

## Quarterly Activity Report and Appendix 4C for Q4 FY2021

26 July 2021

### Highlights

- Critical commercialisation milestones achieved, including clinical trial and pilot program developments for XV Lung Ventilation Analysis Software (XV LVAS™).
- Eight clinical trials active at some of the world's most reputable medical institutions, including Johns Hopkins School of Medicine, University of Miami and Oregon Health & Science University
- Progressing pilot discussions with hospitals and clinics globally, including U.S. Department of Defense and Veterans Affairs affiliated healthcare centres, to integrate XV LVAS™ in everyday clinical practice
- Received US\$600,000 purchase order from the University of Michigan in the U.S. to deploy a Permetium™ preclinical scanner and associated XV Technology™
- Initiated deployment of proceeds from the \$28.9m MRFF Stage 2 grant award and \$46.0m capital raising to support the development and commercialisation of the XVD Scanner™
- Continued investment in R&D driving additional use cases and additional types of existing hospital equipment to deliver broader potential customer base
- Strong cash position with \$80.9 million held as at 30 June 2021

4DMedical Limited (ASX: 4DX, "4DMedical" or the "Company"), a medical technology company focused on commercialising its FDA-cleared and TGA approved respiratory imaging platform, is pleased to release its Quarterly Activity Report and Appendix 4C Cash Flow Report for the quarter ending 30 June 2021.

### Clinical trial progress & updates

The Company has ramped up its commercialisation activities following the rapidly growing vaccination uptake in the U.S., which has allowed for greater access to key decision makers at hospitals and medical institutions. This includes the commencement of several clinical trials that, in conjunction with clinical pilots, perform a crucial role in driving awareness and adoption of XV Lung Ventilation Analysis Software (XV LVAS™) at leading hospitals and medical institutions.

At the end of the quarter, 4DMedical had a total of eight clinical trials with Institutional Review Board (IRB) approval status across the U.S. This includes the clinical trial at Johns Hopkins School of Medicine, which has commenced patient recruitment and initial scanning of approximately 15 participants. The Johns Hopkins trial will focus on studying the clinical benefit of XV LVAS in patients with chronic obstructive pulmonary disease (COPD) – the third highest cause of death in the world<sup>1</sup> – representing a multi-billion-dollar opportunity for 4DMedical's non-invasive, low dose technology.

In April 2021, 4DMedical announced its partnership with the Respiratory Compromise Institute (RCI) to implement XV LVAS at eight clinical sites across the U.S. to evaluate between 75-100 late-stage COPD patients undergoing endobronchial valve procedures. The Company is currently working with Temple University Hospital to be the first clinical site to install XV LVAS under the RCI partnership.

<sup>1</sup> [https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-\(copd\)](https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd))

The Company announced it had commenced its first clinical trial for its contrast-free Ventilation-Perfusion (VQ) product at the University of Miami – well ahead of schedule – in May 2021. This clinical trial will be conducted as part of the Functional Lung Imaging Research Program, a research partnership by 4DMedical and the University of Miami to advance the development of breakthrough lung technologies. The Company expects to conduct at least one further clinical trial to validate its VQ product in preparation to submit an application to the U.S. Food and Drug Administration (FDA) in 2022.

The Company anticipates the results from these clinical trials, as well as others, will begin to be presented at key international conferences and published in medical journals throughout the remainder of the year. In addition to driving awareness of 4DMedical's technologies amongst the medical community, clinical trials provide important evidence for indication-specific use by clinicians. As previously described, 4DMedical has an AusIndustry approved Overseas Finding that allows it to receive credits for up to 43.5% of eligible overseas R&D expenditure, including U.S. clinical trials.

### **Clinical pilot progress & updates**

Compared to clinical trials, which are focused on the output of peer-reviewed research publication, clinical pilots allow clinicians to use XV LVAS in everyday practice by integrating the Company's end-to-end workflow into the hospital infrastructure – this is often a precursor to forming commercial relationships. 4DMedical has made strong headway with clinical pilots, having advanced its existing pilots in the U.S. and Australia, and commenced discussions with potential new sites.

Initially announced to the ASX in January 2021, the Company has been approved to pilot XV LVAS at St. Joseph Hospital, which is owned by Providence Health & Services (the third largest not-for-profit health system in the U.S.). Providence has provided positive feedback regarding the installation of XV LVAS™ across not only St. Joseph Hospital, but also its wider network of over 50 hospitals, resulting in the pilot at St. Joseph Hospital progressing slower than anticipated. Variations in the speed of pilot rollouts is to be expected in larger hospital networks, and 4DMedical management is maintaining continued dialogue with St. Joseph and Providence regarding the pilot.

4DMedical has continued patient scanning as part of a nationwide pilot in Australia, with numerous doctors, primarily within Victoria, referring patients for an XV LVAS scan. Patients referred by clinicians include those with difficult to diagnose cases, such as silicosis and COVID-19 complications. The identity of the pilot partner is confidential and 4DMedical is unable to disclose further information at this time. However, the Company expects to make future announcements as commercial developments are made.

Following the grant of streamlined access to contracts with U.S. Department of Defense (DoD) and Veterans Affairs (VA) affiliated healthcare centres (announced to the ASX on 25 March 2021), the Company has commenced discussions with several sites to pilot XV LVAS. As previously announced, commercial contracts with DoD and VA centres have pre-agreed pricing structures for XV LVAS without requiring separate reimbursement by insurance providers. Whilst clinical pilots will not be required before all future commercial contracts, 4DMedical management believe clinical pilots are important in accelerating the commercial adoption of XV LVAS in the short-term.

### **Permetium™ preclinical scanner sale to University of Michigan**

During the quarter, 4DMedical received an order from the University of Michigan to purchase one of its Permetium™ preclinical scanners and associated XV Technology™ for approximately US\$600,000. The sale is funded by the U.S. National Institutes of Health (NIH) and is expected to be delivered to University of Michigan within the coming months. Preclinical scanners, deployed at key opinion leading sites, assist with generating support and adoption of 4DMedical's software products. Scanner sales are expected to make up a small proportion of overall revenue in the short-to-medium term, particularly as the commercialisation of its software products is accelerated in the U.S. and Australia.

## Deploying MRFF Stage 2 grant funding and capital raising proceeds

As announced in March 2021, 4DMedical subsidiary Australian Lung Health Initiative Pty Ltd (ALHI) was the recipient of \$28.9 million in funding over five years from the Australian Federal Government's Medical Research Future Fund (MRFF) Frontier Stage 2 initiative. Funds will be used to develop the world's first dedicated lung function scanner – XVD Scanner™. The Company also successfully completed a capital raising of approximately \$46.0 million via a strongly supported placement and share purchase plan in March 2021 to assist in the funding of this development.

ALHI has subsequently executed the formal grant agreement with the Commonwealth and has begun deploying initial proceeds from the MRFF funding and subsequent capital raising. As one of the project partners, 4DMedical has commenced purchasing specialist equipment, as well as hiring dedicated staff to develop and commercialise the XVD Scanner.

## Other corporate updates

Given the recent opening up of hospital workflows in the U.S., the Company anticipates that many of its previously delayed sales and marketing events will re-commence over the coming months. This includes visiting key opinion leaders at hospitals across the U.S. and participating in medical conferences, some of which have transitioned to hybrid (online and in-person) events.

As planned, 4DMedical has continued to invest in research and development with a particular focus on enhancing compatibility of XV Technology software with medical imaging hardware. The Company is pleased to announce it has recently made improvements to its operating protocol that allows its technology to be adopted by fluoroscopy machines that have a narrower angle range. This enhancement will provide clinicians with greater flexibility in acquiring input data and expands the Company's opportunity to scan more patients. The Company will continue its investment into further protocol and technology enhancements that will be available across 4DMedical's entire product portfolio.

The Company has continued its intended trajectory of hiring new staff with the addition of 22 employees to its offices in Los Angeles and Melbourne over the quarter. This includes a number of new staff involved in the development and commercialisation of the Company's XVD Scanner following the successful MRFF Stage 2 funding award and capital raising, as well as sales and marketing staff to drive commercialisation of the Company's products. 4DMedical now has a total of 95 employees as of 30 June 2021, which it expects is sufficient to meet the Company's short-term plans and milestones.

## Goldman Sachs Investor Presentation

During the quarter, CEO Andreas Fouras presented at the Goldman Sachs Healthcare Forum on 21 April 2021. Please refer to the following link to view the investor presentation from the event:

<https://investors.4dmedical.com/DownloadFile.axd?file=/Report/ComNews/20210421/02365516.pdf>

## Financials

4DMedical's cash balance was \$80.9 million as at 30 June 2021. Net operating cash outflows for the quarter was \$0.6 million, with \$7.1 million received in government grants and tax incentives and \$0.6 million in receipts from customers, offset by \$8.3 million in payments for research and development, staff costs, administration, and general operating costs.

## Use of Funds (Listing Rule 4.7C.2)

Uses of Funds	Prospectus dated 6 July 2020		Period ended 30 June 2021	
	Amount (\$'000)	%	Amount (\$'000)	% of total
Marketing through clinical trials and trade shows	\$15,230	30.5%	\$4,129	27.1%

Uses of Funds	Prospectus dated 6 July 2020		Period ended 30 June 2021	
	Amount (\$'000)	%	Amount (\$'000)	% of total
Operating expenditure (inc. governance & working capital)	\$13,035	26.1%	\$8,803	67.5%
Product R&D and platform development	\$12,810	25.6%	\$7,336	57.3%
US sales and distribution (inc. clinical liaison & reimbursement)	\$3,075	6.1%	\$3,568	116.0%
Intellectual property and trademarks	\$1,450	2.9%	\$331	22.8%
Cost of the offer	\$4,400	8.8%	\$4,456	101.3%
<b>Total from proceeds of issue of New Shares</b>	<b>\$50,000</b>		<b>\$28,623</b>	

The expenditure for the 12-month period ended 30 June 2021 as set out in the table above is in accordance with the Use of Funds outlined in the Company's prospectus dated 6 July 2020 and there are no material variances against the estimated use of funds.

### Related Party Transactions (Listing Rule 4.7C.3)

Payments to related parties of \$233,169 included in Item 6 of the attached Appendix 4C Cash Flow Report was for salaries and fees paid to executive and non-executive directors during the quarter ended 30 June 2021.

### ENDS

Authorised by the 4DMedical Board of Directors.

### Contacts:

<i>Corporate</i>	<i>Investor</i>	<i>Media</i>
Charlene Stahr	Simon Hinsley	Matthew Wright
Company Secretary	+ 61 401 809 653	+ 61 451 896 420
companysecretary@4dmedical.com	shinsley@4dmedical.com	matt@nwrcommunications.com.au

### About 4DMedical:

Based in Melbourne, Australia and Los Angeles, USA, 4DMedical was founded in 2012 and is listed on the Australian Securities Exchange (ASX: 4DX).

4DMedical is a medical technology company aiming to deliver the global gold standard in respiratory diagnostics for all lung disorders including: coronavirus, asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis and cancer.

The unique 4DMedical technology accurately and quickly scans lung function as the patient breathes, to assist in providing sensitive, early diagnosis, and to monitor changes over time. Our Software-as-a-Service (SaaS) scans deliver much more complete results, showing even subtle variations in lung function down to the finest details, using lower levels of radiation than traditional methods.

Respiratory diagnosis is a US\$31 billion per annum global industry. Through its technology 4DMedical provides clinicians with greater insights into diseases of the lung. 4DMedical is focused on providing better information to doctors and patients about lung function. Better information means better decisions, and better outcomes.

## Appendix 4C

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

#### Name of entity

4DMedical Limited

#### ABN

31 161 684 831

#### Quarter ended ("current quarter")

30 June 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	596	697
1.2 Payments for		
(a) research and development	(3,945)	(9,310)
(b) product manufacturing and operating costs	-	(297)
(c) advertising and marketing	(759)	(1,368)
(d) leased assets	(161)	(286)
(e) staff costs	(1,581)	(5,322)
(f) administration and corporate costs	(1,877)	(5,677)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	18	31
1.5 Interest and other costs of finance paid	(23)	(62)
1.6 Income taxes paid	(13)	(13)
1.7 Government grants and tax incentives	7,160	7,479
1.8 Other (provide details if material)	-	(24)
<b>1.9 Net cash used in operating activities</b>	<b>(585)</b>	<b>(14,152)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(399)	(574)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	(43)	(374)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
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	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash used in investing activities</b>	<b>(442)</b>	<b>(948)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	6,000	96,000
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	(400)	(6,380)
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	(189)	(535)
	(b) net cash paid for settlement of options	-	(1,533)
<b>3.10</b>	<b>Net cash from financing activities</b>	<b>5,411</b>	<b>87,552</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	76,497	8,429
4.2	Net cash used in operating activities (item 1.9 above)	(585)	(14,152)
4.3	Net cash used in investing activities (item 2.6 above)	(442)	(948)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
4.4	Net cash from financing activities (item 3.10 above)	5,411	87,552
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>80,881</b>	<b>80,881</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	80,881	76,497
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>80,881</b>	<b>76,497</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	233
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

<b>7. Financing facilities</b> <i>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.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	-	-
<b>7.5 Unused financing facilities available at quarter end</b>		-
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.	<div style="border: 1px solid black; min-height: 100px; padding: 5px;">                     N/A                 </div>	

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash used in operating activities (item 1.9)	(585)
8.2 Cash and cash equivalents at quarter end (item 4.6)	80,881
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	80,881
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>138*</b>
<p><i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i></p> <p>*Adjusting for unearned grant income, net of expenses in section 1.7 of approximately \$4.5 million would reduce quarters of cash flow to 16. Excluding those funds that were raised in Q3 for specific purposes, the cash at the end of the quarter would have been \$43.2 million representing estimated available funding of 8 quarters.</p>	
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?	
<div style="border: 1px solid black; min-height: 20px; padding: 2px;">                     Answer: N/A                 </div>	
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?	
<div style="border: 1px solid black; min-height: 20px; padding: 2px;">                     Answer: N/A                 </div>	



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

- 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: 26 July 2021

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.