



ASX ANNOUNCEMENT

Lumos Diagnostics Quarterly Activity Statement and Cash Flow Report

Key Highlights from the First Quarter of Financial Year 2025

- **Unaudited revenue of US\$3.4 million for the quarter**, up 209% compared to the prior corresponding period (pcp) (Q1 FY24 - US\$1.1 million).
- **Product revenue** was up 200% over Q1 last year and **Services revenue** was up 210% on the pcp.
- **Successfully completed A\$10.0 million capital raise**, strongly supported by new and existing shareholders, Tenmile and Ryder Capital.
- **Cash balance of US\$5.7 million as at 30 September 2024**, prior to receipt of Retail Offer Proceeds of A\$6.9 million.
- **Operating cash outflow of US\$2.6 million**, including cash receipts of US\$1.2 million with the next Hologic milestone payment expected in Q2.
- **New and expanded FebriDx distributor agreements** with leading distributors, Henry Schein, Thermo Fisher and MediGroup.
- **Post reporting date** 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.

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

MELBOURNE, Australia (29 October 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 first quarter of FY25 (the three months ended 30 September 2024).

Successful A\$10 million Equity Raise Completed

Between September and October 2024, Lumos successfully completed a A\$10.0 million equity raise, comprising an A\$3.1 million placement to institutional and sophisticated investors, which completed on 6 September 2024, plus an A\$6.9 million, majority underwritten, 1 for 1.82 pro rata accelerated non-renounceable entitlement offer, which completed on 8 October 2024.

The capital raise was strongly supported by new shareholder, Tenmile, (owned by Tattarang Pty Ltd, 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 expected to be used to fund the FebriDx CLIA waiver trial in the United States, product development, sales and marketing activities and working capital requirements.

An updated list of the Top 20 shareholders can be found in Appendix 1.

Post Reporting Date

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 coming FebriDx® CLIA waiver study and US FDA application. Payments 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 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 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 agreement, if exercised, to conduct a pediatric study for the authorized use of FebriDx in children under 12 years of age in the US, would increase the total awarded contract value to US\$8.3 million.

Operations Update

Lumos recorded unaudited revenue of US\$3.4 million for the quarter ended 30 September 2024, up 209%, compared with Q1 FY24 (Q1 FY24: US\$1.1 million).

Revenue generated during the quarter from the Services business was US\$3.1 million, up 210% on Q1 FY24, 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.

Revenue from Products during the quarter was US\$0.3 million, which was up 200% on Q1 FY24. The majority of revenue generated during the period was from ViraDx sales, with some sales contributions from FebriDx and Binx.

Hologic Update

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 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 – first of two Phase 2 milestones achieved; second 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 completed the first of two milestones in the second phase of the Development Agreement and expects to receive the US\$0.3 million in November.

The current estimated timeframe to complete the work under the Development Agreement is around 20 months from signing the Agreements. 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.

Development Services and Contract Manufacturing

Lumos generated US\$3.1 million from the provision of diagnostic test development services and contract manufacturing during the September quarter. Development services included ongoing project work for Hologic, Burnet Institute and other customers.

In August, the Company announced an extension of its existing agreement with the Burnet Diagnostics Initiative (BDI) to produce Alanine Transaminase (ALT) lateral flow tests, customized Lumos readers and a mobile phone application for use in an upcoming US based clinical trial. This project marks the continuation of the feasibility studies conducted in 2023 to generate a prototype ALT test for evaluation with clinical specimens.

The new phase of collaboration will specifically support the production of the BDI point-of-care ALT testing system for use by healthcare professionals with high-risk patients undergoing routine liver function monitoring. High levels of ALT in the blood can indicate liver injury, possibly from a drug reaction.

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. Should this project prove successful, Lumos anticipates further supporting BDI in the next phase of trials and regulatory submissions.

US Product Sales Channel

By the end of the quarter, Lumos had expanded its agreements by four to 30 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, plus some 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 United States, UK, Europe, Canada, UAE and Australia.

During the quarter, Lumos continued to develop its distribution network for FebriDx. In July, the Company expanded its distribution agreement for FebriDx with Henry Schein, the world's largest provider of healthcare solutions to office-based dental and medical practitioners to include Australia, New Zealand and Belgium, in addition to Portugal, Spain, the Netherlands, the United Kingdom, and the United States.

In September, an agreement with Fisher Healthcare, a part of Thermo Fisher Scientific, was signed for the distribution of FebriDx® in the United States. This was followed by the awarding of FebriDx®, on the MediGroup national contract, the single largest non-acute care group purchasing organization (GPO) in the United States, making it available to all its members.

As we enter the northern hemisphere flu season Lumos will leverage its distribution and customer partnerships that have been established to-date.

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 strong stocking orders in preparation for the upcoming flu season. We anticipate significant sales growth for ViraDx as we approach the 2024/2025 respiratory infection season.

Summary of Cash Receipts and Outflows

Lumos generated cash receipts from customers of US\$1.2 million for the quarter ended 30 September 2024. Receipts were down 13% on Q1 FY24, and down from US\$7.4 million received in the previous quarter, which 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.

Cash operating expenses decreased by 1% on Q1 FY24, resulting in a net operating cash outflow of US\$2.6 million, a 5% decline on the pcip.

After including the part proceeds, from the institutional component, from the recent capital raise received during the quarter and lease payment expenses, net cash outflows totaled US\$0.8 million.

Lumos finished Q1 FY24 with a cash balance of US\$5.7 million. On a pro-forma basis, as at 30 September 2024, this will increase to around US\$9.8 million (after the receipt of the A\$6.9 million retail offer component, and after paying costs associated with the capital raise).

In closing, CEO, Doug Ward noted: *"We are incredibly excited about the progress we've made in growing the distribution channels for FebriDx, expanding partnership agreements with Henry Schein and signing new agreements with leading healthcare distributors like Fisher Healthcare and MediGroup, in the US.*

This growing network will help increase market penetration for FebriDx, especially if we can successfully complete the pivotal CLIA Waiver study, now supported by BARDA. This study is a critical step toward unlocking substantially larger addressable market opportunities for FebriDx in the U.S., and we look forward to its potential to greatly expand our reach in point-of-care settings.

In addition, recent progress across our Development Services projects, including the continued work with Hologic and the Burnet Diagnostics Initiative, highlights the growing demand for our expertise in diagnostic test development, utilization of our reader intellectual property, and manufacturing. Our successful extension of the BDI collaboration and the advancements with Hologic, position Lumos as a key partner in bringing innovative healthcare solutions to market.

I want to extend my sincere gratitude to our new shareholder, Tenmile, and our long-standing partner, Ryder Capital. We deeply appreciate both groups' strong support during the recent capital raise and look forward to a lasting and successful partnership. Our thanks also go to all shareholders who participated in the entitlement offer and who continue to show support in other ways.

With a strong pipeline of projects and partnerships and balance sheet strength, supported by the recent capital raise, we are well-positioned for continued growth and success."

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\$222,000 comprising directors' fees, consulting fees and superannuation.

Key Priorities

The key focus for Lumos can be summarized as follows:

For the Service business, to build a sustainable and growing pipeline of commercial, revenue-generating projects for both 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 recent capital raise provides funds for Lumos to initiate product development on a new women's health diagnostic test in the point-of-care, rapid test market.

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.

Annual General Meeting

Shareholders are reminded that the Company's AGM is scheduled to be held virtually on 14 November 2024 at 9:00am (AEDT). Please refer to the Notice of Meeting that was announced on 14 October 2024. If shareholders have any questions, please contact the Company Secretary via email at cosec@lumosdiagnostics.com.

-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 1

LUMOS DIAGNOSTICS HOLDINGS LIMITED

ORDINARY FULLY PAID SHARES (Total)

Top Holders - As Of 25 October 2024

Rank	Name	Units	% Units
1	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	166,533,362	22.33
2	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	85,813,030	11.51
3	RYDER INVESTMENT MANAGEMENT PTY LTD	38,359,752	5.14
4	RYDER CAPITAL MANAGEMENT PTY LTD	32,021,878	4.29
5	PALM BEACH NOMINEES PTY LIMITED	25,180,891	3.38
6	PLANET INNOVATION HOLDINGS LTD	23,021,060	3.09
7	CITICORP NOMINEES PTY LIMITED	18,139,570	2.43
8	GZ FAMILY HOLDINGS PTY LTD <GZ FAMILY A/C>	11,860,707	1.59
9	MR LAWRENCE WING MING HO + MRS YING HO <L&Y FAMILY SUPER FUND A/C>	11,000,000	1.48
10	SPICEME CAPITAL PTY LTD	10,000,000	1.34
11	MR JORDAN EDWARD DUNCAN WHICKER	6,400,000	0.86
12	MR KENNETH GRAHAM MILLER	5,398,165	0.72
13	CITY COMFORT PTY LTD	5,273,573	0.71
14	BNP PARIBAS NOMS (NZ) LTD	5,000,000	0.67
15	MR GARRY TEMPLE	4,934,697	0.66
16	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAILCLIENT>	4,880,282	0.65
17	MR ROBERT JULIAN CONSTABLE + MRS JANET MARIE CONSTABLE	4,633,000	0.62
18	BOWVALE INVESTMENTS PTY LIMITED <BOWVALE INVESTMENTS S/F A/C>	4,312,095	0.58
19	PARANJI SUPER FUND PTY LTD <PARANJI SUPERFUND A/C>	4,000,000	0.54
20	RICHFAST PTY LTD <NEIL SCOTNEY SUPER FUND A/C>	3,750,000	0.50
Totals: Top 20 holders of ORDINARY FULLY PAID SHARES		470,512,062	63.09%
Total Remaining Holders Balance		275,247,975	36.91%
Total Ordinary Fully Paid Shares		745,760,037	100.0%

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 2024

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (3 months) US\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,166	1,166
1.2 Payments for		
(a) service delivery, research and development	(787)	(787)
(b) product manufacturing and operating costs	(836)	(836)
(c) sales, advertising and marketing	(317)	(317)
(d) leased assets	-	-
(e) staff costs*	(1,347)	(1,347)
(f) administration and corporate costs	(322)	(322)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	19	19
1.5 Interest and other costs of finance paid	(151)	(151)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(2,575)	(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	(4)	(4)
(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)	-	-
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	(4)	(4)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	2,067	2,067
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	(133)	(133)
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)	(212)	(212)
3.10	Net cash from / (used in) financing activities	1,722	1,722

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (3 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	6,479	6,479
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,575)	(2,575)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(4)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,722	1,722
4.5	Effect of movement in exchange rates on cash held	50	50
4.6	Cash and cash equivalents at end of period	5,672	5,672

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	5,672	6,479
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)	5,672	6,479

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	222
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.</i> <i>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)	2,769	-
7.4	Total financing facilities	2,769	-
7.5	Unused financing facilities available at quarter end		2,769
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. 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). 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. 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. Amounts shown above are for Tranche 2 based on an FX rate of A\$1.00 : US\$0.6922.		

8.	Estimated cash available for future operating activities	US\$'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,575)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,672
8.3	Unused finance facilities available at quarter end (item 7.5)	2,769
8.4	Total available funding (item 8.2 + item 8.3)	8,441
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.3x
<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: **29 October 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.