

**2023 Bioshares Biotech Summit** 

Sander Bangma, CEO



#### **DISCLAIMER**

#### Introduction

The Company is at start-up stage with the objective of developing a medical technology business. The information provided in this Presentation is subject to a number of risks. The following is not intended to be an exhaustive list of the risk factors to which the Company is exposed.

#### Regulatory

Political, taxation, economic, legislative or regulatory change in Australia or in other countries where the Company intends to operate may have an adverse effect on the Company's investments and operations.

#### **Industry**

The industry in which the Company operates carries with it individual risks associated with that industry. It is not possible to detail all of the risk factors that the Company may be exposed to in respect of that industry, but may include factors related to legislation, trends in medical treatment and industry competition.

#### **Timing**

The timing of the necessary steps to commercialise the Company's business plan is dependent on many factors and accordingly the Directors can give no assurance as to the ultimate timing of such events.

#### Returns

Any outcomes and returns are dependent on the ultimate size and scale of the Company's potential business market, the information provided in this Presentation is an indication only and no guarantee on returns.

#### **Economic conditions**

General economic conditions, movements in interest and inflation rates and currency exchange rates may have an adverse effect on the Company's activities, as well as on its ability to fund those activities.

#### **Patents**

The medical technology developed by the Company may not be patentable, or where patents are sought, patents may not be secure. There is no guarantee that current or future patent applications will be successful. The inability to secure such patents could affect the value of the Company's technologies, adversely affecting the operations, financial position and performance of the Company.

#### **Funding**

As a biotechnology company investing in the development of its intellectual property, we don't anticipate product approval or any product revenue in the short term. Therefore we will continue to incur losses, not pay any dividends and we will need to raise additional funding in the future. There is no guarantee that additional funding in the future will be available or the price at which it could be raised.

## **≯** Mosaic

NOVEL MEASURE OF HIGH-RISK PLAQUE ACTIVITY







USE AI TO TRANSFORM ROUTINE CT SCANS INTO A PERSONALISED ASSESSMENT OF YOUR HEART HEALTH

Build up of fatty plaque in arteries





fatal heart attacks globally p.a.



cost of heart disease in the US by 2035

WE NEED BETTER RISK ASSESSMENT



of heart attacks in low-risk patients on CT



expected increase in cardiac CT scans

WE NEED
MORE
AUTOMATED
WORKFLOWS

WE NEED
BETTER
TREATMENT
OPTIONS



patients have another heart attack <2y



shortfall of radiologists by 2027

IMPROVED RISK ASSESSMENT EARLY-STAGE DISEASE & RESIDUAL RISKS MORE COMPLETE PICTURE

BEYOND WHAT IS

CURRENTLY AVAILABLE

ABILITY TO PROCESS
THE INCREASED VOLUME
OF CT SCANS

Measures high-risk plaque activity



Personalised treatment & improved health outcomes



Improved
Al assisted &
automated
workflows
—





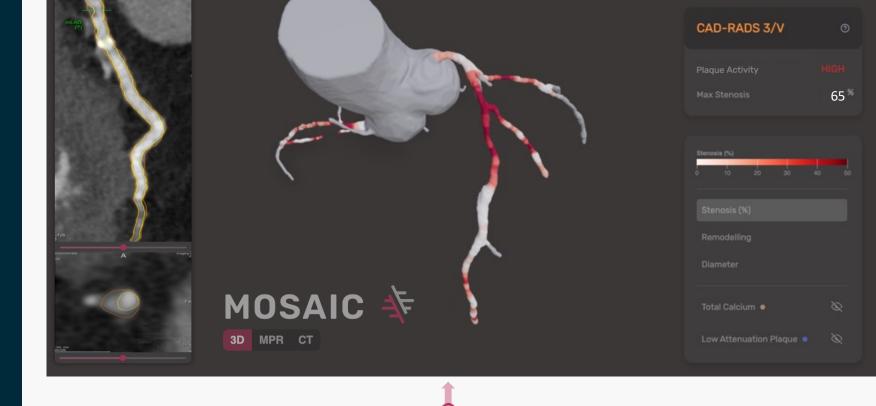


## World-first Al approach

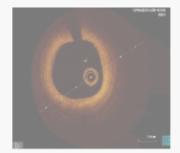
## revealing *invisible*high-risk plaque activity

using only routine CT scans

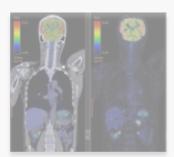








VALIDATED AGAINST
MICROSCOPIC RESOLUTION
IN VIVO IMAGING



HIGH-RISK PLAQUE ACTIVITY
MODEL DERIVED FROM
FUNCTIONAL IMAGING

## An Award-winning Innovation...











Innovation Booster **2023** 

....underpinned by a decade of academic research





### **Business Model**







Highly scalable & always available



No new hardware / scanners needed



Significant margins / low COGS



Minimal user training



Multiple payment options possible (e.g. pay-per-case, subscription models)



Reimbursement available

## **Our Value Proposition**

#### PATIENTS & CLINICIANS



- Better risk assessment
- Personalised treatment plan
- Reduced re-admissions
- Improved patient outcomes

#### **CLINICS & HOSPITALS**



- 🕢 Increased efficiency / revenue
- No hardware / CapEx needed
- Reimbursement codes in US
- **O** Competitive advantage

#### Reimbursement codes (CPT) currently available

- **⊘** CPT code for AI coronary plaque analysis (~US\$1,000) 0625T
- **⊘** CPT code for Al non-coronary plaque analysis (\$TBC) 0710T
- **⊘** CPT code for Al image analysis of stroke (~US\$1,000) 0691T

#### **SHAREHOLDERS**

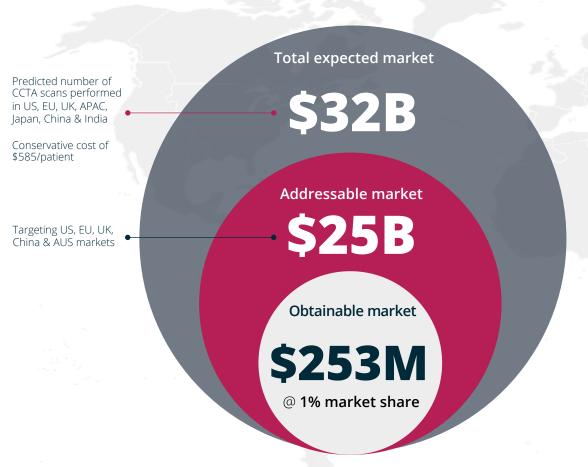


- High-potential company with large global market
- **Early-stage with opportunity** for high ROI
- (2024+)
- **SIC** status for tax offset

## The Opportunity

#### 8-fold increase in coronary CTA expected in coming years

2023 ~ 7M CCTA → 2030 ~ 55M CCTA



This does not include the market opportunity in stroke, aneurysm, peripheral arterial disease......

## The Competition



	BENEFITS	NAVIER	ELUCID	CARISTO	HEARTFLOW	ARTRYA	CLEERLY
	HEART ATTACKS	$\checkmark$	<b>4</b>	<b>V</b>	<b>✓</b>	<b>V</b>	<b>4</b>
STROKE 8	& VASCULAR DISEASE	$\checkmark$	<b>4</b>				
MICRO	DSCOPIC VALIDATION	$\checkmark$	<b>4</b>				
HIGH-RI	SK PLAQUE ACTIVITY	<b></b> ✓					
		<b>第</b>				<b>XX</b>	

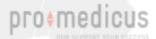
#### **★** mosaic

- Validated against the state-of-the-art reference standards
- World 1st measures of early-stage disease and residual risks
- Predictor of 2-3x increased risk of heart attack

ASX companies active in medical imaging software



ASX: 4DX Respiratory Imaging Mkt cap: ~ \$250M)



ASX: PME

Radiology Information Systems (Mkt cap: ~ v\$6.8B)

## **Product Roadmap**



2023



**7** FDA pre-submission meeting (**June**)

Positive meeting, pathway confirmed

510(k) submission (**Q4 CY23**)

510(k) clearance anticipated (**H1 CY24**)



M Al prototype developed

Predicate identified, pathway confirmed

FDA 510(k) submission

2024+



Plaque activity prototype developed

✓ Initial feedback from FDA

Further development

## **Key upcoming milestones**



#### **OPEN TO OPPORTUNITIES**

- Collaborate with radiology clinics
- Studies with KOL cardiologists
- Additional funding streams

# ASX ticker reserved NMX Assumes favourable market conditions

## Leadership & Management





- Extensive experience and success in investment, funds management and Info/Bio/Med-Tech
- Built and grew IWL Ltd (ASX: IWL) prior to takeover by CommBank (ASX: CBA)
- Director/Chair in several ASX listed biotech companies



- Over 12 yrs experience in medical software, including obtaining FDA, TGA & CE
- Led ASX listed software company Resonance Health Ltd (ASX:RHT) as GM & COO
- Led product strategy & development of 300M+ users global software platform
- MBA, MSc in Computer Science



- International profile in cardiovascular bioengineering with >18 yrs experience
- Program Head of Cardiovascular Science (until 2022) & Head of Vascular Eng. Lab at the Harry Perkins Institute
- Adj. A/Professor of Biomedical Eng. at University of Western Australia (UWA)
- BEng (Biomedical), PhD, FIEAust, GAICD



**Lachlan Kelsey Head of Engineering** 

- Co-developed methods behind Navier Medical during his PhD at UWA / Perkins (with Barry Doyle)
- PhD in Cardiovascular Biomechanics and BEng in Mechanical Engineering

**Bronte Maddock** QA & Reg Manager

- Experienced compliance, regulatory affairs & risk management professional
- Comprehensive understanding of Medical Device ISO standards & regulations, including FDA, TGA and EU





**Navier Medical Ltd** ACN 651 654 858

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## ESIC: tax incentive for early stage investors



Navier Medical Ltd qualifies as an Early-Stage Innovation Company (ESIC).

Investors into qualifying ESIC entities receive tax benefits depending on their individual tax and investment situation. *All investors should seek their own tax advice to determine tax impact.* 

#### The tax benefits include:

- 20% non-refundable carry forward tax offset of the amount paid for their qualifying investments, capped at \$200,000 each income year for Corps Act "Sophisticated Investors";
- modified capital gains tax treatment for equity interests held more than 12 months and less than 10 years, whereby there is no CGT on disposal;
- investors who are not Corps Act "Sophisticated Investors" limited to \$50,000 investment or lose all ESIC benefits.