

# See beyond the structure

4DMedical Limited (ASX:4DX)
Investor Presentation
1 October 2024



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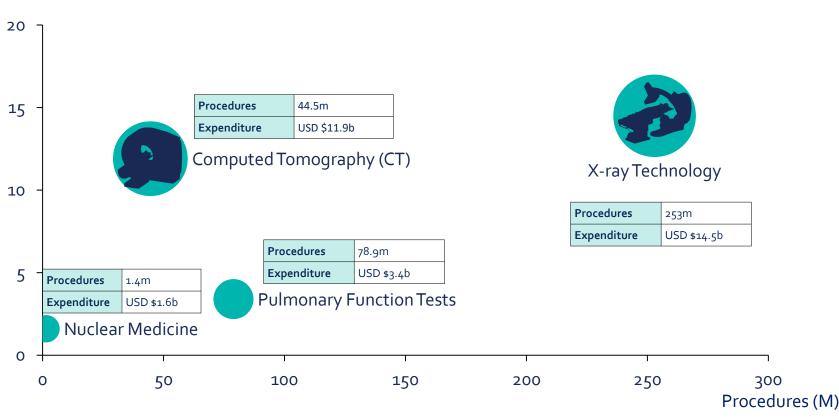
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# Global respiratory diagnostic market valued at US\$31.4 billion per annum

# Four existing lung diagnostic technologies account for 99% of all lung scans:

Expenditure (USD \$B)



Country	Spend (\$USD)	Procedures	
U.S.A	13,716M	73.5M	
Others	4,964M	59.8M	
Germany	2,678M	20.3M	
Japan	1,905M	22.8M	
China	1,851M	101.6M	
UK	1,351M	8.9M	
France	1,191M	10.2M	
Spain	78oM	8.4M	
Italy	681M	8.5M	
Canada	606M	8.oM	
South Korea	450M	6.8M	
Turkey	346M	16.1M	
Australia	285M	5.3M	
India	276M	25.3M	
Switzerland	197M	1.2M	
Israel	69M	1.1M	

378 million global respiratory diagnostics tests performed annually 1

# Current lung diagnostics are failing us

Lung health screening (COPD, silicosis, black lung, lung cancer)



- COPD 4th largest cause of mortality in world1
- Silicosis 600,000 Australian workers exposed to silica dust per annum

Unexplained dyspnoea (shortness of breath)



- \$12.2bn cost of breathlessness in Australia<sup>2</sup>
- 9.5% of Australians have clinically relevant breathlessness

<sup>2</sup>The health and economic burden of breathlessness, Australia, 2019: a national survey

Anthony P Sunjaya<sup>12</sup> , Leanne M Poulos<sup>3</sup>, Gian Luca Di Tanna<sup>14</sup> , Thomas Lunq<sup>1,5</sup>, Guy B Marks<sup>6,7</sup>, Helen K Reddel<sup>3,6,8,9</sup>

# **Burn Pits & DRRD** (Deployment-related Respiratory Disease)



- >6million service personnel exposed to airborne toxic hazards<sup>3</sup>
- No standard diagnostics detecting presence or absence of DRRD

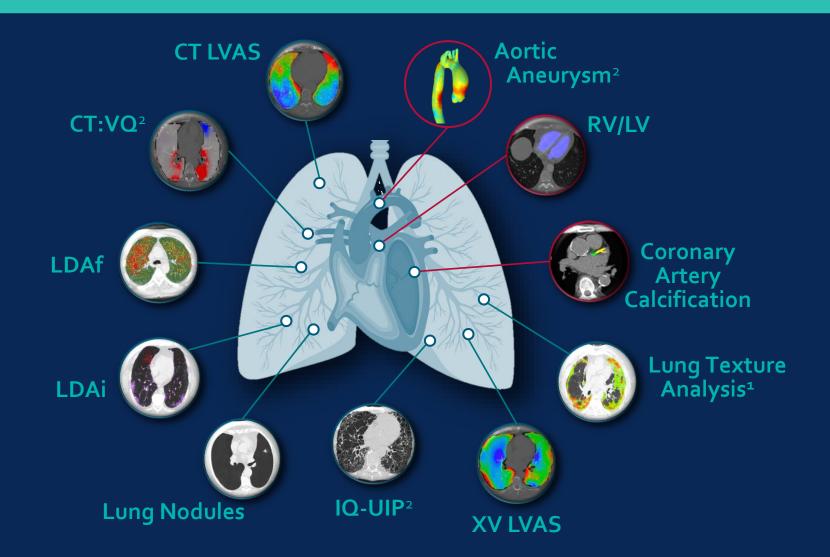
<sup>3</sup> publichealth.va.gov/exposures/burnpits/index.asp

# Comprehensive chest diagnostics product suite















# A complete lung health solution

# **Pulmonary Structure**



# Lung Density

Emphysema, HAA, Fissures



# Lung Texture\*\*

ILD's / Fibrosis



IQ-UIP\*\*\*

**IPF** Screening



# Airway Analysis<sup>^</sup>

Airway morphology



# Lung Nodules\*

Lung Cancer (partner solution)

# **Pulmonary Function**



# XV LVAS®x

Dynamic Ventilation
Analysis (Fluoro)



### CT LVAS™\*

CT-based Ventilation
Analysis



### **CT VQ**\*\*\*

Next Gen VQ (Ventilation + Perfusion)



# Functional LDA\*

Air Trapping + Emphysema

### Cardiovascular



### CAC\*

Coronary Calcification/Heart Disease



### PH Assessment

Hypertension (RV/LV, MPA, Pa/Ao)



# Volumetric Diameter Mapping<sup>^</sup>

Aortic Aneurysm Analysis



# Pulmonary Vessel

FUTURE: Vascular morphology

### **Total Solution**

# Combined product suite

Enabling access to key imaging modalities: CT, X-ray

### Market access

in USA, EU, and AU

# **Established networks**

With market distributors

## **US** reimbursement

for XVLVAS®, CT LVAS™ & LDAf (Medicare)

# Expanded product pipeline

CTVQ + IQ-UIP

# Solving the clinical conundrum for doctors across multiple care areas

# Clinical Conundrum in Lung Assessment

A mismatch between clinical tests and imaging often occurs, whereby anatomic findings can overlap, lag, or precede clinical symptoms.

Need **structural** and **functional** data/information to make a better, informed clinical decision.

Not solved by historical standard of care testing (Spirometry, X-ray, CT scans)

# Clinical Tools Needed to Solve the Conundrum

Functional lung analysis providing visual qualitative and quantitative assessment of ventilation







**Structural** lung analysis providing visual qualitative and quantitative assessment of lung **anatomy** 



# Applications for Technologies in Clinical Practice

### Unexplained dyspnoea

A complex clinical presentation Is it Lung related?

Is it Cardiac related?

Is it other causes or psychosomatic?

Example technology

CT LVAS™

CAC

### **Restrictive diseases**

DRRD / CB Deployment-related respiratory disease/ Constrictive bronchiolitis | ILD Interstitial Lung Disease | IPF Idiopathic pulmonary fibrosis | Dust Exposures — Silicosis, asbestosis, pneumoconiosis XV LVAS® LDA LTA IQ-UIP

### **Obstructive diseases**

**COPD** Chronic Obstructive Pulmonary Disease— Emphysema, Chronic Bronchitis | **Asthma | CF** Cystic Fibrosis LDA CT LVAS™ XV LVAS®

# Intervention and pharmaceutical

Lung Reduction therapies | Disease progression / regression | Compliance

LDA IQ-UIP CT: VQ XV LVAS® LTA

# FY24 achievements – building the foundations

# Acquisition of Imbio

# Engagement across the VA

- Congressional support to evaluate DRRD
- Continued support and engagement with BurnPits 360
- ➤ Imbio contract for research evaluation with VA Houston

- Focus on lung structurecomplementaryproduct offering
- Commercial synergies, including licensing & product extension, and expanded opportunity with the VA
- ➤ Strong product pipeline

# US reimbursement & commercialisation

- ➤ US Medicare reimbursement – 65m+ people; US\$299 procedure for XV LVAS® and \$650.50 For CT LVAS™
- ➤ Facilitates access across community care networks in the US driven by commercial CT LVAS™ agreements in the US
- Outpatient practices in Detroit & Memphis sign agreements to perform XV LVAS® scans

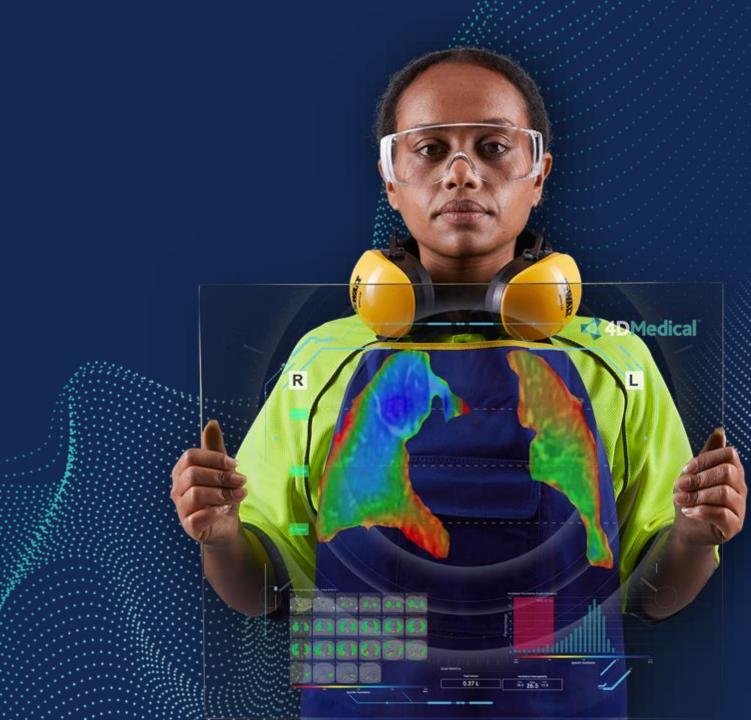
# **Expansion in AU**

- Commercial agreement signed with Jones Radiology in Adelaide
- Additional radiology clinics on-boarded to diversify options for referrers and expand coverage across Australia
- ➤ Initiated GP marketing campaign to drive increased awareness and adoption, comarketing with providers to targeted referrers

# **Philips**

- Master Reseller Agreement executed
- Significant expansion of commercial coverage across multiple sectors in the large US market (Government and commercial payers)
- ➢ Roll out in progress, led by Government accounts and Enterprise Informatics (PACS & AI) business units, and supported by through capital equipment teams
- Revenue anticipated in CY2024

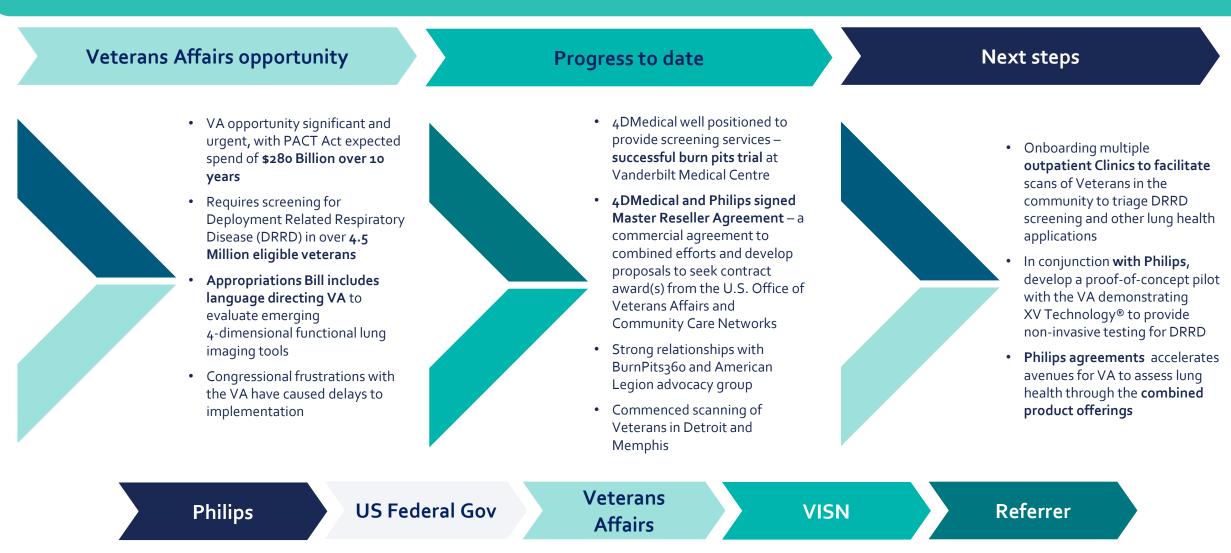
# Commercial Update



# Commercialisation strategy

	US Government	US Commercial	Global Partnerships	Australia
Enablers	Ph	ilips	Olympus	I-MED
	Exclusive	Non-exclusive	Genentech	Jones Radiology
	Reimbursement		Nuance/Aidoc/Blackford	Integral Diagnostics
Sector	Veterans Affairs	Community-based Clinics	Global Pharma Companies	Community Clinics
	Department of Defense	Academic institutes	Global Device Companies	Radiology Networks
	Federal & State facilities	Health Systems (IDN's)		Public Hospitals
		Radiology Networks		National Programs
Rationale	Unmet need to solve for respiratory issues, including deployment-related respiratory diseases (DRRD)	Largest lung diagnostic market with huge economic scale	Large burden of data needed where our technologies can accelerate progress	Early adoption of core technologies in key players to build influence and scale
	PACT Act - US\$280 billion commitment over ten years, covers numerous respiratory illnesses as presumptive conditions. Healthcare eligibility to 3.5 million post-9/11 veterans. Bi-partisan support of veteran care. Philips has long established and significant existing partnerships	Reimbursement rates established covering 4,000 facilities. Over 14,5k CT scanners deployed. Shortage of clinicians creates opportunity for Al tools and faster clinical insights	Custom imaging biomarker development and patient selection tools shorten clinical trial time and expense in the multi billion-dollar pharma development sector. Al marketplaces increase access and coverage through deployment capabilities	Australian radiology is innovative and readily accessible through community practices, networks and hospitals, with a high proportion of CT Scanners (33.9%). Chest CT procedures through Medicare = 330k per annum. Proximity and collaboration with our development team speeds innovation.

# **VA** opportunity



# US reimbursement – XV LVAS® and CT LVAS™

We addressed three key components of

reimbursement

**Code** – describing the procedure

Cat III CPT Code

**Coverage** – defining eligibility for payment

Medicare (65 million people)

**Payment –** assigning a monetary value

XVLVAS® U.S. \$299 rate CTLVAS<sup>TM</sup> U.S. \$650 rate

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We engaged with key industry bodies for support and approval

- ✓ American Medical Association CPT Panel and Advisors
- ✓ Radiology, Respiratory, Pulmonary Societies (RSNA, ATS)
- ✓ Providers & Key Opinion Leaders (KOL)
- ✓ Payor Medical and Clinical Directors
- ✓ Industry advocates
- ✓ Health TEC organisations
- ✓ Key Hospitals
- ✓ Patient advocacy groups
- ✓ Payor Actuary, and Actuarial Health Economics

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CMS reimbursement was approved

- Clinical data demonstrated improved outcomes in patient case and cost of care
- ✓ Utilisation of the technology showed payor coverage and evidence of reimbursement



Reimbursement, CPT codes & FDA clearance all granted from our collected clinical evidence is supporting commercial conversations with large-scale Radiology Networks, taking our AU experiences with the likes of I-MED to the US market

# Philips Update



# Philips overview

# Philips Healthcare – portfolio of businesses<sup>2</sup>

€18.2bn in sales (2023), ~70% in #1 or #2 positions; ~40% sales recurring revenue; ~70k employees 42% North America, 21% Western Europe, 9% other mature geographies, 28% growth geographies

# Diagnosis & treatment:

~50% of sales (2023 full year)

# Diagnostic imaging

Top 3 player

### Ultrasound

#1 Cardiac

### Image Guided Therapy

#1 Systems & devices

### Connected care:

~30% of sales (2023 full year)

# **Enterprise Informatics**

#1 Imaging PACS & interoperability

### Monitoring

Sleep & Respiratory

Care

#2 Globally

#1 in Hospital #1 in Ambulatory

### Personal health:

~20% of sales (2023 full year)

### **Personal Health**

#2 Oral Healthcare #1 Male Grooming #2 Infant Feeding

Systems, smart devices, software and services, powered by AI-enabled informatics

Supporting precision diagnosis and minimally invasive treatment in a growing number of therapeutic areas such as cardiology, peripheral vascular, neurology, surgery, and oncology

Ambulatory, home-based and in-hospital monitoring and workflow solutions fueled by advanced interoperability and patient data insights

Connecting patients and caregivers across care settings, delivering clinical, operational and therapeutic solutions

Broad range of consumer solutions to support people in proactively managing their health and wellbeing

# Market-leading capabilities integrating platforms, informatics, and services

- 1. Source: Philips website: https://www.philips.com/a-w/about
- 2. Source: Philips Investor Centre: <a href="https://www.philips.com/a-w/about/investor-relations.html">https://www.philips.com/a-w/about/investor-relations.html</a>



# Philips reseller agreement

### The Reseller Agreement Philips has long established and significant existing partnership with both the VA and DoD, spanning 45 years **Background** • 50% of VA clinics using Philips imaging solutions, and 35% of critical care information systems in the VA • >6 million Veterans • 5-year agreement Reseller • Exclusivity for government and non-exclusivity for non-US Govt:government/commercial agreement VA & DOD • Minimum performance hurdles: post first year, strongly Scope & key presents multiple growing minimum revenue targets to maintain exclusivity terms across the term opportunities • Transfer pricing – Philips to earn margins of 20% on end customer sales of XV LVAS®, 30% on CT LVAS™, and 35% with VA and US on Imbio products Commercial per annum<sup>1</sup> · Access through the US commercial team with excess of 250 sales personnel within the appropriate business units • Working with the Government, Enterprise Informatics (PACS and AI), Image Guided Therapies (Fixed and Mobile Execution US ~\$5.7 billion2 c-arms) and Computed Tomography business units. Commercia - Agreed support with Staffing, marketing commitments, and incentives

# The opportunity

 Philips & 4DMedical to work together to support the need for scalable, non-invasive lung screening in support of PACT Act

- PACT Act: \$280 billion commitment
- Positions portfolio to provide actionable insights to VA physicians treating patients with chronic lung disease
  - Serving entire VA population
  - Veterans 3x rates of chronic lung disease compared to general population
  - Current VA healthcare budget >\$300 billion
- US commercial opportunity significant
- 10.9 million Thoracic CT scans performed in 2019 on 14,500 scanners, driving spend of
- Reimbursement established:
  - CT LVAS™ \$650.50 per scan;
  - XV LVAS® \$350.00 per scan

<sup>1.</sup> U.S. Department of Veterans Affairs

<sup>2.</sup> Figures adapted from Frost and Sullivan Report 2020 USD \$31.3 billion global spend annually (table)

# FY25 outlook



# Product update

# Major disruptive breakthroughs on the horizon in large market segments



"CT:VQ" represents a significant disruptive breakthrough in respiratory imaging workflow transitioning from nuclear to radiology, improving access to both perfusion and ventilation status for clinicians at better operating efficiencies

Disrupting Nuclear Medicine VQ market estimated opportunity >\$1B

Tapping into the multi billion-dollar pharmaceutical development sector

IQ-UIP is an AI algorithm that identifies patients with radiological usual interstitial pneumonia (UIP) pattern, the first-line diagnostic for Interstitial Pulmonary Fibrosis (IPF). Imaging biomarker development and patient selection tools shorten clinical trial time and expense

# FY25 outlook

### **US Government**

- Veterans Affairs
- Department of Defense
- Federal and State Facilities and stakeholders

# **Philips**

- Activation of Agreement creates large commercial coverage across multiple sectors in US healthcare
- Enabler for commercial success in the US

### **US Commercial**

- Adoption across Community and Radiology Networks
- Contracts with Academic institutes and Health Systems



# Research and Product Development

- CT:VQ FDA submission and approval
- IQ-IUP FDA Submission progressing with Breakthrough
- XV Scanner<sup>TM</sup> deployments generate clinical evidence and workflow gains

### **Australia**

- Continue to build partnerships within respiratory, cardiology and General practice
- Australian National Lung Cancer Screening Program preparation

# **Global Partnerships**

- Contract with Global Pharma / Device companies
- Al Marketplace vendors

# **Executive team**



Dr ANDREAS FOURAS PhD

**Managing Director and CEO** 

Award-winning aerospace engineer and innovator responsible for the conception and development of 4DMedical's core technologies.



**NAOMI LAWRIE General Counsel & Company** Secretary

Experienced ASX-listed company secretary and general counsel with significant legal experience, including in relation to health and technology businesses.



**MATT TUCKER** 

**Chief Commercial Officer** 

Seasoned executive leader, board member and healthcare director, with combined commercial leadership and clinical experience, achieved across global organisations.



**SIMON GLOVER** 

**Chief Financial Officer** 

Experienced ASX-listed MedTech company CFO with significant corporate experience in relation to commercialisation, and a track record of driving revenue growth.



**Dr GREG MOGEL MD** 

**Chief Medical Officer** 

A practicing radiologist and physician executive with a long career in medicine and engineering serving in government, academia, and industry. A proud veteran, he previously held multiple leadership roles at Kaiser Permanente.



**RACHAEL TENKATEN** 

Senior Vice President, Product

Aerospace engineer with experience gained through transformative biomedical, aerospace and defence technology projects.



Dr AIDAN JAMISON PhD

Senior Vice President, Engineering

With a PHD in medical imaging and a Masters of Law (IP), Aidan is an accomplished technical expert leading the R&D of the Company's product pipeline.



**DAVID HANNES** 

Senior Vice President, Global **Business Development** 

David brings nearly 20 years of experience across Commercial Operations, Business Development and Strategy in both Fortune 500 and start-up medical device business to the Imbio team.



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