Quarterly Activity Report and Appendix 4C for Q1 FY2025

31 October 2024

Highlights

- Q1 FY2025 Operating Revenue of $1.4m, up 366% on prior corresponding period
- Strong cash balance of $20.5 million as at 30 September 2024, with a further $7m in grant funding expected in Q2 FY2025
- Philips reseller agreement signed and implementation well-progressed
- Awarded additional $1.9m funding from CRC-P for CT:VQ clinical trials
- Presented population health screening case study at CHEST conference in Boston alongside leading pulmonologists from the Lahey Hospital and Medical Center
- Commercial expansion with new contracts signed in North America and growth in existing networks in Australia

Melbourne, Australia, **31 October 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 September 2024.

Financial Performance

Operating Revenue (unaudited) for Q1 FY2025 was $1.4m, up 366% on the prior corresponding period (pcp). Operating Revenue included Companion Imaging (CDx) SaaS products delivered via the Olympus network, and SaaS income across the XV Technology® and General Radiology product suites.

A key highlight with respect to revenue growth is a 69% increase in General Radiology SaaS income vs Q1 FY2024 on a like-for-like basis, driven by a solid uplift in distributor sites over the past twelve months, coupled with growing subscription and 'pay per scan' income from direct B2B customers.

Net cash operating outflows for the quarter, excluding non-recurring operating costs associated with the acquisition and integration of Imbio, were $9.7m (Q4 FY2024: $10.1m). The decrease in operating cash outflows has been driven by an uplift in receipts, as well as the benefits stemming from our internal cost control program.

4DMedical's cash balance as at 30 September 2024 was $20.5 million. The Company expects to receive approximately $7m in grant income and tax incentives in Q2 FY2025, reflecting the FY2024 R&D tax incentive, final instalment of the MRFF grant, and other government grant funding. This non-dilutive funding, along with contracted cash receipts, further cost control measures, and access to capital via the ATM facility, provides a solid footing for the Company's near-term funding requirements.

4DMedical and Philips sign reseller agreement

The Company recently announced the signing of its reseller agreement with Philips, which represents a critical milestone in 4DMedical's development. Under the agreement, 4DMedical's combined portfolio of functional and structural products will be added to Philips' product catalogue, and will be offered as a third-party solution to its U.S. customer base. The 5-year agreement gives Philips exclusive distribution rights to the 4DMedical suite of products with its U.S. government customers (including the Department

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of Veterans Affairs (VA) and the Department of Defense (DoD)), and non-exclusive rights with all other U.S. commercial customers.

This agreement establishes a transformative commercial pathway for 4DMedical's product suite in the U.S., leveraging Philips' long-established and significant existing commercial partnerships. These existing relationships are particularly strong within the VA and DoD, where Philips has been providing innovative solutions for over 45 years (50% of VA clinics currently use Philips imaging solutions).

The opportunities within the VA are twofold. Firstly, 4DMedical and Philips will work together to support the need for scalable, non-invasive lung screening in support of the PACT Act. The PACT Act represents a US$280 billion commitment over ten years, covering numerous respiratory illnesses as presumptive conditions, and providing healthcare eligibility to 6 million Veterans exposed to airborne hazards while on deployment. 4DMedical's XV LVAS® and LDAf are currently the two leading non-invasive technologies capable of assessing Deployment-Related Respiratory Disease (DRRD).

Secondly, 4DMedical's comprehensive portfolio of functional and structural products is extremely well placed to provide actionable insights to frontline VA physicians treating patients with chronic lung disease, whilst also serving all physicians triaging respiratory conditions across the entire Veteran population. This is particularly relevant as Veterans have three times the rates of chronic lung diseases such as COPD compared to the general population. It is also worth noting that the VA annual healthcare budget is more than US$330 billion per annum.

Outside the VA, the market opportunity in the U.S. is large, with a Frost & Sullivan reporting an estimate of 10.9 million Thoracic CT scans performed in 2019 on approximately 14,500 scanners, with an associated expenditure of US$5.7 billion. Recent news of CMS reimbursement for XV LVAS® and CT LVAS™, paying US$299 and US$650 per scan respectively, creates a compelling mechanism for 4DMedical and Philips to leverage this opportunity.

4DMedical is working closely with Philips to operationalise the reseller agreement, with significant progress already made in respect of identification of opportunities, training, and joint marketing activities. In addition, the Company will be attending the Radiology Society of North America conference ('RSNA') in Chicago in December (see here for more details), and is excited by the prospect of CEO, Andreas Fouras, co-presenting with Philips North America CEO, Jeff DiLullo, on the topic "*Revolutionize Cardiothoracic Imaging with Non-contrast CT-based Ventilation and Perfusion".* The scheduling of a co-presentation demonstrates the depth of commitment both organisations have in ensuring the reseller agreement is a success.

Comprehensive product portfolio

Following the successful integration of Imbio, 4DMedical is now able 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, respiratory and cardiology specialists, and private radiology.

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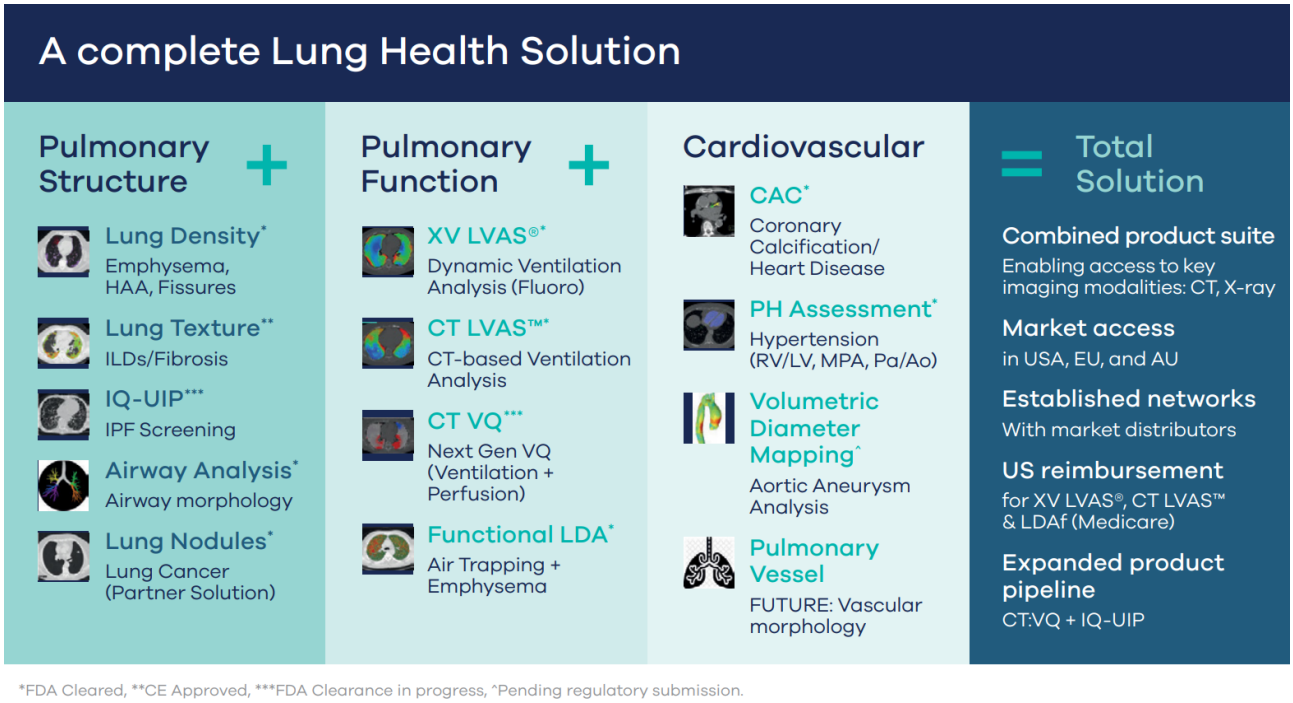

*FDA Cleared, **CE Approved, ***FDA Clearance in progress, ^Pending regulatory submission.

4DMedical presents population health screening findings at CHEST

4DMedical recently attended the American College of Chest Physicians (CHEST) conference in Boston, and presented the findings on a population health screening study alongside leading pulmonologists from the Lahey Hospital and Medical Center (formerly known as the Lahey Clinic). Lahey is a prestigious, physician-led teaching hospital of Tufts University School of Medicine, and is recognised as a leader in the research and development of groundbreaking medical treatments. The purpose of the study was to use 4DMedical's advanced imaging analysis software to identify patients who could benefit from Bronchoscopic Lung Volume Reduction (BVLR) or Lung Volume Reduction Surgery (LVRS). BLVR uses endobronchial valves to minimally invasively reduce lung hyperinflation, while LVRS surgically removes damaged lung tissue.

Emphysema and COPD are underdiagnosed in up to 50% of patients, and often not identified until advanced stages. 4DMedical's population screening provides an opportunity to provide early intervention, and consequently allow patients to benefit from treatments such as BLVR or LVRS, which can significantly improve a patient's quality of life, as well as delivering significant income to the hospital.

The case study involved a comprehensive screening program for 30 days using 4DMedical's advanced imaging analysis software. Over the course of the 30 days, 2,824 scans were performed, of which 9.4% (266) met the initial criteria for advanced emphysema screening. Following further analysis using the 4DMedical SeleCT algorithm, 59 of the 266 patients met radiologic criteria for BLVR to undergo further evaluation. A further 100 patients were identified for referral to a specialist clinical for comprehensive assessment.

The case study generated significant interest at the conference and clearly demonstrates the clinical and commercial ROI to hospitals and device manufacturers when deploying 4DMedical's population screening capability.

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Expanded distribution in North America

The Company has continued to make strong progress with its commercialisation efforts in the U.S., signing contracts directly and through our distribution partners Olympus, Nuance, and Aidoc. Notable contracts were executed during the quarter with South Texas Radiology, Pulmonary & Sleep of Tampa Bay, and the Comprehensive Cancer Centers of Arizona. In addition, multi-year contracts have also been executed for several Canadian hospitals.

In addition to CHEST, representatives of the Company presented at the 2024 IPF Summit in Boston and connected with top industry and academic leaders in the fight against Idiopathic Pulmonary Fibrosis (IPF) and progressive fibrosis. Our team hosted an event where we shared information on 4DMedical's upcoming "IQ-UIP" solution to enable earlier detection and indication of IPF, for use with pharmaceutical trials and clinical care.

In Charlotte, 4DMedical exhibited at the annual meeting for American Association of Bronchology and Interventional Pulmonology (AABIP) and supported our partnership with Olympus in discussions with key interventional pulmonology customers.

4DMedical proudly participated in the 105th American Legion National Convention, held in New Orleans from 23-27th August, where we had the opportunity to engage with Veterans and industry leaders. With Burn Pits 360, we supported their collaborative efforts to fight to ensure Veterans get the care they deserve. Our team presented our advanced imaging technology, discussed its significant potential in enhancing healthcare outcomes for those who have served, and joined senior leadership from Philips in several meetings.

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

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

Following on from the initial launch and subsequent expansion to three sites with Jones Radiology, the Company is also pleased to announce a further expansion to 15 sites. Jones Radiology is a leading radiology network based in Adelaide, with sites across regional South Australia as well as the Northern Territory. The Company has commenced implementation and training of Jones Radiology staff members.

4DMedical has also extended its network in Melbourne to include Cabrini Health. This continues our strong commercial relationship with I-MED, which supports Cabrini Health by providing radiology reporting services. The addition of Cabrini Health to the network provides immediate access to referring clinicians operating within the hospital's sites, and also enables clinical scans for CT LVAS™ to be performed.

Recently, 4DMedical attended the Royal Australian and New Zealand College of Radiologists (RANZCR) annual conference in Perth, where non-executive director, Dr Geraldine McGinty, was invited to speak. The conference resulted in strong engagement with all major radiology providers, as well as in-depth discussions with industry leaders on lung cancer screening. 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 licensed 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 the management of incidental findings.

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Commercialisation of CT:VQ and IQ-UIP progressing to plan

The Company recently won $1.9 million in grant funding from the Cooperative Research Centres Projects (CRC-P) for its ventilation perfusion product, CT:VQ. 4DMedical's successful application for CRC-P funding will expand and accelerate the Company's efforts to generate clinical evidence to support the efficacy of CT:VQ, and represents a major boost in its progress towards commercialisation. 4DMedical will work in partnership with I-MED and Macquarie University to conduct clinical studies and perform health economic analyses, which will enable rigorous clinical assessment of CT:VQ and measurement of its health and economic benefits. The clinical evidence that will be generated is designed to be precisely the information that physicians will need to rapidly substitute 4DMedical's CT:VQ for nuclear medicine VQ scans, while the health economic analyses will provide invaluable intelligence to steer our commercial efforts, including reimbursement.

Clinically, VQ scans are primarily used for diagnosing and managing post-acute pulmonary embolism and associated conditions such as pulmonary hypertension, and chronic thromboembolic pulmonary hypertension. The U.S. market size for nuclear medicine VQ scans is over US$1 billion, with approximately 1 million tests per year at an average cost of over US$1,000 per scan.

4DMedical's CT:VQ technology enables quantitative VQ data and visualisations to be extracted from a CT scan, without the need for any radioactive tracer or contrast. It achieves this by measuring both the regional motion and local density changes of lung tissue.

By extracting VQ information from standard non-contrast CT images, rather than nuclear medicine VQ images (which require radioactive contrast media), hospitals can avoid the significant capital expenditure involved in manufacturing, handling, and disposing of radioactive materials. Furthermore, access to standard non-contrast CT far exceeds access to nuclear imaging equipment, specialist nuclear imaging staff, and short-lived radioactive contrast media.

The commercialisation of CT:VQ is progressing to plan, with the Company on track to complete trials required for FDA, TGA, and other regulatory bodies in calendar year 2024, with regulatory filing in calendar year 2025. Furthermore, 4DMedical is scheduled to co-present on CT:VQ with the Philips' North America CEO, Jeff DiLullo on the topic "*Revolutionize Cardiothoracic Imaging with Non-contrast CT-based Ventilation and Perfusion"* within the Innovation showcase.

In addition, significant progress has been made with 4DMedical's IQ-UIP. IQ-UIP is an AI algorithm that identifies patients with radiological usual interstitial pneumonia (UIP) pattern, the first-line diagnostic for Interstitial Pulmonary Fibrosis (IPF). Imaging biomarker development and patient selection tools shorten clinical trial time and expense, and products such as IQ-UIP provide large pharmaceutical companies with the opportunity to greatly accelerate the time to market and reduce development costs for new products.

It is estimated that clinical trials involving the respiratory system cost over US$115m per trial, whilst the total cost to develop new drugs and take them to market can be as high as US$4.5 billion. IQ-UIP has the potential to dramatically reduce the costs and time taken for clinical trials, which will not only benefit large pharmaceutical companies, but also ensure better health outcomes are delivered to patients in a faster time frame. Currently, 4DMedical is on track for IQ-UIP to be subject to regulatory clearance by early calendar year 2025, with the Company currently briefing large pharmaceutical companies on the commercial opportunities and benefit of reduced clinical trial costs.

XV Scanner installed at Vanderbilt

In July, 4DMedical installed an XV scanner at Vanderbilt Medical Center as part of the Military Exposures

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Research Program (MERP). The MERP is an initiative of the U.S. Department of Veterans Affairs (VA) as part of its commitment to address evidence needs related to toxic exposures and health, often in partnership with education and research institutions. MERP grant funding by the VA will support research using the XV scanner at Vanderbilt University Institute for Imaging Sciences (VUISS) in Nashville, Tennessee, a hub for Veterans' health research.

The XV Scanner is being used to improve understanding of toxic effects of burn pits under military conditions and overcome challenges of exposure assessment as part of the *Post-Deployment Respiratory Illness in Veterans of Iraq and Afghanistan (PRIVIA)* study. The PRIVIA research team intend for this study to positively impact Veterans by advancing their understanding of factors which cause DRRD, and to improve their ability to diagnose DRRD non-invasively. It is anticipated that future studies may also inform their understanding of disease progression and create new surrogate endpoints for future clinical trials.

This scanner compliments the XV scanner already in place at Prince of Wales Hospital in Sydney.

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 September 2024.

4DMedical MD/CEO and Founder Andreas Fouras said:

"We are incredibly excited about the trajectory of the Company following the signing of the Philips reseller agreement, including recent contract wins in North America, the expansion of our network in Australia, and the receipt of grant funding to expand and accelerate 4DMedical's CT:VQ clinical trial program.

Philips represents a watershed moment for the Company - immediately transforming our ability to deliver our technology to more patients and doctors. Furthermore, 4DMedical and Philips are committed to serving the needs of Veterans resulting from toxic exposures whilst on active service through the provision of a scalable, non-invasive lung screening program. The combination of Philips' deep and long-standing relationships with the VA and U.S. government, and our product portfolio, positions the Company to make a meaningful difference to the Veterans.

We are genuinely excited about the development of both CT:VQ and IQ-UIP, with both products progressing to plan. As we previously announced, CT:VQ is shaping as a true disruptive technology in respiratory diagnostics, with the ability to replace nuclear VQ imaging with a faster, safer, cheaper, more convenient, and more accessible technology. We expect to have FDA clearance for CT:VQ in 2025 and are already preparing our market entry into this US$1 billion per annum opportunity.

The outlook for 4DMedical has never been brighter and I look forward to updating you on our commercial progress over the remainder of 2024."

–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

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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 September 2024

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
1.	**Cash flows used in operating activities**		
1.1	Receipts from customers	1,294	1,294
1.2	Payments for		
	(a) research and development	(3,630)	(3,630)
	(b) product manufacturing and operating costs	(35)	(35)
	(c) advertising and marketing	(663)	(663)
	(d) leased assets	(297)	(297)
	(e) staff costs	(3,995)	(3,995)
	(f) administration and corporate costs	(2,639)	(2,639)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	309	309
1.5	Interest and other costs of finance paid	(66)	(66)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (GST inclusive)	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net used in operating activities**	**(9,722)**	**(9,722)**
2.	**Cash flows used in investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(19)	(19)
	(d) investments	-	-

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(e) intellectual property	-	-
	(f) other non-current assets	(103)	(103)
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)	-	-
2.8	**Net cash used in investing activities**	**(122)**	**(122)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	-	-
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	(227)	(227)
	(b) net cash paid for settlement of options	-	-
3.10	**Net cash from financing activities**	**(227)**	**(227)**

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	30,606	30,606
4.2	Net used in operating activities (item 1.9 above)	(9,722)	(9,722)
4.3	Net cash used in investing activities (item 2.8 above)	(122)	(122)
4.4	Net cash from financing activities (item 3.10 above)	(227)	(227)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**20,535**	**20,535**

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	20,535	30,606
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)**	**20,535**	**30,606**

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	380
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.

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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 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.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash used in operating activities (item 1.9)	(9,722)
8.2	Cash and cash equivalents at quarter end (item 4.6)	20,535
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	20,535
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**2**

Answer: N/A

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?

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.

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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 October 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.