



## ASX ANNOUNCEMENT

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

#### Key Highlights from the First Quarter

- Unaudited revenue of US\$1.1 million for the quarter (v US\$3.5 million for Q4 FY2023)
- US FDA provides clearance to market FebriDx in the US and grants Emergency Use Authorisation (EUA) to market ViraDx in the US
- Henry Schein expands distribution coverage of FebriDx to include Spain, Portugal and the Netherlands
- Successful equity capital round raises A\$5.4 million enabling Lumos to redeem all outstanding Convertible Notes previously issued to Lind Global Fund II and SBC Global Investment Fund
- Cash balance at 30 September of US\$2.5 million

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

**MELBOURNE, Australia (31 October 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 first quarter of fiscal year FY2024 ending 30 September 2023.

#### Operations Update

Lumos recorded unaudited revenue of US\$1.1 million for the quarter ending 30 September 2023, compared with US\$3.5 million for the preceding quarter ending 30 June 2023. The majority of revenue generated during the quarter was from the provision of diagnostic test development services and contract manufacturing to clients by the Services side of the business.

Cash usage for the quarter was US\$2.8 million, equivalent to US\$0.9 million per month, as per our guidance, and up from a total of US\$1.2 million for the preceding quarter which benefitted from the timing of

payments from customers, receipt of a payment for manufacturing establishment activities, and some warranty proceeds from returned equipment from the closed Sarasota facility. During the quarter, Lumos received a cash refund of A\$0.7 million arising from eligible R&D expenses under the Federal Government's Research and Development Tax Incentive for the financial year ending 30 June 2022. Lumos had a cash balance of US\$2.5 million on 30 September 2023.

#### Development Services and Contract Manufacturing

Lumos generated US\$1.0 million from the provision of diagnostic test development services and contract manufacturing during the September quarter. Development services included ongoing project work for Hologic, Aptatek, MaximBio, MicroPak and Food-In-Depth and other parties that will continue into future periods.

In July, Lumos announced it had signed a commercial contract to undertake an initial feasibility project with the Burnet Diagnostics Initiative (BDI) of the Macfarlane Burnet Institute for Medical Research and Public Health Ltd. The project will build upon preliminary proof-of-concept work conducted by BDI on a novel companion diagnostic biomarker with utility across a range of human health applications. Lumos will conduct feasibility level development studies to generate a prototype test for evaluation with clinical specimens. This initial feasibility stage of the project is worth up to US\$200,000 in revenue for Lumos and is expected to complete within approximately four months. If successful, Lumos may be engaged to assist with subsequent stages of the project including product design, development and manufacturing.

#### FeбриDx®

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

In July, Lumos announced that the FDA had granted clearance for FeбриDx to be marketed in the US as an aid in the diagnosis of acute bacterial respiratory infections by healthcare professionals. This clearance was based on a new 510(k) application that Lumos filed with the FDA following a pre-submission meeting that was held with the FDA in January 2023.

Lumos is currently undertaking activities to prepare for its launch of FeбриDx in the US market. The Company has been ramping up its production capacity of FeбриDx to meet the anticipated demand and remains on target to have product on the shelf, ready to ship by the end of the calendar year. Lumos believes it will be in a position to ship the first US commercial order for FeбриDx by the end of CY2023.

As discussed below (*US Product Sales Channel*), Lumos is expanding its network of US distributors and has already received a pre-order for FeбриDx from one of the newly signed distributors. In addition, the Company has received several availability and stocking enquiries for FeбриDx from potential end-users at physician offices and urgent care clinics.

During the quarter, global healthcare products distributor Henry Schein expanded its distribution coverage of FeбриDx to include Spain, Portugal and the Netherlands. Henry Schein has been a key distributor of FeбриDx in the UK for several years.

### ViraDx

ViraDx is a rapid POC test that simultaneously tests for acute respiratory infections caused by the COVID-19, influenza A, and influenza B viruses.

During the quarter the US Food and Drug Administration (FDA) has granted Emergency Use Authorisation (EUA) and a CLIA Waiver (Clinical Laboratory Improvement Amendments) for the ViraDx test. Lumos intends to offer ViraDx to healthcare providers in the US through its recently established sales channel for POC products for women's health, STI's and infectious diseases. Lumos will monitor its sales and marketing investment for ViraDx to ensure that it is supported by robust end-user demand.

Lumos is ramping up production of ViraDx and expects to have product ready to ship by the second half of November. The Company has already received a number of initial orders for the test in anticipation of the US flu season which is about to commence.

### US Product Sales Channel

In the previous quarter, Lumos commenced activities directed at establishing a US sales channel for point-of-care diagnostic tests by establishing a network of independent, commission-only sales representatives.

During the quarter Lumos signed distribution contracts with two new distributors and is currently finalising contracts with over ten other parties. These include a number of large, regional distributors that have extensive networks of physician offices and urgent care clinic customers.

### Key Reader Patent Granted

In August, Lumos announced that a core patent covering the camera technology used in its reader platform has been granted for Europe and Japan.

The patent, entitled "Device for reading an IVD assay", covers the use of Lumos' proprietary camera technology which is incorporated in many of its readers. These readers have become a critical component of new point-of-care tests as they automate the reading and quantification of results and allow those results to be seamlessly integrated into electronic medical record systems. This patent covers the use of Lumos' reader technology in the European and Japanese markets until 2036 and has already been granted in the United States and Australia.

### **Corporate Activities**

During the quarter, as intended, Lumos applied some proceeds of the capital raising conducted during July/August toward the early redemption of the outstanding Convertible Notes that were issued to Lind Global Fund II (Lind) and SBC Global Investment Fund (SBC) in January 2023. In aggregate, 1,875,000 Convertible Notes with a face value of A\$1,875,00 were redeemed for consideration of A\$1,575,000 and the issuance of 6,382,979 ordinary shares in Lumos at A\$0.047 per share. With this early redemption completed, the number of Convertible Notes held by both Lind and SBC has been reduced to nil.

During the quarter, Lumos entered into a consultancy agreement with Lumos' Non-Executive Chair, Sam Lanyon, for the provision of advisory services in relation to investor relations, capital raising and commercialisation activities. Lumos' Board recognised the importance for an ASX-listed company to have an Australia-based resource that is able to assist with its capital market activities and to interface with the market in a timely manner.

On 30 October 2023, the Company raised A\$2.65m (before costs) by way of a private placement of 37.9 million shares at A\$0.07 per share to institutional shareholders.

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

Cash usage for the quarter was US\$2.8 million, equivalent to US\$0.9 million per month as per our guidance, and up from a total of US\$1.2 million for the preceding quarter which benefitted from the timing of payments from customers, payment for manufacturing establishment activities, and some warranty proceeds from returned equipment from the closed Sarasota facility. During the quarter, Lumos received a cash refund of A\$0.7 million related to eligible expenses under the Federal Government's Research and Development Tax Incentive for the financial year ending 30 June 2022. Lumos had a cash balance of US\$2.5 million on 30 September 2023. Subsequent to the end of the quarter Lumos raised A\$2.65m (before costs) by way of a private placement of 37.9 million shares at A\$0.07 per share to institutional shareholders.

Operating activities included project service delivery costs plus research and development expenditure of US\$1.0 million, as well as product manufacturing and operating costs of US\$0.8 million.

### **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 A\$85,000 comprising directors' fees, consulting fees and superannuation.

### **Outlook and Future Activities**

The key focus for Lumos 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.

With the recent FDA clearance of FebriDx, Lumos is preparing to scale-up production, marketing materials and 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 POC diagnostic products for womens' health, STIs and other infectious diseases.

With the EUA authorization of ViraDx, Lumos is actively preparing for the launch of this product in the US to take advantage of the forthcoming US flu season and expects first commercial sales this current second quarter of FY2024.

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](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")**

30 September 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter US\$'000</b>	<b>Year to date (3 months) US\$'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	1,338	1,338
1.2 Payments for		
(a) service delivery, research and development	(962)	(962)
(b) product manufacturing and operating costs	(758)	(758)
(c) advertising and marketing	(95)	(95)
(d) leased assets	-	-
(e) staff costs*	(1,387)	(1,387)
(f) administration and corporate costs	(847)	(847)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(208)	(208)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	471	471
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,448)</b>	<b>(2,448)</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	(2)	(2)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (3 months) US\$'000
(f) other non-current assets (including capitalised product development costs)	(9)	(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 Net cash from / (used in) investing activities</b>	<b>(11)</b>	<b>(11)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	3,616	3,616
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	(251)	(251)
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	(1,110)	(1,110)
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other:		
Lease payments (principal component)	(318)	(318)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>1,937</b>	<b>1,937</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter US\$'000</b>	<b>Year to date (3 months) US\$'000</b>
<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	3,015	3,015
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,448)	(2,448)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(11)	(11)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,937	1,937
4.5	Effect of movement in exchange rates on cash held	1	1
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>2,494</b>	<b>2,494</b>

<b>5. Reconciliation of cash and cash equivalents</b>	<b>Current quarter US\$'000</b>	<b>Previous quarter US\$'000</b>
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		
5.1 Bank balances	2,494	3,015
5.2 Call deposits	-	-
5.3 Bank overdrafts	-	-
5.4 Other (provide details)	-	-
<b>5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>2,494</b>	<b>3,015</b>

<b>6. Payments to related parties of the entity and their associates</b>	<b>Current quarter US\$'000</b>
6.1 Aggregate amount of payments to related parties and their associates included in item 1	85
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>	



<b>7. 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.</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	2,598	-
7.4	<b>Total financing facilities</b>	-
	2,598	-
7.5	<b>Unused financing facilities available at quarter end</b>	
		2,598
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.	
	<p>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, with the balance owed subsequently repaid 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 investors.</p> <p>Amounts shown are based on an FX rate of A\$1.00 : US\$0.6494.</p> <p>On 30 October 2023, the company raised A\$2.65m (before costs) by way of a private placement of 37.9 million shares at A\$0.07 per share to institutional shareholders.</p>	

<b>8. Estimated cash available for future operating activities</b>	<b>US\$'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)
	(2,448)
8.2	Cash and cash equivalents at quarter end (item 4.6)
	2,494
8.3	Unused finance facilities available at quarter end (item 7.5)
	2,598
8.4	Total available funding (item 8.2 + item 8.3)
	5,092
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>
	2.1x
	<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:
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:

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:

*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 October 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.