



ASX ANNOUNCEMENT

Lumos Diagnostics FY2023 Full Year Results

HIGHLIGHTS

- *Annual revenue of US\$10.5 million (FY2022: US\$11.6 million) — a decrease of 9% primarily due to reduced sales of point-of-care diagnostic products for COVID-19*
- *Commercial services revenue of US\$10.2 million (FY2022: US\$9.4 million) — an increase of 9% despite significant restructuring and consolidation of operations*
- *Established strategic partnership with leading women's health company Hologic which provided multiple commercial services projects and access to non-dilutive funding*
- *Secured clearance from FDA to market FebriDx® in the US and commenced activities to establish multi-product US sales channel*
- *Significantly expanded and diversified pipeline of commercial services projects with new and established customers for range of different applications*

Details to participate in a webinar that will be held at 11:00am on Wednesday 30 August 2023, during which CEO Doug Ward and CFO Barrie Lambert will discuss the FY2023 result and provide an update on the Company's activities, are provided at the end of this release.

Melbourne, VIC. (30th August 2023) - Lumos Diagnostics (ASX:LDX, "Lumos" or the "Company") today announces its full year results including the Appendix 4E and Annual Report to shareholders for the fiscal year ending on 30 June 2023.

In FY2023, Lumos recorded revenue of US\$10.5 million with the majority of revenue generated in the United States. Revenue from the provision of development and contract manufacturing services was US\$10.2 million, a 9% increase from FY2022 (US\$9.4 million). This was achieved during a period in which the Company completed a significant reorganisation that involved a reduction in headcount of over 60%, closure of its facility in Sarasota FL, and the consolidation of its operations to a single site in Carlsbad, CA.

Revenue from the sale of products by Lumos for FY2023 was US\$0.3 million. In line with expectations, this was materially lower than the previous year (FY2022: US\$2.2 million) which included US\$1.7 million of

pandemic related sales of the CoviDx point-of-care test. This also reflected the significant reduction in sales and marketing investment (US\$0.1 million versus US\$2.3 million) during this period that was necessary to achieve the Company's cost management goal of reducing the cash burn for the year to an average of below US\$1.0 million per month.

The Gross Profit for FY2023 was US\$6.0 million (FY2022: \$5.1 million) representing an improvement in Gross Margin from 44.2% to 56.7% due to improved profitability on commercial services projects and removal of some underlying costs as a result of the consolidation of operations. The underlying EBITDA loss for FY2023 was US\$5.4 million, which is an improvement of over 69% compared to the US\$17.7 million EBITDA loss in FY2022. As a result of the restructuring and significant cost reduction program that commenced in 2H FY2022, the net loss after tax for the financial year was reduced significantly to US\$9.0 million (FY2022: US\$45.7 million loss). The loss for FY2023 included an impairment expense totalling US\$0.7 million (FY22: US\$24.1 million), primarily relating to inventory. The underlying operating expenses for FY2023 were US\$11.9 million (FY2022: US\$22.8 million).

The establishment of deep, long-term strategic partnerships with key players in the diagnostics space is an important area of focus to drive growth for Lumos. In November 2022, Lumos announced it had secured two new service agreements with Massachusetts-based women's health company Hologic. Hologic is a leading innovator in women's health and engaged Lumos to conduct two programs of work focused on the support of an existing on market product, and the development of a commercial rapid, point-of-care test product. Lumos was entitled to receive up to US\$1.5 million in revenue for the provision of its development services on these programs. In December 2022, Lumos signed a third service agreement with Hologic with the potential to generate up to an additional US\$1.0 million in revenue for Lumos. In March 2023, Lumos signed two additional agreements with Hologic worth up to US\$1.7 million to conduct additional work on existing projects.

During the year, Lumos diversified its project pipeline beyond infectious disease applications with the signing of several new commercial services agreement. This included an initial purchase order for the manufacture of a multi-assay, rapid diagnostic cartridge to be used in combination with a customized Lumos digital reader. The Company also supplied test strips for a nutrition test for a US-based client, secured a commercial contract to develop new tests for food safety testing, commenced work on a novel molecular diagnostics platform, and a pilot project focused on the development of a new animal health product. In July 2023, Lumos announced it had secured a feasibility project with the Burnet Diagnostics Initiative to develop a product concept based on novel companion diagnostic biomarker with utility across a range of human health applications. In addition to providing new clients and projects that can provide a basis for future revenue growth, these have provided a more diversified commercial services pipeline which was previously dominated by projects focused on the development and manufacture of point-of-care diagnostic products for infectious diseases.

In 2021, Lumos filed a 510(k) application for FebriDx with the US FDA and in July 2022 was advised the FDA had decided that FebriDx did not demonstrate substantial equivalence to the predicate device that was used to support its 510(k) application. Following feedback from an appeal lodged with the FDA, and a pre-submission meeting that was held in January 2023, Lumos filed a new 510(k) application for FebriDx. In early July 2023, Lumos was informed that, based on this new application, FebriDx was cleared to be

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marketed in the US for use by healthcare professionals as an aid to diagnosing acute bacterial respiratory infections. Lumos has commenced activities to support a US launch of FebriDx, including ordering material and increasing production to meet the anticipated US demand, and expects to receive the first US commercial orders by the end of CY2023. During the year, Lumos received initial orders for FebriDx from distributors in certain European markets and the UK. In July, Henry Schein, Lumos' distributor for FebriDx in the UK, expanded its distribution coverage for FebriDx to include Spain and Portugal, and in August added the Netherlands.

During the second half of FY2023, Lumos commenced activities directed at establishing a US sales channel for point-of-care diagnostic tests. The sales channel will target the same physician offices and urgent care clinics that are relevant for Lumos' own products, including FebriDx. The additional test menu offering will improve the relevance and efficiency of the sales channel and make it economically more attractive, particularly in the early stages of developing Lumos' own product portfolio. Lumos expects to earn industry-standard distribution margins on the external party's products that it sells through this channel.

In addition to its own products Lumos is securing distribution rights for point-of-care products for women's health, STIs, and other infectious diseases. In May, Lumos secured the distribution rights for CLIA-waived, molecular, point-of-care tests for the rapid detection of chlamydia and gonorrhoea from Binx Health. It has also secured distribution rights for additional STI tests as well as influenza and COVID from three other US organisations. Lumos intends to leverage this channel to stimulate customer adoption and incorporate those same customers into its US sale strategy for FebriDx.

Corporate Developments

As part of Lumos' ongoing program to reduce its cash burn, in August 2022 the Company announced the closure of its facility in Sarasota, FL, and the consolidation of its development and manufacturing operations to Carlsbad, CA. This closure was completed within the short timeframe set internally and released Lumos from further lease obligations for the Sarasota site from 30 September 2022. Lumos was able to negotiate termination of the lease with a single, final payment of US\$0.3 million which relieved the Company from more than US\$3.1 million in future lease payment obligations plus the additional costs for running the facility. Equipment and key personnel for Lumos' manufacturing production line have been transferred and installed in Carlsbad and provide sufficient capacity, for the foreseeable future, to meet the needs of Lumos' services and products business.

In November, Lumos announced it had entered into a binding Convertible Note Agreements to raise up to A\$8.0 million in two tranches from two US-based institutional investors—SBC Global Investment Fund and Lind Global Fund II, LP. Shareholder approval to proceed with the issue of these notes was secured at the General Meeting held in December 2022. Following this approval, the first tranche of A\$4.0 million of Convertible Notes were issued in early January 2023. The agreement allowed for second tranche of A\$4.0 million of Convertible Notes to be issued subject agreement by both parties however Lumos currently does not intend to access this second tranche.

Subsequent to the end of the financial year, in July 2023, Lumos conducted a Placement that raised A\$4.75 million and a Share Purchase Plan that raised A\$0.69 million at A\$0.07 per share. Some of the proceeds from this capital raise (A\$1.58 million) were used to buy back the remaining Convertible Notes held by SBC Global Investment Fund and Lind Global Fund II, LP with the balance of proceeds to provide additional working capital for the Company.

Business Outlook

During FY24, Lumos will focus on leveraging its existing assets to drive commercial growth. A key area of focus will be on building a diversified pipeline of customer projects with a key goal on continuing to establish and build existing strategic partnerships with key industry players such as Hologic. With the increasing adoption of point-of-care testing, Lumos is well-positioned to become a partner-of-choice due to the strength of its assay development capabilities and mature proprietary reader technology platform.

The Company also intends to reinvigorate revenue opportunities from the sale of products. This includes launching FebriDx in the US with first commercial orders expected by the end of CY2023 and selling other women's health, STI and infectious disease products through the recently established US sales channel. In addition, Lumos expects to grow sales of FebriDx in Europe and other markets in light of the renewed interest in the product following the FDA clearance and the expanded distribution coverage provided by Henry Schein and other distribution partners.

This announcement has been approved by the Lumos Disclosure Committee

Webinar

Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") is pleased to invite shareholders and other interested parties to a Shareholder Webinar hosted by CEO Doug Ward and CFO Barrie Lambert discuss the FY2023 full year results and provide an update on the Company's activities.

The webinar will be held on **Wednesday 30 August 2023 at 11.00am AEST.**

For the Q&A session, investors are invited to send questions prior to the webinar to:
matt@nwrcommunications.com.au

Register for the webinar at the link below:

https://us02web.zoom.us/webinar/register/WN_92LIOoAKQDa31NSGgn0jGQ

After registering, you will receive a confirmation email containing information about joining the webinar as well as dial-in details for those who would prefer to join by phone. A recording will be available at the above link shortly after the conclusion of the live session.

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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 call +1 941-556-1850.

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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