



ASX ANNOUNCEMENT

Lumos Diagnostics' Quarterly Activity Statement and Cash Flow Report

MELBOURNE, Australia (29 July 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 fourth quarter ending 30 June 2022 of fiscal year FY2022. All numbers in USD, the Company’s reporting currency, unless otherwise stated.

Key Highlights from the Quarter

- Unaudited revenue of \$2.5 million for the quarter (v \$3.8 million for Q3 FY2022), with full year FY2022 unaudited revenue of \$11.6 million
- Cash receipts for the quarter of \$2.3 million (v \$6.0 million for Q3 FY2022)
- Restructuring and rightsizing of the company took place during Q4 of FY2022, reducing the forecast operating expenditure for FY2023
- Lumos completed an entitlement offer during the quarter, raising A\$11.2 million (A\$10.7 million net of costs, equivalent to \$7.4 million at the year-end FX rate)
- New CEO, Doug Ward commenced with the Company during June 2022
- Cash balance on 30 June 2022 of \$8.0 million (v \$6.6 million at 31 March 2022)

Operations Update

Lumos has recorded unaudited revenue of \$2.5 million for the quarter ending 30 June 2022 compared with \$3.8 million for the preceding quarter ending 31 March 2022. Product sales were minimal during the quarter, with the majority of revenue coming from the Service side of the business for the provision of diagnostic test development and manufacturing services to clients.

Development Services and Contract Manufacturing

Lumos generated \$2.5 million from it's the provision of development services and contract manufacturing during the June quarter.

During the quarter, Lumos announced it had secured a development contract with New Jersey-based Aptatek Biosciences Inc., to develop a product to assist with screening and monitoring for phenylketonuria (PKU). The initial phase of this partnership is expected to generate at least \$500,000 in revenue for Lumos with further potential revenue from additional development activities and ongoing instrument manufacturing conducted in subsequent phases of the partnership. The majority of revenue from the initial phase of this partnership is expected to be recorded during 1H FY2023.

Aptatek is aiming to commence further studies and activities using the test developed by Lumos in Q1 CY2023 with US commercial launch expected later in CY2023. Subject to regulatory approvals and execution of a commercial contract manufacturing agreement, Aptatek intends to engage Lumos as the instrument manufacturing partner for the product.

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. To date, Lumos has received regulatory registrations for the use of FebriDx in the UK, Europe, Canada, UAE, Brazil and Australia. In 2021, Lumos filed a 510(k) application for FebriDx with the U.S. FDA.

Subsequent to the end of the quarter, Lumos was advised that, following its review of Lumos' application, the FDA decided that FebriDx did not demonstrate substantial equivalence to the predicate device that was used to support the 510(k) application. As a consequence, FebriDx has not been granted clearance for marketing in the U.S. which the Company considers is a key commercial market for the product. Lumos is currently evaluating options to secure a potential regulatory clearance by the U.S. FDA for FebriDx including filing an appeal which may provide a revised decision within 90 days of submission or guidance for a new 510(k) submission.

ViraDx™

ViraDx is a POC, three-in-one COVID-19/Flu A/Flu B rapid antigen test.

In June, Lumos received Interim Order authorisation from Health Canada for ViraDx. Subject to demand, Lumos is ready to commence production and shipping of ViraDx for use by healthcare professionals in Canada where it will be distributed by the Company's established Canadian distribution partners.

ViraDx is currently under review by the U.S. FDA for Emergency Use Authorisation (EUA). If successful, Lumos intends to expand its North American sales and marketing efforts to include U.S. healthcare providers in hospitals and outpatient settings that serve patients with acute respiratory infections.

CoviDx™

CoviDx is Lumos' SARS-CoV-2 rapid antigen test for the detection of COVID-19 which was granted Interim Order authorisation from Health Canada in November 2021.

In view of recent developments and market conditions, Lumos is currently only considering potential commercial opportunities for CoviDx that require minimal investment in regulatory clearances, manufacturing infrastructure, and sales effort by the Company. At this time, this primarily includes a Standing Order that Lumos has in place with the Canadian government which has the potential to progress into a binding contract, and a potential partnership with the Victorian State Government to establish a Rapid Diagnostics Manufacturing Hub in In Victoria.

Corporate Changes and Management Reorganisation

In April, Lumos announced it had commenced a review of the Company's operations and management, completing a reorganisation during the quarter which included the appointment of Sam Lanyon, Executive Chair, as interim CEO. In June, Lumos announced the appointment of Doug Ward as replacement CEO.

Doug Ward, an experienced commercial diagnostics executive, has been appointed to the CEO role and commenced with Lumos in mid-June. Doug brings over 30 years of experience in the diagnostics and life sciences industries, and has held senior executive roles with leading, multinational healthcare companies including Roche / Ventana Medical, GE, Siemens, Bayer, Chiron and Hologic.

As part of the operations review and restructuring, there has been a rationalisation of staff numbers across all functions within the Company.

Summary of Cash Receipts and Outflows

In June, Lumos completed a fully underwritten A\$11.2 million (US\$7.9 million before costs) equity raising via a 1-for-2.55 pro rata accelerated non-renounceable entitlement offer priced at \$0.19 per share with a free attaching option exercisable at \$0.30 expiring on 30 November 2022 for every new share subscribed. The entitlement offer comprised of an A\$8.0 million (US\$5.6 million) institutional component and a A\$3.2 million (US\$2.3 million) retail component.

During the quarter, Lumos recorded cash receipts from customers of \$2.3 million. Including the net proceeds from the June equity raising, Lumos closed 4Q FY22 with cash of \$8.0 million. Expenditure on operating activities, and payment of employee entitlements, included one-off costs associated with the operational review and restructure of \$1.0 million.

Operating activities included development expenditure for reader and assay development of \$0.9 million to expand the product portfolio, as well as product manufacturing and operating costs of \$1.7 million. The advertising and marketing costs of \$0.2M within Q4 FY22 are costs related to corporate marketing, and the creation of materials for Lumos branded products.

Lumos is continuing to target an average monthly cash burn of less than \$1.0 million per month for FY2023 with the completion of severance payments and the implementation of cost reductions identified in the initial organization review.

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 \$74,000 comprising directors' fees, salary and superannuation

Use of Funds Table

Use of Funds	Per Prospectus ¹	Use of Funds to 30 June 2022 ²
	\$m	\$m
Infrastructure and Capacity Expansion	4.4	1.9
Sales and Marketing	6.3	3.8
Regulatory, Clinical and Quality	2.8	3.0
Development of test pipeline	2.3	3.1
Technology platform development	4.1	1.2
Working Capital ³	5.2	14.6
Offer Costs	3.5	3.6
TOTAL	28.6	31.2

¹ Conversion AUD0.78/USD1.00

² For comparison purposes the Use of Funds table includes some items from FY2021 that relate to the IPO Prospectus (i.e. offer costs and other items) plus 12 months of FY2022, so will not agree exactly to the total cash flows and foreign exchange movements in cash for FY2022 outlined in Appendix 4C which total \$26.9 million.

³ Working Capital is comprised of the following items: Finance, Information Technology, Manufacturing, Technical Operations, Corporate & Administration, Movement in Accounts Receivable, Inventory, Accounts Payable and Other Items, and Operating Lease Payments.

Outlook and Future Activities

The key focus for Lumos going into FY2023 will be the regulatory applications for its own POC diagnostic products including filing an appeal to the FDA regarding its decision for FebriDx, and progressing the applications for regulatory clearance of ViraDx and CoviDx in various jurisdictions.

In addition, Lumos intends to actively focus on building its pipeline of commercial, revenue-generating projects for both its development services and contract manufacturing businesses with a view to accelerating the growth of a sustainable revenue stream from these business units.

-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")

30 June 2022

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (12 months) US\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	2,266	14,026
1.2 Payments for		
(a) research and development	(947)	(8,800)
(b) product manufacturing and operating costs	(1,702)	(9,681)
(c) advertising and marketing	(180)	(859)
(d) leased assets	-	-
(e) staff costs*	(1,510)	(4,626)
(f) administration and corporate costs	(2,342)	(9,040)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(245)	(613)
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	(4,660)	(19,593)

*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	(8)	(1,908)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (12 months) US\$'000
(f) other non-current assets (capitalised product development costs)	(70)	(1,762)
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	(78)	(3,670)

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	7,738	7,738
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	-	95
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(367)	(796)
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	(628)	(1,678)
3.10 Net cash from / (used in) financing activities	6,743	(12,142)

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (12 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	6,578	44,890
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,660)	(19,593)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(78)	(3,670)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,743	(12,142)
4.5	Effect of movement in exchange rates on cash held	(609)	(1,511)
4.6	Cash and cash equivalents at end of period	7,974	7,974

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	7,974	6,578
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)	7,974	6,578

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	74
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 US\$'000	Amount drawn at quarter end US\$'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	US\$'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(4,660)
8.2 Cash and cash equivalents at quarter end (item 4.6)	7,974
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	7,974
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.71
<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 cost reduction measures that have been implemented and are ongoing. The current quarter includes a number of restructuring payments which amounted to \$1.0 million (i.e. severance payments, paying out accrued vacation and other items).	
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: In addition to the cost cutting and rightsizing which is underway, the Company proposes to explore additional financing options.	

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 immediate business objectives on the basis of the recent capital raise completed, reduction in all areas of operational expenditure and additional financing options that are being explored.

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 July 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.