**ASX ANNOUNCEMENT**

# Lumos Diagnostics Holdings Ltd Quarterly Activities and Cash Flow Report

**MELBOURNE, Australia (27 October 2021)** – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") a leader in rapid point-of-care (POC) diagnostic technologies, is pleased to release its Quarterly Activity Statement and its Appendix 4C Cash Flow Report for the quarter ending 30 September 2021.

## Key Highlights from the Quarter

- *Lumos listed on the Australian Stock Exchange (ASX) on 5 July 2021 following a successful Initial Public Offering (IPO) that raised A$63M at $1.25 per share;*
- *Commenced operations at its new manufacturing facility in Sarasota, Florida, USA that is capable of producing up to 10 million POC test strips per month;*
- *Appointed Dr Jerome Adams, immediate former U.S. Surgeon General, as a Strategic Healthcare Adviser on Lumos' Medical Advisory Board; and*
- *Two clinical and economic studies evaluating FebriDx were published in highly regarded peer-reviewed medical journals*

Lumos CEO and President, Rob Sambursky, MD commented, "We are pleased with the progress our Lumos team has made in our first quarter as a publicly listed company. Our new manufacturing facility in Sarasota, Florida, USA is designed for high-volume manufacturing and will provide an attractive, new, long-term revenue stream as we expand our portfolio of product development and manufacturing contracts. We are also delighted that Dr Jerome Adams has joined the Lumos team and we are able to leverage his extensive healthcare insights and real-world experience, particularly as the U.S. FDA actively reviews our 510(k) submission for our FebriDx® test."

### Operations Update

Lumos Diagnostics listed on the Australian Stock Exchange on 5 July 2021, raising a total of A$63 million through an IPO that included a sell-down of A$25 million by existing Lumos shareholders. The IPO proceeds available to the Company will be used to grow the business by supporting the commercial launch of FebriDx, the R&D, clinical trials and commercial launch of new Lumos-branded POC diagnostic

products, and capacity expansion, particularly in the area of diagnostic test manufacturing. The IPO was strongly supported by both Australian and offshore investors with more than 15 new institutional investors participating.

In July Lumos commenced full operations at its new manufacturing facility in Sarasota, Florida. This new facility has the capacity to produce up to 10 million POC diagnostic test strips each month and enables Lumos to offer contract manufacturing services for the products it develops on behalf of its customers, as well contract manufacturing for new customers with existing products. Lumos expects, over time, its contract manufacturing services will make an increasing contribution to group revenues and provide a growing, stable revenue base for the Company.

Lumos has 11 active R&D service programs in various stages of development, from early feasibility and development to more advanced verification, validation and transfer to manufacturing. Currently, Lumos has contracts that include 4 programs in feasibility/early development, 5 programs in development or verification, and 2 programs that successfully transferred to manufacturing.

In September, Lumos announced that Dr Jerome Adams will serve as a Strategic Healthcare Adviser to Lumos and was appointed to the Company's Medical Advisory Board. Dr Adams served as the former immediate U.S. Surgeon General from 2017-2021 and has extensive knowledge on public health, public policy and health equity. It is expected that Dr Adams will assist Lumos on the effective launch of FebriDx in the U.S. after Lumos secures regulatory clearance from the U.S. FDA, which is expected during FY22.

Lumos has continued to build both awareness and the body of data supporting the use of its FebriDx POC test for the rapid identification of patients with a viral or bacterial acute respiratory infection (ARI). For example, Lumos presented a scientific poster entitled, "FebriDx Use in Immunocompromised Patients in a Real-World Hospital Setting During The Second (COVID-19) Wave" at IDWeek, which was a virtual conference hosted by multiple organisations including the Infectious Diseases Society of America (ISDA). This quarter, Lumos also attended the American Association for Clinical Chemistry (AACC) 2021 Annual Scientific Meeting & Clinical Lab in Atlanta, Georgia, USA, as well as the Management in Practice event in London, UK and the Urgent Care Conference in Milton Keynes, UK in support of FebriDx.

During the quarter one clinical and one economic study evaluating FebriDx that evaluated FebriDx were published in highly regarded peer-reviewed medical journals. First, the British Medical Journal (BMJ) published a real-world clinical study involving 3,443 emergency department patients that concluded the Lumos FebriDx test was useful in a triage algorithm to 'rule out' COVID-19 among patient admissions and that using FebriDx reduced the need for isolations rooms by 9.5% per day. Second, the Journal of Health Economics and Outcomes Research (JHEOR) published an economic study commissioned by Lumos that highlighted significant potential savings to the U.S. healthcare system if FebriDx was used to guide the diagnoses and antibiotic treatment for all patients presenting with potential ARIs in outpatient settings.

Subsequent to the end of the quarter, the Emergency Department (ED) at Box Hill Hospital, Melbourne Australia, initiated at 300-subject real-world clinical study using FebriDx to evaluate patients presenting to the ED with suspected COVID-19 infection. This study models a similar study conducted at University Hospital Southampton, UK last year that concluded that FebriDx was highly accurate for identifying viral infections in suspected COVID-19 hospitalised adults and therefore could be deployed as a 'front door trial tool'. FebriDx is currently being evaluated in 10 investigator-led post market studies, including both outcome and clinical validation studies, across Europe and Australia.

**Regulatory Update**

The U.S. FDA is actively reviewing Lumos' 510(k) application for FebriDx for the identification of patients with bacterial or viral acute respiratory infection. Lumos is expecting an outcome from this review process during FY22 which, if successful, will allow Lumos to commence sales and marketing activities in the U.S. FebriDx already has regulatory clearance in Europe, Canada and Australia.

During the quarter, Lumos was advised that the U.S. FDA had deprioritised its Emergency Use Authorization (EUA) review for the Company's CoviDx™ rapid antigen test. CoviDx has regulatory clearance in Europe and has regulatory applications under review in Canada and Australia. Lumos is in dialogue with the FDA to recommence the CoviDx EUA review product and, in parallel, is preparing to complete the development and file an application for its ViraDx™ test that combines the COVID-19 antigen testing with a rapid antigen test for influenza A/B. Lumos' ViraDx test would specifically identify the leading ARI viral infections (COVID-19 and influenza), and potentially provide a natural follow-up test to a positive viral infection reading from FebriDx.

**Financial Update**

Lumos recorded cash receipts from customers of A$5.6M during the first quarter of FY22 and closed the quarter with cash of A$24.6M. Net cash used in operations was A$7.9M included one-off costs associated with the IPO, R&D, and investments in inventory and sales and marketing infrastructure in anticipation of the launch of FebriDx and ViraDx in FY22. The Company also had expenses during the first quarter related to capital investments and commissioning of its new manufacturing facility in Sarasota, Florida. Lumos expects its near-term net cash requirements for future quarters will be around $5.5-$6.5 million as a result of not incurring one-off expenses that occurred during the first quarter and increasing cash receipts from service contracts, manufacturing contracts and Lumos-branded product sales.

**Corporate Update**

Effective 1 October 2021 the Company has restructured their Board committees as follows:

| **Audit and Risk** | **Remuneration and Nomination** | **Disclosure Committee** |
|---|---|---|
| Catherine Robson (Chair) | Catherine Robson (Chair) | Bronwyn LeGrice (Chair) |
| Bronwyn Le Grice | Bronwyn Le Grice | Rob Sambursky |
| Sam Lanyon | Lawrence Mehren | Sam Lanyon |

**Payments to Related Entities**

In Section 6.1 of the Appendix 4C lodged this quarter, the Company discloses payment to related entities of $188,000. This includes $50,000 in payment to the CEO and President in line with Dr Sambursky's employment contract.

**Use of Funds Table**

| Use of Funds | Per Prospectus | Use of Funds to 30 September 2021 |
|---|---|---|
| | $m | $m |
| **Infrastructure and Capacity Expansion** | 5.8 | 2.1 |
| **Sales and Marketing** | 8.4 | 1.4 |
| **Regulatory, Clinical and Quality** | 3.7 | 0.9 |
| **Development of test pipeline** | 3.1 | 1.1 |
| **Technology platform development** | 5.4 | 0.6 |
| **Working Capital** | 7.0 | 1.6 |
| **Offer Costs** | 4.6 | 4.1 |
| **TOTAL** | **38.0** | **11.8** |

**Outlook and Future Activities**

The balance of the year is anticipated to be marked by increasing contributions from contract manufacturing and emphasis on Lumos-branded product sales, leading to a more diversified revenue mix. Investments in Lumos facilities provide opportunities for broader engagement with clients by offering complete development and manufacturing solutions. Lumos will continue to engage with new and existing clients to build out its contract development and manufacturing opportunities and will expand its operational footprint as needed to support the continued growth of the Company.

FebriDx U.S. commercialisation following U.S. FDA 510(k) clearance is anticipated in FY 2022 along with the follow-on publication of clinical trial results. In anticipation of this market access, Lumos will continue to build its U.S. commercial infrastucture, multispecialty medical advisory boards, specialty regional distribution partnerships, and solidify milestones to support Medicare and 3rd party reimbursement. Further, the ability to supply additional synergistic tests to FebriDx through existing sales channels, such as for CoviDx and ViraDx, will enhance market adoption.

**About Lumos Diagnostics**

*Lumos Diagnostics specialises in rapid, cost-effective, and complete point-of-care (POC) diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customised assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercialises novel Lumos-branded POC tests that target infectious and inflammatory diseases.*

*For more information visit lumosdiagnostics.com or febridx.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** | **Quarter ended ("current quarter")** |
| 66 630 476 970 | 30 September 2021 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (3 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | 5,590 | 5,590 |
| 1.2 | Payments for | | |
| | (a) research and development | (5,135) | (5,135) |
| | (b) product manufacturing and operating costs | (4,053) | (4,053) |
| | (c) advertising and marketing | (227) | (227) |
| | (d) leased assets | - | - |
| | (e) staff costs* | (748) | (748) |
| | (f) administration and corporate costs | (3,080) | (3,080) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | - | - |
| 1.5 | Interest and other costs of finance paid | (206) | (206) |
| 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** | **(7,859)** | **(7,859)** |

*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 | (2,093) | (2,093) |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (3 months) $A'000 |
|---|---|---|---|
| | (f) other non-current assets (capitalised development costs) | (877) | (877) |
| 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** | **(2,970)** | **(2,970)** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | - | - |
| 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 | (584) | (584) |
| 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: | | |
| | Sell-down of shares to Planet Innovation | (23,388) | (23,388) |
| | Lease payments | (490) | (490) |
| **3.10** | **Net cash from / (used in) financing activities** | **(24,462)** | **(24,462)** |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (3 months) $A'000 |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 59,710 | 59,710 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (7,859) | (7,859) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (2,970) | (2,970) |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | (24,462) | (24,462) |
| 4.5 | Effect of movement in exchange rates on cash held | 166 | 166 |
| **4.6** | **Cash and cash equivalents at end of period** | **24,585** | **24,585** |

| 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 $A'000 | Previous quarter $A'000 |
|---|---|---|---|
| 5.1 | Bank balances | 24,585 | 59,710 |
| 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)** | **24,585** | **59,710** |

| 6. | Payments to related parties of the entity and their associates | Current quarter $A'000 |
|---|---|---|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 188 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | - |

*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.*

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **Total facility amount at quarter end $A'000** | **Amount drawn at quarter end $A'000** |
|---|---|---|---|
| 7.1 | Loan facilities | | |
| 7.2 | Credit standby arrangements | | |
| 7.3 | Other (please specify) | | |
| 7.4 | **Total financing facilities** | | |

| | | |
|---|---|---|
| 7.5 | **Unused financing facilities available at quarter end** | |
| 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. | |

| 8. | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (item 1.9) | 7,859 |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 24,585 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 24,585 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 3.13 |

*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.*

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: **27 October 2021**

Authorised by: **The 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.