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# EMVISION

## MEDICAL IMAGING INNOVATION

15<sup>th</sup> Bioshares Biotech Summit  
July 2019  
Queenstown, New Zealand



# MEDICAL IMAGING INNOVATION

Microwave imaging is a truly **innovative imaging modality** that has disruptive implications for diagnostics, monitoring and the delivery of care in the future



## NON-DESTRUCTIVE TESTING

Industrial quality control & condition assessment

Microwave frequency  
2 – 18 GHz

## SECURITY

Whole-body Scanners  
Security

Millimeter Frequency  
10 – 80 GHz

## BIOMEDICAL IMAGING

Point of care devices

Microwave frequency  
500 MHz – 5 GHz+

**EMVISION**

### \* Whole Body Diagnostic Applications:

- Neurological > Stroke | TBI | Cerebral Edema | Brain Tumors | Craniocerebral Shrapnel
- Torso > NAFLD / NASH | Pulmonary Edema | Renal Cancer | Congestive Heart Failure
- Skin > Pressure Ulcers | Burns | Skin Cancer

Microwave imaging has the potential to offer fast, safe and cost-effective functional imaging capabilities



## 1<sup>ST</sup> APPLICATION

# STROKE & TRAUMATIC BRAIN INJURY

- Stroke is the second leading cause of death world wide with **1 in 6 people** having a stroke in their lifetime <sup>1</sup>
- **Traumatic Brain Injury (TBI)** is the most frequent cause of death and disability worldwide <sup>2</sup>
- There are effective treatments available but they are **time sensitive** with **neurological imaging** a prerequisite to determining effective treatment protocol

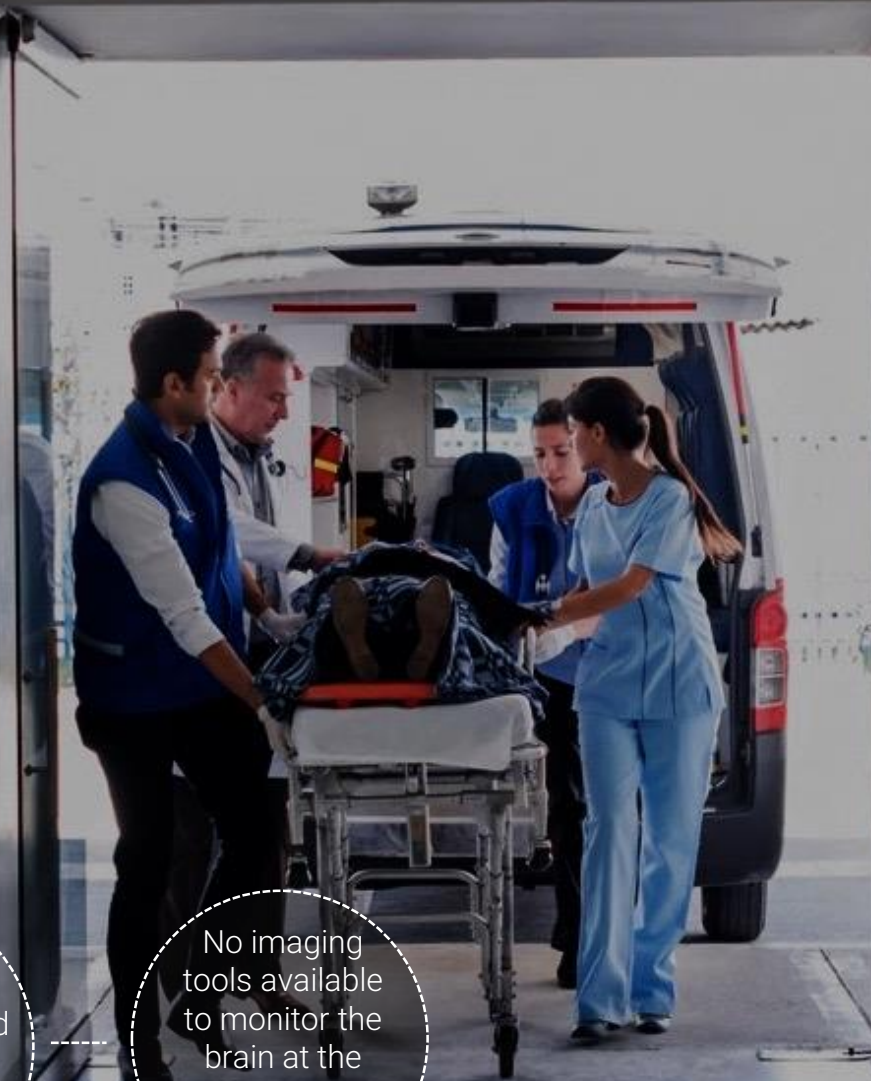
Annual burden of over \$105 (USD) Billion in the US alone <sup>3</sup>

No widely accessible point-of-care imaging available

Current imaging equipment is stationary & expensive

Many patients are not diagnosed early enough for effective treatment

No imaging tools available to monitor the brain at the bedside during recovery



# TYPICAL PATIENT JOURNEY AND TIMELINE

EMvision's opportunity is to bring stroke and traumatic brain injury decision support and monitoring to the patient

Stroke  
Onset



15 mins to 2.5 hours



## Pre-Hospital Triage (2nd Generation)

Speed up pre hospital triage and create opportunity for earlier treatment choices pre-hospital in a manner that does not currently exist today.

< 2.5 hours



## Hospital ED

Standard Hospital  
(Neuroimaging and  
Thrombolysis capable)

OR

Comprehensive Stroke  
Centre (Clot Retrieval and  
Neurosurgery capable)

< 3 hours



## Image Studies

Urgent Non-Contrast CT  
Scan

CT Angiograph

Determine aetiology:  
haemorrhagic including  
cause/source or  
ischaemic including "large  
vessel occlusion"

< 24 hours



## Treatment Plan

Medical (supportive,  
thrombolysis, reverse  
blood thinners:  
depending on cause)

OR

Interventional (including  
clot retrieval or  
neurosurgery)

<24 hours - 3 weeks



## Acute Post Treatment Care (1st Generation)

In ICUs, Stroke and Neurology  
wards the device offers a  
bedside monitoring capability  
that does not currently exist  
for the progress of strokes,  
and response to treatments.

Monitoring for complications,  
extension or secondary  
bleeding

<3 weeks - 3 years+



## Rehabilitation

Inpatient  
rehabilitation units

Outpatient units

Skilled nursing  
facilities

Home-based  
programs

From having assessment and diagnosis in an Australian Mobile Stroke Unit (MSU) ambulance trial, it was preliminarily and conservatively estimated that an annuitised **AUD\$203,033** would be saved in clinician and paramedic time in the emergency department and hospital transfers from one MSU. This does not include long term productivity/staff resourcing benefits. <sup>1</sup>

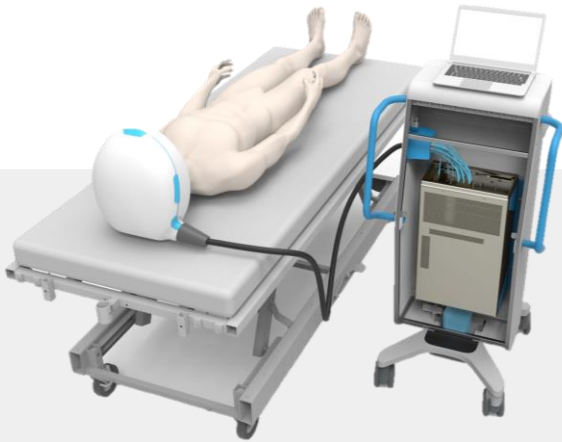
The incremental 30-day cost of care for an in-hospital stroke of average severity can be estimated at **US\$17,500**. With an estimated 35,000 to 75,000 in-hospital strokes in the United States each year, the lifetime **direct and indirect costs for these in-hospital strokes would be approximately 4.9 billion to 10.5 billion dollars.** <sup>2</sup>



# EMVISION'S BRAIN SCANNER

PORTABLE  | COST-EFFECTIVE  | SAFE  | RAPID 

*The Company aims to develop a clinical device that delivers these features*



## CLINICAL TRIAL UNIT

EMvision is in the late stages of developing its Clinical device to be used in its pilot clinical trial.

This device will be used to collect data from patients presenting with acute stroke to refine the imaging system and its algorithms.



## HOSPITAL COMMERCIAL UNIT

EMvision's 1<sup>st</sup> generation commercial device aims to offer a bedside monitoring capability that **does not currently exist** in ICUs, Stroke and Neurology wards

Monitoring for; the progress of strokes, and response to treatment, complications, extension or secondary bleeding



## AMBULANCE COMMERCIAL UNIT

Defibrillator sized portable device expected to provide rapid stroke and TBI decision support in ambulances.

Patients having a severe stroke could be identified and transported directly to specialist hospitals for intervention such as clot retrieval.



# TECHNOLOGY OVERVIEW

Array of antennas send pulses of low-power electromagnetic waves into the head



Waves penetrate tissue in a non-ionizing and harmless manner and get scattered based on the electrical properties of tissue



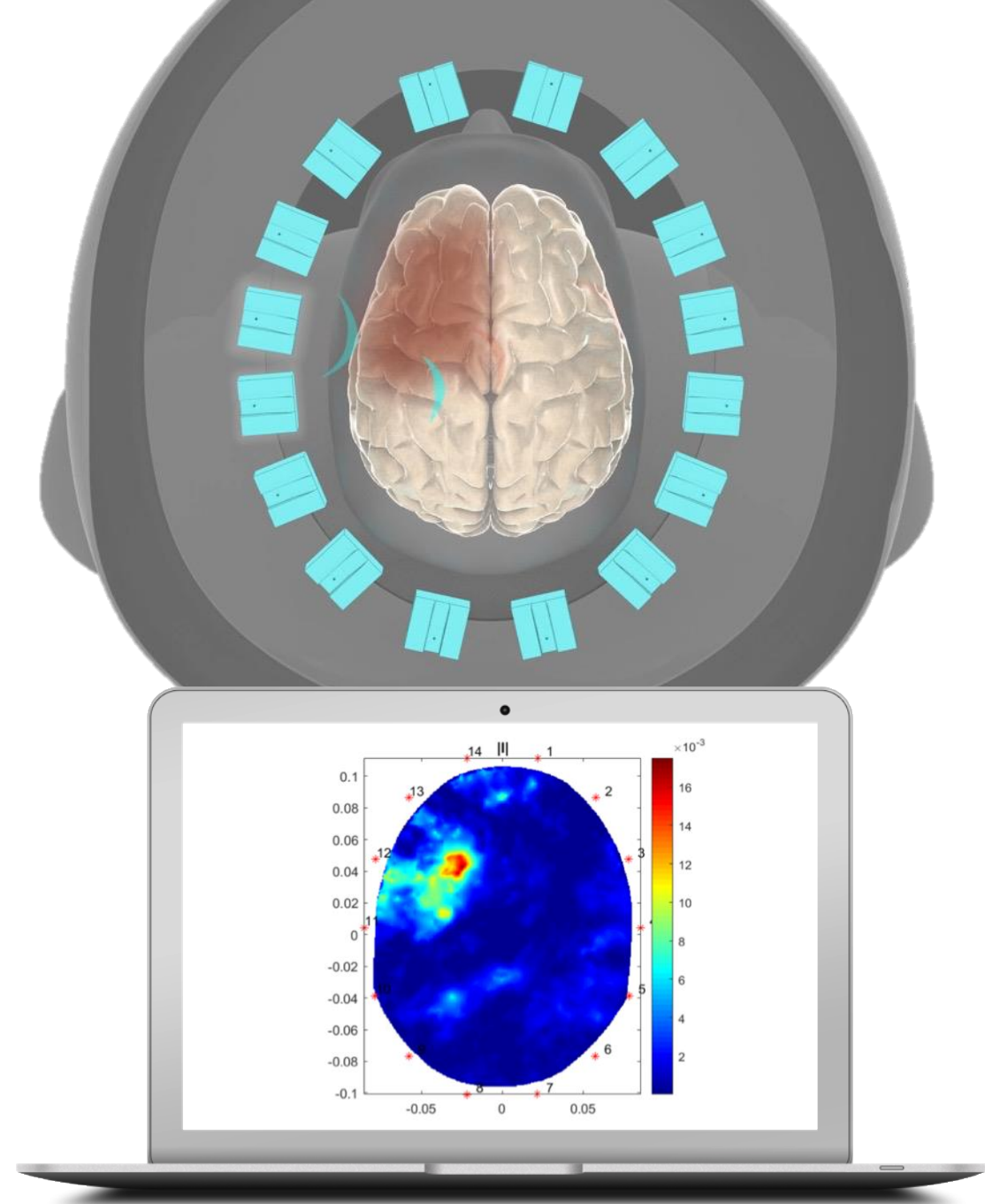
Sensors in the helmet detect these interactions to identify and locate unhealthy tissue



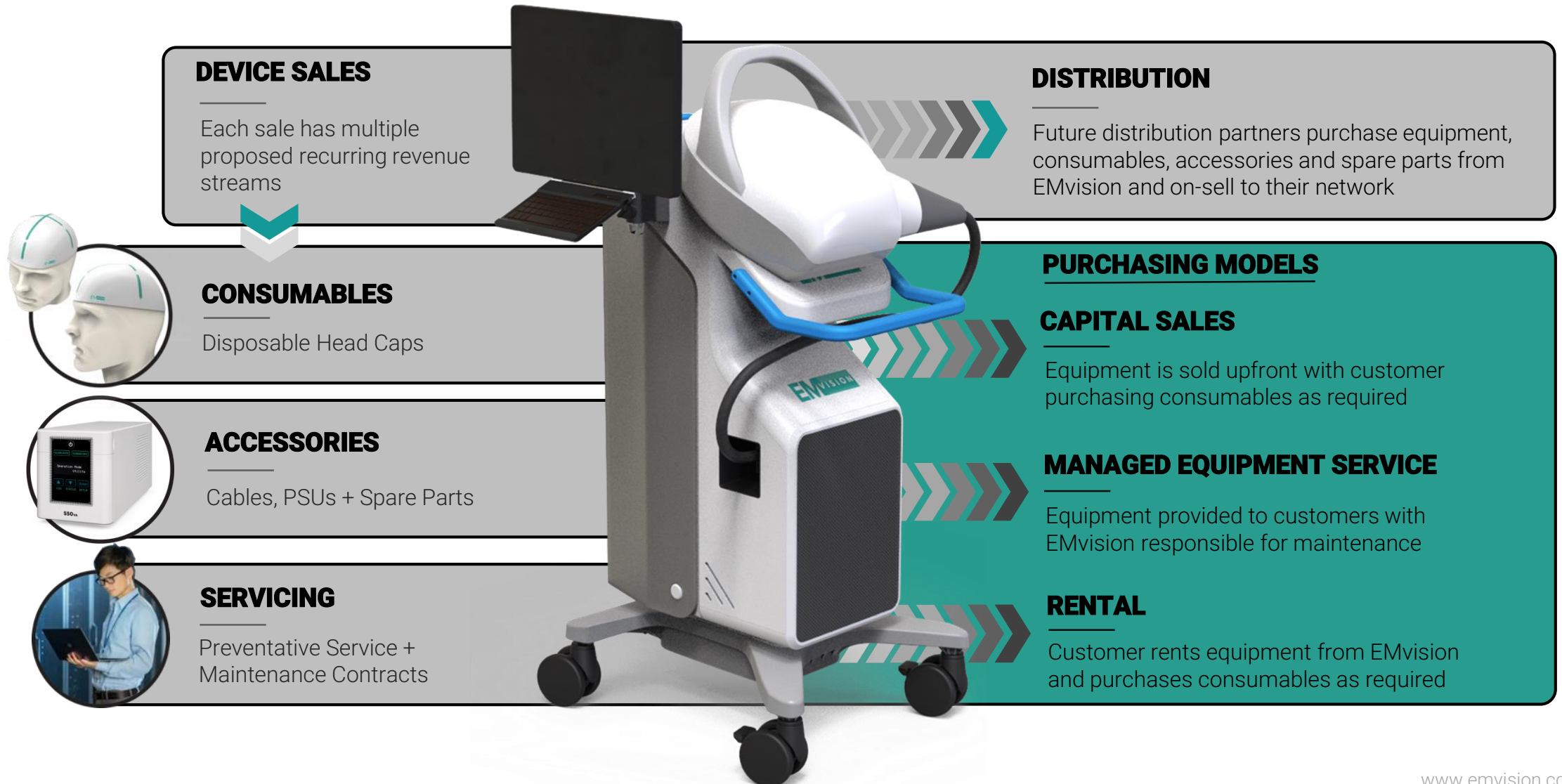
Novel multi-algorithmic AI reconstructs the image



3D images of the brain are displayed on a standard laptop or tablet



# ATTRACTIVE REVENUE MODEL



# KEY ADDRESSABLE MARKETS

## North America +



48,000 Ambulances



5,000 Hospitals



## Europe +



60,000 Ambulances



15,000 Hospitals



## + China



30,000 Hospitals



## Australia +



5,200 Ambulances



1,300 Hospitals



### SECONDARY MARKETS:

- Rural / Remote
- Military
- Humanitarian
- Aged Care
- Sport
- Air / Ships



# PARTNERS & COLLABORATORS



Australian Government  
Department of Industry,  
Innovation and Science

**Awarded EMvision a \$2.6M** CRC-P non-dilutive cash grant, over three years, in Dec'17.

Secured key academic, clinical and industry partners, whom contribute a further \$900,000 non-dilutive cash and ~\$5M of in-kind contributions and resources to the brain scanner program



THE UNIVERSITY  
OF QUEENSLAND  
AUSTRALIA

**Developer of EMvision's IP**, CRC-P partner, and Australia's most successful commercialisation university with more than US\$15.5 billion in gross product sales from UQ licenced technologies.

Over 30 researchers at UQ across software, mechanical and electrical engineering advancing EMvision's imaging modality.



GE Healthcare

GE Healthcare is the \$19 billion healthcare business of GE (NYSE:GE) and a leading global manufacturer and distributor of imaging modalities.

GE Healthcare have partnered with EMvision in a CRC-P program providing **cash and in-kind expertise commitment** towards EMvision's brain scanner program.



AUSTRALIAN  
STROKE ALLIANCE

**EMvision is a key commercial collaborator** with the Australian Stroke Alliance who are looking to deploy portable imaging technologies for pre-hospital stroke triage.

Working towards a Medical Research Future Fund (MRFF) Stage 2 grant pledged at \$50 million or more per group



KEYSIGHT  
TECHNOLOGIES

**Strategic collaboration with Keysight Technologies Inc. (NYSE:KEYS)** via MOU to collaborate on the development of personalized Vector Network Analyser (VNA) units for the healthcare market.

VNA's are a key component in EMvision's brain scanner and allow for accurate measurement of the signals transmitted and received

Princess Alexandra  
Hospital  
BRISBANE • AUSTRALIA

Highly regarded hospital with **world leading neurology, radiology and critical care experts.**

EMvision's CRC-P partner and pilot-clinical trial site where data will be collected from patients with diagnosed ischaemic and haemorrhagic stroke, with confirmatory CT and/or MRI images

# PILOT-CLINICAL TRIAL ROADMAP

**Q1-Q2  
CY 2019**

- ✓ ISO 13485 Certification
- ✓ Successful Healthy Human Trials
- ✓ Clinical trial protocol designed, clinical advisors appointed and ethics clearance obtained
- ✓ Successful hospital site evaluation



*Actual headset and antenna array*

*Concept Image of headset in outer skin*

**Q3  
CY 2019**

Clinical unit bill of materials (BOM) review, release and procurement

Commence fabrication and assembly of clinical units (x2)

Verification and testing of clinical trial units prior to hospital delivery



**Q4  
CY 2019**

Delivery of clinical trial units to hospital

Clinical site initiation visit and training of site staff for trial commencement

Commence data collection from patients with diagnosed ischaemic and haemorrhagic stroke, with confirmatory CT and/or MRI images

**Princess Alexandra Hospital**  
BRISBANE • AUSTRALIA



*Concept image of clinical trial unit*

*Concept image of headset with absorbing material*

# POINT-OF-CARE DEVICE LANDSCAPE

EMvision is setting out to capture a niche with **superior ease of use and image reconstruction**



## POTENTIAL CLINICAL ADVANTAGES:

**Multi-algorithmic** Image Fusion approach incorporating radar based, tomography and statistical techniques for rapid image reconstruction to provide more valuable clinical information

**Fast**, safe, cost effective and can provide powerful functional imaging capabilities in real-time and in three dimensions

**Portable**, light and easy to use, minimising operator/patient variability

It is proposed that EMvision's 1<sup>st</sup> generation device will offer a bedside monitoring capability that **does not currently exist** in ICUs, Stroke and Neurology wards



Progress of Strokes



Response to Treatments



Subsequent Strokes & Bleeding



*"Strokefinder MD100 is a device for decision-support to assist in clinical evaluation and triage of suspected intracranial injuries in the acute situation."*



*"The EMTensor Brain Scanner could provide rapid screening of the brain in adults to provide information allowing clinicians to assess and monitor disorders caused by impaired cerebral circulation, such as hemorrhagic or ischemic strokes."*



*"The Visor™ System is a non-invasive wireless neurological device intended for use as an aid in the assessment of fluid volume asymmetry between the cerebral hemispheres in adult patients undergoing neurologic assessment."*



*"The Lucid Robotic System is an autonomous all-in-one robotic neurovascular ultrasound device designed to non-invasively search, measure and display objective brain blood flow information in real-time."*



## PRODUCT PIPELINE

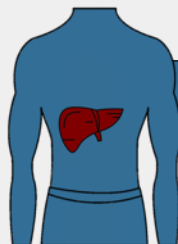
### BRAIN SCANNER

Identify and monitor stroke and traumatic brain injury



### TORSO SCANNER

Identify the severity and monitor the progression of liver disease



Device  
Discovery  
& Concept

Preclinical  
Research &  
Prototype

Healthy  
Human Trials

Ethics  
Clearance

Pilot  
Clinical Trial

Pivotal  
Clinical Trial

Regulatory  
Clearance &  
Commercialisation

Q4 2019

2020

Q3 2019

*Calendar Year*



*The indicative timetable is a guide of EMvision's intentions at the date of this presentation only. EMvision reserves the right to vary the timetable at its discretion, and further notes that the above timings are subject to change due to circumstances outside of its control. It is EMvision's intention to apply for the relevant regulatory clearances as part of its commercialisation strategy at the appropriate point in the development cycle of both the brain and torso scanner, however, EMvision notes there is no guarantee that the requisite clearances will be acquired in a timely manner, or at all.*

## 2<sup>nd</sup> APPLICATION

# IDENTIFYING & MONITORING LIVER DISEASE

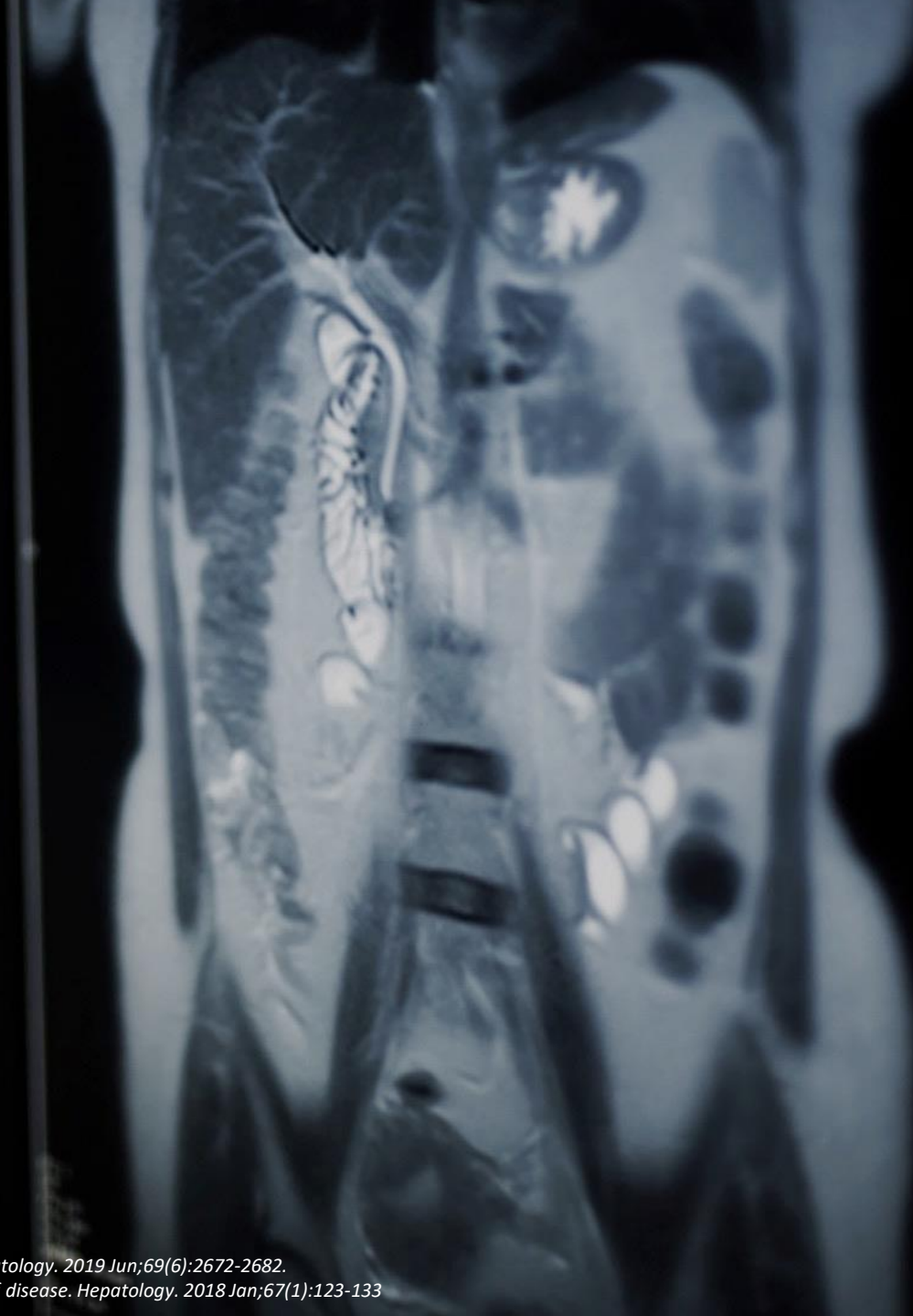
Over 1 BILLION people globally have liver disease



**1 in 4 people worldwide** have a variant known as non-alcoholic fatty liver disease (NAFLD) <sup>1</sup>



Approximately 20% of NAFLD cases are classified as non-alcoholic steatohepatitis (NASH) which can lead to fibrosis, cirrhosis, cancer and mortality <sup>2</sup>



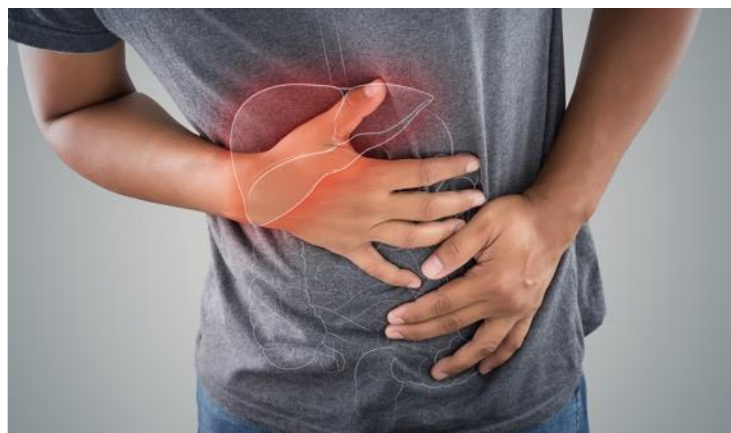
# EARLY DETECTION AND MONITORING OF LIVER DISEASE



## GLOBAL EPIDEMIC FUELED BY OBESITY RATES AND DIABETES

The prevalence of NAFLD is constantly increasing (from 15% of the population in 2005 to 25% in 2010) <sup>1</sup>

The major focus of clinical care is discerning those at highest risk of progressive liver disease. There is an estimated annual burden associated with NAFLD of US\$103 billion in the USA alone<sup>2</sup>

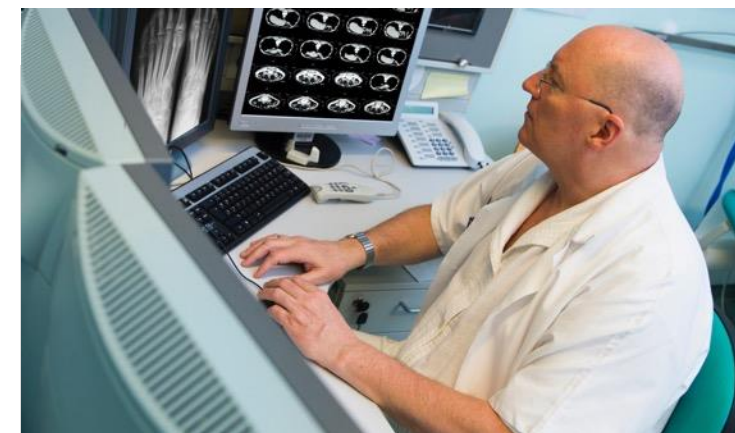


## ZERO PRACTICAL DIAGNOSTIC AND MONITORING SOLUTIONS

Invasive, painful and costly surgical biopsy

or

Largely inaccessible expensive high-end MRIs



## THE BENEFITS OF APPLYING EM MICROWAVE IMAGING

Quantify fat in the liver in a manner not possible today

Could be used non-invasively at the point of care

Fraction of the cost of biopsy or MRI



# EMVISION TORSO SCANNER DEVELOPMENT

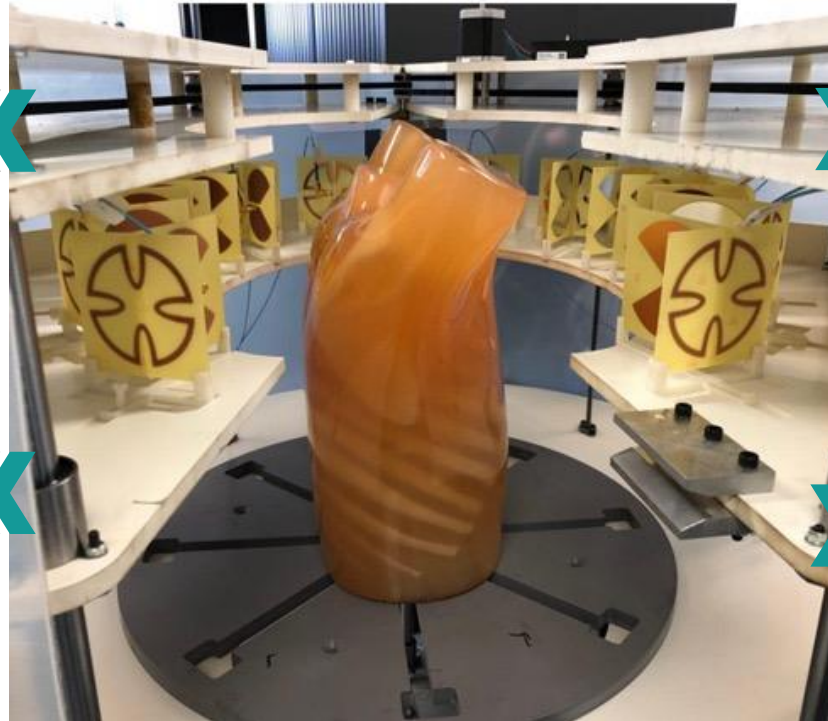
EMvision is exploring the feasibility of a non-invasive and cost-effective Torso Scanner to identify the severity and monitor the progression of NAFLD and NASH

## TISSUE CHARACTERISATION

Tissue characterisation work to inform algorithm development has advanced with samples now collected from several patients with pathology **results expected near term**

## TEAM EXPANDED

The UQ research team has been bolstered with the addition of four experts to the project in the fields of machine learning, classification, signal processing and antenna design



## PHANTOM FABRICATED

An enhanced torso phantom has been fabricated to emulate different stages of fatty liver disease in a lab environment. This phantom is being used to assist in verifying algorithm development

## NEW ANTENNAS DEVELOPED

A new generation of smaller resonance based reflector antennas have also been developed for testing

The Torso Scanner system would utilise the core technology being developed for stroke imaging with custom algorithms and hardware (antennas and switching network)



# COMMON CHALLENGES

Bringing medical devices to market is a complex process; a few critical considerations to look out for are:

01

Ensuring that you have the **best** application. Don't try and get it to do everything. Niche is good.

02

Selecting the right **clinical outcomes** for studies especially for regulatory submissions

03

**The right regulatory path.**  
As per #1 don't bite off more than you can chew

04

Having a reimbursement strategy defined **well ahead of time.**

05

Ensure that you **understand** your customer.

06

Don't build a global sales team before you are **well developed** as a company

# TEAM

Significant experience **developing and commercialising medical devices**



**Dr Ron Weinberger**  
*Chief Executive Officer*

Former Exec Director / CEO of Nanosonics (ASX: NAN), \$1.5BN market cap company

20 yrs experience developing and commercialising medical devices



**John Keep**  
*Executive Chairman*

Former CEO of Queensland Diagnostic Imaging (\$109M Trade sale to Mayne Pharma)

Over 30 yrs senior executive leadership and M&A experience



**Scott Kirkland**  
*Executive Director*

Co-founder of EMvision Medical Devices Ltd

Experienced corporate affairs, capital markets and technology sales executive



**Prof Stuart Crozier**  
*Clinical Development Advisor*

Co-inventor of underlying technology

Globally renowned for MRI advancements (70% installed hold Stuart's patents)



**Robert Tiller**  
*Product Design & Development Executive*

CEO and Founder of Tiller Design (product developer for ResMed and Nanosonics)

25 yrs experience in medical device design, development and commercialisation



**Geoff Pocock**  
*Non-Executive Director*

Former Managing Director / Co-Founder of Hazer Group (ASX: HZR)

20 yrs experience commercialising emerging technologies and capital markets



**Tony Keane**  
*Non-Executive Director*

Over 30 years finance experience in business, corporate and institutional banking

Advisory Board and NED roles including ASX 200 company National Storage REIT (ASX:NSR)



**Ryan Laws**  
*Non-Executive Director*

Co-founder of EMvision Medical Devices Ltd

Experienced corporate advisor & investor



**Emma Waldon**  
*Company Secretary*

Chartered Accountant

Diverse capital markets & corporate governance experience



**Dr. Konstanty Bialkowski**  
*Head of Tech Development*

Co-inventor of underlying technology

Expert in near-field biomedical radar, microwave imaging and signal processing techniques.



**Ruth Cremin**  
*Head of Quality & Regulatory Affairs*

Former Head of Quality and Regulatory at Nanosonics (ASX:NAN) and Snr Regulatory Specialist at Cochlear (ASX:COH)

Multiple successful FDA, TGA and CE mark clearances.



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# GET IN TOUCH



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