

FY2023 Full Year Results

Highlights

- First U.S. hospital contract signed with the University of Miami
- First commercial scan conducted at Harry S. Truman VA and subsequent grant of Authority to Operate
- Scanning commenced at U.S. Department of Defense on full commercial terms
- American Medical Association grants Category III CPT codes to establish reimbursement for XV LVAS®
- Vanderbilt 'burn pit' trial demonstrates XV Technology® can detect the presence of Constrictive Bronchiolitis
- Computed tomography-enabled CT LVAS™ software released, accelerating the uptake of XV Technology®
- First clinical data for CT-based perfusion product unveiled at ATS conference
- Former U.S. Secretary for Veterans Affairs, Dr David Shulkin, joins 4DMedical
- PACT Act signed into law by President Biden, heralding USD\$280 billion expansion of healthcare benefits for millions of Veterans exposed to toxic burn pits
- Successful capital raise of \$45 million resulting in a cash balance of \$69.6 million as at 30 June 2023
- Cash receipts from customers of \$2.2 million, up 413% on FY2022
- Net operating outflow of \$22.7 million, down \$2.6 million on FY2022

Melbourne, Australia, 29 August 2023: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, "4DMedical", or the "Company") today announces its FY2023 Full Year Results and Appendix 4E Cash Flow Report for the full year ended 30 June 2023 ("FY2023").

Financial Year in Review

During FY2023, 4DMedical increased its cash receipts from customers to \$2.2 million or 413%, while net operating cash outflows were \$22.7 million, a reduction of \$2.6 million on the previous financial year.

Total income for FY2023 was \$13.9 million, with operating revenue of \$0.7 million and other income of \$13.2 million. Other income included \$7.7 million of grant revenue, from the Australian Government's Medical Research Future Fund (MRFF) initiative, and from the State Government of Victoria's Manufacturing Industry Development Fund and Medtech Manufacturing Capability Plan, as well as \$5.5 million in R&D Tax Incentive credits.

Operating expenditure for FY2023 was \$45.3 million (FY2022: \$37.0m). The increase relative to last year mainly reflected additional travel and marketing expenditure as the Company's go-to-market efforts in the U.S. gained momentum and the industry recovered from the impact of COVID-19. In particular, the Company made significant investments attending the two major global industry conferences during the year, which both yielded excellent results. After adjusting for expenditures directly funded by government grants and R&D Tax Incentive credits, underlying operating expenditure was \$32.1 million.

The FY2023 net loss after tax for 4DMedical and its controlled entities (the Group or 4DMedical) was \$31.5 million (FY2022: \$24.6 million). The Group reported a net cash balance of \$69.6 million as at 30 June

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2023 (30 June 2022: \$51.1 million) following a successful \$45 million capital raise conducted in June, enabling the Company to accelerate its commercialisation efforts.

First U.S. hospital commercial contract with University of Miami

A significant commercialisation milestone was achieved in April 2023 with the signing of a five-year contract with the University of Miami to provide XV LVAS[®] ventilation reports. This agreement augments a long-standing and deep relationship built on collaborative clinical research demonstrating the utilisation and commercial value of XV Technology[®] across a range of indications, including Chronic Obstructive Pulmonary Disease (COPD).

Under the terms of this commercial contract, which includes agreed minimum annual fees, 4DMedical has deployed XV Technology[®] at the Leonard M. Miller School of Medicine in Miami enabling patient data to be processed on demand whilst simultaneously validating the efficacy and utility of XV Technology[®].

Signing of PACT Act into law commits US\$280 billion to Veterans health

The U.S. military constructed burn pits near bases across the Middle East to dispose of hazardous and non-hazardous waste. A wide range of materials, including uniforms, chemicals, tyres, and even medical, animal and human waste, were burned in pits using jet fuel as an accelerant. After exposure to these burn pit environments, many previously combat-ready troops returned from deployment with a range of disabling respiratory symptoms, including shortness of breath and cough, that prevent them from performing basic physical activities.

On 10th August 2022, President Joe Biden signed into law an additional USD \$280 billion of healthcare benefits for the estimated 3.5 million Veterans exposed to toxic burn pits and other airborne hazards while deployed on operations in the Middle East since 2001. The bipartisan legislation is the biggest expansion of healthcare benefits for service-connected health issues in 30 years. Included in this legislation is the requirement for the Veterans Administration (VA) to provide toxic exposure screening to each of the 9 million Veterans enrolled in the VA healthcare program.

Under the PACT Act, if a Veteran is diagnosed with one of 20-plus listed conditions the VA assumes their service caused the condition. One of the presumptive conditions is Constrictive Bronchiolitis (CB), a disease that results in obstruction of the smallest airways. Unfortunately, CB is a very difficult disease to diagnose. In testimony before the U.S. Senate, Dr Robert Miller, Professor of Pulmonary and Critical Care at Vanderbilt University Medical Center, noted that beyond “not being visible, it’s not detectable with your usual tools; X-rays, CTs, pulmonary function tests are normal.” Until now, the only way to detect the presence of CB has been through highly invasive surgical biopsy, which is not at all scalable.

Major success for Vanderbilt ‘burn pit’ trial

Only weeks after the signing of the PACT Act, 4DMedical announced a major success in the Vanderbilt 'burn pit' trial. The clinical trial demonstrated that XV Technology[®] can detect the presence of CB in Veterans. The success of this trial allows clinicians to use XV Technology[®] to detect CB using a non-invasive, scalable and cost-effective method without the risk of surgical complications or the need for post-operative recovery. The Vanderbilt University Medical Center is in the process of publishing the findings in a peer-reviewed journal.

Increased traction with the Veterans Health Administration

As part of its commercialisation strategy with the VA, the Company has adopted a combined top-down and bottom-up approach. The focus of the top-down approach is to work closely with industry advisors and

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Veteran advocacy groups such as Burn Pits 360 to engage with senior leadership of the VA and legislators. This approach has resulted in the incorporation of language into legislation requiring the VA to consider “emerging technology that uses existing X-ray imaging equipment to derive four-dimensional models of lung function to identify respiratory illnesses and accompanying loss of lung function.”

In addition, the Omnibus Bill used to allocate funding to implement the PACT Act requires the Department to “evaluate this technology for the purposes of conducting population-wide surveillance of Veterans who have been exposed to airborne hazards in order to conduct a full accounting of the health impacts suffered by Veterans and to provide full and effective medical care to this population.”

The Company’s engagement has also extended to meetings with senior members of U.S. Congress, with the Company sending a delegation to speak with advisors of Senator Sherrod Brown (D-OH) and Congressman Raul Ruiz (D-CA25) and to key staff of members of both the Senate and House Veterans Affairs Committees. Veterans’ advocates Rosie Lopez-Torres, Le Roy Torres, Kevin Hemsley and Tim Hauser led 4DMedical’s delegation, urged the adoption of XV Technology® through allocation of PACT Act funding, and discussed their recent experiences of receiving 4DMedical scans.

To further assist in 4DMedical’s top-down efforts, in early April the Company announced that Dr David Shulkin had been appointed as an advisor. Dr Shulkin was previously the Secretary of the Department of Veterans Affairs, having been appointed in 2017, where he oversaw 350,000 employees responsible for serving over 9 million Veterans. As a nationally recognised leader in healthcare quality and population health management, Dr Shulkin brings a comprehensive understanding of integrated healthcare to 4DMedical with particular knowledge of the VA.

The Company is also working with individual hospitals as part of its bottom-up approach, and in May announced it had conducted its first commercial scan at Harry S. Truman Memorial Veterans Hospital, providing Truman VA physicians with insight only available through a four-dimensional scan. The XV LVAS® scan represents the Company’s first commercial activity within the VA and, whilst not immediately material from a revenue perspective, it demonstrates significant validation of the Company’s bottom-up approach to VA engagement.

Related closely to this was the securing of the ‘Authority to Operate’ (ATO) at Harry S. Truman Memorial Veterans Hospital, which is a formal authorisation granted to software vendors to gain access to an information systems and technology infrastructure within the VA’s network. The first ATO is an important milestone for the Company as it demonstrates the robust and secure nature of 4DMedical’s platform. Additionally, once 4DMedical has an ATO at two sites, it is eligible to apply for a National ATO, which will provide the Company with authorisation for all 171 major clinical centres within the VA network.

Commercial piloting win with U.S. Department of Defense

Within days of this Truman VA scan, the Company announced a contractual arrangement covering active military personnel within the U.S. Department of Defense (DoD). This commercial pilot involves scanning on full commercial terms within the Military Health System (MHS), supporting America’s National Defense Strategy of providing a medically ready force, through utilisation of 4DMedical’s unique capabilities. With an annual budget of over USD \$50 billion, the MHS is one of the largest and most advanced healthcare institutions in the U.S. providing 1.3m active military personnel with access to health services across a network of 45 hospitals, offering scope for significant expansion of commercial operations.



Technological advances across modalities widens product line and commercial opportunities

From a product development perspective, the last twelve months have seen some exciting advances in the XV Technology® product suite. In October 2022, 4DMedical proudly announced the launch of its revolutionary image processing software, CT LVAS™, a breakthrough product in the XV Technology® pipeline. This software offers an almost identical report to the proven XV LVAS® product, with a significant advantage being its utilisation of widely available Computed Tomography (CT) imaging infrastructure, making it accessible to more Australians with lung disease.

In addition, 4DMedical announced a significant technological breakthrough and milestone in the Company's product development pipeline, with its CT-based ventilation-perfusion product (CT:VQ) progressing to a development stage that allowed for release of early clinical data. This clinical data was presented at the annual conference of the American Thoracic Society (ATS) in Washington, DC in May 2023.

The ATS's annual conference is the world's largest gathering of pulmonary sciences professionals. 4DMedical was a prominent exhibitor, with visits from the national leadership of the ATS who met with Dr David Shulkin, attending in his capacity as an advisor to the Company.

The development of the perfusion capability represents a significant breakthrough in respiratory imaging by providing vascular perfusion (blood flow) analysis, without the need for either injected radioactive tracers or contrast media. 4DMedical's CT:VQ technology enables quantitative perfusion data and visualisations to be extracted from non-contrast paired inspiratory-expiratory CT scans.

By extracting VQ information from standard non-contrast CT images rather than Nuclear Medicine VQ images (requiring patient exposure to radioactive contrast media), hospitals can avoid the significant expenditure involved in mitigating radiation risks of operating a Nuclear Medicine VQ scanner such as specialised facilities for preparing, handling and disposing of radioactive materials.

Quantifying and visualising the mismatch between ventilation (V) and perfusion (Q) can provide valuable diagnostic information. In certain lung conditions there can be a mismatch between ventilation and perfusion indicating abnormalities in lung function that in the most severe cases can be life threatening.

The Company's CT:VQ technology enables regional changes in ventilation and perfusion to be quantified and visualised, allowing a detailed assessment of V/Q mismatch. Clinically these scans are primarily used for diagnosing and managing pulmonary embolism, but they can also be employed to assess conditions such as chronic obstructive pulmonary disease, pulmonary hypertension, lung parenchymal diseases, and pulmonary vascular disorders.

The Company estimates the current US market size for Nuclear Medicine VQ assessment of pulmonary embolism is approximately 15% of the 4,000,000 patient procedures per annum, at an average cost of ~US\$1,500 per scan (~US\$900 million).



4DMedical delegates with the national leadership team of the ATS and Veterans advocates Rosie Lopez-Torres and Le Roy Torres, at ATS 2023



XV Scanner and CTCM

Development of the XV Scanner continued with a customised variant designed for pre-clinical imaging installed at a South Australian Health and Medical Research Institute (SAHMRI) facility where its capabilities are being exploited by a team of Eureka Prize-winning researchers at the University of Adelaide.

Most recently, 4DMedical announced the award of \$1.1 million in non-dilutive funding from the Clinical Translation and Commercialisation Medtech (CTCM) program, an initiative of the Medical Research Future Fund (MRFF) delivered by MTPConnect.

Following on from the recent technological breakthrough with CT:VQ, CTCM funding will allow the Company to broaden the capability of its XV Scanner beyond ventilation to include the measurement of perfusion. This additional capability will further strengthen 4DMedical’s position as a leader in non-invasive lung diagnostics by providing detailed quantitative data on respiratory function via a single scan.

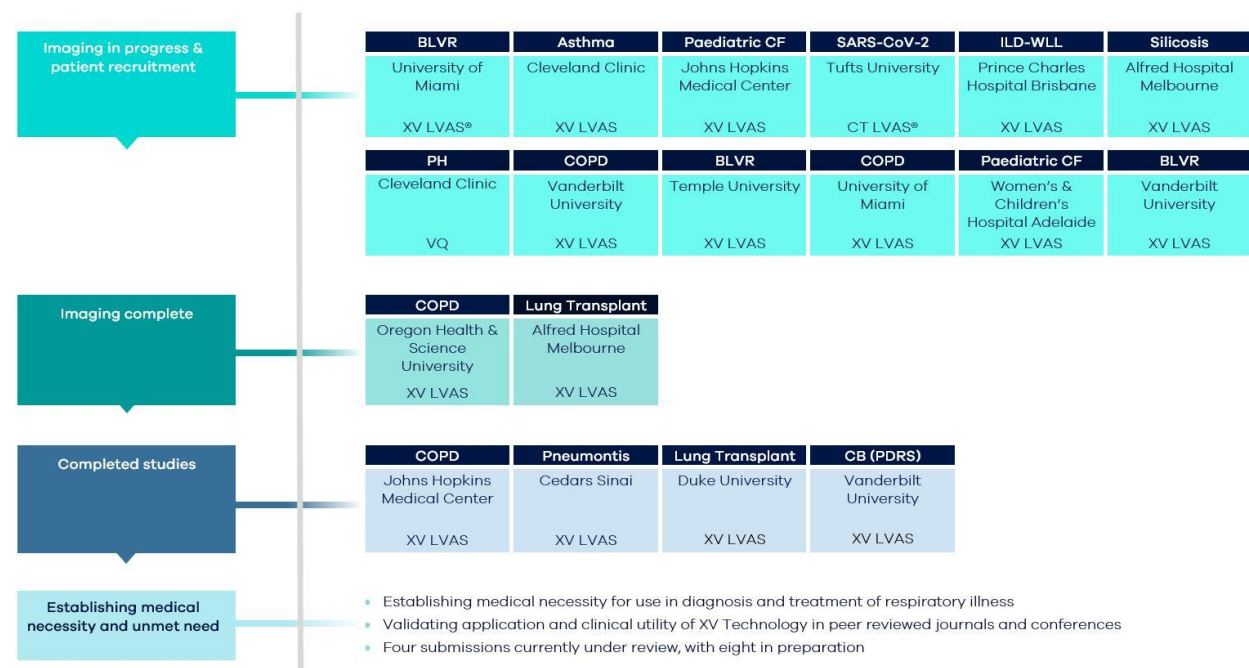
Examples of the XV Scanner were on display at the two major industry conferences, ATS 2023 and Radiological Society of North America (RSNA 2022) during the reporting year, and generated a significant level of interest from researchers and industry leaders alike.

Commercialisation of XV Technology® accelerated in Australian market

Rollout of XV Technology® across the I-MED Radiology Network (I-MED) continued through the reporting period, with installation completed across 42 sites nationwide, up from 7 at the end of last financial year. The emergence of CT LVAS™ software enables computed tomography infrastructure to be used for image acquisition, increasing reach across this distribution channel, and widening patient access.

Clinical trials concluded and expanded, with successful interim results presented to peers

Clinical trials, a fundamental pillar of 4DMedical’s commercialisation strategy, saw strong progress during FY2023, across the entire portfolio – multiple advanced studies progressing towards publication, and new important studies commencing.



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Beyond demonstrating clinical efficacy and utility, a critical step in commercialising any medical technology in the United States is reimbursement: the means by which healthcare providers are paid for services, particularly in the context of insurance plans. Through generation of peer reviewed evidence, clinical trials perform the important function of demonstrating that XV Technology® satisfies an unmet need and/or reduces the costs of providing healthcare.

During the reporting period, new clinical trials utilising the XV LVAS® software product commenced at the Prince Charles Hospital in Brisbane (focused upon interstitial lung disease, or “ILD”), at the Women’s & Children’s Hospital in Adelaide (paediatric cystic fibrosis), expanding the Company’s collaboration with Australian research institutions. In the United States, new trials were initiated at Tufts University (SARS-CoV-2), Temple University (bronchoscopic lung volume reduction, or “BLVR”) and the Cleveland Clinic (Asthma).

Studies were completed at Duke University (candidature optimisation for lung transplantation) and Vanderbilt University Medical Center (constrictive bronchiolitis / post deployment respiratory syndrome) in U.S. Veterans. Imaging was also completed in the lung transplant-focused ‘FIT Study’ led by Professor Greg Snell at the Alfred Hospital in Melbourne.

Presenting interim findings from clinical trials continued in this reporting period. Researchers at the University of Miami presented findings at the ATS annual conference. Earlier in the reporting period, the Company announced results from our COPD study at Johns Hopkins University. Findings from this study verified that XV Technology® derived metrics correspond with COPD disease severity and that XV LVAS® scans visualise and quantify regional ventilation defects, critical to the personalisation and optimisation of treatment therapies.

American Medical Association grants CPT codes to establish reimbursement for XV LVAS®

4DMedical submitted a CPT application to the AMA CPT Editorial Panel for review in September 2022, which resulted in the acceptance and release of two new Category III CPT codes. In accordance with the AMA’s Category III code’s early-release policy, these codes became effective on 1 July 2023, following the six-month implementation period, which began on 1 January 2023.

The issuance of the new distinct Category III CPT codes by the AMA represents a major milestone towards advancing US reimbursement for XV LVAS®, as healthcare providers and facilities will be able to submit claims directly to payers identifying when XV LVAS® is ordered for patients to quantify their pulmonary tissue ventilation. Establishing a clear billing pathway and tracking utilisation of the technology are critical components in achieving US commercialisation success.

Academic and research partnering formalised

The pre-existing close collaboration between 4DMedical and the University of Melbourne was formalised during FY2022-23 with the signing of a Memorandum of Understanding (MoU) solidifying this relationship in respect to joint research initiatives, curriculum development, access to interns and provision of placements for students and doctoral candidates, and ongoing cooperation in various ventures.

This close connection was enhanced with 4DMedical MD/CEO and founder Dr Andreas Fouras subsequently being awarded an honorary professorial fellowship by the University, recognising a career-long contribution to medical research.



Growth in leadership team

Throughout the course of the FY2023, the company sought to increase its capability, with several notable senior additions to the team. In addition to the appointment of Dr Shulkin, the Company welcomed Matt Tucker, former Chief Executive Officer of GE Healthcare Australia to the team, and subsequently to the role of Chief Commercial Officer. The company has for the first time appointed a General Counsel through the appointment of Naomi Lawrie, who also acts as Company Secretary.

4DMedical MD/CEO and Founder Andreas Fouras said:

Our strong cash position following the oversubscribed capital raise in May sustains and accelerates our long-standing commercialisation plan.

Following on from the release of our breakthrough CT-enabled ventilation technology (CT:V), the much-anticipated evolution of our core capability into blood flow (perfusion) through CT:VQ progresses an opportunity to rapidly capture a \$1B market segment ripe for disruption.

Commercial successes included the Company's first scan within the U.S. Department of Defense system, as well as material progress in both our top-down and bottom up strategies within the U.S. Veterans Affairs healthcare system. Highlights with the VA include our first commercial scan and gaining our first Authority to Operate.

These achievements represent a significant year of accelerated progress for 4DMedical. Furthermore, over this year multiple significant developments have been evolving towards maturation, and I look forward to sharing news of these over the remainder of this calendar year.

–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®, 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.

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