

#### Presentation to Bell Potter Healthcare Conference

#### 13 November 2023

**Melbourne, Australia, 13 November 2023**: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, "4DMedical", or the "Company") is pleased to provide a copy of the presentation to be delivered by Dr Andreas Fouras, Managing Director and CEO of 4DMedical, to the Bell Potter Healthcare Conference on 14 November 2023.

#### -ENDS-

Authorised by the 4DMedical Board of Directors.

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#### About 4DMedical

4DMedical Limited (ASX:4DX) is a global medical technology company that has created a step change in the capacity to accurately and quickly understand the lung function of patients with respiratory diseases.

Through its flagship patented XV Technology<sup>®</sup>, 4DMedical enables physicians to understand regional airflow in the lungs and identify respiratory deficiencies earlier and with greater sensitivity as they breathe. This technology powers 4DMedical's FDA-cleared XV Lung Ventilation Analysis Software (XV LVAS<sup>®</sup>) – the first modality to dynamically quantify ventilation throughout the lungs, and its Computed Tomography-enabled counterpart software, CT LVAS<sup>™</sup>.

XV LVAS<sup>®</sup> and CT LVAS<sup>™</sup> reports are prepared using 4DMedical's Software as a Service delivery model using existing hospital imaging equipment or the Company's revolutionary XV Scanner.

To learn more, please visit <u>www.4dmedical.com.</u>

#### The future of lung health

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# The future of lung health

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4DMedical Limited (ASX:4DX) Investor Presentation November 2023

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# Overview

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### **FY23** achievements

		1H FY2023
Commercialisation	Early-stage commercialisation in Australia Expanded relationship with Australia's I-MED Radiology Network	June 2022
Clinical validation	Burn pit trial validates XV Technology <sup>®</sup> Burn pit clinical trial conducted by US-based Vanderbilt University Medical Center indicates XV Technology <sup>®</sup> is a superior way to detect constrictive bronchiolitis	August 2022
Regulatory	XV LVAS <sup>®</sup> technology gets its own CPT code US Current Procedural Terminology (CPT) Editorial Panel creates new Category III CPT code to uniquely identify the use of XV LVAS <sup>®</sup> technology; provides pathway to reimbursement	October 2022
Product expansion	<b>CT LVAS™ technology's Australian release</b> CT LVAS™ technology released in Australia, adding to 4DMedical's product offering	October 2022
Government funding	<b>4DMedical receives a further MRFF payment</b> A further \$9.4 million (ex GST) received from Australian Government's Medical Research Future Fund after meeting product development milestones	November 2022
Product expansion	XV Scanner at RSNA 2023 Display of XV Scanner at RSNA annual conference, world's largest gathering of medical imaging professionals	November 2022







### **FY23** achievements

2H FY2023

Commercialisation	<b>Signing of first US hospital SaaS contract</b> 5-year contract signed with the University of Miami to provide XV LVAS® ventilation reports, its first US hospital SaaS contract	April 2023
Commercialisation	<b>Dr David Shulkin joins 4DMedical</b> Former U.S. Secretary of Veterans Affairs, Dr Shulkin joins 4DMedical in an advisory capacity to provide critical support and advice	April 2023
Commercialisation	<b>First US VA scan completed</b> The first commercial XV LVAS <sup>®</sup> scan completed within the US Veterans Health Administration, conducted at Harry S. Truman Memorial Veterans Hospital in Missouri	May 2023
Commercialisation	<b>First commercial pilot at U.S. Department of Defense</b> 4DMedical wins first commercial pilot at the Military Health System within the U.S. Department of Defense	May 2023
Commercialisation	Authority to Operate granted at major US VA hospital 4DMedical granted Authority to Operate at Harry S. Truman Memorial Veterans Hospital	May 2023
Product expansion	<b>CT:VQ development milestones met</b> 4DMedical's CT:VQ progresses to a developmental stage, opening the way for the release of early clinical data	May 2023
Capital raise	<b>Successful equity raisings to accelerate commercialisation</b> 4DMedical completes successful equity raising and Securities Purchase Plan, raising an additional \$45m in new capital	May 2023



### FY24 achievements to date

1H FY2024

5	Government funding	<b>4DMedical wins \$1.1m CTCM funding</b> Funding enables expansion of XV Scanner capability beyond ventilation into perfusion	July 2023
	Leadership and expertise	<b>Appointment of Geraldine McGinty to Board</b> Appointment of Geraldine McGinty provides critical U.S. healthcare system and processes required in enabling healthcare providers to receive payment from insurance companies	September 2023
5	Commercialisation	<b>Expansion in ANZ</b> Commercial collaboration advanced with imaging partner I-MED Radiology Network Established imaging partnerships in South Australia, Western Australia, and metropolitan Sydney Ongoing refinement of I-MED model with substantive improvements in patient booking process	October 2023
	Commercialisation	<b>Expansion in ANZ with Integral Diagnostics</b> Signing of a distribution agreement with Integral Diagnostics (ASX:IDX), a leading supplier of medical imaging services across Australia and New Zealand.	October 2023
	Commercialisation	<b>CMS (Medicare) approves reimbursement for 4DMedical</b> Inclusion of 4DMedical's XV LVAS <sup>®</sup> procedure to the Centers for Medicare & Medicaid Services (CMS) annual, final payment rates for hospital outpatient-based services, effective 1 January 2024	November 2023



### **FY24 target catalysts**

Commercialisation	VA funded trial
	<ul> <li>2<sup>nd</sup> Authority to Operate awarded enabling National Authority to Operate</li> </ul>
	Extend Department of Defense engagement
	Execution of commercial agreement with US based academic medical center
	Expansion in ANZ
Clinical	Commencement of trials for CT:VQ
	Commencement of XV Scanner trials
	Publication of peer reviewed journals
Regulatory	FDA submissions for XV Scanner and CT:VQ
	Funding and budget appropriation for PACT Act





### **U.S. healthcare landscape**

U.S. healthcare insurance market covers approximately 90% of the population

Health insurance services are provided by both the private and public sectors

- 1. Private sector health insurance
  - Held by 53% of population
  - Commercial coverage insurance provided by employers or paid by individuals
- 2. Public sector health insurance
  - Held by 37% of population
  - Split across Federal and state-funded Medicare or Medicaid



### Established pathway for reimbursement for new technologies

- Regulatory clearance or approval by FDA
- Validation (effectiveness and economic value) of technology by trials and studies
- Granting CPT III Code
- US Centers for Medicare & Medicaid Services (CMS), part of the Department of Health and Human Services (HHS)
- HHS and CMS have defined processes for new technologies
- Medicare typically sets the benchmark that commercial payers follow

### **U.S. reimbursement process**

#### What does 4DMedical need to secure reimbursement with public & private payers in US?

Addressing 3 key components of reimbursement

#### Code – describes procedure

✓ Cat III CPT Code<sup>1</sup>

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Coverage – defines when product or service is eligible for payment

### ✓ Medicare (65m people)

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- Payment assigns monetary value
- ✓ U.S. \$299 avg rate<sup>2</sup>

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

Answering the question: 'What is the UNMET NEED?'

To answer this question, 4DMedical requires:

 Clinical data demonstrating improved outcomes in patient case and cost of care

 Utilisation of the technology showing payor coverage and evidence of reimbursement

### 4DMedical has a Category III CPT code enabling reimbursement now through Medicare

- 1. Cat III CPT Code effective 1 July 2023
- 2. Average rate is for APC 5722 effective date 1 January 2024

### **Investment opportunity**

	Global demand	<ul> <li>The demand for sophisticated respiratory diagnostics solutions is growing</li> <li>Diagnostic technology largely unchanged for ~50 years</li> <li>Lung diagnostics market ripe for disruption</li> </ul>				
	Global commercialisation strategy	<ul> <li>Commercialisation driven by clinical utilisation demonstrating medical necessity</li> <li>Clinical trials well advanced across multiple conditions provide evidence of efficacy and utility</li> <li>Commercial pilots build use case and support reimbursement</li> <li>Long term agreements with hospital &amp; radiology networks</li> </ul>				
	Near term commercialisation opportunity	<ul> <li>Immediate priority to drive adoption with VA in US and ANZ radiology networks</li> <li>VA scan conducted at Harry S. Truman Memorial; target funded multi-site pilot</li> <li>Integration with VA with Authority to Operate</li> <li>4DMedical approved provider for VA; PACT Act \$280 billion</li> <li>ANZ market rollout progressing, target adjacent markets</li> </ul>				
3	Regulatory and reimbursement	<ul> <li>Reimbursement in US for XV Technology<sup>®</sup></li> <li>CPT Category III code from 1 July 2023; US\$299<sup>1</sup> approved payment 1 January 2024</li> <li>Product pipeline strong – perfusion capability in development</li> <li>FDA Submissions for CT:VQ and CT:LVAS</li> </ul>				
	Organisational maturity	<ul> <li>Organisational capability, strong intellectual property, and funding for next stage of growth         <ul> <li>Key appointments to drive commercialisation</li> <li>Strong controls on IP with 71 patents, providing defendable moat</li> <li>Well funded for growth</li> </ul> </li> </ul>				
4DMedical						

1. Average rate is for APC 5722 effective date 1 January 2024

# Background

**4DMedical** 

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### World first technology





### Global medical technology company 4DMedical Limited (ASX:4DX)

We have invented technology to accurately and quickly understand the lung function of patients with respiratory diseases.

### Flagship patented XV Technology®

Enabling physicians to understand regional airflow in the lungs and identify respiratory deficiencies earlier and with greater sensitivity as they breathe.

### FDA-cleared XV Lung Ventilation Analysis Software (XV LVAS®)

The first modality to dynamically quantify ventilation throughout the lungs.

### Computed Tomography-enabled counterpart software, CT LVAS<sup>™</sup>, and XV LVAS<sup>®</sup> reports

Prepared using 4DMedical's Software-as-a-Service (SaaS) delivery model using existing hospital imaging equipment or 4DMedical's revolutionary XV Scanner – the world's first 4D lung diagnostic scanner.

**4DMedical** 

#### Hardware



"4DMedical has all the advantages and none of the disadvantages of existing lung diagnostic technology.

Our XV Technology<sup>®</sup> and Lung Ventilation Analysis Software (XV LVAS<sup>®</sup>) is the latest evolution.

### The opportunities are significant."

Professor Andreas Fouras Founder, Inventor Managing Director & Chief Executive Officer 4DMedical Limited (ASX:4DX)

### **Corporate overview**

Share price performance | 1 November 2022 - 31 October 2023



#### Trading information as at 31 October 2023

52 week high	A\$1.16
52 week low	A\$0.30
Number of shares	346.5M
Market capitalisation (31 Oct 2023)	A\$159.4M
Avg. daily volume (last month)	0.25M Shs / A\$0.12M
Cash Balance as at 30 Sep 2023	A\$59.9M

Shareholder information as at 31 October 2023	
Dr Andreas Fouras (MD and CEO)	19.0%
Number of shareholders	8,672

### **Global market disruption opportunity**



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

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

1. Figures adapted from Frost and Sullivan Report 2020 USD \$31.3 billion global spend annually (table)

### **Global market revenue opportunity**



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

- Four existing respiratory diagnostic technologies account for 99% of current procedures
- These existing lung diagnostics 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 (USD) Procedu		Procedures
U.S.A	13,716M	73.5M
Others	4,964M	59.8M
Germany	2,678M	20.3M
Japan	1,905M	22.8M
China	1,851M	101.6M
UK	1,351M	8.9M
France	1,191M	10.2M
Spain	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

### **Investment opportunity – well funded for growth**



#### Significant commercialisation momentum

- First US hospital contract signed with University of Miami for provision of XV Technology<sup>®</sup>, establishing a framework in the US
- Successful completion of first commercial scan with U.S. Veteran Affairs (VA), at Harry S. Truman Memorial Veterans Hospital in Columbia, Missouri
- Strong pipeline of further commercial agreements expected to be announced in 2023



#### U.S. Veteran Affairs (VA) opportunity

- The U.S. PACT Act has appropriated USD \$280b in additional funding over ten years for affected Veterans
- VA to evaluate "emerging technology using existing x-ray imaging equipment to derive four-dimensional models of lung function"
- Vanderbilt 'burn pit' trial demonstrates XV Technology<sup>®</sup> can detect the presence of constrictive bronchiolitis or PDRS
- Former US Secretary of Veterans Affairs, Dr David Shulkin has joined 4DMedical in an advisory capacity



#### U.S. Department of Defense (DoD) opportunity

- Contractual arrangement with the US DoD involves performing an agreed number of scans using XV Technology<sup>®</sup>, with opportunity to conduct further scans
- Payment is fixed on full commercial terms for the total agreed scans to be performed
- Enables application of XV Technology<sup>®</sup> across a broad range of respiratory illnesses
- Represents another significant milestone in commercialisation strategy



#### American Medical Association (AMA) reimbursement progress

- Progress made toward reimbursement from the American Medical Association (AMA) which represents a major commercialisation milestone.
- Two category III CPT codes for the XV LVAS<sup>®</sup> scan became active from 1 July 2023, CMS assigned \$299<sup>1</sup> per scan from 1 January 2024.
- CPT codes enable streamlined reporting and increased accuracy and efficiency in the healthcare claims process

### 4DMedical

1. Average rate is for APC 5722 effective date 1 January 2024

# Leadership

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### **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 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



#### 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.

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.



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.



#### 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.



### **Executive team**

#### Accelerating 4DMedical's patient outcomes and commercialisaton



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.



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.



MATT TUCKER Chief Commercial Officer

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



NAOMI LAWRIE General Counsel & Company Secretary

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



SIMON GLOVER Chief Financial Officer

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



# Software



Digital rendering of 4DMedical's XV Technology®

### **Software offering & applications**



### Software as a Service (SaaS) revenue model







**4DMedical XV Technology**<sup>®</sup> Lung scanner software and hardware XV LVAS<sup>®</sup>/CT LVAS<sup>™</sup> Technology already offered as SaaS to healthcare providers

**Commercialisation** Underway; high gross margins

- Robust patented IP portfolio
- First mover advantage

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- Products already released
- A well-advanced product pipeline
- Significant barriers to entry
- Capex light business model
- High gross margins expected

Rapid SaaS deployment

- Initially Ventilation Analysis Software (XV LVAS<sup>®</sup> and CT LVAS<sup>™</sup>)
- Used with existing hardware (CT, fluoroscopy)
- Real time non-invasive analysis in early-stage commercialisation
- Perfusion VQ (blood flow) analysis software release of early clinical data at ATS
- XV Scanner (4DMedical hardware)

- Demonstrable progress with VA
- Initial commercial contracts secured in US
- XV LVAS<sup>®</sup> being validated in US trials and pilots
- Extending capability into perfusion with CT:VQ

   significant growth opportunity in nuclear medicine
- US reimbursement process well advanced
- Expanding Australian presence with radiology network I-MED

### **XV Technology® 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



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



Low cost Competitive pricing below incumbent technologies

### XV Technology & Lung Ventilation Analysis Software (XV LVAS®)

XV LVAS<sup>®</sup> is the world's first and only modality which can dynamically quantify ventilation throughout the lungs, exposing patients to lower levels of radiation relative to other diagnostic methods.



### 4DMedical's XV lung ventilation analysis software results





XV technology allows for the detection of high and low areas of ventilation with pinpoint accuracy, with ventilation being calculated for all parts of the lung, in all phases of the breath.

## Hardware

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### **4D lung scanner hardware**

### Invented to support 4DMedical's XV Technology®

- Increasing throughput, reducing costs for healthcare providers
- Facilitating access to XV Technology<sup>®</sup> for more patients, including children and the very unwell unable to be scanned using conventional imaging equipment
- Accelerating uptake of the Company's core SaaS technology product

"From the viewpoint of doctors and patients, the scanner represents a seminal event in the global evolution of respiratory diagnostics. From a commercialisation perspective, this scanner creates multiple opportunities to drive adoption of XV Technology<sup>®</sup>."

> Professor Andreas Fouras Managing Director & Chief Executive Officer 4DMedical Limited (ASX:4DX)



Digital rendering of 4D Medical's XV Scanner installed at Prince of Wales Hospital, Sydney, NSW, Australia

# 4D lung scanner unveiling at RSNA & ATS, deployment at SAHMRI and UNSW

- XV Scanner on display at two major global industry conferences:
  - Radiological Society of North America (RSNA 2022)
  - The American Thoracic Society (ATS 2023)
  - Recipient of 'Best in Show' exhibitor award at ATS 2023
- Commercialisation efforts focused on building research and clinical evidence:
  - The XV Scanner has been installed in the Research Imaging NSW facility at the Prince of Wales Hospital in Randwick, Sydney, NSW, Australia
  - Gen 2.0 XV Scanner designed and built in 4DMedical's advanced manufacturing facility and installed at the South Australian Health and Medical Research Institute (SAHMRI) to be used by researchers at the University of Adelaide
  - CTCM grant (\$1.1m) to fund development of capability to measure perfusion
  - Targeting deployment at US based institutions in FY2024





## **Product pipeline** Extending accessibility



### **CT:VQ development**

Extends accessibility of perfusion and ventilation, reduces costs and improves productivity, and enhances patient experience

### Why CT:VQ?

- 1. Clinical care and coordination
  - Workflow transition from nuclear to radiology improves access to both perfusion and ventilation status for clinicians
  - Utilise existing CT/radiology workflow
  - Decrease need for direct physician availability for intravenous contrast
- 2. Patient and care giver centred experience
  - Non-invasive, reduce test time and increase availability
  - Reduce transport to specific high acuity sites
- 3. Efficiency and cost reduction
  - CT availability increases adoption rates
  - Reduced use of expensive capital equipment
- 4. Safety domain
  - Decrease usage of nuclear isotopes
  - Avoids use of non-ionic bolus injections of contrast agents
- 5. Market opportunity
  - Estimated market opportunity >\$1B
  - High cost and low efficiency of existing diagnostics drivers for rapid substitution

### Status and next steps

- Announced at ATS 2023 (May 2023) CT:VQ progressing to development stage following release of early clinical data
- Targeting regulatory submission FY2024
- Clinical trials in progress to build clinical evidence to support reimbursement



### XV Scanner and extension to measurement of perfusion

### Broadening the capability of 4DMedical's XV Scanner

- Successful application for CTCM funding received \$1.1m
- Purpose of the funding is to broaden capability of XV Scanner to include measurement of blood flow (perfusion, Q)
- Will strengthen product offering for non-invasive lung diagnostics with provision of detailed quantitative data in single scan
- Advantages over existing modalities:
  - Zero contrast agents
  - Ultra low radiation
  - Rapid scan times
  - Improved patient experience
  - Accessible to all patient cohorts, including children, the elderly, and the very unwell
  - Unparalleled functional information spanning both ventilation and perfusion
- Targeting completion of development FY2024



# Commercialisation

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progress



### **Commercialisation strategy**

Clinical trials Validating efficacy and utility **Commercial pilots** Generating clinical use case

Long term agreements Sustainable revenue generation







Research partners delivering the body of scientific evidence for clinical use

Peer reviewed publications of clinical trial results

Physicians gaining familiarity with technology and business case for clinical adoption

Reimbursement – coding, coverage, and payment

Long term agreements with hospital networks and radiology providers

Accessibility & availability for diagnosis; Improved productivity & costs for hospitals

### **Commercialisation update – near term**

### Immediate focus on targeting VA and ANZ rollout, which are not dependent on reimbursement



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### **Commercialisation update – medium term**

### Medium term focus is on achieving reimbursement in the U.S. for XV Technology® product suite

**Recent wins** 

Long term agreements & reimbursement

- University of Miami Hospital commercial agreement
- ATS 2023 presentation of CT:VQ
- Category III CPT code online July 2023
- 4 clinical studies completed

Target for FY2024 - 2025

- Commencement of trials for CT:VQ
- FDA submissions for XV Scanner and CT:VQ
- Execution of commercial agreement with US academic medical centre
- Reimbursement for XV Technology<sup>®</sup> product suite



### **XV Scanner commercialisation update**

### Extension of capability to include measurement of perfusion

**Recent wins** 

- Delivered on project milestones and ensure receipt of funding of \$9.5m in November 2022
  - Recruited experienced medical imaging executive to accelerate the commercialisation of the XV Scanner
  - The XV Scanner made its US debut at the RSNA 2022 conference
  - Awarded CTCM grant for \$1.1m for development of perfusion capability
  - Deployment of scanner at SAHMRI

### Target for FY2024

- Seeking regulatory approval in US
- Extending capability to measurement of perfusion
- Deployment of scanner at US research institutions
- Commencement of clinical trial utilising scanner



### **4DMedical**

**XV Scanner** 

### **Commercialisation strategy – clinical trial validation**

	BLVR	Asthma	Paediatric CF	Lung Transplant	ILD-WLL
	University of Miami XV LVAS®	Cleveland Clinic XV LVAS <sup>®</sup>	John Hopkins XV LVAS®	Alfred Hospital, Melbourne XV LVAS <sup>®</sup>	Prince Charles Hospital XV LVAS <sup>®</sup>
Imaging in progress &	РН	COPD	BLVR	COPD	CF
patient recruitment	Cleveland Clinic VQ	Vanderbilt University XV LVAS <sup>®</sup>	Temple University XV LVAS <sup>®</sup>	University of Miami XV LVAS <sup>®</sup>	Women and Children Hospital Adelaide XV LVAS®
Imaging complete	Duke University XV LVAS®	CB (PDRS) Vanderbilt University XV LVAS®	COPD Oregon Health & Science University XV LVAS®		
	COPD	Pneumonitis			
Completed studies	John Hopkins XV LVAS®	Cedar Sinai XV LVAS®			
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	The importance	of reimbursement to a	chieve commercialisati	on	
Establishing medical necessity and unmet	<ul> <li>The publication of</li> <li>Clinical trials established</li> </ul>	blish <i>a medical necessity</i> for use	edical's ability to secure reimble in diagnosis and treatment of	respiratory illnesses	cialisation
need	4DMedical's clinical trial validation process				

- 4DMedical's XV Technology<sup>®</sup> continues to be validated through application and clinical utility in peer-reviewed journals and conferences
- 4DMedical currently has four submissions under review, with eight in preparation

# Demonstrating clinical application



### **Demonstrating clinical application: reliability & repeatability**

Indication: healthy male with no signs of disease (age 30s)



#### Summary:

- XV LVAS® validated assessment of regional lung function
- XV Technology<sup>®</sup> proved the reliable repeatability of findings
- XV Technology<sup>®</sup> enabled the quantification of regional ventilation defects
- Effective monitoring of disease and treatment effects



#### **Clinical Observations**

- The lung fields are clear without any marked lesions or diseases
- Healthy lungs with consistent green and blues, indicative of healthy lung function as expected with a healthy 30-year-old

### **Demonstrating clinical application: Silicosis**

Indication: Novel treatment for a Severe Progressive Silicosis related Occupational Lung Disease (Male aged 36)



#### 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<sup>®</sup>
- Notably, the right apical region with areas of relative underventilation (red shading) has markedly improved to average ventilation (green shading) following treatment

### Follow-up scan (3 months post-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

### **Demonstrating clinical application: COPD**

Indication: Prior biologics therapeutic for re-current exacerbation of moderate obstructive lung disease (Male, age 60)



#### 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

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### Follow-up scan (5 months post-treatment)

Structural CT Scan

XV imagery of lung ventilation





ΤV	VH	VDP
0.70	47.0	13.4

#### **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

### **Demonstrating clinical application: Long Covid-19**

Indications: Long Covid symptoms (Female; age 52)



#### 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 patient continued to display symptoms of shortness of breath, cough and dyspnoea on exertion
- Following physician consultation, a follow-up CT and 4DMedical XV LVAS<sup>®</sup> were prescribed

#### Follow-up scan (3 months post-treatment)

#### Structural CT Scan



#### XV imagery of lung ventilation



#### **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



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