FY2024 Full year results

30 August 2024

Highlights

- FY2024 operating revenue was $3.8m, up 422% on the prior corresponding period (pcp)
- Net underlying operating expenditure for FY2024 was $30.3 million, while the Group net cash balance was $30.6 million as at 30 June 2024
- Strategic acquisition of Imbio, an AI-driven medical imaging company, specialising in lung and cardiothoracic diagnostics including a suite of four FDA-cleared diagnostic products
- With ongoing revenue growth and further cost synergies being implemented, Imbio is on track to be cashflow positive in CY2024
- 4DMedical and Philips announce the signing of a Teaming Agreement for commercialisation expansion of XV Technology® within the U.S. Department of Veterans Affairs (VA)
- U.S. Food and Drug Administration (FDA) grants clearance for CT LVAS™, expanding patient accessibility to 4DMedical's XV Technology® by leveraging readily available CT hardware in the U.S.
- U.S. Centers for Medicare and Medicaid Services (CMS) approves reimbursement for XV LVAS™ and CT LVAS® at the rates of US$299 and US$650, respectively
- Commercial coverage expanded in Australia following agreements with trans-tasman imaging network, Integral Diagnostics (ASX:IDX), and South Australia-based, Jones Radiology
- Research agreements signed with West Los Angeles VA and Vanderbilt University Medical Center

Melbourne, Australia, 30 August 2024: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, "4DMedical", the "Group", or the "Company") today announces its FY2024 Full Year Results and releases its condensed Appendix 4E for the full year ended 30 June 2024 ("FY2024").

Financial Performance

FY2024 operating revenue was $3.8m, up 422% on pcp (FY2023: $0.7m). This revenue was principally related to Software-as-a-Service ($3.0m), with the remainder related to lease and maintenance revenue. 4DMedical product revenue was $1.1m, up 53% on pcp (FY2023: $0.7m), while Imbio product revenue was $2.7m for the post-acquisition period.

FY2024 other income totalled $11.0m, reflecting MRFF and other grants, as well as R&D tax incentive payments. FY2024 total reported income was $14.8m.

4DMedical operating expenses were down 3.4% on pcp, reflecting a reduction in R&D and clinical trial expenditure offset by increased investment in commercialisation. Imbio operating costs for the post-acquisition period were $3.7m. With ongoing revenue growth and further cost synergies underway, Imbio is on track to be cashflow positive in CY2024.

Net underlying operating expenditure for FY2024 was $30.3 million. The Group net cash balance was $30.6 million as at 30 June 2024.

AUD $m	FY2024	FY2023	$ var	% var
4DMedical Products	1.1	0.7	0.4	53.1%
Imbio Products	2.7		2.7	
Operating Revenue	**3.8**	**0.7**	**3.0**	**422.5%**
Gross Margin	**3.5**	**0.7**	**2.8**	**413.9%**
Other Income	11.0	13.2	(2.2)	(16.7%)
Operating Expenses – 4DMedical	(41.3)	(42.7)	1.4	3.4%
Net Underlying Operating Expenses	**(30.3)**	**(29.6)**	**(0.7)**	**(2.5%)**
Operating Expenses – Imbio	(3.7)		(3.7)	
EBITDA#	**(30.5)**	**(28.9)**	**(1.6)**	**(5.7%)**

 # EBITDA adjusted for one-off Imbio transaction expenses of $2.3m
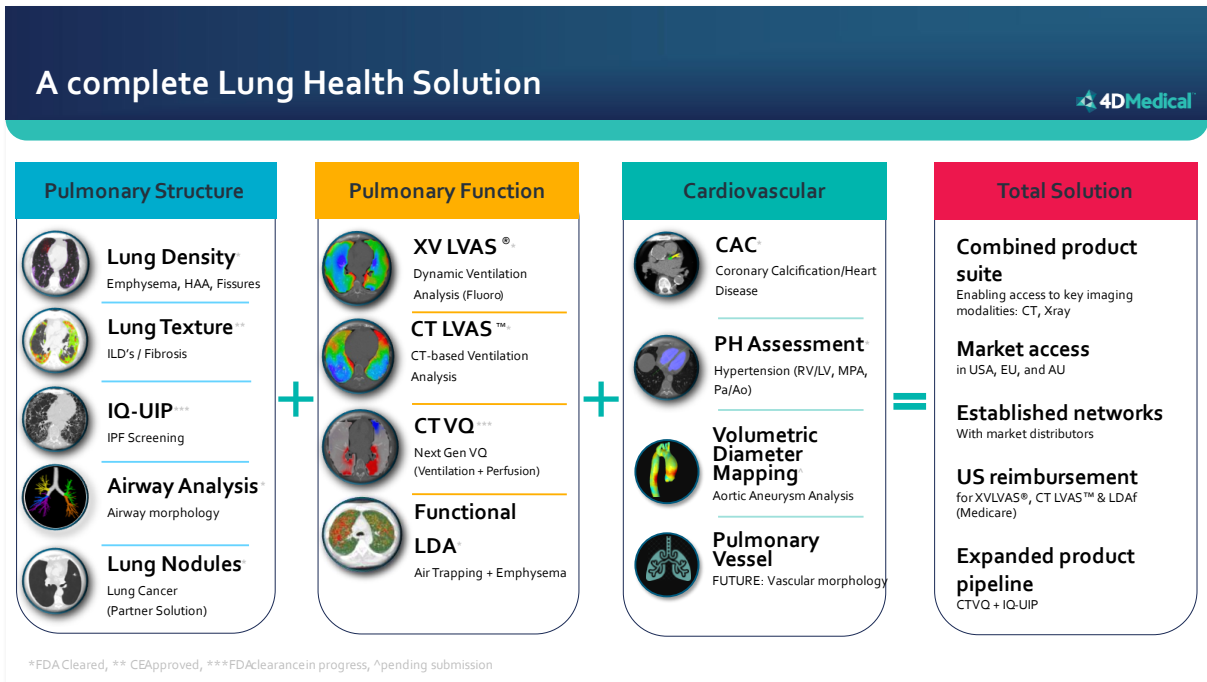
FY2024 Highlights

4DMedical made substantial advancements over FY2024, focusing on the commercialisation and global expansion of its proprietary respiratory imaging technologies. The Company remains focused on accessing U.S. Government contracts, establishing global partnerships, and expanding in Australia. This strategy has been supported by critical enablers such as the signing of the Philips Teaming Agreement, the acquisition of Imbio, CMS reimbursement for XV LVAS™ and CT LVAS®, and most recently, in Australia, the increase in site locations and referring doctors.

Philips Teaming Agreement

In January 2024, 4DMedical announced the signing of a Teaming Agreement with Philips to establish a strategic collaboration to broaden the commercialisation of 4DMedical's XV Technology® within the U.S. Department of Veterans Affairs (VA). This agreement is integral to scaling non-invasive lung screening technologies, supporting the implementation of the PACT Act, which extends healthcare benefits to an additional 6 million Veterans. Both companies are well advanced to establishing a formal reseller agreement under which 4DMedical's products will be added to Philips' product catalogue as third-party solutions for the VA and other U.S. federal agencies in North America.

Acquisition of Imbio: AI-driven diagnostic enhancements

In December 2023, 4DMedical completed the acquisition of Imbio, an AI-driven medical imaging company specialising in lung and cardiothoracic diagnostics. The acquisition aligns with 4DMedical's growth strategy by providing physicians with additional lung diagnostic tools, thereby allowing the Company to offer a comprehensive suite of products that combine structure and function in assessing lung disease.

A complete Lung Health Solution

4DMedical

Pulmonary Structure	Pulmonary Function	Cardiovascular	Total Solution
Lung Density Emphysema, HAA, Fissures	**XV LVAS ®** Dynamic Ventilation Analysis (Fluoro)	**CAC** Coronary Calcification/Heart Disease	**Combined product suite** Enabling access to key imaging modalities: CT, Xray
Lung Texture ILD's / Fibrosis	**CT LVAS ™** CT-based Ventilation Analysis	**PH Assessment** Hypertension (RV/LV, MPA, Pa/Ao)	**Market access** in USA, EU, and AU
IQ-UIP* IPF Screening	**CT VQ *** Next Gen VQ (Ventilation + Perfusion)	**Volumetric Diameter Mapping** Aortic Aneurysm Analysis	**Established networks** With market distributors
Airway Analysis Airway morphology	**Functional LDA** Air Trapping + Emphysema	**Pulmonary Vessel** FUTURE: Vascular morphology	**US reimbursement** for XVLVAS®, CT LVAS™ & LDAf (Medicare)
Lung Nodules Lung Cancer (Partner Solution)			**Expanded product pipeline** CTVQ + IQ-UIP

*FDA Cleared, ** CEApproved, ***FDAclearancein progress, ^pending submission

Imbio's established presence within the VA provides 4DMedical with a stronger entry point into the U.S. healthcare market, positioning the company as a more robust player in respiratory imaging with a comprehensive suite of AI-driven diagnostic tools. Soon after the acquisition, 4DMedical entered another strategic partnership with Blackford Analysis Inc., a provider of AI-driven medical imaging solutions. By leveraging Blackford's extensive network and expertise, 4DMedical aims to accelerate the adoption of its technologies worldwide, ensuring that more healthcare providers can offer advanced respiratory diagnostics to their patients.

4DMedical has largely completed the integration of Imbio operations, bringing finance, information systems, and administrative functions in-house. Platform and software development integration is well advanced and proceeding as planned, with key staff secured to ensure continuity of business function.

In addition, the acquisition accelerates 4DMedical's commercialisation of XV Technology® in the U.S., enhancing the product offering that can be used with major partners, as well as exciting opportunities to enhance patient screening programs for chronic obstructive pulmonary disease (COPD), interstitial lung disease (ILD), lung cancer and heart disease. In the period post-acquisition, the team has been able to present the combined product portfolio to physicians, receiving overwhelmingly positive responses, with genuine excitement in the greater clinical utility.

Finally, the acquisition presents significant revenue and cost synergies through a combination of complementary products, extended reach for 4DMedical product lines, and technical efficiencies. The Company is already seeing the value of the acquisition, with significant growth in revenues from established contracts with medical device manufacturers, large pharma, and AI marketplaces, and the expansion of our product portfolio, covering both structural and functional imaging.

CMS reimbursement for XV LVAS® and CT LVAS™

In FY2024, 4DMedical successfully gained U.S. Centers for Medicare & Medicaid Services (CMS) reimbursement for its XV LVAS® and CT LVAS™ products. As a result, XV LVAS® and CT LVAS™ scans conducted in a U.S. hospital outpatient facility for Medicare beneficiaries may be billed to CMS with a reimbursement of US$299 and US$650, respectively.

CMS is the federal agency providing health coverage through Medicare, which is an important public health insurance scheme for U.S. adults aged 65 years and over, with an estimated 66 million people enrolled. CMS reimbursement provides access to XV LVAS™ and CT LVAS® at over 4,000 Medicare-certified hospitals across the U.S., ensuring these scans are available to Medicare beneficiaries suffering from lung disease. This provides a funding source for providers of the technology beyond full out-of-pocket payment. Importantly, this benchmark payment level serves as a guide for private health insurers in determining their pricing levels, which is typically at a much higher rate.

Site locations, referrers and scans performed continue to grow in Australia

The commercialisation program continued to gain momentum across Australia in FY2024 with an increase in site locations, referrers and scans delivered through an increasing number of radiology networks.

In October 2023, 4DMedical announced the signing of a distribution agreement with Integral Diagnostics (ASX:IDX), a leading provider of medical imaging services with 94 sites across Australia and New Zealand. More recently, in July 2024, 4DMedical signed a commercial agreement with Jones Radiology, an operator of 29 radiology clinics across South Australia and Alice Springs, following a successful pilot of CT LVAS™ conducted at three of Jones Radiology's sites, with scans referred from both specialists and GPs.

The Group increased marketing and educational sessions in FY2024, including presence at key industry events such as the Thoracic Society of Australian and New Zealand Annual Scientific Meeting, is driving engagement with key thought leaders, increasing awareness and resulting in new opportunities for collaboration and scans throughout Australia. With scans now being received from Respiratory Physicians, Cardiologists and GPs across Australia, we are seeing the number of scans grow month-on-month.

Looking further out, 4DMedical is uniquely positioned to support a nationwide rollout of the National Lung Cancer Screening program, due for commencement in July 2025, with the addition of the Imbio portfolio of lung diagnostic tools including the licenced FDA approved lung nodule detection software. This places 4DMedical in a unique position to support radiologists and referrers in the screening of these patients and provide insight into management of incidental findings.

Product development and research initiatives

In FY2024, 4DMedical continued its progress in the development of its CT-based ventilation-perfusion product (CT:VQ), with further clinical data being presented at the annual conference of the American Thoracic Society (ATS) in San Diego in May 2024. The development of this capability represents a significant breakthrough in respiratory imaging by providing vascular perfusion (blood flow) analysis without the need for 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, hospitals can avoid the significant expenditure involved in mitigating radiation risks associated with Nuclear

Medicine VQ scanners, such as specialised facilities for handling and disposing of radioactive materials. With an estimated market size of $1 billion USD, CT:VQ is generating significant interest from clinicians and facilities alike.

In addition, 4DMedical has been actively involved in research initiatives in FY2024, particularly with the VA:

- In May 2024, the Company signed a Cooperative Research & Development Agreement (CRADA) with West Los Angeles VA to utilise XV Technology® across the spectrum of chronic respiratory conditions presenting with undifferentiated symptoms in a cohort of 40 patients.
- In March 2024, the Company announced its participation in a pivotal burn pit research grant awarded to the Nashville VA Medical Center by the Military Exposures Research Program (MERP).
- The Company entered into a research agreement with the VA's Center for Innovations in Quality, Effectiveness, and Safety (IQuESt) to utilise Imbio's Lung Texture Analysis (LTA) in a study assessing interstitial lung abnormalities in a national cohort of Veterans.

4DMedical MD/CEO and Founder Andreas Fouras said:

FY24 was a year of significant operational achievements for 4DMedical. The company's strategic acquisition of Imbio, coupled with its expansion in the U.S. market and key collaboration with Philips, has established a base for long term success. With the largest part of the Imbio integration behind us, realising significant cost synergies, Imbio is on track to be cashflow positive in CY2024.

The successful regulatory and reimbursement milestones, along with ongoing innovation and clinical validation efforts, further enhance 4DMedical's position as a leader in respiratory imaging technology. These strategic moves highlight 4DMedical's commitment to advancing lung diagnostic technologies, improving patient care, and driving growth in key markets. The company continues to focus on expanding its technological offerings, strengthening partnerships, and exploring new market opportunities to solidify its position as a leader in lung diagnostics.

In Australia, our team has been operating with an increasingly sophisticated playbook that is resulting in rapid growth in site locations and scans, and most importantly, in doctors referring for scans. This same playbook is now being deployed in the U.S., where there is the added advantage of an available reimbursement of US$650 for the 66 million Americans enrolled in Medicare.

We continue our progress in the development of our CT-based ventilation-perfusion product (CT:VQ), with exciting clinical data being presented at the annual American Thoracic Society conference in May. With an estimated market size of $1 billion USD, CT:VQ is generating incredibly strong interest from clinicians from across the US and Australia.

This year was transformative, laying strong foundations for growth and putting in place critical building blocks to take advantage of opportunities, most notably in the US Government and commercial sector.

With the team assembled, partnerships established, and the comprehensive product portfolio we are well placed to deliver a strong 2025.

–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