

4DMedical wins \$1.9m funding for CT:VQ clinical studies

23 October 2024

Highlights

- Federal Minister for Industry and Science, the Hon. Ed Husic MP, announces the award of \$1.9 million in non-dilutive funding to 4DMedical through the CRC-P grant program
 - The funding will facilitate expansion and acceleration of 4DMedical's CT:VQ clinical trial program in partnership with I-MED and Macquarie University
 - These trials are specifically designed to provide the evidence necessary to empower physicians to rapidly substitute 4DMedical's CT:VQ for nuclear medicine VQ scans
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Melbourne, Australia, 23 October 2024: 4DMedical Limited (ASX: 4DX, "4DMedical", or the "Company"), a global leader in respiratory imaging technology, today announces the award of \$1.9 million in non-dilutive funding from the Cooperative Research Centres Projects (CRC-P), an initiative of the Federal Government Department of Industry, Science and Resources.

Grant details

4DMedical is delighted to announce that it has received CRC-P funding of \$1.9 million for the project entitled "CT:VQ – A Better Pulmonary Perfusion Test".

4DMedical's successful application for CRC-P funding will expand and accelerate the Company's efforts to generate clinical evidence to support the efficacy of CT:VQ, and represents a major boost to its progress towards commercialisation. 4DMedical will work in partnership with I-MED and Macquarie University to conduct clinical studies and perform health economic analyses, which will enable rigorous clinical assessment of CT:VQ and measurement of its health and economic benefits. The clinical evidence is precisely the information that physicians need to rapidly substitute 4DMedical's CT:VQ for nuclear medicine VQ scans, while the health economic analyses will provide invaluable intelligence to steer our commercial efforts, including reimbursement.

Ventilation Perfusion imaging

Within the lungs, airflow is known as ventilation and blood flow is known as perfusion, and these are often denoted as V and Q, respectively. Quantifying and visualising V and Q, and any potential mismatch between them, can provide valuable diagnostic information. In a healthy lung, ventilation and perfusion are well-matched, meaning that airflow and blood flow are evenly distributed throughout the lungs. While we know well that many lung diseases disrupt ventilation to the lungs, in certain lung conditions there can be disruption to the perfusion and/or a mismatch between V and Q, indicating abnormalities in lung function, which in the most severe cases can be life threatening.

Currently, Ventilation Perfusion (VQ) imaging is performed by a family of scans known collectively as nuclear medicine VQ scans. These modalities require both the inhalation of radioactive tracers and the injection of radioactive contrast. Including the delivery of radioactive agents and imaging, nuclear medicine VQ scans take up to an hour to complete.

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Clinically, these scans are primarily used for diagnosing and managing post-acute pulmonary embolism and associated conditions such as pulmonary hypertension, and chronic thromboembolic pulmonary hypertension. The US market size for nuclear medicine VQ scans is over US\$1 billion, with approximately 1 million tests per year at an average cost of over US\$1,000 per scan.

4DMedical's CT:VQ solution

4DMedical's CT:VQ technology enables quantitative VQ data and visualisations to be extracted from a CT scan, without the need for any radioactive tracer or contrast. It achieves this by measuring both the regional motion and local density changes of lung tissue.

By extracting VQ information from standard non-contrast CT images rather than nuclear medicine VQ images (which require radioactive contrast media), hospitals can avoid the significant capital expenditure involved in manufacturing, handling, and disposing of radioactive materials. Furthermore, access to standard non-contrast CT far exceeds access to nuclear imaging equipment, specialist nuclear imaging staff, and short-lived radioactive contrast media.

4DMedical MD/CEO and Founder Andreas Fouras said:

CT:VQ is set to disrupt a billion dollar segment of respiratory diagnostics by replacing nuclear VQ imaging with a technology that is faster, safer, cheaper, more convenient and more accessible. As a win, win, win change in healthcare practice, CT:VQ represents a once in a generation opportunity. We anticipate closing out clinical trials required for FDA, TGA and other regulators in calendar 2024 and filing in calendar 2025.

We have been working for some time, leveraging hard fought experience with existing products, to build an aggressive market adoption strategy. Our efforts will be assisted by strong tailwinds – we are working to replace an existing product for the same clinical use, but with better workflow, and better accessibility. Core to this market adoption strategy is rapidly building necessary clinical data to empower physicians. We are thrilled that following a highly competitive process, the Federal Government has decided to support this critical work, driving both increased scope and faster delivery.

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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[®], 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[®]) – the first modality to dynamically quantify ventilation throughout the lungs, and its Computed Tomography-enabled counterpart software, CT LVAS[™].

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

In December 2023, 4DMedical acquired Imbio, a leader in artificial intelligence medical imaging solutions for chronic lung and cardiothoracic diseases. Imbio's regulatory-cleared solutions transform the way patients are discovered, diagnosed, and treated, enabling physician productivity and more personalised care for patients.

To learn more, please visit www.4dmedical.com and www.imbio.com