

Quarterly Activity Report and Appendix 4C for Q3 FY2024

30 April 2024

Highlights

- Q3 FY2024 operating revenue was \$1.4m, up 54% on the prior corresponding period ('pcp') on a proforma basis
- Q3 FY2024 year to date operating revenue was \$2.2m, up 28% on the pcp and proforma basis
- Strong cash balance of \$41.7 million as at 31 March 2024
- Commercialisation continues to gain momentum with an increase in site locations, referrers and scans performed throughout the network across Australia and the US during the quarter
- 4DMedical secures participation in pivotal burn pit research grant awarded by the Military Exposures Research Program (MERP), an initiative of the VA
- 4DMedical praises lawmakers for including non-invasive FDA-approved screening technologies in <u>H.R.4366</u> - Consolidated Appropriations Act of 2024
- 18 U.S. Senators sign a <u>letter</u> for the attention of U.S. Secretary of Veterans Affairs, Denis McDonough, urging the VA to fix how Veterans with deployment related respiratory disease receive disability benefits
- 4DMedical signs Teaming Agreement with Philips to establish a strategic collaboration to expand commercialisation of XV Technology[®] within the VA
- Imbio secures additional contracts during the quarter, expanding the reach and coverage of its technology for clinicians

Melbourne, Australia, 30 April 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 March 2024.

Financial Performance

Operating revenue (unaudited) for Q3 FY2024 was \$1.4m, up 54% on the prior corresponding period ('pcp') on a proforma basis. Operating revenue year to date was \$2.2m, up 28% on the pcp and proforma basis. Q3 FY2024 reflects the first full quarter of recording Imbio revenues post acquisition.

Net cash operating outflows for the quarter were \$6.4m (Q2 FY2024: \$8.5m), which included \$2.4m of non-recurring operating costs associated with the acquisition of Imbio. Recurring costs relate to commercialisation activities, clinical trials, staff costs, research and development, and administration expenses.

4DMedical's cash balance as at 31 March 2024 was \$41.7 million.

In March, 4DMedical was included in the ASX All Ordinaries index, marking it one of Australia's top 500 listed companies by market capitalisation.

The future of lung health

Melbourne Level 7 Melbourne Connect 700 Swanston Street Carlton VIC 3053 Tel: +61 (3) 9545 5940

Los Angeles 21255 Burbank Boulevard Suite 120 Woodland Hills CA 91367 Tel: +1 (818) 403-8490

4DMedical Limited ABN: 31 161 684 831 Email: info@4DMedical.com www.4DMedical.com



Key Activities undertaken this quarter:

<u>Australia</u>

The commercialisation program continues to gain momentum across Australia with an increase in site locations, referrers and scans performed through the I-MED and Integral Diagnostics networks. Further engagement with other Australian-based providers continues to develop with scans performed with Jones Radiology (SA) and Spectrum Medical Imaging (NSW). 4DMedical is confident progress in commercial contracts across imaging providers will further expand in the coming quarters.

Operationally, significant progress has been made in the training of radiologists and building the number of referring clinicians, facilitating the establishment of a robust and sustainable network within lung diagnostics. In addition, considerable advances have been achieved in optimising the workflow and improving the end user experience and insights with CT LVAS[™]. This process has been led by Dr Greg Mogel, SVP Executive Medical Director, an experienced and practising radiologist with an extensive career serving in the US Army Medical Corps. Dr Mogel also played a central role in the establishment of Lung Cancer Screening at Kaiser Permanente, one of the largest integrated healthcare delivery systems in the United States.

Increased marketing and presence at key industry events, such as Thoracic Society of Australia and New Zealand, and the Australian Lung Foundation's International Women's Day Dinner is driving engagement with key thought leaders, increasing awareness, resulting in new opportunities for collaboration and scans, throughout Australia. This is most notable with respect to lung cancer screening; 4DMedical is uniquely positioned to support a nationwide rollout, due to the addition of the Imbio portfolio of lung diagnostic tools including FDA approved lung nodule detection software.

United States

U.S. Department of Veterans Affairs (VA)

In August 2022, President Biden signed the Sergeant First Class Heath Robinson Honoring Our Promise to Address Comprehensive Toxics (PACT) Act. The law expands VA health care and benefits for Veterans exposed to burn pits and other airborne hazards, providing US\$280 billion in additional benefits over 10 years. Importantly, it requires the VA to provide toxic exposure screening to each of the 9 million Veterans enrolled in the VA health care program.

A matter of weeks after the signing of the PACT Act, initial results from a clinical trial at Vanderbilt University Medical Center (VUMC) were released, validating 4DMedical's XV Technology[®] as an effective tool for evaluating Veterans who were deployed near burn pits and presented with unexplained shortness of breath. On 1 March 2024, the Company announced the signing of an agreement with VUMC as part of a grant awarded by the Military Exposures Research Program (MERP), an initiative of the VA. This study will utilise 4DMedical's XV Technology[®] to advance the understanding of factors that cause deployment-related respiratory disease (DRRD) and to improve the ability of clinicians to diagnose DRRD non-invasively.

Appropriations Act language pushes for action

Specific language discussing non-invasive lung function screening was included as part of <u>H.R.4366</u> - Consolidated Appropriations Act of 2024, signed by President Biden on 9 March 2024. The Bill's associated report stated: "The Committee notes that the Department has increased its research into Veterans with deployment-related respiratory disease and strongly encourages the Department to continue its efforts to identify and use in clinical practice non-invasive FDA-approved screening



technologies that save Veterans from invasive procedures such as surgical lung biopsies that are often required to establish a diagnosis." Notably, the report also states: "The Committee directs the Department to submit a report to the Committees on Appropriations of both Houses of Congress on their efforts relating to such implementation no later than 90 days after the enactment of this Act." Subsequently, 4DMedical has been active in multiple follow up inquiries and opportunities across the VA, as the pressure continues to mount for adoption of non-invasive screening and triage technologies.

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.

4DMedical signs Teaming Agreement with Philips

In January, 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 represents a major step forward in the Company's commercialisation strategy, particularly within the VA. Philips and 4D Medical will work together to support the massive need to scale non-invasive lung screening in support of the PACT Act.

Progress is well advanced to formalise a reseller agreement under which 4DMedical's XV Technology[®] and Imbio portfolio will be added to Philips' product catalogue and offered as a third-party solution providing access to both software and hardware, 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.

4DMedical was invited to attend AMSUS -The Society of Federal Health Professionals congress alongside Philips to discuss our collaboration to members of the VA and present at the "Toxic Exposure Impact to Lung Health, Screening, Research and New Care Approaches" forum.

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.

During the quarter, multiple Veterans undertook XV LVAS[®] scans performed at the Precision IR lab in Detroit and we continue to explore new opportunities, especially through the Philips install base for additional office-based labs. These 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.

Also, during the quarter the University of Miami completed the set-up of billing for XV LVAS[®] scans, tracking them against the CPT code as they continue to perform clinical scans. Beyond demonstrating the commercial impact of attracting reimbursement, these new distribution partners and operational activities provide further evidence of the progress being made in 4DMedical's U.S. commercialisation efforts.



Dr David Shulkin in Australia

Former Secretary of 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 Board and provides critical guidance and support to 4DMedical, utilising his extensive network and considerable depth of knowledge of the US healthcare system. Throughout the quarter, Dr Shulkin has continued to create awareness of 4DMedical technology including chairing the "Toxic Exposure Impact to Lung Health, Screening, Research and New Care Approaches" session at the AMSUS congress.

Imbio operational update

4DMedical made significant progress with the integration of the Imbio operations, with finance and administrative functions now largely cut over. 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.

Commercially, Imbio continues to secure key agreements across the US, Europe and South America. Imbio won additional contracts across each of its distribution channels (direct, through distributors and via its partnership with Olympus), expanding the reach and coverage of its technology for clinicians.

In February, 4DMedical signed a distribution agreement with Blackford to distribute the Imbio portfolio of AI solutions. Established in 2010, Blackford is one of the world's leading radiology AI marketplaces, with a broad portfolio of third-party applications covering many clinical indications. Blackford has differentiated itself from other providers by successfully positioning itself as the leading white-label platform that supports other major radiology companies' AI offerings. The Blackford white labelled AI platform services major radiology companies today including Bayer Radiology, Intelerad Medical Systems and Merative (formerly IBM Watson Health), with more strategic partnerships under development. Notably, Blackford also provides the white-labelled AI platform for Philips Healthcare. Combined with Imbio's existing distribution agreements with Nuance (Microsoft) and Aidoc, the Blackford agreement means 4DMedical now has partnerships with the three leading medical imaging AI marketplaces for Imbio AI solutions.

On 27 February, 4DMedical announced that Imbio had secured a research agreement with the VA Centre for Innovations in Quality, Effectiveness and Safety (IQuESt). The research project will use Imbio's Lung Texture Analysis (LTA) to retrospectively assess the CT scans of a cohort of Veterans that underwent Lung Cancer Screening (LCS) between 2014 and 2017 to determine the prevalence, diagnostic delay, and mortality associated with interstitial lung abnormalities (ILA) and interstitial lung disease (ILD).

The U.S. Veteran population suffers from ILD at a rate of 10 times the civilian population, with a 260% growth in the incidence of this debilitating condition since 2010. Approximately 1 million Veterans are eligible for lung cancer screening (LCS), and up to 25% of these patients are projected to have findings of ILA/ILD based on lung cancer screening demonstration project data.



While the prevalence of high-risk features for ILA progression are not well characterised, lung texture analysis is effective in the classification of normal versus abnormal tissue and performs well in distinguishing typical pathologies present in lungs with fibrotic disease. Imbio's LTA product will be utilised to retrospectively assess a random sample of 2,000 patients with ILA/ILD from the national cohort, in the project titled, "Novel Machine Learning Tools to Reduce Diagnostic Delays Among Veterans with Pulmonary Fibrosis".

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 March 2024.

4DMedical MD/CEO and Founder Andreas Fouras said:

4DMedical continues to show great momentum with the integration of Imbio proceeding to plan, and on track to deliver on cross-selling opportunities and cost synergies this calendar year. In addition, rollout of Imbio's technology throughout the US gathers pace, with multiple sites being signed up during the quarter.

We are also making great progress with Philips and anticipate that the reseller agreement will be executed within the financial year, enabling 4DMedical to scale up its operations in the US to service not only the VA, but also the Department of Defense and commercial hospital networks.

In addition, it was pleasing to have multiple Veterans undergo scans at the Precision IR lab in Detroit, providing them with the insight to properly diagnose their condition, which up until now had eluded them. 4DMedical is committed to providing support to Veterans as they seek to better understand the impact of DRRD.

The quarter has also seen continued growth in momentum of commercialisation in Australia, through the addition of new specialist providers, as well as the improvement in the workflow and end user experience.

Finally, we were fortunate to have Dr David Shulkin visit Australia during January. It was an honour to host the 9th Secretary of the VA, 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.

Contacts

Corporate Chief Financial Officer Simon Glover sglover@4dmedical.com Administration Company Secretary Naomi Lawrie companysecretary@4dmedical.com Media Enquiries Director of Market Development and Communications Hayley Willis 4dmedia@4dmedical.com



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 Quarter ended ("current quarter")			
31 161 684 831	31 March 2024		

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	1,133	1,531
1.2	Payments for		
	(a) research and development	(4,678)	(12,626)
	 (b) product manufacturing and operating costs 	(33)	(1,298)
	(c) advertising and marketing	(648)	(1,751)
	(d) leased assets	(258)	(916)
	(e) staff costs	(3,909)	(10,950)
	(f) administration and corporate costs	(4,721)	(11,377)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	123	1,155
1.5	Interest and other costs of finance paid	(68)	(195)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (GST inclusive)	6,655	12,683
1.8	Other (provide details if material)	-	-
1.9	Net used in operating activities	(6,404)	(23,744)

2.	Cash flows used in investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	(37,370)
	(b) businesses	-	-
	(c) property, plant and equipment	(34)	(131)
	(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	(36)	(124)
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
2.8	Net cash used in investing activities	(70)	(36,837)

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	(238)	(781)
	(b) net cash paid for settlement of options	-	-
3.10	Net cash from financing activities	(238)	32,167

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	47,874	69,576
4.2	Net used in operating activities (item 1.9 above)	(6,404)	(23,744)
4.3	Net cash used in investing activities (item 2.8 above)	(70)	(36,837)
4.4	Net cash from financing activities (item 3.10 above)	238	32,167
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	41,162	41,162

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	41,162	47,874
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)	41,162	47,874

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	353
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 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.		
	N/A		

8.	Estim	ated cash available for future operating activities	\$A'000	
8.1	Net cash used in operating activities (item 1.9)		(6,404)	
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	41,162	
8.3	Unuse	d finance facilities available at quarter end (item 7.5)	-	
8.4	Total a	available funding (item 8.2 + item 8.3)	41,162	
8.5	Estima item 8	ated quarters of funding available (item 8.4 divided by .1)	6	
	Answe	er: N/A		
8.6	lf item	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?			
	Answe	er: N/A		
	8.6.2	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	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?		
	Answe	Answer: N/A		
	Note: w	here item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 abo	ve must be answered.	

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: 30 April 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.