



## ASX ANNOUNCEMENT

### Lumos Diagnostics' Quarterly Activity Statement and Cash Flow Report

#### Key Highlights from the Second Quarter

- Unaudited revenue of US\$1.7 million for Q2 (Q1 FY24 - US\$1.1 million).
- Commercial production of ViraDx and FebriDx established and shipping to customers commenced.
- US distributors now signed and direct customer accounts for FebriDx and ViraDx established.
- Successfully completed A\$2.65 million private placement supported by existing institutional shareholders.
- Signed major new transformative Development and IP Agreements with leading US women's health company, Hologic.
- Cash balance as at 31 December 2023 of US\$1.4 million. First US\$5.0 million payment received in January 2024 under the Hologic IP agreement, with additional payment to follow.

***All amounts are in USD, the Company's reporting currency, unless otherwise stated.***

**MELBOURNE, Australia (31 January 2024)** – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") a leader in rapid point-of-care diagnostic technologies, is pleased to release its Quarterly Activity Statement and Appendix 4C Cash Flow Report for the second quarter of fiscal year FY2024, ended 31 December 2023.

#### Operations Update

Lumos recorded unaudited revenue of US\$1.7 million for the quarter ended 31 December 2023, an improvement of 55% compared with US\$1.1 million for the preceding quarter ending 30 September 2023. The majority of revenue generated during the quarter was from the provision of diagnostic test development services and contract manufacturing for clients by the Commercial Services business.

### Development Services and Contract Manufacturing

Lumos generated US\$1.5 million from the provision of diagnostic test development services and contract manufacturing during the December quarter. Development services included ongoing project work for Hologic, Aptatek, Alden, MicroPak, Food-In-Depth, plus other parties. This work is anticipated to continue into future periods.

### Development and IP Agreements with Hologic

In early January, Lumos announced that it had signed two new Agreements with US based women's health company, Hologic, Inc.

These Agreements build on previous contract development work conducted by Lumos for Hologic over the last 12 months. The new Agreements focus on the development of a next generation version of Hologic's on market fetal fibronectin diagnostic product for pre-term birth, a women's health product for which Hologic is the global leader. A key focus of the development program is to adapt the test for use on the Lumos proprietary reader platform and provide improved connectivity options.

The two Agreements encompass 1) a Development Agreement and 2) an Intellectual Property ("IP") Agreement. Under the Development Agreement, Lumos is entitled to receive up to US\$4.7 million in payments over an 18-24 month timeframe, subject to achieving certain development milestones.

The body of work under the Development Agreement will be conducted across three phases, providing total milestone payments of up to US\$4.7 million, structured as follows:

- Phase 1 - Product Definition and Planning: define the parameters for the product and establish a project plan - US\$0.4 million;
- Phase 2 - Assay Feasibility: conduct work to demonstrate the assay can detect the biomarkers - US\$0.6 million; and
- Phase 3 - System Prototype Delivery: deliver a working prototype of the system - US\$3.7 million.

The costs associated with this work are typical for standard diagnostic product development programs, including labor, materials, and an allocation for overheads.

The IP Agreement provides Hologic with an exclusive license in the field of fetal fibronectin to the Lumos proprietary reader and POC technologies that will be incorporated into the next generation product under development. This Agreement provides for two non-refundable US\$5.0 million payments to Lumos from Hologic; the first US\$5.0 million payment was received on 17 January 2024 and the second US\$5.0 million payment is due by 30 June 2024. The IP Agreement is a license agreement enabling Hologic to access intellectual property owned by Lumos, consequently it does not have any costs associated with it.

### US Product Sales Channel

During mid-2023, Lumos commenced activities to establish a US sales channel for point-of-care diagnostic tests by establishing a network of independent, commission-only sales representatives.

By the end of the December quarter, Lumos had also signed agreements with 12 distributors or direct customers for both FebriDx and ViraDx. These include a number of large, regional distributors that have extensive networks of physician offices and urgent care clinic customers.

Lumos generated US\$0.2 million from the sale of products during the December quarter.

### FebriDx®

FebriDx is Lumos' rapid, point-of-care test which can be used to detect and aid in the diagnosis of acute bacterial disease states from respiratory infections. To date, Lumos has received regulatory registrations for the use of FebriDx in the US, UK, Europe, Canada, UAE and Australia.

In July 2023, Lumos announced that the FDA had granted clearance for FebriDx to be marketed in the US as an aid in the diagnosis of acute bacterial respiratory infections by healthcare professionals.

Lumos has made significant progress in preparing for the launch of FebriDx in the US market. The Company commenced commercial production of FebriDx to meet anticipated demand, and product was ready for shipping by end December 2023. The first US commercial order for FebriDx was delivered in January 2024.

The Company continues to receive inbound enquiries for FebriDx from potential end-users at physicians' offices and urgent care clinics.

Initial orders were shipped to Henry Schein in Europe, after it expanded its distribution coverage of FebriDx to include Spain, Portugal and the Netherlands. Henry Schein has been a key distributor of FebriDx in the UK for several years.

### ViraDx

ViraDx is a rapid point-of-care diagnostic product that simultaneously tests for acute respiratory infections caused by the COVID-19, influenza A, and influenza B viruses.

In September 2023, Lumos announced that the US Food and Drug Administration (FDA) had granted Emergency Use Authorisation (EUA) and a CLIA Waiver (Clinical Laboratory Improvement Amendments) for the ViraDx test. Lumos offers ViraDx to healthcare providers in the US through its recently established sales channel for point-of-care products for women's health, Sexually Transmitted Infections (STIs) and other infectious diseases.

During the December quarter, Lumos made significant progress in preparation for the launch of ViraDx in the US market. The Company commenced commercial production of ViraDx to meet anticipated demand with product ready for shipment by the end of November. First orders were delivered in December. With the US flu season underway, the Company is continuing to receive orders and enquiries.

#### **Private Placement**

During the quarter, Lumos completed an A\$2.65 million capital raising (before costs) through a private placement to existing institutional shareholders of the Company. The funds provide additional working capital to support the pipeline of opportunities including the launch of FebriDx and ViraDx in the US, plus the growing pipeline of new commercial services opportunities with existing strategic partners (such as the new Hologic agreements) and potential new commercial partners.

#### **Summary of Cash Receipts and Outflows**

Cash usage for the quarter was US\$2.8 million (operating & investing cash flow, plus lease payments), equivalent to US\$0.9 million per month, in line with our guidance, and consistent with the previous quarter. Lumos had a cash balance of US\$1.4 million as at 31 December 2023.

On a pro-forma basis, including the US\$5.0m received on 17 January 2024, under the IP agreement with Hologic, cash stands at US\$6.4m.

Operating activities included project service delivery costs, plus research and development expenditure of US\$0.6 million, as well as product manufacturing and operating costs of US\$0.8 million.

Investing cash outflows remain minimal for the quarter as Lumos continues to be cautious and selective with its investments and focused on commercializing its existing products and intellectual property.

#### **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 payments to related entities of US\$206,000 comprising directors' fees, consulting fees and superannuation.

#### **Key Priorities**

The key focus areas for Lumos continues to be building its pipeline of commercial, revenue-generating projects for both its development services and contract manufacturing businesses, with a strategy of accelerating the growth of sustainable revenue streams from these business units.

With the recent FDA clearance of FebriDx in the US, Lumos has moved into production phase, completing marketing materials and growing sales and distribution channels for the US market, as well as other markets where the test is cleared. Lumos is also developing a commission-only sales channel in the US for FebriDx and other point-of-care diagnostic products for womens' health, STIs and other infectious diseases.

Following the EUA authorization of ViraDx, Lumos is actively in the launch phase of this product in the US, preparing to respond to the current US flu season and expects continued sales during the current quarter.

Lumos will continue to seek regulatory clearances to market its own point-of-care products, and to focus its sales and marketing efforts on 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 and complete point-of-care diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customized assay development and manufacturing services for point-of-care tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes novel Lumos-branded point-of-care tests that target infectious and inflammatory diseases.*

*For more information visit [lumosdiagnostics.com](http://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 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter US\$'000</b>	<b>Year to date (6 months) US\$'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	1,100	2,438
1.2 Payments for		
(a) service delivery, research and development	(571)	(1,533)
(b) product manufacturing and operating costs	(839)	(1,597)
(c) advertising and marketing	(145)	(240)
(d) leased assets	-	-
(e) staff costs*	(958)	(2,345)
(f) administration and corporate costs	(841)	(1,688)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(141)	(349)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	471
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,395)</b>	<b>(4,843)</b>

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

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(7)	(9)
(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)	-	(9)
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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(7)</b>	<b>(18)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,736	5,352
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	(102)	(353)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	(1,110)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other:		
	Lease payments (principal component)	(361)	(679)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>1,273</b>	<b>3,210</b>



Consolidated statement of cash flows		Current quarter US\$'000	Year to date (6 months) US\$'000
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	2,494	3,015
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,395)	(4,843)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(18)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,273	3,210
4.5	Effect of movement in exchange rates on cash held	14	15
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>1,379</b>	<b>1,379</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> 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	1,379	2,494
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>1,379</b>	<b>2,494</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	Current quarter US\$'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	206
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.	<b>Financing facilities</b>	<b>Total facility amount at quarter end US\$'000</b>	<b>Amount drawn at quarter end US\$'000</b>
	<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)	2,724	-
7.4	<b>Total financing facilities</b>	2,724	-
7.5	<b>Unused financing facilities available at quarter end</b>		2,724
7.6	<p>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.</p> <p>The company 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).</p> <p>The company completed the draw down and settlement of Tranche 1 on 5 January 2023, with the balance owed subsequently repaid in full on 10 August 2023, with the cash amount for this loan repayment of \$1.1 million shown above in "cash flows from financing activities".</p> <p>The use of Tranche 2 for A\$4.0m (before costs) is subject to mutual agreement between the company and the two convertible note investors.</p> <p>Amounts shown above are for Tranche 2 based on an FX rate of A\$1.00 : US\$0.6811.</p>		

8.	<b>Estimated cash available for future operating activities</b>	<b>US\$'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,395)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,379
8.3	Unused finance facilities available at quarter end (item 7.5)	2,724
8.4	Total available funding (item 8.2 + item 8.3)	4,103
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	1.7x
	<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 will have an improvement in operating cash flows due to completing the major Development and IP Agreements with Hologic, Inc. that were announced on 11 January 2024.

Under the IP agreement the company received the first US\$5.0m payment on 17 January 2024. Based on this, it is expected that the operating cash flow for Q3, ending 31 March 2024 will be positive.

It also should be noted that there are no costs related to the company's obligation under the IP agreement.

If we include the US\$5.0m received on 17 January 2024, to the US\$1.4m cash on end at 31 December 2023, the pro-forma cash would be US\$6.4m, which provides an available funding pro-forma of US\$9.1m and 3.8x quarters of funding available.

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: Yes, the company completed the major Development and IP Agreements with Hologic, Inc. that were announced on 11 January 2024.

This non-dilutive funding under the IP agreement, provides a materially significant cash injection to the company, which is US\$5.0m that was received on 17 January 2024, and a second US\$5.0m to be received by 30 June 2024.

The company is confident the second payment will be received in the timeframe outlined in the agreement.

It also should be noted that there are no costs related to the company's obligation under the IP agreement.

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: Yes, based on the descriptions provided above. This improvement in cash receipts from customers will provide a significant boost to operating cash flow, and funds available to the company. If we include the US\$5.0m received on 17 January 2024, to the US\$1.4m cash on end at 31 December 2023, the pro-forma cash would be US\$6.4m, which provides an available funding pro-forma of US\$9.1m and 3.8x quarters of funding available. It is expected that the receipts under the IP agreement will put the company into a positive operating cash flow position.

*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 2024

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.