



ASX ANNOUNCEMENT

Lumos Diagnostics FY22 – First Half Year Results

HIGHLIGHTS

- *Half year revenue of US\$5.2 million (v US\$8.4 million pcp);*
- *Commercial services revenue US\$4.2 million (v US\$7.2 million pcp);*
- *Product sales revenue of US\$1.1 million (v US\$1.3 million pcp) from sale of Lumos-branded CoviDx™ and FebriDx® tests in approved markets;*
- *CoviDx™ granted Interim Order authorization by Health Canada and initial commercial orders received and fulfilled in December;*
- *FebriDx® application for regulatory clearance in the U.S. remains on track for decision from the FDA in H2 FY2022.*
- *Cash 31 December 2021 US\$10.5 million*

Melbourne, VIC. (28 February 2022) - Lumos Diagnostics (ASX:LDX, “Lumos” or the “Company”), a leader in rapid point-of-care (POC) diagnostic technologies, today has announced its financial results for the FY2022 half year ending 31 December 2021.

“The demand for new diagnostic test development returned closer to historical growth rates following the unprecedented demand we experienced when the pandemic was in its earlier stages,” said Sam Lanyon, Executive Chairman of Lumos Diagnostics. “While this has resulted in a decline in our Commercial Services revenue from development services, on a like-for-like basis, we have started to see a growing contribution from the sale of our own products and increases in the commercial manufacturing contracts towards the end of the first half. This momentum has continued to build in the current half year, and we fully expect the contribution from these areas to be evident in the full year result.”

H1 FY2022 Results Commentary

Lumos Diagnostics recorded revenues of US\$5.2 million (US\$8.4 million pcp) with the decline primarily attributed to lower revenues from the Services business (US\$4.2 million v US\$7.2 million pcp) as a result of

Lumos Diagnostics Holdings Limited
ACN: 630 476 970

Level 4, 100 Albert Road, South Melbourne VIC 3205 | T: 03 9692 7222



lower demand for the development of new tests than was experienced in the earlier stages of the COVID-19 pandemic. Product sales revenues for the half-year were US\$1.1 million (US\$1.3 million pcp) generated from the sale of FebriDx® and CoviDx™ in markets where they have regulatory clearance.

Lumos has a 510(k) application with the U.S. Food and Drug Administration (FDA) for the regulatory clearance of FebriDx® in the U.S. Based on the feedback and interactions with the FDA to date, Lumos believes it remains on track to have a decision from the FDA on this application during 2H FY2022.

FebriDx® generated sales revenue in UK, Germany and Canada while Lumos' COVID-19 antigen test, CoviDx™, commenced sales with initial orders from Canada following the Interim Order authorization that was granted in November 2021. Momentum for these orders has continued with US\$5.0 million in signed purchase orders received during January 2022.

During 1H FY2022, Lumos' Services generated US\$4.2 million of revenue (2020: US\$7.2 million) from the provision of diagnostic test development and manufacturing services to its clients. The reduction in revenue compared with 1H FY2021 reflects the extraordinary demand for diagnostic test development services that was experienced in 1H FY2021 due to the COVID-19 pandemic. Lumos took advantage of the high demand experienced during 1H FY2021 as an opportunity to further expand its operations in the contract manufacturing of diagnostic tests. Lumos will use this manufacturing capacity for the production of its own diagnostic test products as well as contract manufacturing of its clients' products.

During 1H FY2022, Lumos' Services had eleven active R&D service programs in various stages of development, from early feasibility and development to more advanced verification, validation and transfer-to-manufacturing.

Statutory Financial Results (Summary)		
US\$ in millions	1H FY2021	1H FY 2022
Total revenue	\$8.4	\$5.2
Gross profit	\$4.7	\$2.4
Total Operating Expenses	(\$8.0)	(\$13.5)
Net loss for the year	(\$3.3)	(\$11.1M)

Matters subsequent to the end of the financial half-year

In January 2022, NHS (National Health Service) Liverpool Clinical Commissioning Group and Community Pharmacy Liverpool announced the launch of a new clinical service called "Pharmacy First" that includes the use of Lumos' FebriDx® test to differentiate bacterial from viral respiratory infections in patients.



In February 2022, Lumos advised that the Victorian State Government had announced its intention to provide support for Lumos to establish a A\$17.2 million Diagnostics Manufacturing Facility and Innovation Hub. For this project to proceed to the next step of finalise binding legal agreements, Lumos needs to secure approval from the Therapeutics Goods Administration (TGA) for the over-the-counter/self-test use of its CoviDx™ test. The Company has an application with the TGA aimed at securing the necessary approvals to market CoviDx™ in Australia.

FY 2022 Outlook

During 2H FY2022 Lumos' management team will continue to focus on the Company's key growth areas; namely expanding and diversifying the revenue streams from both its Commercial Services and Products business.

For its Products business, Lumos will continue to focus on securing regulatory clearances for each of its three commercial-ready products (FebriDx®, CoviDx™ and ViraDx™). Once regulatory clearances have been secured, Lumos intends initiate direct and distributor-based commercial sales of those cleared products in relevant geographic markets. A key focus for the company during 2H FY2022 is securing regulatory clearance from the FDA to market FebriDx® in the US. Plans for the anticipated commercial launch of this product, subject to receiving this clearance, have already been developed. In Australia, Lumos is actively working to secure regulatory approval for the over-the-counter (OTC) use of CoviDx™. Regulatory applications for Lumos's ViraDx™ are also underway in the U.S. and Canada with decisions expected during H2 FY2022, subject to the timelines of the relevant regulatory bodies.

Lumos will continue to build and expand its Commercial Services business by securing new development service partnerships and expanding the services and works it provides to existing partnerships. This includes transferring product development projects conducted by Lumos into manufacturing which has the potential to provide ongoing manufacturing revenue streams. In addition, Lumos will aim to leverage its newly established manufacturing capacity to secure additional commercial partnerships.

This announcement was approved by the Lumos Disclosure Committee.

###

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

Lumos Diagnostics Holdings Limited
ACN: 630 476 970

Level 4, 100 Albert Road, South Melbourne VIC 3205 | T: 03 9692 7222



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 call +61 3 9087 1598.

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.

Australia Media Contact:

Matthew Wright - Australia
Director, NWR Communications
matt@nwrcommunications.com.au
+61 (0) 451 896 420

Investor Contact:

Matthijs Smith – Lumos Diagnostics
ir@lumosdiagnostics.com
+61 411 137 080
+61 3 9087 1598

Company Registered Office:

Lumos Diagnostics Holdings Ltd
Level 4, 100 Albert Rd
South Melbourne, VIC 3205
+61 3 9087 1598

Lumos Diagnostics Holdings Limited
ACN: 630 476 970

Level 4, 100 Albert Road, South Melbourne VIC 3205 | T: 03 9692 7222