

IMRICOR MEDICAL SYSTEMS, INC (ASX:IMR)

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Cardiac Arrhythmias – A growing problem globally



Disturbances in the electrical impulses that maintain a regular heart rhythm causes **arrhythmias**, that present as:

- atrial flutter (AFL)
- atrial fibrillation (Afib)
- ventricular tachycardia (VT)



Arrhythmias are a leading cause of stroke and increase the risk of a cardiac event - affect ~2% of the US population, ventricular arrhythmias are estimated to cause 75%-80% of cases of sudden cardiac death¹



Incidence in the U.S has doubled from 1990 to 2019^2 and is expected to <u>double</u> again to 4% of the population by 2030^3

Treatment options

Ablation

- Catheter ablations have become first-line therapy for curing arrhythmias
- Ablations can permanently restore the heart to normal rhythm
- Minimally invasive surgery where a catheter is guided into the heart and energy is applied to destroy the heart cells responsible for the arrhythmia

Drugs

 Anti-arrhythmia medication can be used to help manage the condition, but they do not cure the arrhythmia. Side effect include thyroid issues, liver damage, lung toxicity, depression, risk of new arrhythmia

Implantable device

- Pacemakers and implantable cardioverter-defibrillators.
- Can cost >\$42,000¹ and carry risks of complications, battery replacement, follow ups and potential medication like blood thinners to limit risk of blood clots and stroke



Catheter Ablation

A catheter is guided into the heart and the physician will apply energy (radiofrequency, cryo, pulse field) through the catheter with the purpose of forming scars/lesions that destroy the heart cells responsible for causing the electrical misfiring.

If the right amount of energy is applied in the right areas the arrhythmia can be terminated, and the heart is restored to normal sinus rhythm.

Not being able to visualize the soft tissue of the heart nor the lesions formed has been a key barrier to higher first-time success rates and faster procedures.



X-Ray as an imaging modality

So X-r tiss

X-rays are particularly good for visualizing bones and detecting fractures, dislocations, and bone density issues

LIMITATIONS

Soft Tissue Visualization

X-rays are not as effective at visualizing soft tissues like muscles, ligaments, and organs.

Radiation Exposure

X-rays expose patients to ionizing radiation, which can be harmful in high doses or with repeated exposure.

X-Ray guided cardiac ablation in conventional EP Lab

In the past, doctors had to rely on X-Ray guidance as the only imaging modality available

CHALLENGES OF X-RAY

Cannot visualize soft tissue of the heart

Daily ionizing radiation exposure. Heavy lead gowns required to be worn.

Requires time consuming electrical mapping of the heart



Cannot confirm lesions created are durable

Drives additional tool usage like ICE catheters to cross septum and mapping catheters which increases procedure time and costs for the hospital

Low first-time success rate **38%-95%** depending on the type of arrhythmia

MRI as an imaging modality



MRI is highly sensitive in detecting a variety of conditions, including tumours, brain disorders, spinal cord injuries, joint abnormalities, and vascular diseases.

Detail

MRI provides excellent contrast between different types of soft tissues, making it ideal for imaging the brain, heart, spinal cord, nerves, muscles, and ligaments.

No Radiation

MRI does not use ionizing radiation, so it is safer for repeated use and for certain populations, such as pregnant women and young children.

The Promise of MRI for Cardiac Interventions



Researchers from Johns Hopkins in the 1990's and 2000's demonstrated the benefits of performing ablations under MRI instead of X-Ray guidance.

The promise was for faster procedures, lower costs, higher first-time success rates all in an environment free of ionizing radiation.

• Many have tried, and failed, to solve the engineering problem to unlock the superior imaging capabilities of MRI for electro physicians

Imricor's technology was developed in response to a well-documented need for better visualisation in cardiac surgical procedures

- Market application is already well defined
- Only company globally to have made devices that are safe and effective inside the strong magnetic field created by an MRI scanner



Imricor has pioneered this new approach over 18 years

BENEFITS OF MRI

Superior soft tissue visualization in 3D

Faster procedures, no need to map out the heart with expensive mapping catheter

Lesion verification to allow higher first-time success rates



Lower cost, no need for ICE catheter to guide septal crossing

Lower overall cost burden on health system and insurance companies

Diagnostic revenue when not in use for interventions





Imricor Enable Modern iCMR Labs



• Imricor captures 100% of the consumable revenue for each procedure



Modern iCMR Lab Vendors

MRI COMPATIBLE EQUIPMENT NEEDED	DEVELOPER	IMRICOR REVENUE TYPE
Ablation catheter	Imricor	Consumable
Diagnostic catheter	Imricor	Consumable
Transseptal puncture kit	Imricor	Consumable
Dispersive electrode	Imricor	Consumable
Various sterile cables	Imricor	Consumable
NorthStar 3D Mapping System	Imricor	Purchase + Annual licenses
Ablation generator	Imricor	Capital + annual service
MR Advantage EP Recorder/Stimulator	Imricor	Capital + annual service
MR Wireless Headsets	OptoAcoustics	Capital + annual service
12-lead ECG	MiRTLE Medical	Capital + annual service
In-room Displays	Nordic NeuroLab	Capital + annual service
Defibrillator	MIPM	
Patient Monitor	Philips	
MRI Scanner	Siemens, Philips, GE	

Imricor captures 100% of the consumable revenue for each procedure



imric@r

only

sonal use

"What may have taken several hours in the x-ray lab took less than an hour to perform using NorthStar in the iCMR"

> DR. MARCO GÖTTE Amsterdam University Medical Center





iCMR Lab Economics:

Hospital

Labs

X-ray and iCMR labs cost about the same to build: \$3 million¹

Procedures

Procedure costs	X-ray Lab	iCMR Lab	Annual benefit for iCMR ³
AFL device costs	\$4,443	\$4,000	\$44,430 / yr
VT device costs	\$9,618	\$6,500	\$311,800 / yr
Afib device costs ⁴	\$9,618	\$6,500	\$935,400 / yr
		Total Savings:	\$1.3 million / yr

Plus

iCMR labs generate extra revenue for hospital with diagnostic imaging

Average of four publicly disclosed recent EP lab projects in the US
 <u>https://www.cassling.com/blog/how-much-does-an-mri-scanner-cost</u> plus \$1 million for Imricor and 3rd party EP equipment
 ³ Assumes 100 AFL ,100 VT and 300 Afib procedures per year
 ⁴ Assumes same device set used for VT ablations

alus

iCMR Lab Economics:

Comricor

US Top 50 Hospitals by volume	AFL	VT	Afib	Total
Average procedures pa	434	173	1010	1617
Imricor ASP US\$ per procedure	\$4000	\$6500	\$6500	
Revenue opportunity per hospital US\$	\$1.7m	\$1.1m	\$6.6m	\$9.43m

Total Potential ATRIAL FLUTTER VT **AFIB Revenue per Hospital** Procedures: 100 +/-Procedures: 300 +/-Procedures: 100 +/-**Procedures:** 500* +/-**ASP**: US\$4000 **ASP**: US\$6500 **ASP**: US\$6500 **Recurring revenue** \$3m **Recurring revenue Recurring revenue Recurring revenue** per hospital \$400k \$1.95m \$650k Future products like biopsy probe not included

*Assumes 2 procedures per day, 5 days a week. Larger hospitals do more than the 500 assumed

A strong and growing market in cardiac ablation

A large global addressable market with high growth potential supported by favourable growth drivers



CARDIAC ABLATION DISPOSABLES MARKET: US, EU, ANZ



Millennium Research Group Electrophysiology Mapping and Ablation Devices Europe 2021 July 2020 Millennium Research Group Electrophysiology Mapping and Ablation Devices US 2021 June 2020

Wide Geographical Spread



 Imricor's products are currently approved in 31 countries, with 8 countries containing customer sites

- Estimated over 1,000,000 ablation procedures across the US, EU and Aus in 2023, with growth in these markets estimated at 5.9% CAGR to 2029
- Average estimated consumable revenue of USD \$3,500 - \$6,500 per procedure depending on indication
- Expected US, ANZ, Nordics, and additional Middle East countries will be activated within the next



Key Highlights



Steve Wedan

Founder and CEO

"2024 was a year of significant progress across Imricor, and a turning point for all of us in so many ways. Looking forward, there is no time to pause and appreciate the magnitude of what we have accomplished, because our work is not done.

"We have started 2025 with excellent momentum. A strong balance sheet has allowed us to make measured investments towards several functions, and these are already having a material impact across the business.

"We are advancing iCMR applications, driving towards US commercialisation, expanding in the Middle East, and once again growing our European pipeline to pre-pandemic levels.

"The milestones ahead of us in 2025 are truly groundbreaking. Within Imricor, you can feel the excitement, whilst externally, you can feel the anticipation. It is a special time, and we are genuinely eager to deliver on our mission and on the promise of MRI-guided interventional medicine."

Regulatory

- US FDA modular review process progressed to plan
- NorthStar 3D Mapping System submitted for CE Mark
- First iCMR guided ablation on US soil performed at Johns Hopkins
- Ethics approval received at Amsterdam UMC to commence VISABL-VT trial
- Saudi FDA approval received
- CE Mark received for Vision MR-Diagnostic Catheter

Commercial

- Re-started global rollout with site activations in France, Netherlands, Croatia, Switzerland
- First purchase order received from the Middle East.
- Signed license agreement with ADIS for AI integration into NorthStar
- Completed NorthStar technical objectives to operate on Philips MRI platform
- Began rebuilding global Sales team

Financial

- Revenue of US \$959k, up 56% on pcp
- Operating costs including R&D well contained down 1% to \$17.3m
- Strong balance sheet US \$15.7m cash to fund major milestones





Financial Performance

Profit and loss - Costs well contained as revenue starts to grow

US\$'000	FY24	FY23
Revenue	959	616
Costs and non-R&D expenses	(8,643)	(9,145)
R&D expenses	(7,865)	(7,618)
Other income (expenses), net	307	152
EBITDA	(15,242)	(15,995)
Depreciation & Amortization	(748)	(708)
EBIT	(15,990)	(16,703)
Finance income (costs), net	238	(15)
Foreign exchange gain	198	5
Fair value change	(14,138)	(4,646)
Loss from capital commitment	-	(1,297)
Net loss before tax	(29,692)	(22,626)
Income tax benefit	-	-
Net loss after tax	(29,692)	(22,626)
Underlying net loss after tax	(15,555)	(16,683)



Commentary

- Revenue growth of 56% on pcp driven by capital sales and new site activations.
- Costs and non-R&D expenses decreased 5% primarily due to continued decreases in D&O insurance premiums (\$329) and inventory reserves (\$230).
- R&D expenses increased due to higher staffing costs (\$396) and spending on testing (\$197), which were partially offset by lower spending on regulatory compliance (\$236).
- Net loss impacted by **change in fair value** of convertible note, which **does not affect cash**
- Underlying net loss of \$15.6 million down 7% on prior year



Balance Sheet

US\$'000	Dec-24	Dec-23
Cash and cash equivalents	15,708	832
Accounts receivable	345	393
Inventory	1,502	1,681
Other current assets	794	1,034
Total current assets	18,349	3,940
PP&E, net	1,879	2,274
Inventory, long term	328	838
Operating lease right of use assets	718	891
Other long-term assets	350	365
Total long-term assets	3,275	4,368
Total assets	21,624	8,308
Accounts payable	335	2,104
Accrued expenses	1,493	791
Financing obligation	209	423
Current portion of contract liabilities	60	583
Other current liabilities	259	667
Total current liabilities	2,356	4,568
Convertible note	19,870	8,453
Option and warrant liabilities	4,667	1,945
Long-term contract liabilities	1,099	795
Other long-term liabilities	1,009	1,300
Total long-term liabilities	26,645	12,493
Total liabilities	29,001	17,061
Share capital	134,903	103,834
Accumulated losses	(142,280)	(112,587)
Total equity	(7,377)	(8,753)

Commentary

- Accounts payable decrease follows payment of nonrecurring invoices for 3rd party equipment inventory and regulatory compliance/submission fees that were outstanding in pcp.
- Contract liabilities represent deferred revenue to be recognized in future years
- Convertible note held at fair value under US GAAP; outstanding principal and interest at 31 December was \$6 million
- Option and warrant liabilities relate to securities issued as part of the financing activities in 2023 and are held at fair value under US GAAP



US\$'000	FY24	FY23
Net loss	(29,693)	(22,626)
Other non-cash adjustments	14,889	7,746
Change in other assets and liabilities	(770)	1,903
Operating cash flows	(15,574)	(12,977)
Investing cash flows	(75)	(83)
Proceeds from issuance of common stock (net)	31,000	5,762
Proceeds from issuance of convertible note (net)	-	2,664
Other financing activities	(666)	(212)
Financing cash flows	30,334	8,214
Net change in cash	14,685	(4,846)
Effect of foreign currency changes on cash	191	(10)
Cash at 31 December	15,708	832

Commentary

- Other non-cash adjustments were up vs. prior comparative period primarily due to an increase in the change in fair value charges.
- Cash burn related to other assets and liabilities was higher vs. the prior comparative period primarily due to the decrease in accounts payable.
- Proceeds from issuance of common stock:
 - 2024 proceeds reflect the Company's placements launched in February and July
 - 2023 proceeds reflect the Company's placements in July, August and October
- Proceeds from issuance of convertible note in the prior period relate to the \$2.7 million note issued in March 2023





How Imricor plans to change the standard of care



VISABL-VT will be the world's first real-time iCMR guided VT ablation.

What to expect?

A study¹ in Barcelona of 84 patients, where CMR² was utilised to guide VT procedures through pre-procedural image acquisition³, revealed the following when compared to X-ray only ablation:

	CMR guided	X-Ray guided
Average duration	1 hour 47 mins	3 hours 47 mins
First time success	82%	54%

We believe this study represents a half-step toward Imricor's goal of periprocedural **real-time iCMR** guided VT ablations.

1. Soto-Iglesias et al, "Cardiac Magnetic Resonance-Guided Ventricular Tachycardia Substrate Ablation," JACC: Clinical Electrophysiology, 2020 Cardiac Magnetic Resonance, signifies MRI scanner sits in cardiology department instead of radiology Not real-time guidance, only use of pre-acquired MR images





2.

NorthStar – accelerating towards approval and commercialisation



A strong and growing pipeline globally

Investment in sales resources having an immediate positive impact



■ Jun-24 ■ Feb-25

Middle East active pipeline



PHILIPS

Note: Philips customers in the pipeline are awaiting a major software release from Philips that will unlock connectivity with NorthStar. The release is expected in Q3 2025.

Several key value drivers during 2025/26

E

FDA Approval for US commercial release of platform technology

- 510(k) submissions / approvals
- VISABL-AFL clinical trial
- PMA submissions / approvals



- First-in-human VT ablation guided by MRI
- VISABL-VT clinical trial



NorthStar 3D Mapping System CE mark and launch in EU







Middle East first procedures and further expansion





Pulsed Field Ablation (PFA) research, publications, and product development





Questions?



imric@r



The problems we are solving through MRI-guided ablation procedures



Partners, Hospitals we Provide into and KOL Validation



A strong intellectual property portfolio







Imricor's patents protect technology that allows Imricor to manufacture medical devices that are uniquely MRI compatible.

Trade secrets, 3rd party relationships and difficult regulatory environment leave a deep moat behind Imricor.

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In addition to protecting Imricor's devices and procedures, its patents provide an opportunity for the Company to license its technology to 3rd party medical device companies (particularly implant manufacturers) to help make their devices compatible with MRI



To date, Imricor has executed 3 separate agreements where it has licensed its own patents to 3rd parties for use in implantable devices under which Imricor has received over **US\$12.9m of payments (revenue)** to date



Imricor Leadership: Management



STEVE WEDAN President and Chief Executive Officer. and Board Chair

30 years industry experience

Designed MRI and ultrasound systems for GE Healthcare

United States appointed expert on MR safety and devices

Credited with establishing the 4th known hazard interaction in the MRI



GREG ENGLEHARDT Vice President of Global Sales

20 years industry experience

Led global business development initiatives, identifying and capitalizing on new market opportunities to drive international sales growth at NeuroMetrix

Former combat medic in the U.S. Army



JONATHON GUT Vice President of Finance and Chief **Financial Officer**

15 years industry experience

Previous experience at Gail Medical and Boston Scientific driving financial performance, supporting business growth, and ensuring regulatory compliance

Expertise spans various aspects of financial management, strategic planning, and operational efficiency within the medical device industry



GREGG STENZEL Chief Operating Officer

25 years industry experience

Led the Instrument Technical Operations division at Beckman Coulter, Inc., a leading manufacturer of In Vitro Diagnostic Systems

Seasoned operations executive with expertise in new product development, supply chain management, quality and regulatory systems, and customer support.



NICK CORKILL Vice President Corporate Strateay

16 years industry experience

Experienced capital markets professional having spent 15 years as an equity analyst and portfolio manager at Perpetual Investments, BlackRock Inc and Lennox Capital.

Deep analytical and financial modelling skills across multiple sectors, disciplined approach to capital management.



NICK TWOHY Vice President of Marketina and Business Development

20 years industry experience

Directed international market strategies for Medtronic's Cardiac Resynchronisation Therapies business

Led the successful US launch of the Medtronic Revo MRI pacemaker system, enhancing market.





VIC FABANO Vice President of Operations

25 years industry experience

Held executive positions in Operations, Quality, and Product Development throughout his tenure including VP of Operations and Quality at Osprev Medical

Expert in supply chain scaling and operations infrastructure to support rapid growth, profitability, and quality for start-up to midsize medical device firms



KATE LINDBORG, PHD Vice President of Clinical Affairs

13 years industry experience

Managed a portfolio of clinical trials within Medtronic's Cardiac Rhythm and Heart Failure and Diagnostics Clinical division to gain and maintain market approval of novel devices

Oversaw the generation and dissemination of clinical evidence, enhancing the scientific credibility and market positioning of Medtronic's products



JENNIFER WEISZ Vice President of Regulatory and Quality

20 years industry experience

Contributed to the continuous improvement of the quality and regulatory strategy, development, and implementation during tenure at Medtronic's Global Clinical Operations Quality division

Experienced in bringing medical devices to market and ensuring their compliance with global standards





Imricor Leadership: Board of Directors



Designed MRI and ultrasound systems for GE Healthcare. United States appointed expert on MR safety. 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

Credited with establishing the 4th known hazard interaction in the MRI



MARK TIBBLES Deputy Chair and Lead Independent Director

Entrepreneur, business owner, company director and active venture investor in and advisor to technology, life science and medical device companies

Owner and managing member of STEM Fuse, LLC, one of the largest providers of digital K-12 STEM curriculum in the U.S.

Managing Director of Strategic Stage Ventures, LLC.



PETER MCGREGOR Non-executive Director

Extensive finance management background including partner positions at Goldman Sachs JBWere, and managing director in the institutional banking & markets division of Commonwealth Bank of Australia

Currently serves as a Director of Treasury Corporation of Victoria and True Infrastructure Management Pty Ltd.



ANITA MESSAL Non-executive Director

Comprehensive background in health care and benefits industry, including the successful integration of merged and acquired entities across all areas of the business at AccentCare

Vast background in working with both Fortune 100 and startup companies in public, private and non-profit sectors in both domestic and international markets



Jeffrey Leighton Non-executive Director

Dr Leighton is a cognitive neuroscientist with extensive experience in both academic and corporate settings. He holds a PhD in Cognitive Psychology from Grand Canvon University and has a robust research. teaching, and leadership backaround. Bevond his academic achievements, Dr Leighton has demonstrated strong business acumen as CFO at NDS Wellness. Dr Leighton has held key corporate governance and advisory roles.



Key Terms

Vision-MR Ablation Catheter

Cardiac Arrythmias

Ablation

Catheter Ablation

X-ray vs MRI

iCMR Lab:

Interventional Cardiac Magnetic Resonance

- Medical device developed by Imricor, designed for use within an MRI
- World first, no competitors, all others only compatible with X-ray
- Irregular heartbeat, affects approximately 2% of US population
- Expected to double to 4% of US population by 2030
- Ventricular arrhythmias are responsible for 75% 85% of sudden cardiac deaths, and are a leading cause of strokes
- Minimally invasive surgical procedure to restore heart to normal heartbeat
- Physician will guide catheter into heart
- Physician will then apply energy (radiofrequency, cryo, pulsed field) with the purpose of forming scars/lesions that destroy the heart cells responsible for causing the electrical misfiring
- X-rays are good for bones and bone density, not as effective at visualizing soft tissues like muscles, ligaments, and organs
- MRI provides excellent contrast between different types of soft tissues, making it ideal for imaging the heart
- CMR is the field of MRI used by cardiologists ("Cardiac MR")
- CMR field has grown over 500% since 1998
- A speciality interventional lab fitted with MRI used by cardiologists (interventional + CMR = iCMR)
- Earning potential of over US\$1 million p.a. more than a standard X-ray lab for a hospital





FDA Global Pivotal Trial – June/July 2024



VISABL-AFL Trial – FDA Approval pathway

Trial details

- Treatment of type 1 atrial flutter
- Patients : 91 with possibility to end at 76 if primary endpoints are met (e.g. 80% acute success)
- Participating hospitals: 4
- Expected FDA approval : 2H 2025
- Comment: Regulatory review process already underway, review of clinical trial data is last step
- **Status –** Enrolment underway at ICPS, Johns Hopkins and the CHUV with Amsterdam UMC enrolling soon

European CE Mark trial experience

- Trial details
- Treatment of type 1 atrial flutter
- Participating hospitals : 1
- Patients : 35
- Trial outcome : 100% success at 3 months

MRI guided VT ablation - the most significant event in Imricor's history



VISABL-VT Trial – CE Mark Approval Pathway for 2nd Indication

Trial details

- Treatment of Ventricular Tachycardia
- Patients: 64
- Participating hospitals: 2
- **Comment:** Trial data expected to stimulate new site adoption in preparation
- Status: First procedure planned at Amsterdam
 UMC in coming weeks

Imricor's Pipeline of Leading Tools for iCMR Labs

Current Products

Our iCMR family of products are designed with patented technology to meet the needs of physicians and CVD patients around the world

VISION-MR[™] ABLATION CATHETER

Designed to look, feel, and function like a traditional ablation catheter



VISION-MR™ DIAGNOSTIC CATHETER

Design based on the Vison-MR Ablation Catheter with the ablation features removed



ADVANTAGE-MR[™] EP RECORDER / STIMULATOR

Both a conventional EP recording system and a cardiac stimulator within the iCMR environment



VISION-MR[™] DISPERSIVE ELECTRODE

Designed to minimize eddy currents induced on the device's conductive pads during MR scanning

Future Products

Products are developed and going through approvals to expand indications into VT and Afib



NORTHSTAR™ MAPPING SYSTEM

Receives 3D MR images in real time. Tracks Imricor catheters, facilitates electroanatomic mapping and registers therapy points



VISION-MR[™] ABLATION CATHETER – GEN 2

Provides improved torque transfer, return to straight, and maneuverability. 2 curve sizes (32mm & 48mm)



NAVTRAC-MR™ TRANSSEPTAL KIT

Consists of MR kit, fluoro kit and needle



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