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## **Imricor Medical Systems**

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 MRIguided 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 2022.

## **AGM Details**

Imricor will hold its Annual Meeting of Stockholders on Friday, 12 May 2023 at 8:00 am Sydney time (on Thursday, 11 May 2023, at 5:00 pm U.S. Central Daylight Time).

This is a completely virtual Annual Meeting. Stockholders can watch and participate in the Annual Meeting virtually via the online platform by visiting www.meetnow.global/ MDVKVKA on your smartphone, tablet or computer. You will need the latest versions of Chrome, Safari, Edge or Firefox. Please ensure your browser is compatible.

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

# **Chairman's Letter**

#### Dear Shareholder,

Welcome to the 2022 Annual Report for Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR).

Imricor is a US-based company that develops MRIcompatible medical devices for cardiac catheter ablation procedures. We aim to improve the success rates and reduce the overall costs of such procedures, thereby making a significant impact on patients, healthcare professionals, and healthcare facilities worldwide.

The foundations of our mission to change the standard of care for cardiac catheter ablation, as well as other life-changing and life-saving interventions, are based on three key strategic pillars. First, we are growing the customer base of sites that have Interventional Cardiac Magnetic Resonance (iCMR) capabilities and are performing procedures with our products. Secondly, we are working to increase the number of different types of ablation procedures, known as indications, that doctors can perform with our products. This happens through clinical trials that demonstrate the safe and effective use of our devices for these expanded indications and the subsequent regulatory approvals that follow. Thirdly, we are working to broaden the geographic reach of our products by pursuing regulatory approvals outside of our core European markets, such as in the US, Australia, New Zealand, and most recently the Middle East.

I am pleased to report that we made significant progress in 2022. We grew our contracted sites, improved and increased our product range, signed further agreements with our partners, and surpassed significant milestones in the clinical trial processes that aim to expand our products' indications and expand our geographic reach. These achievements all advance the foundational strategies I mentioned.

I'd like to highlight a couple of key achievements from 2022 and provide an outlook for 2023 and beyond.

## EXPANDING INDICATIONS - VENTRICULAR TACHYCARDIA TRIAL

The progress made towards ventricular tachycardia (VT) in 2022 is considerable. After years of developing various Imricor devices and partnering with multiple third-party companies for additional products, our team completed the extensive testing and documentation required to submit for regulatory approval to initiate the "Vision-MR Ablation of VT" or VISABL-VT trial. The amount of work involved in this process was extraordinary, as clinical trial submissions typically only involve a single device or a small set of devices. In our case, the VISABL-VT trial includes 10 investigational Imricor devices, and two third-party investigational devices.

Our VISABL-VT trial aims to expand the indications for our products to include ventricular tachycardia ablations in the iCMR lab. The trial has received approval from the Ethics Committee at the Leipzig Heart Center and is currently under review by the German Competent Authority. Once final approval is granted, we expect to begin enrollment in the coming months.

Furthermore, as we complete the final testing and documentation for our NorthStar 3D mapping system, which I'll discuss below, we plan to seek approval to initiate the VISABL-VT trial in the Netherlands, as well, and include sites utilising the Siemens MRI platform in that country.

#### NORTHSTAR 3D MAPPING SYSTEM - SUPPORTING GEOGRAPHY AND INDICATION EXPANSION AND CONTROLLING OUR TIMING

The NorthStar 3D mapping system is one of our most significant achievements of 2022. It supports so much of what we do now and what we plan to do in the future. NorthStar is a 3D mapping system that connects to both the MRI scanner and Imricor's Advantage-MR EP Recorder/Stimulator. NorthStar allows the user to control the MRI scanner, receive MR images in real-time from the scanner, display those MR images in 3D, actively track Imricor trackable devices, and create 3D electroanatomical maps that include intracardiac electrogram signals from the Advantage-MR system. Our team was able to complete the development of NorthStar in less than a year and in December we successfully evaluated the system in first-in-human cases at Haga Hospital in the Netherlands. NorthStar is not yet approved for sale, but we are moving quickly toward the required approvals.

NorthStar is currently compatible with Siemens MRI scanners, and we secured the agreements with Siemens to deploy NorthStar wherever a customer has the appropriate Siemens MR scanner – no further approvals from Siemens are required. As the documentation and testing of NorthStar are finalized for submission to the VISABL-VT trial, we are also working to adapt NorthStar for use with Philips and GE Healthcare MRI platforms. Together, these three MRI manufacturers cover the majority of MRI systems sold worldwide. The goal is to provide a consistent user experience, through NorthStar, across all MRI platforms used in iCMR labs.

Importantly, NorthStar finally removes our reliance on others to develop 3D mapping systems needed for complex ablation procedures, and it puts control of our timelines back in our hands.

## EXPANDING GEOGRAPHIES – GROWING BEYOND EUROPE

As I mentioned, it's important that we expand beyond Europe, and we are progressing this on many fronts, including in Australia, New Zealand, and the Middle East.

But one of the most significant and difficult geographic markets to break into is the US. That's why we were so pleased that the US FDA approved our Investigational Device Exception (IDE) in January to commence a global clinical trial called "Vision-MR Ablation of Atrial Flutter" or VISABL-AFL. The VISABL-AFL trial, which we are planning to conduct in parallel with the VISABL-VT trial starting in the coming months, aims to support FDA approval of our platform of devices in the US.

#### LOOKING TO THE YEAR AHEAD

Today, we are treating atrial flutter in Europe. This is, and always has been, just the start. Starting with a straightforward ablation procedure like atrial flutter gives us the opportunity to establish iCMR ablations as a clinical procedure, and to obtain approval for the devices we and others produce to support such procedures – we have been building a foundation. We are following this path outside of Europe as well, including in the US.

Next, we will expand our indications to treat more complex arrhythmias, where we believe MRI will add the most value. These are the kinds of procedures I had in mind when I started the company. The two main targets are ventricular tachycardia (VT) and atrial fibrillation (AF). As I mentioned, we are targeting VT first, but we are also planning smaller pilot studies this year to demonstrate the benefits of MRI for AF ablations.

Looking ahead, we have many exciting things on the horizon. We will, of course, continue to focus on launching our products in the post-pandemic environment and re-building the momentum lost during COVID. We will start the VISABL-VT and VISABL-AFL trials at sites in Europe and the US as I mentioned, which we expect will grow our indications and geographies in big ways.

And this means that now is the beginning of the future of Imricor. We showed, through atrial flutter ablations, that routine cardiac ablations can be performed in the iCMR lab, and now we plan to show all the advantages MRI adds to complex ablation procedures, like VT. We are building a future around the advantages MRI can offer to patients, physicians, and healthcare systems in general. We see a future where our NorthStar 3D mapping system, connected to an MRI and enabled with AI. helps physicians diagnose the root cause of diseases. We see a future where NorthStar provides a simple environment in which to treat these diseases in the iCMR lab with individualized strategies based on each patient's unique anatomy and disease state. And we see a future, where we expand into new and exciting areas, such as

pulsed field ablation (PFA), where we believe MRI will add the same value that it does to RF ablation, or cardiac biopsy or targeted regenerative therapy.

This is the moment we've been working toward, and it is a great time to be Imricor.

I would like to thank our Management and staff for their efforts over the past year, which have been considerable given our progress amid a somewhat challenging operating environment. Our team has worked with dedication, determination, and the shared belief and focus that we are changing the world of interventional medicine.

I also thank my fellow Board members for their contributions, and importantly, I thank our Shareholders for their support and belief in Imricor's mission and our ability to deliver on our goals.

With our strong foundations in place, I could not be more excited about the progress we will make in 2023 and beyond.

Sout

**Steve Wedan** Executive Chair, President and CEO

"This is the moment we've been working toward, and it is a great time to be Imricor."

# **Key Achievements & Core Strategies**

## **DELIVERING ON OUR STRATEGIC PLAN**



## 2022 KEY ACHIEVEMENTS



- 9 active sites across Europe
- Contracted 2 new sites
   across Europe
- Expanded Company's geographical footprint into Croatia and Italy
- Renewed sales focus on sites owned by Cardiology department



### PRODUCTS

- Second generation ablation catheter submitted for approval in Europe
- First clinical evaluation of NorthStar 3D Mapping System
- Diagnostic Catheter Technical Review Complete



### **NEW FUNDING SECURED**

- Secured a US\$1.5 million loan under the North Dakota Commerce Department's Innovation Technology Loan Fund program
- US\$5 million convertible
   note deal
- A\$2.92m placement completed in the September quarter



### PARTNERSHIPS

- Two agreements signed with Siemens
  - First agreement was an Access-I License Agreement
  - Second agreement was a Local Coil Agreement

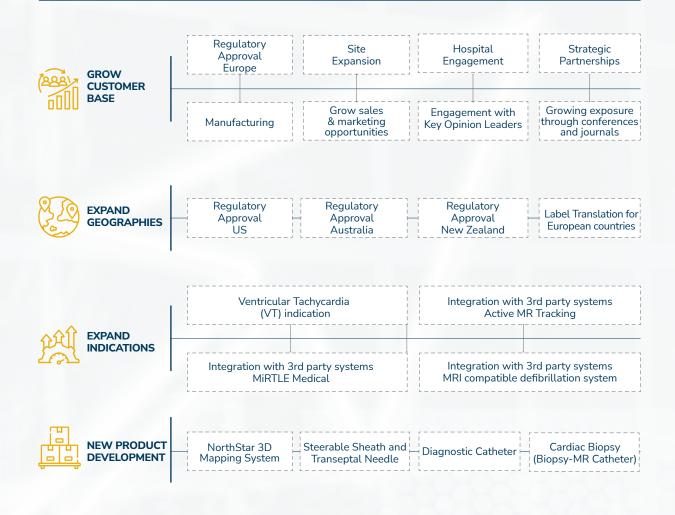


- Submitted for approval to commence VT ablation trial
- Trial named Vision-MR Ablation of VT or VISABL-VT
- Received first of two approvals from Leipzig Heart Centre Ethics Committee



- US restriction on CHESS depository Interests removed
- Hosted virtual open house investor session
- Jonathon Gut promoted to CFO role

## **KEY INITIATIVES TO SUPPORT OUR STRATEGY**



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# Expanding Indications and Geographical Reach









## **UNITED STATES**

FDA strategy well advanced

Received approval from FDA for Investigational Device Exemption in January 2023

Clinical trials expected to enroll in mid-2023



## EUROPE

CE mark received

9 active sites across four countries

VT Clinical trials expected to enroll in mid-2023



## AUSTRALIA AND NEW ZELAND

Appointed Regional Health Care Group (RHCG) in Australia to help facilitate TGA and Medsafe approvals

Medsafe approval received for all Imricor products in New Zealand

Received TGA approval on Imricor's Advantage-MR System



### FRANCE

Clinical site established at South Paris Cardiovascular Institute

## SWITZERLAND

Imricor products included in Sana GPO approved catalogue of materials

### **GERMANY**

Nine clinical sites with signed purchase agreements across Germany

Imricor products included in Sana GPO approved catalogue of materials

## THE NETHERLANDS

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

## HUNGARY

Clinical site signed at Semmelweis University Heart and Vascular Centre

## GREECE

Clinical site established at Henry Dunant Hospital Centre

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# **Our Products**



Vision-MR Ablation Catheter



Advantage-MR EP Recorder/ Stimulator System



#### Vision-MR Dispersive Electrode

## DESCRIPTION

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.

- 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.
- 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.

## TECHNICAL SPECIFICATION

- 9F (3.0mm) catheter with a 4mm openirrigated deflectable tip and two gold electrodes (1.3mm spacing)
- 3.7mm tip electrode and a 1.4mm ring electrode
- 2 MR-receive coils in the distal end for realtime MR active catheter imaging
- Provides the functionality of both a conventional EP recording system and a cardiac stimulator
- Compatible with the Imricor Vision-MR Ablation Catheter
- Dual-lobe dispersive electrode used with a detached cable
- Includes adhesive conductive gel (hydrogel) to ensure full contact with the patient's skin

## TYPE OF PRODUCT

- Disposable
- Received CE mark January 2020
- Capital Good
- Received CE mark
   January 2016
- Disposable
- Received CE mark January 2020



NavTrac-MR Transseptal Kit



Vision-MR Diagnostic Catheter



**Biopsy Catheter** 

- The NavTrac-MR Transseptal Kit is a 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.
- 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.
- Innovative delivery sheath design with best-in-class torque transfer and superior curve retention through tortuous anatomy.

#### DEFLECTABLE/STEERABLE SHEATH

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

#### ACTIVELY TRACKWSWWED DILATOR

- Dilator outside diameter .152"
- 2 MR-receive coils in the distal end for realtime 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
- Needle reveal of .275"
- Disposable
- In development

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

- Disposable
- In regulatory review with Notified Body
- Disposable
- In development

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# NorthStar 3D Mapping System

TAKING CONTROL OF OUR TIMELINE AND FUTURE



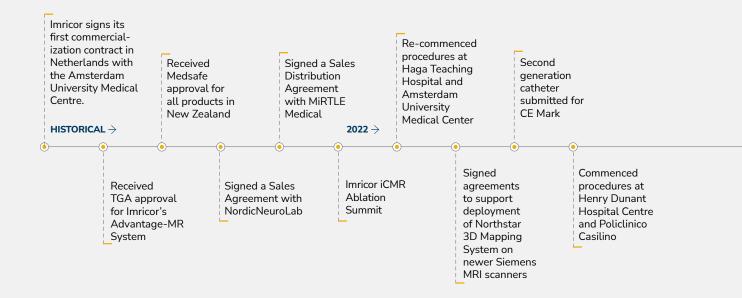
## DESCRIPTION

- System evaluated successfully in human setting
- Planning to also apply NorthStar to other MRI platforms, such as GE and Philips, so the user has the same 3D mapping system experience no matter what kind of MRI system you have
- Imricor no longer reliant on MRI manufacturers to commercialize their mapping systems
- Planning rapid development and expansion in coming years

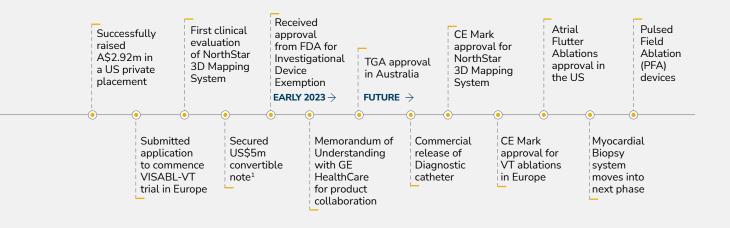


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# Timeline







1. The convertible note was issued in two tranches. The first US\$2.3m was issued in December 2022 and the second US\$2.7m was issued in March 2023.



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# **Board of Directors**





Deputy Chair and Lead Independent Director

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 30 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 Board of Directors of Medical Device Research Forum, Inc. and Water Rescue Innovations, Inc., as well as the Advisory Board of Poiesis Medical, LLC.

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. 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 OMEDZA.com, Inc. and Operandi, Inc.; Poiesis Medical LLC's Chief Strategy Officer and Executive Committee Member; an owner and managing member of STEM Fuse, LLC, one of the largest providers of digital K-12 STEM curriculum in the U.S.; and the Managing Director of Strategic Stage Ventures, LLC.

Prior to his current roles, Mr Tibbles was a Board member of the Nerdery, LLC as well as an owner and member of Intuitive Technology Group until it was sold in 2017. Mr Tibbles was also a 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.



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), True Infrastructure Management Pty Ltd and Chain Collective Pty Ltd.

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

Ms. Messal has over 35 years of experience in the health care and benefits industry, most recently as the Chief Integration Officer at AccentCare where she was responsible for the successful integration of merged and acquired entities accross all areas of the business.

Anita has experience in health plan services, health care delivery, care management, and benefits administration. She has worked with self-funded, fully insured and CMS funded care. Her customers and partners include large and mid-size employers, health plans, insurance carriers, brokers, resellers, enterprise software companies and consumers.

Ms. Messal has participated in fund raising from start-up through IPO and sale to strategic buyers and private equity. Anita has worked in both F100 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.

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# **Executive Team**



STEVE WEDAN

President and Chief Executive Officer, & Chair

Refer to page 16



JONATHON GUT Vice President of Finance and Chief Financial Officer

Mr Gut joined Imricor in 2020 and has served as the Company's Chief Financial Officer since July 2022.

Mr Gut has over 14 years of accounting and finance experience, the last 10 of them in the medical device industry, having previously worked for both private and publicly owned companies, including Galil Medical and Boston Scientific.

Mr Gut holds a Bachelor of Accounting from the University of Minnesota-Duluth and a Master of Accountancy from the University of Minnesota-Twin Cities. He is a licensed Certified Public Accountant.



**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 25 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 25 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.



#### 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.



**VIC FABANO** 

Vice President of Operations

Mr Fabano has more than 25 years of experience in the medical device industry, holding executive positions in Operations, Quality, and Product Development. His expertise is efficiently scaling up the supply chain and operations infrastructure to support rapid growth. profitability, and quality. Prior to joining Imricor, Mr Fabano was Vice President of Operations and Quality at Osprey Medical for 11 years, and served in a similar capacity for several start-ups to midsize medical device firms in the Twin Cities Mr Fabano has a bachelor's degree in Mechanical Engineering from the University of North Dakota.



NICK TWOHY Vice President 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

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

launch of the Revo MRI

pacemaker system.



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 more than 20 years of experience working in the medical device industry with 18 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.



KATE LINDBORG Director of Clinical Affairs

Dr. Lindborg joined Imricor in 2020 and is responsible for developing the company's clinical strategy and leading preclinical and clinical investigations.

Dr. Lindborg has over 12 years of experience in the medical device industry primarily focused on clinical study development, execution, and evidence generation.

Prior to joining the Company, Dr Lindborg held various roles within Medtronic's Cardiac Rhythm and Heart Failure and Diagnostics Clinical organizations. Dr Lindborg's roles included leading pre and post-market clinical investigations, managing evidence generation, and clinical strategy development to gain and maintain market approval of novel devices

Dr Lindborg holds a Doctor of Philosophy and Master of Science in Physiological Sciences from the University of Arizona as well as a Bachelor of Arts from Gustavus Adolphus College.



THOMAS WORGUL

Director of Sales Europe

Mr. Worgul joined Imricor in 2022 and as a Director of Sales Europe and is leading the team in Europe to expand our footprint in various markets.

Mr. Worgul has more than 25 years of experience in the medical device industry and has held in the past several positions as a Sales Director. His main focus was working in the cardiology and radiology space and launching new technologies. Prior to his role at Imricor he worked for example at Acist Medical Systems, RenalGuard and MedAlliance in several management positions.

Mr. Worgul has a degree in Master of Business Administration.

# **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 collaborates with the three leading, global MRI vendors: GE, Philips and Siemens, who provide MRI systems for iCMR labs.

The Company has performed contract research on and liscenced 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 estimated to be in excess of US\$5.5 billion worldwide, with a CAGR of 8.2%. 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 seventeen sites having executed purchased agreements across Germany, The Netherlands, France, Hungary, Greece, Italy and Croatia. Imricor aims to expand its installed base with a dedicated European sales team targeting clinical sites across these and other European countries.

Within each targeted country, Imricor will first target ablation centres which historically have carried out larger volumes of procedures or which have influential key opinion leaders. The Company is focused on establishing new iCMR labs which are owned and controlled by cardiology to support higher procedure volumes at each site. 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, Imricor has received approval for an Investigational Device Exception (IDE) from the US Food and Drug Administration (FDA) to initiate a global clinical trial: "**Vis**ion-MR **Abl**ation of **A**trial **Fl**utter" or VISABL-AFL. The study is a prospective, single-arm multi-centre interventional investigation designed to demonstrate the safe and effective use of the Vision-MR Ablation Catheter 2.0 for the treatment of type 1 atrial flutter and will enroll up to 91 patients at sites in the US and Europe, with an enrollment cap of 50% of the total enrollment population coming from outside the US. An interim analysis will be completed after 76 patients have achieved the 7-day follow-up with final follow-up occuring 3 months after the procedure. The Company expects to begin enrolling patients in the study around mid-year.

In conjunction with organic growth across existing products, the Company is targeting growth through expanding its product line, providing the opportunity for Imricor's products to be used across a broader range of MR-guided interventional procedures (i.e. beyond type 1 atrial flutter). To further this effort, during the year the Company submitted for approval to commence a real-time iCMR-guided ventricular tachycardia (VT) ablation clinical trial in Europe. The study, named "**Vis**ion-MR **Abl**ation of **VT**" or VISABL-VT, is a prospective, single-arm multi-centre interventional investigation of the safety and efficacy of radiofrequency (RF) ablation of ventricular tachycardia associated with ischemic cardiomyopathy performed with the Vision-MR Abalation Catheter 2.0 in the iCMR environment. The study calls for treating 64 patients and includes a 6-month follow-up for each patient, as is typical. The Company received the first of two required approvals to initiate the trial in Germany at the Leipzig Heart Center and the submission is now under review by the Federal Institute for Drugs and Medical Devices (BfArM), the German Competent Authority. The Company expects to submit for approval to commence the trial at other sites in Europe, including in the Netherlands.

#### **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.
- Going concern: The Company continues to incur losses from operations and negative cash flows from operations and is
  in need of additional working capital to fund future operations. Under U.S. generally accepted accounting principles
  (U.S. GAAP), these conditions raise substantial doubt about its ability to continue as a going concern. If the Company is
  not able to raise additional working capital through an equity or debt offering, it would have an adverse effect on the
  operations of the Company and continuing research and development of its product, as well as commercialization.

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 2022, the Company generated revenue of US\$0.816 million compared to US\$0.696 million for the prior corresponding period due to increased product sales, largely driven by more active sites able to perform procedures and the easing of COVID related restrictions throughout the current year. Total product sales of US\$0.647 million were up approximately US\$0.276 million, or 74%, compared to the prior corresponding period. The Company's sales have been limited by lingering impacts of the pandemic and MRI availability at sites where cardiology departments do not yet own their own MRI; however, the Company expects both effects to diminish as time passes and additional hospitals invest in a dedicated iCMR lab. Further, the Company is making steady progress toward obtaining CE Mark on our devices needed to perform complex ablations, such as VT in Europe, and FDA approval for atrial flutter devices in the U.S., which will expand the Company's reach for treating patients.

Imricor reported a net loss of US\$17.356 million compared to US\$19.733 million in the prior corresponding period due to decreased compensation expenses and research and development costs, reflecting the cost reduction measures which were implemented earlier in the year.

#### **Financial position**

For the 12-month period ending 31 December 2022, Imricor's net cash outflow from operations was US\$16.510 million compared to US\$17.489 million for the prior year. Net cash outflows from investing activities of US\$0.239 were down slightly compared to US\$0.695 million for the prior year.

Net cash inflows from financing activities of US\$3.943 million were predominately associated with Imricor's September US placement and the convertible note issued in December.

At 31 December 2022, Imricor maintained a cash balance of US\$5.688 million (FY21 US\$18.516 million) which supports the continuation 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

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 20 to 21 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
Peter McGregor	May 2019
Anita Messal	March 2021

The specific duties, qualifications and experience of each Director are set out on pages 16 to 17 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		ctor Board Audit & Risk Committe			Nomination & Remuneration Committee		
	Held	Attended	Held	Attended	Held	Attended	
Steve Wedan	3	3	-	-	-	-	
Mark Tibbles	3	3	7	7	2	2	
Peter McGregor	3	3	7	7	2	2	
Anita Messal	3	3	7	7	2	2	

Held: represents the number of meetings held during the time the director held office or was a member of the relevant committee.

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	4,983,586	3,417,132
Mark Tibbles	5,943,582	526,806
Peter McGregor	407,253	246,906
Anita Messal	83,791	38,340

#### 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 6 January 2023, the Company obtained a \$1.5 million loan from the Bank of North Dakota under the North Dakota Commerce Department's Innovation Technology Loan Fund (LIFT) to further support Imricor's growth strategy.

On 28 March 2023, the Company issued the second tranche of convertible notes and warrants under the Securities Purchase Agreement announced on 18 December 2022 in exchange for gross proceeds of approximately \$2.7 million, which will be used to further support Imricor's growth strategy.

#### **Likely developments**

Imricor will continue to pursue its product and geographic-led growth strategy, with a focus on product distribution and the establishment of new customer sites in existing markets, as well as expansion into new markets. The Company will also continue efforts to raise funds in order to support these operating activities of the business.

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.

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.

# Directors' Report (cont.)

#### **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, BDO USA, LLP, did not perform other services beyond the audit and review of the financial statements.

#### 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.

Sent

Steve Wedan Chairman 6 April 2023

# **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;
- Chief Operating Officer (COO), Gregg Stenzel;
- Chief Financial Officer (CFO), Jonathon Gut (appointed 1 July 2022); and
- Former Chief Financial Officer (CFO), Lori Milbrandt (retired 30 June 2022).

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, COO, Gregg Stenzel and CFO, Jonathon Gut.

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), Peter McGregor, and Anita Messal.

The Nomination and Remuneration Committee has a formal charter which can be viewed on the Company's website at 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. No external advisors were engaged to provide remuneration benchmarking services during the year.

#### **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.

#### 2022 remuneration structure

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

# Remuneration Report (cont.)

#### **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.

#### 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 2022 the maximum target opportunity was 50% for the President and CEO, Steve Wedan, 40% for the COO, Gregg Stenzel, and 30% for the CFO, Jonathon Gut. The Former CFO, Lori Milbrandt, was not eligible for STI due to her planned retirement in the middle of the fiscal year.

Performance targets determined by the Board in relation to 2022 were based 50% on sales revenue, clinical study enrollment and FDA approval of the IDE for the VISABL-AFL trial and 50% based upon departmental objectives. While strong progress was made toward achieving many of these goals during the year, the Board exercised discretion and determined no payout of STI to KMP was warranted for 2022.

#### 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.

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 at 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 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 FY22:

- 205,000 options with exercise price of US\$0.65, expiring 10 February 2032
- 50,000 options with exercise price of US\$0.47, expiring 6 April 2032
- 3,099,244 options with exercise price of US\$0.28, expiring 9 May 2032
- 199,264 options with exercise price of US\$0.21, expiring 26 July 2032
- 1,130,000 options with exercise price of US\$0.31, expiring 18 August 2032

#### **Unissued shares**

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

Expiry date	Exercise price US\$	Time-Based	Performance-Based	Total Number of Shares
17 June 2023	0.60	60,000	-	60,000
19 May 2024	0.60	60,000	-	60,000
15 March 2029	0.52	4,332,487	-	4,332,487
30 August 2029	0.98	576,665	-	576,665
17 December 2029	0.75	425,000	-	425,000
6 January 2030	0.80	168,619	53,956	222,575
18 January 2030	0.80	25,000	-	25,000
20 February 2030	1.14	25,000	-	25,000
13 May 2030	0.89	748,970	524,476	1,273,446
7 October 2030	1.96	210,000	-	210,000
7 April 2031	1.61	35,000	-	35,000
5 May 2031	1.55	255,900	-	255,900
7 May 2031	1.57	120,132	698,665	818,797
10 February 2032	0.65	205,000	-	205,000
6 April 2032	0.47	25,000	-	25,000
9 May 2032	0.28	125,000	2,974,244	3,099,244
26 July 2023	0.21	25,000	174,264	199,264
18 August 2032	0.31	890,000	-	890,000

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

#### Shares issued on exercise of options

During FY22 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
59,300	US\$0.52

# Remuneration Report (cont.)

#### Executive remuneration during the year

The remuneration of key management personnel in respect of the financial year ended 31 December 2022 is summarised below. The options to be granted under the long-term incentive plan for the CEO in relation to 2023 remuneration must be approved by stockholders at the 2023 Annual Meeting of Stockholders (AGM).

Executive	Base salary	Short-term Incentive <sup>1</sup>	Long-term incentive
Steve Wedan President and CEO	US\$464,900	Nil	1,098,627 options granted on 9 May 2022 at an exercise price of US\$0.28 <sup>2</sup>
			174,264 options granted on 26 July 2022 at an exercise price of US\$0.21 <sup>2</sup> 1,426,949 options to be granted following stockholder approval <sup>3</sup>
Gregg Stenzel COO	US\$300,000	Nil	793,671 options granted on 9 May 2022 at an exercise price of US\$0.28 <sup>2</sup>
Jonathon Gut CFO	US\$207,500	Nil	180,000 options granted on 10 February 2022 at an exercise price of US\$0.65 <sup>4</sup>
Lori Milbrandt Former CFO <sup>5</sup>	US\$157,500	Nil	Nil

1. Determined at the discretion of the Board as discussed above.

2022 Options: 2.

Tranche	Percentage of2022 Options	Vesting Conditions
1	50%	First occurrence of profitable HY results
2	30%	Five clinical sites installed in the United States
3	20%	Three clinical sites installed in Australia

Options value determined based on 50% of base salary for 2023 and short-term incentive paid in 2023 for 2022, subject to stockholder approval at 3. Imricor's 2023 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 US Dollars using the prevailing exchange rate.

Tranc	Percentage the of2023 Options	Vesting Conditions
1	35%	Three clinical sites installed in Australia
2	35%	Five clinical sites installed in the United States
3	30%	First clinical sale for VT ablation
4.	The options shall vest annually over	r four years, 25% on each anniversary of the appointment of Mr Gut as CFO (1 July 2022).

5. Ms Milbrandt retired from the Company on 30 June 2022.

#### **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 to 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 2022 is summarised below:

Non-Executive Director	Cash fees	Restricted Stock Granted <sup>1</sup>
Peter McGregor	US\$80,000	107,253
Mark Tibbles	US\$80,000	107,253
Anita Messal	US\$75,000	83,297

1. Restricted stock vests annually over four years, 25% on each anniversary of the grant date.



Minneapolis, Minnesota

Including Independent Auditor's Report

As of and for the years ended December 31, 2022 and 2021

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### Independent Auditor's Report

Stockholders and Board of Directors Imricor Medical Systems, Inc. Burnsville, Minnesota

### Opinion

We have audited the financial statements of Imricor Medical Systems, Inc. (the Company), which comprise the balance sheet as of December 31, 2022, and the related statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes to the financial statements.

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

### **Basis for Opinion**

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

#### Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 3 to the financial statements, the Company has suffered recurring losses from operations, an accumulated deficit, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

#### Other Matter

The 2021 financial statements of the Company were audited by other auditors, whose report dated February 23, 2022 expressed an unmodified opinion on those statements.

### Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation

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and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

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

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

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

In performing an audit in accordance with GAAS, we:

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

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

BDO USA, LLP

February 22, 2023

BALANCE SHEETS

As of December 31, 2022 and 2021

ASSETS				
A00210	2022		2021	
CURRENT ASSETS				
Cash	\$	5,687,816	\$	18,516,208
Accounts receivable		125,544		94,735
Inventory		2,276,743		2,582,813
Prepaid expenses and other current assets		1,594,211		1,505,556
Total Current Assets		9,684,314		22,699,312
ACCOUNTS RECEIVABLE-LONG TERM		228,984		201,544
PROPERTY AND EQUIPMENT, NET		2,563,356		2,951,924
OTHER ASSETS		227,779		363,676
OPERATING LEASE RIGHT OF USE ASSETS		996,428		647,951
TOTAL ASSETS	\$	13,700,861	\$	26,864,407
LIABILITIES AND STOCKHOLDER	S' EQU	ΙΤΥ		
CURRENT LIABILITIES				
Accounts payable	\$	259,267	\$	686,724
Accrued expenses		924,936		1,354,428
Current portion of contract liabilities		23,358		175,286
Current portion of operating lease liabilities		198,073		186,498
Current portion of finance lease liability		160,680		332,157
Current portion of financing obligation		508,424		-
Total Current Liabilities		2,074,738		2,735,093
LONG-TERM LIABILITIES				
Convertible note		2,182,900		-
Contract liabilities, net of current portion		492,853		509,604
Operating lease liabilities, net of current portion		1,329,890		992,319
Finance lease liability, net of current portion		65,999		226,677
Other long-term liabilities		44,041		-
Total Liabilities		6,190,421		4,463,693
COMMITMENTS AND CONTINGENCIES (NOTE 7)				
STOCKHOLDERS' EQUITY				
Preferred stock, \$0.0001 par value:				
25,000,000 shares authorized and 0 shares outstanding as of both				
December 31, 2022 and 2021		-		-
Common stock, \$0.0001 par value:				
535,000,000 shares authorized as of both December 31, 2022 and				
2021 and 151,347,625 and 143,234,637 shares issued and		45 405		44.004
outstanding as of December 31, 2022 and 2021, respectively		15,135		14,324
Additional paid-in capital		97,456,289		94,991,107
Accumulated deficit Total Stockholders' Equity		(89,960,984) 7,510,440		(72,604,717) 22,400,714
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	13,700,861	\$	26,864,407
	Ψ	13,700,001	Ψ	20,004,407

See accompanying notes to financial statements

STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2022 and 2021

	2022		2021			
REVENUES						
Product revenue	\$	647,230	\$	371,340		
Service revenue		120,835		69,223		
Government contract revenue		47,946		255,704		
Total Revenues		816,011	696,267			
COSTS AND EXPENSES						
Cost of goods sold		2,342,795	2,592,191			
Sales and marketing	2,804,769			2,868,360		
Research and development	7,946,129			9,675,493		
General and administrative	4,982,404			5,819,622		
Total Costs and Expenses	18,076,097			20,955,666		
Loss from Operations		(17,260,086)		(20,259,399)		
OTHER INCOME (EXPENSE)						
Interest income	107,999			16,725		
Employee retention credit	-			757,714		
Foreign currency exchange loss	(17,955)			(42,990)		
Interest expense	(177,917)			(108,849)		
Fair value change in convertible note	14,200			-		
Other expense		(22,508)		(95,741)		
Total Other Income (Expense)		(96,181)		526,859		
NET LOSS	\$	(17,356,267)	\$	(19,732,540)		
EARNINGS PER SHARE:						
Basic and diluted loss per common share	\$	(0.12)	\$	(0.15)		
Basic and diluted weighted average shares outstanding		145,744,865		130,801,707		

See accompanying notes to financial statements

STATEMENTS OF STOCKHOLDERS' EQUITY For the Years Ended December 31, 2022 and 2021

	Common Stock		Additional	Accumulated	Total Stockholders'		
-	Shares	F	mount	Paid-in Capital	Deficit	Equity	
<b>BALANCES, December 31, 2020</b> Stock-based compensation expense Exercise of stock options, net of fees Issuance of common stock, net of	125,549,550 - 185,259	\$	12,556 - 18	\$ 81,675,671 1,149,598 87,828	\$(52,872,177) - -	\$	28,816,050 1,149,598 87,846
issuance costs of \$716,863	17,499,828		1,750	12,078,010	-		12,079,760
Netloss	-		-	-	(19,732,540)		(19,732,540)
BALANCES, December 31, 2021	143,234,637	\$	14,324	\$ 94,991,107	\$(72,604,717)	\$	22,400,714
Stock-based compensation expense Exercise of stock options, net of fees Issuance of common stock and restricted stock, net of issuance	- 59,300		- 6	320,835 29,825	-		320,835 29,831
costs of \$22,924 Issuance of warrants, net of fees	8,053,688 -		805 -	1,992,673 121,849	- -		1,993,478 121,849
Net loss BALANCES, December 31, 2022	- 151,347,625	\$	- 15,135	- \$ 97,456,289	(17,356,267) \$(89,960,984)		(17,356,267) 7,510,440
DALANOLO, DECEMBER JI, 2022	101,047,020	Ψ	10,100	ψ 51,400,209	ψ(00,000,004)	Ψ	7,010,440

See accompanying notes to financial statements

STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2022 and 2021

CASH FLOWS FROM OPERATING ACTIVITIES         \$ (17.356.267)         \$ (19.732.540)           Adjustments to reconcile net loss to net cash flows from operating activities:         712.491         689.114           Stock-based compensation expense         320.835         1,149.598           Loss on disposal of property and equipment         509         82.970           Change in linentory reserves         682.187         668.464           Foreign currency exchange loss         17.955         42.990           Change in lair value of convertible note         (14.200)         -           Amortization of issuance costs of covertible note         (14.44.967)         (181.357)           Prepriad expenses and other assets         585.196         (22.3.616)           Accounds payable         (404.192)         148.762           Accrued expenses         (416.510.221)         (17.488.546)           Proceeds from service of stock options         238.859         (625.745)           Purchases of property and equipment         (238.859)         (625.745)           Proceeds from financing obligation         839.148         -           Proceeds from financing obligation         (84.121)         (337.804)           Proceeds from issuance oots on convertible note         (47.749)         -           Proceeds from isou			2022		2021
Adjustments to reconcile net loss to net cash flows from operating       activities:         Depreciation       712,491       689,114         Stock-based compensation expense       320,835       1,149,598         Loss on disposal of property and equipment       509       82,970         Change in inventory reserves       682,187       668,464         Foreign currency exchange loss       17,955       42,990         Change in fair value of convertible note       (103,937       -         Change in sest and liabilities       (66,217)       154,062         Accounts receivable       (66,217)       154,062         Inventory       (444,467)       (181,357)         Prepaid expenses and other assets       585,196       (623,616)         Accounts payable       (404,192)       148,762         Accounts payable       (16,510,221)       (17,486,546)         Contract liabilities       (16,510,221)       (17,486,546)         Purchases of property and equipment       -       (69,500)         Purchases of property and equipment       -       (69,500)         Proceeds from financing obligation       839,148       -         Proceeds from insuance of stock options       29,831       87,846         Proceeds from insuence of oormon stock	CASH FLOWS FROM OPERATING ACTIVITIES	•		•	(
activities:         Depreciation         712,491         689,114           Stock-based compensation expense         320,835         1,149,598           Loss on disposal of property and equipment         509         82,970           Change in inventory reserves         682,187         668,464           Foreign currency exchange loss         17,955         42,990           Change in assets and liabilities         (14,200)         -           Accounts receivable         (68,217)         154,062           Inventory         (444,967)         (181,357)           Prepaid expenses and other assets         586,196         (623,616)           Accounts payable         (404,192)         148,762           Accrued expenses         (476,809)         218,125           Contract liabilities         (16,510,221)         (17,488,546)           Purchases of property and equipment         -         (69,560)           Purchases of property and equipment         238,859)         (625,745)           Net Cash Flows used in Investing Activities         (238,859)         (625,745)           Proceeds from financing obligation         839,148         -           Proceeds from financing obligation         (864,121)         (337,804)           Proceeds from financing obligation			(17,356,267)	\$	(19,732,540)
Depreciation         712,491         669,114           Stock-based compensation expense         320,835         1,149,598           Loss on disposal of property and equipment         509         82,970           Change in inventory reserves         662,187         668,464           Foreign currency exchange loss         17,955         42,990           Changes in assets and liabilities         103,937         -           Accounts receivable         (68,217)         154,062           Inventory         (444,967)         (181,357)           Prepaid expenses and other assets         535,196         (623,816)           Accounts payable         (404,192)         148,762           Accourd expenses         (416,609)         218,125           Contract liabilities         (165,10221)         (17,488,546)           Proceeds from NEVESTING ACTIVITIES         (69,560)         (228,859)           Equity investment         -         (69,560)           Proceeds from exercise of stock options         29,831         87,846           Proceeds from exercise of stock options         29,831         87,846           Proceeds from insuance octo convertible note         (47,749)         -           Proceeds from insuance of common stock         2,016,402		g			
Stock-based compensation expense         320,835         1,149,998           Loss on disposal of property and equipment         509         82,970           Change in inventory reserves         682,187         668,464           Foreign currency exchange loss         17,955         42,990           Change in fair value of convertible note         103,937         -           Accounts receivable         (68,217)         154,062           Inventory         (444,967)         (181,357)           Prepaid expenses and other assets         555,196         (823,816)           Accounts payable         (404,192)         148,762           Accrued expenses         (166,510,221)         (17,488,546)           Contract liabilities         (168,679)         94,882           Net Cash Flows used in Operating Activities         (238,859)         (695,305)           CASH FLOWS FROM INVESTING ACTIVITIES         -         (69,560)           Purchases of property and equipment         (238,859)         (695,305)           CASH FLOWS FROM FINANCING ACTIVITIES         -         (69,749)           Proceeds from exercise of stock options         29,831         87,846           Proceeds from invention stock and restricted stock         (22,924)         -           Payments on financo					
Loss on disposal of property and equipment         509         82,197           Change in inventory reserves         682,187         668,464           Foreign currency exchange loss         17,955         42,990           Changes in fair value of convertible note         103,937         -           Changes in assets and liabilities         (68,217)         154,062           Accounts receivable         (68,217)         154,062           Accounts payable         (404,192)         148,762           Accounds payable         (404,192)         148,762           Accounds payable         (16,500)         218,125           Contract liabilities         (16,510,221)         (17,486,546)           Purchases of property and equipment         -         (69,560)           Purchases of property and equipment         (238,859)         (625,745)           Net Cash Flows used in Investing Activities         (238,859)         (625,745)           Proceeds from financing obligation         839,148         -           Proceeds from financing obligation         (844,121)         (33,7804)           Proceeds from financing obligation         (844,121)         (33,7804)           Proceeds from financing obligation         (844,121)         (33,7804)           Proceeds from financi	•				
Change in inventory reserves         682,187         668,464           Poreign currency exchange loss         17,955         42,990           Change in fair value of convertible note         113,937         -           Changes in assets and liabilities         (68,217)         154,062           Inventory         (444,967)         (181,357)           Proped expenses and other assets         585,196         (623,816)           Accounts receivable         (404,192)         148,762           Account expenses         (476,809)         2218,125           Contract liabilities         (168,679)         94,882           Net Cash Flows used in Operating Activities         (165,510,221)         (17,488,546)           Purchases of property and equipment         (238,859)         (695,500)           Purchases of property and equipment         (238,859)         (695,306)           Proceeds from funkncing Activities         (238,859)         (695,306)           CASH FLOWS FROM FINANCING ACTIVITIES         29,831         87,846           Proceeds from funknoing obligation         839,148         -           Proceeds from financing obligation         839,148         -           Payments on financing obligation         839,148         -           Debt issuance costs on con					
Foreign currency exchange loss         17,955         42,990           Change in fair value of convertible note         (14,200)         -           Amortization of issuance costs of convertible note         (103,937)         -           Changes in assets and liabilities         (444,967)         (181,357)           Accounts receivable         (68,217)         154,062           Inventory         (444,967)         (181,357)           Prepaid expenses and other assets         585,196         (822,316)           Accounts payable         (404,192)         148,762           Accrued expenses         (476,809)         218,125           Contract liabilities         (165,510,221)         (17,488,546)           Net Cash Flows used in Operating Activities         (165,510,221)         (17,488,546)           Purchases of property and equipment         (238,859)         (692,500)           Net Cash Flows used in Investing Activities         (238,859)         (695,300)           Proceeds from exercise of stock options         29,831         87,846           Proceeds from financing obligation         839,148         -           Proceeds from issuance costs on convertible note         (47,749)         -           Proceeds from issuance of common stock         2,016,402         12,079,760					-
Change in fair value of convertible note(14,200)-Amortization of issuance costs of convertible note103,937-Changes in assets and liabilities(68,217)154,062Accounts receivable(64,497)(181,357)Prepaid expenses and other assets585,196(622,616)Accounts payable(404,192)148,762Accound expenses(404,192)148,762Accrued expenses(404,192)148,762Contract liabilities(16,510,221)(17,488,546)CASH FLOWS FROM INVESTING ACTIVITES(168,679)94,882Equity investment(238,859)(695,305)Purchases of property and equipment(238,859)(695,305)Proceeds from financing obligation839,148-Proceeds from financing obligation839,148-Proceeds from insuing obligation(864,121)(337,804)Proceeds from insuing obligation(864,121)(337,804)Proceeds from susance of common stock2,016,40212,079,760Issuance costs of convertible note(47,749)-Proceeds from insuing obligation(32,2155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Payments on financing obligation(12,805,648)(6,597,547)CASH - Beginning of Year\$5,687,816\$CASH - Beginning of Year\$\$5,687,814CASH - Beginning of Year\$\$\$18,516,208Supplemental cash flow disclosure\$ <td< td=""><td>- · · ·</td><td></td><td></td><td></td><td></td></td<>	- · · ·				
Amortization of issuance costs of convertible note       103,937       -         Changes in assets and liabilities       (66,217)       154,062         Accounts receivable       (66,217)       164,062         Inventory       (444,967)       (181,357)         Prepaid expenses and other assets       585,196       (823,616)         Accrude expenses       (476,809)       218,125         Contract liabilities       (166,679)       94,482         Net Cash Flows used in Operating Activities       (16,510,221)       (17,488,546)         CASH FLOWS FROM INVESTING ACTIVITIES       Equity investment       -       (69,560)         Purchases of property and equipment       (238,859)       (695,305)       (695,305)         Net Cash Flows used in Investing Activities       (238,859)       (695,305)       -         Proceeds from exercise of stock options       29,831       87,846       -         Proceeds from exercise of stock options       29,831       87,848       -         Proceeds from insunce of common stock       2,016,402       12,079,760       -         Issuance costs on convertible note       (47,749)       -       -         Proceeds from issuance of common stock       2,016,402       12,079,760       -         Issuance costs o	<b>o i</b>				42,990
Changes in assets and liabilitiesAccounts receivable(68,217)154,062Inventory(444,967)(181,357)Prepaid expenses and other assets585,196(823,616)Accounts payable(404,192)144,762Accrued expenses(476,809)218,125Contract liabilities(168,679)94,882Net Cash Flows used in Operating Activities(16,510,221)(17,488,546)CASH FLOWS FROM INVESTING ACTIVITIES(238,859)(695,500)Equity investment(238,859)(695,305)Net Cash Flows used in Investing Activities(238,859)(695,305)CASH FLOWS FROM FINANCING ACTIVITIES29,83187,846Proceeds from financing obligation839,148-Proceeds from financing obligation(864,121)(337,804)Proceeds from financing obligation(864,121)(337,804)Proceeds from financing obligation(2,232,00)-Debt issuance costs on convertible note(47,749)-Proceeds from financing obligation(864,121)(337,804)Proceeds from financing obligation(2,2924)-Payments on finance lease liability(32,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Payments on finance lease liability(32,155)(243,498)Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year\$5,687,81618,516,208Effect of foreign currency exchange rate changes on cash(22,744)<	5		. ,		-
Accounts receivable         (68,217)         154,062           Inventory         (444,967)         (181,357)           Prepaid expenses and other assets         585,196         (823,616)           Accounts payable         (404,192)         148,762           Accrued expenses         (476,809)         218,125           Contract liabilities         (16,510,221)         (17,488,546)           CASH FLOWS FROM INVESTING ACTIVITIES         (238,859)         (625,745)           Equity investment         -         (69,560)           Purchases of property and equipment         (238,859)         (625,745)           Net Cash Flows used in Investing Activities         (238,859)         (625,745)           Proceeds from financing obligation         839,148         -           Proceeds from financing obligation         (864,121)         (337,804)           Proceeds from insuance of common stock         2,016,402         12,079,760           Debt issuance costs of common stock and restricted stock         (22,924)         -           Issuance costs of common stock and restricted stock         (22,924)         -           Payments on financing obligation stock         (22,924)         -           Issuance costs of common stock and restricted stock         (22,924)         -			103,937		-
Inventory $(444,967)$ $(181,357)$ Prepaid expenses and other assets $565,196$ $(822,616)$ Accounts payable $(404,192)$ $148,762$ Accrued expenses $(476,809)$ $218,125$ Contract liabilities $(168,679)$ $94,882$ Net Cash Flows used in Operating Activities $(16,510,221)$ $(17,488,546)$ CASH FLOWS FROM INVESTING ACTIVITIESEquity investment- $(69,560)$ Purchases of property and equipment $(238,859)$ $(625,745)$ Net Cash Flows used in Investing Activities $(238,859)$ $(695,305)$ CASH FLOWS FROM FINANCING ACTIVITIESProceeds from financing obligation $839,148$ -Proceeds from financing obligation $(864,121)$ $(337,804)$ Proceeds from insuance of stock options $29,831$ $87,846$ Proceeds from insuance of common stock $2,025,000$ -Debt issuance costs on convertible note $(47,749)$ -Payments on financing obligation $(864,121)$ $(337,804)$ Proceeds from insuance of common stock $2,016,402$ $12,079,760$ Issuance costs of common stock $22,024$ -Payments on financing obligation $(26,77,764)$ -Payments on financing obligation $(26,671)$ $(243,498)$ Net Cash Flows provided by Investing Activities $3,943,432$ $11,586,304$ Net Change in Cash $(12,805,648)$ $(6,597,547)$ CASH - Beginning of Year $$5,687,816$ $$18,516,208$ Supplemental cash	0				
Prepaid expenses and other assets585,196(823,616)Accounts payable(404,192)148,762Accrued expenses(476,809)218,125Contract liabilities(168,679)94,882Net Cash Flows used in Operating Activities(16,510,221)(17,488,546)CASH FLOWS FROM INVESTING ACTIVITIESEquity investment-(69,560)Purchases of property and equipment(238,859)(652,745)Net Cash Flows used in Investing Activities(238,859)(652,745)CASH FLOWS FROM FINANCING ACTIVITIESProceeds from exercise of stock options29,83187,846Proceeds from convertible note and warrant2,325,000-Proceeds from inancing obligation(864,121)(337,804)Proceeds from insuca costs on convertible note(47,749)-Proceeds from insuca ocits of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Cash Flow sprovided by Investing Activities(2,924)-CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 73,932\$ 176,674Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 68,850\$ -Cash pai			· ,		
Accounts payable(404,192)148,762Accrued expenses(476,809)218,125Contract liabilities(168,679)94,882Net Cash Flows used in Operating Activities(16,510,221)(17,488,546)CASH FLOWS FROM INVESTING ACTIVITIESEquity investment(238,859)(625,745)Net Cash Flows used in Investing Activities(238,859)(625,745)CASH FLOWS FROM FINANCING ACTIVITIES(238,859)(695,305)Proceeds from financing obligation(864,121)(337,804)Proceeds from financing obligation(864,121)(337,804)Proceeds from insuance octs on convertible note and warrant2,325,000-Proceeds from insuance octs on convertible note and warrant2,325,000-Proceeds from insuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Cash Flow sprovided by Investing Activities3,943,43211,586,304Supplemental cash flow disclosure\$5,687,816\$Cash paid for interest\$73,932\$176,674Noncash investing and financing activities\$5,687,816\$-Supplemental cash flow disclosure\$\$5,687,816\$-Cash paid for interest\$73,932\$176,674Noncash investing and financing activiti			· · · · ·		. ,
Accrued expenses(476,809)218,125Contract liabilities(166,679)94,882Net Cash Flows used in Operating Activities(16,510,221)(17,488,546)CASH FLOWS FROM INVESTING ACTIVITIES-(69,560)Equity investment(238,859)(625,745)Net Cash Flows used in Investing Activities(238,859)(695,305)CASH FLOWS FROM FINANCING ACTIVITIES29,83187,846Proceeds from exercise of stock options29,83187,846Proceeds from financing obligation839,148-Payments on financing obligation(864,121)(37,804)Proceeds from convertible note and warrant2,325,000-Debt issuance costs on convertible note(47,749)-Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - Beginning of Year\$5,687,816\$Supplemental cash flow disclosure\$3,50,41\$Cash paid for interest\$73,932\$176,674Noncash investing and financing activities\$35,041\$Property and equipment included in					· · /
Contract liabilities(168,679)94,882Net Cash Flows used in Operating Activities(16,510,221)(17,488,546)CASH FLOWS FROM INVESTING ACTIVITIES(238,859)(625,745)Fquity investment-(69,560)Purchases of property and equipment(238,859)(625,745)Net Cash Flows used in Investing Activities(238,859)(695,305)CASH FLOWS FROM FINANCING ACTIVITIES(238,859)(695,305)Proceeds from exercise of stock options29,83187,846Proceeds from convertible note and warrant2,325,000-Debt issuance costs on convertible note(47,749)-Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on financing obligation(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year\$ 5,687,816\$ 18,516,208Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 73,932\$ 176,674Noncash investing and financing activities\$ 35,041\$ -Property and equipment included in accounts payable\$ 16,723\$ -Leasehold improvements paid by landlord\$ 35,041\$ - <td></td> <td></td> <td>. ,</td> <td></td> <td></td>			. ,		
Net Cash Flows used in Operating Activities(16,510,221)(17,488,546)CASH FLOWS FROM INVESTING ACTIVITIES Equity investment-(69,560)Purchases of property and equipment(238,859)(625,745)Net Cash Flows used in Investing Activities(238,859)(695,305)CASH FLOWS FROM FINANCING ACTIVITIES Proceeds from financing obligation839,148-Payments on financing obligation(864,121)(337,804)Proceeds from convertible note and warrant2,325,000-Debt issuance costs on convertible note(47,749)-Proceeds from issuance of common stock(2,024)-Payments on financing obligation(332,155)(243,488)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year\$ 18,516,20825,139,812Effect of foreign currency exchange rate changes on cash CASH - End of Year\$ 73,932\$ 176,674Supplemental cash flow disclosure Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 35,041\$ -Property and equipment included in accounts payable Transfer from inventory to property and equipment\$ 35,041\$ -Lease hold im provements paid by landlord Deprating lease right of use assets in exchange for operating lease isability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570			· ,		
CASH FLOWS FROM INVESTING ACTIVITIES Equity investmentEquity investment-(69,560)Purchases of property and equipment(238,859)(625,745)Net Cash Flows used in Investing Activities(238,859)(695,305)CASH FLOWS FROM FINANCING ACTIVITIES Proceeds from financing obligation29,83187,846Proceeds from exercise of stock options29,83187,846Proceeds from convertible note and warrant2,325,000-Debt issuance costs on convertible note(47,749)-Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$5,687,816\$Supplemental cash flow disclosure\$73,932\$Cash paid for interest\$73,932\$Noncash investing and financing activities\$68,850\$Property and equipment included in accounts payable\$16,723\$Lease hold improvements paid by landlord\$35,041\$-Operating lease right of use assets in exchange for operating lease liability\$570,752\$- <td></td> <td></td> <td>· ,</td> <td></td> <td>,</td>			· ,		,
Equity investment-(69,560)Purchases of property and equipment(238,859)(625,745)Net Cash Flows used in Investing Activities(238,859)(695,305)CASH FLOWS FROM FINANCING ACTIVITIES29,83187,846Proceeds from exercise of stock options29,83187,846Proceeds from financing obligation(864,121)(337,804)Payments on financing obligation(864,121)(337,804)Proceeds from issuance costs on convertible note(47,749)-Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,488)Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$5,687,816\$Supplemental cash flow disclosure\$3,943,65\$Cash paid for interest\$73,932\$176,674Noncash investing and financing activities\$35,041\$-Property and equipment included in accounts payable\$16,723\$-Issuance costs included in accounts payable\$35,041\$-Lease hold improvements paid by landlord\$35,041\$-Supplemental cash flow disclosure\$\$-\$Lease hold improvements paid	Net Cash Flows used in Operating Activities		(16,510,221)		(17,488,546)
Purchases of property and equipment(238,859)(625,745)Net Cash Flows used in Investing Activities(238,859)(695,305)CASH FLOWS FROM FINANCING ACTIVITIESProceeds from exercise of stock options29,83187,846Proceeds from financing obligation839,148-Payments on financing obligation(864,121)(337,804)Proceeds from covertible note and warrant2,325,000-Debt issuance costs on convertible note(47,749)-Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on financing obligation(332,155)(243,488)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$5,687,816\$Supplemental cash flow disclosure\$3,5,041\$Cash paid for interest\$73,932\$176,674Noncash investing and financing activities\$3,5,041\$-Supplemental cash flow disclosure\$\$3,5,041\$-Leasehold improvements paid by landlord\$\$3,5,041\$-Coperating lease right of use assets in exchange for operating lease liability\$\$570,752\$-	CASH FLOWS FROM INVESTING ACTIVITIES				
Net Cash Flows used in Investing Activities(238,859)(695,305)CASH FLOWS FROM FINANCING ACTIVITIES Proceeds from exercise of stock options29,83187,846Proceeds from inancing obligation839,148-Payments on financing obligation(864,121)(337,804)Proceeds from convertible note and warrant2,325,000-Debt issuance costs on convertible note(47,749)-Proceeds from insucing obligation(332,155)(243,488)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 73,932\$ 176,674Noncash investing and financing activities\$ 68,850\$ -Property and equipment\$ 68,850\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570,752\$ -	Equity investment		-		(69,560)
CASH FLOWS FROM FINANCING ACTIVITIESProceeds from exercise of stock options29,83187,846Proceeds from financing obligation839,148-Payments on financing obligation(864,121)(337,804)Proceeds from convertible note and warrant2,325,000-Debt issuance costs on convertible note(47,749)-Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,488)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year(12,805,648)(22,744)Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$5,687,816\$Supplemental cash flow disclosure\$18,516,208Cash paid for interest\$73,932\$Noncash investing and financing activities\$68,850\$Property and equipment included in accounts payable\$66,850\$Transfer from inventory to property and equipment\$68,850\$Leasehold improvements paid by landlord\$35,041\$Operating lease right of use assets in exchange for operating\$570,752\$lease liability\$\$570,752\$-	Purchases of property and equipment		(238,859)		(625,745)
Proceeds from exercise of stock options29,83187,846Proceeds from financing obligation839,148-Payments on financing obligation(864,121)(337,804)Proceeds from convertible note and warrant2,325,000-Debt issuance costs on convertible note(47,749)-Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$5,687,816\$Supplemental cash flow disclosure\$73,932\$Cash paid for interest\$73,932\$Noncash investing and financing activities\$68,850\$Property and equipment\$68,850\$-Leasehold improvements paid by landlord\$35,041\$-Operating lease right of use assets in exchange for operating lease liability\$570,752\$-Issuance costs included in accounts payable and accrued\$570,752\$-	Net Cash Flows used in Investing Activities		(238,859)		(695,305)
Proceeds from financing obligation839,148-Payments on financing obligation(864,121)(337,804)Proceeds from convertible note and warrant2,325,000-Debt issuance costs on convertible note(47,749)-Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$5,687,816\$Supplemental cash flow disclosure\$73,932\$176,674Cash paid for interest\$73,932\$176,674Noncash investing and financing activities\$68,850\$-Property and equipment\$68,850\$-Leasehold improvements paid by landlord\$35,041\$-Operating lease right of use assets in exchange for operating lease liability\$570,752\$-Issuance costs included in accounts payable and accrued\$570,752\$-	CASH FLOWS FROM FINANCING ACTIVITIES				
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Debt issuance costs on convertible note(47,749)-Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year(12,805,648)(6,597,547)Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 16,723\$ -Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 68,850\$ -Property and equipment included in accounts payable\$ 68,850\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570,752\$ -	Payments on financing obligation		(864,121)		(337,804)
Proceeds from issuance of common stock2,016,40212,079,760Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year(12,805,648)(26,057)Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 73,932\$ 176,674Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 68,850\$ -Property and equipment included in accounts payable\$ 16,723\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570,752\$ -	Proceeds from convertible note and warrant		2,325,000		-
Issuance costs of common stock and restricted stock(22,924)-Payments on finance lease liability(332,155)(243,498)Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 73,932\$ 176,674Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 68,850\$ -Property and equipment included in accounts payable\$ 16,723\$ -Leasehold improvements paid by landlord\$ 35,041-Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570,752\$ -	Debt issuance costs on convertible note		(47,749)		-
Payments on finance lease liability Net Cash Flows provided by Investing Activities(332,155) 3,943,432(243,498) 11,586,304Net Change in Cash CASH - Beginning of Year(12,805,648) (12,805,648)(6,597,547) (18,516,208(6,597,547) (22,744)CASH - End of Year(12,805,648) (22,744)(26,057) (26,057)(26,057) (22,744)Supplemental cash flow disclosure Cash paid for interest\$ 73,932 (243,498)18,516,208Noncash investing and financing activities Property and equipment included in accounts payable Transfer from inventory to property and equipment\$ 68,850 (35,041)-Leasehold improvements paid by landlord Operating lease right of use assets in exchange for operating lease liability\$ 570,752 (\$	Proceeds from issuance of common stock		2,016,402		12,079,760
Net Cash Flows provided by Investing Activities3,943,43211,586,304Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 73,932\$ 176,674Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 68,850\$ -Property and equipment included in accounts payable\$ 16,723\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570,752\$ -	Issuance costs of common stock and restricted stock		(22,924)		-
Net Change in Cash(12,805,648)(6,597,547)CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosureCash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 16,723\$ -Property and equipment included in accounts payable\$ 16,723\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570,752\$ -	Payments on finance lease liability		(332,155)		(243,498)
CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 73,932\$ 176,674Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 16,723\$ -Property and equipment included in accounts payable\$ 68,850\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570,752\$ -	Net Cash Flows provided by Investing Activities		3,943,432		11,586,304
CASH - Beginning of Year18,516,20825,139,812Effect of foreign currency exchange rate changes on cash(22,744)(26,057)CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure\$ 73,932\$ 176,674Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 16,723\$ -Property and equipment included in accounts payable\$ 68,850\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570,752\$ -	Net Change in Cash		(12,805,648)		(6,597,547)
CASH - End of Year\$ 5,687,816\$ 18,516,208Supplemental cash flow disclosure Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 73,932\$ 176,674Property and equipment included in accounts payable Transfer from inventory to property and equipment\$ 68,850\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 570,752\$ -	-		18,516,208		25,139,812
Supplemental cash flow disclosure Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 73,932\$ 176,674Property and equipment included in accounts payable\$ 16,723\$ -Transfer from inventory to property and equipment\$ 68,850\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ 10,723\$ -	Effect of foreign currency exchange rate changes on cash		(22,744)		(26,057)
Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 16,723\$ -Property and equipment included in accounts payable\$ 16,723\$ -Transfer from inventory to property and equipment\$ 68,850\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ -\$ -	CASH - End of Year	\$	5,687,816	\$	18,516,208
Cash paid for interest\$ 73,932\$ 176,674Noncash investing and financing activities\$ 16,723\$ -Property and equipment included in accounts payable\$ 16,723\$ -Transfer from inventory to property and equipment\$ 68,850\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ -\$ -	Supplemental cash flow disclosure				
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Property and equipment included in accounts payable\$ 16,723\$ -Transfer from inventory to property and equipment\$ 68,850\$ -Leasehold improvements paid by landlord\$ 35,041\$ -Operating lease right of use assets in exchange for operating lease liability\$ 570,752\$ -Issuance costs included in accounts payable and accrued\$ -\$ -	•	Ŷ	10,002	Ψ	
Transfer from inventory to property and equipment       \$ 68,850       \$ -         Leasehold improvements paid by landlord       \$ 35,041       \$ -         Operating lease right of use assets in exchange for operating lease liability       \$ 570,752       \$ -         Issuance costs included in accounts payable and accrued       \$ 570,752       \$ -		¢	16 722	¢	
Leasehold improvements paid by landlord       \$ 35,041       -         Operating lease right of use assets in exchange for operating lease liability       \$ 570,752       -         Issuance costs included in accounts payable and accrued       -       -		_			-
Operating lease right of use assets in exchange for operating lease liability       \$ 570,752         Issuance costs included in accounts payable and accrued					-
lease liability     \$ 570,752     \$ -       Issuance costs included in accounts payable and accrued     \$ -		\$	35,041	\$	-
Issuance costs included in accounts payable and accrued					
		\$	570,752	\$	-
		\$	62,239	\$	-

See accompanying notes to financial statements

NOTES TO FINANCIAL STATEMENTS As of and for the years ended December 31, 2022 and 2021

### NOTE 1 – Summary of Significant Accounting Policies

#### 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 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 is the Vision-MR Ablation Catheter, which 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 MRIcompatible 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 dollars, which is also the functional currency.

#### Impact of COVID-19 Pandemic

During the years ended December 31, 2022 and 2021, the Company's revenue was impacted by the COVID-19 pandemic. The Company continued to observe intermittent suspension of many elective procedures associated with various surges in COVID-19, including procedures that utilize the Company's products. The impact of COVID-19 has varied by region and by healthcare facility. As a result, lab adoption and procedure volumes have been constrained. While restrictions on elective procedures have now been lifted, there have been shortages of personnel at hospitals which has hampered the ability to perform procedures using the Company's products.

The Company is unable to accurately predict the full impact that COVID-19 will have on its results from operations, financial condition, liquidity, and cash flows due to numerous uncertainties, including the duration and severity of outbreaks and containment measures, the emergence of new variants, and the impact on the Company's customers and its vendors. The Company's future results of operations and liquidity could be adversely impacted by delays in payments from customers, supply chain disruptions, product design changes, and uncertain demand which could lead to expiration of inventory. The Company will continue to monitor the situation and take further actions that it determines are in the best interest of its 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 As of and for the years ended December 31, 2022 and 2021

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

#### Accounts Receivable and Customer Concentrations

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 provides 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 significant write-offs or significant deterioration of its accounts receivable aging, and therefore, no allowance for doubtful accounts was considered necessary as of December 31, 2022 or 2021. During the year ended December 31, 2022, the Company had sales from 4 customers that accounted for 72% of revenue and accounts receivable from 5 customers that represented 97% of the accounts receivable balance. During the year ended December 31, 2021, the Company had sales from 3 customers that accounted for 67% of revenue and accounts receivable from 3 customers that represented 96% of the accounts receivable balance.

Accounts receivable includes unbilled receivables of \$41,874 and \$37,205 as of December 31, 2022 and 2021, 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, 2023.

#### 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:

	December 31,			
	2022		2021	
Raw materials	\$	1,456,282	\$	1,476,630
Work in process		400,059		549,303
Finished goods		997,871		1,512,106
Less: excess and obsolescence reserves		(577,469)		(955,226)
	\$	2,276,743	\$	2,582,813

The Company utilizes significant estimates in determining the realizable value of its inventory, including the future revenue forecasts that will result in product sales. These estimates have a corresponding impact on the inventory values recorded as of December 31, 2022 and 2021. Management continually evaluates the likelihood of future sales based on current economic conditions, restrictions on ability for customers to perform elective procedures, expiration timing of products, and product design changes prior to sale of product on hand. If actual conditions are less favorable than those the Company has projected, it may need to increase its reserves for excess and obsolete inventories. Any increases in the Company's reserves will adversely impact its results of operations. The establishment of a reserve for excess and obsolete inventory establishes a new cost basis in the inventory. Future sales of inventory on hand at December 31, 2022 will result in recognition of cost of sales based on initial inventory costs, net of reserves taken for expected realization values.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

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

The Company recognizes an expense for commitments of inventory purchases that will not provide future economic benefit when that is known. Based upon estimates of future demand for its products and the timing of future generation products, the Company recorded an expense of \$113,888 for the year ended December 31, 2022, which is included in Cost of goods sold on the statements of operations. The Company had a balance of \$194,823 in Accrued expenses on the balance sheets related to these commitments at December 31, 2022. For the year ended December 31, 2021, the Company recorded an expense of \$212,931 related to these commitments, which is included in Cost of goods sold on the statements of operations and in Accrued expenses on the balance sheets.

#### 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 - 5 years
MRI scanner	7 years
Leasehold improvements	Lesser of useful life or remaining lease term

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 and an equity investment of \$69,560 made during the year ended December 31, 2021. The equity investment is held at cost, less impairment plus or minus changes resulting from observable price changes. There have been no impairment losses or observable price changes recognized for the years ended December 31, 2022 and 2021.

#### Patents

Expenditures for patent costs are charged to operations as incurred.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

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

#### 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 145,744,865 and 130,801,707 for the years ended December 31, 2022 and 2021, respectively.

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 options outstanding 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, 2022 and 2021.

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per share for the years ended December 31 because to do so would be anti-dilutive:

	2022	2021
Exercise of stock options	12,913,186	11,253,506
Conversion of convertible note	8,659,794	-
Exercise of warrant	907,141	-
Total	22,480,121	11,253,506

#### Foreign Currency Exchange Gains (Losses)

During the years ended December 31, 2022 and 2021, the Company had accounts payable that are denominated in Australian dollars, British pound sterling, and Euros and cash accounts and accounts receivable 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).

#### **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, the timing of which varies on an individual customer basis.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

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

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.

All revenue is derived from foreign countries. 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.

#### 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 25, 2020 for up to \$399,539 to develop an MRI compatible myocardial biopsy system. The Company recognized \$47,946 and \$255,704 as revenue during the years ended December 31, 2022 and 2021, respectively.

#### Contract Liabilities

In 2013, the Company licensed certain intellectual property to a customer in exchange for an upfront nonrefundable 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. A total of \$373,333 of this amount is deferred and is included in long-term contract liabilities as of December 31, 2022 and 2021. 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, 2022 and 2021, the Company had total current and long-term contract liabilities of \$516,211 and \$684,890, respectively, of which \$492,853 and \$509,604 was included in long-term liabilities as of December 31, 2022 and 2021, respectively.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

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

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

	2022		 2021	
Balance at the beginning of the year Decrease from revenue recognized for completion of performance obligations that were included in contract liabilities at the beginning of the period included in:	\$	684,890	\$ 590,008	
Equipment revenue		(97,842)	-	
Service revenue		(73,419)	(40,202)	
Increase for revenue deferred as the performance				
obligation has not been satisfied		2,582	135,084	
Balance at the end of the year	\$	516,211	\$ 684,890	

#### 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 stock options with a market condition is estimated at the date of grant, using 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.

The Company's policy is to account for forfeitures as they occur and compensation expense is recognized on a straight-line basis over the vesting period for awards with service and market conditions; for awards with performance conditions, expense is recognized for those that are probable of being achieved. 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.

See NOTE 9 for further details and assumptions regarding the Black-Scholes pricing model.

#### Fair Value Measurement

ASC 820, Fair Value Measurements, ("ASC 820") provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.
- Level 3: Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

NOTES TO FINANCIAL STATEMENTS As of and for the years ended December 31, 2022 and 2021

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

The Company evaluates assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them for each reporting period. This determination requires significant judgments to be made by the Company.

The carrying value of financial assets and liabilities recorded at fair value is measured on a recurring or nonrecurring basis. Financial assets and liabilities measured on a non-recurring basis are those that are adjusted to fair value when a significant event occurs. The Company had no financial assets or liabilities carried and measured on a nonrecurring basis during the reporting periods. Financial assets and liabilities measured on a recurring basis are those that are adjusted to fair value each time a financial statement is prepared. The convertible note (Note 8) is recognized at fair value on a recurring basis at December 31, 2022 and is a Level 3 measurement. There have been no transfers between levels.

As of December 31, 2022 and 2021, the recorded values of cash, prepaid expenses, accounts payable, and accrued expenses and other liabilities approximate their fair values due to the short-term nature of these items.

#### 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.

#### Employee retention credit

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law providing numerous tax provisions and other stimulus measures, including an employee retention credit ("ERC"), which is a refundable tax credit against certain employment taxes. The Taxpayer Certainty and Disaster Tax Relief Act of 2020 and the American Rescue Plan Act of 2021 extended and expanded the availability of the ERC.

The Company qualified for the ERC as it experienced a significant decline in gross receipts in 2021 and 2020. The Company determined that it was eligible for the ERC as follows:

	Total
Quarter ended September 30, 2020	\$ 269,654
Quarter ended December 31, 2020	22,995
Quarter ended September 30, 2021	 465,065
Total	\$ 757,714

As it relates to the 2020 amounts, the Company applied for the ERC by amending its previously filed forms 941 and, as a result, the Company has accounted for this government grant by way of analogy to Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 410, Asset Retirement and Environmental Obligations. ASC 410-30-35-8 indicates that a claim for recovery should be recognized only when the claim is probable of recovery as defined in ASC 450-20-25-1 (i.e. Contingencies). Accordingly, the Company believes that the recovery of employment tax amounts previously paid is probable and, therefore, has recorded amounts shown above.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

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

As it relates to the 2021 amounts, the Company has elected to account for the credit as a government grant. U.S. GAAP do not include grant accounting guidance related to transfers of assets from governments to business entities, therefore, the Company has elected to follow the grant accounting model in International Accounting Standard ("IAS") 20, Accounting for Government Grants and Disclosure of Government Assistance. In accordance with IAS 20, the Company cannot recognize any income from the grant until there is reasonable assurance (similar to the "probable" threshold in U.S. GAAP) that any conditions attached to the grant will be met and that the grant will be received. Once it is reasonably assured that the grant conditions will be met and that the grant will be received, grant income is recorded on a systematic basis over the periods in which the Company recognizes the payroll expenses for which the grant is intended to compensate. Income from the grant was intended to compensate.

During the year ended December 31, 2021, the Company recorded ERC benefits of \$757,714 in other income (expense) on the statements of operations. The receivable balance of \$474,445 and \$757,714 as of December 31, 2022 and 2021, respectively, is included in Prepaid expense and other current assets on the balance sheets. The Company collected the remaining receivable balance in January 2023.

#### Recent Accounting Pronouncement

During June 2016, the FASB issued ASU No. 2016-13, Measurement of Credit Losses on Financial Instruments. ASU 2016-13 requires financial assets measured at amortized cost to be presented at the net amount expected to be collected, through an allowance for credit losses that is deducted from the amortized cost basis. The measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. During November 2018, April 2019, May 2019, and November 2019, the FASB also issued ASU No. 2018-19, Codification Improvements to Topic 326, Financial Instruments - Credit Losses; ASU No. 2019-04, Codification Improvements to Topic 326, Financial Instruments - Credit Losses; ASU No 2019-05, Targeted Transition Relief and ASU No. 2019-11, Codification Improvements to Topic 326, Financial Instruments - Credit Losses. ASU No. 2018-19 clarifies the effective date for nonpublic entities and that receivables arising from operating leases are not within the scope of Subtopic 326-20, ASU Nos. 2019-04 and 2019-05 amend the transition guidance provided in ASU No. 2016-13, and ASU No. 2019-11 amends ASU No. 2016-13 to clarify, correct errors in, or improve the guidance. ASU No. 2016-13 (as amended) is effective for annual periods and interim periods within those annual periods beginning after December 15, 2022. Early adoption is permitted for annual and interim periods beginning after December 15, 2018. The Company does not expect the adoption of this ASU to have a material impact on the financial statements.

In August 2020, the FASB issued Accounting Standards Update ("ASU") 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for scope exception, and it simplifies the diluted earnings per share calculation in certain areas. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023 and should be applied on a full or modified retrospective basis, with early adoption permitted beginning on January 1, 2021. The Company has elected to early adopt ASU 2020-06 on January 1, 2022. Adoption of the ASU did not impact the Company's financial position, results of operations or cash flows upon adoption.

NOTES TO FINANCIAL STATEMENTS As of and for the years ended December 31, 2022 and 2021

#### NOTE 2 – Out of Period Adjustment

During the year ended December 31, 2022, an error was identified relating to financing arrangements entered into in 2019, 2020, and 2021 in connection with obtaining annual insurance contracts. The Company has corrected this immaterial error by recognizing a prepaid insurance asset and financing liability in the amount of \$533,000 pertaining to the financing arrangement that existed as of December 31, 2021. Accordingly, the statements of cash flows for the year ended December 31, 2022 reflects the \$533,000 cash provided from operating activities and \$533,000 cash used in financing activities as a result of the out of period adjustment related to this arrangement. The Company evaluated the error both quantitatively and qualitatively and concluded that the errors are not material for any prior periods and has adjusted the amounts on a cumulative basis in 2022.

#### NOTE 3 – Going Concern

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, 2022 and 2021, had an accumulated deficit as of December 31, 2022 and is in need of additional working capital to fund future operations. These conditions raise substantial doubt about its ability to continue as a going concern for twelve months from the report date.

To continue in existence and expand its operations, the Company will be required to, and management plans to, raise additional working capital through an equity or debt offering and ultimately attain profitable operations. If the Company is not able to raise additional working capital, it would have a material adverse effect on the operations of the Company and continuing research and development of its product, as well as commercialization. These financial statements do not include any adjustments related to the recoverability and classification of recorded assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

#### **NOTE 4 – Accrued Expenses**

Accrued expenses consisted of the following:

	December 31,			
	 2022		2021	
Compensation	\$ 147,453	\$	595,942	
Firm inventory commitments	194,823		212,931	
Other accruals	582,660		545,555	
	\$ 924,936	\$	1,354,428	

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

# NOTE 5 – Property and Equipment

Substantially all property and equipment is held in the U.S. as of December 31, 2022. Property and equipment consisted of the following:

	Decem	ber 31	,
	 2022		2021
Office furniture and equipment	\$ 272,267	\$	293,216
Lab and production equipment	1,754,068		1,525,226
Computer equipment	240,669		264,859
MRI scanner	1,200,000		1,200,000
Leasehold improvements	1,641,837		1,597,087
	 5,108,841		4,880,388
Less: accumulated depreciation and amortization	(2,545,485)		(1,928,464)
	\$ 2,563,356	\$	2,951,924

Depreciation expense was \$712,491 and \$689,114 for the years ended December 31, 2022 and 2021, respectively.

#### NOTE 6 – Leases

#### **Operating Leases**

In March 2007, the Company entered into an operating lease agreement for its office and manufacturing space (Gateway) 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 lease was amended to increase the square footage and extend the term for five years. Upon commencement of the amended lease in March 2022, the Company recorded a right to use asset and lease liability of \$570,752. As part of the amendment, the landlord also agreed to reimburse the Company for \$35,041 in leasehold improvements. The Company received the reimbursement in October 2022.

The Company entered into a second operating lease agreement for office and warehouse space (Design Center) 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. 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.

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.

As the leases do not provide an implicit rate, the Company uses its 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, 2022 and 2021, the remaining lease term was 6.4 and 7.9 years, respectively, and the discount rate was 5.5%. For the year ended December 31, 2022 and 2021, the operating cash outflows from operating leases for office and manufacturing space was \$227,210 and \$221,136, respectively.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

#### NOTE 6 - Leases (cont.)

As of December 31, 2022, maturities of the Company's operating lease liabilities are as follows:

	 2022
2023	\$ 277,973
2024	292,571
2025	301,375
2026	310,467
2027	217,689
2028 and thereafter	 426,754
Total lease payments	 1,826,829
Less: interest	 (298,866)
Present value of lease liabilities	1,527,963
Less: current portion	 (198,073)
Operating lease liability, net of current portion	\$ 1,329,890

The cost components of the Company's operating leases, which were included in General and administrative expenses on the statements of operations were as follows for the years ended December 31, 2022 and 2021:

	December 31,			
	 2022		2021	
Operating lease cost Variable lease cost	\$ 227,210 137,997	\$	221,136 122,880	
	\$ 365,207	\$	344,016	

#### Finance Lease Liability

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 was 36 months with a monthly rental payment of \$54,865 and an implied interest rate of 21.5%. The lease originally met the requirements to be classified as a financing obligation. It was considered a failed sale leaseback arrangement as the lease agreement included an option to repurchase the related assets for \$425,000 at the end of the lease term, which the Company deemed it was reasonably certain to do. On December 8, 2021, the Company executed a revised lease to extend the term of lease for an additional 24 months after the expiration of the original lease, with the Company owning the scanner outright at the conclusion of the extension term. Consequently, the lease no longer qualified as a financing obligation and was classified as a finance lease liability on the balance sheets beginning December 31, 2021. Beginning June 1, 2022, the start of the amended agreement term, the monthly rental payment is \$13,342 and the implied interest rate is 7.0%.

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

As of and for the years ended December 31, 2022 and 2021

#### NOTE 6 – Leases (cont.)

As of December 31, 2022, maturities of the Company's finance lease liabilities are as follows:

	2022	
2023	\$	171,370
2024		67,159
Total payments		238,529
Less: amount representing interest		(11,850)
Present value of total payments		226,679
Less: current portion		(160,680)
Finance lease liability, net of current portion	\$	65,999

#### 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.

#### **NOTE 7 – Commitments and Contingencies**

For the year ended December 31, 2022, the Company had accounts payable to three vendors that accounted for 11%, 10% and 10% of the total outstanding balance. For the year ended December 31, 2021, the Company had accounts payable to one vendor that accounted for 16% of the total outstanding balance.

#### Purchase Commitments

At December 31, 2022 and 2021, the Company had \$1,294,613 and \$1,195,602 in outstanding firm purchase commitments, respectively. As of December 31, 2022, payment of the purchase commitments is expected to be made within one year.

#### Financing Obligation

The Company entered into an agreement to finance a portion of an annual insurance premium for the policy period beginning August 2022. The financing obligation is to be paid in 10 monthly installments of \$86,203 beginning in September 2022, and the stated interest rate is 5.91%.

#### Retirement Plan

The Company maintains retirement plans for its employees in which eligible employees can contribute a percentage of their compensation. The Company contributed \$257,480 and \$309,929 to these plans during the years ended December 31, 2022 and 2021, respectively.

#### **Employment Agreements**

The Company has employment agreements with the CEO and certain 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.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

#### **NOTE 8 – Convertible Note with Warrant**

On December 16, 2022, the Company entered into a Securities Purchase Agreement for the issue of unsecured, unquoted convertible promissory notes, to be issued in two tranches, to raise a maximum aggregate amount of \$5,000,000.

The first tranche was issued on December 23, 2022. The Company received \$2,325,000 in gross proceeds from the issuance of the convertible note. The convertible note bears interest of 10% per annum, compounded annually. All or a portion of the principal is convertible into CDIs at a price of \$0.2691 per share at the election of the holder following the 36 month anniversary of the closing date. All or a portion of accrued and unpaid interest is convertible into CDIs at a price of \$0.263 per share at the election of the holder during the same time frame. The maximum number of CDIs to be issued upon conversion of the principal amount and interest is no more than 12,849,949 CDIs.

The maturity date on the note is the earliest occurrence of (i) a change-in-control event, at which time the Company would be required to pay the holder the greater of 125% of the then outstanding balance plus accrued and unpaid interest or the amount the holder would receive if the principal and accrued and unpaid interest had been converted to CDIs at a conversion price equal to the variable weighted average price ("VWAP") of the CDIs for the 10 day period ending on the change-in-control event date; or (ii) December 23, 2026, the four year anniversary of the closing date.

Also on December 23, 2022, pursuant to the Securities Purchase Agreement, the Company issued a warrant exercisable for 907,141 CDIs, with an exercise price of \$0.2563 per share. The warrant expires five years after the date of issuance.

The Company accounts for its convertible promissory note under ASC 815, Derivatives and Hedging ("ASC 815"). Under 815-15-25, the election can be made at the inception of a financial instrument to account for the instrument under the fair value option under ASC 825. The Company has made such election for its convertible promissory note. Using the fair value option, the convertible promissory note is required to be recorded at its initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the note are recognized as non-cash change in the fair value of the convertible promissory note in the statements of operations.

The convertible note was recorded as a liability on the balance sheets at the date of issuance. The following table provides a summary of change in fair value of the convertible note as of December 31, 2022:

Fair market value at issuance	\$ 2,197,100
Fair value change in convertible note	(14,200)
Fair market value at December 31, 2022	\$ 2,182,900

The fair value of the convertible note is measured in accordance with ASC 820 "Fair Value Measurement" using the "Monte Carlo Method" modeling incorporating the following inputs:

	Decem	iber 31, 2022	Decen	nber 23, 2022
Expected dividend yield		0%		0%
Expected stock-price volatility		80%		80%
Risk-free interest rate		3.90%		4.03%
Stock price	\$	0.2514	\$	0.2481
Conversion price	\$	0.2691	\$	0.2691

NOTES TO FINANCIAL STATEMENTS As of and for the years ended December 31, 2022 and 2021

#### NOTE 8 - Convertible Note with Warrant (cont.)

Significant assumptions used to determine the fair value of the convertible note include the estimated probability of a change in control event, which is based on management's expectation of future transactions, and the volatility of the stock price, which is estimated 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 due to the limited volatility history for the Company's shares relative to the term of the note.

The Company evaluated the warrant under ASC 480, "Distinguishing Liabilities from Equity" and ASC 815. The warrant does not meet the characteristics for liability classification under either provision and as such is classified as equity under ASC 815. Given that the convertible note was subject to fair value remeasurement, the fair value of the convertible note was carved out from gross proceeds and the remainder of the gross proceeds of \$127,900 was allocated to warrants. The warrant was recorded as Additional paid-in capital on the balance sheets at the date of issuance. No subsequent remeasurement of the warrant is required.

The issuance costs attributable to the convertible note of \$103,937 were recorded as interest expense given the fair value accounting treatment, in accordance with ASC 825-10-25-3. Issuance costs allocated to the warrant of \$6,051, were recorded in Additional paid-in capital given the equity classification of the warrants.

The second tranche of the convertible promissory notes to be issued, which is subject to stockholder approval, calls for \$2,675,000 of gross proceeds to be received. The second tranche is subject to the same terms as the first tranche. The Securities Purchase Agreement calls for a warrant exercisable for 1,043,699 CDIs, to be issued concurrently with the second tranche of the convertible promissory notes.

#### NOTE 9 - Stockholders' Equity

#### Capital Stock Authorized

As of both December 31, 2022 and 2021, 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

The Australian Securities Exchange ("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, depositary instruments called CHESS Depositary Interests ("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 is held by a depositary, CHESS Depositary Nominees Pty Ltd ("CDN"), which is a wholly-owned subsidiary of the ASX, and is an approved general participant of ASX Settlement.

During January 2021, a total of 120,000 options to purchase common stock were exercised with a portion of the exercise via a cashless exercise. 50,000 options to purchase common stock were exercised at \$0.50 per share for total proceeds of \$23,384, net of expenses. In addition, 70,000 options to purchase common stock were exercised at \$0.50 per share on a cashless exercise basis at a fair market value of \$1.83 per share, resulting in the issuance of 50,995 shares of common stock.

During June 2021, a total of 50,625 options were exercised at \$0.98 per share for total proceeds of \$47,983, net of expenses.

During July 2021, a total of 33,639 options were exercised at \$0.52 per share for total proceeds of \$16,479, net of expenses.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

#### NOTE 9 – Stockholders' Equity (cont.)

In September 2021, the Company completed an equity raise on the ASX which consisted of 16,500,000 CDIs representing the same number of shares of common stock at \$1.00 Australian dollar per share for proceeds of \$11,351,689, net of expenses.

In October 2021, the Company completed a security purchase plan on the ASX which consisted of 999,828 CDIs representing the same number of common stock at \$1.00 Australian dollar per share for proceeds of \$728,071, net of expenses.

During January 2022, a total of 59,300 options to purchase common stock were exercised at \$0.52 per share for total proceeds of \$29,831, net of expenses.

During May 2022, the Company issued 298,297 shares of restricted stock to its three independent board directors. See *Restricted Stock* section below for further detail.

In September 2022, the Company completed an equity raise from US investors which consisted of 7,755,391 shares of common stock at \$0.26 US dollar per share for proceeds of \$1,994,445, 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.

#### 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 stockholders, 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 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 stockholders at the Annual Meeting on May 12, 2020. On January 14, 2021, the Board of Directors approved an increase of 844,471 shares to the option pool. On April 6, 2022, the Board of Directors approved an increase of 848,695 shares to the option pool.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

#### NOTE 9 – Stockholders' Equity (cont.)

Options 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. Generally, vesting terms of outstanding options range from immediate to four years. In addition, some options have been issued to the executive management team that vest upon completion of certain milestones, performance requirements, and market conditions; as of December 31, 2022, 4,506,538 of these options are issued and outstanding. For these performance-based awards, expense is recognized when it is probable the performance condition will be achieved. If at any point the Company determines that the performance condition is improbable, any previously recognized expense is reversed. Adjustments for forfeitures are recorded as the occur. 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 Option Shares	Ēx	ed-Average ercise Price	In	gregate trinsic /alue
Options outstanding - December 31, 2021	11,253,506	\$	0.81		
Exercised	(59,300)		0.52		
Forfeited and expired	(2,964,528)		0.78		
Granted	4,683,508		0.30		
Options outstanding - December 31, 2022	12,913,186	\$	0.64	\$	7,971
Options exercisable - December 31, 2022	6,090,036	\$	0.66	\$	-
Weighted average fair value of options granted during the year ended December 31, 2022		\$	0.19		
Weighted average fair value of options granted during the year ended December 31, 2021		\$	0.96		

As of December 31, 2022, the Company had 829,811 shares available for grant under the Plan.

The weighted average remaining contractual life of options outstanding and exercisable was 7.27 and 5.51 years, respectively, as of December 31, 2022.

The intrinsic value of options exercised during the years ended December 31, 2022 and 2021 was \$16,379 and \$202,923, respectively.

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

	2022	2021
Expected life	5.70 - 6.82 years	5.57 - 6.95 years
Volatility	63.58% - 64.96%	66.16%
Risk-free interest rate	2.00% - 3.01%	1.24%
Dividend yield	0%	0%

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

#### NOTE 9 – Stockholders' Equity (cont.)

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 due to the limited volatility history for the Company's shares relative to the expected life of the option awards granted. 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. The Company's policy is to account for forfeitures as they occur and records stock-based compensation expense only for those awards that are expected to vest.

Total stock-based compensation expense resulting from options is charged to the Company's statements of operations as follows:

	December 31,			
		2022		2021
Cost of goods sold	\$	31,309	\$	36,894
Sales and marketing		81,914		112,220
Research and development		62,913		233,991
General and administrative		131,207		766,493
	\$	307,343	\$	1,149,598

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, 2022, the total unrecognized compensation cost related to unvested stock options then outstanding was \$2,021,199. Future stock-based compensation expense is expected to be as follows for the years ending December 31:

	2022	
2023	\$	522,792
2024		290,325
2025		105,672
2026		39,422
Total related to options expected to vest		958,211
Performance grants not probable of achievement		1,062,988
Total unrecognized compensation expense	\$	2,021,199

The performance grants not probable of achievement are generally related to the receipt of regulatory approvals or sales milestones predicated on the receipt of regulatory approvals not yet received. Under current U.S. GAAP, these milestones are generally not considered probable until the regulatory approval is obtained.

Issuance of additional options subsequent to December 31, 2022 could affect future expected amounts.

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

#### NOTE 9 – Stockholders' Equity (cont.)

#### Restricted Stock

On May 9, 2022, the Company issued 298,297 shares of restricted stock to its three independent board directors. The restricted stock vests annually over four years on the anniversary of the grant date, provided that the participant continuously provides services to the Company through the applicable vesting date. The fair market value on the date of grant was \$0.28 per share.

Total stock-based compensation expense resulting from grants of restricted stock was \$13,492 for the year ended December 31, 2022. 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, 2022, the total unrecognized compensation cost related to unvested restricted stock was \$70,032. Future unrecognized stock-based compensation expense is expected to be as follows for the years ended December 31 thereafter:

	 2022
2023	\$ 20,867
2024	20,867
2025	20,866
2026	7,432
Total	\$ 70,032

#### Warrant

As part of the convertible note issuance, the Company issued a warrant to purchase CDIs which are summarized below:

	Number of Warrants	0	ted-Average cise Price
Warrants outstanding - December 31, 2021	-	\$	-
Warrants issued	907,141		0.2563
Warrants exercised	-		-
Warrants expired/forfeited	-		-
Warrants outstanding - December 31, 2022	907,141	\$	0.2563
Warrants exercisable - December 31, 2022	907,141	\$	0.2563

#### NOTE 10 – Income Taxes

As of December 31, 2022, the Company had generated approximately \$73,312,000 of net operating losses ("NOL") for federal tax purposes. As a result of the Tax Cuts and Jobs Act, for U.S. income tax purposes, NOLs generated prior to December 31, 2017 can still be carried forward for up to 20 years, while NOLs generated after December 31, 2017 carryforward indefinitely, but are limited to 80% utilization against taxable income. Of the total federal NOL of \$73,312,000, \$18,662,000 will begin to expire in 2028 and \$54,650,000 will not expire but will only offset 80% of future taxable income.



NOTES TO FINANCIAL STATEMENTS As of and for the years ended December 31, 2022 and 2021

#### NOTE 10 - Income Taxes (cont.)

As of December 31, 2022, the Company had also generated approximately \$35,184,000 of state NOLs. The state NOLs can be carried forward for up to 15 years and are limited to 80% utilization against taxable income. The state NOLs begin to expire in 2023 if they are not used.

As of December 31, 2022, the Company had approximately \$1,584,000 of federal research and development ("R&D") credit carryforwards available for federal tax purposes. As of December 31, 2022, the Company also had approximately \$881,000 of state R&D credit carryforwards available for Minnesota. The federal and state R&D credits carryforwards begin to expire in 2027 and 2028, respectively, if they are not used.

Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), annual use of the Company's NOLs and R&D credit carryforwards may be limited if there is a cumulative change in ownership of greater than 50% within a three-year period. The amount of annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. If limited, the related tax assets would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. A preliminary analysis of past and subsequent equity offerings by the Company, and other transactions that have an impact on the Company's ownership structure, concluded that the Company may have experienced one or more ownership changes under Sections 382 and 383 of the Code. As such, the Company has established a valuation allowance as the realization of its deferred tax assets have not met the more likely than not threshold requirement.

The Company conducts intensive research and experimentation activities, generating R&D tax credits for Federal and state purposes under Section 41 of the Code. The Company has not performed a formal study validating these credits claimed in the tax returns. Once a study is prepared, the amount of R&D tax credits available could vary from what was originally claimed on the tax returns.

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

	2022		2021	
Current:	•		•	
Federal	\$	-	\$	-
State		-		-
		-		-
Deferred:				
Federal		(3,961,000)		(4,310,000)
State		305,000		(1,104,000)
		(3,656,000)		(5,414,000)
Deferred tax asset valuation allowance		3,656,000		5,414,000
Total provision (benefit)	\$	-	\$	-

NOTES TO FINANCIAL STATEMENTS

As of and for the years ended December 31, 2022 and 2021

#### NOTE 10 - Income Taxes (cont.)

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

	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 18,119,000	\$ 15,481,000
Research and development credit carryforwards	2,280,000	1,943,000
Section 174 Capitalization of R&D	753,000	-
Stock-based compensation	294,000	222,000
Accrued expenses	372,000	363,000
Deferred revenue	111,000	178,000
Fixed assets	210,000	-
Depreciation and amortization	-	16,000
Gross deferred tax assets	 22,139,000	18,203,000
Valuation allowance	(21,730,000)	(18,074,000)
Deferred tax assets, net	 409,000	129,000
Deferred tax liabilities:		
Section 174 Amortization of R&D	63,000	-
Prepaid expenses and other assets	303,000	74,000
Foreign currency exchange	40,000	55,000
Fair value change in convertible note	3,000	-
Net deferred tax assets (liabilities)	\$ -	\$ -

The change in the valuation allowance was \$3,656,000 and \$5,414,000 for the years ended December 31, 2022 and 2021, respectively.

The effective tax rate for the year ended December 31, 2022 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 \$615,000 and \$486,000 for uncertain tax positions which was recorded directly against the valuation allowance as of December 31, 2022 and 2021, respectively. If recognized, these benefits would favorably impact the effective tax rate.

The tax years from inception through December 31, 2022 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 statements of operations.

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

#### **NOTE 11 – Subsequent Events**

For the year ended December 31, 2022, the Company evaluated, for potential recognition and disclosure, events that occurred through the date the financial statements were available for issuance, February 22, 2023.

On January 6, 2023, the Company obtained a \$1.5 million loan from the Bank of North Dakota under the North Dakota Commerce Department's Innovation Technology Loan Fund ("LIFT"). The loan matures in five years and has an interest rate of 0% for the first 3 years and 2% for the next two years of the loan, with monthly interest payments due.



NOTES TO FINANCIAL STATEMENTS As of and for the years ended December 31, 2022 and 2021

#### NOTE 11 – Subsequent Events (cont.)

The loan includes certain restrictions on the use of the funds. The Company may use the funding only to conduct applied research, experimentation, or operational testing within the state of North Dakota. The funds may not be used for capital or building investments or for general corporate purposes to support existing operations outside the state of North Dakota.

As of the date of these financial statements, the Company has not drawn on the loan.

# **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 22 March 2023, 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>	151,347,625
Total number of issued CDIs	100,833,615

1. Includes shares held by CHESS Depositary Nominees Pty Limited (100,833,615).

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

Rank	Name	Number	% of issued capital
1	CITICORP NOMINEES PTY LIMITED < DOMESTIC HIN A/C>	19,376,860	12.80
2	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	12,151,749	8.03
3	BNP PARIBAS NOMINEES PTY LTD < IB AU NOMS RETAILCLIENT DRP>	8,870,165	5.86
4	SIEMENS MEDICAL SOLUTIONS USA INC	8,384,150	5.54
5	WARREN G HERREID II	7,819,431	5.12
6	BNP PARIBAS NOMS(NZ) LTD <drp></drp>	6,373,066	4.21
7	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	3,365,707	2.22
8	KAHR FOUNDATION	2,950,988	1.95
9	STEVEN R WEDAN	2,693,720	1.78
10	BAUER PRIVATE EQUITY FUND VI LLC	1,696,555	1.12
11	STEVEN R WEDAN & CHERRI J WEDAN JT TEN	1,427,373	0.94
12	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	1,393,726	0.92
13	RONALD D BERGER	1,300,000	0.86
14	PACIFIC PREMIER TRUST CUST FBO JEFFREY J QUINN IRA	1,288,462	0.85
15	BRADICA NOMINEES PTY LTD <l &="" a="" bradica="" c="" f="" j="" s=""></l>	1,160,421	0.77
16	ALL STATES SECRETARIAT PTY LIMITED <all a="" c="" f="" ltd="" s="" sec="" states=""></all>	1,000,000	0.66
EQUIT	Y TRUST COMPANY CUST FBO KRISTIN KNIGHT IRA	961,538	0.64
18	BNP PARIBAS NOMS PTY LTD <drp></drp>	928,581	0.61
19	FLEITMAN KOPPA INVESTMENTS LLC	901,530	0.60
20	SHEAR FAMILY GROUP PTY LTD <shear a="" c="" family=""></shear>	874,123	0.58
	Top 20 holders	84,918,145	56.11%
	Remaining holders	66,429,480	43.89%
	Total	151,347,625	100.00%

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# 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	10,770,419	7.12
Saville Capital	10,000,000	6.61
BlackRock Group	8,696,947	5.75
Siemens Medical Solutions USA, Inc.	8,384,150	5.54

# **Distribution of CDIs and Shares**

Range	Number	% of issued capital	No. of holders
1 – 1,000	107,225	0.06	205
1,001 – 5,000	745,804	0.50	263
5,001 – 10,000	911,438	0.60	116
10,001 - 100,000	3,535,643	2.34	409
100,001 and over	146,047,515	96.50	202
Total	151,347,625	100.00	1,195

There are 243 investors holding less than a marketable parcel of CDIs or Shares, based on a minimum of A\$500 parcel at A\$0.33 per CDI or Share (close of trade price on 21 March 2023)

#### **Distribution of Options**

Range	Number	% of issued capital	No. of holders
1 – 1,000	-	-	1
1,001 – 5,000	9,400	0.07	2
5,001 – 10,000	50,000	0.39	7
10,001 - 100,000	1,253,640	9.84	32
100,001 and over	11,425,338	89.70	15
Total	12,738,378	100	57

#### Warrants and Convertible Note

As at 22 March 2023, the Company has 907,141 Warrants and One Convertible Note issued to the K.A.H.R. Foundation (see ASX announcement dated 19 December 2022 for full details).

#### Securities Subject to Voluntary Escrow (VE)

Restricted Stocks Granted to Directors

Expiry of VE	May 9 <sup>th</sup> 2023	May 9 <sup>th</sup> 2024	May 9 <sup>th</sup> 2025	May 9 <sup>th</sup> 2026	Total
Number	74,574	74,574	74,574	74,575	298,297

#### Placement Shares Issued in September 2022

Expiry of VE	September 16 <sup>th</sup> 2023	Total
Number	7,755,391	7,755,391

#### **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 (i.e., 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.

#### **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 themeeting 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 thepurposes 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.

# imric@r

# **Corporate directory**

# **US Office and Headquarters**

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# **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

# Share Registry

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