

Quarterly Activity Report and Appendix 4C for Q1 FY2024

31 October 2023

Highlights

- Australian commercial coverage expanded through agreement signed with trans-Tasman imaging network, Integral Diagnostics (ASX: IDX)
- New investment boosts partnership with I-MED Radiology Network and GP marketing campaign gains traction
- Continued progress with U.S. Departments of Veterans Affairs (VA) and Defense (DoD)
- 4DMedical hosts a webinar on the anniversary of the signing of the PACT Act with senior VA leadership and key opinion leaders
- Internationally recognised leader in health care strategy and imaging economics, Dr Geraldine McGinty, joins 4DMedical board
- Lil Bianchi to succeed Bruce Rathie as Chair of Board following AGM
- Prominent presence and more clinical evidence presented at RANZCR, Australia's largest radiology conference
- 4DMedical wins \$1.1m of CTCM funding enabling expansion of XV Scanner capability beyond ventilation to include perfusion
- Strong cash position with \$59.9m cash at bank as at 30 September 2023

Melbourne, Australia, 31 October 2023: 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 2023.

Financial Performance

4DMedical's cash balance as at 30 September 2023 was \$59.9m (30 June 2023: \$69.6m).

Cash receipts from customers for the quarter were \$0.2 million, which consisted of SaaS contracts, hardware support, and maintenance services.

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

The Company has a cash runway of approximately six quarters, in line with previous guidance. This is based on forecasted net cash outlay expectations, the existing cash balance of \$59.9m, and allows for existing grant funds yet to be received.

Commercial distribution in Australia widened through agreement signed with Integral Diagnostics

Domestic availability of XV Technology® was significantly expanded as 4DMedical announced the signing of an agreement with Integral Diagnostics (ASX:IDX), a leading provider of medical imaging services across Australia and New Zealand.



Integral Diagnostics' network of 71 imaging clinics includes 20 locations in New Zealand centred upon Auckland, providing a potential longer-term conduit for the first trans-Tasman availability of 4DMedical's unique XV Technology®.

The initial phase of this relationship commences with at two Integral Diagnostics clinical sites at Ballarat in regional Victoria, providing a basis for further expansion of proven systems and processes. Signing of this agreement enables Integral Diagnostics to offer 4DMedical's core XV Technology® products, delivered using a Software-as-a-Service (SaaS) automated workflow. Access to both fluoroscopy-enabled XV LVAS® software and computed tomography (CT)-based CT LVAS™ software is covered in the agreement. This enables a wider cohort of patients to access insights available only through 4DMedical-developed technologies.

New investment boosts partnership with I-MED Radiology Network

4DMedical's commercial team has focused on substantive improvements in collaboration with I-MED Radiology Network (I-MED). The booking system to incorporate I-MED's main contact centre will go live on 23 October, enabling better connectivity and easier patient referrals. An online booking portal will go live in the subsequent weeks with training of the I-MED sales and marketing teams on the new booking process and 4DMedical clinical offerings now complete. Connectivity to I-MED for medical practitioners has been enhanced through establishment of dedicated CT LVAS™ and XV LVAS® pages on I-MED's clinician-facing website, reinforced by a targeted marketing campaign informing referrers of these changes to booking processes using I-MED's centralised main customer contact centre.

Improvements to the booking procedures have already resulted in growth in the number of referrers during the quarter. In addition, distribution was enhanced during the quarter with the number of I-MED sites growing with all CT Scanners in the I-MED network now connected and capable of performing CT LVAS™ scans. Phased training of staff and clinicians continues to be rolled out across these sites with 51 sites fully on-boarded.

Australian collaboration expanded with imaging partnerships

4DMedical's commercial team has embarked on expanding referrer access to XV Technology by adding new groups that are validated to offer clinical scan data to generate ventilation reports. This expansion builds upon the substantive footprint offered through our partnership with I-MED to offer services beyond the scope of that agreement. Clinical scans have been undertaken in South Australia, through Jones Radiology, and in regional Victoria, at Lake Imaging (part of the Integral Diagnostics group (ASX:IDX). Additional scans have been reviewed for ChestRAD, a boutique medical imaging practice in Perth, specialising in chest imaging, and we look forward to finalising an agreement with Spectrum Medical Imaging, an independent radiology practice that provides state-of-the-art imaging services with links to Prince of Wales hospital and Liverpool hospital. This diversification of imaging providers continues to accelerate generation of clinical trial data and expand patient access in Australia.

Respiratory clinicians excited to utilise 4DMedical scans in Western Victoria

"4DMedical can offer ventilation data in fine detail to our patients, as we investigate their lung health" said Dr Andrew Bradbeer, Respiratory and Sleep Medicine Specialist, CEO of Manse Medical. "The flagship patented XV Technology® enables physicians to understand regional airflow in the lungs and identify respiratory deficiencies earlier and with greater sensitivity as they breathe or exclude lung pathologies as the cause for symptoms, such as unexplained shortness of breath.



Manse Medical is dedicated to providing high-quality, comprehensive care across a wide range of respiratory and sleep diseases to improve the health of our patients and empower them to lead happier, healthier lives. The potential of providing this 4DMedical technology to our patients is exciting."

GP marketing campaign gains traction

In conjunction with the changes introduced at I-MED, 4DMedical launched a General Practice-targeted marketing campaign through <u>AusDoc</u>, an online platform for the medical profession providing news, opinion and information. This campaign is commencing with digital content on the *Australian Doctor* website and its Respiratory Specialist Update webpages, via e-newsletter and dedicated website content. The focus of the campaign is on the challenging clinical presentation of unexplained dyspnoea (shortness of breath).



This campaign is scheduled to continue through the remainder of the calendar year through varying print and digital formats, with content designed to increase awareness amongst referring clinicians.

Positive feedback received to date and response metrics across digital channels is an early indicator of effectiveness of the Company's campaign strategy.

Anniversary of the PACT Act

The Company continues to work with key advocacy groups to engage with the VA and its leadership. The first anniversary of the PACT Act being signed into law by President Biden was marked with 4DMedical hosting a webinar, *PACT Act One Year Later – What have we done and where do we go from here?* Speakers in this discussion included The Honourable Dr David Shulkin, former United States Secretary of Veterans Affairs, and Rosie Lopez Torres, co-founder and executive director of Veterans advocacy organisation Burn Pits 360. This informative session was moderated by Jimmy Anderson, former White House Director of Veterans' engagement.

Separately, the Public Broadcasting Service screened an edition of its flagship PBS NewsHour program, updating how the PACT Act is being implemented one year after becoming law, featuring interviews with current Secretary for Veterans Affairs, Denis McDonough, and including a response to a video clip by Dr Robert Miller from Vanderbilt University Medical Center outlining clinical challenges faced managing patients presenting with Deployment Related Respiratory Disease and Chronic Bronchiolitis.



A recording of this globally broadcast edition of PBS NewsHour can be accessed online here.

U.S. VA and DoD relationship update

During the quarter, the Company continued to make progress in commercialising its opportunity with the health care systems within the United States Departments of Veterans Affairs (VA) and Defense (DoD).

Specifically, the company is well advanced with a further two applications for Authority to Operate (ATO) with the VA, and we anticipate successfully closing at least one of these before the end of the year. As previously announced, 4DMedical successfully applied for an ATO at the Harry S. Truman Memorial Veterans Hospital, and upon successfully securing a second ATO, 4DMedical will be eligible to apply for a



National ATO providing the Company with authorisation to install software and carry out scanning at all 171 major clinics in the VA network.

In addition, the Company commenced scanning under its agreement with the DoD, and received positive feedback on the insights provided to clinicians regarding patients' respiratory function. The Company is in active discussions with the DoD for further developments/opportunities.

Appointment of Dr Geraldine McGinty as non-executive director

Recognised internationally as a leader in health care strategy and imaging economics, Dr Geraldine McGinty's appointment to the 4DMedical Board of Directors dramatically expands the Company's expertise with respect to reimbursement in the U.S. market.

Dr McGinty's corporate governance experience spans NextGen Healthcare (NASDAQ:NXGN), Ireland's Industrial Development Authority and the National University of Ireland.

A certified radiologist and accomplished health care economist possessing an MBA degree from Columbia University, Dr McGinty is Professor of Clinical Radiology and Population Health Sciences at Weill Cornell Medical Center in New York.

In 2018, Dr McGinty became the first woman elected as Chair of the American College of Radiology's (ACR) Board of Chancellors, making a significant contribution to the ACR through a reorganisation of its Data Science Institute enabling greater board communication and diversity of opinion. The ACR is "the voice of radiology" in matters of legislation and regulation, responsible for guiding radiology reimbursement and coding issues including relative value units, managed care, alternative payment models and Medicare regulations.

As a member of the American Medical Association's Relative Value Unit Update Committee from 2012 to 2016, Dr McGinty was instrumental in recommending reimbursement policy to Medicare, impacting the economics of the entire U.S. healthcare delivery system, and hence possesses an in-depth knowledge of the process and steps required in enabling healthcare providers to receive payment from insurance companies.

Dr Geraldine McGinty commented, "over my years of experience in healthcare I have seen many companies fail because they were unable to navigate the complex systems of payment, and I am excited by the opportunity to help 4DMedical navigate through these systems and thereby drive their innovative technology to create positive change in healthcare."

Appointment of Chair of the Board

During the Quarter, the Company announced that current non-executive director, Lil Bianchi, is assuming the role of Chair following the retirement of Mr Bruce Rathie. Joining the Board in December 2019, Ms Bianchi has chaired the Audit and Risk Committee, and possesses international board and CEO experience across sectors including health, finance and infrastructure. Her professional background is in technology and Artificial Intelligence.

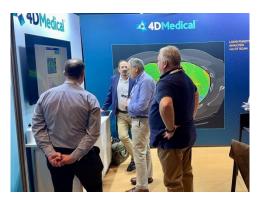
The contribution of Bruce Rathie to 4DMedical's corporate governance was recognised by Chief Executive Officer, Dr Andreas Fouras, who thanked Mr Rathie for his significant contribution as the Company's Chair over a four-year period inclusive of an Initial Public Offering and subsequent capital raises.

Prominent presence at RANZCR Conference

4DMedical presented and exhibited at the 73rd Annual Scientific Meeting of the Royal Australian and New Zealand College of Radiologists (RANZCR) in Brisbane 17-20 October.



4DMedical's U.S.-based Consultant Radiologist, Dr Greg Mogel, was also present to support discussions with key Australasian radiologists, along with members of the Company's Australian sales team. Strategic meetings were undertaken with Radiologists and executives from private practices, corporate groups and system-wide public health networks who experienced our product solutions on the 4DMedical booth.



Dr Greg Mogel, MD, from 4DMedical, presenting CT LVAS™ to Associate Professor Ronnie Ptasznik, Program Director Monash Health Imaging, at the 73rd ASM for the Royal Australian and New Zealand College of Radiologists (RANZCR) in Brisbane.

Dr Nina Eikelis presented on the topic, "More accessible functional lung imaging: Non-contrast CT-ventilation demonstrates strong association and agreement with PET-ventilation", as part of the Innovation session within the scientific program's Clinical Radiology stream. This topic highlighted the opportunity CT LVAS™ presents in providing a more accessible and accurate tool for assessing lung function in remote and regional communities, where access to most types of respiratory function tests is limited or non-existent.

Regulatory progress sustained for CT LVAS™ and XV LVAS® software products

4DMedical's 510(k) application for the CT LVAS™ imaging capability was submitted to the FDA on 9 August and officially accepted for review shortly thereafter, with no requests for clarification received. The Company is confident of a successful outcome from this detailed submission in the coming months.

Well ahead of the TGA's November 2024 deadline for the transition of legacy 'Software as a Medical Device' products to their new device classifications, 4DMedical submitted XV LVAS® to the TGA in September 2023. The application was successful in maintaining ARTG inclusion for the product as a Class IIa medical device under the revised regulatory requirement.

\$1.1 million CTCM funding win bringing perfusion capability to XV Scanner

On 24 July, Federal Minister for Health and Aged Care the Hon. Mark Butler, MP, announced the award of \$1.1m in non-dilutive funding to 4DMedical through the Clinical Translation and Commercialisation (CTCM) program administered by industry growth centre MTPConnect. The CTCM program identifies and nurtures high quality medical device projects that have commercial potential and supports their translation through early clinical trials.

This success allows the Company to broaden the capability of its XV Scanner beyond ventilation to include the measurement of blood flow (perfusion). Adding this capability strengthens 4DMedical's position as a leader in non-invasive lung diagnostics and accelerates the Company's product pipeline.

Once complete, doctors and patients will be able to order detailed ventilation and perfusion maps of pulmonary function where the underlying images are acquired using X-ray, CT or 4DMedical's purpose-built XV Scanner.



Further non-dilutive funding from governmental investment is anticipated with dedicated resources being employed in this area of operation.

Profile through 'The Imaging Wire'

The Imaging Wire is a highly respected and widely accessed multimedia news and information source for radiological professionals in the United States and globally.

Editor Brian Casey (formerly editor-in-chief of 'AuntMinnie.com') interviewed 4DMedical's CEO Dr Andreas Fouras and resident radiologist Dr Greg Mogel for the October episode of *The Imaging Wire Show*.



Discussion on 'Advances in Functional Lung Imaging' emphasised the critical role radiologists can play having functional and structural information when assessing lung health for their patients.

This insightful episode is accessible online via YouTube here.

Related Party Transactions (Listing Rule 4.7C.3)

Payments to related parties of \$0.3 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 2023.

4DMedical MD/CEO and Founder Andreas Fouras said:

The appointment of Lil Bianchi as successor to Bruce Rathie as Chair provides an opportunity for continued growth in the Company's good governance. The addition of Dr Geraldine McGinty to the Board further reflects the evolution of 4DMedical; her expertise in reimbursement will be very important to the Company and I am thrilled to have a leader of Geraldine's stature and integrity join our mission.

We are pleased to have been awarded the \$1.1 million CTCM funding announced by Minister Butler. Combining both functional components of airflow and blood flow into a single analytical process provides the ideal test for phenotyping, early detection and evaluation of specific treatment responses for high-impact lung diseases such as Chronic Obstructive Pulmonary Disease (COPD), Cystic Fibrosis, pulmonary hypertension and pulmonary embolism. Our XV Scanner and automated SaaS workflow will enable this testing in high volume, bringing insight to more people.

The agreement with Integral Diagnostics means more patients and clinicians, particularly in regional Australia, will gain access to insights that only our proven XV Technology® can deliver. Commencing with operations at Ballarat demonstrates a commitment to increase the accessibility of XV Technology® and a commitment to improve healthcare across the regions.

The one-year anniversary of the PACT Act being signed into law is an opportunity to reflect on the Company's commitment to supporting Veterans. Our relationship with the U.S. Department of Veterans Affairs has progressed with the prospect of gaining a National Authority to Operate within the VA health system, and we are providing insights to active-duty personnel through scanning within the Department of Defense. The promise of XV Technology® to inform respiratory care for serving and former military continues to be realised in accordance with both our commercial strategy and our corporate culture.



-ENDS-

Authorised by the 4DMedical Board of Directors.

Contacts

Corporate
Chief Finance Officer
Simon Glover
sglover@4dmedical.com

Administration
Company Secretary
Naomi Lawrie
companysecretary@4dmedical.com

Media Enquiries
The Capital Network (TCN)
Julia Maguire
julia@thecapitalnetwork.com.au

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 clinical imaging equipment or the Company's revolutionary XV Scanner.

To learn more, please visit <u>www.4dmedical.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 September 2023

Cor	solidated 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	188	188
1.2	Payments for		
	(a) research and development	(4,826)	(4,826)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(593)	(593)
	(d) leased assets	(401)	(401)
	(e) staff costs	(3,534)	(3,534)
	(f) administration and corporate costs	(929)	(929)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	201	201
1.5	Interest and other costs of finance paid	(65)	(65)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (GST inclusive)	676	676
1.8	Other (provide details if material)	-	-
1.9	Net used in operating activities	(9,283)	(9,283)

2.	Cash flows used in investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(87)	(87)
	(d) investments	-	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
	(e) intellectual property	-	-
	(f) other non-current assets	(45)	(45)
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	(132)	(132)

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	(19)	(19)
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	(271)	(271)
	(b) net cash paid for settlement of options	-	-
3.10	Net cash from financing activities	(290)	(290)

Con	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	69,576	69,576
4.2	Net used in operating activities (item 1.9 above)	(9,283)	(9,283)
4.3	Net cash used in investing activities (item 2.8 above)	(132)	(132)
4.4	Net cash from financing activities (item 3.10 above)	(290)	(290)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	59,871	59,871

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	59,871	69,576
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)	59,871	69,576

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	344
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.		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)	(9,283)
8.2	Cash and cash equivalents at quarter end (item 4.6)	59,871
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	59,871
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	6
	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.

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 October 2023

Authorised by: Board of Directors

(Name of body or officer authorising release – see note 4)

Notes

- 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.
- 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.