

Quarterly Activity Report and Appendix 4C for Q1 FY2023

27 October 2022

Highlights

- PACT Act signed into law by President Biden, heralding a USD \$280 billion expansion of healthcare benefits for millions of Veterans exposed to toxic burn pits.
- Vanderbilt 'burn pit' trial demonstrates XV Technology® can detect the presence of constrictive bronchiolitis.
- American Medical Association accepts XV LVAS® application to establish a new CPT code.
- Commercial rollout expands to include Hobart and Launceston during the quarter, bringing the total number of sites to nine.
- 4DMedical releases CT LVAS™ in Australia and expects accelerated rollout.
- Strong cash balance of \$42.8 million as at 30 September 2022.

Melbourne, Australia, 27 October 2022: 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 2022.

The United States of America

PACT Act signed into law by President Biden

The U.S. military constructed burn pits near bases across the Middle East to dispose of hazardous and non-hazardous waste. A wide range of materials, including uniforms, chemicals, tyres, and even medical, animal and human waste, were burned in pits using jet fuel as an accelerant. After exposure to these burn pit environments, many previously combat-ready troops returned from deployment with a range of disabling respiratory symptoms, including shortness of breath and cough, that prevent them from performing basic physical activities.

On 10 August 2022, President Joe Biden signed into law a broad expansion of healthcare benefits for millions of Veterans exposed to toxic burn pits. The estimated 3.5 million Veterans exposed to harmful toxins whilst deployed on operations since 2001 will now have access to an additional USD \$280 billion healthcare commitment over ten years. Importantly, the new law also relieves the Veteran of the burden of proof that an illness is associated with exposure to toxic substances, with constrictive bronchiolitis ('CB') listed as a presumptive condition. Included in this legislation is the requirement for the Veterans Health Administration ('VHA') to provide toxic exposure screening to each of the 9 million Veterans enrolled in the VHA health care program.

Major success as Vanderbilt 'burn pit' trial hits primary endpoint

During the quarter, 4DMedical announced a major success in the Vanderbilt 'burn pit' trial. The clinical trial demonstrates that XV Technology® can detect the presence of CB in Veterans. Up until now surgical biopsy has been the only way to diagnose CB, with existing CT and pulmonary function testing appearing normal. The success of this trial allows clinicians to use XV Technology® to detect CB using a non-invasive, scalable and cost-effective method without the risk of surgical complications or the need for post-operative recovery. The Vanderbilt University Medical Center is in the process of publishing the findings in a peer-reviewed journal.



Congressional support

On 29 September in Washington D.C., 4DMedical met with Congresswoman Mikie Sherrill (D-NJ) and Rosie Torres of Burn Pits 360, a prominent Veterans advocate who was instrumental in the passage of the PACT Act. In a formal [media release](#) following the meeting, Congresswoman Sherill referenced 4DMedical saying, "I am pleased that the PACT Act is law, and now we must work quickly and efficiently to implement its key provisions. New and emerging technologies can not only expedite the implementation of PACT Act but also ensure every veteran has access to early treatment and the full benefits they deserve."



Rep. Mikie Sherrill (centre) with (L-R) Liesl Sheehan, Dr. Andreas Fouras, Rosie Torres and 4DMedical's Mick Brown

Clinical Trials

Clinical trials are a fundamental pillar of the Company's commercialisation strategy. In addition to driving awareness of 4DMedical's technology amongst the medical community, clinical trial data provides essential evidence for indication-specific use by clinicians.

During the quarter, Duke University completed imaging on the final patient in its lung transplant clinical trial. The clinical trial employed XV Technology® to measure lung ventilation and in particular ventilation heterogeneity as a means to assess rejection in lung grafts. The Company anticipates Duke University will publish its findings upon completion of compilation and analysis of results. In addition, Temple University has imaged the first patient in its bronchoscopic lung volume reduction (BLVR) clinical trial. The progression of these clinical trials supports the efficacy of the technology and its clinical use in a wide array of respiratory diseases whilst supporting the commercialisation of XV Technology® in the U.S.

Completed Studies

COPD
Cedars Sinai
XV LVAS

COPD
Johns Hopkins
XV LVAS

Imaging Complete

Lung Transplant
Duke University
XV LVAS

CB (PDRS)
Vanderbilt University
XV LVAS

Imaging in Progress

BLVR
University of Miami
XV LVAS

PH
Cleveland Clinic
VQ

COPD
Oregon Health & Science University
XV LVAS

Paediatric CF
Johns Hopkins
XV LVAS

Lung Transplant
Alfred Hospital Melbourne
XV LVAS

COPD
Vanderbilt University
XV LVAS

BLVR
Temple University
XV LVAS

COPD
University of Miami
XV LVAS

Stages Patient Recruitment Imaging in Progress Imaging Complete Completed Study

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American Medical Association ('AMA') accepts application to establish a new CPT Code

The AMA Current Procedural Terminology (CPT) Editorial Panel accepted 4DMedical's application for the addition of a new Category III CPT code ('Cat III code') to identify the use of its XV Lung Ventilation Analysis Software ('XV LVAS®') amongst healthcare providers and payers.

CPT codes represent a national, standardised system that U.S. healthcare providers use to report medical services and procedures under public and private health insurance programs. Cat III codes are a set of temporary codes for new and emerging technologies created for data collection to substantiate the widespread use of the technology.

Creating a distinct Cat III code for 4DMedical's XV LVAS® technology is a critical step towards commercial success in the U.S.. The new Cat III code will allow healthcare providers to identify when a patient has received an XV LVAS® scan, provide a billing pathway amongst payers, and enable tracking utilisation of the technology. Additionally, a distinct Cat III code opens the door for early engagements with payers to introduce XV LVAS® technology while also enabling discussions to establish reimbursement as 4DMedical continues to advance its U.S. commercialisation rollout demonstrating the positive real-world clinical outcomes and economic value of the technology.

Australia

Commercial rollout expands to include Hobart and Launceston

4DMedical has a nationwide distribution contract with I-MED Radiology Network ('I-MED'), Australia's largest outsourced radiology provider, with more than 250 clinics offering various diagnostic services to private and public hospitals. During the quarter, 4DMedical expanded its reach to nine commercial sites employing XV LVAS® nationwide through the addition of clinics in Hobart and Launceston.

4DMedical releases CT LVAS™ in Australia

After the reporting period, 4DMedical announced the release of its breakthrough image processing software, CT LVAS™. CT LVAS™ provides an almost identical report to 4DMedical's proven XV LVAS® product, but utilises widely available Computed Tomography (CT) imaging infrastructure, (instead of utilising X-ray equipment), providing clinicians and patients with the benefits of XV Technology®.

CT LVAS™ will allow 4DMedical to leverage I-MED's extensive existing CT network to provide greater patient access. The software uses existing CT hardware and easily integrates into clinical workflows across the I-MED network. In line with the Company's commercialisation strategy, the I-MED agreement represents a significant opportunity to drive revenue for the Company, as it creates a framework for the rapid commercialisation of the CT LVAS™ product in Australia.

Financials

4DMedical's cash balance as of 30 September 2022 was \$42.8 million. Cash received from operations for the quarter includes receipts of \$0.3 million in government grants

Operating cash outflows were \$9.2 million, mainly relating to payments for research and development, staff costs, administration, and general operational costs.

Based on the Company's net cash outlay expectations and allowing for an additional \$15.0 million in MRFF funds yet to be received and the existing strong cash balance of \$42.8 million, the Company has a significant cash runway of approximately five quarters.



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 2022.

4DMedical CEO and Founder Andreas Fouras said:

“Our commercialisation model combining clinical trials and commercial piloting continues to deliver progress, with accelerating clinical validation of our technology in the United States and a significant expansion of accessibility in Australian markets with the release of CTLVAS.”

–ENDS–

Authorised by the 4DMedical Board of Directors.

Contacts

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About 4DMedical

4DMedical Limited (ASX:4DX) is a global medical technology company that has created a step change in the capacity to accurately and quickly understand the lung function of patients with respiratory diseases.

Through its flagship patented XV Technology[®], 4DMedical enables physicians to understand regional airflow in the lungs and identify respiratory deficiencies earlier and with greater sensitivity as they breathe. This technology powers 4DMedical’s FDA-cleared XV Lung Ventilation Analysis Software (XV LVAS[®]), the first modality to dynamically quantify ventilation throughout the lungs.

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 www.4dmedical.com.

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 September 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows used in operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(4,295)	(4,295)
(b) product manufacturing and operating costs	(1)	(1)
(c) advertising and marketing	(588)	(588)
(d) leased assets	(297)	(297)
(e) staff costs	(2,840)	(2,840)
(f) administration and corporate costs	(1,485)	(1,485)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	51	51
1.5 Interest and other costs of finance paid	(78)	(78)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives (GST inclusive)	319	319
1.8 Other (provide details if material)	-	-
1.9 Net used in operating activities	(9,214)	(9,214)
2. Cash flows used in investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(30)	(30)
(d) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
(e) intellectual property	-	-
(f) other non-current assets	(53)	(53)
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	(83)	(83)

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	-	-
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other		
(a) receipt of lease incentives	955	955
(b) net cash paid for settlement of options	-	-
3.10 Net cash from financing activities	955	955

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.	Net (decrease)/increase in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	51,115	51,115
4.2	Net used in operating activities (item 1.9 above)	(9,214)	(9,214)
4.3	Net cash used in investing activities (item 2.8 above)	(83)	(83)
4.4	Net cash from financing activities (item 3.10 above)	955	955
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	42,773	42,773

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 year \$A'000
5.1	Bank balances	42,773	51,115
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)	42,773	51,115

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	343
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 <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>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-
7.5 Unused financing facilities available at quarter end		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
N/A		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash used in operating activities (item 1.9)	(9,214)
8.2 Cash and cash equivalents at quarter end (item 4.6)	42,773
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	42,773
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	5
<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>	
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	
<i>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.</i>	

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: 27 October 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.