



ASX ANNOUNCEMENT

Lumos Diagnostics Quarterly Activity Statement and Cash Flow Report

Key Highlights from the Fourth Quarter

- **Positive cash flow for the quarter of US\$3.1 million**, with the cash balance as at 30 June 2024 of US\$6.5 million.
- **Unaudited revenue of US\$4.3 million for the quarter**, up 8% compared to the prior quarter (Q3 FY24 - US\$4.0 million).
- **Unaudited revenue of US\$11.1 million for FY24**, up 6% compared to the prior FY23 year of US\$10.5 million.
- **The Services business grew strongly** through the quarter, with revenue up 21% on Q3.
- **Cash receipts of US\$7.4 million for the quarter** (Q3 FY24 US\$6.7 million), including US\$5.0 million non-refundable payment from Hologic under the IP Agreement.
- **Key “Phase 1 Milestone” of the Hologic fFN Development Agreement achieved** and the US\$0.4 million milestone payment received.
- **Post reporting date**, Lumos expanded its FebriDx distribution agreements with Henry Schein in Australia, New Zealand and Belgium.

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

MELBOURNE, Australia (31 July 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 fourth quarter of FY24 (the three months ended 30 June 2024).

Operations Update

Lumos recorded unaudited revenue of US\$4.3 million for the quarter ended 30 June 2024, up 8% compared with the prior quarter (Q3 FY24: US\$4.0 million), and unaudited revenue of US\$11.1 million for FY24, up 6% compared to the prior FY23 year of US\$10.5 million.

Revenue generated during the quarter from the Services business was US\$4.0 million, up 21% on Q3, with the majority from consulting development services under the Hologic fFN Development Agreement and the intellectual property licensing revenue associated with the Hologic IP Agreement, announced to the ASX on 11 January 2024. Unaudited revenue for Services was US\$9.9 million for FY24, down 3% compared to the prior FY23 year of US\$10.2 million (which included some one-off contract manufacturing fees).

Revenue from Products during the quarter was US\$0.3 million, which was lower than the prior quarter. This was anticipated and in line with management expectations, given the US 2023/24 flu season has largely concluded, leading to lower sales of ViraDx and FebriDx in the quarter. Unaudited revenue for Products was US\$1.2 million for FY24, up 300% compared to the prior FY23 year of US\$0.3 million, driven by the growth in FebriDx and ViraDx sales.

Development Services and Contract Manufacturing

Lumos generated US\$4.0 million from the provision of diagnostic test development services and contract manufacturing during the June quarter. Development services included ongoing project work for Hologic, Aptatek, and Burnett Institute, plus other medical and non-medical customer projects. Along with signing two new customers, the successful delivery of several projects during the quarter resulted in customers requesting additional scope, expanding the total project value. This work is anticipated to continue into future periods.

Development and IP Agreements with Hologic

On 11 January 2024, Lumos announced that it had signed two new Agreements with US based women's health company, Hologic. An Intellectual Property agreement valued at US\$10.0 million, and a Development Agreement valued at US\$4.7 million. The Agreements focus on the development of a next generation version of Hologic's on-market fFN diagnostic product for pre-term birth, a women's health product for which Hologic is the only manufacturer globally. 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.

As previously announced, the body of work under the Development Agreement is being 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 - complete;
- Phase 2 - Assay Feasibility: conduct work to demonstrate the assay can detect the biomarkers - US\$0.6 million – in progress; and
- Phase 3 - System Prototype Delivery: deliver a working prototype of the system - US\$3.7 million – not started.

During the quarter, Lumos received the second Tranche of US\$5.0 million payment under the IP Agreement, bringing the total payments received under the IP Agreement to US\$10.0 million.

The IP Agreement provides Hologic with an exclusive license in the field of fetal fibronectin (fFN) to the Lumos proprietary reader and point of care technologies that will be incorporated into the next generation Hologic fFN diagnostic product under development. The collaboration enhances the test for use on the Lumos proprietary reader platform, incorporating improved connectivity options.

Lumos also successfully completed Phase 1 of the related Development Agreement, which focused on Product Definition and Planning. In June, Lumos received a payment of US\$0.4 million, relating to the completion of Phase 1.

Lumos has commenced Phase 2 of the Development Agreement entitled, “Assay Feasibility”, designed to demonstrate that the assay can detect the biomarkers associated with the new fFN test. Successful completion of all parts of Phase 2 will trigger a US\$0.6 million payment. The balance of the Development Agreement of US\$3.7 million is payable following the successful completion of all parts of Phase 3.

The current estimated timeframe to complete the work under the Development Agreement is around 20 months from signing the two contracts and beginning work in January 2024. As the Development Agreement and IP Agreement are intrinsically linked, Lumos is recognizing the revenue from both contracts over time, a combined US\$14.7 million, over a 20-month period, with 6 months recognized in FY24.

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 distributors and independent, commission-only sales representatives.

By the end of the June quarter, Lumos had signed agreements with 25 distributors or direct customers covering 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\$0.3 million from the sale of products during the quarter, primarily related to ViraDx product sales, and also with sales from FebriDx in the US, and overseas markets.

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 launching FebriDx in the US market. The Company commenced commercial production of FebriDx to meet anticipated demand, and product was ready for shipping by the end of December 2023. The first US commercial order for FebriDx was delivered in January 2024. Following the first shipment, multiple new customers, both direct and through distributors, have implemented FebriDx. These initial early adopters are utilizing the test in the university student health and urgent care markets.

The Company continues to receive inbound enquiries for FebriDx from potential strategic partners, distributors, end users at physicians' offices and urgent care clinics. In addition to the February announcement that Henry Schein had been appointed as a distributor of FebriDx products in the USA, post quarter end, Lumos expanded agreements with Henry Schein to distribute FebriDx in Australia, New Zealand and Belgium.

On 8 April 2024 Lumos announced that the respected international journal, *Infectious Diseases and Clinical Microbiology*, has published results of a FebriDx study in 216 paediatric patients. The study and subsequent peer-reviewed publication were conducted by collaborators at Sant Joan de Déu Hospital, Barcelona, one of Spain's largest paediatric hospitals. The study aimed to determine FebriDx's impact on the management of antibiotics in paediatric patients presenting to the emergency department with Acute Respiratory Infection. The study concluded FebriDx® could be a useful tool for optimizing antibiotic use in children with acute febrile respiratory infections and FebriDx may also decrease the need for unnecessary chest X-rays, improving the management of febrile respiratory illnesses in children. Refer to the ASX announcement for additional details of the study.

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 Authorization (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.

Following its strong debut in the point of care testing market in the March quarter, ViraDx contributed the majority of the US\$0.3 million in product sales for the fourth quarter. A total of 19 ViraDx partnerships were executed with distributors in FY24. Three of these agreements were signed in Q4, with four potential new distribution agreements currently in negotiation. This is a strong indicator that ViraDx is being well received in the marketplace.

Given the US flu season has now largely concluded, sales have been lower in Q4, as expected, but COVID patient infections are still being recognized and purchase orders are expected to continue in the US summer

months. These ViraDx sales orders, in addition to expected distribution stocking orders in the September-October months, should provide a robust start to FY25.

Summary of Cash Receipts and Outflows

Lumos generated cash receipts from customers of US\$7.4 million for the quarter ended 30 June 2024, up from US\$6.7 million received in the previous quarter. This included US\$5.4 million from Hologic, for Tranche 2 of the IP Agreement payment of US\$5.0 million, and US\$0.4 million for completion of Phase 1 of the fFN Development Agreement.

Positive net cash generation for the quarter of US\$3.1 million (operating & investing cash flow, plus lease payments), was an improvement on the US\$2.0 million cash generation in the previous quarter. Lumos finished Q4 with a cash balance of US\$6.5 million.

Operating costs of US\$4.0 million were down by 9% on the US\$4.4 million reported in the previous quarter.

Investing cash outflows remained 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 Appendix 4C the Company discloses payments to related entities of US\$296,000 comprising directors' fees, consulting fees and superannuation.

Key Priorities

The key focus for Lumos continues to be growing revenue in its Service and Products businesses.

For the Service business, this includes a strategy of building a sustainable and growing pipeline of commercial, revenue-generating projects for both its development services and contract manufacturing businesses. Secondly, ensuring that Lumos delivers on its milestones relating to the fFN Development Agreement with Hologic.

For the Products business, the focus is on growing sales of our two in-market proprietary products, FebriDx and ViraDx. With the recent FDA clearance of FebriDx in the US, Lumos has moved into production, marketing and sales phase, completing marketing materials and growing sales and distribution channels for the US, as well as other markets where the test has been cleared. In addition, Lumos is preparing for the trial needed to extend the label for FebriDx from the current *moderate-complex* label to include *CLIA waived* settings, which will greatly expand our market opportunity for FebriDx in the US. The Company has aligned with the FDA on the approach required and aims to start the trial in late Q1 FY25 / early Q2 FY25. Our goal is to complete the trial by the end of the US 2024/25 flu season, with a submission to be lodged with the FDA in Q4 FY25.

Lumos will continue to seek regulatory clearances to market its own point-of-care products, focusing its sales and marketing efforts on markets where FebriDx and ViraDx have secured clearances, as well as seeking new partnering opportunities for its products.

In closing, CEO, Doug Ward noted: *“It was pleasing to see our efforts rewarded in the second half of FY24, with the momentum continuing to build. The Hologic Agreement, announced in January 2024, helped position Lumos on a solid footing. Supported by positive cashflow generation in the final two quarters of the year, our balance sheet finished in great shape with US\$6.5 million cash in the bank.*

We delivered on our Phase 1 milestones of the Hologic fFN Development Agreement and are currently progressing on delivering Phase 2 of the Agreement.

We continued to extend our distribution agreements for FebriDx with Henry Schein in the US, Australia, New Zealand and Belgium. Our distribution channels for ViraDx have also expanded over the period. This provides much optimism for delivering product sales growth in the upcoming northern hemisphere flu season.

Looking into the first quarter of the new financial year, we are preparing for the commencement of our FebriDx trial in the upcoming US flu season. A successful trial outcome, leading to CLIA Waived labelling in the US has the potential to open significant market opportunities in future periods.

During FY25, we will also continue to pursue new partnerships with leading women’s health companies, whilst exploring opportunities for developing and commercializing new in-house products.”

I am very optimistic about the future outlook for Lumos and look forward to providing further positive updates to the market over the course of the year.”

-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.

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.

Media Contacts:

Haley Chartres – Australia

HACK Director

haley@hck.digital

+61 423 139 163

Investor Contact:

Jane Lowe

Managing Director, IR Department

ir@lumosdiagnostics.com

+61 411 117 774

Company Registered Office:

Lumos Diagnostics Holdings Ltd

Level 4, 100 Albert Rd

South Melbourne, VIC 3205

info@lumosdiagnostics.com

+61 3 9087 1598

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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 2024

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	7,447	16,569
1.2 Payments for		
(a) service delivery, research and development	(1,145)	(3,396)
(b) product manufacturing and operating costs	(539)	(3,044)
(c) advertising and marketing	(53)	(414)
(d) leased assets	-	-
(e) staff costs*	(1,139)	(5,054)
(f) administration and corporate costs	(978)	(3,695)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(118)	(537)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	471
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	3,475	900

*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	(21)	(43)
(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 (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)	-	-
2.6	Net cash from / (used in) investing activities	(21)	(52)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	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	-	(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)	(337)	(1,259)
3.10	Net cash from / (used in) financing activities	(337)	2,630

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	3,366	3,015
4.2	Net cash from / (used in) operating activities (item 1.9 above)	3,475	900
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(21)	(52)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(337)	2,630
4.5	Effect of movement in exchange rates on cash held	(4)	(14)
4.6	Cash and cash equivalents at end of period	6,479	6,479

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	6,479	3,366
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)	6,479	3,366

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	296
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 <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>	Total facility amount at quarter end US\$'000	Amount drawn at quarter end US\$'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	2,667	-
7.4	Total financing facilities	2,667	-
7.5	Unused financing facilities available at quarter end		2,667
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\$0.6667.</p>		

8.	Estimated cash available for future operating activities	US\$'000
8.1	Net cash from / (used in) operating activities (item 1.9)	3,475
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,479
8.3	Unused finance facilities available at quarter end (item 7.5)	2,667
8.4	Total available funding (item 8.2 + item 8.3)	9,146
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
	<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: N/A	
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: N/A	

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: N/A

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 July 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.