



ASX ANNOUNCEMENT

Lumos Diagnostics' Quarterly Activity Statement and Cash Flow Report

Key Highlights from the Quarter

- Unaudited revenue of \$2.3 million for the quarter (v \$2.8 million for Q1 FY2023)
- Cash usage for the quarter of \$3.7 million, average of \$1.2 million per month (excl. impact of FX)
- Signed three services agreements with Hologic, with potential to provide up to \$2.5 million in revenue for Lumos, for the development of a new, point-of-care diagnostic product
- Signed contracts for four new development programs including one with a new customer in the area of animal health
- Convertible Notes for A\$8.0 million approved at the general meeting in December with Tranche 1 of A\$4.0m settled in early January

MELBOURNE, Australia (30 January 2023) – 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 of fiscal year FY2023 ending 31 December 2022. All numbers in USD, the Company’s reporting currency, unless otherwise stated.

Operations Update

Lumos recorded unaudited revenue of \$2.3 million for the quarter ending 31 December 2022 compared with \$2.8 million for the preceding quarter ending 30 September 2022. The majority of revenue was generated from the Services side of the business for the provision of diagnostic test development and manufacturing services to clients.

Development Services and Contract Manufacturing

Lumos generated \$2.2 million from the provision of development services and contract manufacturing during the December quarter.

In November, Lumos announced it had secured two new service agreements with Massachusetts-based women's health company Hologic. Hologic is a leading innovator in women's health and has engaged Lumos to conduct two programs of work focused on the development of a commercial rapid, point-of-care test product. The programs covered under these two agreements are expected to be completed by the middle of 2023 and Lumos is entitled to receive up to \$1.5 million in revenue for the provision of its development services on these programs. In December, Lumos signed a third service agreement with Hologic which has the potential to generate up to an additional \$1.0 million for Lumos. As highlighted at the recent Annual General Meeting, the establishment of deep, long-term strategic partnerships with key players in the diagnostics space is an important area of focus to drive growth for Lumos.

In addition to the Hologic agreements, during the quarter Lumos signed three commercial contracts for new phases of projects with existing clients, including development work on a novel molecular diagnostics platform, and an initial pilot project with a new client for an animal health product. If successful, these projects may form the basis for future programs to develop new point-of-care diagnostic test products for commercial sale.

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 September 2022, the FDA advised Lumos that it was upholding its initial decision that FebriDx had not demonstrated substantial equivalence to the predicate device cited in its 510(k) application and consequently was not eligible for US clearance based on this application.

Following this decision, Lumos secured a presubmission meeting that was held with the FDA in January 2023 to discuss the requirements for a potential future regulatory submission for FebriDx. The feedback from this meeting indicated that the existing clinical and performance data that Lumos has for FebriDx may be sufficient to support a new 510(k) application to the FDA with less broad claims for the test. Based on this feedback, Lumos intends to submit a new 510(k) application for FebriDx to the FDA and expects to have an outcome from this process within the next 12-months.

During the quarter, Lumos received new orders for FebriDx from distributors in four European markets and commenced fulfilling these orders in December and January.

ViraDx™

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

ViraDx is currently under review by the US FDA for Emergency Use Authorization (EUA). Due to the high volume of EUA applications for respiratory diagnostic tests currently under consideration by the FDA, Lumos is still awaiting an outcome from its EUA application. In order to meet demand arising from the US 'flu season while this review process is being completed, during the quarter Lumos commenced distribution of the Status™ COVID-19/Flu A&B product to customers in the US under its agreement with LifeSign LLC.

In June 2022, ViraDx was awarded Interim Authorization by Health Canada. During the quarter, Lumos received and commenced fulfilling a number of initial purchase orders for ViraDx from its Canadian distributors.

CoviDx™

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

Lumos is not currently actively selling CoviDx.

Summary of Cash Receipts and Outflows

In November, Lumos announced it had entered into a binding Convertible Note Agreements to raise up to A\$8.0 million in two tranches from two US-based institutional investors—SBC Global Investment Fund and Lind Global Fund II, LP. Shareholder approval to proceed with the issue of these notes was secured at the General Meeting held in December 2022. Following this approval, the first tranche of A\$4.0 million of Convertible Notes were issued in early January with the second tranche of A\$4.0 million of Convertible Notes to be issued subject to Lumos's capital needs and mutual agreement between Lumos and the Investors.

During the quarter, Lumos recorded cash receipts from customers of \$1.3 million. Lumos closed Q2 FY2023 with cash of \$0.8 million, and \$5.4 million of financing facilities available from the total convertible notes facility. The expenditure on operating activities, and payment of employee entitlements, included one-off costs associated with the operational review and restructure of approximately \$0.1 million.

Operating activities included project service delivery costs plus research and development expenditure of \$0.9 million, as well as product manufacturing and operating costs of \$1.0 million. The advertising and marketing costs of \$0.2 million within Q2 FY2023 are costs related to services and corporate marketing, and the creation of materials for Lumos branded products.

Lumos is continuing to target an operating monthly cash burn of less than \$1.0 million per month for FY2023. Cash burn for this quarter averaged \$1.2 million per month (excluding the impact of foreign exchange movements) due to costs associated with additional severance and vacation payouts, plus pre-payments made in the prior financial year by customers for some of the services activities conducted by Lumos during the quarter.

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 \$76,000 comprising directors' fees, salary and superannuation.

Use of Funds Table

In accordance with Listing Rule 4.7C.2 the following table includes the Use of Funds summary:

Use of Funds	Per Prospectus ¹	Use of Funds to 31 December 2022 ²
	\$m	\$m
Infrastructure and Capacity Expansion	4.4	1.9
Sales and Marketing	6.3	4.0
Regulatory, Clinical and Quality	2.8	4.0
Development of test pipeline	2.3	3.1
Technology platform development	4.1	1.2
Working Capital³	5.2	20.5
Offer Costs	3.5	3.6
TOTAL	28.6	38.3

¹ Per the Prospectus dated 7 June 2021. Total proceeds received by the company was A\$38.0m. At a conversion of approximately US\$0.75 this equated to US\$28.6m.

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, plus 6 months of FY2023 to 31 December 2022. As a result, this table will not agree to the total cash flows and foreign exchange movements in cash for FY2023 outlined in Appendix 4C.

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 during FY2023 is 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.

Lumos will continue to seek regulatory clearances to market its own point-of-care products, and to focus its sales and marketing efforts on those markets where its products have secured clearances.

-Ends-

This announcement has been approved by the Lumos Disclosure Committee.

About Lumos Diagnostics

Lumos Diagnostics specializes 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 customized assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes novel Lumos-branded POC tests that target infectious and inflammatory diseases.

For more information visit lumosdiagnostics.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 2022

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	1,306	2,974
1.2 Payments for		
(a) service delivery, research and development	(920)	(2,097)
(b) product manufacturing and operating costs	(954)	(1,718)
(c) advertising and marketing	(170)	(263)
(d) leased assets	-	-
(e) staff costs*	(953)	(2,155)
(f) administration and corporate costs	(1,224)	(2,510)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(84)	(172)
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	(2,999)	(5,941)

*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	(17)	(19)
(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 (including capitalised product development costs)	(10)	(24)
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	(27)	(43)

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:		
Lease payments	(671)	(1,095)
3.10 Net cash from / (used in) financing activities	(671)	(1,095)

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

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	4,434	7,978
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,999)	(5,941)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(27)	(43)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(671)	(1,095)
4.5	Effect of movement in exchange rates on cash held	50	(112)
4.6	Cash and cash equivalents at end of period	787	787

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	787	4,434
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)	787	4,434

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	76
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.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1	-	-
7.2	-	-
7.3	5,444	-
7.4	Total financing facilities	-
	5,444	-
7.5	Unused financing facilities available at quarter end	5,444
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.	
	The company has put in place an A\$8.0m convertible note facility which was approved by shareholders at the general meeting on 22 December 2022. The facility is comprised of Tranche 1 of \$A4.0m and Tranche 2 of A\$4.0m (before costs). The company completed the draw down and settlement of Tranche 1 on 5 January 2023. The use of Tranche 2 is subject to mutual agreement between the company and investors.	

8. Estimated cash available for future operating activities	US\$'000
8.1	Net cash from / (used in) operating activities (item 1.9)
	(2,999)
8.2	Cash and cash equivalents at quarter end (item 4.6)
	787
8.3	Unused finance facilities available at quarter end (item 7.5)
	5,444
8.4	Total available funding (item 8.2 + item 8.3)
	6,231
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)
	2.08
	<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 continues to target operating cash flow improvements in subsequent quarters from cost reduction measures that have been implemented and improved business performance. The current half year includes a number of restructuring payments which amounted to \$0.6 million (i.e. severance payments, paying out accrued vacation, lease termination 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, the Company completed a capital raising from the convertible note facility.

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 reduction in all areas of operational expenditure, improved business performance, convertible note facility available, 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: **30 January 2023**

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.