

The Future of Lung Health

## Investor Presentation | September 2022

4DMedical Limited (4DX)



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### The global respiratory diagnostic market represents - USD \$31.3<sup>1</sup> billion per annum opportunity

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Corporate overview

Approximately 378 million respiratory diagnostic tests are performed per annum globally. •

patients with lung disease via its four-dimensional lung imaging platform – XV Technology®

mathematical models and algorithms to convert X-ray images into quantitative scan data.

Existing lung diagnostics are decades out of date, not fit for purpose and ripe for displacement.

4DMedical is a software company creating a step change in the capacity of physicians to diagnose and manage

Focused on commercialising our flagship XV Lung Ventilation Analysis software (XV LVAS<sup>®</sup>), which utilises

Clinically validated to provide real-time, non-invasive analysis of regional lung motion and airflow analysis.

Initial focus on the U.S. respiratory diagnostic market worth USD \$13.7 billion per annum. ٠

### The Company is well funded to execute on commercialisation strategy

- Offering is focused on improving hospital and patient outcomes with limited CAPEX requirements. ٠
- Capital light business model with rapid SaaS deployment expected > 90% gross margins margin. ٠
- First mover advantage with a robust IP portfolio and advanced product pipeline present significant entry barriers. ٠
- Strong balance sheet of AUD \$51.1 million as at 30 June 2022 and zero debt.

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4DMedical

Technology conceived 2005 Incorporation Melbourne 2012

Globally recognised U.S hospital customers and collaborators

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SaaS Model

USD \$31.3 billion

global market opportunity

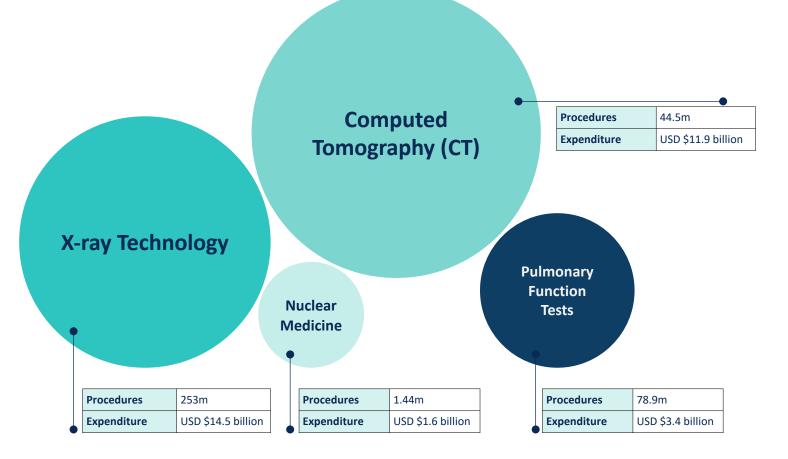
**Global** Patents

Market opportunity Respiratory diagnostics

### **4DMedical**

## Market opportunity

### USD \$31.3 billion p.a. global spent on respiratory diagnostics



### Market Opportunity by Country<sup>2</sup>

Country	Spend (USD)	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

• These four technologies account for **99%** of the 378<sup>2</sup> million respiratory diagnostics tests performed annually.

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## Market opportunity

### Veterans' health in the United States



- 3.5 million U.S. troops have been exposed to toxic burn pits since 1991.
- PACT Act is set to appropriate USD \$280 billion in additional funding over ten years for affected veterans.
- Recognition of the impact of Post-Deployment Respiratory Syndrome and the need for a structured clinical response.

- Process for securing contracts with DoD<sup>1</sup> and VA<sup>2</sup> through NASA's SEWP<sup>3</sup> program at a pre-agreed pricing structure of USD \$171 per scan.
- VA to evaluate "emerging technology using existing x-ray imaging equipment to derive four-dimensional models of lung function" as part of the FY23 appropriations bill.<sup>4</sup>

4DMedical

### **4DMedical**

Spirometry: 1846





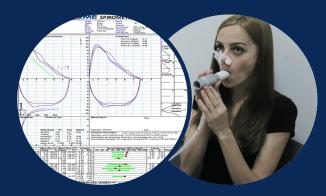


X-ray: 1895

Nuclear Medicine: 1971

### **4DMedical**

Spirometry: 1846 1D technology Accurate but insensitive 20% market





X-ray: 1895 2D technology Inexpensive, but tells us very little about airflow 67% market

Cost	Spirometry: USD \$72; Complete PFT: USD \$750
Advantages	Functional; Accurate; Zero dose; Non-invasive; Low cost (Spirometry)
Limitations	<ul> <li>Insensitive</li> <li>Non-specific</li> <li>Complete PFT expensive and time consuming</li> <li>Effort dependent (repeatability issues)</li> <li>Not applicable to all patient cohorts</li> </ul>



Nuclear Medicine: 1971 3D technology Measures both ventilation and perfusion, but has significant limitations 1% market

These four technologies account for **99% of the 382 million respiratory diagnostics test** performed per annum globally

### **4DMedical**

Spirometry: 1846 1D technology Accurate but insensitive 20% market





X-ray: 1895 2D technology Inexpensive, but tells us very little about airflow 67% market

CT: 1971 3D technology Sensitive, but expensive and high radiation dose 11% market



Cost	USD \$120 (Average estimated)	<b>7</b> 4
Advantages	2-dimensional scan; Ubiquitous; Relatively inexpensive; Low radiation dosage (0.1 mSv)	/1 on and
Limitations	<ul> <li>Measures structure rather than function</li> <li>Limited clinical value</li> <li>Overlapping anatomy means features can be hidden and be missed</li> <li>Poor record in screening applications</li> </ul>	cant

These four technologies account for **99% of the 382 million respiratory diagnostics test** performed per annum globally

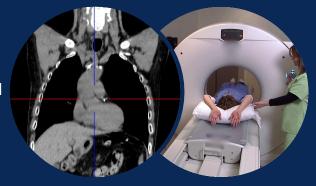


Spirometry: 1846 1D technology Accurate but insensitive **20% market** 



X-ray: 1895 2D technology Inexpensive, but tells us very little about airflow 67% market

CT: 1971 3D technology Sensitive, but expensive and high radiation dose 11% market



Cost	USD \$525 (Average estimated)	
Advantages:	3-dimensional scan (can't miss features); Sensitive; High-resolution detail of images	1
Limitations:	<ul> <li>Expensive: 4 times the cost of an X-ray</li> <li>High radiation dose: 70 times an X-ray</li> <li>High rate of false positives (~95% in NLCST vs 3% mortality for surgery)</li> <li>Measures structure rather than function</li> <li>Very high rate of utilisation based on availability</li> </ul>	an an

These four technologies account for **99% of the 382 million respiratory diagnostics test** performed per annum globally

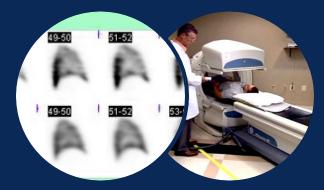


Spirometry: 1846 1D technology Accurate but insensitive 20% market

Cost	VQ Scan: USD \$1,503 (Average estimated)
Advantages:	Perfusion analysis capability; Only modality that can identify ventilation-perfusion mismatch; Importance in treating pulmonary embolism & hypertension
Limitations:	<ul> <li>High cost, poor resolution of outputs</li> <li>Time consuming (1 hour to complete)</li> <li>Use of dual radioactive particulate contrast agents raises toxicity concerns,</li> <li>Expensive testing equipment needed</li> <li>Complex to administer, requires expert analysis, onerous safety precautions</li> </ul>



X-ray: 1895 2D technology Inexpensive, but tells us very Iittle about airflow 57% market



Nuclear Medicine: 1971 3D technology Measures both ventilation and perfusion, but has significant limitations 1% market

four technologies account for **99% of the 382 million respiratory diagnostics test** performed per annum globally



XV Technology<sup>™</sup>

### Viewing

- Coronal: XV Scan Layer
- Airways
- Vasculature
- Ribs

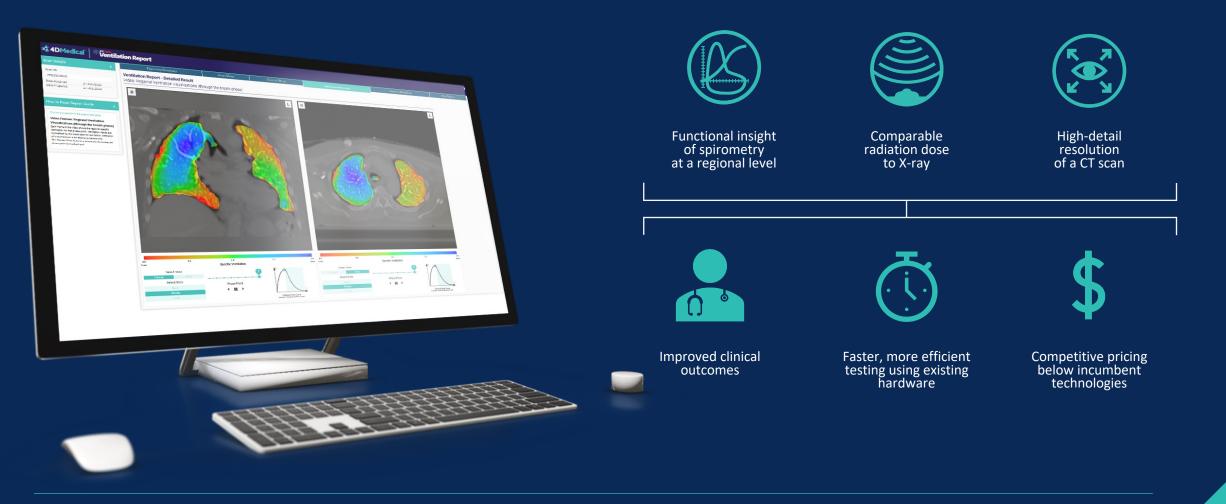


XV Sc	an: Spec	ific Ventil	ation		Airway	/s: Tube	Diamete	r		Vascu	lature: Ti	ube Diam	neter	
Less				More	Smaller				Larger	Smaller				Larger
0.0	0.5	1.0	15	2.0	0.0	3.75	7.5	11.25	15	0.0	2.5	5	7.5	10

For demonstration purposes only. Not yet available for sale in the US.

## Advantages of existing modalities in a single platform

**4DMedical** 

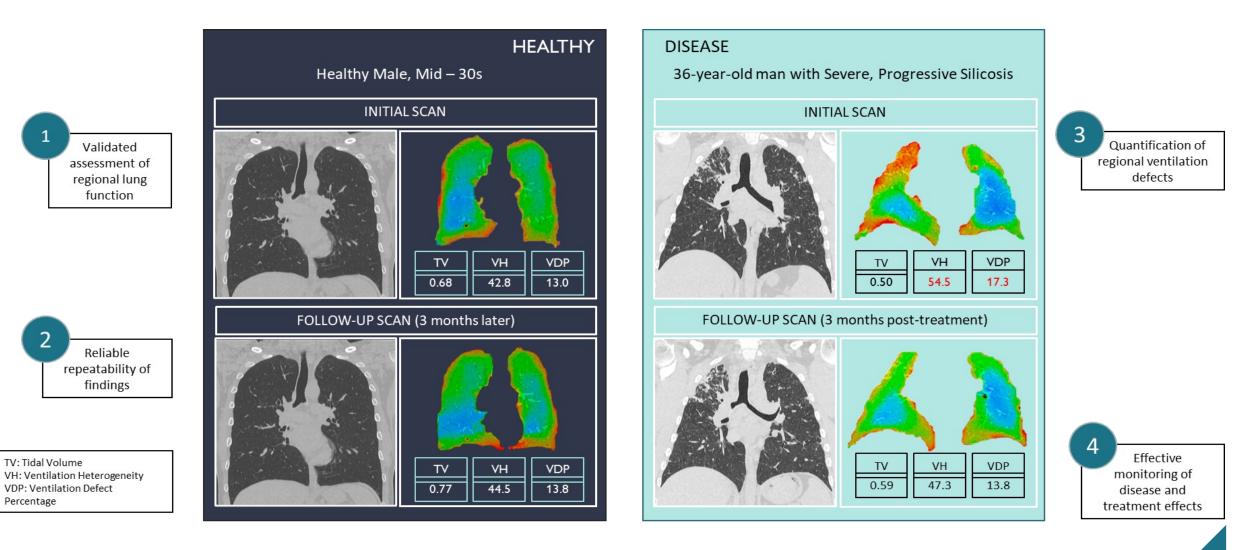


# **Clinical Value Proposition**



### Clinical use case: Silicosis

### **4DMedical**



## Clinical use case: COPD

### **4DMedical**



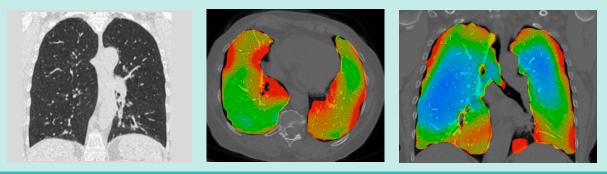
Prior biologics therapeutic for re-current exacerbation of moderate obstructive lung disease.

- Summary SOB for further investigation.
  - At baseline CT was unremarkable. Placed on biologics for history of exacerbation.
  - Following Tx, there are functional improvements in regional ventilation indices (reduced VH and VDP). Notably, appearance of improved. ventilation, specifically in the dependent areas of the right and left lungs.
  - Corresponding with patient reported improvement in symptoms.

### **Clinical Observations**

- Improved symptoms demonstrated a clinical correlation with improvements in regional ventilation function. Continued therapy with novel biologics.
- Functional assessment of regional ventilation assists in tracking response to therapy and management.

### Baseline

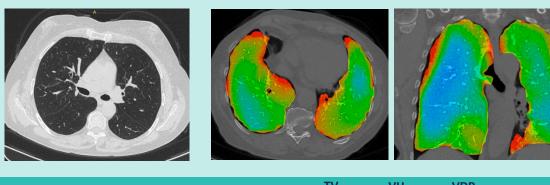


Structural CT

TV VH 0.69L 60.8%

VDP % 18.1%

#### 5 Months Post-Tx



**XV LVAS** 

	VV/ LV/AC	TV	VH	VDP
Structural CT	XV LVAS	0.7L	47.0%	13.4%

## Clinical use case: Long COVID

### 💐 4D Medical®

### Age 52 Indications Long COVID symptoms

Sex	Ŷ	ې ډک

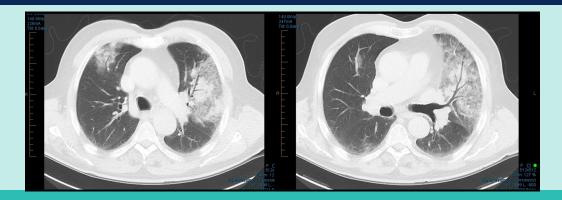
### Summary • Patient hospitalised for COVID-19.

- During admission chest CT observed peripheral ground-glass and consolidative pulmonary opacities (no XV LVAS<sup>®</sup> imaging was captured).
- Following Tx and discharge from hospital, the Pt continued to display symptoms of shortness of breath, cough and dyspnea on exertion.
- Following physician consultation, a follow-up CT and 4DMedical XV LVAS<sup>®</sup> were prescribed.

### **Clinical Observations**

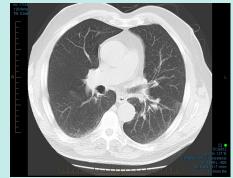
- Follow-up CT observed a resolution of the peripheral ground-glass and consolidative pulmonary opacities
- XV LVAS<sup>®</sup> highlighted heterogeneity between the left and right lung regional performance
- Additionally, previous areas of ground-glass and consolidative pulmonary opacities displayed under ventilation specific to that region of the lung.

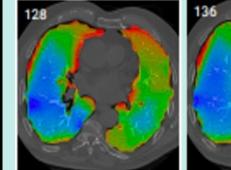
#### **Chest CT: Acute COVID-19 Infection**



Structural CT: Peripheral ground-glass and consolidative pulmonary opacities

#### **3 Months Post-acute COVID-19 Infection**





Structural CT

XV LVAS

# Commercialisation



## Commercialisation: Two Pillars

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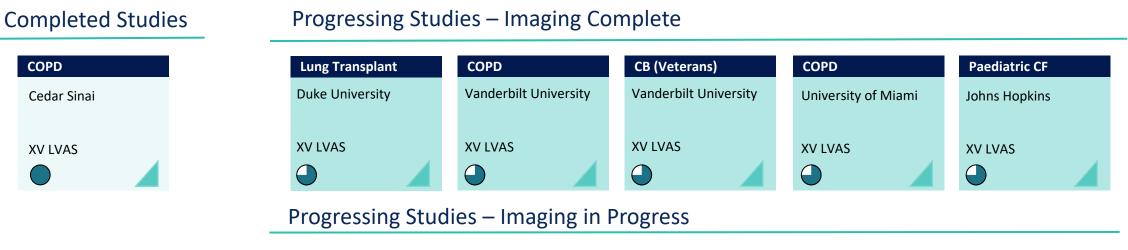
Research partners delivering the body of scientific evidence for clinical use

## Commercial pilots

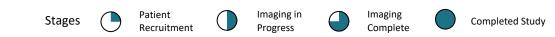


Physicians gaining familiarity with technology and business case for clinical adoption

Who	Why	Who	Why
<ul> <li>Eminent researchers and leading medical institutes</li> </ul>	<ul> <li>Diagnostics, treatment efficacy, monitoring, disease progression and</li> </ul>	<ul> <li>Respiratory specialists, imaging centres, hospitals</li> </ul>	<ul> <li>Assess holistic regional lung function for patient managemen         <ul> <li>ventilation and perfusion</li> </ul> </li> </ul>
motifates	more		Alternative to nuclear medicine
Outcomer		Outcome:	
• Scientific investigation into ca	se applications	Clinical familiarisation	
<ul> <li>Publishing manuscripts and p</li> </ul>	resenting research to industry	<ul> <li>Clinical and business case for te</li> </ul>	echnology adoption
Study design: Full scientific n	nethod per researcher	<b>Pilot design:</b> Tiered per facility &	physician interest

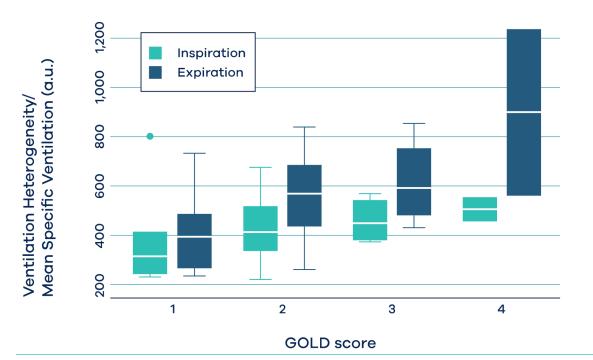


COPD	BLVR	РН	COPD	Lung Transplant
Johns Hopkins	University	of Miami Cleveland C	inic Oregon Healt Science Unive	
XV LVAS	XV LVAS	VQ O		

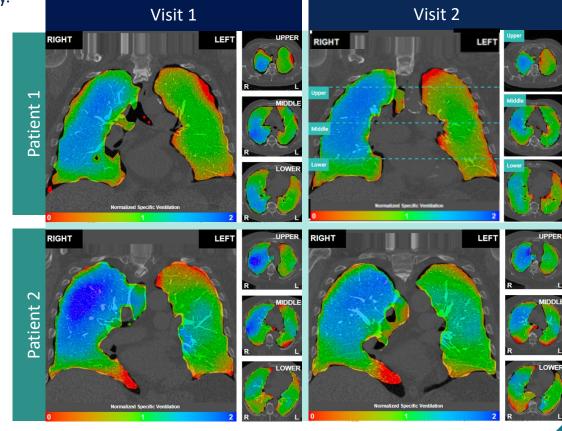


## Commercialisation: Johns Hopkins COPD trial result

- Has the capability of assessing regional ventilation defects, which is critical to optimising therapies.
- Is a repeatable lung assessment tool in a cohort of COPD patients.
- Illustrates distribution of airflow within the lungs, corresponding with COPD severity.



Ventilation Heterogeneity By Disease Severity

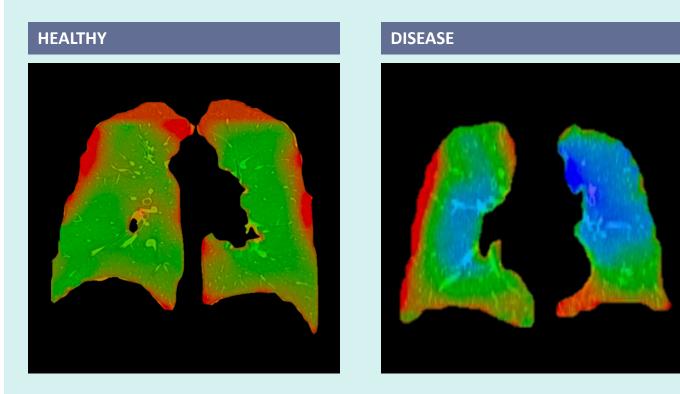


**4**DMedical

## Commercialisation: Vanderbilt PDRS trial results

- PDRS is not detectable by Spirometry, X-ray or CT only via surgical biopsy.
- 4DMedical's XV Technology<sup>®</sup> detects the presence of constrictive bronchiolitis.
- Quantitative scores identify the differences between Veterans with constrictive bronchiolitis and healthy controls.
- XV Technology<sup>®</sup> confirmed the diagnosis of CB with <0.001% uncertainty.</li>
- Ongoing assessment of the Vanderbilt clinical trial data is expected to lead to publication.

### XV clinical trial outputs displaying ventilation variation



### XV Technology<sup>®</sup> confirmed the diagnosis of CB with <0.001% uncertainty.

### 💐 4DMedical

### **Commercialisation:** Australia



- Three-year contract signed with Australia's largest radiology provider I-MED with a 250-site network.
- Successfully rolled out the Company's XV Technology<sup>®</sup> across 7 sites spanning 5 states.
- Release of CT variant to accelerate rollout.
- Used to assist in diagnosis, the unique capability and low-dosage modality developed is proving particularly useful as a surveillance tool in understanding lung disease.



- MRFF provided AUD \$28.9 million in funding, with AUD \$15.0 million yet to be received.
- First XV Scanner installed at the Prince of Wales Hospital.



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## **Commercialisation: United States of America**





Providence St.JosephHealth

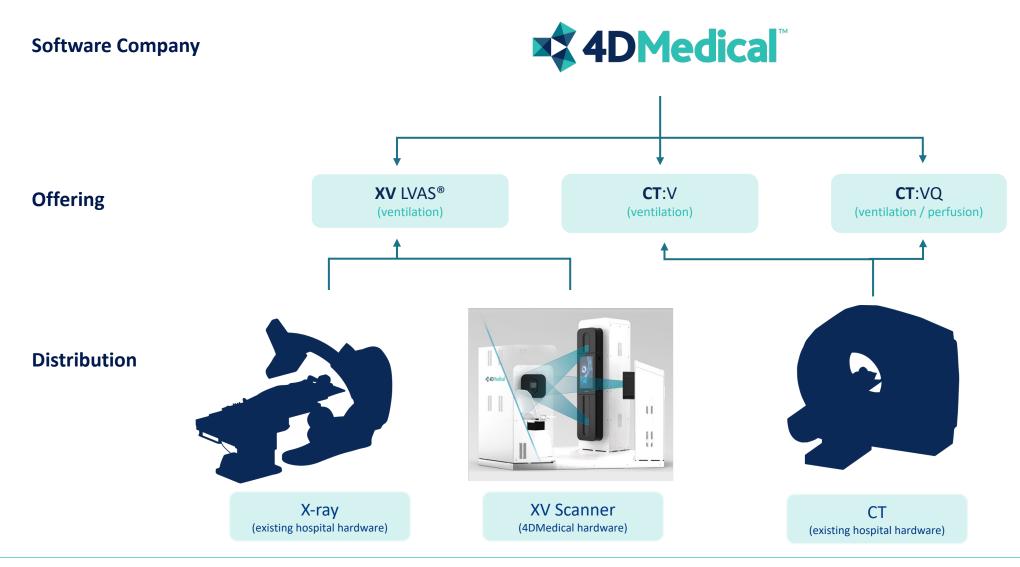
- The PACT Act legislation removes the burden of proof on veterans and provides an additional USD \$280 billion to be spent over 10 years.
  - Ensuring veterans get the care they need includes ensuring that they are screened for toxic exposure.<sup>1</sup>
- Streamlined process for securing contracts with the DoD and VA through NASA's SEWP program, including a pre-agreed pricing structure of USD \$171 per scan.
- The VHA FY23 budget is USD \$301.4 billion<sup>2</sup>, operating 1,255 healthcare facilities and serving 19.2 million veterans across the United States.
- Providence St. Joseph, is one of 52 hospitals with 1085 clinics<sup>3</sup> in the world-class Providence Healthcare network.
- XV LVAS<sup>®</sup> software is used to assist in screening for multiple respiratory conditions, including Chronic Obstructive Pulmonary Disease and long-COVID.



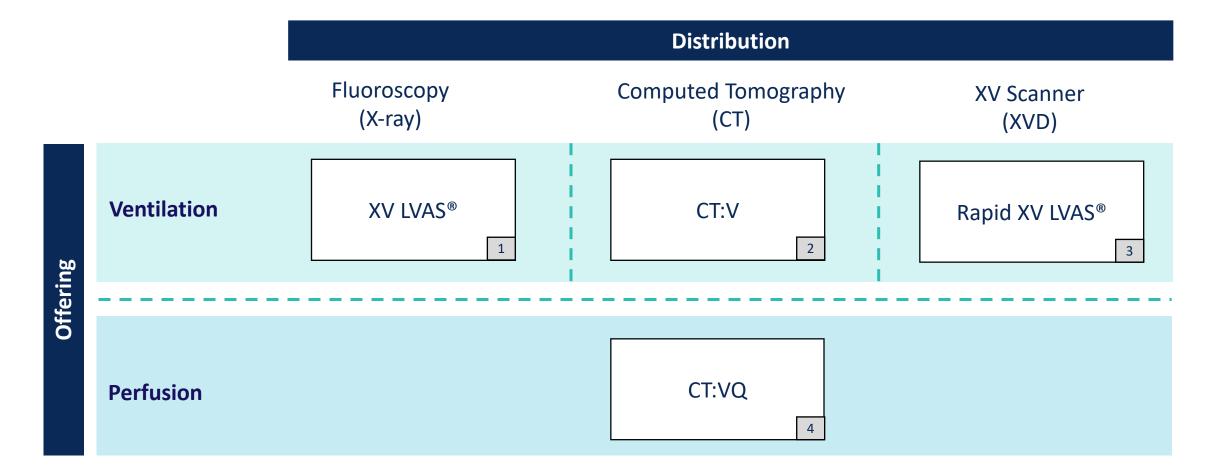
# Product pipeline

## Product pipeline

**4DMedical** 



• The simplicity of offering (Ventilation or Perfusion) with the flexibility of distribution





**4DMedical** 

# Experienced Team

# Experienced team

### **4DMedical**



#### Dr ANDREAS FOURAS PhD CEO

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



RACHAEL TENKATEN Chief of Staff

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.



#### NICHOLE MURRAY Vice President Regulatory Affairs & Quality Assurance

Over 20 years of experience in regulatory affairs and quality assurance functions in the pharmaceutical and medical device industries.



#### Dr JASON KIRKNESS PhD Senior Vice President Medical & Clinical Affairs

Over 20 years' training and experience in pulmonary physiology and sleep medicine, including faculty position at Johns Hopkins and global industry leaders.



BETH PLUNKETT Corporate Counsel

Accomplished commercial lawyer with expertise spanning corporate, finance, technology licensing and research collaboration contracts.



Dr JON DUSTING PhD Chief Research Officer

Demonstrated capabilities in translating ambitious research vision into disruptive biotechnology products, including the MRFF-funded XV Scanner.



SIMON GLOVER Chief Finance Officer

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

### Experienced team Board of directors

#### BRUCE RATHIE Non-Executive Chairman

Experienced lawyer, Investment Banker and Company Director; currently Non-Executive Director of PolyNovo Limited (PNV.ASX) and Netlinkz Limited NET.ASX).



#### Dr ANDREAS FOURAS PhD Managing Director and Chief Executive Officer

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



#### Chief LIL BIANCHI Non-Executive Director; 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 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.

### **Advisory board**



#### Dr SAM HUPERT MBBS Advisory Board Member

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

**4DMedical** 



#### Dr RAYMOND CASCIARI MD Advisory Board Member

Former Chief Medical Officer at St. Joseph Hospital in Orange, CA with over 40 years' experience in Pulmonary Disease, Internal Medicine and Intensive Care Medicine.



#### 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.



#### 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 Non-Executive Director; Chair Remuneration & Nomination Committees

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



#### EVONNE COLLIER Non-Executive Director

Experienced in board appointments (ASX, private, publicly unlisted) with executive background in marketing, innovation/tech and commercial roles; Graduate of the Australian Institute of Company Directors.

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### Executive Summary

- Clinically validated technology: richer diagnostic value, safer, lower cost.
- Significant global market with attractive growth opportunities in the core U.S. market.
- Top tier relationships: clinical and commercial
- Massively scalable SaaS business model.
- Strong pipeline protected by a strong (and growing) IP portfolio.
- Highly experienced Board of Directors and senior management.





# APPENDICES



# Additional XV Case Studies

### Case Study: Novel Treatment

### 💐 4DMedical

#### 60



Novel treatment for a Severe Progressive Silicosis related Occupational Lung Disease

#### Summary

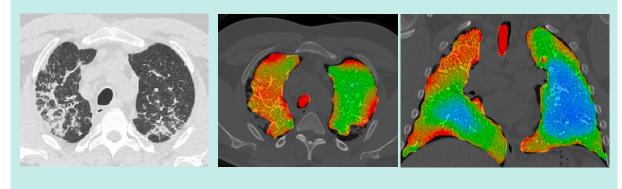
- At baseline, there are advanced changes of chronic, complicated silicosis as marked by nodular coalescence and fibrosis in the apical regions bilaterally, leading to progressive massive fibrosis.
- No significant structural changes are seen after treatment (on CT).
- Following treatment, there are functional improvements in all inspiratory metrics visible on XV LVAS. Notably, the right apical region with areas of relative underventilation (red shading) has markedly improved to average ventilation (green shading) following treatment.

#### **Clinical Observations**

Quantifiable, regional improvements in inspiratory function have been observed following treatment for lung disease, which assists the clinician in monitoring treatment effectiveness.

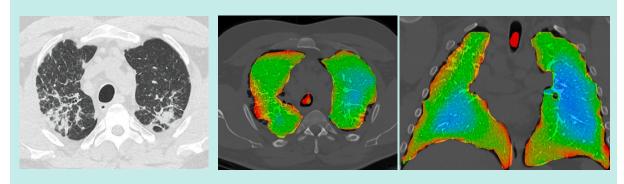
In comparison, serial chest CTs showed no significant change following this treatment

### Baseline



Structural CT	XV LVAS	тv <b>0.5L</b>	vн <b>54.5%</b>	VDP 1 <b>7.3%</b>	

#### 3 Months Post-WLL



Star strand CT	VV/IV/AC	TV	VH	VDP	
Structural CT	XV LVAS	0.6L	47.3%	13.5%	

### Case Study: Assessment of Hiatal Hernia

### **4DMedical**

Age 69 Indications • Past history of COVID-19 • Gastric esophageal reflux disease • Recurrent chest infections

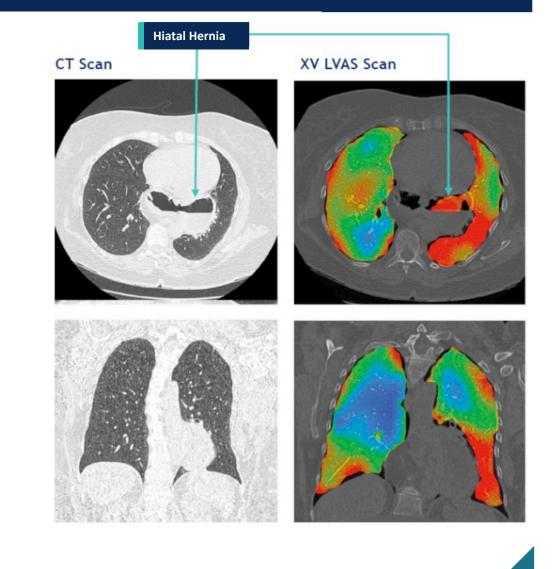
#### Summary

• CT imaging indicated a large hiatal hernia. XV LVAS demonstrated a greater functional reduction in ventilation than expected from CT changes.

### **Clinical Observations**

#### XV LVAS:

Relative reduced ventilation in left lower zone due to mass effect from hernia (non-obstructive atelectasis). Not fully appreciated on CT scan.



Product pipeline (in detail)

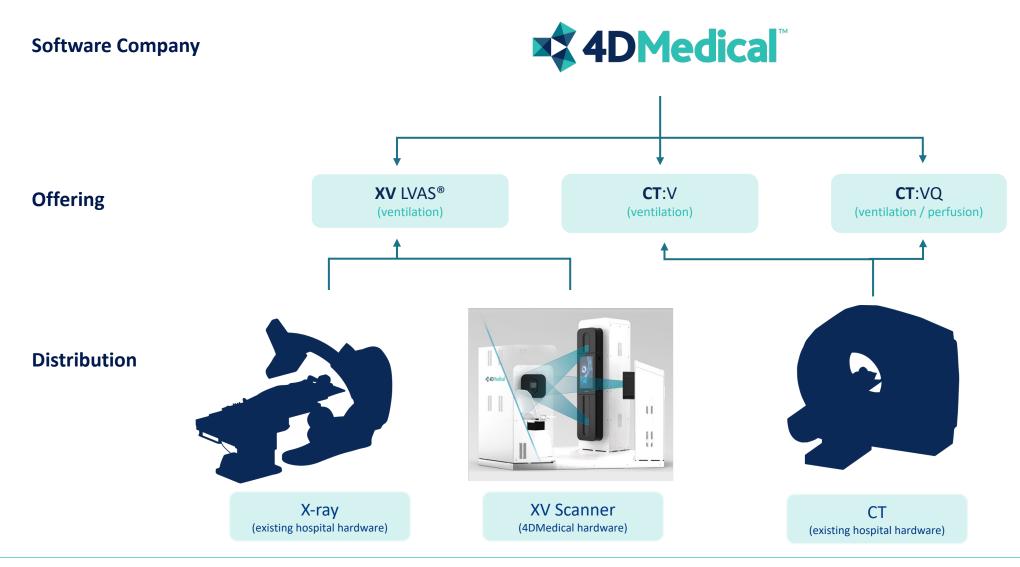


		DISTRIBUTION		
		Fluoroscopy (X-ray)	Computed Tomography (CT)	XV Scanner (XVD)
OFFERING	Ventilation	XV LVAS®	CT:V	Rapid XV LVAS®
OFFE	Perfusion	X:VQ	CT:VQ	Rapid VQ

- Ventilation (V) refers to the flow of air into and out of the alveoli.
- Perfusion (Q) refers to the flow of blood to alveolar capillaries.

## Product pipeline

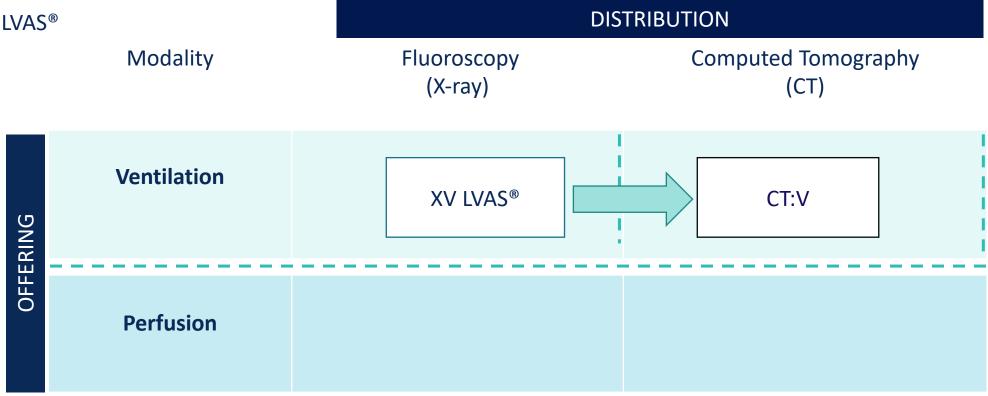
**4DMedical** 



- The simplicity of offering (Ventilation or Perfusion) with the flexibility of distribution
- 4Dimensional Data
- High resolution
- Low Dose

		DISTRIBUTION		
	Modality	Fluoroscopy (X-ray)	Computed Tomography (CT)	
OFFERING	Ventilation	XV LVAS®		
OFF	Perfusion			

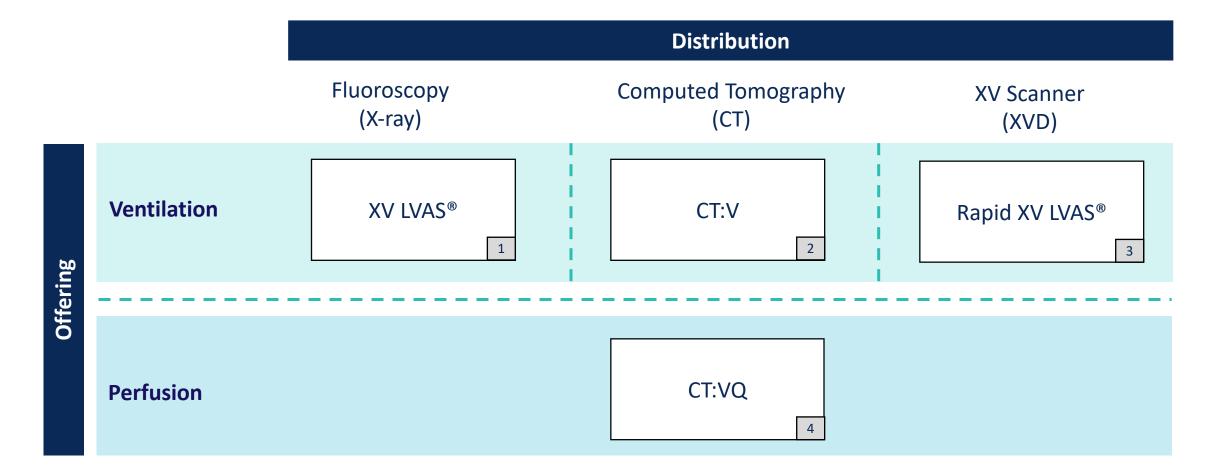
- The simplicity of offering (Ventilation or Perfusion) with the flexibility of distribution
- 3Dimensional Data
- Highly accessible
- Same output as XV LVAS<sup>®</sup>



- The simplicity of offering (Ventilation or Perfusion) with the flexibility of distribution
- Ventilation and Perfusion
- 3Dimensional Data
- Highly accessible
- No contrast required

		DISTRIBUTION		
ed	Modality	Fluoroscopy (X-ray)	Computed Tomography (CT)	
OFFERING	Ventilation	XV LVAS®	CT:V	
OFF	Perfusion		CT:VQ	

• The simplicity of offering (Ventilation or Perfusion) with the flexibility of distribution



## Product pipeline

Stage	CY2022	CY2023	CY2024	CY2025
Research & Developmer	nt			
CT:V				
CT:VQ				
XV Scanner				
Regulatory & Review				
CT:V				
CT:VQ				
XV Scanner				
Commercialisation				
XV LVAS®				
CT:V				
CT:VQ				
XV Scanner				



The Future of Lung Health

### **Corporate** CFO

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