

Quarterly Activity Report and Appendix 4C for Q2 FY2024

31 January 2024

Highlights

- 1H FY2024 operating revenue was \$0.8m, up 60% on the prior corresponding period; on a proforma basis, operating revenue for 1H FY2024 was \$2.8m
- 4DMedical acquires US-based 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
- U.S. Centers for Medicare & 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.
- Special Advisor to 4DMedical and former VA Secretary, Dr David Shulkin, visits Australia
- Strong cash position of \$47.8m as at 31 December 2023

Melbourne, Australia, 31 January 2024: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, "4DMedical", or the "Company") today announces its Quarterly Activity Report and Appendix 4C Cash Flow Report for the quarter ended 31 December 2023.

Financial Performance

Operating revenue (unaudited) for 1H FY2024 was \$0.8m, up 60% on the prior corresponding period (1H FY2023: \$0.5m), reflecting increased SaaS revenue and Imbio revenues for the period post acquisition. On a proforma basis, operating revenue for 1H FY2024 was \$2.8m.

Cash receipts from customers for the quarter were \$0.2m, which consisted of SaaS contracts, hardware support, and maintenance services. Cash receipts also included customer receipts for the period post acquisition for Imbio.

Net cash operating outflows for the quarter were \$8.1m (30 September 2023: \$9.3m), the majority of which relate to costs for commercialisation, clinical trials, staff costs, research and development, and administration expenses.

Net cash received from financing activities for the quarter was \$32.7m, reflecting net proceeds from the successful capital raise undertaken in December for the purpose of acquiring US-based Imbio.

4DMedical's cash balance as at 31 December 2023 was \$47.8m.

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4DMedical acquires Imbio following successfully completed equity raising

During the quarter, 4DMedical acquired U.S.-based medical technology company Imbio, a recognised leader in lung and heart artificial intelligence (AI)-driven technology transforming how patients with lung and cardiothoracic conditions are detected, diagnosed and treated.

Imbio's technology complements 4DMedical's existing functional imaging capability with structural imaging products, providing a more complete cardiothoracic imaging suite and improving respiratory health solutions, particularly for U.S. Veterans affected by service-related exposure to airborne hazards.

The acquisition aligns with 4DMedical's growth strategy by providing physicians with four additional lung diagnostic tools, thereby allowing the Company to offer a comprehensive suite of products that combine structure and function in assessing lung disease, effectively 'owning the lung'.

Furthermore, the acquisition accelerates 4DMedical's commercialisation of XV Technology® in the U.S., opening up exciting opportunities to enhance patient screening programs for chronic obstructive pulmonary disease (COPD), interstitial lung disease (ILD), lung cancer and heart disease.

Additionally, this acquisition presents significant revenue and cost synergies through a combination of complementary products, extended reach for 4DMedical product lines, and technical efficiencies.

Imbio provides another entry point into the U.S. Department of Veterans Affairs (VA) healthcare system through an established program and a combined product offering creating further opportunities for delivering a comprehensive and integrated diagnostics screening program.

4DMedical successfully completed a capital raising of A\$35 million by way of a placement to partly fund the acquisition. Approximately 44.3 million new 4DX shares were issued as well as one free-attaching option for every two shares issued, which received shareholder approval at the Extraordinary General Meeting held on 22 January 2024. The placement was well supported by new and existing institutional investors.

Imbio was acquired for an upfront purchase price of US\$25 million (approximately A\$37.4 million), plus a contingent earnout including one tranche of up to US\$10 million in CY2024 and two tranches of up to US\$5 million each in CY2025, conditional on the achievement of key commercial and regulatory milestones. 4DMedical intends to settle any contingent earnout payable via the issue of new 4DMedical shares.

Imbio operational update

Imbio is in its 3rd year of a strategic partnership with Olympus as the exclusive provider of the Olympus "SeleCT" image analysis service that helps physicians qualify patients for endobronchial valve (EBV) therapy. SeleCT is based on a customised version of Imbio Lung Density Analysis (LDA) that incorporates fissure integrity assessment and other customised deliverables.

Olympus and Imbio are now expanding their partnership further and working together to expand the market for endobronchial valves by offering a population screening program called "SeleCT Screening". SeleCT Screening is an Imbio provided service that analyses all chest CT's across a health system and proactively identifies patients who may be eligible for EBV therapy.

In recent days, Olympus has signed the first commercial customer for SeleCT Screening, Avera St. Luke's in Aberdeen, South Dakota, with several additional sites in discussions. Both companies are excited about SeleCT Screening as a new growth opportunity for EBV therapy and patients who can benefit from it.



Teaming Agreement signed with Philips Healthcare

On 22 January 2024, 4DMedical announced the signing of a commercial agreement (Teaming 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 for deployment-related respiratory disease in North America.

Following the announcement late last year that the companies had entered a Memorandum of Understanding to expand the commercial reach and access for 4DMedical, the signing of the Teaming Agreement represents a major step forward in the Company’s commercialisation strategy, particularly within the VA. Under the terms of the agreement, 4DMedical and Philips will combine to develop proposals to provide solutions for Toxic Exposure and Lung Screening using 4DMedical’s XV Technology® software and Philips fluoroscopy and CT systems.

Philips has long-established and significant existing partnerships with both the VA and the 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. Accessing this team of industry experts, with unparalleled relationships in global healthcare, provides an unprecedented opportunity to accelerate 4DMedical’s go-to-market activities, particularly in the VA.

In parallel with providing solutions to the VA under the Teaming Agreement, 4DMedical and Philips have begun working towards a reseller agreement, where it is anticipated that 4DMedical’s XV Technology® will be added to Philips’ product catalogue and offered as a third-party solution providing access to both software and hardware, including the Imbio portfolio, to other US-based Federal agencies and commercial organisations in North America. The parties will also consider other markets outside of North America for expansion.

U.S. Centers for Medicare & Medicaid Services (CMS) approves reimbursement for 4DMedical

Centers for Medicare & Medicaid Services (CMS) is the federal agency providing health coverage through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. Medicare is an important public health insurance scheme for U.S. adults aged 65 years and over; as of 1 March 2023, there were 65.7m people enrolled in the program.

Last year 4DMedical was successful in establishing a new and distinct AMA Category III CPT code identifying the use of XV LVAS® by healthcare providers and payers. Category III CPT codes are a set of temporary codes for new and emerging technologies that are created for data collection in substantiating the widespread usage of a technology. CMS has now included assignment of payment levels to the CPT III codes for XV LVAS® in the 2024 HOPPS Proposed Rule.

CMS has various payment methodologies and fee schedules applicable to procedures, services and products based upon where services are rendered. After review and consideration of the information and public comment provided by 4DMedical, CMS accepted the reimbursement request and finalised assignment of the Category III CPT code for XV LVAS® to the rate of US\$299 per scan.

CMS payment policy changes affect care delivery at over 4,000 Medicare-certified hospitals across the country. This significant and positive change ensures that XV LVAS® is available to Medicare patients afflicted with lung disease and provides a funding source for providers of the technology beyond full out-of-pocket payment.



Expanded distribution in the U.S.

Following CMS reimbursement, 4DMedical signed two new outpatient clinics in the U.S., expanding access to XV LVAS® scans in Detroit and Memphis with imaging available from 1 January 2024.

Outpatient facilities provide patients with an alternative to hospital networks, thereby increasing patient and referrer access to XV LVAS® scans, and in an environment that is often regarded as more convenient and patient-centric.

Beyond demonstrating the commercial impact of attracting reimbursement, these new distribution partners provide further evidence of the progress being made in 4DMedical's U.S. commercialisation efforts.

FDA grants clearance for CT LVAS™

On 20 November 2023, 4DMedical announced that clearance for its computed tomography (CT)-enabled ventilation product CT LVAS™ had been received from the United States Food and Drug Administration (FDA).

CT LVAS™ provides an almost identical report to 4DMedical's proven, FDA-cleared, XV LVAS® product, utilising widely available CT imaging infrastructure (instead of X-ray equipment) providing clinicians and patients with greater access to XV Technology®.

FDA clearance follows the 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 significant, with 43 CT scanners per million population (versus Australia at 70, France at 20, and Canada at 15 per million), therefore significantly broadening accessibility of functional lung imaging for people in the U.S. living with lung disease.

Dr David Shulkin in Australia

Former Secretary for Veterans Affairs in the Obama and Trump administrations, and Special Advisor to 4DMedical, Dr David Shulkin, visited Australia during January, engaging with staff, institutional investors and retail shareholders.

A highlight of Dr Shulkin's visit was participation in a webinar hosted by David Nayagam, Evans & Partners' Executive Director Healthcare Research at their Sydney offices. The webinar focused on the US Healthcare market, specifically the provision of care to Veterans and the opportunity that 4DMedical's XV Technology® has in delivering accurate, non-invasive and scalable solutions for toxic exposure and lung screening that the VA must now provide as mandated by the PACT Act.

Dr Shulkin is a key member of 4DMedical's Advisory Committee and provides critical guidance and support to 4DMedical, utilising his extensive network and considerable depth of knowledge of the US healthcare system.

Related Party Transactions (Listing Rule 4.7C)

Payments to related parties of \$0.4 million included in Item 6 of the attached Appendix 4C Cash Flow Report were for salaries and fees paid to executive and non-executive directors during the quarter that ended 31 December 2023.



4DMedical MD/CEO and Founder Andreas Fouras said:

4DMedical enters 2024 with considerable momentum with a transformational acquisition and an impressive number of significant commercial milestones accomplished over the last quarter, the most recent of which is the signing of the Teaming Agreement with Philips.

4DMedical's acquisition of a U.S. company offering complementary technologies and expertise is an important moment, indicative of growth and ambition. Imbio's highly regarded capabilities utilising AI are now 4DMedical capabilities, with the additional advantage of gaining an established conduit into the VA healthcare system and access to commercial relationships already in place.

Reimbursement is critical for commercial success in the U.S. market, enabling insurer coverage of the use of our XV Technology®, and adoption by clinicians and patients. CMS approval builds upon acquisition of a CPT III Code and enables 65.7million Americans to potentially access our Company's product.

Gaining FDA approval for the CT LVAS™ product aligns a variant of our core XV Technology® with the prevalence of CT infrastructure across the United States. Beyond delivering greater insights to more people, this achievement is highly significant in widening the commercial opportunity in 4DMedical's primary market.

Having the privilege of hosting Dr David Shulkin during a visit to Australia was a professional and personal highlight, and I am delighted by the shareholder participation in the webinar through which Dr Shulkin was able to share his vision for XV Technology® as a means for improving the lives of Veterans.

–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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

4DMedical Limited

ABN

31 161 684 831

Quarter ended ("current quarter")

31 December 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows used in operating activities		
1.1 Receipts from customers	210	398
1.2 Payments for		
(a) research and development	(3,122)	(7,948)
(b) product manufacturing and operating costs	(1,265)	(1,265)
(c) advertising and marketing	(510)	(1,103)
(d) leased assets	(257)	(658)
(e) staff costs	(3,507)	(7,041)
(f) administration and corporate costs	(5,727)	(6,656)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	831	1,032
1.5 Interest and other costs of finance paid	(62)	(127)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives (GST inclusive)	5,352	6,028
1.8 Other (provide details if material)	-	-
1.9 Net used in operating activities	(8,057)	(17,340)
2. Cash flows used in investing activities		
2.1 Payments to acquire or for:		
(a) entities	(37,370)	(37,370)
(b) businesses	-	-
(c) property, plant and equipment	(10)	(97)
(d) investments	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
	(e) intellectual property	-	-
	(f) other non-current assets	(43)	(88)
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Research and development tax incentive	-	-
2.6	Capitalisation of development costs to intangible assets	-	-
2.7	Other (provide details if material)	788	788
2.8	Net cash used in investing activities	(36,635)	(36,767)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	35,000	35,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2,033)	(2,052)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other		
	(a) payment of lease liabilities	(272)	(543)
	(b) net cash paid for settlement of options	-	-
3.10	Net cash from financing activities	32,695	32,405

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.	Net (decrease)/increase in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	59,871	69,576
4.2	Net used in operating activities (item 1.9 above)	(8,057)	(17,340)
4.3	Net cash used in investing activities (item 2.8 above)	(36,635)	(36,767)
4.4	Net cash from financing activities (item 3.10 above)	32,695	32,405
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	47,874	47,874

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	47,874	59,871
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	47,874	59,871

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	367
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

7. Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-
7.5 Unused financing facilities available at quarter end		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	<div style="border: 1px solid black; padding: 5px; min-height: 100px;"> <p>N/A</p> </div>	

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash used in operating activities (item 1.9)	(8,057)
8.2 Cash and cash equivalents at quarter end (item 4.6)	47,874
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	47,874
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	6
<div style="border: 1px solid black; padding: 5px;"> <p>Answer: N/A</p> </div>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
<div style="border: 1px solid black; padding: 5px;"> <p>Answer: N/A</p> </div>	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
<div style="border: 1px solid black; padding: 5px;"> <p>Answer: N/A</p> </div>	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
<div style="border: 1px solid black; padding: 5px;"> <p>Answer: N/A</p> </div>	
<p><i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i></p>	

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 31 January 2024

Authorised by: Board of Directors
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.