



ASX ANNOUNCEMENT

Lumos Diagnostics Quarterly Activity Statement and Cash Flow Report

Key Highlights from the Second Quarter of Financial Year 2025

- **Unaudited revenue of US\$2.9 million for the quarter**, up 71% compared to the prior corresponding period (PCP) (Q2 FY24 - US\$1.7 million).
- **Product revenue** was up 200% over Q2 last year and **Services revenue** was up 53% on PCP.
- **Successfully completed retail entitlement component** on 8 October 2024 (A\$6.9 million) of A\$10.0 million capital raise, strongly supported by new and existing shareholders, Tenmile and Ryder Capital.
- **Signed partnership agreement with BARDA** for US\$3.0 million in non-dilutive funding to support FebriDx CLIA waiver trial in the US, with funding options to expand to US\$8.3 million.
- **CPT PLA procedure code approval** for FebriDx in the US – reimbursement rate of US\$41.38 per test.
- **FebriDX CLIA Waiver study commenced** 19 December 2024 – first patient tested.
- **Cash balance of US\$5.5 million** as at 31 December 2024, prior to receipt of BARDA milestone payments of US\$0.9 million in January 2025. Proforma cash balance of US\$6.4 million.
- **Operating cash outflow of US\$3.7 million**, including cash receipts of US\$1.9 million with the next Hologic milestone payments expected in Q3.

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

MELBOURNE, Australia (31 January 2025) – 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 FY25 (the three months ended 31 December 2024).

Operational Update

Lumos recorded unaudited revenue of US\$2.9 million for the quarter ended 31 December 2024, up 71%, compared with Q2 FY24 (Q2 FY24: US\$1.7 million).

Revenue generated during the quarter from the Services business was US\$2.3 million, up 53% on Q2 FY24, with the majority of revenue derived from the Hologic fFN Development Agreement and the Intellectual Property licensing revenue associated with the Hologic IP Agreement, as announced to the ASX on 11 January 2024.

Revenue from Products business during the quarter was US\$0.6 million, which was up 200% on PCP (Q2 FY24: US\$0.2 million). The majority of revenue generated during the period was from ViraDx sales, with some sales contributions from FebriDx and the Binx product that Lumos distributes.

Development Services and Contract Manufacturing Division

Lumos generated US\$2.3 million from the provision of diagnostic test and custom reader development services, contract manufacturing and IP license revenue during the December quarter. Development services included ongoing project work for Hologic, Burnet Diagnostics Initiative and other customers.

Hologic

On 11 January 2024, Lumos announced an IP and Development agreement with Hologic, a leading global women's health provider, to develop the next generation of Hologic's on-market fFN diagnostic product for pre-term birth, for which Hologic is the only global manufacturer. 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 – first of two Phase 2 milestones completed; second in progress; and
- Phase 3 - System Prototype Delivery: deliver a working prototype of the system - US\$3.7 million – first of six Phase 3 milestones is in progress.

The second of the two milestones relating to Phase 2 is progressing well and is expected to complete around April 2025.

Due to some small delays on the project so far, the estimate for the total project timeline has increased by a further four months from 20 to 24 months (now running from January 2024 to December 2025). From a financial reporting perspective for Lumos, this will reduce the monthly revenue recognition rate of the Intellectual Property Agreement (US\$10.0 million upfront payment) from US\$0.50 million to US\$0.37

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million per month, and reduce the revenue recognised from the Development Agreement from US\$0.24 million per month to US\$0.17 million, over the remaining period, from October 2024. As such, the total impact on Q2 versus Q1 revenue recognised from the Development and IP Agreements was a reduction of \$0.59 million for the quarter.

Burnet Diagnostics Initiative (BDI)

On 26 August 2024, Lumos announced an extension of its existing agreement with Burnet Diagnostics Initiative (BDI) to manufacture a lateral flow test developed at the BDI and develop and manufacture customised Lumos readers to monitor liver function in an upcoming US based clinical trial. As part of this engagement, Lumos will perform development, regulatory and manufacturing services over a 9 - 12 month period, generating fees between US\$0.7 million and US\$1.0 million.

By the end of December 2024, Lumos had successfully transferred the BDI Alanine Transaminase (ALT) lateral flow test formula into its Carlsbad, California manufacturing site and begun production of ALT test kits for BDI. Lumos had also completed customization activities to its existing camera reader platform and started manufacturing readers for the BDI liver function test. BDI's US based clinical trial is expected to start in February 2025 and is likely to be expanded into Australian clinical trials later in 2025.

Products Division

Lumos generated US\$0.6 million from the sale of products during the quarter, an increase of 100% on the previous quarter and 200% on the prior corresponding period. The majority of the sales revenue primarily related to ViraDx sales in the US. FebriDx also made a contribution to sales, from international customers and gained some initial sales traction in the US during the 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 United States, UK, Europe, Canada, UAE and Australia. During the quarter, FebriDx achieved a number of pivotal milestones.

Lumos and BARDA to Partner to Support FebriDx® bacterial/non-bacterial point-of-care test CLIA Waiver Study and Application: On 3 October 2024, Lumos announced it had been awarded US\$3.0 million in non-dilutive funding from the Biomedical Advanced Research and Development Authority (BARDA) (US) to support the FebriDx® CLIA waiver study and US FDA application. Payments of up to US\$3.0 million will be subject to achieving agreed milestones.

BARDA will support the CLIA waiver study, comparing test usage among untrained users in a CLIA waived setting to trained users, and also provide regulatory expertise and support for the application to obtain a CLIA-waiver from the US FDA.

The partnership aims to expand authorized testing to CLIA-waived, point-of-care settings, including U.S. physician offices, urgent care clinics, or other outpatient clinics, where empiric antibiotic prescription is

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common practice. Lumos anticipates that CLIA waiver authorization will expand the US addressable market opportunity by up to 15 times, to more than US\$1.0 billion.

A further option contained in the BARDA agreement, if exercised, to conduct a pediatric study for the authorized use of FebriDx in children under 12 years of age in the US, valued at US\$5.3 million, would increase the total awarded contract value to US\$8.3 million.

Lumos Diagnostics Commences FebriDx CLIA Waiver Study: Lumos commenced the pivotal FebriDx CLIA waiver study in the United States, with the first patient successfully tested on 19 December 2024. It is anticipated between 500 – 800 patients will need to be enrolled across at least six sites to achieve the required 120 positive bacterial cases for the study. Completion of the study is anticipated by the forthcoming US spring season of 2025.

Official study commencement and first patient tested triggered the first two milestone payments under the BARDA partnership, valued at a total of US\$0.9 million. This payment was received in January 2025. The next milestone payment of US\$0.3 million will be triggered upon the testing of the 500th patient.

CPT PLA Procedure Code Approval Received for FebriDx in the US: On 5 December 2024, Lumos received approval from the Centers for Medicare and Medicaid Services (CMS) Panel for the FebriDx Proprietary Laboratory Analyses (PLA) code 0442U, to be reimbursed at a rate of US\$41.38 per test. The FebriDx PLA code has been published on the Clinical Lab Fee Schedule and takes effect on January 1, 2025.

The PLA code, issued by the American Medical Association, will play a vital role in securing reimbursement for FebriDx from both government and private insurers. Lumos is now engaging with US private and government payers, as well as other key stakeholders, to establish reimbursement and coverage policies. This process is a critical step towards enhancing FebriDx's accessibility and adoption and by making it more affordable, is expected to facilitate broader use of the test over time.

Post Reporting Date: In January 2025, Lumos announced the partnership with MedPro Associates for national contract sales coverage across hospital and primary care markets in the US. MedPro's national team of more than 60 territory representatives will provide sales representation, training, and in-servicing for the FebriDx test in the US. Lumos has completed the launch and training activities for the entire MedPro organization during January and field activity is already positive.

Also in January, the U.S. Defense Logistics Agency (DLA) awarded FebriDx a Distribution and Pricing Agreement (DAPA) under the DLA Troop Support Medical Supply Chain Acquisition Program. This agreement authorizes FebriDx sales representatives to promote the product to the U.S. Military Services; however, it does not guarantee procurement.

Looking ahead, Lumos anticipates FebriDx will be added to the DLA's Electronic Catalog (ECAT) around May 2025, with inclusion in the Federal Supply Schedule (FSS) expected by August 2025. The FSS listing will provide Veterans Administration (VA) hospitals with the ability to purchase FebriDx directly, though they will also have the option to procure it through the DAPA in the interim.

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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.

ViraDx contributed the majority of product sales during the quarter, with stocking orders received in October in preparation for the upcoming flu season. Subsequently, the US flu season has commenced some 6 – 8 weeks later than expected, which had an impact on product sales in November and December. With the US flu season now underway, we anticipate robust sales for ViraDx across the third quarter of FY25.

The US market is experiencing growing competition from international organizations, with aggressive pricing, however, ViraDx continues to see an increase in new customer adoption due to the rise in infection rates.

Retail Component of A\$10.0 million Equity Raise Completed 8 October 2024

Lumos successfully completed the 1 for 1.82 pro rata accelerated non-renounceable retail entitlement component on 8 October 2024, raising A\$6.9 million. This was in addition to the A\$3.1 million placement to institutional and sophisticated investors, which completed on 6 September 2024, bringing the total capital raise to A\$10.0 million.

The capital raise was strongly supported by new shareholder, Tenmile, (owned by Tattarang, one of Australia's largest private investment groups) and long-term shareholder, Ryder Capital.

The capital raised (after deduction of the costs associated with equity raise) is being used to fund the FebriDx CLIA waiver trial in the United States, product development, sales and marketing activities, and working capital requirements (especially related to building for the US flu season).

Summary of Cash Receipts and Outflows

Lumos generated cash receipts from customers of US\$1.9 million for the second quarter, ended 31 December 2024, which were up 66% on Q1 FY25.

Cash operating expenses increased by 54% over Q1 FY25, due to payments associated with medical affairs and clinical trial costs, investment in working capital in preparation for the US flu season and other general operating costs. The net operating cash outflow for Q2 FY25 was US\$3.7 million.

After including the proceeds, from the retail component, from the recent capital raise received during the quarter, capital expenditure (which was minimal) and lease payment expenses, net cash inflows for the quarter totaled US\$0.3 million.

Lumos finished Q2 FY25 with a cash balance of US\$5.5 million. This balance was prior to the payments from BARDA of US\$0.9 million, which were received in January, and represent a refund of costs incurred by Lumos in Q1 and Q2. On a pro-forma basis, including BARDA payments, as at 31 December 2024, cash would be US\$6.4 million. It should also be noted that the decline in AUD against the USD had a negative impact

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on closing cash of US\$0.4 million (as most proceeds from the retail component of the capital raise are held in AUD). If the AUD appreciates against the USD in future, this will increase the amount of USD available to Lumos.

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\$339,000 comprising directors' fees, consulting fees, salary & wages and superannuation.

Key Priorities

As outlined at the November 2024 Annual General Meeting, Lumos' priorities for FY2025 are as follows:

- Monetize the Lumos-owned, cleared point-of-care test products: FebriDx and ViraDx, through sales, licenses and partnerships;
- Complete a successful CLIA waiver trial for FebriDx in the US, and achieve FDA label extension;
- Continue to build the foundation for long-term growth through strategic partnerships, and delivering on milestones relating to the Hologic fFN development agreement; and
- Initiate product development on Lumos branded women's health diagnostics tests.

In closing, CEO, Doug Ward noted: *“The progress achieved by the Company this quarter, particularly with FebriDx, has been highly encouraging and marks a significant step forward. Securing a reimbursement rate of US\$41.38 per test will make FebriDx much more accessible to the broader US population, empowering patients to seek better health outcomes. While there is still work to be done to unlock substantial financial returns, the foundations are being firmly established.*

Negotiations with public and private payers to finalize reimbursement policies and procedures are underway. Additionally, with the support of our valued partner, BARDA, we initiated the CLIA waiver study in late December 2024. By the US Spring 2025, we anticipate being ready to submit an application to the FDA—a critical milestone in bringing FebriDx to even more patients.

I'm also pleased to share that our collaboration with Hologic continues to drive innovation, particularly with the new fFN test. Phase 2 of the project is nearing completion, and we are progressing with the milestones under Phase 3.

With the successful recent capital raise, along with a strong pipeline of projects and partnerships, the Company is well-positioned for continued growth and success.”

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Investor Briefing

The Company invites investors and analysts to attend an online briefing on Wednesday, 5 February 2025 at 10.15am (AEDT).

During the briefing, Chief Executive Officer, Doug Ward and Chief Financial Officer, Barrie Lambert will present an overview of the results and discuss recent progress. This will be followed by a Q+A session.

Participants can pre-register ahead of time via the following link:

https://us02web.zoom.us/webinar/register/WN_v9-IXNkeQeS6lXOLiAUYCQ

Once the registration form is completed, investors will receive a confirmation email with details on how to access the briefing. If you would like to ask a question during the briefing, please send your question ahead of the session to: george.kopsiaftis@irdepartment.com.au.

The Lumos team looks forward to welcoming those shareholders and potential investors who are able to attend.

-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 December 2024

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (6 months) US\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,936	3,009
1.2 Payments for		
(a) service delivery, research and development	(936)	(1,723)
(b) product manufacturing and operating costs	(1,187)	(2,025)
(c) sales, advertising and marketing	(425)	(742)
(d) medical affairs and clinical trial costs	(514)	(514)
(e) leased assets	-	-
(f) staff costs*	(1,637)	(2,984)
(g) administration and corporate costs	(849)	(1,169)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	20	39
1.5 Interest and other costs of finance paid	(149)	(300)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	93
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(3,741)	(6,316)

*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)	(17)
(d) investments	-	-

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Consolidated statement of cash flows		Current quarter US\$'000	Year to date (6 months) US\$'000
	(e) intellectual property	-	-
	(f) other non-current assets (including capitalised product development costs)	-	-
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)	(17)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	4,698	6,765
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	(410)	(543)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other:		
	Lease payments (principal component)	(226)	(438)
3.10	Net cash from / (used in) financing activities	4,062	5,784

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (6 months) US\$'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,672	6,479
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,741)	(6,316)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(13)	(17)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	4,062	5,784
4.5	Effect of movement in exchange rates on cash held	(448)	(398)
4.6	Cash and cash equivalents at end of period	5,532	5,532

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	5,532	5,672
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)	5,532	5,672

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	339
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. 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)	2,486	-
7.4	Total financing facilities	2,486	-
7.5	Unused financing facilities available at quarter end		2,486
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.</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\$0.6214.</p>		

8.	Estimated cash available for future operating activities	US\$'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,741)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,532
8.3	Unused finance facilities available at quarter end (item 7.5)	2,486
8.4	Total available funding (item 8.2 + item 8.3)	8,018
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	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: 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 January 2025**

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.