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## 2020 Annual Report

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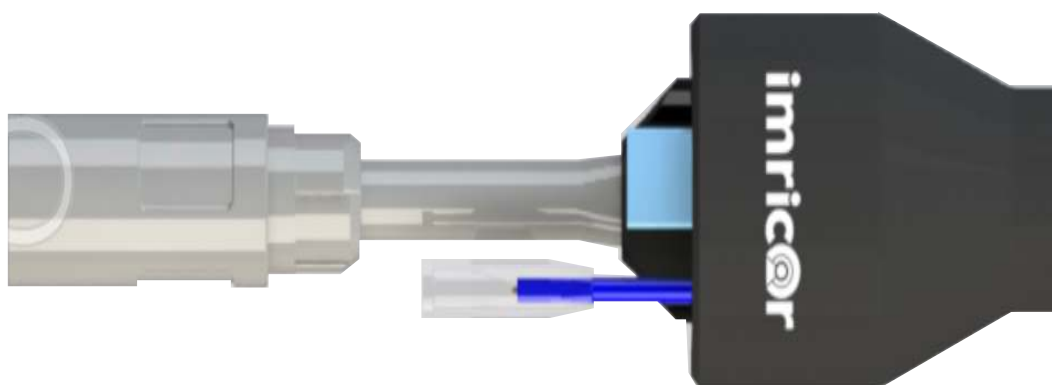
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# 2020 Annual Report

## Imricor Medical Systems, Inc.

Imricor Medical Systems, Inc. (ASX:IMR) is a pioneer and leader in developing innovative MRI-compatible medical devices which can be used to carry out MRI-guided cardiac catheter ablation procedures. Imricor is the first company in the world to bring commercially viable and safe MRI-compatible products to the cardiac catheter ablation market.

Headquartered in the US, Imricor seeks to make a meaningful impact on patients, healthcare professionals and healthcare facilities around the world by increasing the success rates and bringing down the overall costs of cardiac catheter ablation procedures.

## About this report

Imricor Medical Systems, Inc. listed on the Australian Securities Exchange (ASX) and commenced trading on 30 August 2019. References to "Imricor" or "the Company" in this Annual Report are references to Imricor Medical Systems, Inc. The information contained in this report reflects the results for Imricor for the year ended 31 December 2020.

## AGM Details

Imricor will hold its Annual Meeting of Stockholders on Thursday, 6 May 2021 at 9:00am, Sydney time (Wednesday 5 May at 6:00pm US Central Daylight Time). Due to restrictions on travel and public gatherings associated with the COVID-19 pandemic, this meeting will be held as a virtual meeting. Stockholders are encouraged to watch and participate in this meeting via the online platform using a computer at <https://web.lumiagm.com> (meeting number: 305-621-561) or a mobile device using the Lumi AGM app which can be downloaded from the Apple App Store or Google Play Store.

Further details are provided to stockholders in Imricor's Notice of Annual Meeting.



*"We achieved two important milestones in 2020, the first of these was the granting of our CE mark approval in Europe, which was quickly followed by the first procedures using our products in Germany."*

## Dear Investor,

On behalf of the Board of Directors, it is my pleasure to present Imricor's Annual Report for 2020.

This time last year, the world was changing rapidly, due to the threat posed by COVID-19 and the containment measures put in place by governments all over the world.

For Imricor, those effects were felt most directly in the delays we experienced to our planned roll-out of new clinical sites and the broad suspension of non-emergent medical procedures.

I am very proud of the way our team has responded to the challenges placed in front of us. We introduced a number of important initiatives to maintain our momentum across the business, ensuring both Imricor and our customers were well positioned as restrictions began to ease. An important aspect of our approach was the adjustments we made to installation and training, thereby minimizing disruption to our activities through reduced reliance on US in-person involvement. We were also able to quickly adjust our business development activities by moving our customer outreach and education initiatives to a virtual platform. Importantly, we have continued to make strong progress on our key strategic goals of expanding both our products' indications for use and our geographic footprint.

A key priority for us remains the health and wellbeing of all the members of the Imricor team, their families and communities. To this end, we have maintained a number of important initiatives and procedures in the way we work to ensure we provide a safe and resilient working environment for our people.

## 2020 Annual Results

We commenced the year in a strong position, achieving two important milestones. The first of these was the granting of our CE mark certification, which enabled Imricor to commence selling its products in the European Union. Effective inventory and logistics forward planning ensured that we were well positioned to supply our products once this certification was received. CE mark was quickly followed by the first procedures using our products, which was particularly exciting as these were the first iCMR-guided ablation procedures to be performed anywhere in the world with market-approved devices.

In April, we signed a Master Purchasing Agreement with Sana Hospital Group Purchasing Organisation in Germany, which not only streamlines the establishment of new sites, but facilitates access to approximately 80 sites in Germany and Switzerland that currently perform cardiac catheter ablations. This agreement has contributed a number of new sites to our pipeline.

An important step in the evolution of our business was the establishment in July of our sales agreement with Philips. This agreement will further fuel our pipeline by enabling our capital product – the Advantage-MR EP Recorder/Stimulator System – to be sold as part of a Philips comprehensive iCMR lab installation package. In effect, the agreement enables the extensive Philips sales force to help drive lab adoption. We also continue to work very closely with Siemens with the aim of establishing a similar agreement.

Due to COVID-related hospital closures in our key markets, sales were affected by the slower-than-expected rate of clinical site rollout, as well as reduced procedure volumes. In response to these conditions, and with adequate inventory in place, we redeployed portions of our manufacturing workforce to product development activities, with a focus on building products for testing and future clinical trials.

More recently, I am very pleased to report that in February 2021 the first procedures were carried out at one of our newest sites, the Maastricht University Medical Centre in the Netherlands. This was followed in early March with the commencement of procedures at Helios Leipzig Heart Centre in Germany. The Leipzig Heart Centre is an Imricor Centre of Excellence which will also provide training for new sites as they adopt iCMR ablations. We are very encouraged by this renewed activity and the early signs of other hospitals reopening across Europe.

## Positioned for Growth

The size and forecast growth of the ablation market, as well as the ability of our technology to deliver solutions that will expand this market, underpins our growth strategy. This is overlaid by the fact that we are the only company globally to offer cardiac catheter ablation devices for use in the MRI environment.

While COVID-19 temporarily stalled the launch of new labs, we have been working to ensure that the foundations are laid for our future success and that Imricor is well positioned as restrictions ease.

We have established training and installation teams in Europe, supported by teams based in the United States, providing us with the capacity to accelerate lab adoption as COVID-19 restrictions ease.

# Chair's Message



We also continue to selectively grow our workforce across almost all functional areas, further building our organizational strength. We have a team of talented people who have responded to challenges that COVID-19 has thrown at us, remaining focused on our future success and on delivering great outcomes for patients and healthcare professionals.

### Regulatory approvals to drive future growth

A key growth driver for Imricor is expanding the approved indications for our products to procedures in the left side of the heart, including ventricular tachycardia and atrial fibrillation. While we have started with treatments for atrial flutter, we are not stopping there. We are driving to deliver on the full promise of iCMR guided ablations for complex procedures with a goal to make them the new standard of care.

Expanding our geographic reach is another important pillar of our strategy, and we are making good progress with our plans for securing approvals in the United States and Australia.

In the United States, we have been actively engaged with the Food and Drug Administration (FDA). We are expecting to reach alignment on a clinical trial design in due course, with a target to execute the trial during 2021-2022, which will support a future FDA approval.

In Australia we have appointed Regional Health Care Group, a local agent to help facilitate an approval from the Therapeutic Goods Administration. We have also entered into a distribution agreement with them and they will be the exclusive distributor of Imricor's consumable products in Australia and New Zealand and a non-exclusive distributor of Imricor's capital equipment. We do not expect clinical trials to be a requirement for TGA approval.

### Outlook

While the effects of the pandemic have presented us with some challenges – and we are alert to the possibility of setbacks in the world's fight against COVID-19 that could impact our rollout – the Imricor team is responding effectively to the circumstances. The business is well positioned, with an exciting outlook as we work to expand our clinical sites, indications for our products, our product range and geographic footprint.

We continue to work closely with customers to schedule installation and training, in preparation to commence procedures as COVID-19 restrictions ease.

Our research and development pipeline remains a clear priority to drive growth, and our pipeline remains very strong.

Finally, our commercialization and growth plans are supported by a strong financial position. At year end, we had net cash of US\$25.1 million.

On behalf of the Board and management, we extend our thanks to our employees for their commitment, hard work and resilience during this challenging year.

Finally, we thank our investors for their continued support.



**Steve Wedan**  
Executive Chair, President and CEO  
Imricor Medical Systems, Inc.

*"The business is well positioned, with an exciting outlook as we work to expand our clinical sites, indications for our products, our product range and geographic footprint."*



*"We are the only company globally to offer cardiac catheter ablation devices for use in the MRI environment."*



**CE mark approval received**  
enabling the sale of Imricor's products in the European Union



**Successful commercial launch**  
at Heart Centre Dresden also providing training to future sites



**9 sites contracted**  
with a growing pipeline of new sites



**Procedures undertaken**  
are delivering excellent outcomes for surgeons and patients

# Key Achievements & Core Strategies





### Go to market strategies

- Collaborative sales distribution agreement with Philips
- Strategic relationship with Siemens
- Growing awareness through sales and marketing activities
- Engagement with Key Opinion Leaders
- Comprehensive training and support at clinical sites



### Geographic expansion

- CE mark approval enables the sale of products in the EU
- Strategy to obtain FDA approval in the US well advanced and targeting clinical trials in 2021-2022
- Entered into an agreement with local agent to support TGA approval in Australia



### Expanded indications

- Ablation catheter has CE mark approval for the treatment of atrial flutter
- Atrial flutter comprises only 23% of ablation procedures in the EU
- Planning to commence clinical trials to expand CE mark approval to other indications



### Expanded Product Range

- Diagnostic catheter under development to support margin improvement
- Steerable sheath and transseptal needle supporting expanded indications
- NIH contract to develop a device to biopsy the inner walls of the heart guided by MRI



### Sales agreement with Philips

enabling Philips to sell Imricor's capital equipment as part of iCMR lab installation package



### Strategic agreements signed

that further promote future iCMR lab adoption



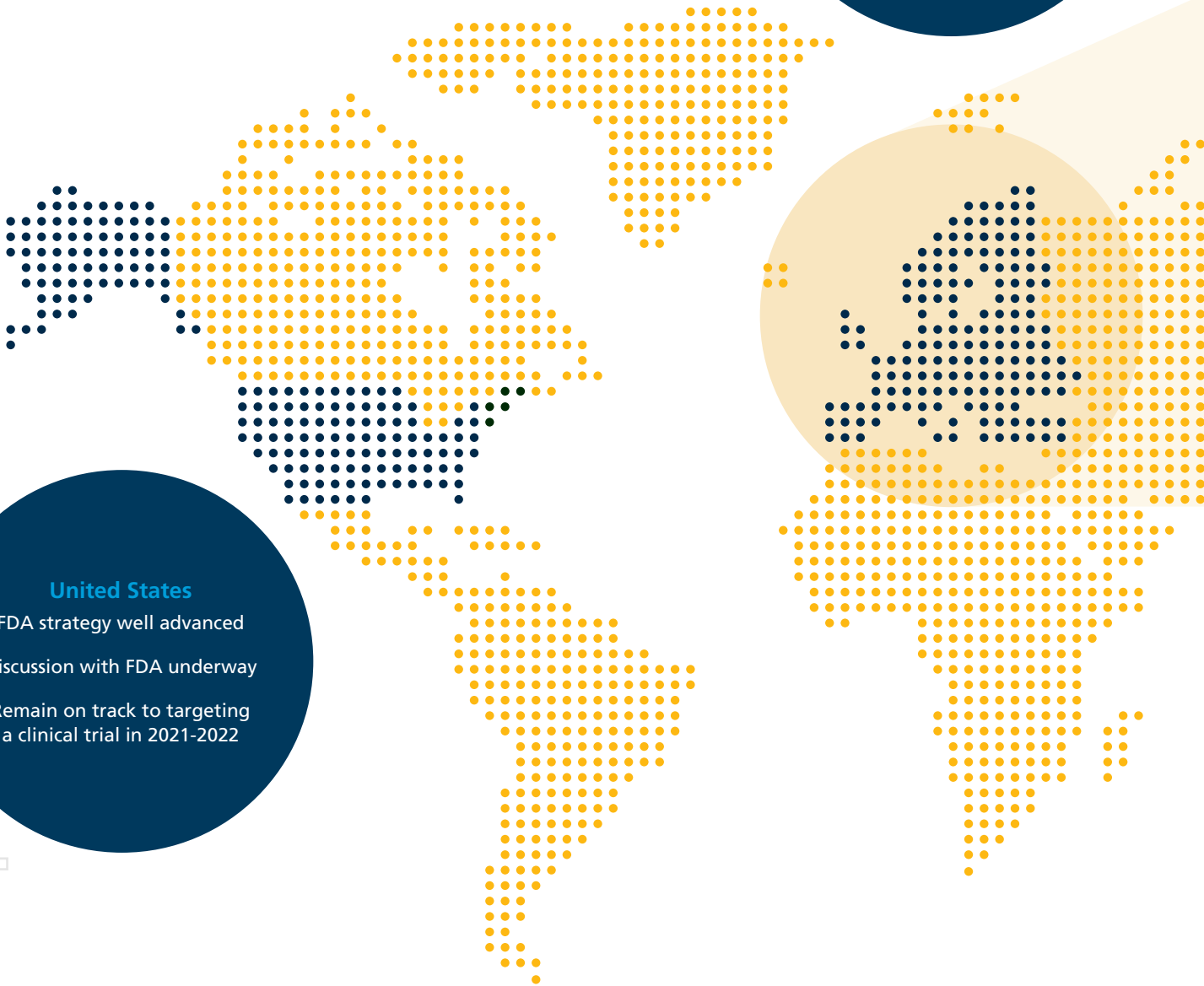
### Local agent selected to support TGA approval

remaining on track with initiatives to expand indications and geographies



### Expanded workforce

with 27 new hires in 2020 including hires from high calibre organisations



**United States**

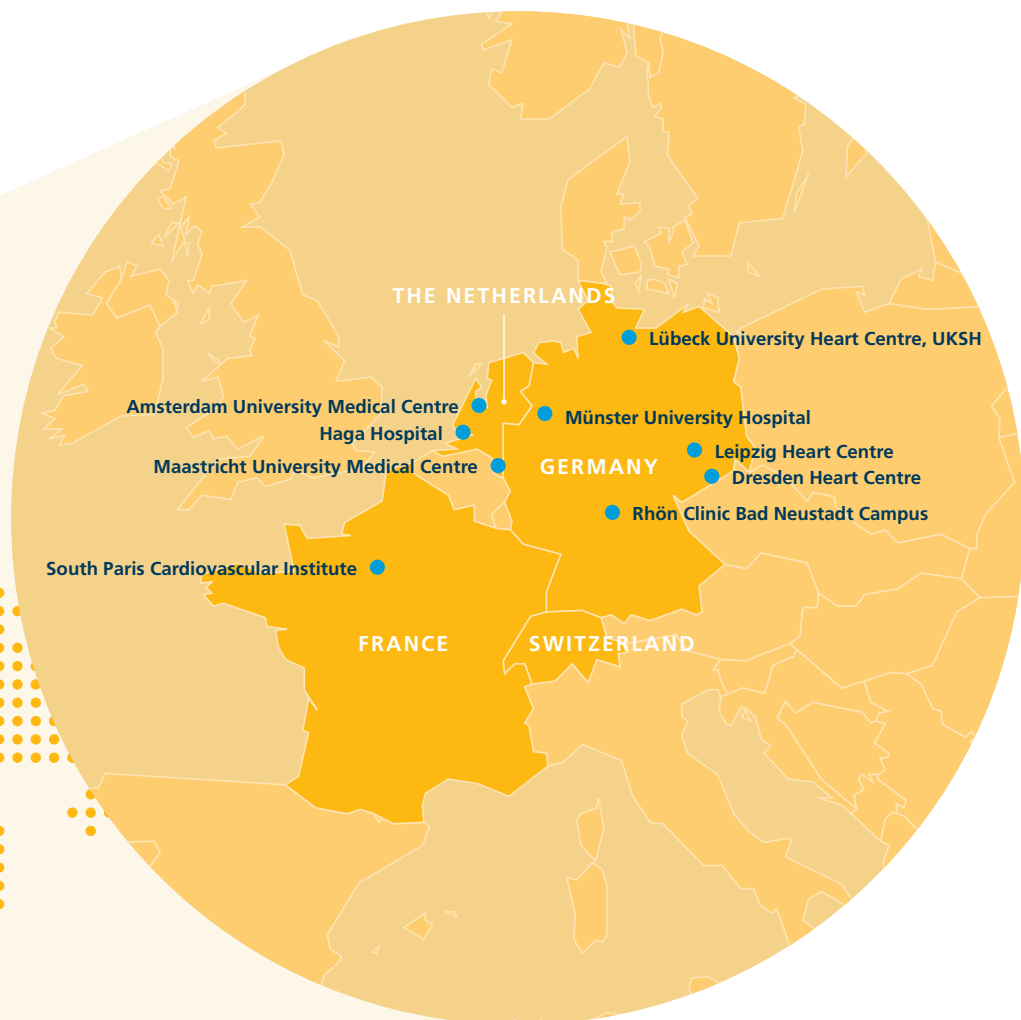
FDA strategy well advanced  
Discussion with FDA underway  
Remain on track to targeting  
a clinical trial in 2021-2022

**Europe**

CE Mark received  
  
We have an established sales  
force targeting Germany  
and the Netherlands  
  
Remain on track to targeting  
a clinical trial for VT Ablations  
in late 2021 – early 2022

# Geographic Expansion





#### Australia

Entered into a distribution agreement with a local agent to help facilitate TGA approval and act as agent for Imricor's products.

Detailed approval strategy in planning phase

#### The Netherlands

- Clinical sites established at Haga Hospital, Amsterdam UMC and Maastricht University Medical Centre

#### Germany

- Five clinical sites with signed purchase agreements across Germany
- Imricor products included in Sana GPO approved catalogue of materials

#### Switzerland

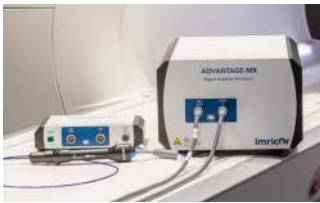
- Imricor products included in Sana GPO approved catalogue of materials

#### France

- Clinical site with signed purchase agreement at South Paris Cardiovascular Institute



Vision-MR Ablation Catheter



Advantage-MR EP Recorder/Stimulator System



Vision-MR Dispersive Electrode

DESCRIPTION

- |  |  |   |
|--|--|---|
| <ul style="list-style-type: none"><li>• The Vision-MR Ablation Catheter is an MR-Conditional (1.5T) RF ablation catheter containing patented technology that allows it to be used while the patient is being actively scanned with MRI. It is designed to look, feel, and function like a traditional ablation catheter.</li></ul> | <ul style="list-style-type: none"><li>• Advantage-MR EP Recorder/Stimulator System provides proven technology that allows the physician to utilize both the EP recording system and a cardiac stimulator while ablating within the iCMR environment.</li></ul> | <ul style="list-style-type: none"><li>• The Vision-MR Dispersive electrode is used with the Advantage-MR EP Recorder/Stimulator system. It acts like a standard ablation dispersive electrode, but also minimizes eddy currents induced on the device's conductive pads during MR scanning.</li></ul> |
|--|--|---|

TECHNICAL SPECIFICATION

- |  |  |  |
|--|--|--|
| <ul style="list-style-type: none"><li>• 9F (3.0mm) catheter with a 4mm open-irrigated deflectable tip and two gold electrodes (1.3mm spacing)</li><li>• 3.7mm tip electrode and a 1.4mm ring electrode</li><li>• 2 MR-receive coils in the distal end for real-time MR active catheter imaging</li></ul> | <ul style="list-style-type: none"><li>• Provides the functionality of both a conventional EP recording system and a cardiac stimulator</li><li>• Compatible with the Imricor Vision-MR Ablation Catheter</li></ul> | <ul style="list-style-type: none"><li>• Dual-lobe dispersive electrode used with a detached cable</li><li>• Includes adhesive conductive gel (hydrogel) to ensure full contact with the patient's skin</li></ul> |
|--|--|--|

TYPE OF PRODUCT

- |  |  |  |
|--|--|--|
| <ul style="list-style-type: none"><li>• Disposable</li><li>• Received CE mark January 2020</li></ul> | <ul style="list-style-type: none"><li>• Capital Good</li><li>• Received CE mark January 2016</li></ul> | <ul style="list-style-type: none"><li>• Disposable</li><li>• Received CE mark January 2020</li></ul> |
|--|--|--|

Our Products



**NavTrac-MR Transseptal Kit**



**Vision-MR Diagnostic Catheter**



**Biopsy Catheter**

- The NavTrac-MR Transseptal Kit is designed to access the left atrium during iCMR EP procedures. NavTrac-MR includes an actively tracked dilator to allow for precise anatomical positioning during left-sided EP procedures. *NavTrac-MR name is currently going through the trademark process*
- Includes trackable dilator, steerable sheath, and transseptal needle

- The Vision-MR Diagnostic Catheter is an MR-Conditional (1.5T) 9F diagnostic catheter containing patented technology that allows it to be used while the patient is being actively scanned with MRI. It facilitates sensing and pacing during cardiac electrophysiology procedures.

- The Imricor Biopsy-MR Catheter is designed to obtain intracardiac tissue specimens while the patient is being actively scanned with MRI.

#### Deflectable/Steerable Sheath

- 16 F outside diameter
- Curl diameter 30mm
- Usable length 71cm

#### Actively Tracked Dilator

- Dilator outside diameter .152"
- 2 MR-receive coils in the distal end for real-time MR active catheter imaging. (Coil spacing 5mm)
- Dilator reveal length .97"

#### Needle

- Tip outer diameter: 0.028"
- Overall Length (including handle): 43.4"
- Useable Length (just tubing with tip): 41.1"
- Hollow shaft to allow a guidewire to pass through to facilitate access to the atrial septum

- 9F (3.0mm) catheter with a deflectable tip and two gold electrodes (1.3mm spacing)
- 1.5mm tip electrode and a 1.4mm ring electrode
- 1 MR-receive coil in the distal end for real-time MR active catheter imaging

- 7Fr catheter with an actuatable forceps at the tip
- 2 MR-receive coils in the distal end for real-time MR active catheter imaging

- Disposable
- In development

- Disposable
- In development

- Disposable
- In development

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**The Heart Centre Dresden** was the first hospital to perform an iCMR ablation anywhere in the world outside of a clinical trial. In February 2020, three procedures were successfully performed over two days by Dr. Christopher Piorkowski and Dr. Thomas Gaspar, using the Company's products following the CE mark of the Vision-MR Ablation Catheter.

Imricor signs its first commercialisation contract in Netherlands with the Amsterdam University Medical Centre

First cases at Dresden Heart Centre, Germany

Leipzig Heart Centre, Rhon Clinic & Maastricht University purchase agreements signed

Münster University Hospital purchase agreement signed

Imricor signs sale distribution Agreement with Philips

ICPS Paris & Lübeck University purchase agreements signed

Imricor awarded National Institutes of Health contract

HISTORICAL →

2020 →

IPO launched

Imricor signs agreement with Sana

iCMR lab opened and cases commence at Haga Hospital, The Netherlands

# Timeline



**The Leipzig Heart Institute**, housed within the Heart Centre, has been established by Imricor as a Centre of Excellence in which visitors from new sites can observe clinical cases prior to commencing iCMR guided ablations at their own facilities.

**Maastricht University Medical Centre+ (MUMC+)** is the first site to commence procedures since the extended Covid lockdowns across Europe precluded elective surgeries. MUMC+ is one of the sites where cardiology and radiology are partnering to utilise an existing MRI suite as an iCMR lab to start performing ablations using Imricor's products immediately, while future plans are being made for constructing dedicated iCMR lab facilities.



Imricor enters into sales collaboration with Optoacoustics

Maastricht University Medical Centre commences procedures

Entered into a distribution agreement with Regional Health Care Group, a local agent in Australia

Transseptal needle & steerable sheath ready for clinical trial

CE Mark approval for VT ablations in Europe

Myocardial Biopsy system moves into next phase

**FUTURE** →

Imricor signs supply and sales agreement with Osypka

Leipzig Heart Centre commences procedures

TGA approval in Australia

Commercial release of Diagnostic catheter

Atrial Flutter Ablations approval in the US

## Board of Directors

### Steve Wedan

*President and Chief Executive Officer, and Chair*

Joined Board in May 2006

Mr Wedan co-founded the Company in 2006 and has served as CEO since that time.

Mr Wedan is responsible for the overall management and strategic direction of the Company.

Mr Wedan has over 29 years of experience in the medical device industry including design engineering of MRI and ultrasound systems for GE Healthcare, as well as Vice President and Chief Technology Officer for Applied Biometrics Inc. Immediately prior to co-founding Imricor, Mr Wedan founded and operated a technical consulting company, Wedan Technologies Inc., from 2000-2006. Mr Wedan is a member of various international standards committees in the fields of MRI safety and the compatibility of implanted and interventional products in MRI.

Mr Wedan currently serves on the boards of Medical Device Research Forum and Water Rescue Innovations, Inc.

Mr Wedan holds a Bachelor of Science in Electrical Engineering from Michigan Technological University (summa cum laude), and a Master of Science in Electrical Engineering from Marquette University.

### Mark Tibbles

*Deputy Chair and Lead Independent Director*

Chair of the Nomination and Remuneration Committee

Member of the Audit and Risk Committee

Joined Board in September 2014

Mr Tibbles is an entrepreneur, business owner, company director and active venture investor in and advisor to technology, life science and medical device companies.

Mr Tibbles is currently a Board member of THE NERDERY, LLC, OMEDZA.com, Inc., the Managing Director of Strategic Stage Ventures, LLC and an owner and managing member of STEM Fuse, LLC one of the largest providers of digital K-12 STEM curriculum in the U.S.

Prior to his current roles, Mr Tibbles was an owner and member of Intuitive Technology Group until it was sold in 2017. Mr Tibbles was also President and founder of PRC Consulting, Inc., a company specialising in the management and implementation of IT projects for Fortune 1000 companies, from 1998 until 2013, when PRC was sold.

Mr Tibbles holds a Bachelor of Arts from Oral Roberts University.





## Doris Engibous

*Non-executive Director  
Term Expired*

Joined Board in May 2019

Retired from Board in March 2021 upon expiration of term

Ms Engibous has over 40 years of experience in the medical device industry. From 2004 to 2010, she served as President and CEO of Hemosphere Inc., an early commercialisation stage medical technology company, before it was acquired by CryoLife Inc. (NYSE: CRY).

Prior to 2004, Ms Engibous held various roles with Nellcor (a business of Tyco Healthcare Group/Tyco International Ltd., now Covidien/Medtronic, NYSE: MDT) for 17 years, including serving as President from 2000 to 2003. From 2004 to 2018, Ms Engibous served as an independent non-executive director of Nasdaq-listed, Natus Medical Incorporated.

Ms Engibous holds a Bachelor of Science in Chemical Engineering from the University of Michigan.

## Peter McGregor

*Non-executive Director*

Chair of the Audit and Risk Committee

Member of the Nomination and Remuneration Committee

Joined Board in May 2019

Mr McGregor has over 30 years' experience in senior finance and management roles, including having been a partner in the investment banking firm of Goldman Sachs JBWere and a Managing Director in the institutional banking & markets division of Commonwealth Bank of Australia. He is also a former Chief Financial Officer of the ASX50 transport company, Asciano Limited (ASX: AIO), and Chief Operating Officer of ASX listed Australian Infrastructure Fund Limited (ASX: AIX).

Mr McGregor is an experienced Company Director and currently serves as a Director of Pivotal Systems Corporation (ASX:PVS).

Mr McGregor holds a Bachelor of Commerce from the University of Melbourne, is a member of the Australian Institute of Company Directors and a Fellow of the Financial Services Institute of Australasia.

## Anita Messal

*Non-Executive Director*

Member of the Audit and Risk Committee

Member of the Nomination and Remuneration Committee

Joined Board in March 2021 and will stand for election at the Company's upcoming Annual Stockholder Meeting

Ms Messal has 35 years of experience in the healthcare sector and is currently the Chief Integration Officer at AccentCare, Inc. a US based national post-acute healthcare provider, where she is responsible for the successful integration of merged and acquired entities across all areas of the business.

Prior to AccentCare, she most recently served as President & Chief Operating Officer of PlanSource.

Ms. Messal has participated in fund raising from start-up through IPO and sale to strategic buyers and private equity. She has worked in both Fortune 100 and start-up companies with experience in public, private and non-profit businesses. Her experience includes working in domestic and international markets, with time spent developing programs and partnerships in the United Kingdom and Europe.

Ms. Messal holds a B.A. from the University of Minnesota and an MBA from the Carlson School of Management at the University of Minnesota.



### Steve Wedan

*President and Chief Executive Officer, and Chair*

Refer to page 12.

### Lori Milbrandt

*Vice President of Finance and Chief Financial Officer*

Ms Milbrandt has served as the Company's Chief Financial Officer since 2007, initially on a contract basis and since May 2018, as a full-time employee of Imricor.

Ms Milbrandt has over 30 years of accounting, finance, and HR experience. Prior to transitioning to the role of CFO on a full-time basis, Ms Milbrandt was a contract CFO for several medical device companies. Ms Milbrandt has previously held management positions with companies including Microvena, ev3, and DiaSorin (FKA Incstar) and spent the first seven years of her career with KPMG.

Ms Milbrandt holds a Bachelor of Business Administration from the University of Wisconsin-Eau Claire and a Master of Business Administration (Finance) from the University of St. Thomas.

### Gregg Stenzel

*Chief Operating Officer*

Mr Stenzel commenced his role as Chief Operating Officer in January 2021 and is responsible for leading the execution of Imricor's strategic plan across most functional areas of the business.

Mr Stenzel was previously Imricor's Vice President of Operations with responsibility for the Company's operations and the development of manufacturing strategies, including personnel, facilities and outsourcing. He has over 20 years of medical device experience with deep knowledge in new product development, supply chain management, quality and regulatory systems and customer support.

Prior to joining Imricor in 2007, Mr Stenzel was the Manager of Instrument Technical Operations at Beckman Coulter, Inc. a leading manufacturer of In Vitro Diagnostic Systems.

Mr Stenzel holds a Bachelor of Science in Electrical Engineering from the University of Wisconsin - Madison and a Master of Business Administration from the University of Minnesota - Carlson School of Business.

### Dan Sunnarborg

*Vice President of Engineering*

Mr Sunnarborg joined Imricor in 2007 and is responsible for all hardware and software development activities at the Company, including platform development, system control, image processing, user interface, and outsource partnerships.

Mr Sunnarborg has more than 20 years of engineering experience in fields such as medical devices, telecommunications, defense, and consumer electronics. Mr Sunnarborg has also held various design software engineering positions and has led development groups for more than 15 years.

Mr Sunnarborg holds a Bachelor of Science in Engineering Physics from North Dakota State University and a Master of Science in Electrical Engineering from Marquette University.

## Executive Team



### Jennifer Weisz

*Vice President of Regulatory and Quality*

Ms Weisz joined Imricor in 2012 and commenced her current role in 2018. Ms Weisz is responsible for implementing and managing the Company's regulatory strategy and quality system.

Ms Weisz has over 19 years of experience in the medical device industry, including product development, clinical evidence development, quality system implementation, and regulatory strategy development and implementation.

Prior to joining the Company, Ms Weisz was a member of the Medtronic Global Clinical Operations Quality team.

Ms Weisz holds a Bachelor of Science in Electrical Engineering from North Dakota State University and a Master of Science in Technical Management from the University of St. Thomas.

### Tom Lloyd

*Vice President of Clinical Research*

Mr Lloyd commenced his current role at Imricor in 2012 and is responsible for leading preclinical and clinical studies, managing intellectual property, and developing new technologies.

Mr Lloyd began his career at the Company in 2007 as a radio-frequency engineer and is the lead inventor on many of the Company's patents.

Mr Lloyd has over 13 years of medical device design experience primarily focused on interactions between implanted devices and the electromagnetic fields associated with MRI.

Mr Lloyd holds a Bachelor and Master of Science in Electrical Engineering from Iowa State University.

### Greg Englehardt

*Executive Director of Sales*

Mr Englehardt joined Imricor in 2018 and is responsible for developing and managing the Company's global sales strategies and performance.

Mr Englehardt has 18 years of experience working in the medical device industry with 16 years of sales leadership experience. Prior to joining the Company, Mr Englehardt served as Regional Business Director at Medtronic from 2011 to 2018. Before joining Medtronic, he worked at NeuroMetrix from 2004 until 2011, where he was promoted to multiple sales and leadership roles including Director of Global Business Development/Sales and National Director of Sales.

Mr Englehardt also served as a combat medic in the U.S. army and holds a Bachelor of Science in Nursing from Louisiana State University.

### Nick Twohy

*Executive Director of Marketing*

Mr Twohy joined Imricor in 2019 and is responsible for global portfolio management, including the product roadmap, product management, marketing teams and communications.

Mr Twohy has over 20 years of experience in the medical devices industry. Most recently he worked as the International Marketing Director for Medtronic in the Cardiac Resynchronisation Therapies business. There he led business planning and execution for the International Markets. Prior to that role, Mr Twohy led multiple product launches at Medtronic including various launches in the CareLink remote monitoring business, and in the Cardiac Rhythm Management business where he led the US launch of the Revo MRI pacemaker system.

Mr Twohy holds a Bachelor of Arts from Hamline University and a Master of Business Administration from the University of St. Thomas.



# Operating & Financial Review

## Overview

Imricor is a US-based medical device company that seeks to address the current issues with traditional x-ray guided ablation procedures through the development of MRI-guided technology. The Company's principal focus is the design, manufacturing, sale and distribution of MRI-compatible products for cardiac catheter ablation procedures.

Imricor is a pioneer and leader in developing MRI-compatible products for cardiac catheter ablation procedures and in early 2020, brought the first commercially viable and safe MRI-compatible products to the cardiac catheter ablation market.

In January 2020, Imricor obtained CE mark approval for its key consumable products, the Vision-MR Ablation Catheter (with an indication for treating type 1 atrial flutter) and the Vision-MR Dispersive Electrode. The Vision-MR Ablation Catheter is the Company's prime product offering, specifically designed to work under real-time MRI guidance with the intent of enabling higher success rates along with a faster and safer treatment compared to conventional procedures using x-ray guided catheters. The Company also has approval for the sale of its capital product, the Advantage-MR EP Recorder/Stimulator System, in the European Union.

Imricor is in the early stage of commencing the sale of its capital and consumable products to hospitals and clinics for use in Interventional Cardiac Magnetic Resonance Imaging (iCMR) labs, in which ablation procedures using the Vision-MR Ablation Catheter can be performed. The installation of iCMR labs is driven primarily by MRI equipment vendors working collaboratively with Imricor. These vendors help to target certain sites and support the design and construction of iCMR labs for those sites.

Imricor has joint development agreements with two leading, global MRI vendors, Philips and Siemens. In addition, the Company has a sales distribution agreement with Philips and is working towards a similar agreement with Siemens.

The Company also performs contract research on and licences some of its IP for use in other MRI compatible devices. Moving forward, Imricor expects its primary revenue source to be from the sale of its capital and consumable products. Sales revenue will depend on the number of established clinical sites and the procedure volume at each of those sites, as well as the types of arrhythmias the products are used to treat.

## Business strategy and opportunities

Imricor's products are designed to operate in a global cardiac catheter ablation market which is expected to increase to US\$4.37 billion in 2021 from US\$3.03 billion in 2016; growth by a CAGR of 7.6%. The global growth is underpinned by several favourable drivers, including rising incidences of cardiac disease due to changing demographic trends, a shift towards minimally invasive procedures and cost savings that have been associated with catheter ablation as a treatment method for certain arrhythmias.

Following receipt of CE mark approval for the Vision-MR Ablation Catheter, Imricor has commenced a controlled release of its key products across Europe, with nine sites having executed purchased agreements across Germany, The Netherlands & France. Imricor aims to expand its focus with three dedicated Sales Managers targeting clinical sites across other European countries.

Within each targeted country, Imricor will first target ablation centres which historically have carried out larger volumes of procedures. Imricor believes targeting locations which are geographically proximate to existing clinical sites may also promote growth.

In Australia, Imricor has entered into a distribution agreement with Regional Health Care Group (RHCG), based in Sydney, who will be the exclusive distributor of Imricor's consumable products and a non-exclusive distributor of Imricor's capital equipment. RHCG will also help facilitate the necessary regulatory approvals and support of Imricor's products.

In the United States discussions with the FDA are well progressed, and Imricor is on track for clinical trials in late 2021 – early 2022.

In conjunction with organic growth across existing products, the Company has identified or is targeting growth through expansion in its product line providing the opportunity for Imricor's products to be used across a broader range of MR-guided interventional procedures. The Company therefore intends to pursue regulatory approval for its products with expanded indications (ie. for treating arrhythmias other than typical atrial flutter).

## Material business risks

The material business risks faced by the Company that have the potential to impact the financial prospects of the Company include:

- **Regulatory risk:** The sale of Imricor's products requires regulatory approval in each relevant jurisdiction. The Company is not assured of receiving future regulatory clearances for its existing products outside of the European Union or approvals for expanding indications or additional products currently in Imricor's product pipeline.
- **Market adoption risk:** The ability of Imricor to generate revenue is dependent on hospitals and clinics with ablation centres in markets where it obtains the required regulatory approval establishing an iCMR lab and adopting Imricor's MRI-compatible technology for cardiac catheter ablation procedures. While Imricor works collaboratively with leading MRI vendors to drive lab adoption, there can be no guarantee on the outcome.
- **Integration with third party mapping systems:** Active MR Tracking and 3D mapping are required for several expanded indications Imricor is targeting in the future, such as the treatment of atrial fibrillation and ventricular tachycardia. Imricor's ablation system is designed to work with third-party 3D mapping systems developed by leading MRI vendors which have Active Tracking functionality. In order to be made commercially available, these 3D mapping systems require certain approvals (CE mark or local ethics committee approval) which have not yet been obtained.

Beyond these risks, the Company maintains general risk exposure associated with market competition, employee capability and intellectual property as well as potential financial capacity constraints within the healthcare sector.

## Financial performance

For the year ended 31 December 2020, the Company generated revenue of US\$0.702 compared to US\$0.640 million for the previous corresponding period. Imricor reported a net loss of US\$12.446 million (FY19 US\$13.294 million). This net loss decreased from the prior year primarily due to non-recurring non-cash interest and note conversion-related charges during the year ended 31 December 2019. Operating costs increased to US\$12.658 million from US\$7.187 million in the year due to higher expenses associated with staffing expansion and D&O insurance, as well as incremental costs associated with being a public company.

## Financial position

For the 12-month period ending 31 December 2020, Imricor's net cash outflow from operations was US\$12.231 compared to US\$6.628 million for the prior year. Net cash outflows from investing activities of US\$0.774 compared to US\$0.529 million for the prior year relate primarily to the purchase of manufacturing and R&D equipment and payments for security deposits. Net cash inflows from financial activities of US\$33.025 were predominately associated with Imricor's February and November placements and the December Security Purchase Plan. Net cash inflows from financial activities during the prior year of US\$10.5 million were predominantly associated with Imricor's IPO completed during the year.

At 31 December 2020, Imricor maintained a cash balance of US\$25.140 million (FY19 US\$5.049 million) which supports the progress of its commercialisation plans and growth strategy.

# Directors' Report

## Principal activities

Imricor is a US-based medical device company focused on addressing the current issues with traditional x-ray guided ablation procedures through the development of MRI-guided technology.

The principal activities of Imricor during the course of the year were to design, manufacture and sell MRI-compatible products for cardiac catheter ablation procedures to treat arrhythmias.

There were no significant changes in the nature of the activities of the Company during the year.

## Significant changes in the state of affairs

In response to the COVID-19 pandemic, the Company adjusted its sales, marketing and physician education strategies to be virtual. In addition, the European sales team was trained to perform site installations in order to alleviate the impact of international travel restrictions on US personnel. Various other internal adjustments to the pandemic were made to support the continued progression of the Company's strategic plans of geographic expansion, indication expansion, and product development.

There were no other significant changes in the state of affairs of the Company during the year.

## Operating and financial review

The operating and financial review is set out on pages 16 to 17 of this Annual Report.

## Directors qualifications and experience

The directors of Imricor at any time during or since the end of the financial year are:

Director	Appointed
Steve Wedan	May 2006
Mark Tibbles	September 2014
Doris Engibous*	April 2019
Peter McGregor	May 2019
Anita Messal	March 2021

\*Resigned on 1 March 2021.

The specific duties, qualifications and experience of each Director are set out on pages 12 to 13 of this Annual Report.

## Company secretary

Mr Kobe Li was appointed as the Australian company secretary and local agent in April 2019. Mr Li provides company secretarial and corporate governance consulting services to ASX listed companies. Mr Li has previously worked at the ASX Listings Compliance team for eight years as a Senior Adviser. Mr Li is a member of the Governance Institute of Australia.

## Directors' meetings

The number of Directors' meetings (including meetings of Committees of Directors) and number of meetings attended by each of the Directors of the Company during the financial year are:

Director	Board		Audit & Risk Committee		Nomination & Remuneration Committee	
	Held	Attended	Held	Attended	Held	Attended
Steve Wedan	8	8	–	–	–	–
Mark Tibbles	8	8	6	6	3	3
Doris Engibous	8	8	6	6	3	3
Peter McGregor	8	7	6	6	3	3

Mr Wedan is an invitee and attends the Audit & Risk Committee and Nomination & Remuneration Committee meetings.



### Directors' interests

In this section, reference is made to Share ownership. The instruments registered for trade on the Australian Securities Exchange are CHESS Depositary Interests (CDIs). One CDI is equivalent to one Share.

The relevant interest of each Director in the Shares and stock options of Imricor, as notified by the Directors to the Australian Securities Exchange (ASX) in accordance with ASX Listing Rule 3.19A.2, at the date of this report is as follows:

Director	Number of Shares	Number of Options
Steve Wedan	4,424,733	1,839,987
Mark Tibbles	4,581,878	485,910
Doris Engibous	Nil	201,571*
Peter McGregor	Nil	206,010
Anita Messal	Nil	Nil

### Directors' directorships in other listed entities

Please refer to the Board of Directors section above.

### Dividends

No dividends were paid or declared by Imricor during the year.

### Subsequent events

On 2 March 2021, the Company announced the resignation of Doris Engibous from the Board and the appointment of Anita Messal, effective 2 March 2021.

On 1 April 2021, the Company announced it had entered into a Distribution Agreement with Australian-owned medical distribution company Regional Health Care Group Pty Ltd (RHCG), based in Sydney.

### Likely developments

Imricor will continue to pursue its product and geographic-led growth strategy, with a focus on product distribution and lab roll-out in existing markets and expansion in to new markets including Australia.

Due to the effects of the COVID-19 pandemic, Imricor has experienced some delays in the establishment of European clinical sites in which its products can be used to perform cardiac catheter ablation procedures due to hospital restrictions on external personnel and elective procedures. In early 2021, the first procedures were carried out at the Maastricht University Medical Centre in the Netherlands and the Helios Leipzig Heart Centre in Germany. The Leipzig Heart Centre is an Imricor Centre of Excellence which will also provide training for new sites as they adopt iCMR ablations.

Further information about likely developments in the operations of Imricor and the expected results of those operations in future financial years has not been included in this report because disclosure of the information would be likely to result in unreasonable prejudice to the Company.

### Environmental regulation

Imricor is not subject to any significant environmental regulation under United States legislation.

### Indemnities and insurance of officers

As permitted under Delaware law, Imricor indemnifies its Directors and certain officers and is permitted to indemnify employees for certain events or occurrences that happen by reason of their relationship with, or position held at, Imricor. The Company's Certificate of Incorporation and Bylaws provide for the indemnification of its Directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law.

Imricor has entered into indemnification agreements with its Directors and certain officers to this effect, including advancement of expenses incurred in legal proceedings to which the Director or officer was, or is threatened to be made, a party by reason of the fact that such Director or officer is or was a Director, officer, employee or agent of Imricor, provided that such a Director or officer acted in good faith and in a matter that the Director or officer reasonably believed to be in, or not opposed to, the Company's best interests. At present, there is no pending litigation or proceedings involving a Director or officer for which indemnification is sought, nor is the Company aware of any threatened litigation that may result in claims for indemnification.

# Directors' Report (cont.)

Imricor maintains insurance policies that indemnify the Company's Directors and officers against various liabilities that might be incurred by any Director or officer in his or her capacity as such. The premium paid has not been disclosed as it is subject to confidentiality provisions under the insurance policy.

## Corporate Governance

Imricor's Corporate Governance Statement is available on the Imricor website at <https://imricor.com/corporate-governance/>.

## Non-audit services

During the year, the Company's auditor Baker Tilly Virchow Krause, LLP has performed certain other services in addition to the audit and review of the financial statements.

The Board has considered the non-audit services provided during the year by the auditor and in accordance with written advice provided by resolution of the Audit and Risk Committee, is satisfied that the provision of those non-audit services during the year is compatible with, and did not compromise, the auditor independence requirements of the Public Company Accounting Oversight Board (United States) ('PCAOB') for the following reasons:

- All non-audit services were subject to the corporate governance procedures adopted by the Company and have been reviewed by the Audit and Risk Committee to ensure they do not impact the integrity and objectivity of the auditor.
- The non-audit services provided do not undermine the general principles relating to auditor independence as set out in PCAOB Rule 3520, as they did not involve reviewing or auditing the auditor's own work, acting in a management or decision-making capacity for the Company, acting as an advocate for the Company or jointly sharing risks and rewards.

Details of the amounts paid to the auditor, Baker Tilly Virchow Krause, LLP for audit and non-audit services provided during the year are set out below:

	2020 US\$	2019 US\$
<b>Fees paid for audit and other services:</b>		
Taxation services	9,730	7,645
Audit or review of the financial statements	92,515	73,177

## Jurisdiction of incorporation

Imricor is a company incorporated in the State of Delaware in the United States and registered in Australia as a foreign company. As a foreign company registered in Australia, Imricor is subject to different reporting and regulatory regimes than Australian public companies.

## Presentation currency

The functional and presentation currency of the Company is United States Dollars (US Dollars). The financial report is presented in US Dollars with all references to dollars, cents or \$'s in these financial statements presented in US currency, unless otherwise stated.

## Directors authorisation

This Directors' Report is made out in accordance with a resolution of the Directors.



Steve Wedan  
Chairman  
13 April 2021

# Remuneration Report

Imricor 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 Australia and the United States. This remuneration report forms part of the Directors' Report and has been prepared using the requirements of section 300A of the *Australian Corporations Act 2001* (Cth) as a proxy to determine the contents that the Board has chosen to report.

The Report details the remuneration arrangements for Imricor's key management personnel (KMP):

- Non-Executive Directors (NEDs);
- President and Chief Executive Officer (CEO), Steve Wedan; and
- Chief Financial Officer (CFO), Lori Milbrandt.

KMP are those persons who, directly or 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 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, Steve Wedan and CFO, Lori Milbrandt.

The Nomination and Remuneration Committee:

- Establishes processes for the identification of suitable candidates for appointment to the Board;
- Establishes processes for reviewing the performance of individual Directors, the Board as a whole, and Board committees;
- Determines executive remuneration policy and Non-Executive Director remuneration policy;
- Reviews all equity-based incentive plans and makes recommendations to the Board regarding their adoption and implementation; and
- Ensures that the remuneration policies of Imricor are balanced and do not reward behaviour that is inconsistent with its values.

The Nomination and Remuneration Committee comprises three Non-Executive Directors: Mark Tibbles (Chair), Doris Engibous (to March 2021) and Peter McGregor. Anita Messal replaced Doris Engibous in March 2021.

The Nomination and Remuneration Committee has a formal charter which can be viewed on the Company's website <https://imricor.com/corporate-governance/>.

## Use of external remuneration advisors

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.

During the year the Committee appointed 21-Group to provide remuneration benchmarking services used in determining the remuneration framework for 2020. These services were provided to the Nomination and Remuneration Committee free from any undue influence by management. The total amount incurred to 21-Group in 2020 was US\$11,775.

## Principles of compensation

Imricor's remuneration framework 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 operational 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 Company's current stage of development.

## 2020 remuneration structure

Imricor's executive compensation packages include a mix of fixed and variable compensation, and short and long-term performance-based incentives.

### Fixed component

The Company aims to provide a competitive base salary with reference to the role, market and experience of the individual. The performance of the Company and the individual are considered during the annual remuneration review.

# Remuneration Report (cont.)

## Short-term incentive component

The Company allocates cash bonuses linked to annual performance targets determined by the Board. These targets are established to promote and reward outstanding performance, beyond what is expected in the ordinary course of business.

The target STI opportunity is set as a percentage of fixed remuneration. For 2020 the maximum target opportunity was 50% for the President and CEO, Steve Wedan and 30% for the CFO, Lori Milbrandt.

Performance targets determined by the Board in relation to 2020, were based 50% on lab adoption, revenue projections and post-market study enrolment and 50% based upon individual objectives. Commercialization efforts were significantly negatively impacted due to COVID 2020. As such the Board exercised discretion in granting short-term incentives for 2020 in recognition of the achievements delivered by the management team during the year, including the signing of 9 labs, the installation of 5 labs, successful financings, a greater than 100% increase in market capitalization, increased media coverage and public awareness in Australia, and the implementation of an inventory management system.

## Long-term incentives component

Imricor's 2019 Equity Incentive Plan (2019 Plan) provides equity-based compensation for individuals that is linked to service, the growth and profitability of the Company and increases in stockholder value. The 2019 Plan is designed to align the interests of management with its stockholders, while maintaining a total remuneration opportunity that enables the Company to retain, attract and motivate qualified and high-performing executives.

Options granted under the 2019 Plan during the year had time-based vesting conditions only. Further options were granted in 2020, or in the case of the CEO are proposed to be granted, in relation to 2019 remuneration that incorporate both time-based and performance-based vesting conditions. All vesting is subject to continuous service and options expire 10 years following the grant date.

The 2019 Plan replaced the 2016 Stock Option Plan, with the Company ceasing to grant new awards under the 2016 Plan in February 2019. The predecessor to the 2016 Plan was the 2006 Plan. The rules of all plans were released to the ASX on 30 August 2019 and copies are available on the ASX Announcements section of the Company's website <https://imricor.com/investors/>.

## Other benefits

Certain other benefits are afforded to the executives including medical insurance, life and disability insurance, health savings and flexible spending account, and participation in the Company's 401(k) Plan. Since listing on the ASX, the Company matches 50% of employee contributions made to the 401(k) Plan to a maximum of 4% of the employee's annual income.

## Share options

### Options granted

The following options were granted during FY20:

- 497,714 options with exercise price of US\$0.80, expiring 6 January 2030
- 25,000 options with exercise price of US\$0.80, expiring 18 January 2030
- 125,000 options with exercise price of US\$1.14, expiring 20 February 2030
- 1,690,280 options with exercise price of US\$0.89, expiring 13 May 2030
- 100,000 options with exercise price of US\$1.10, expiring 14 July 2030
- 135,000 options with exercise price of US\$1.96, expiring 7 October 2030

### Unissued shares

At the date of this report, unissued Shares under option are:

Expiry date	Exercise price US\$	Number of Shares
21 March 2022	0.600	485,000
17 June 2023	0.600	60,000
19 May 2024	0.600	60,000
15 July 2025	0.730	124,000
15 March 2029	0.520	5,411,100
30 August 2029	0.980	685,625
17 December 2029	0.750	460,000
6 January 2030	0.800	497,714
18 January 2030	0.800	25,000
20 February 2030	1.140	25,000
13 May 2030	0.890	1,623,709
14 July 2030	1.100	100,000
7 October 2030	1.960	135,000

The options (with the exception of those expiring on 6 January 2030 and 1,481,689 of those expiring on 13 May 2030) are subject to time-based vesting and have been issued under one of the 2006 Plan, 2016 Plan or 2019 Plan as discussed above. The remaining options expiring on 6 January 2030 and 1,481,689 options expiring on 13 May 2030 are subject to time-based and performance-based vesting and have been issued under the 2019 Plan.

These options do not entitle the holder to participate in any share issue of the Company.

### Shares issued on exercise of options

During FY20 the Company issued Shares as a result of the exercise of options as follows (there are no amounts unpaid on the Shares issued):

Number of Shares	Amount paid on each Share
175,000	US\$0.341
178,333	US\$0.50
40,000	\$US0.52
20,000	\$US0.60

# Remuneration Report (cont.)

## Executive remuneration during the year

The remuneration of key management personnel in respect of the financial year ended 31 December 2020 (including remuneration yet to be paid) is summarised below. The options to be granted under the long-term incentive plan for the CEO in relation to 2020 remuneration must be approved by stockholders at the 2021 Annual Meeting of Stockholders (AGM).

Executive	Base salary	Short-term Incentive <sup>1</sup>	Long-term incentive
Steve Wedan President and CEO	US\$452,000	US\$113,000 25% of base salary	124,030 options granted on 13 May 2020 at an exercise price of US\$0.89 <sup>2</sup>  455,157 options granted on 13 May 2020 at an exercise price of US\$0.89 <sup>3</sup>  304,254 options to be granted following stockholder approval <sup>4</sup>
Lori Milbrandt CFO	US\$315,000	US\$47,250 15% of base salary	134,920 options granted on 6 January 2020 at an exercise price of US\$0.80 <sup>2</sup>  329,898 options granted on 13 May 2020 at an exercise price of US\$0.89 <sup>3</sup>

1. Determined at the discretion of the Board as discussed above and paid in January 2020.

2. 2019 Options:

Tranche	Percentage of 2019 Options	Vesting Conditions								
1	50%	Options will vest over a four-year period, with 25% vesting on each anniversary of the grant date.								
2	30%	<p>Options will vest based on absolute total stockholder return (TSR) over a three-year period commencing on the grant date. TSR growth will be calculated using the volume weighted average market price of the CDIs (in Australian dollars) for the five trading days prior to:</p> <p>(a) the grant date (to calculate the baseline price); and</p> <p>(b) the three-year anniversary of the grant date (to calculate TSR at the vesting date).</p> <p>Vesting will occur in accordance with the following table:</p> <table><tr><th>TSR Growth Rate</th><th>Percentage Vesting</th></tr><tr><td>Below 8%</td><td>0%</td></tr><tr><td>8% to &lt;20%</td><td><math>25+6.5 \times (\text{TSR Rate} - 8)\%</math></td></tr><tr><td>20% or greater</td><td>100%</td></tr></table>	TSR Growth Rate	Percentage Vesting	Below 8%	0%	8% to <20%	$25+6.5 \times (\text{TSR Rate} - 8)\%$	20% or greater	100%
TSR Growth Rate	Percentage Vesting									
Below 8%	0%									
8% to <20%	$25+6.5 \times (\text{TSR Rate} - 8)\%$									
20% or greater	100%									
3	10%	Options will vest upon the approval of the Therapeutic Goods Administration of the Company's first device in Australia on or prior to the expiration of the Options.								
4	10%	Options will vest upon the approval of the US Food and Drug Administration of the Company's first device in the US on or prior to the expiration of the Options.								



3. 2020 Options:

Tranche	Percentage of 2020 Options	Vesting Conditions								
1	50%	Options will vest over a four-year period, with 25% vesting on each anniversary of the grant date.								
2	30%	<p>Options will vest based on absolute total stockholder return (TSR) over a three-year period commencing on the grant date. TSR growth will be calculated using the volume weighted average market price of the CDIs (in Australian dollars) for the five trading days prior to:</p> <p>(c) the grant date (to calculate the baseline price); and</p> <p>(d) the three-year anniversary of the grant date (to calculate TSR at the vesting date).</p> <p>Vesting will occur in accordance with the following table:</p> <table><tr><th>TSR Growth Rate</th><th>Percentage Vesting</th></tr><tr><td>Below 8%</td><td>0%</td></tr><tr><td>8% to &lt;20%</td><td>25+6.5*(TSR Rate - 8))%</td></tr><tr><td>20% or greater</td><td>100%</td></tr></table>	TSR Growth Rate	Percentage Vesting	Below 8%	0%	8% to <20%	25+6.5*(TSR Rate - 8))%	20% or greater	100%
TSR Growth Rate	Percentage Vesting									
Below 8%	0%									
8% to <20%	25+6.5*(TSR Rate - 8))%									
20% or greater	100%									
3	20%	Options will vest upon the Customer sites (labs) equalling or exceeding 50.								

4. Options value determined based on 50% of base salary for 2021 and short-term incentive paid in 2021 for 2020, subject to stockholder approval at Imricor's 2021 AGM. As set out in the Company's Notice of Meeting, the number of Options proposed to be issued to Mr Wedan was determined by dividing the LTI Grant Value by the Black-Scholes value of an Option assuming an exercise price per Option equal to the closing sale price of a CDI as of the immediately preceding trading day prior to the Record Date, converted from Australian dollars to U.S. dollars using the prevailing exchange rate.

Tranche	Percentage of 2021 Options	Vesting Conditions
1	50%	First sale of product in the United States following FDA approval
2	25%	First sale of product in Australia following TGA approval
3	25%	First sale of product for use in a Ventricular Tachycardia ablation procedure following CE Mark approval

### Non-executive Directors (NED)

Under Imricor's Bylaws, the Directors decide the total amount paid to all Directors for their services as a Director of Imricor. However, under the ASX 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 Imricor in a general meeting. This amount has been fixed at US\$400,000.

The Board seeks to set NED fees at a level that provides the Company with the ability to attract and retain NED of high calibre with relevant professional expertise and reflects the demands that are made on, and the responsibilities of, the NED, while incurring a cost that is acceptable to stockholders. As Imricor's operations are in the initial stages of commercialisation, the Company has structured NED fees to include both cash remuneration and options in order to maintain appropriate remuneration structures and preserve cash flow. Options issued NED do not have performance hurdles attached.

NED serving on the board of directors will receive US\$65,000 in annual fees. Committee chairs will receive an additional US\$10,000 in annual fees. Committee members will receive an additional US\$5,000 in annual fees. All fees for Australian NED are inclusive of superannuation. The Chairman, Mr Steve Wedan, receives no remuneration.

The remuneration of Non-Executive Directors in respect of the financial year ended 31 December 2020 is summarised below:

Non-Executive Director	Cash fees	Options Granted <sup>1</sup>
Peter McGregor	US\$95,000	71,010
Doris Engibous	US\$86,250	66,571
Mark Tibbles	US\$95,000	71,010

1. The options shall vest over four years 25% on each anniversary of grant date.

**IMRICOR MEDICAL SYSTEMS, INC.**

Minneapolis, Minnesota

Including Independent Auditors' Report

As of and for the years ended December 31, 2020 and 2019

**IMRICOR MEDICAL SYSTEMS, INC.**  
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# Independent Auditors' Report



## Independent Auditors' Report

To the Stockholders and Board of Directors of  
Imricor Medical Systems Inc.

We have audited the accompanying financial statements of Imricor Medical Systems Inc., which comprise the balance sheets as of December 31, 2020 and 2019, and the related statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes to the financial statements.

### **Management's Responsibility for the Financial Statements**

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

### **Auditors' Responsibility**

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements 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 entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### **Opinion**

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Imricor Medical Systems Inc. as of December 31, 2020 and 2019 and the results of its operations and cash flows for the years then ended, in accordance with accounting principles generally accepted in the United States of America.

*Baker Tilly US, LLP*

Minneapolis, Minnesota  
February 24, 2021

Baker Tilly US, LLP, trading as Baker Tilly, is a member of the global network of Baker Tilly International Ltd., the members of which are separate and independent legal entities.

# Balance Sheets

As of 31 December 2020 and 2019

<b>ASSETS</b>			
	2020	2019	
<b>CURRENT ASSETS</b>			
Cash	\$ 25,139,812	\$ 5,048,893	
Accounts receivable	223,237	256,294	
Inventory	3,069,920	1,220,616	
Prepaid expenses and other current assets	491,628	287,787	
Total Current Assets	28,924,597	6,813,590	
<b>ACCOUNTS RECEIVABLE-LONG TERM</b>	238,749	277,070	
<b>PROPERTY AND EQUIPMENT, NET</b>	3,094,721	2,285,390	
<b>OTHER ASSETS</b>	224,320	192,174	
<b>OPERATING LEASE RIGHT OF USE ASSETS</b>	795,365	453,305	
<b>PREPAID SERVICE AGREEMENT</b>	291,664	500,000	
<b>TOTAL ASSETS</b>	<u>\$ 33,569,416</u>	<u>\$ 10,521,529</u>	
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
<b>CURRENT LIABILITIES</b>			
Accounts payable	\$ 529,132	\$ 540,980	
Accrued expenses	1,068,908	367,497	
Current portion of contract liabilities	40,202	14,557	
Current portion of operating lease liabilities	189,143	118,843	
Current portion of finance lease liability	8,886	8,420	
Current portion of financing obligation	462,961	374,023	
Total Current Liabilities	2,299,232	1,424,320	
<b>LONG-TERM LIABILITIES</b>			
Other long-term liabilities	67,395	-	
Contract liabilities, net of current portion	549,806	592,853	
Operating lease liabilities, net of current portion	1,168,644	330,803	
Finance lease liability, net of current portion	19,274	28,160	
Financing obligation, net of current portion	649,015	1,111,976	
Total Liabilities	<u>4,753,366</u>	<u>3,488,112</u>	
<b>COMMITMENTS AND CONTINGENCIES (NOTE 7)</b>			
<b>STOCKHOLDERS' EQUITY</b>			
Preferred stock, \$0.0001 par value:			
25,000,000 shares authorized and 0 shares outstanding as of both December 31, 2020 and 2019	-	-	
Common stock, \$0.0001 par value:			
535,000,000 shares authorized as of both December 31, 2020 and 2019 and 125,549,550 and 92,682,535 shares issued and outstanding as of December 31, 2020 and 2019, respectively	12,556	9,268	
Additional paid-in capital	81,675,671	47,449,853	
Accumulated deficit	(52,872,177)	(40,425,704)	
Total Stockholders' Equity	<u>28,816,050</u>	<u>7,033,417</u>	
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 33,569,416</u>	<u>\$ 10,521,529</u>	

See accompanying notes to financial statements  
Page 2

# Statements of Operations

For the years ended 31 December 2020 and 2019

	2020	2019
<b>REVENUES</b>		
Product revenues	\$ 468,263	\$ 376,321
Service revenue	38,009	-
Consulting revenue	100,000	-
Government contract revenue	95,889	263,383
Total Revenue	702,161	639,704
<b>COSTS AND EXPENSES</b>		
Cost of goods sold	1,099,833	377,365
Sales and marketing	1,683,653	573,058
Research and development	5,546,324	3,601,203
General and administrative	4,328,611	2,635,453
Total Operating Expenses	12,658,421	7,187,079
Loss from Operations	(11,956,260)	(6,547,375)
<b>OTHER INCOME (EXPENSE)</b>		
Interest income	29,237	13,856
Foreign currency exchange gain (loss)	(198,398)	216,139
Down round expense ( <b>NOTE 5</b> )	-	(1,802,129)
Beneficial conversion feature expense ( <b>NOTE 5</b> )	-	(4,129,856)
Interest expense	(300,637)	(1,030,732)
Other expense	(20,415)	(13,879)
Total Other Expense	(490,213)	(6,746,601)
<b>NET LOSS</b>	<u>\$ (12,446,473)</u>	<u>\$ (13,293,976)</u>
<b>EARNINGS PER SHARE:</b>		
Basic and diluted loss per common share	\$ (0.11)	\$ (0.22)
Basic and diluted weighted average shares outstanding	110,137,915	60,526,541

See accompanying notes to financial statements  
Page 3



# Statements of Stockholders' Equity (Deficit)

For the years ended 31 December 2020 and 2019

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-in Capital	Deficit	Stockholders' Equity (Deficit)
<b>BALANCES, December 31, 2018</b>	42,002,813	\$420,028	\$20,817,689	\$(27,131,728)	\$(5,894,011)
Stock-based compensation expense	-	-	533,110	-	533,110
Exercise of warrants	150,000	1,500	49,650	-	51,150
Exercise of stock options	2,281,538	21,924	133,166	-	155,090
Change in par value from \$0.01 to \$0.0001	-	(439,009)	439,009	-	-
Issuance of common stock for convertible notes and accrued interest	29,217,437	2,922	12,530,842	-	12,533,764
Issuance of common stock, net of issuance costs paid in cash of \$1,752,176	15,662,650	1,566	7,014,739	-	7,016,305
Issuance of common stock for services related to equity financing	180,722	18	(18)	-	-
Issuance of down round common stock	3,187,375	319	1,801,810	-	1,802,129
Beneficial conversion feature of convertible notes	-	-	4,129,856	-	4,129,856
Net loss	-	-	-	(13,293,976)	(13,293,976)
<b>BALANCES, December 31, 2019</b>	92,682,535	\$9,268	\$47,449,853	\$(40,425,704)	\$7,033,417
Stock-based compensation expense	-	-	821,952	-	821,952
Exercise of warrants, net of fees	406,849	41	295,384	-	295,425
Exercise of stock options, net of fees	413,333	41	174,154	-	174,195
Issuance of royalty conversion shares	7,197,634	720	(720)	-	-
Issuance of common stock, net of issuance costs paid in cash of \$1,863,233	24,849,199	2,486	32,935,048	-	32,937,534
Net loss	-	-	-	(12,446,473)	(12,446,473)
<b>BALANCES, December 31, 2020</b>	125,549,550	\$12,556	\$81,675,671	\$(52,872,177)	\$28,816,050

See accompanying notes to financial statements  
Page 4

# Statements of Cash Flows

For the years ended 31 December 2020 and 2019

	2020	2019
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (12,446,473)	\$ (13,293,976)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation	528,089	257,300
Stock-based compensation expense	821,952	533,110
Gain on disposal of property and equipment	-	(26,250)
Amortization of debt issuance costs	-	174,044
Accrued interest	-	578,295
Beneficial conversion feature expense	-	4,129,856
Down round expense	-	1,802,129
Foreign currency exchange gain	198,398	(216,139)
Changes in assets and liabilities		
Accounts receivable	71,378	(160,968)
Inventory	(1,849,304)	(846,300)
Prepaid expenses and other assets	(24,958)	(40,260)
Accounts payable	(281,175)	249,138
Accrued expenses	768,806	217,471
Contract liabilities	(17,402)	14,557
Net Cash Flows from Operating Activities	(12,230,689)	(6,627,993)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Payment of security deposit	(32,146)	(164,580)
Purchases of property and equipment	(741,886)	(364,758)
Net Cash Flows from Investing Activities	(774,032)	(529,338)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from exercise of options and warrants	469,620	206,240
Proceeds from convertible notes	-	1,745,932
Proceeds from financing obligation	-	1,700,000
Payments on financing obligation	(374,023)	(214,001)
Proceeds from issuance of common stock, net	32,937,534	7,016,305
Payments on finance lease liability	(8,420)	(3,004)
Net Cash Flows from Financing Activities	33,024,711	10,451,472
<b>Net Change in Cash</b>	20,019,990	3,294,141
CASH - Beginning of Year	5,048,893	1,588,348
Effect of foreign currency exchange rate changes on cash	70,929	166,404
<b>CASH - End of Year</b>	<u>\$ 25,139,812</u>	<u>\$ 5,048,893</u>
<b>Supplemental cash flow disclosure</b>		
Cash paid for interest	\$ 300,637	\$ 278,393
<b>Noncash investing and financing activities</b>		
Common stock issued for 2019 and 2018 Notes and accrued interest	\$ -	\$ 12,533,764
Leasehold Improvements paid by landlord	\$ 595,534	\$ -
Operating lease right of use asset	\$ 606,277	\$ -

See accompanying notes to financial statements  
Page 5

# Notes to Financial Statements

As of and for the years ended 31 December 2020 and 2019

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## NOTE 1 - Summary of Significant Accounting Policies

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### *Nature of Operations and Basis of Presentation*

Imricor Medical Systems, Inc. ("Imricor" and the "Company") is a U.S.-based medical device company that seeks to address the current issues with traditional x-ray-guided ablation procedures through the development of Magnetic Resonance Imaging (MRI) guided technology. Incorporated in the State of Delaware in 2006, the Company's principal focus is the design, manufacturing, sale and distribution of MRI-compatible products for cardiac catheter ablation procedures. Imricor's unique technology utilizes an intellectual property (IP) portfolio that includes technology developed in-house, as well as IP originating from Johns Hopkins University and Koninklijke Philips N.V. The Company is headquartered in Burnsville, Minnesota, where it has development and manufacturing facilities. The Company's primary product offering, the Vision-MR Ablation Catheter is specifically designed to work under real-time MRI guidance, with the intent of enabling higher success rates along with a faster and safer treatment compared to conventional procedures using x-ray guided catheters. Historically, Imricor generated revenue from licensing some of its IP for use in implantable devices and performing contract research, but expects to generate most of its future revenue from the sale of the MRI-compatible products it has developed for use in cardiac catheter ablation procedures (comprising single-use consumables and capital goods). On January 13, 2016, Imricor obtained CE mark approval to place one of its key products, the Advantage-MR EP Recorder/Stimulator System, on the market in the European Union. On January 23, 2020, the Company obtained CE mark approval for its other key products, the Vision-MR Ablation Catheter (with an indication for treating type I atrial flutter) and the Vision-MR Dispersive Electrode.

The Company has prepared the accompanying financial statements and notes in conformity with accounting principles generally accepted in the United States of America (US GAAP).

The Company's financial statements and notes are presented in United States dollar, which is also the functional currency.

### *Impact of COVID-19 Pandemic*

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic, which continues to spread throughout the world and has resulted in travel restrictions, quarantines, "stay-at-home" and "shelter-in-place" orders, business limitations and shut downs. During the year ended December 31, 2020, the Company's revenue was impacted by the COVID-19 pandemic as hospital restrictions banned outside personnel and postponed most elective procedures. Our products treat conditions that are considered elective.

We have implemented several steps in response to COVID-19 including restricting all unnecessary travel, working from home when possible, social distancing and masking and adopting more stringent cleaning procedures in our facilities.

We are unable to accurately predict the full impact that COVID-19 will have on our future results from operations, financial condition, liquidity and cash flows due to numerous uncertainties, including the duration and severity of the pandemic and containment measures, impact on our customers and our vendors, for an indefinite period of time. Our future results of operations and liquidity could be adversely impacted by delays in payments from customers, supply chain disruptions, and uncertain demand.

We will continue to monitor the situation and take further actions that we determine are in the best interest of our stakeholders.

### *Cash*

Cash consists of funds in depository accounts. The Company holds cash with high quality financial institutions and at times, such balances may be in excess of federal insurance limits.

# Notes to Financial Statements (cont.)

As of and for the years ended 31 December 2020 and 2019

## NOTE 1 - Summary of Significant Accounting Policies (cont.)

### *Accounts Receivable*

Accounts receivable are unsecured, are recorded at net realizable value, and do not bear interest except if a revenue transaction has a significant financing component. The Company makes judgments as to its ability to collect outstanding receivables based upon significant patterns of uncollectability, historical experience, and managements' evaluation of specific accounts and will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers' financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. To date the Company has not experienced any write-offs or significant deterioration of its accounts receivable aging, and therefore, no allowance for doubtful accounts was considered necessary as of December 31, 2020 or 2019.

Accounts receivable includes unbilled receivables of \$38,321 and \$39,470 as of December 31, 2020 and 2019, respectively, which represents the current portion of minimum royalties due to the Company during the following year. The accounts receivable-long term relates to minimum royalties due to the Company for years ending after December 31, 2021.

### *Inventory*

Inventories are stated at the lower of cost or net realizable value, with cost determined on the first-in, first-out ("FIFO") method. The establishment of allowances for excess and obsolete inventories is based on historical usage and estimated exposure on specific inventory items. Inventories are as follows as of December 31, 2020 and 2019:

	December 31,	
	2020	2019
Raw materials	\$ 1,216,964	\$ 822,217
Work in process	423,666	65,765
Finish goods	1,716,052	409,544
Less: obsolescence reserve	(286,762)	(76,910)
	<u>\$ 3,069,920</u>	<u>\$ 1,220,616</u>

### *Property and Equipment*

Property and equipment are stated at cost. Additions and improvements that extend the lives of assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Amortization of leasehold improvements is computed on a straight-line basis over the shorter of the estimated useful lives of the related assets or life of the lease.

The standard estimated useful lives of property and equipment are as follows:

Office furniture and equipment	5 years
Lab and production equipment	5 years
Computer equipment	3 years
MRI scanner	7 years
Leasehold improvements	7 years

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**NOTE 1 - Summary of Significant Accounting Policies (cont.)**

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The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the impairment tests indicate that the carrying value of the asset, or asset group, is greater than the expected undiscounted cash flows to be generated by such asset or asset group, further analysis is performed to determine the fair value of the asset or asset group. To the extent the fair value of the asset or asset group is less than its carrying value, an impairment loss is recognized equal to the amount the carrying value of the asset or asset group exceeds its fair value. The Company generally measures fair value by considering sale prices for similar assets or asset groups, or by discounting estimated future cash flows from such assets or asset groups using an appropriate discount rate. Considerable management judgment is necessary to estimate the fair value of assets or asset groups, and accordingly, actual results could vary significantly from such estimates. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. To date, the Company has not recognized any impairment loss for property and equipment.

*Research and Development Costs*

The Company expenses research and development costs as incurred.

*Other Assets*

Other assets on the balance sheet include security deposits related to the Company's operating and financing obligations.

*Other Long-term liabilities*

A certain portion of the Company's share of Social Security tax was deferred in accordance with The Coronavirus, Aid, Relief and Economic Security Act and is included in other long-term liabilities.

*Patents*

Expenditures for patent costs are charged to operations as incurred.

*Income Taxes*

Income taxes are recorded under the liability method. Deferred income taxes are provided for temporary differences between financial reporting and tax bases of assets and liabilities. Deferred tax assets are reduced by a valuation allowance to the extent the realization of the related deferred tax asset is not assured.

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

*Loss per Share*

Basic loss per share is computed by dividing net loss by the weighted average shares outstanding during the reporting period. The weighted average common shares outstanding were 110,137,915 and 60,526,541 for the years ended December 31, 2020 and 2019, respectively.

# Notes to Financial Statements (cont.)

As of and for the years ended 31 December 2020 and 2019

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## NOTE 1 - Summary of Significant Accounting Policies (cont.)

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Dilutive net income (loss) per share assumes the exercise and issuance of all potential common stock equivalents in computing the weighted-average number of common shares outstanding, unless their effect is antidilutive. The effects of including incremental shares associated with convertible notes, options, warrants and unvested royalty conversion rights are anti-dilutive due to the net loss incurred and are not included in the diluted weighted average number of shares of common stock outstanding for the years ending December 31, 2020 and 2019.

### *Foreign currency exchange gains (losses)*

During the years ended December 31, 2020 and 2019, the Company had accounts payable that are denominated in both Australian dollars and Euros and accounts receivable denominated in Euros. As of December 31, 2019, the Company had cash accounts denominated in both Australian dollars and Euros. As of December 31, 2020, the Company had cash accounts denominated in Euros. These assets and liabilities have been translated into U.S. dollars at year-end exchange rates. Foreign currency exchange gains and losses are included in the statements of operations within other income (expense).

### *Financial Instruments*

The carrying amounts for all financial instruments approximate fair value. The carrying amounts for cash, accounts payable and accrued expenses approximate fair value because of the short maturity of these instruments. The fair value of convertible notes approximates carrying value and have been estimated based on discounted cash flows using interest rates being offered for similar instruments having the same or similar maturities and collateral requirements.

### *Revenue Recognition*

The Company recognizes revenue for product sales when its customers obtain control of the products, which occurs at a point in time, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods. Control is transferred to customers when title to the goods and risk of loss transfers, which was upon shipment for products sales recognized.

The Company's product sales contain a single performance obligation and the transaction price is based on invoice price as there is no variable consideration impacting the transaction price.

Sales tax and value added taxes in foreign jurisdictions that are collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from net sales. Product sales include shipment and handling fees charged to customers. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of goods sold.

Revenue from service contracts is recognized over the contract period on a straight-line basis.

### *Royalties*

On June 1, 2012, the Company licensed certain intellectual property to a customer which included a royalty of 3% of product sales, subject to a minimum of \$50,000 per year. The minimum guaranteed royalties were recognized upon the execution of the license agreement as these proceeds were not variable consideration. The remaining minimum royalty payments to be received, less the portion which represents future interest expected to be received within 12 months is included in Accounts Receivable and the amounts expected to be received in future periods beyond 12 months are included in Accounts Receivable-Long term. Any royalties received in the future which are more than the minimum guaranteed royalty will be recognized when they are earned.



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**NOTE 1 - Summary of Significant Accounting Policies (cont.)**

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*Consulting Revenue*

In June 2015, the Company entered into a Joint Research Agreement. The Agreement was amended in August 2017 whereby the Company received an upfront payment of \$100,000 to cover costs incurred in the course of providing certain services, which had been included in Contract liabilities-net of current portion. The agreement was to terminate upon the earlier of completion of the project or five years. The project was not completed and has terminated. Therefore, \$100,000 has been recognized as Consulting revenue for the year ended December 31, 2020.

*Government Contract Revenue*

The Company recognizes revenue for government contracts over time using the "as invoiced" practical expedient.

The Company was awarded a contract with the U.S. government on September 26, 2017 for up to \$2,402,951 to develop a MRI compatible injection catheter for MRI-guided procedures. The Company recognized \$0 and \$263,383 as revenue during the years ended December 31, 2020 and 2019, respectively. The Company cancelled the contract in December 2019 to allow engineering resources to focus on the development of its core pipeline products.

The Company was awarded a contract with the U.S. government on September 25, 2020 for up to \$399,539 to develop an MRI compatible myocardial biopsy system. The Company recognized \$95,889 as revenue during the year ended December 31, 2020.

*Contract Liabilities*

On November 27, 2013, the Company licensed certain intellectual property to a customer in exchange for an upfront non-refundable license fee and milestone payments, which can total up to \$7,000,000. The Company collected \$6,000,000 of these milestone payments, including the non-refundable license fee, on or before October 2016.

\$373,333 is included in long-term contract liabilities as of December 31, 2020 and 2019. The customer sold the portion of the business which held this license in May 2018. The license has been assigned to the purchaser. The project is still on hold with no plans to work on final development during the next 12 months, and therefore, the contract liability is included in long-term liabilities.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as contract liabilities in the accompanying balance sheets, with the contract liabilities to be recognized beyond one year being classified as non-current contract liabilities. As of December 31, 2020 and 2019, the Company had contract liabilities of \$590,008 and \$607,410, respectively.

The following table sets forth information related to the contract liabilities for the years ended December 31:

	2020	2019
Balance at the beginning of the year	\$ 607,410	\$ 592,853
Decrease from revenue recognized for completion of performance obligations that were included in contract liabilities at the beginning of the period included in:		
Consulting revenue	(100,000)	-
Service revenue	(14,557)	-
Increase for revenue deferred as the performance obligation has not been satisfied	97,155	14,557
Balance at the end of the year	<u>\$ 590,008</u>	<u>\$ 607,410</u>

# Notes to Financial Statements (cont.)

As of and for the years ended 31 December 2020 and 2019

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## NOTE 1 - Summary of Significant Accounting Policies (cont.)

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### *Stock-Based Compensation*

The Company measures and records compensation expense using the applicable accounting guidance for share-based payments related to stock option awards granted to directors and employees. The fair value of stock options, including performance awards, without a market condition is estimated, at the date of grant, using the Black-Scholes option-pricing model. The fair value of restricted stock awards and stock options with a market condition is estimated, at the date of grant, using the Monte Carlo Simulation model. The Black-Scholes and Monte Carlo Simulation valuation models incorporate assumptions as to stock price volatility, the expected life of options or awards, a risk-free interest rate and dividend yield.

Compensation expense is recognized on a straight-line basis over the vesting period for all awards, net of an estimated forfeiture rate, resulting in the recognition of compensation expense for only those shares expected to vest. Compensation expense is recognized for all awards over the vesting period to the extent the employees or directors meet the requisite service requirements, whether or not the award is ultimately exercised. Conversely, when an employee or director does not meet the requisite service requirements and forfeits the award prior to vesting, any compensation expense previously recognized for the award is reversed.

### *Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### *Subsequent Events*

For the year ended December 31, 2020, the Company evaluated, for potential recognition and disclosure, events that occurred prior to the issuance of the financial statements through February 23, 2021.

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## NOTE 2 – Liquidity

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The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company incurred losses from operations and negative cash flows from operations for both of the years ended December 31, 2020 and 2019, had an accumulated deficit as of December 31, 2020. As of December 31, 2020, the Company's cash balance was \$25.1 million. The Company's ability to achieve profitability and positive cash flow is dependent upon its ability to increase revenue and contain its expenses.

The Company believes that it will have sufficient working capital to operate for at least twelve months beyond February 23, 2021.

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**NOTE 3 – Accrued Expenses**

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Accrued expenses consist of the following:

	December 31,	
	2020	2019
Compensation	\$ 504,372	\$ 228,888
Other accruals	564,536	138,609
Total accrued expenses	<u>\$ 1,068,908</u>	<u>\$ 367,497</u>

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**NOTE 4 – Property and Equipment**

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Property and equipment consisted of the following:

	December 31,	
	2020	2019
Office furniture and equipment	\$ 390,160	\$ 186,030
Lab and production equipment	1,414,136	1,099,744
Computer equipment	277,821	194,890
MRI scanner	1,200,000	1,200,000
Leasehold improvements	1,459,919	723,952
	<u>4,742,036</u>	<u>3,404,616</u>
Less: Accumulated depreciation and amortization	<u>(1,647,315)</u>	<u>(1,119,226)</u>
	<u>\$ 3,094,721</u>	<u>\$ 2,285,390</u>

Depreciation expense was \$528,089 and \$257,300 for the years ended December 31, 2020 and 2019, respectively. The MRI scanner and leasehold improvements related to new space for the MRI scanner were placed in service in May 2019, which is when depreciation began on those assets.

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**NOTE 5 – Convertible Notes**

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During September and October 2017, the Company issued \$2,325,000 in unsecured convertible notes ("2017 Notes") with several equity investors, including \$885,000 issued to related parties. The notes bore interest at a rate of six percent annually from the date of issuance and principal and interest were due on August 31, 2018. The 2017 Notes, including accrued interest, were automatically convertible into the next round of equity financing if at least \$5,000,000 in new funding was raised ("Qualified Financing") prior to the maturity date, at a conversion price equal to 94% of the price per share paid by investors in the Qualified Financing. As the conversion features were contingent upon completion of a Qualified Financing, no beneficial conversion feature was recorded upon commencement of the notes.

During April 2018, the 2017 Notes and accrued interest of \$2,398,115 were converted, with a six percent discount of \$153,071, into \$2,551,186 in new unsecured convertible notes ("2018 Notes"), of which \$967,686 was to related parties. The Company also issued \$7,379,420 of new 2018 Notes with several current and new investors, including \$260,000 to related parties. In connection with the issuance of the 2018 Notes, a strategic investor invested \$3,400,000 consisting of \$1,000,000 in cash, and \$2,400,000 of in-kind contribution. The in-kind contribution includes \$1,200,000 for an MRI scanner, \$500,000 for a four-year prepaid service agreement on the MRI scanner, and \$700,000 in a leasehold improvement allowance to build out space to house the MRI scanner. The MRI scanner and leasehold improvements are included in property and equipment as of both December 31, 2020 and 2019. The prepaid service agreement to be amortized within one year is included in prepaid expenses and other current assets and the amount to be recognized beyond one year is included as prepaid service agreement in other long-term assets. During the year ended December 31, 2020, the Company recorded \$83,336 in expense which is included in research and development expenses.

# Notes to Financial Statements (cont.)

As of and for the years ended 31 December 2020 and 2019

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## NOTE 5 – Convertible Notes (cont.)

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In connection with the 2018 Notes, the Company incurred debt issuance costs of \$278,007, of which \$228,660 were settled with the issuance of additional 2018 Notes. These debt issuance costs were being amortized straight-line over the expected maturity date and recognized as interest expense. The remaining unamortized balance was expensed upon the Company's completion of its Initial Public Offering ("IPO") and associated listing on the Australian Securities Exchange ("ASX") on August 26, 2019. The 2018 Notes bore interest at a rate of eight percent compounded annually from the date of issuance until the outstanding principal was converted.

On February 4, April 3 and April 4, 2019, the Company issued \$1,745,932 in additional convertible notes ("2019 Notes"), including \$662,506 to related parties. The notes bore interest at a rate of eight percent compounded annually from the date of issuance until the outstanding principal was converted.

The 2018 and 2019 Notes and accrued interest totaling \$12,533,764 automatically converted into 29,217,437 Conversion Shares immediately prior to, and contingent upon, the allotment of CHES Depositary Interests (CDIs) as a result of the IPO, (see **NOTE 8**). The number of Conversion Shares issued upon conversion of the 2018 and 2019 Notes was 75% of the IPO share price of \$0.5654 per share. The Company recorded \$578,295 in interest expense related to the 2018 and 2019 Notes for the year ended December 31, 2019.

A beneficial conversion feature expense of \$4,129,856 was recorded upon completion of the Company's IPO and is included as "beneficial conversion feature expense" in the Statement of Operations for the year ended December 31, 2019.

During 2016 and 2017, the Company issued \$2,680,000 in unsecured convertible notes ("Notes") with several equity investors, including \$100,000 to related parties. The notes bore interest at a rate of six percent annually from the date of issuance and were due on August 1, 2017. In August 2017, the Company converted the Notes and accrued interest totaling \$2,798,674 into 3,833,799 shares of Common stock. In the event the Company issued securities within the 180-day period immediately following the conversion of the Notes ("Qualified Financing"), the Noteholders were to receive additional shares of Common stock such that total shares issued would be based upon a price that was 94% of the price paid by the subsequent investors. The 2017 Notes (described above) met the definition of a Qualified Financing. Consequently, in connection with the IPO, the Company issued 3,187,375 additional shares such that the total shares received was based upon an adjusted purchase price of \$0.3986 per share in 2019. The fair value of the additional shares issued was \$1,802,129 and is included as "Down round expense" in the Statement of Operations for the year ended December 31, 2019 (See **NOTE 8**).

Interest expense related to the convertible notes for the year ended December 31, 2019 was \$578,295 including \$93,721 to related parties.

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## NOTE 6 – Leases

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### *Operating Leases*

In March 2007, the Company entered into an operating lease agreement for its office and manufacturing space which was originally set to expire in July 2014. The lease was extended through July 2019. In June 2019, the lease was extended through October 2022. The Company entered into a second operating lease agreement for office and warehouse space in August 2018 which commenced on January 1, 2019 and was originally set to expire in March 2026. In February 2020, this lease was amended to include an expansion of space and an increase to the term through May 2030. Neither lease includes renewal or extension rights. Both lease agreements require the Company to pay a pro rata portion of the lessor's actual operating expenses which are considered variable lease costs as the expenses are trued up on an annual basis.

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**NOTE 6 – Leases (cont.)**

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On January 1, 2019, the Company recorded a \$220,000 right to use asset and lease liability associated with these leases. In June 2019, when the extension for the office space lease was executed, the Company recorded a \$358,506 right to use asset and lease liability associated with the lease extension. The remaining consideration associated with the Company's office and warehouse space lease has been reallocated and the lease liability remeasured as the amended lease provided for additional space and the lease term has been extended. In addition, the landlord agreed to pay \$593,534 in leasehold improvements. Upon commencement of the lease in June 2020, the Company recorded \$593,534 in leasehold improvements, a \$606,277 right to use asset, and a \$1,201,811 lease liability.

As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments. As of December 31, 2020 and 2019, the remaining lease term was 8.5 and 4.5 years and discount rate was 5.5% and 8.0%, respectively. For the year ended December 31, 2020 and 2019, the operating cash outflows from our operating lease for office and manufacturing space was \$192,166 and \$144,195, respectively.

As of December 31, 2020, maturities of our operating lease liabilities are as follows:

2021	\$ 262,522
2022	236,191
2023	148,966
2024	153,437
2025	158,050
2026 and thereafter	756,399
Total lease payments	1,715,565
Less interest	(357,778)
Present value of lease liabilities	1,357,787
Less current portion	(189,143)
Operating lease liability, net of current portion	<u>\$ 1,168,644</u>

The cost components of the Company's operating leases were as follows for the years ended December 31, 2020 and 2019:

	2020	2019
Operating lease cost	\$ 192,166	\$ 154,687
Variable least cost	117,356	73,735
Total	<u>\$ 309,522</u>	<u>\$ 228,062</u>

*Finance Lease Liability*

In December 2019, the Company entered into a \$36,580 finance lease agreement for certain equipment. The Company traded in fully depreciated equipment worth \$26,250. The total equipment value of \$62,380 is included in property and equipment. The interest rate implied in the finance lease is 5.4% and the term of the lease is four years.

# Notes to Financial Statements (cont.)

As of and for the years ended 31 December 2020 and 2019

## NOTE 6 – Leases (cont.)

The Company's remaining payments under the terms of the finance lease are as follows as of December 31, 2020:

2021	\$	10,188
2022		10,188
2023		10,188
Total payments		30,564
Less amount representing interest		(2,404)
Total present value of total payments		28,160
Less current portion		(8,886)
Finance lease liability, net of current portion	\$	<u>19,274</u>

### Financing Obligation

On June 1, 2019, the Company entered into a sale leaseback agreement for the purchase of its MRI scanner (\$1,200,000) and related Service Agreement (\$500,000). The term of the lease is 36 months with a monthly rental payment of \$54,865. The lease meets the requirements to be classified as a finance lease. Therefore, the agreement is considered a failed sale leaseback arrangement and is not accounted for as a lease, but rather is accounted for as a financing obligation. The MRI scanner is included in property and equipment and the Service Agreement is included as Prepaid Service Agreement. The lease agreement includes an option to repurchase the related assets for \$425,000 at the end of the lease term, which the Company deems it is reasonably certain to do. The interest rate implied in the financing obligation is 21.5%.

The Company's remaining payments under the terms of the financing obligation are as follows as of December 31, 2020:

2021	\$	658,380
2022		274,325
Expected buy out at end of lease term		425,000
Total payments		1,357,705
Less amount representing interest		(245,729)
Total present value of total payments		1,111,976
Less current portion		(462,961)
Financing obligation, net of current portion	\$	<u>649,015</u>

## NOTE 7 - Commitments and Contingencies

### Vendor concentration

Certain components and products that meet the Company's requirements are available only from a single supplier or a limited number of suppliers. The inability to obtain components and products as required, or to develop alternative sources, if and as required in the future, could result in delays or reductions in product shipments, which in turn could have a material adverse effect on the Company's business, financial condition, and results of operations. The Company believes that it will be able to source alternative suppliers or materials if required to do so.

For the year ended December 31, 2020, the Company had accounts payable to two vendors that accounted for 12% and 11% of the total outstanding balance.

### Purchase Commitments

At December 31, 2020, the Company had \$241,431 in outstanding firm purchase commitments.



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**NOTE 7 - Commitments and Contingencies (cont.)**

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*Retirement Plan*

The Company maintains a 401(k) retirement plan for its employees in which eligible employees can contribute a percentage of their compensation. The Company contributed a safe harbor match of \$170,062 during the year ended December 31, 2020 and a discretionary contribution of \$22,770 during the year ended December 31, 2019.

*Employment Agreements*

The Company has employment agreements with the CEO and senior executives of the Company. The agreements require severance of twelve and six months, respectively, of current annual salary and medical insurance in the event employment is terminated without cause, respectively.

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**NOTE 8 - Stockholders' Equity**

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*Capital Stock Authorized*

As of both December 31, 2020 and 2019, the Board of Directors of the Company had authorized 560,000,000 shares of capital stock, consisting of 535,000,000 shares of common stock and 25,000,000 shares of preferred stock.

Common Stock

During January and March 2019, 150,000 warrants to purchase common stock were exercised at \$0.341 per share for total proceeds of \$51,150.

During January 2019, a total of 2,400,000 options to purchase common stock were exercised with a portion of the exercise via a cashless exercise. 1,282,474 options to purchase common stock were exercised at \$0.097 per share for total proceeds of \$124,400. In addition, 1,117,526 options to purchase common stock were exercised at \$0.097 per share on a cashless exercise basis at a fair market value of \$0.52 per share, resulting in the issuance of 909,064 shares of common stock.

On August 29, 2019, 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, 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 14,578,313 CDIs representing the same number of shares of common stock at \$0.83 Australian dollars per share and 1,084,337 common shares at \$0.5654 US dollars per share in a concurrent US Private Placement, for total proceeds of \$7,016,305, net of expenses.

180,722 CDIs were issued in exchange for services related to the Company's equity financing. 3,187,375 shares of common were issued to Noteholders in connection with the down round liability (see **NOTE 5**).

In December 2019, 90,000 options to purchase common stock were exercised at \$0.341 per share for total proceeds of \$30,690.

In February 2020, the Company completed an equity raise on the ASX which consisted of 12,083,333 CDIs representing the same number of shares of common stock at \$1.68 Australian dollars per share for proceeds of \$12,653,221, net of expenses.

# Notes to Financial Statements (cont.)

As of and for the years ended 31 December 2020 and 2019

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## NOTE 8 - Stockholders' Equity (cont.)

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During April 2020, 406,849 warrants to purchase common stock were exercised at \$0.73 per share for total proceeds of \$295,425, net of expenses.

In February 2007, the Company issued rights to 7,200,000 shares of common stock (as adjusted for a subsequent stock split) upon the earlier of an acquisition transaction, an initial public offering pursuant to an effective registration statement under the US Securities Act of 1933 (an initial public offering in the US), or the expiration of certain license agreements. The number of shares to be issued was to be reduced for the value of any royalties paid. In April 2020, the agreements related to these rights expired and the Company issued 7,197,634 shares of common stock. The number of shares issued was reduced by 2,366 to reflect the value of royalties paid. The value of the shares was recorded as an expense upon issuance, which was when the liability was fixed and determinable.

During the year ended December 31, 2020, 413,333 options to purchase common stock were exercised at prices ranging from \$0.341 to \$0.60 per share for total proceeds of \$174,195, net of expenses.

In October 2020, the Company completed an underwritten placement on the ASX which consisted of 12,106,383 CDIs representing the same number of shares of common stock at \$2.35 Australian dollars per share for proceeds of \$19,195,477, net of expenses.

In November 2020, the Company completed an underwritten security purchase plan on the ASX which consisted of 659,483 CDIs representing the same number of common stock at \$2.35 Australian dollars per share for proceeds of \$1,088,836, net of expenses.

### *Dividend Rights*

Subject to the prior rights of holders of all classes of stock at the time outstanding having prior rights as to dividends, the holders of the common stock shall be entitled to receive, out of any assets of the Corporation legally available therefore, any dividends as may be declared from time to time by the Board of Directors. The right to such dividends shall not be cumulative, and no right shall accrue by reason of the fact that dividends are not declared in any prior period.

### *Voting Rights*

The holder of each share of common stock shall have the right to one vote for each such share, and shall be entitled to notice of any stockholders' meeting in accordance with the Bylaws of the Corporation, and shall be entitled to vote upon such matters and in such manner as may be provided by law.

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**NOTE 8 - Stockholders' Equity (cont.)**

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*Stock Option Plans*

The Company and its stockholders adopted a stock incentive plan (the "2006 Plan") in 2006. The 2006 Plan, as amended on January 26, 2011 by the shareholders, reserved 10,918,500 shares of the Company's common stock for the granting of incentive and nonqualified stock options to employees, directors and consultants. On May 22, 2016, the Company replaced the 2006 Plan with the 2016 Plan, as the 2006 Plan was expiring. The terms of the 2016 Plan were the same as the 2006 Plan. In August 2018, the Board of Directors approved an increase of 500,000 shares to the option pool. On February 14, 2019, the Board of Directors terminated the 2016 Plan and approved the 2019 Plan, reserving 11,418,500 shares of the Company's common stock for the granting of incentive and nonqualified stock options to employees, directors and consultants. On February 14, 2019, the Board of Directors also authorized the Company to offer to current employees, directors and consultants an option to exchange certain previously issued options for repriced options with additional vesting requirements ranging from two to four years. As a result, 5,462,600 incentive and nonqualified stock options were cancelled and reissued on March 15, 2019 resulting in incremental value of \$563,546 which will be expensed over the revised vesting terms. On June 4, 2019, the Board of Directors approved an increase of 2,000,000 shares to the option pool and provided that on the first day of each of the Company's fiscal years during the term of the 2019 Plan beginning in 2020, the number of shares of Common Stock available for issuance from time to time under the 2019 Plan will be increased by an amount equal to the lesser of (i) five percent (5%) of the aggregate number of shares reserved under this Plan on the last day of the immediately preceding fiscal year, and (ii) such number of shares determined by the Board (the "Annual Increase"). On April 20, 2020, the Board of Directors approved an increase of 3,470,925 shares to the option pool, which was approved by the shareholders at the Annual Meeting on May 12, 2020. Prior to the Company's offering on the ASX, the Board of Directors determined the exercise price of all options, but the exercise price of incentive options shall not be less than the fair value of the common stock at the date of grant. Options granted after completion of the offering on the ASX are granted at a price equal to the closing sale price of a CDI as of the date of grant, converted from Australian dollars to US dollars using the prevailing exchange rate. Vesting terms of outstanding options range from immediate to four years. In addition, some options issued to the executive management team vest upon completion of certain milestones, performance requirements, and market conditions. In no event are the options exercisable for more than ten years after the date of grant. The Company issues new shares of common stock when stock options are exercised.

Information regarding the Company's stock options is summarized below:

	Number of Options	Weighted- Average Exercise Price	Aggregate Intrinsic Value
Options outstanding - December 31, 2019	8,064,933	\$ 0.58	
Exercised	(413,333)	0.44	
Cancelled	(261,500)	0.69	
Granted	2,572,994	0.95	
Options outstanding – December 31, 2020	9,963,094	\$ 0.68	\$ 10,530,311
Options exercisable – December 31, 2020	5,310,350	\$ 0.57	\$ 6,776,761
Weighted average fair value of options granted during the year ended December 31, 2020		\$ 0.58	
Weighted average fair value of options granted during the year ended December 31, 2019		\$ 0.46	

As of December 31, 2020, the Company had 2,648,598 shares available for grant under the Plan.

The weighted average remaining contractual life of options outstanding and exercisable was 8.01 and 7.30 years, respectively, as of December 31, 2020.

The intrinsic value of options exercised during the years ended December 31, 2020 and 2019 was \$306,453 and \$1,059,729, respectively.

# Notes to Financial Statements (cont.)

As of and for the years ended 31 December 2020 and 2019

## NOTE 8 - Stockholders' Equity (cont.)

The fair value of option awards granted was determined using the Black-Scholes option pricing model utilizing the following assumptions:

	2020	2019
Expected life	7 years	5 - 7 years
Volatility	68.3%	48.12%
Risk-free interest rate	0.64%	2.50%-2.83%
Dividend Yield	0%	0%

The Company reviews its current assumptions on a periodic basis and adjusts them as necessary to determine the option valuation. The expected life represents the period that the stock option awards are expected to be outstanding and is based on an evaluation of historic expected lives from the Company's stock option grants. Volatility is based on historic volatilities of traded shares from a selected publicly traded peer group, believed to be comparable after consideration of size, maturity, profitability, growth, risk and return on investment. The Company did not use its own historical volatility as the majority of stock option grants were issued prior to or in connection with the IPO and the Company has limited volatility history. The risk-free interest rate is based on the yield of constant maturity U.S. treasury bonds with a remaining term equal to the expected life of the awards at the grant date. The expected dividend yield is zero, as the Company has not paid or declared any dividends to common stockholders and does not expect to pay dividends in the foreseeable future. Historical data is used to estimate pre-vesting forfeitures and the Company records stock-based compensation expense only for those awards that are expected to vest.

Total stock-based compensation expense resulting from options granted was \$821,952 and \$533,110 for the years ended December 31, 2020 and 2019, respectively, and charged to the Company's Statement of Operations as follows:

	December 31,	
	2020	2019
Sales and marketing	\$ 64,315	\$ 26,798
Research and development	296,421	184,991
General and administrative	461,216	321,321
	<u>\$ 821,952</u>	<u>\$ 533,110</u>

No income tax benefits were recognized related to this compensation expense due to the full valuation allowance provided on the Company's deferred income tax assets.

As of December 31, 2020, the total unrecognized compensation cost related to unvested stock options then outstanding was \$2,034,998. Future stock-based compensation expense is expected to be as follows for the years ending December 31:

	Total
2021	\$ 807,178
2022	612,219
2023	469,930
2024	145,671
Total	<u>\$ 2,034,998</u>

Issuance of additional options subsequent to December 31, 2020 could affect future expected amounts.

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**NOTE 8 - Stockholders' Equity (cont.)**

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*Stock Warrants*

The Company has also issued warrants to purchase shares of common stock which are summarized below:

	Number of Warrants	Weighted- Average Exercise Price
Warrants outstanding – December 31, 2019	787,909	\$ 0.73
Warrants cancelled	(381,060)	0.73
Warrants exercised	(406,849)	0.73
Warrants outstanding – December 31, 2020	-	\$ -

During January and March 2019, 150,000 warrants to purchase common stock were exercised at \$0.341 per share for total proceeds of \$51,150. During April 2020, 406,849 warrants to purchase common stock were exercised at \$0.73 per share for total proceeds of \$295,425, net of expenses. The intrinsic value was \$46,121. The remaining 381,060 warrants were cancelled.

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**NOTE 9 - Income Taxes**

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The Company has generated both federal and state net operating losses (NOL) of approximately \$41,265,000 and federal and state research and development credit carryforwards of approximately \$1,498,000 as of December 31, 2020, which, if not used, will begin to expire in 2023. The Company believes that its ability to fully utilize the existing NOL and credit carryforwards could be restricted by changes in control that may have occurred or may occur in the future and by its ability to generate net income. The Company has not yet conducted a formal study of whether, or to what extent, past changes in control of the Company impairs its NOL and credit carryforwards because such NOL and credit carryforwards cannot be utilized until the Company achieves profitability. The Company has established a full valuation allowance as of December 31, 2020 and 2019, that offsets the net tax benefits associated with the NOL and credit carryforwards since realization of these tax benefits is not more likely than not.

Income tax expense (benefit) consists of the following for the year ended December 31:

	2020	2019
Current:		
Federal	\$ -	\$ -
State	-	-
	-	-
Deferred:		
Federal	(3,141,000)	(1,936,000)
State	-	-
	(3,141,000)	(1,936,000)
Deferred tax asset valuation allowance	3,141,000	1,936,000
Total provision (benefit)	\$ -	\$ -

# Notes to Financial Statements (cont.)

As of and for the years ended 31 December 2020 and 2019

## NOTE 9 - Income Taxes (cont.)

Components of deferred income taxes are as follows as of December 31:

	2020	2019
Deferred tax assets (liabilities):		
Net operating loss carryforwards	\$ 10,752,000	\$ 8,020,000
Research and development credit carryforwards	1,498,000	1,348,000
Stock-based compensation	185,000	154,000
Accrued expenses	17,000	5,000
Deferred revenue	153,000	158,000
Prepaid expenses and other assets	(73,000)	(130,000)
Foreign currency exchange	18,000	(43,000)
Depreciation and amortization	110,000	7,000
Gross deferred tax assets (liabilities)	12,660,000	9,519,000
Less valuation allowance	(12,660,000)	(9,519,000)
Net deferred tax assets	\$ -	\$ -

The change in the valuation allowance was \$3,141,000 and \$1,936,000 for the years ended December 31, 2020 and 2019, respectively.

The effective tax rate for the year ended December 31, 2020 differs from the federal and state statutory tax rates mainly due to the change in full valuation allowance, incentive stock option expense, and research and development credits.

The Company has recognized a reserve of approximately \$374,000 and \$337,000 for uncertain tax positions which was recorded directly against the valuation allowance as of December 31, 2020 and 2019, respectively. If recognized, these benefits would favorably impact the effective tax rate.

The tax years from inception through December 31, 2020 remain subject to examination by all major taxing authorities due to the net operating loss carryforwards. The Company is not currently under examination by any taxing jurisdiction. In the event of any future tax assessments, the Company has elected to record the income taxes and any related interest and penalties as income tax expense in the Company's Statement of Operations.

Changes in tax laws and rates may affect recorded deferred tax assets and liabilities and our effective tax rate in the future.

# Additional Stockholder Information

## Additional Stockholder Information

The Company has CHESS Depositary Interests (CDIs) quoted on the Australian Securities Exchange (ASX) trading under the ASX code IMR. Each CDI represents an interest in one share of Class A common stock of the Company (Share). Legal title to the Shares underlying the CDIs is held by CHESS Depositary Nominees Pty Ltd (CDN), a wholly owned subsidiary of the ASX. The Company's securities are not quoted on any other exchange.

Except where noted, all information provided below is current as at 18 March 2021, except as otherwise stated. To avoid double-counting, the holding of Shares by CHESS Depositary Nominees Pty Limited (underpinning the CDIs on issue) have been disregarded in the presentation of the information below, unless otherwise stated.

## Share Capital

Type of Security	Number of Securities
Total number of issued shares <sup>1</sup>	125,650,545
Total number of issued CDIs	67,403,955

1. Includes shares held by CHESS Depositary Nominees Pty Limited (39,931,218).

## Top 20 Holders of CDIs and Shares Combined (based on share registry reports)

Rank	Name	Number	% of issued capital
1	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	16,615,426	13.22
2	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	10,786,843	8.58
3	SIEMENS MEDICAL SOLUTIONS USA INC	8,384,150	6.67
4	WARREN G HERREID II	7,819,431	6.22
5	CITICORP NOMINEES PTY LIMITED <DOMESTIC HIN A/C>	7,597,406	6.05
6	NATIONAL NOMINEES LIMITED	5,245,222	4.17
7	CS THIRD NOMINEES PTY LIMITED <HSBC CUST NOM AU LTD 13 A/C>	3,016,440	2.40
8	KAHR FOUNDATION	2,950,988	2.35
9	STEVEN R WEDAN	2,518,720	2.00
10	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	2,443,504	1.94
11	HENRY R HALPERIN	1,800,000	1.43
12	BAUER PRIVATE EQUITY FUND VI LLC	1,696,555	1.35
13	MARK A TIBBLES	1,682,665	1.34
14	STEVEN R WEDAN & CHERRI J WEDAN JT TEN	1,427,373	1.14
15	RONALD D BERGER	1,300,000	1.03
16	UBS NOMINEES PTY LTD	1,241,683	0.99
17	PENSCO TRUST COMPANY LLC CUST FBO THOMAS TULP IRA	1,188,819	0.95
18	ALBERT C LARDO AND JENNIFER S LARDO	1,175,333	0.94
19	FLEITMAN KOPPA INVESTMENTS LLC	901,530	0.72
20	PENSCO TRUST COMPANY LLC CUST FBO DAVID CARTWRIGHT IRA	867,896	0.69
Top 20 holders		80,659,984	64.19
Remaining holders		44,990,561	35.81
Total		125,650,545	100.00



# Additional Stockholder Information (cont.)

## Substantial Holders

The names of substantial holders in the Company and their respective holdings of equity securities (to the best of the Company's knowledge) are as follows:

Name	Number of equity securities	% voting
Warren G. Herreid II & KAHR Foundation	10,771,092	8.57
Siemens Medical Solutions USA, Inc.	8,384,150	6.67
BlackRock Investment Mgt (Australia)	7,851,367	6.25

## Distribution of CDIs and Shares

Range	Number	% of issued capital	No. of holders
1 – 1,000	2,616	0.00	191
1,001 – 5,000	4,382	0.00	189
5,001 – 10,000	13,799	0.01	87
10,001 – 100,000	3,956,278	3.15	256
100,001 and over	121,673,470	96.83	148
<b>Total</b>	<b>125,650,545</b>	<b>100</b>	<b>871</b>

There are 34 investors holding less than a marketable parcel of CDIs or Shares, based on a minimum of A\$500 parcel at A\$2.24 per CDI or Share (close of trade price on 18 March 2021)

## Distribution of Options

Range	Number	% of issued capital	No. of holders
1 – 1,000	-	-	-
1,001 – 5,000	-	-	-
5,001 – 10,000	-	-	-
10,001 – 100,000	962,625	9.93	25
100,001 and over	8,729,523	90.07	14
<b>Total</b>	<b>9,692,148*</b>	<b>100</b>	<b>39</b>

\*150,946 options lapsed since the last Appendix 2A was lodged with the ASX on 2 February 2021.

## Securities subject to escrow at 18 March 2021

Last day of escrow	ASX imposed Or Voluntary	Number of escrowed Shares/CDIs	Number of escrowed Options/Warrants
29 August 2021	ASX Imposed and voluntary	12,437,246	2,045,000 Options

\*Note: the above table discloses the net effect of number of securities to be released from escrow including overlap between ASX imposed and voluntary escrows.

## Required Statements

- There is no current on-market buy-back of the Company's securities.
- The Company is incorporated in the state of Delaware in the United States of America.
- 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).
- The Company's securities are not quoted on any exchange other than the ASX.
- The Company's Australian Company Secretary is Mr Kobe Li.
- 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 (Securities Act) for offers 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. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities Exchange (ASX). This designation restricts any CDIs from being sold on the ASX to US persons. However, you are still able to 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.
- From the time of the Company's admission to the ASX until 31 December 2020, the Company has used the cash and assets in a form readily convertible to cash, that it had at the time of admission, in a way that is consistent with its business objectives at that time.
- On 25 April 2020, the Company issued a total of 7,197,634 Royalty Shares (see ASX announcement dated 1 May 2020).

## Voting Rights

Every holder of Shares present in person or by proxy is entitled one vote for each Share held on the record date for the meeting on all matters submitted to a vote of stockholders. Options and Warrants do not carry a right to vote.

CDI holders may attend and vote at the Company's general meetings. The Company must allow CDI holders to attend any meeting of stockholders 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 CDI Registry before the meeting.
- inform the Company that they wish to nominate themselves or another person to be appointed as CDN's proxy for the purposes of attending and voting at the general meeting: or
- convert their CDIs into a holding of Shares and vote these at the meeting. Afterwards, if the former CDI holder wishes to sell their investment on the ASX, the holder would need to convert the Shares back to CDIs. In order to vote in person, the conversion of CDIs to Shares must be completed before the record date for the meeting. For information on the process for converting CDIs to common stock, please contact the CDI registry.

One of the above steps must be undertaken before CDI holders can vote at stockholder meetings. CDI voting instruction forms and details of these alternatives will be included in each notice of meeting or proxy statement sent to CDI holders.

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# Corporate directory

## US Office and Headquarters

Imricor Medical Systems, Inc.  
400 Gateway Boulevard  
Burnsville, Minnesota 55337  
United States  
Telephone: +1 952 818 8400

## Board of Directors

Steve Wedan (Chairman and CEO)  
Mark Tibbles (Non-executive Director)  
Anita Messal (Non-executive Director)  
Peter McGregor (Non-executive Director)

## Local Agent & Company Secretary

Kobe Li

## Australian Registered Address

c/- Case Governance Pty Ltd  
Level 13, 41 Exhibition Street  
Melbourne VIC 3000 Australia

## CDI Registry

Computershare Investor  
Services Pty Limited  
GPO Box 2975  
Melbourne, Victoria 3001  
Australia  
Telephone: 1300 850 505  
(within Australia) or  
+61 3 9415 4000 (outside Australia)  
[www.computershare.com](http://www.computershare.com)

## Share Registry

Computershare Trust Company, N.A.  
250 Royal Street  
Canton, Massachusetts 02021  
United States  
[www.computershare.com](http://www.computershare.com)

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## ASX Code

ASX: IMR

## Website

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

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