



ASX ANNOUNCEMENT

Lumos Diagnostics Quarterly Activity Statement and Cash Flow Report

Key Highlights from the Third Quarter

- **Transformative Development and IP Agreements signed** with leading US women's health company, Hologic.
- **Cash receipts of US\$6.7 million** (Q2 FY24 US\$1.1 million), including US\$5.0 million non-refundable payment from Hologic for IP Agreement. Second US\$5.0 million payment expected by 30 June 2024.
- **Positive cash flow for the quarter of US\$2.0 million**, with the cash balance as at 31 March 2024 of US\$3.4 million.
- **Unaudited revenue of US\$4.0 million**, up 135% compared to the prior quarter (Q2 FY24 - US\$1.7 million).
- **ViraDx and FebriDx sales grew substantially** through the quarter, up 250% on Q2, following their launch and benefiting from the US flu season.
- Agreement signed with **Henry Schein for distribution of FebriDx in the US**.

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

MELBOURNE, Australia (23 April 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 third quarter of FY24 (three months ended 31 March 2024).

Operations Update

Lumos recorded unaudited revenue of US\$4.0 million for the quarter ended 31 March 2024, up 135% compared with the prior quarter (Q2 FY24: US\$1.7 million).

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Revenue generated during the quarter from the Services business was US\$3.3 million, with the majority from consulting development services and the intellectual property licensing revenue associated with the Hologic IP agreement, announced to the ASX on 11 January 2024.

Revenue from Products during the quarter was US\$0.7 million, with initial sales of the ViraDx and FebriDx products strong contributors to the improved revenue performance, coinciding with the US flu season.

Development Services and Contract Manufacturing

Lumos generated US\$1.8 million from the provision of diagnostic test development services and contract manufacturing during the March quarter. Development services included ongoing project work for Hologic, Aptatek, Alden, Burnett Institute, MicroPak, Food-In-Depth, plus other parties. This work is anticipated to continue into future periods.

Development and IP Agreements with Hologic

In January 2024, Lumos announced that it had signed two new Agreements with US based women's health company, Hologic, Inc. Through this third quarter, work to deliver upon the Agreements also commenced, with Phase 1 expected to complete by the end of April.

The Agreements build on previous contract development work conducted by Lumos for Hologic over the prior 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. Lumos is recognizing the US\$10 million license fee over a period of 20 months, to coincide with the estimated time to complete the Development Agreement, with US\$1.5 million of revenue recognized during the third quarter.

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 March quarter, Lumos had also signed agreements with 17 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\$0.7 million from the sale of products during the March quarter, with ViraDx product sales leading the revenue growth.

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 been 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 the end of 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 strategic partners, distributors, 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. On 12 February 2024, it was announced that Lumos had signed an agreement with Henry Schein to distribute FebriDx in the United States.

The US is the biggest commercial opportunity for FebriDx due to the routine use of point-of-care tests in standard clinical workflow and established reimbursement. Lumos believes that FebriDx has a unique role in ensuring that antibiotics are only given to patients who are likely to benefit from them.

On 8 April 2024 Lumos announced that 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 optimising 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.

ViraDx had a strong debut in the point of care testing market, contributing the majority of the US\$0.7 million in product sales for the quarter. This pleasing performance benefited from the timing of the US flu season. Given the US flu season has now largely concluded, the Company would expect to see this impact on the sales of ViraDx for the fourth quarter.

Summary of Cash Receipts and Outflows

Lumos generated cash receipts of US\$6.7 million for the quarter ended 31 March 2024, up from US\$1.1 million received in the previous quarter. This included US\$5.0 million from the first payment for the signing of the Hologic IP Agreement.

Positive cash flow for the quarter of US\$2.0 million (operating & investing cash flow, plus lease payments), was a significant improvement on the cash usage of US\$2.8 million in the previous quarter. Lumos had a cash balance of US\$3.4 million as at 31 March 2024.

Operating activities included project service delivery costs, plus research and development expenditure of US\$0.7 million, as well as product manufacturing and operating costs of US\$0.9 million.

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\$292,000 comprising directors' fees, consulting fees and superannuation.

Key Priorities

The key focus 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, marketing and sales 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, responding to the current US flu season and expects continued sales during the current quarter, although we anticipate at a lower level than the third 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.

In closing, CEO, Doug Ward noted: "With the benefit of significant and transformative milestones in the Services and Product businesses during 1H FY24, the foundations are in place to enable Lumos to accelerate building and growth of the company."

"The Company remains on track to see revenue growth through 2H FY24 on the prior half year, led by the Hologic IP payments, Services revenue and Product sales. In addition, overall cash flow is on track to improve, underpinned by growing revenue streams and prudent cost management."

-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.

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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 March 2024

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (9 months) US\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	6,684	9,122
1.2 Payments for		
(a) service delivery, research and development	(718)	(2,251)
(b) product manufacturing and operating costs	(908)	(2,505)
(c) advertising and marketing	(121)	(361)
(d) leased assets	-	-
(e) staff costs*	(1,570)	(3,915)
(f) administration and corporate costs	(1,029)	(2,717)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(70)	(419)
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	2,268	(2,575)

*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	(13)	(22)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (9 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	(13)	(31)

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)	(243)	(922)
3.10	Net cash from / (used in) financing activities	(243)	2,967

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (9 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	1,379	3,015
4.2	Net cash from / (used in) operating activities (item 1.9 above)	2,268	(2,575)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(13)	(31)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(243)	2,967
4.5	Effect of movement in exchange rates on cash held	(25)	(10)
4.6	Cash and cash equivalents at end of period	3,366	3,366

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	3,366	1,379
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)	3,366	1,379

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	292
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	2,606	-
7.4	2,606	-
7.5	Unused financing facilities available at quarter end	
		2,606
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 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\$0.6516.</p>	

8. Estimated cash available for future operating activities	US\$'000
8.1	2,268
8.2	3,366
8.3	2,606
8.4	8,240
8.5	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: The second payment of US\$5.0m under the IP Agreement with Hologic is due 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: This improvement in cash receipts from customers will provide a significant boost to operating cash flow, and funds available to the company.

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: **23 April 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.