

Quarterly Activity Report and Appendix 4C for Q4 FY2024

31 July 2024

Highlights

- FY2024 operating revenue of \$3.8m, up 422% on the prior corresponding period (pcp)
- Strong cash balance of \$30.6 million as at 30 June 2024
- From May 2024, CT LVAS™ scans conducted in a U.S. hospital outpatient facility for Medicare beneficiaries can be billed to CMS with a reimbursement of US\$650.50
- 4DMedical signed an agreement with West Los Angeles VA where XV Technology® will be used to characterise Veterans with undifferentiated dyspnoea and other respiratory symptoms
- In early July 2024, 4DMedical signed a commercial agreement with Jones Radiology, an operator of 29 diagnostic and interventional radiology clinics across South Australia and Alice Springs
- 4DMedical was prominent at the American Thoracic Society (ATS) conference in May, delivering two Innovation Hub presentations, two oral presentations and 15 poster presentations
- Commercialisation continues to gain momentum with an increase in site locations, referrers and scans performed throughout the network across Australia and the U.S. during the quarter

Melbourne, Australia, 31 July 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 30 June 2024.

Financial Performance

Operating revenue (unaudited) for Q4 FY2024 was \$1.5m, which consisted of general radiology software services, SaaS contracts, and support and maintenance services. For the 12-month period to 30 June 2024, operating revenue was \$3.8m, up 422% on pcp and up 34% on a proforma basis.

Net cash operating outflows for the quarter excluding non-recurring operating costs associated with the acquisition and integration of Imbio were \$9.8m (Q4 FY2023: \$9.3m). Net operating cashflows for FY2024 excluding acquisition and integration costs of Imbio were \$28.7m (FY2023: \$23.5m). The increase in FY2024 net cash operating outflows was driven primarily by an increase in U.S.-based commercialisation activities, including the newly acquired Imbio operations.

4DMedical's cash balance as at 30 June 2024 was \$30.6 million.

Commercialisation update

4DMedical and Philips closing in on reseller agreement

In January 2024, 4DMedical formalised the Philips MoU with the signing of a Teaming Agreement for commercialisation expansion of XV Technology® within the U.S. Department of Veterans Affairs (VA). The signing of this agreement represented a major step forward in the Company's commercialisation strategy, particularly within the VA, with 4DMedical and Philips working together to support the massive need to scale non-invasive lung screening in support of the PACT Act.

Both companies have been working towards a formal reseller agreement under which 4DMedical's suite of products will be added to Philips' product catalogue and offered as a third-party solution, thereby

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providing the VA and other U.S.-based government agencies in North America with access to XV Technology® and the Imbio product suite. While the process for finalising the reseller agreement has been rigourous, management is confident the process remains on track and is excited about the transformational commercial opportunities expected to flow from it.

Imbio integration

As previously announced, 4DMedical acquired Imbio in December 2023. This strategic acquisition enables 4DMedical to provide its referrers with a comprehensive portfolio of functional and structural lung analysis tools. This portfolio, coupled with a cardiology analysis suite, is unique to 4DMedical and provides a meaningful current revenue stream as well as the opportunity for significant growth.

This suite of lung analysis applications (see figure below) is now the basis for the 4DMedical product offering to referrers in Australia and the U.S.. This offering, combined with CMS reimbursement in the U.S., facilitates growth opportunities across various markets including the VA, private radiology, respiratory and cardiology specialists.



The consolidated resources and expertise within the combined organisation enable 4DMedical to further leverage and capitalise on the relationships from both parties, including Philips, the VA and commercial partners both in the U.S. and Australia.

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



CMS reimbursement for CT LVAS™

In May 2024, the American Medical Association (AMA) CPT Editorial Panel notified 4DMedical that providers may utilise two existing Category III CPT codes for the reimbursement of its CT LVAS™ technology. As the codes were already in place with a reimbursement payment of US\$650.50 per scan, CT LVAS™ scans conducted in a U.S. hospital outpatient facility for Medicare beneficiaries can be billed to CMS immediately.

CMS reimbursement now provides access to CT LVAS™ at over 4,000 Medicare-certified hospitals across the U.S., ensuring that CT LVAS™ technology, which can be performed on existing CT scanners, is 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, set for hospital outpatient procedures, serves as a guide for private health insurers in determining their pricing levels, typically at a much higher rate.

The Company now has CMS reimbursement for both CT LVAS™ and XV LVAS®, having last year successfully established a new and distinct AMA Category III CPT code identifying the use of XV LVAS® by healthcare providers and payers at the CMS rate of US\$299.

U.S. Senators write to Secretary of Veterans Affairs

On 15 April 2024, 18 U.S. Senators signed a <u>letter</u> for the attention of U.S. Secretary of Veterans Affairs, Denis McDonough, urging the VA to expedite the implementation of the PACT Act. Amongst other things, the letter reflected that the VA's use of pulmonary function tests, which it uses to measure the severity of other respiratory conditions, does not support sufficient specificity to accurately rate constrictive bronchiolitis (CB) claims. In this regard, it is clear that non-invasive, scalable, FDA-approved technologies, such as 4DMedical's XV Technology®, can help more Veterans receive the benefits and recognition the PACT Act provides.

On 11 July 2024, 4DMedical supported the American Legion alongside co-sponsor Philips on the second anniversary of the passage of the Sgt. First Class Heath Robinson Honouring our Promising to Address Comprehensive Toxins (PACT) Act. This event, held at Capitol Hill Washington DC, bought together key stakeholders within the VA, BurnPits360, Congressmen Rep. Greg Murphy, House Veterans Affairs Health Subcommittee member and Rep. Chris Pappas, House Veterans Affairs Disability Assistance and the Memorial Affairs Subcommittee ranking member to discuss how the VA has reached over 1 million Veterans in screenings for toxic exposure and what efforts are underway to efficiently triage Veterans who are identified as exposed to burn pits and experiencing symptoms. The next steps included a focus on enhanced healthcare services, a more efficient benefits process, and better support for Veterans exposed to toxins.

Veterans Affairs Functional Lung Imaging Study (VAFLIS)

In May 2024, 4DMedical signed a Cooperative Research & Development Agreement (CRADA) with West Los Angeles VA Medical Center for utilisation of 4DMedical's XV Technology® in the Veteran Affairs Functional Lung Imaging Study (VAFLIS). This study will utilise XV Technology® across the spectrum of chronic respiratory conditions presenting with undifferentiated symptoms.

The study will enrol a cohort of 40 patients and utilise XV Technology® to correlate regional ventilation and ventilation heterogeneity with quality of life, the six-minute walk test and dyspnoea scores, to determine if changes can be identified in lung function post treatment. The data collected will be used to optimise treatment pathways, including possible rehospitalisation or further medical follow up.



This follows the announcement in March of 4DMedical's participation in a pivotal burn pit research grant awarded to the Nashville VA Medical Center by the Military Exposures Research Program (MERP), and this CRADA further demonstrates the Company's commitment to the long-term lung health of U.S. Veterans.

4DMedical prominent at the American Thoracic Society (ATS) conference in San Diego

In May 2024, the American Thoracic Society (ATS) held their annual conference in San Diego, California. Over the course of the three-day event, 4DMedical delivered a comprehensive engagement with the pulmonology community through multiple innovative presentations and collaborations. The conference served as a platform to introduce our expanded portfolio of products to the pulmonology community. Key highlights include:

- Two Innovation Hub Presentations: "A New Tool Allowing Ventilation and Perfusion Analysis of Non-Contrast Chest CT," presented by Andreas Fouras and Trishul Siddharthan.
 - "Veterans in Crisis: Uncovering the Realities of Burn Pit Exposure and DRRD" featured U.S. veteran panellists and was moderated by Rosie Torres and Dr. Greg Mogel. The panel built awareness of deployment-related respiratory disease (DRRD) and shared personal stories with ATS pulmonologists.
- **Poster Presentations:** The Medical and Clinical Affairs team presented a record 15 posters highlighting advancements in XV Technology® and developments in AI. Details of these posters can be found here.
- Respiratory Innovation Summit (RIS): 4DMedical presented a poster at ATS's RIS, showcasing the latest product developments in AI and Deep Learning. This presentation underlined our commitment to integrating cutting-edge technologies into pulmonology.
- **Oral Presentations:** Andreas Fouras delivered two oral presentations, one each covering the company's latest advances in CT:VQ and DRRD.

Overall, our participation at ATS 2024 underscored 4DMedical's dedication to advancing respiratory diagnostics and treatment through innovation, collaboration, and a commitment to improving patient outcomes.

BurnPits360 Partnership

During the quarter 4DMedical continued to develop its relationship and alliance with BurnPits360.

BurnPits360 is a non-profit organisation dedicated to educating the public about the impact of toxic chemical exposure from military burn pits, advocating for affected Veterans and their families, and empowering them to seek justice and support. They operate an independent burn pit registry, provide resources and alternative treatment options through the Warrior Hope Network, and run a support center to assist Veterans and their families. BurnPits360 also actively works to ensure the rights of Veterans are protected under legislation like the PACT Act

BurnPits360's relentless efforts towards realising the PACT Act are enabling generations of Veterans to access the healthcare they deserve. A core principle of the Act is the notion of 'presumptive conditions,' where the VA automatically assumes that military service is the cause of a Veteran's health issues. Although the burden of proof has been removed, the ability of Veterans exposed to toxins to fully understand the extent of their respiratory compromise is limited by the lack of sensitivity of existing modalities used within the VA system.

At this year's American Thoracic Society (ATS) conference, BurnPits360 joined the 4DMedical booth and participated in a combined Innovation Hub session on "Veterans in Crisis: Uncovering the Realities of



Burn Pit Exposure and DRRD." The presentation, led by BurnPits360 co-Founder and renowned patient advocate, Rosie Torres, and with 4DMedical CMO Dr. Greg Mogel, offered a unique opportunity to hear directly from Veterans battling DRRD. The session covered the science, medicine, policy and the lived experiences of those who have served and often suffer the "hidden wounds of war."

Several Veterans shared their experiences with toxic exposure, the challenges of navigating the VA healthcare system for diagnosis, treatment, and benefits all while living with the impact of this poorly understood condition, as well as how XV Technology® can assist in the diagnosis and ongoing treatment of this debilitating condition.

Expanded distribution in the U.S. and globally

The Company has continued to make progress with our commercialisation efforts in the U.S., signing contracts directly, and through our distribution partners Olympus, Nuance and Aidoc. Notable commercial contracts were received from UCSF, Stanford, The Cleveland Clinic and Northwell Health. Within the last quarter, our Imbio portfolio has been contracted at several hospitals across Europe including Spain, Italy and France, plus a multiyear contract in Brazil.

The team is actively working up opportunities from the ATS conference in San Diego for contracts and clinical pilots, from the high-quality leads captured. In excess of 100 interested contacts and multiple business development opportunities were collected at the event.

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

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

In early July, 4DMedical signed a commercial agreement with Jones Radiology, Adelaide, following a successful pilot of CT LVAS™ conducted at three of Jones Radiology's sites, with scans referred from both specialists and GPs. 4DMedical is confident progress made to date with commercial contracts across imaging providers will further expand these contracts in the coming quarters.

Increased marketing and educational sessions, 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.

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.

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 30 June 2024.



4DMedical MD/CEO and Founder Andreas Fouras said:

We are now seeing the justification of our strategic acquisition of Imbio: the rounding out of our product portfolio, covering both structural and functional imaging, and the over 4x growth in revenues. With the largest part of the integration behind us, we have recognised significant cost synergies and can now enjoy substantial cross selling opportunities.

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\$650.50 for the 66 million Americans enrolled in Medicare.

ATS provided us with a great opportunity to provide leading doctors with the latest clinical trial evidence of the capabilities of CT:VQ. The excitement around this product continues to grow exponentially, paving the way for rapid penetration into a >\$1Billion market.

While these conditions set 4DMedical up for a sustained period of rapid organic growth, we continue to invest into the very significant opportunity we have with the VA, both in day-to-day healthcare and for Veterans experiencing DRRD. We expect to be able to provide important updates within coming weeks.

-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 <u>www.4dmedical.com</u> and <u>www.imbio.com</u>

Appendix 4C

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

Name of entity

4DMedical Limited	
ABN	Quarter ended ("current quarter")
31 161 684 831	30 June 2024

Cor	nsolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows used in operating activities		
1.1	Receipts from customers	1,357	2,888
1.2	Payments for		
	(a) research and development	(3,497)	(16,123)
	(b) product manufacturing and operating costs	(26)	(1,324)
	(c) advertising and marketing	(691)	(2,442)
	(d) leased assets	(251)	(1,167)
	(e) staff costs	(4,321)	(15,271)
	(f) administration and corporate costs	(2,729)	(11,957)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	83	1,238
1.5	Interest and other costs of finance paid	(69)	(264)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (GST inclusive)	-	12,683
1.8	Other (provide details if material)	-	-
1.9	Net used in operating activities	(10,144)	(31,739)

2.	Cash flows used in investing activities		
2.1	Payments to acquire or for:		
	(a) entities	(136)	(39,655)
	(b) businesses	-	-
	(c) property, plant and equipment	(24)	(155)
	(d) investments	-	-

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
	(e) intellectual property	-	-
	(f) other non-current assets	(22)	(146)
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) ^[1]	-	788
2.8	Net cash used in investing activities	(182)	(39,168)

[1] Cash acquired as part of the Imbio acquisition.

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	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	-	(2,052)
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	(230)	(1,011)
	(b) net cash paid for settlement of options	-	-
3.10	Net cash from financing activities	(230)	31,937

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 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	41,162	69,576
4.2	Net used in operating activities (item 1.9 above)	(10,144)	(31,739)
4.3	Net cash used in investing activities (item 2.8 above)	(182)	(39,168)
4.4	Net cash from financing activities (item 3.10 above)	(230)	31,937
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	30,606	30,606

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	30,606	41,162
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)	30,606	41,162

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	374
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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.

7.	Financing facilities 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.	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 qu	arter end	-
7.6	Include in the box below a description of eac rate, maturity date and whether it is secured facilities have been entered into or are proposinclude a note providing details of those facilities.	or unsecured. If any addised to be entered into af	tional financing
	N/A		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash used in operating activities (item 1.9)	(10,144)
8.2	Cash and cash equivalents at quarter end (item 4.6)	30,606
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	30,606
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	3
	Answer: N/A	

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

B.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?

Answer: N/A

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?

Answer: N/A

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?

Answer: N/A

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.

Compliance statement

- 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 July 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.