

Accelerating progress as 4DMedical reports positive 1H FY2023

28 February 2023

Highlights

- Total income of \$6.5 million for 1H FY2023, up 37% on prior corresponding period ('pcp')
- Revenue from ordinary activities of \$0.5 million, up 210% on pcp
- Receipts from customers of \$0.7 million, up 396% on pcp
- Strong cash balance of \$45.7 million as at 31 December 2022, runway extended to end of March 2024
- PACT Act signed into law, heralding an incremental USD \$280 billion of healthcare funding for US Veterans exposed to burn pits and other toxic substances. Included is the requirement for the Veterans Health Administration (VHA) to provide toxic exposure screening to each of the 9 million Veterans enrolled in the VHA healthcare program
- Vanderbilt 'burn pit' clinical trial demonstrates efficacy of XV Technology® in detecting lung disease in Veterans
- Prominent U.S. Veterans' advocates successfully scanned in Miami using XV Technology®
- American Medical Association (AMA) grants Category III CPT codes enabling clinical use of XV LVAS® to be identified and monitored by healthcare providers and payers
- Prominent exposure exhibiting the first export XV Scanner® at RSNA 2022 in Chicago
- CT LVAS™ rolling out across the I-MED network with onboarding completed at 27 locations, widening patient access to XV Technology® and broadening the base for Software-as-a-Service (SaaS) revenue
- Ex-GE Healthcare chief joins 4DMedical senior leadership team

Melbourne, Australia, 28 February 2023: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, "4DMedical", or the "Company") today announces accelerating progress in the commercialisation of its core XV Technology® and complementary product lines during the first half of the financial year.

Financial Performance

Cash receipts from customers for the half were \$0.7 million up 396% over 1H FY2022.

The 1H FY2023 net loss after tax for the Group was \$16.3 million, an increase of 31% on pcp (1H FY2022: \$12.5 million). Total income for 1H FY2023 was \$6.5m, up 37% on pcp (1H FY2022: \$4.8 million).

The 1H FY2023 revenue from ordinary activities of the Group was \$0.5m, an increase of 210% on pcp (1H FY2022: \$0.2 million). Revenue during the half year was derived from hardware revenue, software-as-a-service analysis and licence fees, on-going preclinical hardware support and maintenance contracts, and other hardware associated revenue.

1H FY2023 other income was \$6.0 million, an increase of 31% on pcp (1H FY2022: \$4.6 million). Other income comprised mainly grant income, including \$3.6m reported by the wholly owned subsidiary, Australian Lung Health Initiative, under the Federal Government's Medical Research Future Fund initiative, and \$2.4 million in Research & Development Tax Incentive credits.

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The 1H FY2023 operating expenditure (exclusive of finance costs) was \$22.7 million, an increase of 32% on pcp (1H FY2022: \$17.2 million). Operating expenditures increased from the prior corresponding period due to 4DMedical's continued commercialisation efforts, investment in clinical research and product development activities and higher marketing expenditures through participation in international medical conferences and trade shows.

The Group reported a net cash balance of \$45.7 million as at 31 December 2022. Through a combination of higher revenues, cost controls and this strong cash balance, the Company has a cash runway of approximately five quarters, representing an improvement of one quarter on previous guidance.

United States

PACT Act signed into law by President Biden

On 10 August 2022, President Joe Biden signed into law a broad expansion of healthcare benefits for millions of Veterans exposed to toxic burn pits. The estimated 3.5 million Veterans exposed to harmful toxins whilst deployed on operations since 2001 will now have access to an additional USD \$280 billion healthcare commitment over ten years. Importantly, the new law also relieves the Veteran of the burden of proof that an illness is associated with exposure to toxic substances, with constrictive bronchiolitis (CB) listed as a presumptive condition. Included in this legislation is the requirement for the VHA to provide toxic exposure screening to each of the 9 million Veterans enrolled in the VHA health care program.



In December, the Omnibus Appropriations Bill passed the Senate. The Omnibus Bill enshrines into legislation a directive for the VHA 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'. As well, the Bill allocates \$5 billion for the Cost of War Toxic Exposures Fund, which provides additional funding to implement the PACT Act.

Major success as Vanderbilt 'burn pit' trial hits primary endpoint

4DMedical's efforts to secure a contract with the VHA were given a significant boost with the release during the period of early data from the Vanderbilt 'burn pit' trial, which demonstrates that XV Technology® can detect the presence of CB in Veterans. The clinical trial enrolled a group of Veterans who had undergone surgical lung biopsy and a control group. The data from the trial showed that XV Technology® confirmed the diagnosis of CB with excellent sensitivity and specificity, setting it apart from conventional diagnostic methods such as lung imaging and pulmonary function tests, and as a dramatically safer and less expensive alternative to surgical biopsy.



Congressional engagement

On 29 September in Washington D.C., 4DMedical met with Congresswoman Mikie Sherrill (D-NJ) and Rosie Torres of Burn Pits 360, a prominent Veteran's advocate who was instrumental in the passage of the PACT Act. In a formal [media release](#) following the meeting, Congresswoman Sherrill referenced 4DMedical saying, "I am pleased that the PACT Act is law, and now we must work quickly and efficiently to implement its key provisions. New and emerging technologies can not only expedite the implementation of the PACT Act but also ensure every veteran has access to early treatment and the full benefits they deserve."



Rep Mikie Sherrill (centre) with (L-R) Liesel Sheehan, Dr. Andreas Fouras, Rosie Torres and 4DMedical's Mick Brown.

Veteran support

4DMedical subsequently scanned two high-profile Veterans' advocates as part of its clinical research program at the University of Miami. Accompanied by significant national media exposure, Captain Le Roy Torres was quoted: "My scan today is a major step forward for fellow Veterans who are suffering from burn pit exposures and are desperate for answers. With the passage of the PACT Act, the United States Department of Veterans Affairs and Congress can develop protocols and use cutting-edge technologies that will bring new and expanded healthcare services to thousands of Veterans like me."

The Company applauded U.S. Senator Kirsten Gillibrand's recommendation that the highly visible contribution of Captain Torres and his wife Rosie to Veteran healthcare be recognised through award of the Presidential Medal Of Freedom.

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 become effective on 1 July 2023, following the six-month implementation period, which began on 1 January 2023:

0807T: Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with previously acquired computed tomography (CT) images, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report

0808T: in combination with computed tomography (CT) images taken for the purpose of pulmonary tissue ventilation analysis, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report

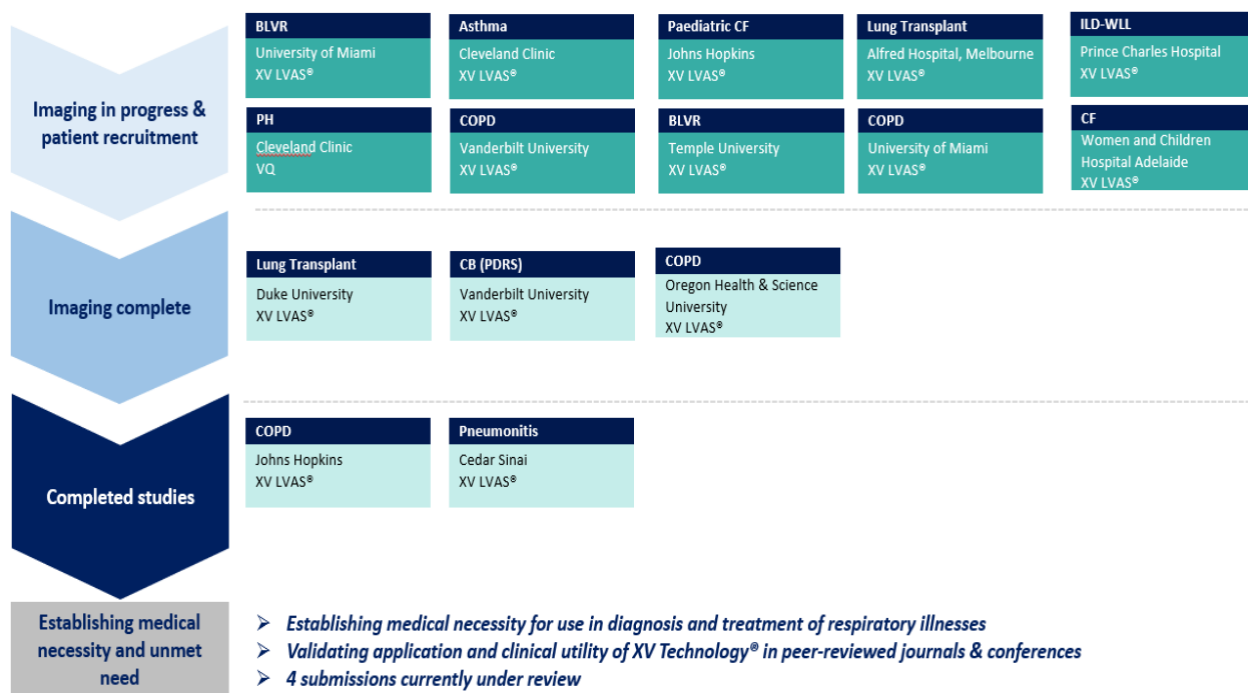
The issuance of the new distinct Category III CPT codes by the AMA represents a major milestone towards advancing US reimbursement for XV LVAS®, as healthcare providers and facilities will be able to submit claims directly to payers identifying when XV LVAS® is ordered for patients to quantify their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

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Clinical trial results are building a body of evidence to drive adoption

Clinical trials are a fundamental pillar of the Company’s commercialisation strategy. In addition to driving awareness of XV Technology® amongst the medical community, clinical trial data provides essential evidence for indication-specific use by clinicians.



A number of clinical trials made meaningful progress over the period:

- Duke University completed imaging on the final patient in its lung transplant clinical trial. The clinical trial employed XV Technology® to measure lung ventilation and ventilation heterogeneity, as a means to assess rejection in lung grafts;
- Temple University imaged the first patient in its bronchoscopic lung volume reduction (BLVR) clinical trial; and
- Data from both the Vanderbilt ‘burn pit’ trial and the University of Miami COPD trial were submitted for publication.

High profile participation at RSNA 2022

The annual conference of the Radiological Society of North America (RSNA) in Chicago is the world’s largest gathering of medical imaging professionals. 4DMedical was a prominent exhibitor at RSNA 2022 during December, displaying the first export example of the XV Scanner – the world’s first and only dedicated respiratory imaging platform – enabling rapid, low dose and high throughput scanning of patients using the company’s core XV Technology® software on a commercial basis.

Beyond exposure to the largest professional audience of its kind globally, the Company conducted valuable meetings with potential clients and key influencers in the sector. Media coverage of 4DMedical’s presence included major U.S. television news networks (inclusive of Fox, NBC, ABC and CBS affiliates) and specialty industry channels.

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Australia

CT LVAS™ rollout expands patient access to XV Technology® in Australia

In October, 4DMedical announced the release of its breakthrough image processing software, CT LVAS™, which provides an almost identical report to the Company's proven XV LVAS® product with industry leading richness and fidelity, and utilising widely available Computed Tomography (CT) imaging infrastructure instead of X-ray equipment.

Australia stands above the U.S., and every other nation outside of Japan, in terms of the number of CT scanners per head of population, making Australia the sensible launch point for the second XV Technology® product in 4DMedical's product pipeline. More importantly, it significantly broadens the accessibility to functional lung imaging for Australians living with lung disease.

CT LVAS™ uses existing CT hardware, enabling simple and seamless integration into clinical workflows. The Company's existing distribution agreement with the I-MED Radiology Network (I-MED) has allowed a dramatic acceleration of the installation base, taking the total number of Australian sites to 27, with commercial CT LVAS™ scanning already being undertaken at multiple locations.

Ex-GE Healthcare chief Matt Tucker joins 4DMedical senior leadership

Highly experienced medical imaging executive, Mr Matt Tucker commenced as the Company's new Senior Vice President of Business Development and Strategy in early December 2022. Mr Tucker's knowledge and skillset has been gained in a career working for leading global healthcare companies including GE Healthcare (as chief executive for Australia), SonoSite and Philips.

Mr Tucker is making a valuable contribution to the ongoing commercialisation of the XV Scanner hardware product line, emulating success in GE Healthcare's turnaround strategy resulting in market leadership across the ultrasound product space.

4DMedical CEO and Founder Andreas Fouras said:

The fast-paced environment within which 4DMedical thrives means it is easy to overlook the considerable achievements of a six-month period in which so much progress has been made.

Our team's ability to roll out the CT LVAS product line in such a short timeframe demonstrates our capacity to deliver against our ambitious plan. This success is enabling greater access to XV Technology for patients and their clinicians across Australia.

4DMedical has a genuine commitment to supporting Veterans, shared with legislators, advocates and the healthcare workers within the VHA. Our technology has been shown to be the only safe and scalable source of insight into lung dysfunction impacting returned service personnel. I am particularly humbled to pursue justice for Veterans alongside Le Roy and Rosie Torres.

Overall, we have seen exciting successes across multiple parts of the business, which in combination have delivered an outstanding revenue result for the company this quarter. I look forward to continuing and building on this growth over the coming quarters.



–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.

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