



ASX ANNOUNCEMENT

Lumos Diagnostics' Quarterly Activity Statement and Cash Flow Report

MELBOURNE, Australia (29 April 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 third quarter ending 31 March 2022 of fiscal year FY22.

Key Highlights from the Quarter

- Cash receipts for the quarter of US\$6.0 million (v US\$1.6 million, Q2 FY2022) with unaudited revenue of US\$3.8 million for the quarter (v US\$5.2 million for H1 FY2022);
- Trial of FebriDx™ to guide antibiotic prescribing in >100 pharmacies in Liverpool announced with potential to expand to other regions in the UK if successful;
- Victorian Government announced a potential partnership with Lumos to establish Rapid Diagnostics Innovation and Manufacturing Hub, contingent on TGA approval of Lumos' CoviDx® test;
- Review process for Lumos' Febrix™, ViraDx® and CoviDx® tests in key jurisdictions nearing completion with outcomes expected in the coming months;
- Announced management changes and commenced ongoing cost reduction program to improve operational efficiencies and alignment between resource allocation and commercial revenue;
- Cash balance on 31 March 2022 of US\$6.6 million (v US\$10.5 million at 31 December 2022)

Lumos Diagnostics interim CEO and Chair Sam Lanyon commented, “While we are pleased to see the increasing revenue momentum in the March quarter compared with first half of the year, we believe there is scope for the company to improve both its operational and commercial performance going forward. This is particularly critical at a time when we have three of our own POC diagnostic products

neering the conclusion of their regulatory review processes for a number of key markets. Our focus now is on securing these approvals and being fully prepared to take advantage of the commercial opportunities that they generate. In parallel, we will be ensuring that the pipeline of development services and contract manufacturing is commercially robust, and that our operations are appropriately resourced to deliver on that pipeline.”

Operations Update

Lumos has recorded unaudited revenue of US\$3.8 million for the quarter ending 31 March 2022 compared with US\$5.2 million for the 6 months ending 31 December 2021. Product sales accounted for US\$1.7 million of revenue and were primarily from the sale of Lumos’ CoviDx test in Canada. The remaining US\$2.1 million was from the provision of diagnostic test development and manufacturing services to clients.

FebriDx®

FebriDx is Lumos’ rapid, point-of-care test which can be used to detect and aid in differentiating bacterial from viral acute respiratory infections.

In January, Lumos announced that the NHS Liverpool Clinical Commissioning Group and the Community Pharmacy Liverpool in the UK, were planning to launch a new clinical service which includes using Lumos’ FebriDx test to differentiate bacterial from viral respiratory infections at more than 100 pharmacies. This trial is part of a nationwide initiative called ‘Pharmacy First’ which aims to ease the high workload faced by primary care physicians in the UK. The trial of FebriDx in pharmacies in Liverpool is designed to enable rapid diagnosis and appropriate antibiotic prescribing without the need for a prior general practitioner (GP) consultation. This trial is expected to commence once the National Health Service (NHS) guidance on the procedures for antibiotic prescribing have been finalised.

In February, Lumos announced that Brazil’s Health Regulatory Agency, ANVISA, had granted market authorization for FebriDx. At that time, Lumos also reported that a meta-analysis of data from five, investigator-led clinical studies that involved 2,309 patients had been published in a peer-reviewed journal. The conclusion of this meta-analysis was that, in addition to its intended use for differentiating bacterial from viral respiratory infections, FebriDx may have clinical value for the rapid screening of patients with suspected COVID-19 in acute healthcare settings.

In 2021, Lumos filed a 510(k) application with the FDA that is currently under review. The Company believes this review process is on track to conclude by the end of the FY2022 financial year (30 June 2022). If Lumos receives regulatory clearance for FebriDx, it will allow the Company to commence marketing activities in the US for FebriDx.

CoviDx™

CoviDx is Lumos' SARS-CoV-2 rapid antigen test for the detection of COVID-19.

In November 2021 CoviDx received Interim Order authorization from Health Canada. In January 2022, Lumos announced it had received US\$5 million of signed purchase orders, the majority of which the Company expected to ship prior to the end of the March quarter. Due to a combination of factors, including the availability of low-cost imported COVID-19 RAT tests, the lifting of restrictions and testing requirements in Canada, and the passing of the peak infection from the Omicron variant, only approximately 30% of these orders were fulfilled during the March quarter. Whilst the signed purchase orders remain open, the timing and quantum of future shipments under them is uncertain at this stage.

Lumos has a Standing Offer in place with the Canadian government for the supply of CoviDx. A Standing Offer is made with pre-qualified suppliers of a product and defines a pre-agreed set of commercial terms for supply of that product to the Canadian government. A Standing Offer is not a commitment until the government issues a "call-up" against it, at which time a binding contract is established which typically include minimum volumes and time-based purchase commitments. Lumos believes the Canadian government is expected to issue contracts to one or more the suppliers of COVID-19 RATs with which it has Standing Offers in the coming months.

In February, the Victorian State Government announced an intended package of support for Lumos to establish a Rapid Diagnostics Manufacturing and Innovation Hub in Victoria. One of the requirements for this project to proceed is for Lumos to secure approval from the TGA for the over-the-counter (OTC) use of its CoviDx product. As a result, funding for the project has not yet commenced. However Lumos remains in continued dialogue with the Victorian State Government to enable this project to proceed rapidly once the required conditions have been met.

ViraDx™ Regulatory Process Underway

ViraDx is a POC, three-in-one COVID-19/Flu A/Flu B rapid antigen test. In December 2021, 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 now been filed in the US and Canada where the test falls into a category that is prioritized for regulatory review. Lumos is expecting to receive the decision from both Health Canada and the FDA on these applications during Q4 ending 30 June 2022.

Development Services and Contract Manufacturing

Lumos generated US\$2.1 million from it's the provision of development services and contract manufacturing during the March quarter.

There were no new commercial development services projects started during the March quarter due to market conditions and delays in the commencement of some anticipated projects. Lumos is currently reviewing its pipeline of active and potential projects and the appropriate level of resources required to deliver on them. In addition, the Company intends to invest prudently in business development activities

to build the pipeline of commercial development services projects and to diversify the product focus of client projects which are currently dominated by products for the diagnosis and management of COVID-19.

Lumos provided limited contract manufacturing for clients during the March quarter with most of the manufacturing that was conducted being focused on the Company's own POC diagnostic products in anticipation of successfully securing regulatory clearances and commercial launch. Contract manufacturing services for the March quarter were negatively impacted by anticipated contracts that were delayed due to the performance or extension of the development programs for the client's COVID-19 diagnostic products.

Lumos is actively reviewing its pipeline of current and potential contract manufacturing projects as well as its internal manufacturing needs for its own diagnostic products and to establish appropriate level of resources required to deliver on them. Subject to the project with the Victorian State Government proceeding, Lumos intends to establish a manufacturing capability in Victoria and potentially may deploy some of the equipment and automation currently located in Sarasota, Florida, to support that initiative.

Corporate Changes and Management Reorganisation

In February, Lumos announced that Rob Sambursky had resigned from the Board of Directors and that Barrie Lambert was appointed to the role of Chief Financial Officer. Barrie has extensive experience in leading rapid growing, publicly traded companies and, for the past five years, has been the Chief Financial Officer of Planet Innovation, one of the founding shareholders of Lumos. Barrie's appointment has brought a heightened capability to the financial management of the Company.

Following the end of the quarter, in April, the company announced it had initiated an operational review that had identified a number of areas where the Company had scaled its capacity and personnel ahead of its immediate requirements. Subsequently, the Company announced that Executive Chair, Sam Lanyon, had been appointed as Interim CEO, and that Rob Sambursky had transitioned to the role of Chief Medical Officer. An executive search for a permanent, replacement CEO is currently underway.

As a consequence of the initial review of operations, Lumos commenced an initial round of cost reduction activities across both the Carlsbad and Sarasota sites. The Company expects this cost reduction process to be ongoing to ensure that its operating expenditure is appropriately aligned with the short-to-medium revenues and to realise further operational efficiencies as they are identified

Summary of Cash Receipts and Outflows

Lumos recorded cash receipts from customers of US\$6.0M during the third quarter of FY22 and closed the quarter with cash of US\$6.6M. Operating activities included development expenditure for reader and assay development of US\$1.4M to expand the product portfolio, as well as product manufacturing and operating costs of US\$3.8M related primarily to Contract Manufacturing and internal products such

as CoviDx. The advertising and marketing costs of US\$0.2M within Q3 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\$82,000 comprising directors' fees, salary and superannuation

Use of Funds Table

Use of Funds	Per Prospectus ¹	Use of Funds to 31 March 2022
	\$USm	\$USm
Infrastructure and Capacity Expansion	4.4	1.9
Sales and Marketing	6.3	3.1
Regulatory, Clinical and Quality	2.8	2.6
Development of test pipeline	2.3	2.4
Technology platform development	4.1	1.2
Working Capital	5.3	10.8
Offer Costs	3.5	3.2
TOTAL	28.6	25.2

¹: Conversion AUD0.78/USD1.00

Outlook and Future Activities

The key focus for Lumos for the remainder of FY2022 is on progressing the regulatory applications for its own POC diagnostic products that are currently under review, and preparing for the commercial launch of these products subject to these applications being successful. The Company has filed applications for FebriDx, ViraDx and CoviDx in various jurisdictions, and is expecting decisions on these in the coming months.

Lumos' management and Board is also actively reviewing its pipeline of commercial projects for both its development services and contract manufacturing business units to ensure that the level of resources that the Company provides for them is appropriate, with a view to making further cost-reductions and adjustments where required. The Company also intends to prudently invest in business development activities focused on actively building its pipeline of development services and contract manufacturing projects and to diversify the client products it is working on beyond the diagnosis and management of COVID-19.

-Ends-

This announcement has been approved by the Lumos Disclosure Committee.

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 March 2022

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (9 months) US\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	6,025	11,760
1.2 Payments for		
(a) research and development	(1,415)	(7,853)
(b) product manufacturing and operating costs	(3,811)	(7,979)
(c) advertising and marketing	(219)	(679)
(d) leased assets	-	-
(e) staff costs*	(1,616)	(3,116)
(f) administration and corporate costs	(2,141)	(6,698)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(108)	(368)
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	(3,285)	(14,933)

*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	(91)	(1,900)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (9 months) US\$'000
(f) other non-current assets (capitalised product development costs)	(192)	(1,692)
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	(283)	(3,592)

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	95	95
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	(469)	(1,050)
3.10 Net cash from / (used in) financing activities	(374)	(18,885)

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (9 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	10,465	44,890
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,285)	(14,933)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(283)	(3,592)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(374)	(18,885)
4.5	Effect of movement in exchange rates on cash held	55	(902)
4.6	Cash and cash equivalents at end of period	6,578	6,578

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 US\$'000	Previous quarter US\$'000
5.1	Bank balances	6,578	10,465
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)	6,578	10,465

6.	Payments to related parties of the entity and their associates	Current quarter US\$'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	82
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>		

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

7. Financing facilities	Total facility amount at quarter end US\$'000	Amount drawn at quarter end US\$'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>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	\$US'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(3,285)
8.2 Cash and cash equivalents at quarter end (item 4.6)	6,578
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	6,578
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.00
<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 is targeting net operating cash flow improvements in subsequent quarters from an increased conversion rate of orders leading to increase receipts from customers. In addition, the Company has implemented and will continue to implement cost reduction measures to reduce operating expenditure to more closely match expected revenues.	
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 the final stages of negotiation with regard to a US\$3.0m working capital facility to assist in the funding of accounts receivable for the increase in customer orders.	

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 an improved pipeline of orders, reduction in areas of operational expenditure and addition of a US\$3.0m working capital facility currently being negotiated.

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: **29 April 2022**

Authorised by: **The Lumos 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.