

## 4DMEDICAL COMMENCES PATIENT RECRUITMENT FOR VENTILATION-PERFUSION (VQ) CLINICAL TRIAL

### Highlights

- 4DMedical has successfully recruited and scanned the first cohort of participants in its Ventilation-Perfusion (VQ) clinical trial at the University of Miami – four months ahead of schedule
- 4DMedical's VQ product is the second product in line for commercialisation and is designed to compete with nuclear medicine scans without the use of radioactive contrast agents
- The clinical trial will involve the recruitment of approximately 70 participants and will directly compare 4DMedical's VQ outputs against that of traditional nuclear medicine VQ
- The clinical trial will assist the Company to validate its VQ product in preparation to submit an application to the U.S. Food & Drug Administration (FDA) in 2022

**20 May 2021:** 4DMedical Limited (ASX: 4DX, "4DMedical" or the "Company"), a medical technology company focused on commercialising its patented respiratory imaging platform, is pleased to announce that it has successfully recruited and scanned the first cohort of participants of its clinical trial to validate the Company's Ventilation-Perfusion (VQ) product at the University of Miami.

4DMedical's VQ product is its first combination diagnostic tool that measures both airflow (ventilation) and blood flow (perfusion) in the lungs without the use of any contrast agents. Ventilation-perfusion measurements provide valuable insights to clinicians by enabling earlier detection and intervention of lung diseases. For example, a ventilation-perfusion mismatch in the lungs may indicate increased blood pressure or a blockage within the arteries of the lungs, which are common symptoms of pulmonary hypertension or pulmonary embolism, respectively.

The commencement of recruitment and scanning follows on from Institutional Review Board (IRB) approval of the ethical design of the study, which facilitates clinical research to be conducted prior to regulatory approval. The clinical trial aims to recruit and image 70 participants, comprising of patients with obstructive lung disease, restrictive lung disease and controls, over the next 6 months. The study's objective is to compare the data obtained from 4DMedical's VQ scans against nuclear medicine VQ scans.

Nuclear medicine VQ scans are typically completed in 1-2 hours and undertaken in two procedures. For the perfusion scan, a technician injects a radioactive dye into a patient's bloodstream and monitors blood flow into the lungs using a nuclear VQ scanner. For the pulmonary ventilation scan, airflow in the lungs is measured using a second nuclear VQ scanner that images a radioactive particulate that is inhaled by the patient and deposited into the lungs.

In addition to exposing patients to radioactive materials, nuclear medicine VQ scans deliver lower resolution than other medical imaging modalities and require the availability of specialised capital equipment and operators that are not available at all hospitals at all times of the day.

4DMedical's VQ product utilises standard hospital imaging equipment with the imaging protocol designed to be completed in less than 10 minutes and without the use of any contrast agents. The VQ product was built upon the technology developed from XV Lung Ventilation Analysis Software (XV LVAS™), which is used to measure the ventilation component of the VQ scan. Despite only making up 1.1% of total lung diagnostic

procedures, nuclear VQ scans represent a US\$1.17 billion market opportunity in the U.S. based on an average price of US\$1,503 per procedure.

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

"I am extremely proud of our team's progress towards the development of our VQ product. The recommencement of U.S. hospital workflows, following relief from the COVID-19 vaccination program, has allowed our clinical trials to recommence recruitment and scanning. The ability of 4DMedical's VQ product to measure ventilation-perfusion without the use of any contrast agents provides compelling advantages for clinicians to perform scans more frequently and on a broader patient population."

The Company anticipates it will conduct at least one other clinical trial to study its VQ product in preparation to submit an application to the U.S. Food and Drug Administration (FDA) in 2022. Clinical trials, in conjunction with clinical pilots, will continue to play an important role in validating and increasing adoption of 4DMedical's technology as it is commercialised.

As announced to the ASX on 2 December 2020, 4DMedical has partnered with the University of Miami in establishing the Function Lung Imaging Research Program to advance breakthrough lung technologies. In addition to 4DMedical's VQ clinical trial, the Company has also made significant progress in clinical trial programs for XV LVAS with studies active at leading U.S. medical institutions. This includes a clinical trial to validate the clinical use of XV LVAS to assess patients with lung conditions associated with military service at Vanderbilt University Medical Center in Nashville, Tennessee, U.S.

#### ENDS

Authorised by Andreas Fouras, Managing Director and CEO.

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#### About 4DMedical:

Based in Melbourne, Australia and Los Angeles, U.S., 4DMedical was founded in 2012 and is listed on the Australian Securities Exchange (ASX:4DX).

4DMedical is a medical technology company aiming to deliver the global gold standard in respiratory diagnostics for all lung disorders including: coronavirus, asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis and cancer.

The unique 4DMedical technology accurately and quickly scans lung function as the patient breathes, to assist in providing sensitive, early diagnosis, and to monitor changes over time. Our Software-as-a-Service (SaaS) scans deliver much more complete results, showing even subtle variations in lung function down to the finest details, using lower levels of radiation than traditional methods.

Respiratory diagnosis is a US\$31 billion per annum global industry. Through its technology 4DMedical provides clinicians with greater insights into diseases of the lung. 4DMedical is focused on providing better information to doctors and patients about lung function. Better information means better decisions, and better outcomes.