



# The future of lung health

4DMedical Limited (ASX:4DX)  
Acquisition & Capital Raising Presentation  
December 2023



# Executive Summary

- **4DMedical is making significant progress in executing on its commercialisation strategy**, with particular progress made in the US
  - Granted US\$299 reimbursement benefit for XV LVAS<sup>®</sup> from the US Centers for Medicare and Medicaid Services (CMS), accelerating the utilisation of XV LVAS<sup>®</sup> under the existing Category III CPT code
  - Received FDA clearance for CT-based ventilation product (CT LVAS<sup>™</sup>), increasing the accessibility of functional lung imaging in the US and expedites the commercialisation of the CT:VQ technology
  - Executed SaaS contracts outpatient practices in Detroit and Memphis to perform commercial XV LVAS<sup>®</sup> scans, illustrating the increased uptake from the reimbursement benefit and pathway to additional revenue
  - Announcement of Memorandum of Understanding with Philips, to expand federal and commercial sales opportunities, particularly within the US Veterans' Health Administration, a major addressable market for 4DMedical's XV Technology<sup>®</sup>
- In addition to 4DMedical's ongoing operational success, the **Company has reached an agreement to acquire Imbio, a complementary diagnostic business**
  - Strong commercial synergies with established customer base and recurring revenues, complementary products, and adjacent markets
  - Provides 4DMedical with capabilities in lung structure diagnostics, enabling a comprehensive offer to clinicians
  - Imbio's AI-driven technology includes a suite of 4 FDA-cleared diagnostic products, accelerating the pathway to 'owning the lung'
  - Accelerates 4DX's product development pipeline and commercialisation of XV Technology<sup>®</sup> into established Imbio contracts
  - Acquisition consideration of US\$25 million (approximately A\$38.5 million)<sup>1</sup>, in addition to a contingent earn out of US\$20 million in 4DMedical scrip (subject to shareholder approval)
  - Imbio CY2023 revenues forecast US\$3.0m (9 months actuals + 3 months forecast), at +84% gross margins
  - Imbio CY2024 revenues forecast US\$6.3m, growing 112% year on year, underpinned by signed contracts and significantly expanded pipeline
  - 4DMedical management expects the Imbio business to be cashflow positive in its first full year of operations
- Upfront consideration for acquisition to be funded by **capital raising, raising A\$35.0 million**
  - Issuing approximately 44.3 million shares at an Offer Price of A\$0.79 representing a discount of -17.3% to the last close of A\$0.955 on 6 December 2023

# 4DMedical Update

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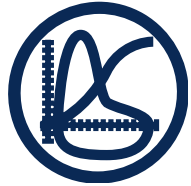


# XV Technology<sup>®</sup> advantages

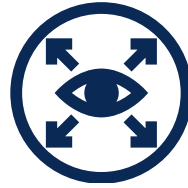
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**New medical insights**  
Functional insight of  
spirometry at a regional level



**Improved safety**  
Comparable radiation  
dose to X-ray



**Superior results**  
High-detail resolution  
of a CT scan



**Patient outcomes**  
Improved clinical  
outcomes



**Time efficient**  
Faster, more efficient  
testing using existing  
hardware



**Low cost**  
Competitive pricing  
below incumbent  
technologies



XV Technology<sup>®</sup> 4D view of lung performance

# Material acceleration in commercialisation across 2Q FY2024, with Imbio acquisition a step change

*Objective: Become the standard of care for lung diagnosis across both ventilation and perfusion*

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## CMS (Medicare) Reimbursement

- US Medicare reimbursement – 65m+ people
- Accelerates adoption of XV Technology® across Medicare network
- US\$299 per procedure
- Achieved well ahead of schedule

## FDA approval of CT:LVAS™

- US clearance for CT:LVAS™ in addition to XV LVAS®
- Expands access to XV Technology® by leveraging CT hardware in US
- De-risks regulatory pathway for CT:VQ

## SaaS contracts in Detroit & Memphis

- In response to CMS reimbursement, 4DMedical wins SaaS contracts
- Outpatient practices in Detroit & Memphis sign agreements to perform XV LVAS® scans

## Philips MoU

- Commercial expansion agreement of XV Technology®
- Prominent operations with VA
- 50% of VA clinics use Philips imaging systems
- Focus on screening solution for Veterans exposed to burn pits

## Imbio Acquisition

- Focus on structure of lung - complementary product offering
- Commercial synergies with scalable solution and recurring revenue
- Cost synergies
- Licensing & product extension
- Established VA relationships
- Combined expertise will assist in 'Owning the lung'

Recent developments validate commercialisation strategy:

1. Regulatory approval with FDA enable greater patient access for CT LVAS™, de-risks CT:VQ
2. Medicare reimbursement facilitates adoption and utilisation
3. SaaS contracts - proof points of utilisation
4. Philips MoU provides ability to leverage VA opportunity
5. Imbio adds complementary product suite + recurring revenue

# FY24 target catalysts

## Commercialisation

- VA funded trial
- 2<sup>nd</sup> Authority to Operate awarded enabling National Authority to Operate
- Extend Department of Defense engagement
- Execution of commercial agreement with US based academic medical center
- Expansion in ANZ
- Rapid expansion of Philips partnership

## Clinical

- Commencement of XV Scanner trials
- Publication of peer reviewed journals

## Regulatory

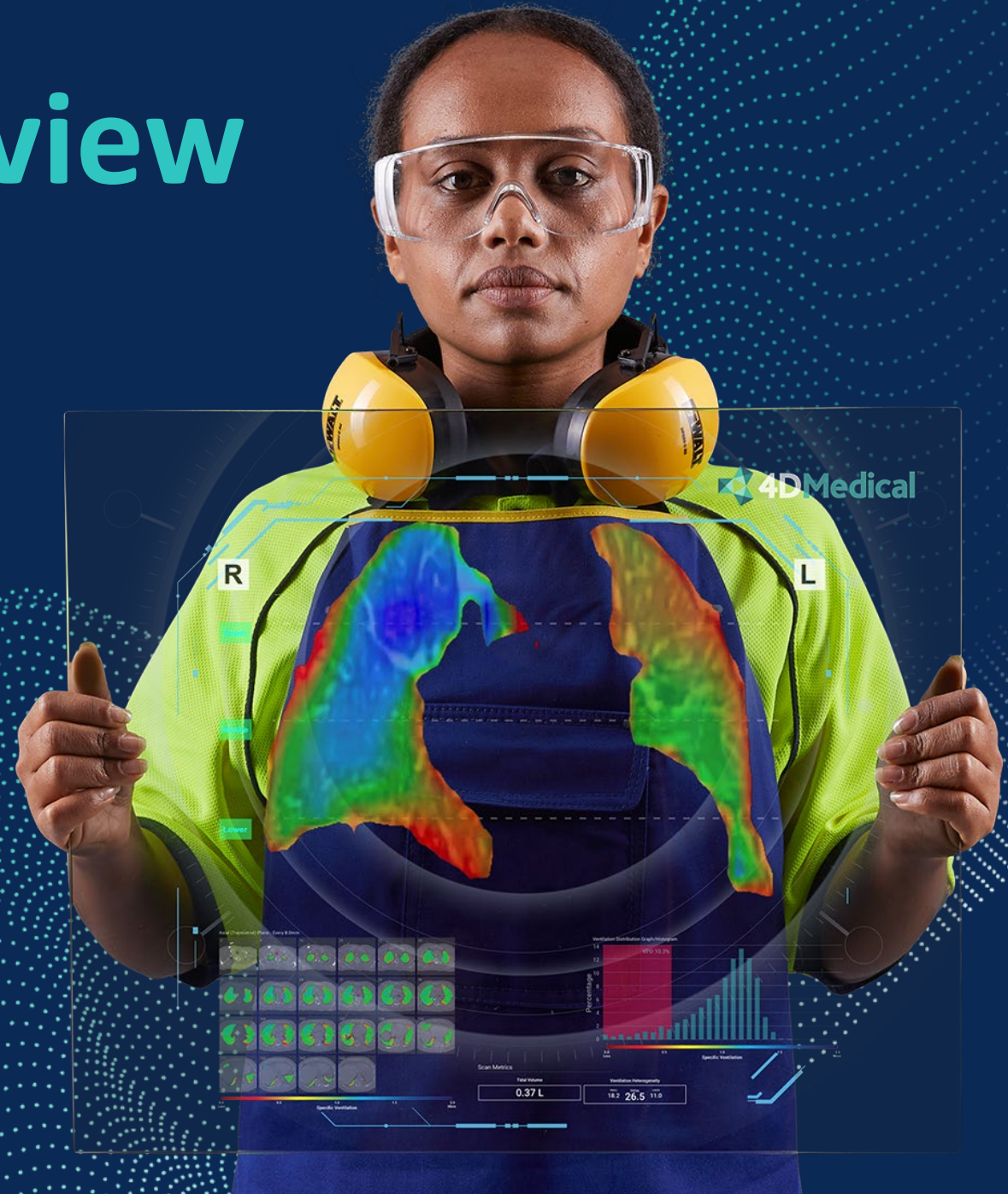
- FDA submissions for CT:VQ
- FDA submissions for XV Scanner
- Funding and budget appropriation for PACT Act



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# Transaction Overview

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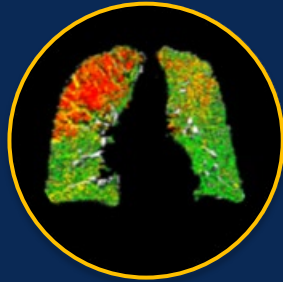
# AI solutions that span lung and heart conditions affecting 1 in every 5 adults

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## Lung Density Analysis

*COPD, Asthma, Pneumonia, BOS*

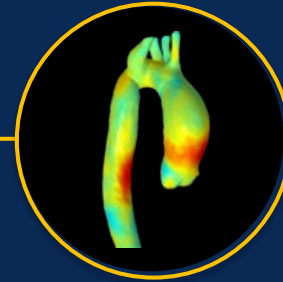
FDA CE



## Aortic Aneurysm

*Incl. patented VDM*

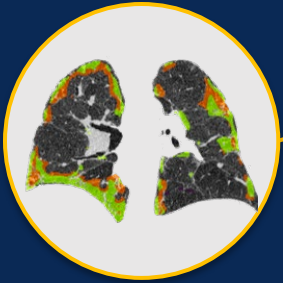
FDA - TBD CE - TBD



## Lung Texture Analysis

*ILA's, ILD/IPF drug-induced fibrosis*

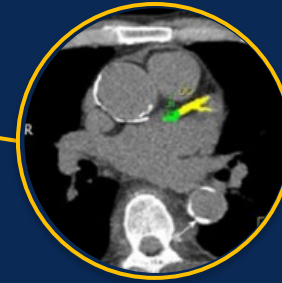
FDA 2024 CE



## CAC Scoring

*CAD/Heart Disease*

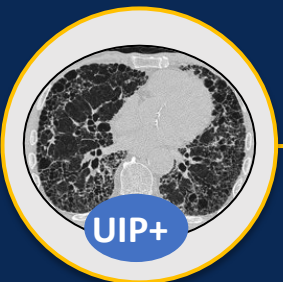
FDA CE 2023



## IQ-UIP

*automated UIP/IPF screening*

FDA 2024 CE 2024



## Lung Nodules

*Lung Cancer (Partner Solution)*

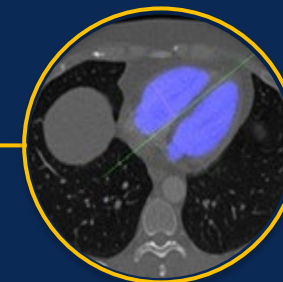
FDA CE



## RV/LV and PAH Analysis

*Pulmonary Embolism, Pulmonary Hypertension*

FDA CE





# Imbio today



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Recognised leader in Lung & Cardiothoracic imaging AI

Forecasted CY2023 revenue of US\$3.0M, with strong track record of growth

4 FDA-cleared devices, 4 EU CE marked, more in process

KOL adoption & support

U.S. & international distributors

Pharma and device partnerships in companion diagnostics (CDx)

## Two major channels for 'Go-to-market'

### Companion Diagnostics (CDx)

- for Med Device & Pharma

- Partnerships to grow therapeutic franchises through imaging-based screening & qualification of patients
- Business model: per-patient or per-site fees paid by device/pharma
- **US\$4B** therapeutic markets for current partnerships

Current Partners:

**OLYMPUS**  
Endobronchial Valves

**Genentech**  
IPF/Fibrotic Therapies

**INARI**  
PE Devices

### General Radiology

- for Healthcare Providers

- Population Health programs to grow clinical care service lines while improving productivity & quality
- Business model: US\$20-\$50K annual subscriptions for AI solutions
- **US\$1B** radiology AI market with 16% CAGR

Channel Partners:

**NUANCE** Microsoft

**aidoc**

# Acquisition Highlights

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## Function + Structure 'Owning the lung'

Additional 4 lung diagnostic products, resulting in a full suite of products providing a comprehensive lung offering

## Commercialisation

Deliver XV Technology® into established Imbio contracts, accelerating US commercialisation

## Growth opportunity

Potential to provide screening program offerings across COPD, heart disease and lung cancer\* in AU and US markets

## US Veterans Health Administration

Established agreements; Complementary relationships; Compelling product range for comprehensive diagnostics for screening programs

## Revenue contribution from long-term contracts at high gross margin

CY2024 expected revenue contribution US\$6.3 million; Adjacent markets and customers in pharma and device  
Gross margin +84%

## Strong strategic benefits

Revenue and cost synergies; Complementary products in adjacent markets & customers; Extends reach of 4DX's products; Platform and technology efficiencies

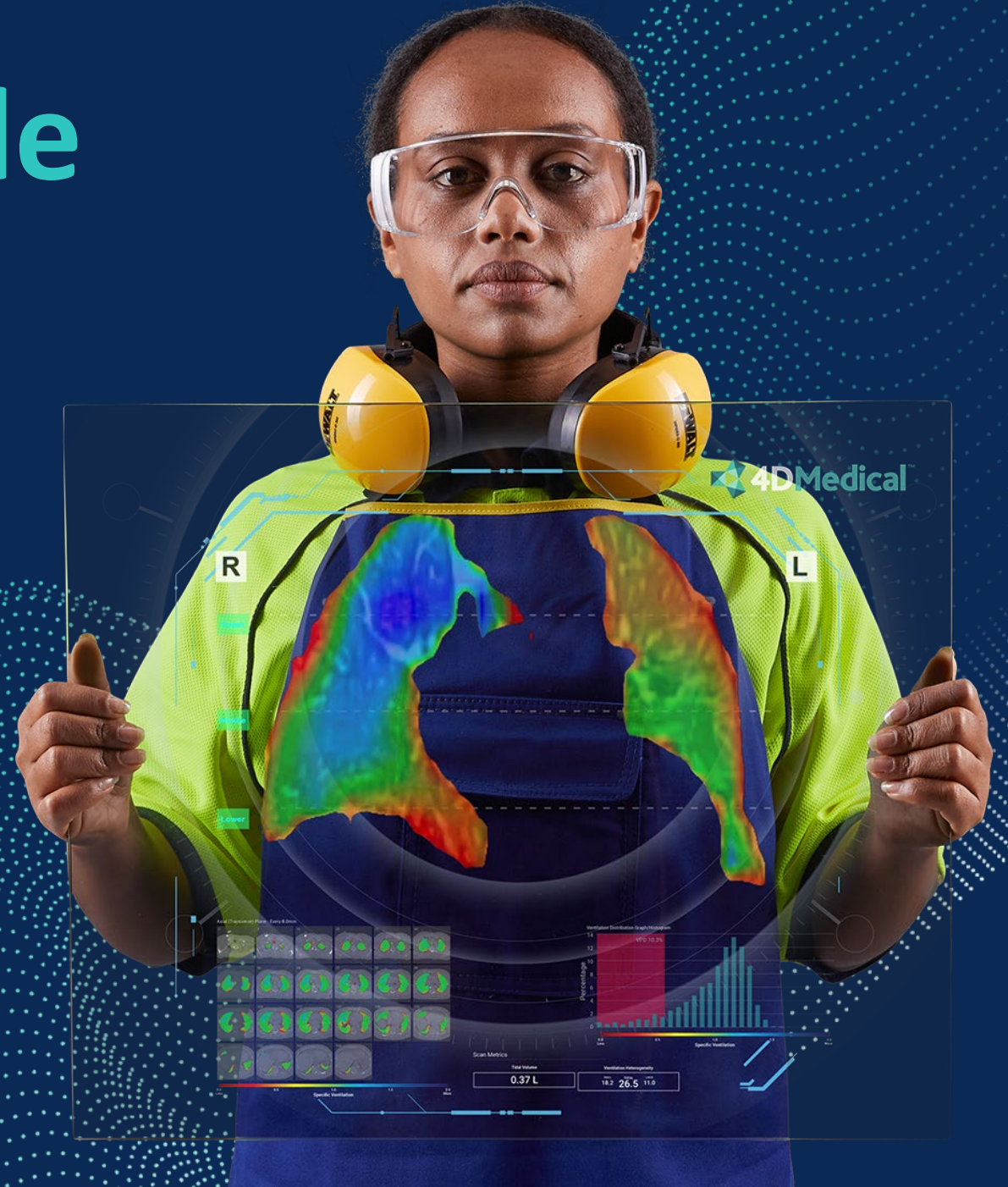
# Transaction summary

## *Binding agreement to acquire Imbio Inc. for a mix of upfront cash consideration and contingent consideration*

Transaction details	<ul style="list-style-type: none"><li>4DMedical to acquire Imbio Inc. (Imbio), a recognised leader in lung imaging AI, for an upfront consideration of US\$25 million and up to US\$20 million in contingent consideration. Subject to obtaining shareholder approval, 4DMedical intends to settle the contingent consideration in the form of new scrip.</li></ul>
Seller and acquisition structure	<ul style="list-style-type: none"><li>Imbio is to be acquired from Invenshure, LLC, Invenshure Fund I, LP and Invenshure Fund II, LP (collectively, Invenshure) and Imbio's other equity holders (collectively, the Sellers). Invenshure currently holds approximately 63% of equity interests in Imbio.</li><li>The acquisition is structured as a merger. Imbio Inc. will be merged into a new wholly-owned subsidiary of 4DMedical US Inc. On Completion, Imbio will thereby become a wholly-owned subsidiary of 4DMedical Limited.</li></ul>
Upfront consideration	<ul style="list-style-type: none"><li>US\$25 million (approximately A\$38.5 million)<sup>1</sup> in cash will be payable upfront on completion of the acquisition by 4DMedical to the Sellers.</li></ul>
Summary of milestones for contingent consideration	<ul style="list-style-type: none"><li>CY2024 revenue growth – an amount equal to four times the incremental revenue growth (over US\$3.5 million) of Imbio products in CY2024 from forecasted CY2023 revenue, up to a maximum earnout payment of US\$10 million.</li><li>CY2025 revenue – an amount equal to (1) the amount by which CY2025 revenue exceeds US\$4.0 million multiplied by (2) 0.812, up to a maximum earnout payment of US\$5 million.</li><li>New Product FDA Clearance by 31 December 2025 – an amount equal to \$US5 million if Imbio were to obtain FDA clearance by 31 December 2025 for any one of Imbio's (1) IQ-UIP product, (2) Aortic Aneurysm product, or (3) next generation PE/PAH product.</li><li>Please see Appendix A for full details.</li></ul>
Financial impact	<ul style="list-style-type: none"><li>Expected to be revenue accretive in the first full year of ownership – incremental A\$5 million in FY2023.</li><li>Gross margins +80% in FY2023.</li><li>Positive impact on cashflow in first full year of operations.</li></ul>
Acquisition timing	<ul style="list-style-type: none"><li>The Merger Agreement was signed on 7 December 2023 and is expected to complete on or about 15 December 2023, subject to satisfaction or waiver of all conditions to completion.</li></ul>

# Strategic Rationale

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# Strategic rationale

## Accessing capabilities in lung structure to build compelling offer and ‘owning the lung’

1

### ***Significant growth opportunities in place***

- Established contracts allows acceleration with device and pharma companies needing lung imaging analysis
- Complementary products allow for both structural and functional analysis, providing a comprehensive, compelling offering to clinicians

2

### ***Complementary products – combined technology leadership position***

- XV Technology® current and pipeline software products provide regional quantification of lung function using existing imaging equipment – leader in lung function analysis
- Imbio deploys AI solutions to assess lung structural integrity, with a focus on COPD and Fibrosis, from CT scans –clinical leader in lung structure analysis
- Subscription or licensing of software products are available from both companies to serve radiology facilities

3

### ***Company fit***

- Commercial synergies evident with Imbio’s strength in contracting with device and pharma companies complementary to 4DMedical’s direct clinician commercial opportunity
- Alignment exists in many aspects of the team structure, infrastructure, including IT and software platforms

4

### ***Licensing of product extensions***

- Olympus – License software used in the feasibility and planning of treatment of COPD patients with endobronchial Spiration Valve System
- Genentech – License and joint collaboration development agreement to provide CT scan analysis (UIP) for pulmonary fibrosis therapies
- Riverain Technologies - bilateral distribution agreement providing Imbio access to Riverain’s Lung Nodule detection software

5

### ***Customers (including VA)***

- Both companies target customer segments are providing clinicians insights into Pulmonary health through Diagnostic Imaging modalities
- Assessment of lung structure in diagnosis and treatment planning are applicable for both companies with synergistic offerings
- Imbio is actively engaged with VA in textural analysis to help detect Interstitial Lung Disease (ILD) in their lung cancer screening program

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# Combined software suite

Imbio brings increased breadth of product offering to CT modality

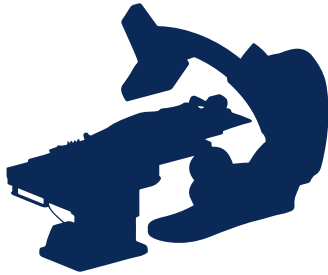


## Functional diagnosis

**XV LVAS<sup>®</sup>**  
(ventilation)

**CT LVAS<sup>™</sup>**  
(ventilation)

**CT:VQ**  
(ventilation / perfusion)



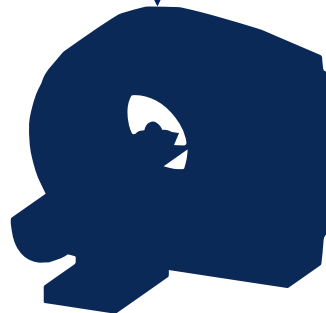
### X-ray

Existing hospital & radiology hardware



### XV Scanner

4DMedical hardware utilising 4DMedical software



### CT

Existing hospital & radiology hardware



## Structural diagnosis

**Lung Density Analysis**  
(LDAi, LDAf, LDA+)

**Automated ILD UIP**  
(IQ - UIP)

**RV/LV and PAH Analysis**

**CAC Scoring**

**Lung Nodules**

Imbio software provides structural diagnosis using CT scanners, significantly increasing 4DMedical's product offering for this modality

Extends reach 4DMedical reach into CT<sup>1</sup>:

- 44.5m procedures
- US\$11.9b expenditure

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Image acquisition  
4DMedical  
software offering  
modality



# Growth opportunity:

*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** to make a better, informed clinical decision.
- Not solved by historical standard of care testing (Spirometry, chest 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 (shortness of breath)

- Complex clinical presentation
  - Is it Lung related?
  - Is it Cardiac related?
  - Is it other causes or psychosomatic?

### Restrictive diseases

- Deployment-related respiratory disease (DRRD) - Constrictive bronchiolitis (CB)
- Idiopathic pulmonary fibrosis (IPF)
- Interstitial Lung Disease (ILD)
- Dust Exposures - silicosis, asbestosis, pneumoconiosis (Coal workers' / Hard Metals fibrosis/ chemical workers')

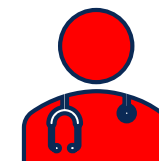
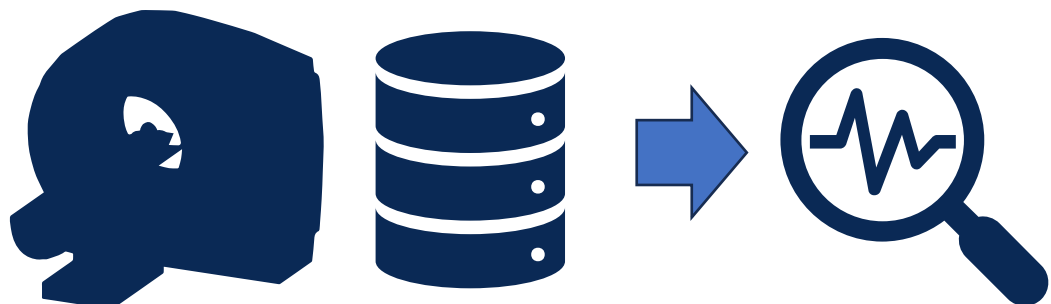
### Obstructive diseases

- Chronic Obstructive Pulmonary Disease (COPD) – Emphysema, Chronic Bronchitis
- Asthma
- Cystic Fibrosis (CF)

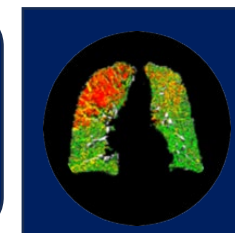
# Growth opportunity:

## Extending Screening Solutions in multiple care areas

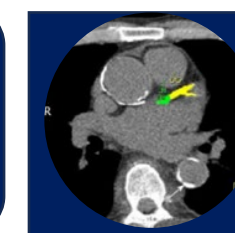
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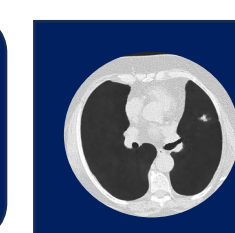
**COPD:**  
#4 cause of death in the U.S.<sup>1</sup>, COPD affects 1 in 15 adults<sup>1</sup>



**Heart Disease:**  
#1 cause of death in the U.S.<sup>2</sup>, CAD affects 1 in 20 adults<sup>2</sup>



**Lung cancer:**  
#1 cause of cancer death in the U.S.<sup>3</sup>



- All 3 conditions are detectable from a single patient chest CT
- All 3 conditions are critical findings in growing lung cancer screening
- All 3 AI devices (SaMD's) are FDA-cleared

All are targets for additional CDx partnerships

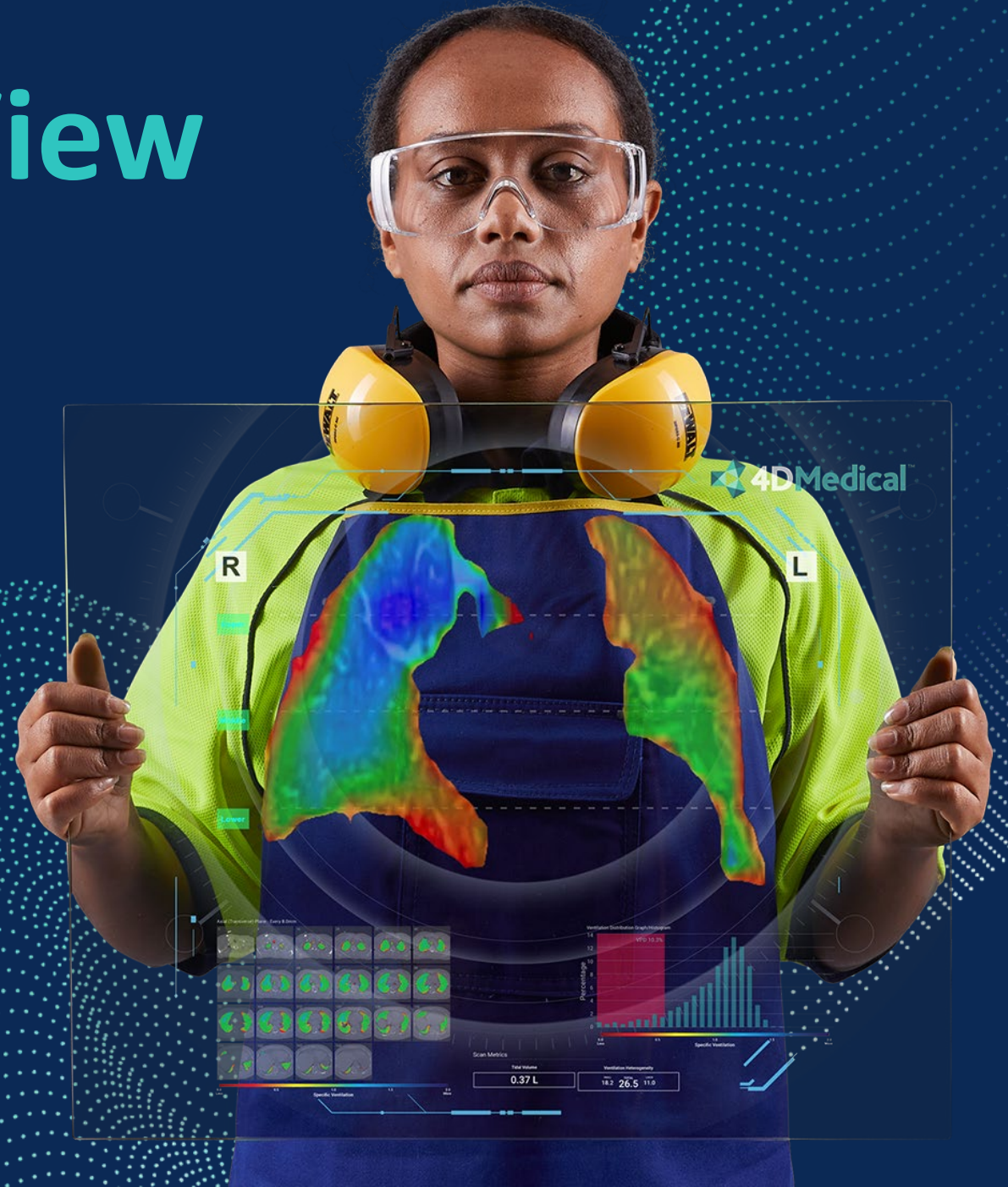


[1] Centers for Disease Control and Prevention: Basics About COPD, 2023; [2] Centers for Disease Control and Prevention: Heart Disease Facts, 2023; [3] Centers for Disease Control and Prevention, Lung Cancer Statistics, 2023



# Imbio: Detailed View

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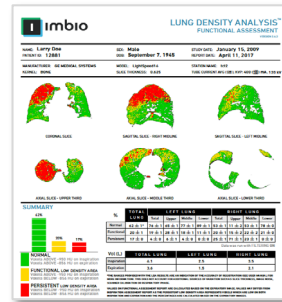


# Imbio at a glance

AI capabilities to detect, diagnose, and treat cardiothoracic conditions preemptively

Automated, condition detection, quantification and visualisation

Standard lung CT | Imbio AI Analysis



- Normal
- Early Disease
- Advanced Disease

Up to 50% of patients that Imbio identifies are not under active care

System-wide Patient Imaging

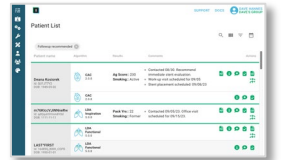
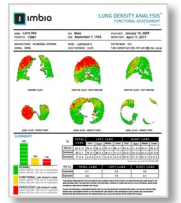
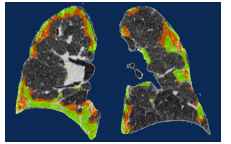
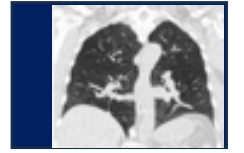
Early Detection and Referral for Care

1 Receive data

2 Apply AI

3 Results to Physicians

4 Patient Mgt Tools

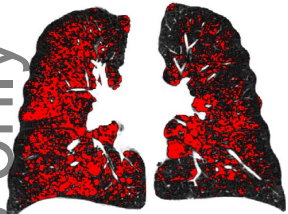


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# Imbio Technology sophisticated and scalable

## Clinical Algorithms – core products

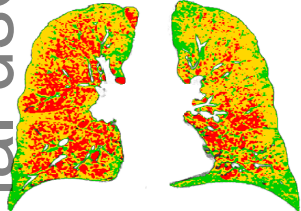
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### INSPIRATION ANALYSIS (LDAi)

for rapid detection & diagnosis of emphysema

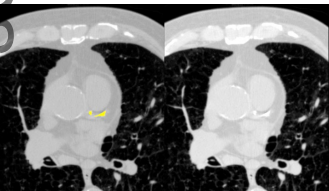
- Fully-automated assessment of areas of low attenuation (LAA, indicative of emphysema) and high attenuation (HAA) based on a single inspiratory chest CT



### AIR TRAPPING ANALYSIS (LDAf)

for a complete picture of COPD, and other density-evident conditions

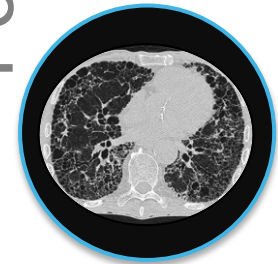
- Fully-automated, analysis providing a complete mapping of normal lung vs. areas indicative of air-trapping & emphysema



### CALCIUM SCORE (CAC Analysis)

is a fully-automated AI solution that detects, visualises, and quantifies coronary artery calcification from a qualifying chest CT scan

- CAC provides visualisations and reports for radiologists and cardiologists to rapidly and accurately determine the location and extent of calcification



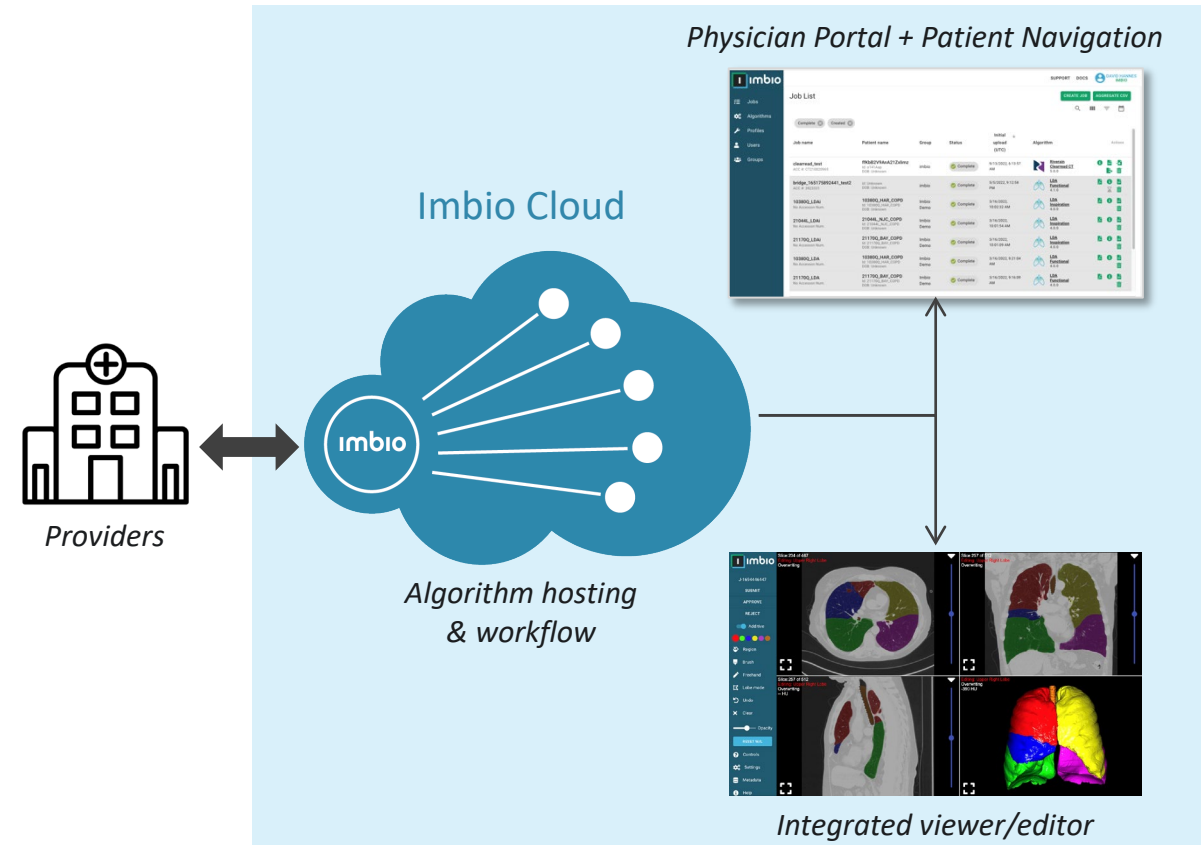
### AUTOMATED ILD UIP SCREENING (IQ-UIP)

a computer-aided software indicated for use in passively notifying interstitial lung disease (ILD) centres of radiological findings suggestive of radiological usual interstitial pneumonia (UIP)

- UIP received FDA Breakthrough Device notification November 14<sup>th</sup> 2023



## Imaging Platform



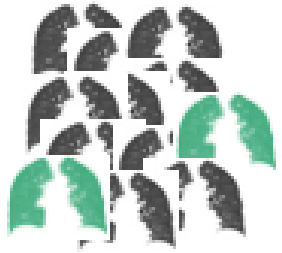
- AI Marketplace scalable solution, HIPAA and GDPR compliant
- White-label capability and customizable workflows for CDx partners
- Integrated imaging viewer, physician portal, and patient navigation tool

# Companion Diagnostics (CDx)

Why Pharma and Med Device needs Imaging AI

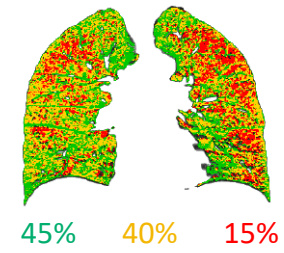
Companion imaging can grow device & pharma businesses by impacting clinical decisions across the entire course of patient care.

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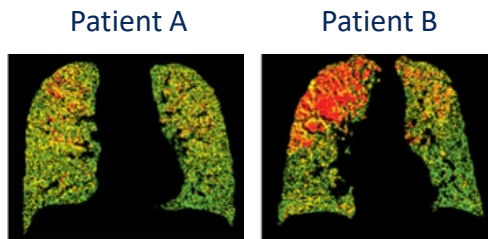
**Find more patients**  
Automated  
Screening

**Olympus SelectCT program**  
*Hospital CT database mining for COPD and candidates to triage for treatment*



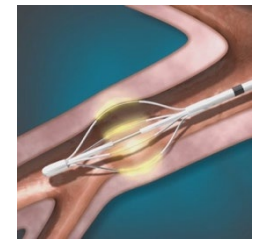
**Improve Accuracy & Staging**  
AI-enabled Diagnosis

**Imbio LDAi and LDAf**  
*Quantitative CT scans to show areas of structural change in COPD and ILD's*



**Treat the right patients**  
Patient selection,  
Procedure Planning

**Imbio LDAf**  
*Endobronchial valve therapy planning for candidate suitability and planning of valve placement*



**Procedure quality & productivity**  
e.g. Real-time guidance

**Imbio LDAf images to reduce diseased lung volume**  
*Provide guidance for COPD treatment with Endobronchial valve placement*



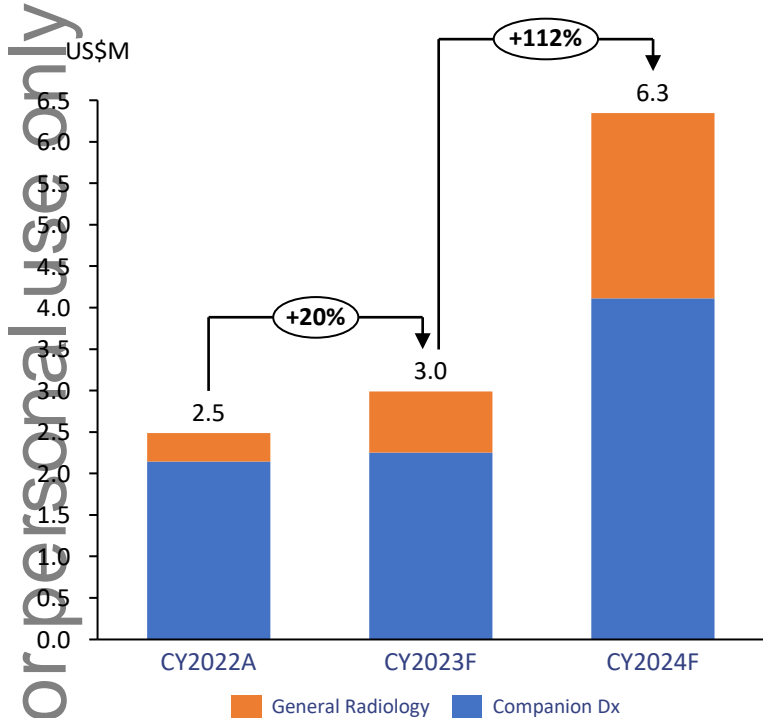
**Track & Prove Efficacy**  
Quantitative  
response metrics

**Imbio LDAf**  
*Provide report of quantitative CT measurements and images for physicians*

# Imbio performance and network

Strong revenue growth from established contracts plus expanding General Radiology network

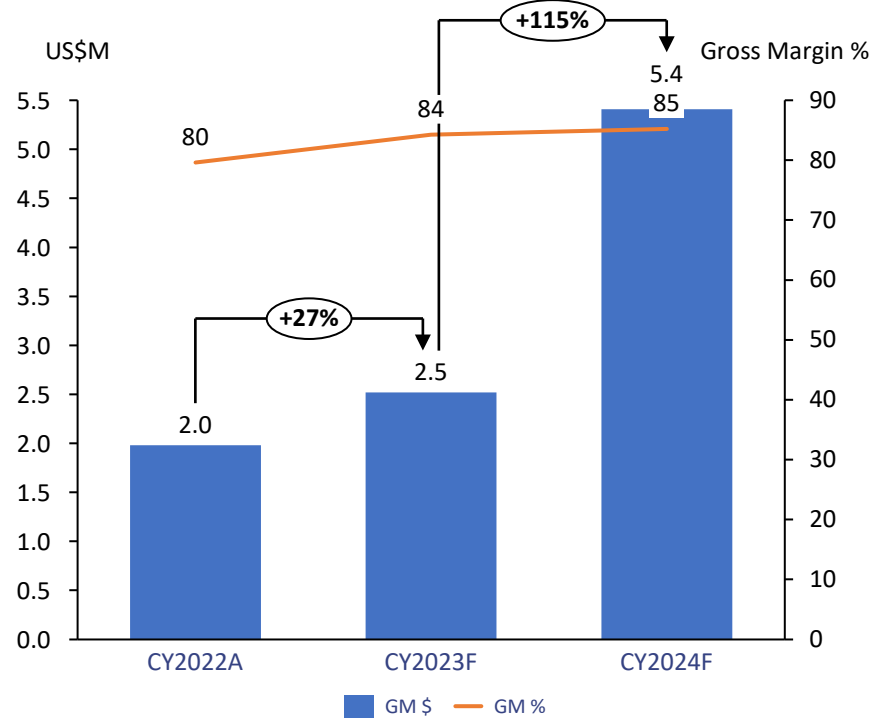
## Revenue<sup>1,2</sup>



Strong revenue CY2024 forecast US\$6.3m, up 112% year on year, underpinned by signed contracts and significantly expanded pipeline.

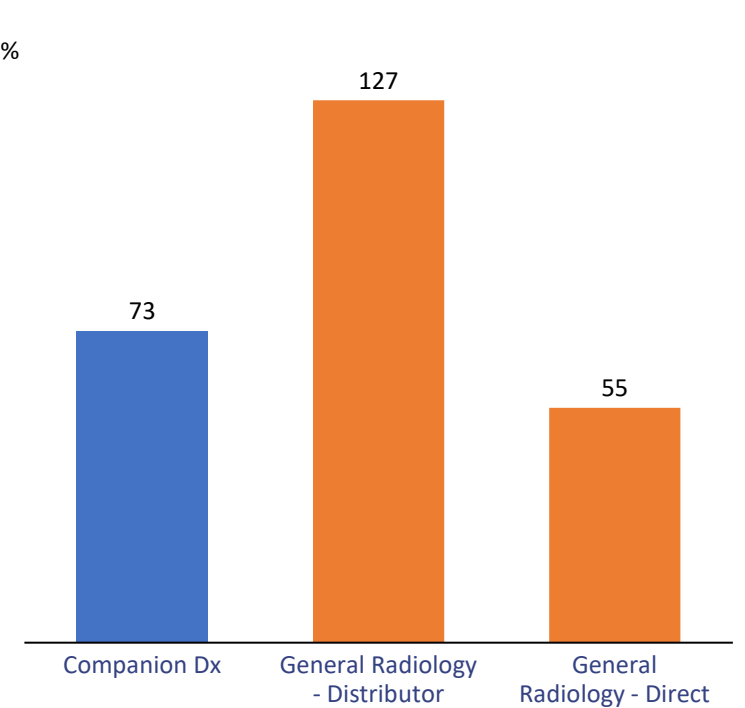
- 4DMedical management expects the Imbio business to be cashflow positive in its first full year of operations

## Gross Margin<sup>1</sup> \$



- Strong gross margin, ~84% for CY2023
- Expect further margin accretion as volumes grow

## Network – sites<sup>3</sup>



- Networks well established within the U.S. healthcare network
- Reach extended into VA network

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# Transaction Funding and Outlook

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# Transaction Funding

## Transaction Funding Details

### Upfront consideration

- US\$25 million (A\$38.5 million) in cash will be payable upfront on completion of the acquisition by 4DMedical to the Sellers.

### Contingent consideration

- Contingent consideration of up to US\$20 million to be paid on achievement of key milestones (see Appendix A).
- Subject to receiving shareholder approval, 4DMedical intends to satisfy any contingent consideration payable by the issue of shares in 4DMedical, based on the share's 30-day volume weighted average price prior to the date of expiry of the relevant performance milestone period.
- 4DMedical maintains the discretion to pay out any contingent consideration in cash.

### Sources and Uses

Sources	AUD \$'000
Placement <sup>1</sup>	35,000
Funding from existing cash	5,212
<b>Total Sources</b>	<b>40,212</b>

Uses	AUD \$'000
Cash Consideration <sup>2</sup>	38,462
Offer costs	1,750
<b>Total Uses</b>	<b>40,212</b>

# Equity Raising Timetable

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Trading halt	Thursday, 7 December 2023
Placement opens	Thursday, 7 December 2023
Placement closes	Friday, 8 December 2023
Capital raising results announced and trading halt lifted	Monday, 11 December 2023
Settlement of Placement	Thursday, 14 December 2023
Allotment of New Shares under the Placement	Friday, 15 December 2023
EGM held to approve issue of Options under Placement	Monday, 22 January 2024
Issue of Options under Placement (subject to obtaining shareholder approval at the EGM)	Tuesday, 23 January 2024



# Equity Raising Details

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Placement	<p>A placement to sophisticated and professional investors of A\$35.0 million.</p> <ul style="list-style-type: none"><li>The issue of 44.3 million new, ordinary fully paid 4DMedical Shares (<b>New Shares</b>) under ASX Listing Rule 7.1</li></ul>
Offer price	<ul style="list-style-type: none"><li>Offer Price of A\$0.79 per New Share represents a:<ul style="list-style-type: none"><li>-17.3% discount to the last close of A\$0.955 on 6 December 2023</li><li>-18.6% discount to the 5-day volume-weighted average price of A\$0.970</li><li>-16.8% discount to the 10-day volume-weighted average price of A\$0.949</li></ul></li></ul>
Attaching Options	<ul style="list-style-type: none"><li>New Shares will be offered under the Placement with one free attaching option for every two New Shares issued (<b>Options</b>)</li><li>The Options are intended to be quoted on the ASX</li><li>The Options will have an exercise price of \$1.365 and will expire on 31 December 2025</li><li>The issue of Options is subject to shareholder approval at an Extraordinary General Meeting (EGM)</li></ul>
Offer document	<p>The New Shares will be issued without a disclosure document while the Options will be offered under a transaction-specific prospectus</p>
Ranking	<p>The New Shares issued under the Placement will rank equally with existing Shares on issue</p>
Joint Lead Managers	<p>E&amp;P Corporate Advisory Pty Limited and Bell Potter Securities Limited are Joint Lead Managers to the Offer</p>

# Board of Directors

Significant medical and commercial sector experience



**LIL BIANCHI**

**Non-Executive Chair  
Chair, Audit & Risk Committee**

Experienced contributor of business transformations for US listed technology companies with a beneficial technology product expertise in AI and SaaS offerings.



**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.



**Dr ROBERT A. FIGLIN MD**

**Non-Executive Director**

Globally recognised leader in genitourinary and thoracic oncology, as well as Editor of the Kidney Cancer Journal and Spielberg Family Chair in Hematology/Oncology at Cedars Sinai.



**Dr GERALDINE MCGINTY MD**

**Non-Executive Director**

Internationally recognised expert in health care strategy and imaging economics, and prominent advocate for patient-centered care. Professor of Radiology and Population Health Sciences at Weill Cornell Medicine in New York City



**JULIAN SUTTON**

**Non-Executive Director**

Chartered Financial Analyst who began his career as an actuarial analyst in Melbourne before moving into funds management with Schroders and Credit Suisse in London.



**JOHN LIVINGSTON**

**Executive Director**

Founding partner of ASX listed Integral Diagnostics (ASX:IDT) and an industry leader in the implementation of PACS and RIS in radiological settings.

# Key advisors

Medical experts



**Dr SAM HUPERT MBBS**  
**Advisory Board Member**

Co-founder and Chief Executive Officer of Pro Medicus Ltd (ASX:PME) which develops and markets health imaging software primarily for radiologists in the U.S., Europe and Australia.



**Prof BRUCE THOMPSON PhD**  
**Advisory Board Member**

Board Member and Past President of the Thoracic Society of Australia and New Zealand; currently Dean of the School of Health Sciences at the University of Melbourne, and a former Head of Physiology Services at the Alfred Hospital.



**Dr DAVID J. SHULKIN MD**  
**Key Advisor**

Highly respected physician and health care executive, Dr Shulkin was previously the Secretary of the United States Department of Veterans Affairs (VA). As Secretary of the VA, Dr Shulkin oversaw the US government's second largest agency, with over 350,000 employees and 1,700 facilities, serving over 9 million Veterans.

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# Summary

Rapid and substantial progress across key dimensions of commercialisation:

- Reimbursement of XV:
  - Ahead of schedule with increased payment
  - Removes largest barrier to commercialisation in US
  - 2 new US sites signed up under payment
- FDA approval of CT LVAS™
  - Expansion into US, following Australian model
  - Reduces risk and FDA timeframe for CT:VQ
- Philips partnership
  - Leverage scalability, relationships and contracts
  - Initial focus on VA, grow across US and globally



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# Summary

Imbio acquisition synergistically interacts with all facets of commercialisation:

- Function combined with structure for a comprehensive offering
- Sales synergies into over 200 sites across USA
- Population health opportunities including lung cancer screening
- Expands and accelerates VA opportunities through additional products and relationships
- Revenue from long-term contracts at high gross margin
- Revenue and cost synergies, platform and technology synergies



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# Appendix A Transaction Details

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# Transaction summary

## Upfront consideration of US\$25 million (approximately A\$38.5 million) in cash and contingent consideration of up to US\$20 million

Transaction details	<ul style="list-style-type: none"> <li>4DMedical has entered into a binding agreement to acquire Imbio Inc. (Imbio) for a mix of upfront cash consideration and contingent consideration. Subject to obtaining shareholder approval, 4DMedical intends to settle the contingent consideration in the form of new scrip.</li> </ul>
Seller and acquisition structure	<ul style="list-style-type: none"> <li>Imbio is to be acquired from Invenshure, LLC, Invenshure Fund I, LP and Invenshure Fund II, LP (collectively, Invenshure) and Imbio's other equity holders (collectively, the Sellers). Invenshure currently holds approximately 63% of equity interests in Imbio.</li> <li>The acquisition is structured as a merger. Imbio Inc. will be merged into a new wholly-owned subsidiary of 4DMedical USA Inc. On completion, Imbio will thereby become a wholly-owned subsidiary of 4DMedical Limited.</li> </ul>
Upfront consideration	<ul style="list-style-type: none"> <li>US\$25 million (approximately A\$38.5 million) in cash will be payable upfront on completion of the acquisition by 4DMedical to the Sellers.</li> </ul>
Contingent consideration	<ul style="list-style-type: none"> <li>Contingent consideration of up to US\$20 million to be paid on achievement of key milestones.</li> <li>Subject to receiving shareholder approval, 4DMedical intends to satisfy any contingent consideration payable by the issue of shares in 4DMedical, based on the share's 30 day volume weighted average price prior to the expiry of the relevant performance milestone period. 4DMedical maintains the discretion to pay out any contingent consideration in cash.</li> <li>The earnout payments are conditional on achieving the following milestones:             <ul style="list-style-type: none"> <li>CY2024 revenue growth – Within 120 days after the end of CY2024, 4DMedical will pay the Sellers an amount equal to four times the incremental revenue growth (over US\$3.5 million) of Imbio products in CY2024 from eligible forecasted CY2023 revenue, up to a cap of US\$2.5 million of incremental revenue growth for a maximum earnout payment of US\$10 million.</li> <li>CY2025 revenue – Within 120 days after the end of CY2025, 4DMedical will pay the Sellers an amount equal to (1) the amount by which CY2025 revenue exceeds US\$4.0 million (up to a cap of US\$6.1 million of revenue in excess of CY2025 US\$4 million revenue), multiplied by (2) 0.812, for a maximum earnout payment of US\$5 million</li> <li>New Product FDA Clearance by 31 December 2025 – Within 70 days after the end of CY2025, 4DMedical will pay the Sellers an earnout amount equal to US\$5 million if Imbio were to obtain FDA clearance by 31 December 2025 for anyone of Imbio's (1) 'IQ-UIP product, (2) Aortic Aneurysm product, or (3) next generation PE/PAH product.</li> </ul> </li> </ul>
Overview of Imbio	<ul style="list-style-type: none"> <li>Imbio is a recognised leader in lung and cardiothoracic imaging AI, with revenues in excess of US\$3 million in CY2023.</li> <li>Imbio specialises in the leveraging clinical algorithms to effectively and efficiently screen patients for severe COPD and assess suitability for procedures such as Broncho-Pulmonary Valve Reduction interventions.</li> </ul>
Strategic rationale	<p><b>"Owning the Lung"</b></p> <ul style="list-style-type: none"> <li><b>Growth and material financial contribution</b> – significant revenue streams established with considerable growth opportunities.</li> <li><b>Complementary products</b> - Imbio deploys AI solutions to assess lung structural integrity, compared to 4DMedical that provides regional quantification of lung function.</li> <li><b>Company fit</b> – strong alignment with team structure and infrastructure, including IT platforms; operational synergies provide opportunity to leverage capabilities in 4DMedical and Imbio.</li> <li><b>Licensing of product extensions</b> – ability to extend into adjacent markets and provide greater scope of services, facilitating objective of 'owning the lung'.</li> <li><b>Customer alignment</b> - target customer segments for both companies are providing clinicians insights into Pulmonary health through Diagnostic Imaging modalities.</li> <li><b>VA engagement</b> – Imbio actively engaged with VA in textural analysis to help detect Interstitial Lung Disease (ILD) in a lung cancer screening program, complementing 4DMedical's engagement with the VA in diagnosis of DRRD (deployment related respiratory diseases).</li> </ul>
Conditions precedent	<ul style="list-style-type: none"> <li>Completion of the acquisition is subject to:             <ul style="list-style-type: none"> <li>the successful completion of the Offer to raise at least US\$19.5 million;</li> <li>the absence of any material adverse changes in the financial conduct, results of operations and assets of Imbio's business;</li> <li>requisite Imbio stockholder approval being obtained from Imbio Securityholders who collectively hold at least 90% of the outstanding stock in Imbio;</li> <li>other customary conditions precedent.</li> </ul> </li> </ul>
Funding	<ul style="list-style-type: none"> <li>4DMedical to raise A\$35.0 million via the Offer.</li> <li>Bell Potter Securities Limited and E&amp;P Corporate Advisory Pty Limited have been appointed as Joint Lead Managers to the Offer.</li> </ul>

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# Transaction summary – acquisition terms

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Escrow of contingent consideration shares	<ul style="list-style-type: none"> <li>Insofar as any contingent consideration is satisfied via the issue of new shares in 4DMedical (<b>Earnout Shares</b>), each tranche of Earnout Shares issued to the Sellers will be held in escrow for a period of (a) 45 days post issuance with respect to 25% of the tranche; (b) 90 days post issuance with respect to 25% of the tranche; (c) 135 days post issuance with respect to 25% of the tranche; and (d) 180 days post issuance for the final 25% of the tranche, subject to the ability to transfer to affiliates (with the escrow otherwise to remain in place).</li> </ul>
Board observer seat	<ul style="list-style-type: none"> <li>Until the later of (a) 31 March 2026; or (b) the expiration of all escrow periods for the Earnout Shares (if any), the Sellers will be granted the right to appoint an observer to attend all meetings of the 4DMedical board of directors and receive all information provided to the 4DMedical’s board of directors, subject to conventional limitations and 4DMedical’s constituent documents and relevant policies.</li> </ul>
Completion obligations	<ul style="list-style-type: none"> <li>Both parties are obliged to deliver customary deliverables at completion and the acquisition is subject to the conditions precedent described on the previous slide.</li> </ul>
Completion date	<ul style="list-style-type: none"> <li>The acquisition is expected to be completed on or around 15 December 2023.</li> </ul>
Representations and warranties	<ul style="list-style-type: none"> <li>The Merger Agreement includes customary representations and warranties and some specific indemnities.</li> </ul>
Indemnity Escrow Amount	<ul style="list-style-type: none"> <li>US\$2,500,000 of the purchase price is to be held in escrow as an indemnity escrow amount to fund potential claims by 4DMedical under the Merger Agreement. Subject to any claims, 50% of these funds are to be released from escrow 6 months after Closing and 50%, 15 months after Closing.</li> </ul>
Monetary limit on claims by 4DMedical	<ul style="list-style-type: none"> <li>The general monetary limit on claims is the Indemnity Escrow Amount.</li> <li>With respect to Fundamental Representations, claims may be made against Invenshure up to its pro rata share of the Purchase Price (the <b>Invenshure Cap</b>). Similarly, claims may be made against other security holders up to their portion of the Purchase Price (in respect of Fundamental Representations specific to such security holders).</li> <li>4DMedical has a right to offset against the earnout consideration, subject to certain limitations.</li> </ul>
Time limits on claims by 4DMedical	<ul style="list-style-type: none"> <li>Fraud, willful misconduct or intentional misrepresentation: 6 years</li> <li>Fundamental Representations: 3 years</li> <li>Other representations and warranties: Indemnity Escrow Amount: 15 months from Closing.</li> </ul>
Transition Services	<ul style="list-style-type: none"> <li>Invenshure, Imbio and 4DMedical have agreed to enter into an agreement for the provision of transition services by Invenshure to Imbio for up to 12 months.</li> </ul>

# Financial impact of acquisition

*Following completion of the acquisition, 4DMedical will be well funded to continue investment in growth*

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AUD \$'000	4DX	Equity Raising <sup>1</sup>	Upfront consideration <sup>2</sup>	Capital Raise Costs	Acquisition Costs	Pro Forma as at 30 September 2023
Cash and cash equivalents	59,871					59,871
Proceeds from capital raise		35,000	(38,462)	(1,750)	(750)	(5,962)
<b>Net Cash</b>	<b>59,871</b>	<b>35,000</b>	<b>(38,462)</b>	<b>(1,750)</b>	<b>(750)</b>	<b>53,909</b>

- Capital raise of \$35.0m, at an offer price of \$A0.79 per share
- Capital raise costs \$1.75m (5.0%)
- Acquisition related expenses ~\$0.8m
- Does not include the impact of existing options from May 2023 capital raise



# Appendix B

## Key Risks

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# Key risks

## Acquisition

### Transaction due diligence and reliance on information provided by Imbio

4DMedical has undertaken financial, operational, business and other analysis in respect of Imbio in order to determine its attractiveness to 4DMedical and whether to pursue the acquisition.

Risks may exist in relation to Imbio of which 4DMedical may be unaware, including latent, future or otherwise unknown claims or liabilities. The analysis undertaken by 4DMedical may draw conclusions and forecasts that are inaccurate or which are not realised in due course. There is no assurance that the due diligence conducted was conclusive and that all material issues and risks in respect of the acquisition have been identified.

To the extent a risk was identified there is no assurance that the materiality of the risk has been accurately assessed or, to the extent that a material risk has been identified, that it is effectively mitigated. To the extent that the actual results achieved by the acquisition are weaker than those indicated by 4DMedical's analysis, there is a risk that there may be an adverse impact on the financial position and performance of 4DMedical, and therefore on the return 4DMedical receives from its ownership of Imbio.

The due diligence undertaken by 4DMedical relied partly on the review of financial and other information provided by Imbio. 4DMedical has not been able to verify the accuracy, reliability or completeness of all the information which was provided to it against independent data.

### Completion risk

There is a risk that the proposed acquisition of all the outstanding equity interests in Imbio may not complete on the current terms and expected timing. As completion of the proposed acquisition will occur only after completion of the Offer, there is a risk that 4DMedical will have raised the proceeds of the Offer and the acquisition will be terminated. If this occurs, 4DMedical will utilise the proceeds of the Offer by way of general working capital. If completion of the acquisition is delayed, 4DMedical may incur additional costs and it may take longer than anticipated for 4DMedical to realise the benefits of the proposed acquisition.

Any failure to complete, or delay in completing the proposed acquisition may have a material adverse effect on 4DMedical's operations, financial position and performance and the price of its shares.

### Superior proposal risk

There is a risk that the transaction would not proceed in the event Imbio receives a superior proposal prior to completion. Imbio is permitted to terminate the Merger Agreement in connection with a superior offer received prior to obtaining the written consent of its securityholders to approve and adopt the Merger Agreement. While such approval is expected to be received within a short timeframe post execution of the Merger Agreement, there is a risk that such approval could be delayed, thereby creating a longer time period with which a superior proposal could be presented to Imbio.

### Break Fees

Imbio is required to pay 4DMedical a break fee of US\$250,000 (approximately A\$384,615) in a number of circumstances including if:

- 4DMedical USA Inc. terminates the Merger Agreement following the failure of the Imbio's board recommend the approval and adoption of the Merger Agreement to its securityholders;
- 4DMedical USA Inc. terminates the Merger Agreement following Imbio's board retracting its recommendation to its securityholders to approve and adopt the Merger Agreement;
- terminates the Merger Agreement in connection with accepting a superior proposal.

4DMedical USA Inc. is required to pay Imbio a reverse break fee of US\$250,000 (approximately A\$384,615) if certain conditions to completion are not satisfied, including if 4DMedical fail to successfully complete the equity raising.

# Key risks

## Acquisition

### Transition risk

The transition of ownership brings with it a range of risks that need to be managed. These risks include:

- possible loss of key Imbio personnel or corporate knowledge;
- reduced employee productivity due to uncertainty arising as a result of the proposed acquisition;
- possible difficulties in bringing together the cultures and management styles of both organisations in an effective manner;
- disruption to the ongoing operations of both businesses;
- impacts to the existing business of 4DMedical from the increase in scale of the business upon implementation of the proposed acquisition;
- unanticipated costs arising from unforeseen issues, litigation or regulatory actions; and
- higher than anticipated costs, delays or failures relating to integration of businesses, IT , accounting or other systems.

### Customer risk

Imbio's business relies on a number of key customer and supplier contracts and arrangements. There can be no assurance that key customer and supplier contracts or arrangements will continue, or where formal contracts exist, will be renewed upon their expiration or that the terms of any renewal will be as favourable to Imbio as the terms of the current arrangements. The loss of a significant portion of these customers and suppliers, a significant reduction in sales to customers, or a significant change in the commercial terms of the relationships with these customers and suppliers could have a material adverse impact on Imbio's financial performance and prospects.

### Legal risk

The proposed acquisition will involve 4DMedical and its related bodies corporate entering into a number of transaction documents. While the documents contain some protections in respect of certain historical liabilities of Imbio, there is always a risk that potential liabilities or risks in relation to Imbio's business or other costs are not matters for which 4DMedical has protection under those transaction documents, potentially exposing 4DMedical to the risk of future costs or disputes arising in relation to the proposed acquisition.

### Future earnings

To the extent that the actual financial performance achieved by Imbio is weaker than anticipated by 4DMedical in its analysis of whether to pursue the proposed acquisition, there are difficulties in integrating the operations of Imbio with 4DMedical or operating costs are higher than anticipated, the profitability and future earnings of Imbio may be materially less favourable than the pro-forma financial performance presented in this presentation.

### Foreign jurisdiction compliance risk

Imbio operates in the United States of America, Canada, Australia and the European Union and such operations are subject to extensive laws, regulatory requirements and industry standards and codes. A failure by Imbio to hold relevant licences or approvals could, if not rectified, result in Imbio being liable to fines, penalties and requirements to pay compensation for damages as well as reputational damage and the possibility, ultimately, of revocation of licences or approvals which could have a material adverse impact on the business carried out in those jurisdictions. If 4DMedical or Imbio do not have appropriate systems and procedures in place to manage its regulatory compliance, Imbio could be subject to fines, penalties and requirements to pay compensation for damages as well as reputational damage and the possibility of revocation of licences.

### Economic, political and social conditions in foreign jurisdictions

Due to its operations in the United States of America, Imbio's business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, social and legal conditions in the United States of America. Imbio's operations in the United States of America are also governed by local laws and regulations in which may differ from the jurisdictions in which 4DMedical currently operates.

# Key risks

## Acquisition

### Personnel risks

Pursuant to a consulting agreement (**Consulting Agreement**) between Imbio and Invenshure LLC (**Invenshure**), Invenshure provides certain consulting services to Imbio and certain office management and equipment. Those consulting services include executive / infrastructure, engineering, and accounting / administrative services performed by approximately 25 Invenshure employees, including the Chairman of the Imbio's board of directors. Given Imbio has only eight employees, Imbio leverages these consultants to perform numerous services that could only be done if Imbio directly hired additional employees.

If the Consulting Agreement were terminated, there is a risk that Imbio would not be able to perform critical business functions utilising its own employees due to its heavy reliance on contractors engaged under this arrangement. Additionally, if Imbio intends to hire any of the Invenshure employees listed in the Consulting Agreement to work for Imbio following completion, Imbio would be liable to pay Invenshure a fee equal to 50% of that individual's salary in accordance with the Consulting Agreement.

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# Key risks

## General

Sufficiency of funding	The Directors consider that, on receipt of funds under the Offer, 4DMedical will have sufficient working capital to carry out its objectives. However, financial resources are limited and there is a risk that 4DMedical may never achieve profitability. 4DMedical may be required to raise additional funds from time to time to finance the development and commercialisation of its products and other longer-term objectives. The ability to raise additional funding is subject to factors beyond the control of 4DMedical and its Directors. The Directors can give no assurance that future funds can be raised by the Company on favourable terms, or at all.
Barrier to entry	Competitors in the respiratory imaging sector may seek to minimise the ability of 4DMedical and Imbio (together, the <b>Group</b> ) to penetrate the market by seeking to impede or disrupt the Group's ability to establish product distribution and maintenance pathways.
Future profitability is uncertain	4DMedical is not yet profitable and has historically incurred losses. 4DMedical is still in the early sales and commercialisation stage for its XV Technology®. Although FDA and TGA clearance has been obtained for the XV (Ventilation) product (XV LVAS), CT LVAS and 5 Imbio diagnostic products, there is no guarantee that regulatory approval will be obtained for any of the Group's other products or that regulatory approval of the Group's products will guarantee market adoption of its products, which is crucial for revenue generation and profitability.
Foreign exchange risk	The Group's financial position may be negatively affected by exchange rate fluctuations. In particular, Imbio's revenue and 4DMedical's initial revenue from operations are, and are expected to continue to be, substantially U.S. dollar denominated. The Group is subject to adverse exchange movements, particularly in the USD:AUD exchange rate.
Intellectual property risks	The Group's success, in part, depends on its ability to obtain patents, maintain trade secret protections and operate without infringing the proprietary rights of third parties. If patents are not granted, or if granted only for limited claims, the Group's intellectual property may not be adequately protected and other third parties may be able to copy or reproduce the Group's intellectual property. The Group has developed and owns a range of proprietary items of intellectual property that management believe are novel and inventive. The granting of a patent does not guarantee that the rights of others are not infringed or that competitors will not develop technology to circumvent the patented technologies. Imbio does not have any patents. It holds exclusive licences to several third-party patents.
Key personnel risk	The successful operation of the Group in part relies on the Group's ability to retain its existing key management personnel who have intimate knowledge of the business and its products. The loss of any key members of management, or the inability to attract additional skilled individuals to key management roles, may adversely affect the Group's capacity to develop and implement its business strategies.
Changes in law	The legislative framework in key countries may vary without notice and adversely impact the Group's operations and profitability. Failure by the Group to comply with legislative or regulatory requirements may result in compliance orders being issued against the Group, financial penalties being levied against the Group, a cessation of its operations or reputational damage.

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# Key risks

## General

### Regulatory risk

There is a risk that regulatory bodies will not grant the Group regulatory clearance to market its products or will significantly delay the grant of such clearances. Failure to receive regulatory clearance will have a negative impact on the Group's future revenue streams. In addition, changes to regulatory regimes may become more burdensome in the future. If this occurs, the Group may be required to dedicate more time and resources to ensuring that it complies with these regulations, which could adversely affect its financial performance and future prospects.

### Superseding technology and competition from new entrants

There is a risk that new technology will be developed that will supersede the Group's technology. Although new technologies have significant development and commercialisation times, 4DMedical cannot guarantee that the Group's technology will not be superseded by a competitor. The Group's potential competitors may include companies with substantially greater resources and access to more markets. Therefore, competitors may succeed in developing products that are more effective or otherwise commercially superior to the Group's products.

### Technology supplier risk

There is a risk that the Group's cloud delivery suppliers could breach their delivery agreements or another relevant contractual arrangements and that the Group would be required to replace on or more suppliers. A significant interruption to the Group's ability to deliver its SaaS products could adversely impact its business, operating results and financial performance. Further, the Group currently relies on third party software licensors to enable certain functionality and workflows in its software. If the Group's ability to rely such third-party software is compromised, then its ability to service customers would be impacted.

### Product liability

There are no assurances that there will not be unforeseen performance characteristics or defects arising in relation to the Group's products. Adverse events relating to its products could expose the Group to product liability claims, litigation or the removal of its regulatory approvals. Product liability claims also have the potential to damage the Group's reputation and the ongoing viability of the Group if there is a significant erosion in the reputation of the Group.

### The Group's business may not achieve its intended goals

There is a risk that the Group may fail to achieve commercialisation and distribution goals. The Group's technology needs to find acceptance in a competitive market. Market acceptance depends on numerous factors (including convincing current and potential consumers and partners of the attractiveness of the Group's products).

### Future acquisitions

The Group may seek to acquire businesses or companies to achieve its objectives. There is a risk that any due diligence investigations undertaken by the Group may not identify issues which are material to the acquisitions and which could result in additional liability affecting the Group.

### Privacy risk

The Group seeks to ensure that it has appropriate security measures and risk management systems in place to maintain the confidentiality and privacy of personal information collected from its customers, end-user patients, employees and others. However, those security measures are subject to various risks (including computer viruses, electronic theft, physical damage, third party provide failures or similar disruptions). The failure of the Group to maintain the confidentiality of this information could breach law and cause significant operational, financial and reputational damage.

# Key risks

## General

### Macroeconomic and socioeconomic factors

The performance of 4DMedical will continue to be influenced by the overall condition of the economy in Australia and the jurisdictions in which it has operations and any deterioration in employment or economic growth could adversely affect 4DMedical's business. In light of recent Australian and global macroeconomic events, Australia may experience an economic recession or downturn of uncertain severity and duration which will continue to impact on the operating and financial performance and prospects of 4DMedical.

Other socioeconomic and macroeconomic factors that could have a material adverse impact on 4DMedical's business and financial performance, include higher unemployment rates, lower household income levels and lower birth rates.

### General market and share price risks

There are general risks associated with any investment in the share market. The price of 4DMedical shares may increase or decrease due to a number of factors. These factors include fluctuations in domestic or global financial markets and general economic conditions, including interest rates, inflation rates, exchange rates, commodity and oil prices, changes to government fiscal, monetary or regulatory policies, legislation or regulation, the removal or inclusion of 4DMedical from market indices, and the nature of markets in which 4DMedical operates.

### Tax and accounting

Australian accounting standards and tax laws (including GST and stamp duty taxes), or the way they are interpreted, are subject to change from time to time, which may impact 4DMedical's financial position or performance.

### Dividends

There are a range of factors that determine the payment of dividends on 4DMedical's shares. These include the profitability of the business, its cash reserves, future capital requirements and obligations under debt facilities. 4DMedical's Board will determine any future dividend levels based upon 4DMedical's operating results and financial standing at the time. There is no guarantee that any dividend will be paid by 4DMedical, or guarantee that future dividends will equal or exceed previous payments.

### Litigation

Legal proceedings and claims may arise from time to time in the ordinary course of 4DMedical's business and may result in high legal costs, adverse monetary judgments and / or damage to 4DMedical's reputation which could have an adverse impact on 4DMedical's financial position or performance and the price of its shares.

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# Appendix C

# 4DMedical Overview

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# Software offering and applications



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4DMedical software offering

Current product release

XV LVAS®  
(ventilation)

CT LVAS™  
(ventilation)

CT:VQ  
(ventilation / perfusion)

Currently in development

Image acquisition modality



X-ray

Existing hospital & radiology hardware



XV Scanner

4DMedical hardware utilising 4DMedical software



CT

Existing hospital & radiology hardware

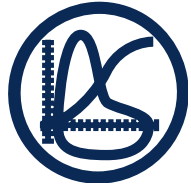
# XV Technology<sup>®</sup> advantages

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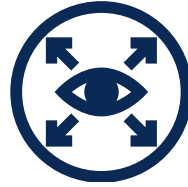
## New medical insights

Functional insight of spirometry at a regional level



## Improved safety

Comparable radiation dose to X-ray



## Superior results

High-detail resolution of a CT scan



## Patient outcomes

Improved clinical outcomes



## Time efficient

Faster, more efficient testing using existing hardware



## Low cost

Competitive pricing below incumbent technologies



XV Technology<sup>®</sup> 4D view of lung performance

# Global market revenue opportunity

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The global respiratory diagnostic market is valued at ~US\$31.3 billion<sup>1</sup> per annum

- Four existing respiratory diagnostic technologies account for 99% of current procedures
- These existing lung diagnostic technologies are decades out of date, not fit for purpose and ripe for displacement
- Penetration of the global respiratory diagnostic market is a longer-term target for 4DMedical

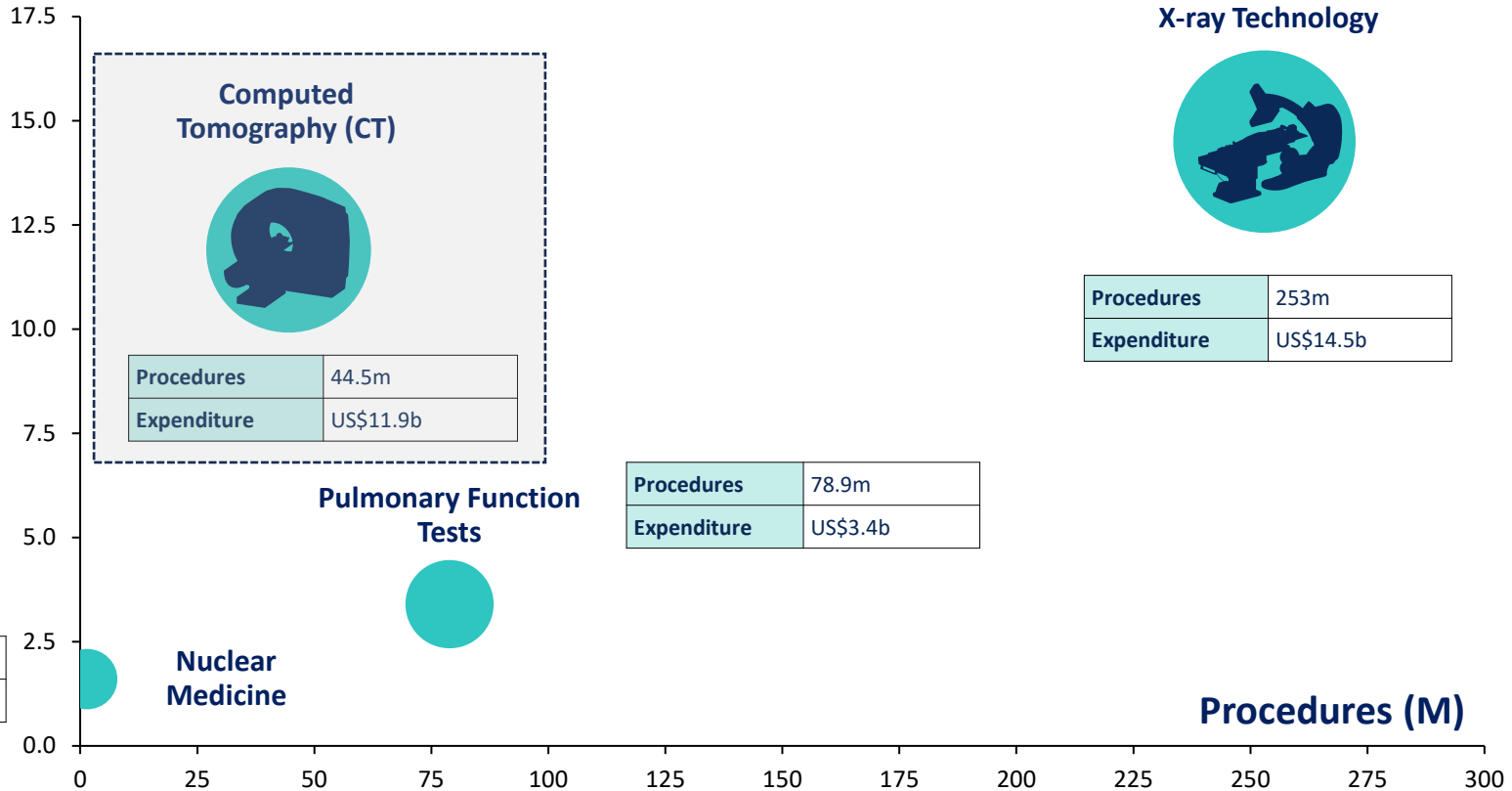
## Market opportunity by country<sup>1</sup>

Country	Spend (US)	Procedures
US	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	780M	8.4M
Italy	681M	8.5M
Canada	606M	8.0M
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

# Global market disruption opportunity

Four existing lung diagnostic technologies: CT, X-ray, Nuclear Medicine, Pulmonary Function Tests

Expenditure (US\$bn)



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Imbio acquisition provides greater reach into the CT market; TAM worth ~ US\$11.9b



Accounting for 99% of the 378 million global respiratory diagnostics tests performed annually<sup>1</sup>

# US reimbursement approved – XV LVAS™

We addressed three key components of reimbursement ...

1 Code – describing the procedure

✓ *Cat III CPT Code<sup>1</sup>*

2 Coverage – defining eligibility for payment

✓ *Medicare (65m people)*

3 Payment – assigning a monetary value

✓ *U.S. \$299 avg rate<sup>2</sup>*

... and engaged stakeholders across multiple bodies ...

- American Medical Association CPT Panel and Advisors
- Radiology, Respiratory, Pulmonary Societies
- Providers & Key Opinion Leaders (KOL)
  
- Payor Medical and Clinical Directors
- KOL, Industry advocates
- Health TEC organisations
- Providers (hospitals etc.)
  
- Providers, Patients
- Payor Actuary, and Actuarial Health Economics

... which paved the way to U.S reimbursement

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

From 1 January 2024, XV LVAS® scans conducted in a US hospital can be billed to the US Centers for Medicare Services

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# 4DMedical and Philips sign Memorandum of Understanding

## ➤ Key points:

- Initial focus of the partnership will be to offer 4D lung imaging as a critical screening solution for Veterans exposed to burn pits.
- 4DMedical's XV Technology® will be added to Philips' product catalogue and offered as a third-party solution.
- Philips has a long established and significant existing partnership with both the VA and DoD:
  - 45-year relationship;
  - 35% of the critical care information systems across the VA; and
  - 50% of VA clinics use Philips imaging solutions.
- Subsequently, intent is to expand access to both software and hardware solutions, including to other US based Federal agencies and commercial organisations in North America.
- The parties will also consider other markets outside of North America for expansion.



# PHILIPS

# Appendix D

# Imbio Product Suite

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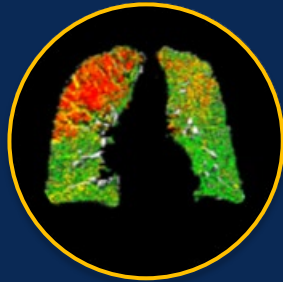
# Attractive product portfolio

AI solutions that span lung and heart conditions affecting 1 in every 5 adults

## Lung Density Analysis

*COPD, Asthma, Pneumonia, BOS*

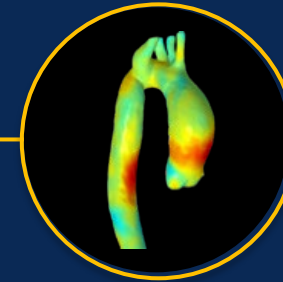
FDA CE



## Aortic Aneurysm

*Incl. patented VDM*

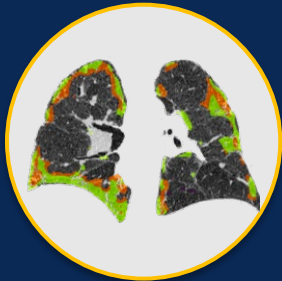
FDA - TBD CE - TBD



## Lung Texture Analysis

*ILA's, ILD/IPF drug-induced fibrosis*

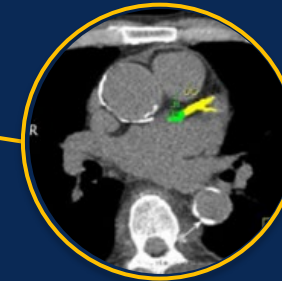
FDA 2024 CE



## CAC Scoring

*CAD/Heart Disease*

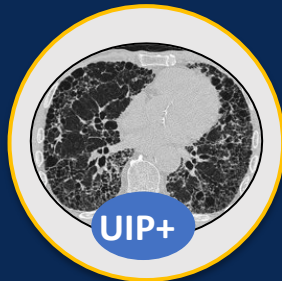
FDA CE 2023



## IQ-UIP

*automated UIP/IPF screening*

FDA 2024 CE 2024



## Lung Nodules

*Lung Cancer (Partner Solution)*

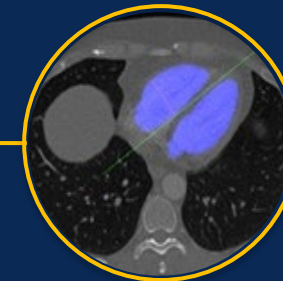
FDA CE



## RV/LV and PAH Analysis

*Pulmonary Embolism, Pulmonary Hypertension*

FDA CE



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# Imbio product suite: in detail

*Product suite has 4 FDA cleared products with a significant pipeline*

Product Name	Description	Regulatory clearance
<b>Lung Density Analysis</b> Inspiration (LDAi)	<ul style="list-style-type: none"> <li>Provides results based on a standard inspiratory chest CT.</li> <li>Fully-automated detection, visualization and quantification of areas of low attenuation (LAA);</li> <li>Validated for use with low-dose CT scans as a component of lung cancer screening programs; includes a report to assist with smoking cessation counselling.</li> <li>COPD, Asthma, Pneumonia, BOS</li> </ul>	
<b>Lung Density Analysis</b> Functional (LDAf) “Air Trapping”	<ul style="list-style-type: none"> <li>Fully-automated image analysis tool providing a complete mapping of normal lung, air-trapping, and areas indicative of emphysema in a combined image to visualize and quantify the components of COPD.</li> <li>Information for personalized care decisions as well as surgical and interventional procedure planning.</li> <li>Advanced density analysis for patients with COPD, Asthma, Bronchiolitis Obliterans Syndrome, and other conditions</li> </ul>	<b>FDA cleared (Imbio)</b>
<b>Lung Density Analysis</b> (LDA+)	<ul style="list-style-type: none"> <li>Provides quantification of airspace disease severity and extent, including areas potentially indicative of consolidation and ground glass.</li> <li>Assists the diagnosis and assessment of COVID-19 or pneumonia severity, and potential co-existing emphysema via quantification of low and high-density regions in chest CT images.</li> </ul>	
<b>RV/LV and PAH</b> <b>Analysis</b>	<ul style="list-style-type: none"> <li>Assess potential ventricular dilation by measuring the maximal diameters of the right and left ventricles of the heart, and reporting as a ratio</li> <li>Provides annotated images showing the ventricular measurements and a summary report of the ratio</li> <li>Pulmonary Embolism, Pulmonary Hypertension</li> </ul>	<b>FDA cleared (Imbio)</b>
<b>CAC Scoring</b>	<ul style="list-style-type: none"> <li>CAC provides visualizations and reports for radiologists and cardiologists to rapidly and accurately determine the location and extent of calcification</li> </ul>	<b>FDA cleared (Imbio)</b>
<b>Lung Nodules</b>	<ul style="list-style-type: none"> <li>Lung Cancer (Partner Solution)</li> <li>ClearRead CT allows radiologists to move beyond standard background-impaired imaging interpretation. Its unique suppression technology enables radiologists to see past obstructions to correctly and quickly detect cardio-thoracic diseases leading to faster reads and improved nodule detection</li> </ul>	<b>FDA cleared</b>
<b>Product Pipeline:</b>		
<b>Lung Texture</b> <b>Analysis (LTA)</b>	<ul style="list-style-type: none"> <li>Provides a detailed map and quantification of the lung textures that are key to identifying Interstitial Lung Diseases (ILD’s) and other fibrotic conditions (normal, ground glass, reticular, honeycomb and hyperlucent)</li> </ul>	Subject to FDA clearance 2024
<b>IQ-UIP</b>	<ul style="list-style-type: none"> <li>Computer-aided software indicated for use in passively notifying interstitial lung disease (ILD) centres of radiological findings suggestive of radiological usual interstitial pneumonia (UIP)</li> <li>UIP received FDA Breakthrough Device notification November 14<sup>th</sup> 2023</li> </ul>	Subject to FDA clearance 2024
<b>Aortic Aneurysm</b>	<ul style="list-style-type: none"> <li>Imbio Aortic Aneurysm Analysis (AAA) provides both, an automated measurement of the maximal diameters of the thoracic aorta at standard landmark locations from a single contrast chest CT scan, and a full volumetric assessment and visualization of aortic growth (a Volumetric Deformation Map) comparing a follow-up versus a prior scan.</li> </ul>	FDA clearance TBC

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4DMedical Limited (ASX:4DX)

Investor Presentation

December 2023

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