration of the warrant agreement. The aggregate fair value attributed to the tranche one, tranche two and tranche three warrants was \$1,329,621, \$1,526,399, and \$624,981, respectively,

at the grant date. These warrants are classified as equity in the accompanying consolidated balance sheets.

On September 26, 2021, Company amended the tranche one, tranche two and tranche three warrants and reduced the exercise price to \$0.589113 per share. The Company elected to account for the modification of the warrants under ASU 2021-04. Accordingly, the Company recognized the effect of the modification as a dividend because the convertible notes had previously been converted in the New Series B Convertible Preferred Stock. The Company evaluated the difference between the fair value of the modified warrant and the fair value of the warrant immediately before it was modified. The deemed dividend attributed to the warrants was \$847,509 at the modification date.

The fair value for the tranche one warrants as originally issued and as modified was calculated using the Black-Scholes model with the following assumptions:

	As originally issued	As modified
Dividend yield	0.00%	0.00%
Volatility	36.82%	34.60%
Risk-free interest rate	1.49%	1.32%
Expected life	7 yrs.	7.92 yrs.

The fair value for the tranche two warrants as originally issued and as modified was calculated using the Black-Scholes model with the following assumptions:

	As originally issued	As modified
Dividend yield	0.00%	0.00%
Volatility	46.35%	34.50%
Risk-free interest rate	0.89%	1.36%
Expected life	7 yrs.	8.46 yrs.

The fair value for the tranche three warrants as originally issued and as modified was calculated using the Black-Scholes model with the following assumptions:

	As originally issued	As modified
Dividend yield	0.00%	0.00%
Volatility	49.20%	34.50%
Risk-free interest rate	0.85%	1.42%
Expected life	7 yrs.	9.38 yrs.

In connection with the Silicon Valley Bank note payable as discussed in Note 4, which occurred in March 2020, the Company issued a warrant to purchase 441,500 shares of common stock at an exercise price of \$0.14 per share. These warrants are exercisable, in whole or in part at any time up until the expiration of the warrant agreement at March 24, 2030. The aggregate fair value attributed to these warrants was \$29,831 at the grant date. These warrants are classified as equity in the accompanying consolidated balance sheets.

Notes to Consolidated Financial Statements

The fair value for the warrants issued was calculated using the Black-Scholes model with the following assumptions:

Dividend yield	0.00%
Volatility	47.28%
Risk free interest rate	0.77%
Expected life	7 yrs.

Below is a summary of warrants outstanding at December 31, 2021 and 2020:

	Number of Shares	Weighted average exercise price	Weighted average remaining contractual term
Balance at January 1, 2020	6,990,442	\$ 0.74	7.88
Issued	4,864,889	0.76	9.20
Exercised	-	-	-
Expired/forfeited	-	-	-
Balance at December 31, 2020	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

Note 9 – Convertible Preferred Stock

In connection with the Initial Public Offering (“IPO”), as discussed in Note 10, “Common Stock” all shares of convertible preferred stock then outstanding were automatically converted into 147,566,974 shares of its common stock on a one-for-one basis. No convertible preferred securities were outstanding as of December 31, 2021.

As of December 31, 2020, Convertible Preferred Stock consisted of the following:

	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value & Liquidation Preferences	Shares of Common Stock Issuable Upon Conversion
Convertible Preferred Stock				
New Series A	3,523,428	3,488,010	\$ 2,875,864	3,488,010
New Series B	195,000,000	81,368,446	67,088,284	81,368,446
Total convertible preferred stock at December 31, 2020	198,523,428	84,856,456	\$ 69,964,148	84,856,456

In June 2021, the convertible note holders elected to convert the aggregate principal balance and accrued interest from the tranche one, tranche two and tranche three 2019

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.

In November 2021, the 2017 Convertible Note holders and 2021 Convertible Note holders elected to convert the aggregate principal balance and accrued interest convertible notes payable. The principal balance of \$26,445,143 and accrued interest of \$460,677 converted into 21,692,195 shares of the New Series B Convertible Preferred Stock.

Note 10 – 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, 2021 and 2020, no dividends have been declared.

As of December 31, 2021 and 2020, 600,000,000 shares and 240,000,000 shares, respectively, were authorized, of which 267,985,340 shares and 13,190,604 shares, respectively, were outstanding.

During the twelve-month period ended December 31, 2021, a total of 5,375,911 options to purchase common shares were exercised for total proceeds of \$829,022.

On November 23, 2021, the Company completed its Initial Public Offering and associated listing on the Australian Securities Exchange (“ASX”). 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, CHESS depository instruments called 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 \$74,894,127, net of expenses.

Additionally, the Company has reserved the following shares of common stock for issuance as of December 31, 2021:

Conversion of Common Stock warrants	2,392,107
Conversion of New Series A warrants	21,649
Conversion of New Series B warrants	11,173,698
Conversion of New Series B2 warrants	6,223,574
2013 Equity Incentive Plan	28,525,671
2021 Equity Incentive Plan	35,064,607
Total shares of Common stock reserved for issuance	<u>85,401,306</u>

Note 11 – 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

Notes to Consolidated Financial Statements

2021 Plan 35,064,607 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, 2021, options to purchase a total of 2,182,947 shares of common stock remained outstanding and 32,881,660 shares remain available for grant under the 2021 Plan. As of December 31, 2021, options to purchase a total of 28,525,671 shares of common stock remained outstanding under the 2013 Plan. As of December 31, 2021 no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the twelve-month period ended December 31, 2021 was as follows:

	Shares	Weighted Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)
Outstanding at January 1, 2021	29,964,075	\$ 0.15	
Granted	6,469,771	0.34	
Cancelled	(349,317)	0.14	
Exercised	(5,375,911)	0.15	
Outstanding at December 31, 2021	<u>30,708,618</u>	<u>\$ 0.19</u>	7.59
Vested and expected to vest at December 31, 2021	30,708,618	\$ 0.19	7.59
Exercisable at December 31, 2021	24,813,084	\$ 0.15	7.26

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 options granted during the twelve-month period ended December 31, 2021, was \$0.17 per share.

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

Expected Term (in years)	7.00
Expected Volatility	47.52% - 53.09%
Expected Dividend Yield	0.00%
Risk-Free Interest Rate	0.75% - 1.55%

The following table presents classification of stock-based compensation expense within the accompanying consolidated statements of operations and comprehensive loss:

Research and development	\$ 96,835
Sales and marketing	48,659
Clinical and regulatory	50,792
General and Administrative	262,894
Total	<u>\$ 459,180</u>

At December 31, 2021, there was \$1,534,187 of unamortized stock-based compensation cost related to unvested stock options which is expected to be recognized over a weighted average period of 2.97 years.

Note 12 – Income Taxes

The Company did not record any income tax expense for the twelve-month period ended December 31, 2021 and 2020. 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% for the twelve-month period ended December 31, 2021 and 2020, differs from the statutory U.S. federal rate as follows:

	2021	2020
Statutory tax rate	\$ (8,365,182)	\$ (5,400,848)
R&D credit generation	(49,341)	(148,597)
State and foreign tax benefit	(1,162,345)	(733,859)
Other non-deductible expenses	3,451,555	1,301,124
Change in valuation allowance	6,125,313	4,982,180
Effective tax rate	<u>\$ -</u>	<u>\$ -</u>

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

Net operating loss carryovers	\$ 40,097,000
Other accruals	267,000
Stock based compensation	111,000
Tax credit carryover	1,531,000
Fixed assets	<u>13,202,000</u>
Gross deferred tax assets	55,208,000
Less valuation allowance	<u>(55,208,000)</u>
Net deferred tax assets	<u>\$ -</u>

Notes to Consolidated Financial Statements

As of December 31, 2021, 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 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, 2021, the Company's valuation allowance was \$55,208,000 which increased by approximately \$6,124,000 for the twelve-month period ended December 31, 2021.

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, 2021, the Company had federal NOL carryforwards of \$139,258,467, available to reduce taxable income, of which \$45,825,483 expire beginning 2023 and \$93,432,984 do not expire. The Company had state NOL carryforwards of \$100,885,313 available to reduce future state taxable income, as of December 31, 2021, which expire beginning 2028.

As of December 31, 2020, the Company also had federal and state research and development credit carryforwards of \$1,592,506 and \$752,771 respectively. The federal research and development credit carryforwards expire beginning in 2035 and the state credit carryforwards do not expire.

Note 13 – 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, 2021 and 2020, there was no outstanding liability for amounts due to the stockholder of the Company.

Note 14 – Subsequent Events

The Company has evaluated subsequent events that have occurred through February 24, 2022, 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



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 sheets as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the years 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 2020, and the results of its operations and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinion

We conducted our audits 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 audits. 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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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

Shareholder Information

Overview

The Company has CHESS Depository 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 Depository Nominees Pty Ltd (**CDN**), a wholly owned subsidiary of the ASX.

Except where noted, all information provided below is current as at 31 March 2022. 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 ¹	268,315,340
Total number of issued Options	34,046,118
Total number of issued Warrants ²	19,811,028

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	8.63%
H.E.S.T. Australia Limited ss 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	5.93%
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	2.70%
Total					17.26%

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	8.76%
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	7.86%
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	0.90%
Total					17.52%

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	2.70%
	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	0.90%
	MRCF3 Services Pty Ltd	MRCF3 Services Pty Ltd	Power to Control Voting and Disposal of Securities	7,243,522 CDIS	2.70%
	MRCF3 Services (SW) Pty Ltd	MRCF3 Services (SW) Pty Ltd	Power to Control Voting and Disposal of Securities	2,415,200 CDIS	0.90%
	MRCF3 Services (CSL) Pty Ltd	MRCF3 Services (CSL) Pty Ltd	Power to Control Voting and Disposal of Securities	1,557,250 CDIS	0.58%
	MRCF3 Pty Ltd	MRCF3 Pty Ltd	Power to Control Voting and Disposal of Securities	48,432 CDIS	0.02%
Total					7.81%¹

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).

Shareholder Information

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	5.58%
Carnegie Innovation Fund No.2 L,P	Carnegie Innovation Fund No.2 L,P	Carnegie Innovation Fund No.2 L,P	Registered Holder	14,162,839 CDIS	5.29%
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	1.24%
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	2.92%
Total					15.03%

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	2.61%
Split Rock Partners, LP	Split Rock Partners, LP	Split Rock Partners, LP	Registered Holder	19,732,458 CDIS	7.35%
Total					9.96%

Distribution of CDIS² and Shares

Range	Number	% of issued capital	No. of holders
1 – 1,000	204,865	0.08	276
1,001 – 5,000	3,000,501	1.12	867
5,001 – 10,000	5,677,521	2.12	655
10,001 – 100,000	29,655,935	11.05	1,029
100,001 and over	229,776,518	85.63	105
Total	268,315,340	100.00	2,932

2. The below holdings do not include CDN.

Unmarketable parcels

Based on the market price on 31 March 2022, there were 2,190 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	0	0.00	0
1,001 – 5,000	0	0.00	0
5,001 – 10,000	18,000	0.05	2
10,001 – 100,000	2,165,892	6.36	38
100,001 and over	31,862,226	93.59	39
Total	34,046,118	100.00	79

Distribution of Warrants

Range	Number	% of Options Issued	No. of Holders
1 – 1,000	720	0.01	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	1.93	9
100,001 and over	19,403,626	97.94	22
Total	19,811,028	100.00	40

Shareholder Information

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 31 March 2022. [Related but separate legal entities are not aggregated for the purposes of the table below.]

	Name of Registered Holder	No. of CDIs and Shares held	% of total of CDIs and Shares
1	Split Rock Partners LP	19,732,458	7.35
2	MRCF3 Services (H) Pty Ltd <MRCF3 (H) A/C>	18,480,532	6.89
3	MRCF3 Services (HP) Pty Ltd <MRCF3 (HP) A/C>	16,823,969	6.27
4	Carnegie Innovation Fund No 2 LP	14,162,839	5.29
5	CHV III LP	12,818,782	4.78
6	Argo Investments Limited	9,182,633	3.42
7	MRCF3 Services Pty Ltd <MRCF3 (AS) A/C>	8,782,983	3.27
8	Carnegie Healthcare Fund LP	8,776,909	3.27
9	Emergent Medical Partners II LP	8,479,871	3.16
10	SPVC VI LLC	6,996,473	2.61
11	MHC Fund Services B Pty Ltd <MHC Hostplus Co-Invt A/C>	6,615,306	2.47
12	Carnegie Venture Captial Pty Ltd <Carnegie Healthcare F/LP A/C>	6,175,754	2.30
13	MRCF3 Services (SW) Pty Ltd <MRCF3 (SW) A/C>	6,161,947	2.30
14	MRCF5 Service (TS) Pty Ltd <Mrcf5 (TS) A/C>	6,111,111	2.28
15	Mr Allan Will <AR Will U/A DT 6/14/12 A/C>	5,827,224	2.17
16	MRCF3 Services (HP) Pty Ltd <MRCF3 (HP) A/C>	4,709,239	1.76
17	MRCF3 Services (H) Pty Ltd <MRCF3 (H) A/C>	4,638,382	1.73
18	MRCF3 Services (SW) Pty Ltd <MRCF3 (SW) A/C>	4,629,630	1.73
19	BMYG Capital Pty Ltd <BMYG Paramount Fund A/C>	3,472,223	1.29
20	Oks-Clear Ltd	3,286,270	1.22
	Total CDIs and Shares held by top 20	175,864,535	66.55
	Total CDIs and Shares held by all other holders	92,450,805	34.45
	Total	268,315,340	100.00

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.

Last day of ASX	Number of restricted CDIs	Number of restricted Options	Number of restricted Warrants
24 June 2022	4,591,477	–	3,063,365
3 October 2022	–	–	3,063,365
18 November 2022	550,181	–	–
23 November 2023	5,785,188	11,546,742	1,104,030
Total	10,926,846	11,546,742	7,230,760

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.

Last day of voluntary escrow	Number of escrowed CDIs	Number of escrowed Options	Number of escrowed Warrants
23 November 2022	45,537,901	–	–
23 November 2023	114,221,926	21,997,408	18,486,748
Total	159,759,827	21,997,408	18,486,748

ASX Listing Rule 10.14 Waiver

Prior to the Company's listing, ASX granted the Company a waiver from Listing Rule 10.14 to the extent necessary to permit the Company to issue a total of 776,140 options (**Options**) under the Company's 2021 Equity Incentive Plan (**2021 Plan**) to its directors, Allan Will, John McCutcheon, Bronwyn Evans, David Steinhaus and Karen Drexler (together, the **Directors**), without shareholder approval.

Details of the Options issued to the Directors under the 2021 Plan are provided in the Remuneration Report of this Annual Financial Report.

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

Shareholder Information

• 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

Corporate Directory

Board of Directors and Secretaries

Allan Roger Will, Executive Chair
John Graham McCutcheon, President, CEO and 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, Unites 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
+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,
United States

Company – Registered Office in Australia

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

US Auditor

Price, Kong, & Co., C.P.A.'s, P.A.
5300 N. Central #200
Phoenix, Arizona 85012
USA
Telephone: 602 776 6300
Telephone: + 1 888 346 0072
Facsimile: +1 602 279 4537
www.pricekong.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
United States of America
Computershare Investor Services Pty Limited:
1300 850 505 (within Australia) or
+61 3 9415 4000 (outside Australia)

Investors Relations

Joel Seah
Vesparum Capital
T: (61) 3 8582 4800
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 Thursday, 12 May 2022 at 9:00am Australian Eastern Standard Time (Wednesday, 11 May 2022 at 4:00pm U.S. Pacific Daylight Time).

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