

# Quarterly Activity Report and Appendix 4C for Q2 FY2022

31 January 2022

## Highlights

- Successfully initiated commercial rollout of its XV LVAS™ software with I-MED, Australia's largest diagnostic imaging provider, with the completion of first respiratory scans at the Berwick clinic, Melbourne
- Expanded XV LVAS™ software rollout to I-MED sites in Brisbane and Wagga Wagga, with further locations anticipated in 2022
- Imaging complete at Johns Hopkins COPD clinical trial
- Continued progress on commercial pilots in the U.S., particularly with Veterans Health Administration
- XVD project developing federally funded (Medical Research Future Fund) project to design world first dedicated lung scanner proceeding on track and on time
- Novartis U.S. pharmaceutical-led clinical program to validate therapies to treat COPD achieves 1<sup>st</sup> milestone with enrolment of clinical trial subjects
- Ms Evonne Collier appointed as independent non-executive director of 4DMedical
- Strong cash position with \$60.2 million held as at 31 December 2021, well-funded to scale-up and execute commercialisation opportunities

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 ended 31 December 2021.

## Commercial rollout with I-MED

4DMedical sealed its commercial arrangement with Australia's largest diagnostic imaging provider with its first commercial respiratory scan at I-MED Radiology Network (I-MED)'s clinic in Berwick, Melbourne in December. This arrangement was secured following the successful completion of 4DMedical's XV Lung Ventilation Analysis Software (XV LVAS™) clinical pilot program with I-MED during the quarter ended 31 December 2021.

I-MED is Australia's largest outsourced provider of radiology, with more than 200 clinics nationwide, offering a range of diagnostic imaging services to private and public hospitals. The commencement of this commercial arrangement follows the successful completion of comprehensive pilot programs conducted at multiple clinical locations by 4DMedical in collaboration with I-MED.

As announced in December 2021, 4DMedical's state-of-the-art respiratory technology is available to general practitioners, specialists and their patients based in and around the Casey region of Victoria, Australia, on a pay-per-scan basis. Patients referred to I-MED's imaging clinic in Berwick can access 4DMedical's unique XV Technology which provides rich, quantitative information to medical practitioners enabling more appropriate treatment plans.



As foreshadowed, 4DMedical's XV LVAS software was also successfully installed at I-MED's Brisbane and Wagga Wagga sites in early January 2022, allowing general practitioners, specialists, and their patients in these areas to begin to benefit from 4DMedical's groundbreaking technology.

The Company continues to look to rapidly expand to selected locations across I-MED's nationwide network of clinics.

### **Clinical trial updates**

Clinical trials remain a fundamental pillar of the Company's commercialisation plan. The Company continues to make strong progress with these clinical trials, and we are pleased that imaging is complete in the Johns Hopkins COPD trial. Results from these trials will undergo analysis with results being disseminated via scientific conferences and peer reviewed journal publications.

### **Commercial pilot progress & updates**

In addition to the commercial rollout with I-MED, 4DMedical continued to make progress with commercial pilots in the United States during the quarter. The Company has a strong near-term commercialisation pipeline in the U.S. market, particularly within the large and important Veterans Health Administration (VHA) healthcare system.

The VHA healthcare system represents the largest integrated healthcare system in the U.S., providing life-long care and services to eligible military veterans and their families. The US\$250B p.a. VHA operates 1,255 healthcare facilities, including 170 medical centres and 1,074 outpatient clinics, offering a variety of care to over 9 million veterans enrolled in the VHA healthcare program. As announced last year, 4DMedical has won the right to paid contracts in the VHA without the need for further reimbursement.

### **XVD Generation One scanner**

4DMedical's vision to transform medical imaging has evolved through significant progress with development of the prototype XVD scanner at the Company's Advanced Manufacturing Facility in Port Melbourne. This is the world's only dedicated lung scanner integrating software and hardware in one platform.

Powering up this first scanner in January 2022 validated its systems and functions, representing significant progress towards obligations to the Medical Research Future Fund (MRFF) against \$28.9 million of funding from the Australian Government's Department of Health.

4DMedical holds exclusive rights to commercialise XVD scanners worldwide and will receive 100 percent of revenue from hardware sales, in addition to software revenue from SaaS-enabled scanning operations using these scanners.

### **Contract with Novartis**

The Company has previously announced that it had signed its first pharmaceutical-focused contract with international pharmaceutical giant Novartis for the commercial use of XV LVAS. The clinical program with Novartis has delivered its first milestone with the successful enrolment of the trial subjects. While the contract is not material in terms of revenue, the Company has invoiced Novartis for the milestone achievement, continues to build on this relationship, and looks to commercialise other opportunities in the lucrative pharmaceutical space.



## Other corporate updates

On 17 December 2021, 4DMedical appointed Ms Evonne Collier as an independent non-executive director of the Company. Ms Collier brings to 4DMedical considerable multinational experience across SaaS, sales and marketing in industries spanning MedTech, FinTech, Pharmaceutical/Health, eCommerce/Digital and FMCG.

Ms Collier is an experienced leader in business scale-up, transformation and digital disruption, and has served as non-executive director on various boards since 2011. Evonne currently serves as non-executive director of Sage Automation (global SaaS analytics), Curae Health (digi-healthtech), Sniip (SaaS FinTech), and Motorama Group Holdings.

During the quarter, CEO Andreas Fouras presented at the Bell Potter Healthcare Conference on 9 November 2021 (<https://youtu.be/a5lHi7G9zkU>) and at the NWR Virtual Healthcare Day on 24 November 2021 (<https://youtu.be/IO4XmdbuGyU>).

## Financials

4DMedical's cash balance was \$60.2 million as at 31 December 2021. Net operating cash outflows for the quarter were \$9.9 million, mostly relating to payments for research and development, staff costs, administration, and general operating costs. Allowing for the additional \$23.9 million in MRFF funds yet to be received, and the existing strong cash balance of \$60.2 million, the Company has a cash runway of over eight quarters.

4DMedical commenced commercial rollout with I-MED in December and expects cash receipts in the quarter ending 31 March 2022.

The Company's strong cash balance includes unspent MRFF funds of \$0.4 million. MRFF funding received to date total \$5.0 million (\$4.6 million spent).

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

Uses of Funds	Prospectus dated 6 July 2020		Period ended 31 December 2021	
	Amount (\$'000)	%	Amount (\$'000)	% of total
Marketing through clinical trials and trade shows	\$15,230	30.5%	\$5,949	39.1%
Operating expenditure (inc. governance & working capital)	\$13,035	26.1%	\$16,857	129.3%
Product R&D and platform development	\$12,810	25.6%	\$10,196	79.6%
U.S. sales and distribution (inc. clinical liaison & reimbursement)	\$3,075	6.1%	\$5,869	190.9%
Intellectual property and trademarks	\$1,450	2.9%	\$248	17.1%
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>\$43,576</b>	



The expenditure for the 18-month period ended 31 December 2021 as set out in the table above is broadly in accordance with the Use of Funds outlined in the Company's prospectus dated 6 July 2020. The largest deviation relates to the significant underspend in marketing through tradeshow, with every relevant tradeshow in Australia and the U.S. since the IPO cancelled due to COVID-19.

#### **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 was for salaries and fees paid to executive and non-executive directors during the quarter ended 31 December 2021.

**–ENDS–**

Authorised by the 4DMedical Board of Directors.

#### **Contacts**

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#### **About 4DMedical**

Based in Melbourne, Australia and Los Angeles, U.S., 4DMedical Limited 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 diagnostics 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")**

31 December 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	149	149
1.2 Payments for		
(a) research and development	(4,776)	(8,055)
(b) product manufacturing and operating costs	(217)	(218)
(c) advertising and marketing	(610)	(943)
(d) leased assets	(226)	(377)
(e) staff costs	(2,708)	(5,073)
(f) administration and corporate costs	(1,509)	(3,604)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	25	55
1.5 Interest and other costs of finance paid	(18)	(38)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	28	11
<b>1.9 Net cash used in operating activities</b>	<b>(9,862)</b>	<b>(18,093)</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	(1,874)	(2,142)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	(28)	(65)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 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	Research and development tax incentive	-	-
2.6	Capitalisation of development costs to intangible assets	-	-
2.7	Other (provide details if material)	-	-
<b>2.8</b>	<b>Net cash used in investing activities</b>	<b>(1,902)</b>	<b>(2,207)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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	(198)	(389)
	(b) net cash paid for settlement of options	-	-
<b>3.10</b>	<b>Net cash used in financing activities</b>	<b>(198)</b>	<b>(389)</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</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	72,154	80,881
4.2	Net cash used in operating activities (item 1.9 above)	(9,862)	(18,093)
4.3	Net cash used in investing activities (item 2.8 above)	(1,902)	(2,207)
4.4	Net cash used in financing activities (item 3.10 above)	(198)	(389)
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>60,192</b>	<b>60,192</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	60,192	72,154
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>60,192</b>	<b>72,154</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	260
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.</b>	<b>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)	-	-
7.4	<b>Total financing facilities</b>	-	-
7.5	<b>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.		
	N/A		

<b>8.</b>	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash used in operating activities (item 1.9)	(9,862)
8.2	Cash and cash equivalents at quarter end (item 4.6)	60,192
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	60,192
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>6*</b>
	<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>	
	* When allowing for an additional \$23.9 million in MRFF funds yet to be received, and the existing cash balance of \$60.2 million, the Company has a cash runway of over eight quarters.	
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

- 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 January 2022

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.