

# Quarterly Activity Report and Appendix 4C for Q4 FY2023

# 31 July 2023

# **Highlights**

- Successful capital raise of \$45 million resulting in a cash balance of \$69.6 million as at 30 June 2023
- Cash receipts from customers of \$0.2 million for Q4 FY2023
- 12-month cash receipts from customers of \$2.2 million, up 413% on FY2022
- Operating cash outflows were \$9.9 million, down 19% on the pcp
- Net operating cash outflows for FY2023 were \$23.5 million, a reduction of \$1.8 million on FY2022
- Matt Tucker's role expanded to Chief Commercial Officer
- First commercial scan conducted at Harry S. Truman VA and subsequent grant of Authority to Operate
- Scanning commenced at U.S. Department of Defense on full commercial terms
- Unveiling of first clinical data for CT-based perfusion product at ATS conference
- Awarded \$1.1m in non-dilutive funding through the CTCM program to advance product pipeline
- XV Technology® now installed at 42 I-MED sites
- Prototype Gen2.0 XV Scanner successfully launched at SAHMRI

**Melbourne, Australia, 31 July 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 June 2023.

#### **Financial Performance**

Cash receipts from customers for the quarter were \$0.2 million, which consisted of SaaS contracts, hardware, and support and maintenance services. For the 12-month period to 30 June 2023, cash receipts from customers were \$2.2 million, up 413% on the prior corresponding period (pcp). Total cash receipts for FY2023 were \$17.9 million, reflecting a combination of customer receipts, interest payments, government grants and tax incentives.

Operating cash outflows for the quarter were \$9.9 million, and included payments for clinical trials, staff costs, research and development, and general operational costs. These operating cash outflows were down 19% on the pcp. Net operating cash outflows for FY2023 were \$23.5 million, a reduction of \$1.8 million on the pcp.

Cash received from financing activities for the quarter was \$42.3 million, reflecting net proceeds from the recent successful capital raise undertaken in May 2023. 4DMedical's cash balance as at 30 June 2023 was \$69.6 million.

#### Successful \$45 million capital raise completed

In June, the Company successfully completed a \$45 million capital raise, comprising a \$20 million placement to institutional and sophisticated investors, and a Securities Purchase Plan (SPP) of \$25 million to retail shareholders.

Tel: +1 (818) 403-8490



The \$20 million placement to institutional and sophisticated investors was significantly oversubscribed and included the addition of several new institutional investors to the Company's register. The SPP also received very strong support with over 1,100 eligible shareholders subscribing for \$25 million worth of shares, surpassing the initial target of \$15 million. In recognition of the long-term support of retail investors, and to maximise growth opportunities, the Company exercised its discretion under the terms of the SPP and determined not to scale back subscriptions.

The SPP and Placement combined raised \$45 million (before costs) and is being deployed to strengthen and accelerate the Company's commercialisation strategy.

#### First commercial scan conducted at Harry S. Truman VA and subsequent grant of Authority to Operate

Early in May the Company successfully completed its first commercial XV LVAS® scan at Harry S. Truman Memorial Veterans Hospital, one of 171 major clinical centres within the Veterans Health Administration (VA). This scan represents the Company's first commercial activity within the VA and demonstrates its ability to deliver an XV LVAS® scan in a routine VA hospital clinical setting.

Later in the month the Company was granted Authority to Operate (ATO) at Harry S. Truman VA. As a SaaS vendor to the VA, 4DMedical requires ATO at each VA site where it seeks to deliver scans at scale through its fully automated SaaS platform. The first ATO is an important milestone for the Company as it demonstrates the robust and secure nature of 4DMedical's platform. Additionally, once 4DMedical has ATO at two sites it is eligible to apply for a National ATO, which will provide the Company with authorisation at all 171 major clinical centres within the VA network.

As well as engaging VA hospitals on a bottom-up basis, the Company made significant progress with its top-down strategy of lobbying government and senior VA officials. As recently as April 26, the Company announced a meeting with senior members of the US Congress. Veterans' advocates Rosie Lopez Torres, Le Roy Torres, Kevin Hemsley and Tim Hauser led 4DMedical's delegation, urged the adoption of XV Technology® through allocation of PACT Act funding, and discussed their recent experiences of receiving 4DMedical scans.

To further assist in 4DMedical's top-down efforts, in early April the Company announced that Dr David Shulkin had been appointed as an advisor. Dr Shulkin was previously the Secretary of the VA, having been appointed in 2017, where he oversaw 350,000 employees responsible for serving over 9 million Veterans. As one of the most influential leaders in U.S. health care, Dr Shulkin brings a comprehensive understanding of integrated health care to 4DMedical with particular knowledge of the VA.

# 4DMedical wins commercial pilot with U.S. Department of Defense

In May, the Company announced a significant commercial milestone with the initiation of a commercial pilot at the Military Health System (MHS) within the U.S. Department of Defense (DoD). The MHS is one of the largest and most advanced health care institutions in the U.S., with an annual budget of over USD \$50 billion, providing the 1.3 million active military personnel with access to health services across a network of 45 hospitals and inpatient facilities.

The arrangement between 4DMedical and the DoD involves an agreed number of scans on full commercial terms. Whilst not immediately material, the arrangement has the potential to expand if successful, and further validates the utility of XV Technology® to provide rich respiratory health insights across a range of lung diseases.



# Perfusion capability unveiled at American Thoracic Society conference

4DMedical announced a significant technological breakthrough and milestone in the Company's product development strategy, with its CT-based ventilation-perfusion product (CT:VQ) progressing to a development stage that allowed for release of early clinical data. The clinical data was presented at the annual conference of the American Thoracic Society (ATS) in Washington, DC on 22 May 2023.

The development of this capability represents a significant breakthrough in respiratory imaging by providing perfusion (blood flow) analysis without the need for either injected radioactive tracers or contrast media. 4DMedical's CT:VQ technology enables quantitative perfusion data and visualisations to be extracted from non-contrast paired inspiratory-expiratory CT scans.

By extracting VQ information from standard non-contrast CT images rather than Nuclear Medicine VQ images (requiring patient exposure to radioactive contrast media), hospitals can avoid the significant expenditure involved in mitigating radiation risks of operating a Nuclear Medicine VQ scanner such as specialised facilities for preparing, handling and disposing of radioactive materials.

Quantifying and visualising the mismatch between ventilation (V) and perfusion (Q) can provide valuable diagnostic information. In certain lung conditions there can be a mismatch between ventilation and perfusion indicating abnormalities in lung function that in the most severe cases can be life threatening.

The Company's CT:VQ technology enables regional changes in ventilation and perfusion to be quantified and visualised, allowing a detailed assessment of V/Q mismatch. Clinically these scans are primarily used for diagnosing and managing pulmonary embolism, but they can also be employed to assess conditions such as chronic obstructive pulmonary disease, pulmonary hypertension, lung parenchymal diseases, and pulmonary vascular disorders.

The Company estimates the current US market size for Nuclear Medicine VQ assessment of pulmonary embolism is approximately 15% of the 4,000,000 patient procedures per annum, at an average cost of ~US\$1,500 per scan (~US\$900 million).

## 4DMedical wins \$1.1 million CTCM funding to develop perfusion capability for the XV Scanner

After the end of the quarter, 4DMedical announced the award of \$1.1 million in non-dilutive funding from the Clinical Translation and Commercialisation Medtech (CTCM) program, an initiative of the Medical Research Future Fund (MRFF), delivered by MTPConnect.

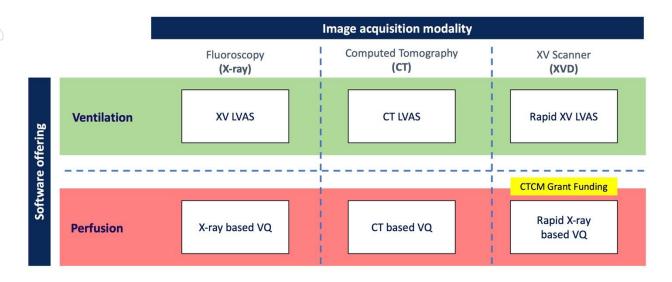
Following on from the recent technological breakthrough with CT:VQ, CTCM funding will allow the Company to broaden the capability of its XV Scanner beyond ventilation to include the measurement of pulmonary perfusion. This additional capability will further strengthen 4DMedical's position as a leader in non-invasive lung diagnostics by providing detailed quantitative data on respiratory function via a single scan that has many advantages over existing modalities:

- rapid scan times;
- improved patient experience;
- accessible to all patient cohorts, including children, the elderly and the very unwell;
- zero contrast agents;
- low radiation; and
- unparalleled functional information, spanning both ventilation and perfusion.

The CTCM funding will help to accelerate the final stage of 4DMedical's long-standing 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. Each of these modalities offer advantages and disadvantages over each other, but importantly, together, they dramatically broaden patient access to XV Technology®.



## **Expanded role for Matt Tucker**

The Company recently expanded Matt Tucker's role to that of Chief Commercial Officer, which will oversee all of 4DMedical's commercialisation activities globally. Matt Tucker joined the business in December following his previous role as CEO of GE Healthcare and has made an immediate and significant contribution to the Company.

#### **Commercialisation in Australia**

Progress continues to steadily build throughout the I-Med Radiology Network with a total of 42 sites now on-boarded across Australia. The Company's initial efforts have been focused on the larger metropolitan sites across Melbourne, Sydney and Brisbane, complimented by sites outside of these major cities, including across Tasmania, Cairns and Adelaide. The Company is now able to onboard new sites rapidly and efficiently, and is balancing the pace of onboarding with clinical and operational training requirements to ensure clinics are set up for managing new patient and referrer requests, and to provide an exceptional client experience.

Overall, the radiology market in Australia is experiencing significant structural and competitive pressures, accentuated by cost-of-living pressures on discretionary spending. The Company continues to refine its commercialisation processes, with the support of I-Med, as it expands its presence in the market.

#### 4DMedical widens product line revealing pre-clinical XV Scanner

A prototype Gen2.0 XV Scanner was designed and built at 4DMedical's advanced manufacturing facility in Port Melbourne, and installed at the South Australian Health and Medical Research Institute (SAHMRI). SAHMRI already possesses a Permetium pre-clinical scanner and the new XV Scanner expands the pre-clinical capability for SAHMRI and University of Adelaide researchers. According to SAHMRI Director Professor Steve Wesselingh, "working with 4DMedical on this project is very exciting ... we can see enormous benefits in commercialising this product". Initial scans under the direction of the University of Adelaide's Associate Professor David Parsons commenced in July.



# Exhibiting at ATS 2023 conference in Washington, DC

The American Thoracic Society's annual conference is the world's largest gathering of professionals across pulmonary medicine. 4DMedical was a prominent exhibitor and participant in the ATS program held 19-24 May delivering presentations such as "Bringing advanced and scalable lung imaging to the VA and beyond", and interacting with researchers through scientific poster presentations. The Company was also a key participant in the prologue Respiratory Innovation Summit program, bringing together innovators, investors, clinicians and advocacy groups.

The presence of an XV Scanner gained attention throughout this globally significant event, and 4DMedical's presence in the exhibition hall was acknowledged by the ATS through a Best in Class award.





**Left:** Senior leadership of the ATS visiting the 4DMedical booth, along with Veterans' advocates Rosie Lopez Torres and Le Roy Torres.

**Above:** 9<sup>th</sup> Secretary of the VA, Dr David Shulkin, supporting 4DMedical at ATS.

# Professor Andreas Fouras honoured by the University of Melbourne

4DMedical's Dr Andreas Fouras was recognised by the University of Melbourne through appointment as an Honorary Professorial Fellow, announced at an event hosted by the Dean of Engineering and Information Technology, Professor Mark Cassidy.

The University of Melbourne is an internationally recognised teaching and research institution with an outstanding reputation, having recently been ranked 14th in the world in the QS global ranking. It awards honorary appointments recognising individuals who make significant ongoing contributions through world-class, values-based teaching, research, research training, engagement, enterprise, leadership, and service.



## 4DMedical MD/CEO and Founder Andreas Fouras said:

The overwhelmingly positive response by shareholders to our capital raising solidifies our cash position and allows us to accelerate our commercialisation strategy.

During the quarter the Company won our first scans within the U.S. Department of Defense, gained our first Authority to Operate, and completed our first commercial scan within the VA. During this period, we were also able to share the results of CT:VQ to global leaders in lung health at the annual ATS conference.

The development of CT:VQ represents a significant breakthrough by providing perfusion analysis without the need for either injected radioactive tracers or contrast media and unlocks the opportunity to disrupt a US\$900 million market segment.

Each of these achievements represent a significant milestone for 4DMedical. Combined, they represent validation of our commercialisation strategy within the VA and DOD, and confirm the clinical value of our product offering.

Although this quarter's revenues are below our recent trend, underlying progress has been very strong, and I look forward to sharing news associated with our continued acceleration over the coming weeks and months.

#### -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 hospital 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 June 2023

Con	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	232	2,205
1.2	Payments for		
	(a) research and development	(5,023)	(18,951)
	(b) product manufacturing and operating costs	(1)	(36)
	(c) advertising and marketing	(638)	(2,758)
	(d) leased assets	(298)	(1,183)
	(e) staff costs	(2,790)	(12,005)
	(f) administration and corporate costs	(1,058)	(6,198)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	331	607
1.5	Interest and other costs of finance paid	(68)	(294)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (GST inclusive)	33	15,078
1.8	Other (provide details if material)	-	-
1.9	Net used in operating activities	(9,280)	(23,535)

2.	Cash flows used in investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(210)	(421)
	(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	(40)	(311)
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	(250)	(732)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	44,960	44,960
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	132	132
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2,535)	(2,535)
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	(267)	171
	(b) net cash paid for settlement of options	-	-
3.10	Net cash from financing activities	42,290	42,728

Consolidated 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	36,816	51,115
4.2	Net used in operating activities (item 1.9 above)	(9,280)	(23,533)
4.3	Net cash used in investing activities (item 2.8 above)	(250)	(732)
4.4	Net cash from financing activities (item 3.10 above)	42,290	42,726
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	69,576	69,576

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	69,576	36,816
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)	69,576	36,816

335
r -

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, interestrate, 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.		itional financing
	N/A		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash used in operating activities (item 1.9)	(9,278)
8.2	Cash and cash equivalents at quarter end (item 4.6)	69,576
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	69,576
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	7
	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 July 2023

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.
- 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.