4DMedical targets US$2.5B PE market entry for CT:VQ™

2 June 2026

Highlights

- 4DMedical launches CLEAR, a clinical evidence program designed to fast-track CT:VQ™ entry into the acute pulmonary embolism (PE) market
- CLEAR opens pathway for CT:VQ™ to address both the existing nuclear VQ market (~1 million scans per annum), and the materially larger CTPA-dominated PE opportunity (~5 million scans per annum), growing the obtainable market for CT:VQ™ in the U.S. to US$3B
- Core study for CLEAR is a multi-centre, multinational, prospective, observational study putting CT:VQ™ head-to-head with CTPA in patients with suspected PE
- 4DMedical has entered into a clinical research agreement with Mass General Brigham (MGB) affiliated teaching hospitals as the lead site for CLEAR

Melbourne, Australia, 2 June 2026 – 4DMedical Limited (ASX: 4DX, "4DMedical" or the "Company") a global leader in respiratory imaging technology, today announces the launch of CLEAR (Contrast-free Lung Evaluation for Acute Risk in pulmonary embolism), a clinical evidence program designed to fast-track CT:VQ™ entry into the acute pulmonary embolism market, thereby growing the obtainable market for CT:VQ™ in the U.S. to US$3B.

Pulmonary embolism: over-imaged, under-diagnosed

Pulmonary embolism (PE) is a major acute cardiovascular condition. Epidemiological studies and public-health reporting in the United States indicate that PE results in approximately 600,000–650,000 diagnosed clinical episodes per annum, with the true burden likely higher due to under-diagnosis, and in a meaningful proportion of cases sudden death is the first presentation.

Because PE presents with non-specific symptoms such as chest pain and shortness of breath, and carries significant morbidity and mortality if untreated, clinical pathways are intentionally biased toward exclusion rather than confirmation. As a result, imaging volumes significantly exceed disease incidence.

CTPA has become the de facto imaging modality for suspected PE. Since 2004, CTPA utilisation has increased dramatically, with multiple large health-systems reporting 4x growth in scan volumes. This growth has occurred despite the introduction of validated clinical decision rules designed to limit unnecessary imaging.

This persistent overuse has been accompanied by declining diagnostic efficiency. Across large cohorts, the positive diagnostic yield of CTPA has been reported in the range of approximately 3–10%, meaning the vast majority of patients (90-97%) undergo iodinated contrast exposure without confirmation of PE. Consequently, large volumes of patients are subjected to higher-cost imaging using contrast injections to rule-out PE as part of standard emergency and acute-care workflows.

Based on aggregated health-system utilisation trends, total U.S. CTPA imaging for suspected PE is widely estimated at approximately 4–6.5 million studies per annum, with ~5 million scans per year representing a conservative midpoint estimate.

Melbourne
Level 7 Melbourne Connect
700 Swanston Street
Carlton VIC 3053
Tel: +61 (3) 9545 5940

Los Angeles
21255 Burbank Boulevard
Suite 120
Woodland Hills CA 91367
Tel: +1 (818) 403-8490

4DMedical Limited
ABN: 31 161 684 831
Email: info@4DMedical.com
www.4DMedical.com

Expansion beyond the nuclear VQ market

CT:VQ™ generates quantitative, three-dimensional ventilation and perfusion maps from routine, non-contrast inspiratory and expiratory CT scans, enabling contrast-free functional lung assessment within standard CT workflows. Importantly, the underlying VQ indication is already FDA-cleared, de-risking the regulatory pathway, while CLEAR generates the clinical evidence to drive adoption in acute PE.

4DMedical is already displacing nuclear VQ at pace. The Company believes the high-quality clinical evidence from CLEAR positions CT:VQ™ to extend beyond that core market into the materially larger (~5 million scans per annum in the U.S.) acute PE opportunity.

This is a significant step-change in scale, lifting 4DMedical's obtainable market to US$3B per annum.

CLEAR clinical evidence program

Supporting this market expansion, 4DMedical has entered into a clinical research agreement with Mass General Brigham (MGB), anchored at Massachusetts General Hospital (MGH), the original and largest teaching hospital of Harvard Medical School, and one of the world's leading academic medical centres (AMC).

With MGB as the lead site, the broader company-sponsored CLEAR program comprises the following key elements:

- A prospective, observational comparison of CT:VQ™ head-to-head with CTPA, the current standard of care for patients with suspected acute PE;
- MGH serving as the principal enrolling site, with the ability to extend to additional MGB hospitals; and
- Total funding committed of approximately US$2M, supporting patient recruitment, imaging analysis and data generation.

Mass General Brigham is a leading integrated academic healthcare system and a principal teaching affiliate of Harvard Medical School, known for generating high-quality clinical research and translating it into routine care, informing clinical practice, advancing standards of care, and improving patient outcomes across major disease areas.

This development extends CT:VQ™ into high-volume emergency and acute imaging, materially increasing the Company's market without reliance on new scanner hardware, iodinated contrast agents, or nuclear infrastructure.

Webinar

4DMedical will host an investor webinar at 11:00am AEST on Tuesday 9 June 2026, where CEO and Founder, Dr Andreas Fouras, will discuss recent Company developments, and host a live Q&A.

Please register in advance using the following links:
Webcast: **https://ccmediaframe.com/?id=RzjkAsul**
Phone registration: **https://s1.c-conf.com/diamondpass/10055210-786yhg.html**

After registering, you will receive a confirmation email containing information about joining the webinar or dial-in details for those who would prefer to join by telephone.

4DMedical MD/CEO and Founder Andreas Fouras said:

The detection of pulmonary embolism remains a significant problem in emergency medicine. Today, we image too many patients for PE, exposing them to costly and potentially risky contrast, while still missing dangerous clots, contributing to unnecessary death and disease burden.

This problem represents an enormous opportunity for 4DMedical to drive meaningful clinical impact at scale, improving outcomes for hundreds of thousands of patients, by reshaping one of the largest acute CT imaging workflows globally.

CT:VQ™ enables contrast-free functional lung assessment within routine CT workflows, unlocking expansion beyond our current market. Our US$2M investment in CLEAR accelerates entry into the US$2.5B pulmonary embolism segment.

We continue to gain share in our core segment as CT:VQ™ displaces nuclear VQ in the United States at an incredible pace. Leveraging our war chest, we are also expanding into new segments: adding 50% through our entry into Europe, and now, through this investment, multiplying our opportunity sixfold. 4DMedical continues to accelerate.

–ENDS–

Authorised by the 4DMedical Board of Directors.

Contacts

Corporate
Investor Relations
investor.relations@4dmedical.com

Administration
Company Secretary
companysecretary@4dmedical.com

Media Enquiries
Julia Maguire
julia@thecapitalnetwork.com.au

About 4DMedical

4DMedical Limited (ASX:4DX) is a global medical technology company revolutionizing respiratory care with advanced imaging and artificial intelligence. Its patented **XV Technology®** transforms standard scans into rich, functional insights that allow physicians to detect, diagnose, and monitor lung disease earlier and with greater precision.

4DMedical's expanding software portfolio includes the FDA-cleared **XV Lung Ventilation Analysis Software (XV LVAS®)**, **CT LVAS™**, and the ground-breaking **CT:VQ™** solution designed to set new benchmarks in cardiothoracic imaging by combining ventilation and perfusion analysis.

Delivered seamlessly through a Software-as-a-Service (SaaS) model, 4DMedical's solutions integrate into existing hospital infrastructure, enhancing physician productivity and enabling more personalized patient care. With the addition of advanced AI capabilities from its 2023 acquisition of **Imbio** and 2026 acquisition of **contextflow**, 4DMedical continues to push the boundaries of medical imaging to redefine how respiratory disease is understood and treated worldwide.

Learn more at www.4dmedical.com