

4DMedical reports positive 1H FY2024 results

28 February 2024

Highlights

- Operating revenue of \$0.8 million for 1H FY2024, up 63% (1H FY2023: \$0.5 million) on pcp
- Proforma operating revenue (including Imbio) of \$3.1 million for 1H FY2024
- Net operating expenditures (adjusted for expenditure directly funded by grant income and Research and Development Tax Incentive credits), down 14.5% on pcp
- Strong cash balance of \$47.9 million as at 31 December 2023
- Transformational acquisition of Imbio, a recognised leader in lung and heart artificial intelligence (AI) – powered diagnostic products
- 4DMedical and Philips formalise their Memorandum of Understanding by signing a Teaming Agreement to expand the commercialisation of XV Technology[®] within the U.S. Department of Veterans Affairs (VA)
- U.S. Centres for Medicare and Medicaid Services (CMS) approves reimbursement for XV LVAS[®] at the rate of US\$299
- Following CMS reimbursement, two outpatient practices in Detroit and Memphis sign commercial agreements to perform XV LVAS[®] scans starting 1 January 2024
- FDA grants clearance for CT LVAS[™] product, expanding patient accessibility to 4DMedical’s ventilation reports by leveraging readily available CT hardware in the U.S.
- 4DMedical successfully launches pilot with Integral Diagnostics in Australia

Melbourne, Australia, 28 February 2024: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, “4DMedical”, or the “Company”) today announces significant progress against strategy with the announcement of its first half results for FY2024.

Financial performance

The 1H FY2024 net loss after tax for the Group was \$15.6 million, a decrease of 4% on pcp (1H FY2023: \$16.2 million). Operating revenue for 1H FY2024 was \$0.8 million, up 63% on pcp (1H FY2023: \$0.5 million). On a proforma basis (including Imbio), operating revenue was \$3.1 million, up 32% on a like-for-like basis on pcp. Revenue during the half year was derived from software-as-a-service analysis and licence fees, ongoing preclinical hardware support and maintenance contracts, and Imbio’s Companion Dx and General Radiology product offerings.

1H FY2024 other income was \$7.1 million, an increase of 17.9% on pcp (1H FY2023: \$6.0 million). Other income comprised of grant income, including \$4.0 million reported by the wholly owned subsidiary, Australian Lung Health Initiative Pty Ltd under the Federal Government’s Medical Research Future Fund (MRFF) initiative, \$0.3 million under the Clinical Translation and Commercialisation - MedTech (CTCM) Program and \$2.8 million in Research & Development Tax Incentive credits.

The 1H FY2024 operating expenditure (exclusive of one-off transaction expenses and finance costs) was \$20.3 million, a decrease of 5.4% on pcp (1H FY2023: \$21.5 million). After adjusting for expenditure directly funded by grant income and Research and Development Tax Incentive credits, net operating expenditure was down 14.5% on pcp.

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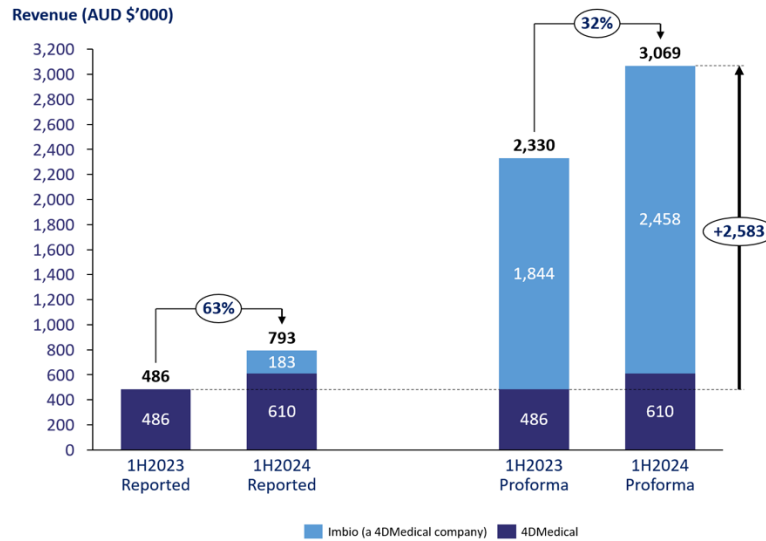
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The Group reported a strong cash balance of \$47.9 million as at 31 December 2023.



Operating revenue +63% on a reported basis, +32% on half year proforma basis including Imbio

Capital raise and Imbio acquisition

On 15 December 2023, the Company acquired Imbio, a U.S.-based medical technology company specialising in lung and heart artificial intelligence (AI)-driven technology for an upfront consideration of US\$25 million plus contingent earnouts. The acquisition expanded 4DMedical's product offering by incorporating Imbio's suite of diagnostic products, including four FDA-cleared products, and is expected to enhance 4DMedical's growth strategy and accelerate the commercialisation of XV Technology® in the U.S., particularly in patient screening programs for lung and heart diseases. The acquisition was partly funded through a successful and well supported capital raising of \$35 million (before costs).

The acquisition aligns with 4DMedical's strategy to provide comprehensive lung diagnostics and opens opportunities for diagnostic screening programs. Imbio's portfolio complements 4DMedical's technology, aiming to revolutionise lung disease diagnosis and provide comprehensive cardiothoracic analysis. The acquisition holds the potential to address unexplained dyspnoea, improve lung cancer screening, and transform cardiothoracic perfusion assessment, leading to a deeper understanding of lung and cardiac disease.

Philips Teaming Agreement

In January 2024, 4DMedical signed a commercial agreement with Koninklijke Philips N.V. (NYSE: PHG, or "Philips"), a leading global healthcare company, to establish a strategic collaboration to advance solutions to evaluate Veterans with deployment-related respiratory disease (DRRD), interstitial lung disease (ILD) and other respiratory illnesses in North America.

Following the announcement late last year that the companies had entered into a Memorandum of Understanding (MoU) to expand the commercial reach and access for 4DMedical, the signing of this agreement represents a major step forward in the Company's commercialisation strategy, particularly within the VA. Philips and 4DMedical will work together to support the massive need to scale non-invasive lung screening in support of the PACT Act, which extended eligibility for benefits to an additional 4.5 million Veterans. Philips has long-established and significant existing partnerships with both the VA and the

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Department of Defense (DoD) going back 45 years, deploying 35% of the critical care information systems across the VA, and having Philips imaging solutions in 50% of VA hospitals.

Centers for Medicare & Medicaid Services (CMS) reimbursement

4DMedical announced a milestone in the commercialisation of its XV LVAS[®] procedure in the United States when the U.S. Centers for Medicare & Medicaid Services (CMS) assigned a reimbursement benefit of US\$299 for XV LVAS[®] scans conducted in hospital outpatient facilities for Medicare patients, effective 1 January 2024.

This decision establishes a benchmark payment level for hospital outpatient procedures, influencing private health insurers in determining their pricing levels. The CMS reimbursement, obtained under 4DMedical's existing Category III CPT code, is a significant step toward achieving broader reimbursement across the U.S. healthcare system.

The inclusion of XV LVAS[®] in CMS payment rates widens access for Medicare patients and provides a funding source for providers, enhancing care delivery for individuals with lung disease. CMS reimbursement will accelerate utilisation of XV LVAS[®] under 4DMedical's existing Category III CPT code, a key criterion for the American Marketing Association (AMA) when considering granting a Category I CPT code.

SaaS contracts in Detroit and Memphis

Shortly after being assigned its CMS reimbursement benefit, the Company signed Software as a Service (SaaS) agreements with PrecisionIR in Detroit, Michigan, and Memphis Vascular Center in Tennessee to provide XV LVAS[®] scans in their outpatient clinics starting from 1 January 2024. These outpatient facilities offer a more accessible and patient-centric environment, potentially increasing the adoption of 4DMedical's technology. The agreements highlight the positive impact of reimbursement on the Company's uptake in the U.S. market.

FDA approval of CT LVAS[™]

The Company received U.S. Food and Drug Administration (FDA) clearance for its CT-based ventilation product, CT LVAS[™], which provides an almost identical report to 4DMedical's proven, FDA-cleared, XV LVAS[®] product, but utilises widely available Computed Tomography (CT) imaging infrastructure (instead of X-ray equipment), providing clinicians and patients with greater access to XV Technology[®].

FDA clearance follows the successful rollout of CT LVAS[™] in Australia, which was chosen as the Company's first market due to its high density of CT scanners per head of population. According to OECD data, the U.S. install base for CT scanners is also material, with 43 CT scanners per million population (compared to Australia at 70, France at 20, and Canada at 15 per million population) and will therefore significantly broaden the accessibility of functional lung imaging for people in the U.S. living with lung disease.

The Company is working towards an application for a new Category III CPT code for CT LVAS[™] reimbursement, aligning with its strategy for XV LVAS[®]. The clearance for CT LVAS[™] will serve as a predicate for its CT-based ventilation-perfusion product (CT:VQ), offering a non-contrast alternative for diagnosing conditions such as pulmonary embolism.

Integral Diagnostics distribution agreement

The Company announced it entered into a distribution agreement with Integral Diagnostics (ASX:IDX), a leading provider of medical imaging services in Australia and New Zealand.

The contract expands the reach of 4DMedical's XV Technology[®], including XV LVAS[®] and CT LVAS[™] product lines, across Integral Diagnostics' extensive network of 71 sites in Victoria, New South Wales, Queensland



and Western Australia. The initial phase involves piloting at two Integral Diagnostics clinical sites in Ballarat, Victoria, with plans for a comprehensive marketing and engagement campaign to precede a wider rollout.

Other corporate updates

During the half-year, Bruce Rathie resigned from the Board of Directors after four years in the position, with long standing non-executive Director, Lilian Bianchi, assuming the role of the Chair of the Board at the conclusion of the FY23 AGM.

In addition, Evonne Collier resigned as non-executive director during the half-year, while Dr. Geraldine McGinty, an internationally recognised leader in health care strategy and imaging economics based in the U.S., was appointed as non-executive director.

4DMedical CEO and Founder Andreas Fouras said:

4DMedical enters 2024 with considerable momentum, with recent announcements demonstrating the transformational impact made by the acquisition of Imbio. Already, the combined group has made considerable progress, with the recent VA announcement involving Imbio being incredibly exciting.

The acquisition of Imbio delivers a portfolio of clinically approved products, established customer contracts generating recurring revenue, and a strong pipeline of new products. By way of example, the proforma revenue for the first half including Imbio is \$3.1 million, compared to \$0.5 million this time last year, whilst our underlying spending (adjusting for grants and R&D credits) is down 14%.

Progress in reimbursement continues to gather pace with the recent approval of XV LVAS® by CMS providing access to over 65.7 million Americans. We are working actively on extending the coverage and payment to the wider market, thereby removing the greatest barrier to commercialisation.

4DMedical and Philips continue to work closely on completing a Reseller Agreement - the final stage of the documentation for providing diagnostic services to the VA. Working with Philips greatly improves the scaling of our offering within the VA and provides much needed answers to the millions of Veterans exposed to airborne toxins.

–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.

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

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