



ASX ANNOUNCEMENT

Lumos Diagnostics' Quarterly Activities and Cash Flow Report

MELBOURNE, Australia (31 January 2022) – Lumos Diagnostics (ASX: LDX), (“Lumos” or the “Company”) a leader in rapid point-of-care (POC) diagnostic technologies, is pleased to release its Quarterly Activity Statement and its Appendix 4C Cash Flow Report for the second quarter ending 31 December 2021 of fiscal year FY22.

Key Highlights from the Quarter

- ***CoviDx™** received Interim Order authorization by Health Canada and initial orders valued at US\$250,000 were received and shipped in December;*
- *Recruitment for investigator-led trial of **FebriDx®** at Box Hill Hospital Emergency Department complete with data verification and analysis in progress;*
- *All development, verification and validation activities to support regulatory submissions for **ViraDx™** in the U.S. and Canada were completed in December, with U.S. emergency use authorization (EUA) application filed in January;*
- *Expanded **contract manufacturing services** to support Diabetomics CovAb antibody test demand; and,*
- *Continued progress on Lumos' 510(k) application to the U.S. FDA for **FebriDx®** with a decision expected during FY22;*

Lumos Diagnostics CEO and President, Rob Sambursky, MD commented, “We are pleased with the commercial, clinical and regulatory progress we’ve made during the second quarter of FY22, which positions the Company for a strong second half of the year.”

Operations Update

CoviDx™ Commercial Momentum in Canada

Lumos' CoviDx™ SARS-CoV-2 Rapid Antigen Test is a lateral flow assay intended for the qualitative detection of SARS-CoV-2. In November, Lumos' CoviDx™ SARS-CoV-2 Rapid Antigen Test (RAT) was granted an Interim Order authorization by Health Canada permitting its use by qualified healthcare professionals for evaluating symptomatic patients and for serial testing of patients without symptoms.

In December, Lumos announced it had received initial orders for CoviDx™, which the Company started shipping in December. These orders were generated from multiple Canadian distributors and a large-scale healthcare provider. The market demand and commercial momentum for CoviDx™ in Canada has accelerated the product ramp-up for Lumos and its suppliers. Since the initial orders were announced to the market in December 2021, a further US\$5M of signed purchase orders have been received by the Company, with the majority expected to ship prior to the end of the March quarter.

Regulatory and Clinical Progress for FebriDx®

Lumos' FebriDx® is a rapid point-of-care test which can be used to detect and aid in differentiating bacterial from viral acute respiratory infection. During the quarter, Lumos received market clearance to sell FebriDx® in the United Arab Emirates. The Company also continued to work proactively with the US FDA on its 510(k) application for FebriDx®. The Company believes that it remains on track to have a decision from the FDA on this application during FY22. If successful, this will allow Lumos to commence marketing activities for FebriDx® in the U.S.

During the quarter, the Emergency Department (ED) at Box Hill Hospital, Melbourne, initiated a real-world clinical study using FebriDx® to evaluate patients presenting to the ED with a suspected COVID-19 infection. This study models a similar study that was conducted at University Hospital Southampton (UK). Recruitment for this trial has been completed and verification and the analysis of data collected from subjects that participated in this trial is currently underway.

Subsequent to the end of the quarter, Lumos announced that the Liverpool Clinical Commissioning Group (CCG) and Community Pharmacy Liverpool (UK) initiated a study in December 2021 which includes FebriDx® testing as part of a new clinical service to be provided at more than 100 pharmacies across Liverpool.

ViraDx™ Regulatory Process Begins

ViraDx™ is a POC, three-in-one COVID-19/Flu A/Flu B rapid antigen test. In December, Lumos completed all the development, verification and validation activities to support regulatory submission for ViraDx™, the Company's new three-in-one COVID-19/Flu A/Flu B rapid antigen test. Regulatory submissions for ViraDx™ have commenced in the U.S. and Canada where the test falls into a category that is prioritized for regulatory review.

Services Expands Contract Manufacturing for Diabetomics

Lumos continues to perform contract manufacturing for Diabetomics, which has noted increased demand for Diabetomics' CovAb™ antibody test. Lumos has increased its monthly manufacturing volumes to support this growth.

In addition, Lumos' Services business unit currently has 11 active R&D service programs in various stages of development, from early feasibility and development to more advanced verification, validation and transfer to manufacturing.

Summary of Cash Receipts and Outflows

Lumos recorded cash receipts from customers of US\$1.6M during the second quarter of FY22 and closed the quarter with cash of US\$10.5M. Operating activities included development expenditure for reader and assay development of US\$2.7M to expand the portfolio , as well as product manufacturing and operating costs of US\$1.2M related primarily to Contract Manufacturing and internal products such as CoviDx. The advertising and marketing costs of US\$0.3M within Q2 FY22 are costs related to the creation of materials for Lumos branded products .

Payments to Related Entities

In accordance with Listing Rule 4.7C.3 and as outlined in Section 6.1 of the Appendix 4C the Company discloses payment to related entities of US\$92,000 comprising directors' fees, salary and superannuation

Use of Funds Table

Use of Funds	Per Prospectus¹	Use of Funds to 31 December 2021
	\$USm	\$USm
Infrastructure and Capacity Expansion	4.4	1.8
Sales and Marketing	6.3	1.9
Regulatory, Clinical and Quality	2.8	1.3
Development of test pipeline	2.3	1.4
Technology platform development	4.1	0.9
Working Capital	5.3	5.6
Offer Costs	3.5	3.0
TOTAL	28.6	15.9

¹: Conversion AUD0.78/USD1.00

Outlook and Future Activities

COVID continues to create considerable short to medium term opportunities for Lumos, for both product sales and contract manufacturing. The global demand for rapid point-of-care tests currently exceeds the available supply and Lumos is ramping its manufacturing capabilities to capitalise on this demand.

The balance of the year is anticipated to be marked by increasing sales of Lumos-branded products, especially CoviDx™ and revenues from contract manufacturing services. Lumos will continue to engage with new and existing clients to build out its contract development and manufacturing opportunities and will expand its operational footprint as needed to support the continued growth of the Company.

-Ends-

About Lumos Diagnostics

Lumos Diagnostics specialises in rapid, cost-effective, and complete point-of-care (POC) diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customised assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercialises novel Lumos-branded POC tests that target infectious and inflammatory diseases.

For more information visit lumosdiagnostics.com or febridx.com.

Forward-Looking Statements

This announcement contains forward-looking statements, including references to forecasts. Forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions, and other important factors, many of which are beyond Lumos' control and speak only as of the date of this announcement. Readers are cautioned not to place undue reliance on forward-looking statements.

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Appendix 4C

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

Name of entity

Lumos Diagnostics Holding Limited

ABN

66 630 476 970

Quarter ended ("current quarter")

31 December 2021

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (6 months) US\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,626	5,735
1.2 Payments for		
(a) research and development	(2,664)	(6,438)
(b) product manufacturing and operating costs	(1,189)	(4,168)
(c) advertising and marketing	(293)	(460)
(d) leased assets	-	-
(e) staff costs*	(950)	(1,500)
(f) administration and corporate costs	(2,293)	(4,557)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(109)	(260)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(5,872)	(11,648)

*Staff costs have been allocated to their respective departments above.

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(271)	(1,809)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (6 months) US\$'000
(f) other non-current assets (capitalised development costs)	(855)	(1,500)
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)	-	-
2.6 Net cash from / (used in) investing activities	(1,126)	(3,309)

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	-	(429)
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:		
Sell-down of shares to Planet Innovation	-	(17,501)
Lease payments	(221)	(581)
3.10 Net cash from / (used in) financing activities	(221)	(18,511)

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (6 months) US\$'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	17,716	44,890
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,872)	(11,648)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,126)	(3,309)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(221)	(18,511)
4.5	Effect of movement in exchange rates on cash held	(32)	(957)
4.6	Cash and cash equivalents at end of period	10,465	10,465

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	10,465	17,716
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)	10,465	17,716

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	92
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>		

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<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>		
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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(5,872)
8.2 Cash and cash equivalents at quarter end (item 4.6)	10,465
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	10,465
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.78
<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: The Company expects net operating cash flows to improve in subsequent quarters as a result of an increased conversion rate of orders leading to increase receipts from customers together with a reduction in operational expenditure.	
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: The Company is in advanced discussion with regard to working capital facilities to assist in the funding of for the increase in customer orders associated with CoviDx.	

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: The Company does expect to continue operations and meet business objectives on the basis of the improved pipeline of orders and reduction of areas of operational expenditure.

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: **The Disclosure Committee**
(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.