

# 1H FY2025 Half-year results

### **28 February 2025**

# Highlights

- 4DMedical receives strong support from new and existing institutional investors for \$5.5m
  Placement
- Company launches Share Purchase Plan (SPP), which is underwritten to \$7m
- 1H FY25 operating revenue of \$3.8m, up 265.3% on the prior corresponding period (pcp)
- Gross margin stable at over 90% (93.5% vs 93.6% pcp)
- 1H FY2025 net operating expenditure of \$18.8m, down 11% v 2H FY24
- Over 8,000 scans delivered in 1H FY25, up 37% from 2H FY24 and 77% on pcp
- 4DMedical now operating at 301 sites, up 24% from 2H FY24 and 41% on pcp
- Momentum continues to build with the implementation of the Philips Reseller Agreement with the 4DMedical products now live in catalogue, allowing full commercial activity to commence
- Strong progress in commercialisation activities with signing of key reference sites in the U.S.
  (UChicago Medicine and UCSD Health) and large radiology clinics in Australia (PRC and Qscan)
- FDA clearance of IQ-UIP™, marking eighth commercial product to be granted clearance in the US market, and subsequent CMS reimbursement for US\$650
- Major progress for blockbuster product CT:VQ<sup>™</sup> ahead of FDA clearance: successful clinical trial data presented at RSNA, contract win to supply CT:VQ<sup>™</sup> scans to US DoD, and \$1.9 million CRC-P grant to fund health economics and clinical evidence generation
- Group net cash balance was \$16.0 million as at 31 December 2024

**Melbourne, Australia, 28 February 2025**: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, "4DMedical", the "Group", or the "Company") today announces its half-year results and releases its Appendix 4D for the half-year ended 31 December 2024 ("1H FY25").

### **Capital Raise**

On 21 February 2025, the Company announced the successful completion of a Placement of \$5.5m at \$0.425 per share to new and existing institutional investors.

In addition to the Placement, the Company launched a Share Purchase Plan (SPP), underwritten to \$7m, providing Eligible Shareholders in Australia and New Zealand with the opportunity to participate. The SPP will allow Eligible Shareholders to purchase between \$1,000 and \$30,000 worth of New Shares at an offer price being the lower of (i) \$0.425 per share, and (ii) a 2.5% discount to the VWAP of shares traded on the ASX during the five trading days up to the closing date of the SPP, rounded to the nearest half cent. The offer to acquire shares under the SPP opened on Tuesday, 25 February 2025 and will close on Tuesday, 18 March 2025. The Company reserves the right to close the offer early and/or to accept oversubscriptions of shares under the SPP, subject to the ASX Listing Rules and the *Corporations Act 2001*.

New shares issued under the Placement and SPP will have a free attaching option for every New Share issued, with an exercise price of \$0.55 and an expiry date of the earlier of: (i) 28 February 2026, and (ii) the date being 30 days from the date on which the Company announces FDA clearance for its ventilation and perfusion technology, CT:VQ<sup>™</sup> (FDA Announcement).



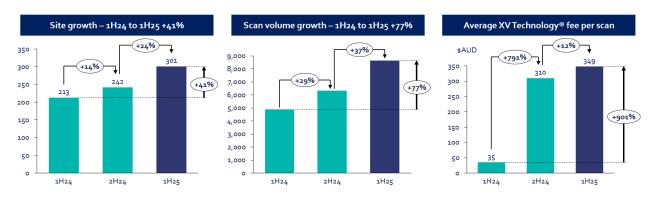
Upon their exercise, holders of New Options will receive a fully paid ordinary share and a further Piggyback Option for nil consideration, which will be exercisable at \$0.75 per Piggyback Option and expire on the earlier of 29 February 2028 and the date being 2 years from the date of the FDA Announcement.

### **Financial Performance**

Revenue from ordinary activities of the Group increased by 265.3% to \$2.9m (1H FY24: \$0.8m). Operating revenue was principally related to Software-as-a-Service (SaaS) contracts. Gross margin was stable at an impressive 93.5% (1H FY24: 93.6%), demonstrating the Company's operating leverage and ability to materially scale up operations whilst maintaining consistently low costs to serve. Other income totalled \$4.9m, reflecting government grants and R&D tax incentives. 1H FY25 total reported income totalled of \$7.8m.

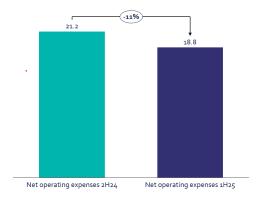
Recent contract signings of IPOC, UCSD Health, UChicago Medicine, Qscan, and PRC have not contributed to 1H FY25, and will be incremental to the SaaS revenue run rate going forwards.

4DMedical is now delivering SaaS products at 301 sites globally, up from 242 sites in 2H FY2024 (24% growth), and up 41% on pcp. The Company delivered over 8,000 scans in 1H FY2025, up 37% from 2H FY2024 and 77% on pcp.



4DMedical growth in sites, scan volume and fee per scan over 18 months to December 2024

Operating expenditure attributable to the core 4DMedical operations was \$20.1m (based on constant currency), down 0.8% vs pcp, presenting effective cost control measures across the Company. Net operating expenditure (based on constant currency) was down 11% vs 2H FY24, driven primarily by a re-prioritisation of resources away from R&D to commercially aligned activities, and the completion of the integration of the Imbio acquisition. It is expected these two factors will deliver further savings in 2H FY25, as the product portfolio matures, and R&D costs continue to reduce.



Net operating expenditure offset by grant income and on constant currency basis



### **Philips Reseller Agreement**

Momentum continues to build with the implementation of the Philips reseller agreement. In February 2025, the Philips sales team first gained access to 4DMedical's SaaS catalogue, opening the door to full commercial activity and first sales in 3Q FY25.

Philips and 4DMedical have commenced combined sales presentations, ensuring that the funnel of sales opportunities to deliver on our targets is growing rapidly.

Philips' commitment to the partnership was highlighted at the RSNA conference, where a joint presentation by Andreas Fouras, and Philips CEO for North America, Jeff DiLullo, emphasised the synergies between 4DMedical's advanced technologies and Philips' extensive healthcare presence. Together, the companies illustrated how their collaboration enhances diagnostic precision, streamlines clinical workflows, and broadens access to advanced respiratory care solutions.

### Expansion in the US and AU with key opinion leading reference sites

Establishing strong reference sites is a critical foundation for driving the successful adoption of 4DMedical's technology. These sites influence other healthcare providers and institutions to integrate the technology into their practices. During the period, 4DMedical announced several additional key partnerships, reflecting the readiness of leading healthcare providers to adopt, and pay for, its innovative solutions.

A notable example is 4DMedical's new partnership with nationally recognised University of Chicago Medicine (UChicago Medicine). This agreement facilitates UChicago Medicine clinicians to utilise 4DMedical's comprehensive portfolio of structural and functional lung imaging products, including CT:LVAS™. UChicago Medicine, an academic medical center (AMC) with an internationally renowned Pulmonary and Critical Care Medicine Department, is at the forefront of advancing treatments for complex lung diseases. By integrating 4DMedical's revolutionary imaging technology, UChicago Medicine is poised to deliver unprecedented precision in diagnosing and managing lung conditions, reinforcing its position as a leader in pulmonary care innovation.

UCSD Health also signed with 4DMedical during the quarter, and subsequently expanded its agreement to include SeleCT, a screening service that analyses chest CTs to identify patients suitable for treatment with endobronchial valves. As disclosed at the time of the announcement, the institution's leading clinician, Dr Jonathan Chung, an expert in interstitial lung disease, occupational lung disease, nontuberculous mycobacterial pneumonia, and large and small airway diseases, articulated the clinical utility of 4DMedical's technology, expressing that it would not only "improve population healthcare at a medical centre, but also can help with the bottom line for the hospital as patients are directed into the correct sub-specialised clinics for appropriate therapy and procedures".

Beyond AMCs, 4DMedical secured additional agreements with leading radiology network providers in both the U.S. and Australia. In November 2024, the company signed a commercial contract with Imaging Partners of Orange County (IPOC) in the U.S. to provide CT LVAS™ and LDAf (Lung Density Analysis™) scans. This marks 4DMedical's first commercial contract with an independent radiology provider since the Centers for Medicare & Medicaid Services (CMS) approved reimbursement for CT LVAS™, signalling significant progress in the technology's commercialisation.

In Australia, 4DMedical signed a commercial contract with Perth Radiological Clinics (PRC) to deliver XV Technology®-enabled ventilation reports across 16 initial clinics in Perth. PRC, a leading provider of diagnostic imaging services in Western Australia, serves a significant portion of the region's population through its network of clinics. On 24 January, 4DMedical announced the signing of a commercial contract



with Qscan Radiology Clinics, a leading provider of diagnostic imaging services in Queensland. This agreement follows a successful pilot of 4DMedical's products with QScan and represents the first Australian contract to incorporate products from both the Pulmonary Function and Pulmonary Structure suites, including CT LVAS™.

# Continuation of successful engagement with U.S. Government

The U.S. Government sector presents a significant opportunity for 4DMedical, particularly with the Department of Veterans Affairs (VA) and the Department of Defense (DoD). Distinct from the VA, the DoD oversees one of the world's largest healthcare systems, serving over 9.5 million active-duty service members, their families, and retirees through the Military Health System (MHS). With more than 200 military hospitals and clinics worldwide, the MHS is committed to delivering integrated, high-quality healthcare that ensures the readiness and resilience of U.S. Armed Forces.

Recently, 4DMedical secured a contract with the DoD to pilot its CT:VQ<sup>™</sup> technology, designed to assess lung health in a fixed cohort of active-duty personnel. This builds on a prior agreement with the DoD for deploying CT LVAS<sup>™</sup> in a pilot program. The new contract highlights the DoD's recognition of 4DMedical's technology as a critical tool for delivering advanced health insights for military personnel.

In addition to the opportunity with the DoD, the Company's portfolio of functional and structural imaging products is well-suited to provide actionable insights for VA physicians across the Veteran population. This is particularly critical as Veterans experience chronic lung diseases, such as COPD, at three times the rate of the general population.

4DMedical and Philips are collaborating across the VA, including the support of scalable, non-invasive lung screening aligned with the PACT Act. 4DMedical's XV LVAS® and LDAf technologies are widely recognised as the two leading non-invasive solutions for evaluating Deployment-Related Respiratory Disease (DRRD).

# FDA clearance for IQ-UIP™ broadens 4DMedical's product portfolio

In January 2025, 4DMedical announced it had received FDA clearance for its IQ-UIP™ product, an advanced Al-driven lung diagnostic tool designed to revolutionise the diagnosis of Usual Interstitial Pneumonia (UIP), the hallmark radiological pattern for diagnosing Interstitial Pulmonary Fibrosis (IPF).

Usual Interstitial Pneumonia (UIP), often linked to Idiopathic Pulmonary Fibrosis (IPF), is a severe condition characterised by chronic inflammation and progressive lung fibrosis. The median survival post-diagnosis ranges from 1 to 2 years, and the condition affects approximately 140,000 individuals in the U.S. alone, with over 50,000 new cases diagnosed each year. The global IPF treatment market was US \$4.01 billion in 2024 and is expected to grow to US \$7.81 billion over the next 10 years.

Diagnosing UIP poses a significant clinical challenge due to symptoms often mimicking more prevalent respiratory conditions like COPD, bronchitis, or asthma. In fact, more than 50% of UIP cases are initially misdiagnosed, hampering timely interventions that could extend life expectancy, highlighting the urgent need for innovative solutions such as IQ-UIP™. In addition to its diagnostic applications, IQ-UIP™ has the potential to shorten clinical trial timelines and reduce costs for pharmaceutical companies by providing a reliable imaging biomarker and patient selection tool. Clinical trials in this sector cost over US \$115 million per trial on average, while the total cost to develop new drugs and take them to market can be as high as US \$4.5 billion. IQ-UIP™ has the potential to dramatically reduce the costs and time taken for clinical trials, which will benefit pharmaceutical companies, while also delivering better health outcomes to patients in a faster time frame.



# 4DMedical gains regulatory approval for CT LVAS™ in Canada

The approval of CT LVAS™ in Canada adds to the existing approvals for Lung Density Analysis (LDA), Lung Texture Analysis (LTA) and Lung Nodules in Canada, reinforcing 4DMedical's commitment to delivering cutting-edge respiratory imaging technology to patients and healthcare providers. The regulatory status of the Company's portfolio of products is presented below:

	Product		Regulatory Clearance			
			US	Canada	Europe	Australia
Pulmonary Function	XV LVAS®	Dynamic Ventilation Analysis (Fluoroscopy)	✓			✓
	CT LVAS™	CT-based Ventilation Analysis	✓	✓		✓
	CT:VQ™	Next Gen VQ (Ventilation + Perfusion) – clearance yet to be submitted				
	Functional LDA (LDAf)	Air Trapping + Emphysema	✓	~	✓	~
Pulmonary Structure	Lung Density Analysis™ (LDAi)	Emphysema, HAA, Fissures	✓	✓	✓	✓
	Lung Texture Analysis™ (LTA)	ILD's / Fibrosis		✓	✓	✓
	IQ-UIP™	IPF Screening for UIP pattern	✓			
	Lung Nodules	Lung Cancer (Partner Solution)	✓	✓	✓	✓
Cardio- vascular	CAC	Coronary Calcification/Heart Disease	✓		✓	
	PH Assessment	Hypertension (RV/LV, MPA, Pa/Ao)	✓		✓	

Canada spends 63% more on healthcare than Australia. With a population of over 40 million people, the Canadian GDP is over US\$2.1 trillion and is ranked 10<sup>th</sup> in the world. Within Canada, there are 560 CT scanners, predominantly located within hospitals (94%), with 12.7% of 6.4 million total CT examinations per annum relating to respiratory imaging. This significant opportunity lies within easy reach of our US-based sales teams, with 70% of Canada's population living below the 49<sup>th</sup> parallel and a further 20% living within 160 km of the US border.

CT LVAS™ enables clinicians to assess lung ventilation using standard CT scans, providing valuable insights into lung function without the need for additional imaging or contrast agents. The software is designed to improve the diagnosis and monitoring of lung diseases, including chronic obstructive pulmonary disease (COPD) and other respiratory conditions, ultimately enhancing patient outcomes.

With the addition of CT LVAS™ to 4DMedical's portfolio of cleared products in Canada, the Company is well-positioned for the potential future approval of its CT:VQ™ imaging technology. CT:VQ™, once cleared, would further enhance diagnostic capabilities by integrating ventilation and perfusion imaging for a more comprehensive assessment of lung function.

The Company will continue to pursue regulatory approvals in Canada as part of its strategy to drive commercial adoption and improve respiratory care across North America.

# Major progress for CT:VQ™

One of 4DMedical's most exciting advancements is the unveiling of its CT:VQ™ technology.

At RSNA 2024, 4DMedical presented clinical trial data for its groundbreaking CT:VQ™ technology, an advanced imaging solution offering a compelling alternative to traditional Nuclear VQ scans. This innovative approach delivers comparable diagnostic insights without the need for radioactive isotopes or expensive infrastructure. During the session, 4DMedical demonstrated how CT:VQ™ improves access to



care, delivers faster results, and enhances patient safety. The presentation, attended by industry professionals, showcased  $CT:VQ^{TM}$ 's potential to revolutionise lung ventilation and perfusion imaging, driving significant progress in respiratory diagnostics.

The U.S. market for Nuclear VQ scans exceeds US \$1 billion annually, with approximately one million scans performed each year at an average cost of over US \$1,000 per scan. 4DMedical's CT:VQ™ technology offers the opportunity to replace this outdated and inefficient diagnostic tool while enhancing patient experience and extending its use to a broader audience.

Adding to this momentum, 4DMedical recently received \$1.9 million in CRC-P funding for its project, "CT:VQ – A Better Pulmonary Perfusion Test." This funding will accelerate the generation of clinical evidence to validate CT:VQ's efficacy and advance commercialisation. Additionally, the CRC-P grant will further accelerate efforts to provide the clinical evidence necessary for physicians to adopt CT:VQ $^{\text{TM}}$  as an immediate replacement for Nuclear VQ scans.

#### **Imbio Earn Out**

The hurdle set for the first Imbio earn out for CY2024 revenues was not fully satisfied, and as a result, 4DMedical will not be required pay the seller the US\$10.0 million in shares.

As disclosed on in the Company's announcement on 7 January 2025, the FDA clearance of IQ-UIP™ is one of three products that can trigger the obligation to pay earnout consideration of U5\$5 million in 4DMedical shares to the sellers of Imbio Inc, the issue of such shares having been approved at the Company's EGM held on 22 January 2024. Once the issue of shares is finalised, shareholders will be updated.

#### XV Scanner installed at VUMC

In July 2024, 4DMedical installed the XV Scanner at Vanderbilt University Medical Center as part of the Military Exposures Research Program (MERP). The MERP is an initiative of the U.S. Department of Veterans Affairs (VA) as part of its commitment to address evidence needs related to toxic exposures and health, often in partnership with education and research institutions. MERP grant funding by the VA enabled the installation of an XV Scanner at Vanderbilt, a hub for Veterans' health research.

The XV Scanner is being used to improve understanding of toxic effects of burn pits under military conditions and overcome challenges of exposure assessment as part of the Post-Deployment Respiratory Illness in Veterans of Iraq and Afghanistan (PRIVIA) Study. Researchers expect this study will positively impact Veterans by advancing their understanding of factors which cause deployment related respiratory disease (DRRD) and improves their ability to diagnose DRRD non-invasively.

# 4DMedical MD/CEO and Founder Andreas Fouras said:

We are experiencing strong growth in the number of sites, the number of scans per site and the revenue earned per scan. These three layers of growth are now becoming clearly visible on our top line. In addition, the recent regulatory approval of  $IQ-UIP^{\text{TM}}$  and subsequent CMS reimbursement adds considerable weight to the attractiveness of the product portfolio.

The foundations for our recent growth rest on our comprehensive portfolio of products that combine to meet the needs of doctors and patients. While we have built this portfolio, our sales team has been hard at work to refine our commercialisation strategy. In combination these factors have allowed our sales team of 10 to drive SaaS revenues from a low base to a run rate greater than \$6m in 2 short years. I am excited by the imminent prospect of the full might and scale of the Philips sales team augmenting these efforts.



Later in the year, as  $CT:VQ^m$  comes online, we gain yet another dramatic catalyst for growth.  $CT:VQ^m$  is set to disrupt a billion dollar segment of respiratory diagnostics by displacing Nuclear VQ imaging with a technology that is faster, safer, cheaper, more convenient and more accessible. We have been working for some time, leveraging hard fought experience with existing products, to build an aggressive market adoption strategy, and this contract win with the DoD, prior to FDA clearance, is testament to that work and the clear competitive advantages of our product.

I would also like to extend my sincere thanks to the shareholders for their continued support as we complete the fully underwritten \$7.0m Share Purchase Plan. We feel the structure of the SPP allows our existing shareholders, who have been incredibly supportive over the years, to benefit in the future successes of the Company.

We have rapid organic growth unfolding right now, ready to be turbocharged by the addition of Philips. Add a blockbuster product to this mix, and we have the ingredients for an incredible year ahead.

# -ENDS-

Authorised by the 4DMedical Board of Directors.

#### **Contacts**

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#### **About 4DMedical**

4DMedical Limited (ASX:4DX) is a cutting-edge global medical technology company revolutionizing respiratory care. By harnessing advanced imaging and AI-powered solutions, 4DMedical delivers unprecedented insights into lung function, enabling earlier and more precise diagnoses of respiratory diseases.

At the heart of 4DMedical's innovation is its patented XV Technology®, a groundbreaking platform that dynamically quantifies ventilation throughout the lungs as patients breathe. This technology underpins the company's FDA-cleared XV Lung Ventilation Analysis Software (XV LVAS®) and its CT LVAS™, empowering physicians to detect and monitor regional airflow abnormalities with unparalleled sensitivity.

4DMedical's solutions integrate seamlessly into existing hospital infrastructure via its Software as a Service (SaaS) model, transforming routine imaging into powerful diagnostic tools.

In December 2023, 4DMedical expanded its leadership in medical imaging with the acquisition of Imbio, a pioneer in artificial intelligence solutions for chronic lung and cardiothoracic diseases. Imbio's Al-driven platforms enhance physician productivity, improve diagnostic precision, and support personalized care, aligning seamlessly with 4DMedical's mission to redefine respiratory healthcare.

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