



ASX ANNOUNCEMENT

Lumos Diagnostics FY22 Full Year Results

HIGHLIGHTS

- *Annual revenue of US\$11.6 million – 38% decrease from FY21;*
- *Commercial services revenue of US\$9.4 million – 45% decrease from FY21;*
- *Regulatory clearances for CoviDx™ and ViraDx™ granted in Canada;*
- *FebriDx® cleared for marketing in Brazil and United Arab Emirates;*
- *Experienced commercial diagnostics executive appointed as CEO;*
- *Improved cash management through ongoing cost reduction program and capital raise.*
- *Webinar to be held at 11am AEST today – [register here](#)*

Melbourne, VIC. (26th August 2022) - 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 2022.

In FY22, Lumos generated revenue of US\$11.6 million with US\$9.4 million from the provision of development and contract manufacturing services to its customers, and US\$2.2 million from the sale of Lumos’ own POC diagnostic products. As with other companies in the Point-of-Care (POC) diagnostics industry, Lumos experienced operational and commercial challenges during FY22. In particular, the changing nature of the SARS-CoV-2 pandemic and the continual emergence of new variants of concern has provided a difficult regulatory environment for new infectious disease diagnostic products – particularly as public health initiatives to manage the pandemic evolve, dynamically.

During FY21, Lumos Commercial Services experienced unprecedented demand due to a large number of customers wanting to develop new POC diagnostic tests to leverage commercial opportunities for the ongoing management of the SARS-CoV-2 pandemic. As forecasted, industry demand for diagnostic test development services re-aligned closer to pre-pandemic levels. For comparison, services revenue for FY20 was US\$5.3M. This dynamic also impacted on the transition of development projects into longer term manufacturing contracts.

Despite these challenging headwinds, Lumos Commercial Services delivered a solid, operational result during the year generating US\$9.4 million in revenue. From this base, Lumos Commercial Services is now expanding its pipeline of non-Covid commercial development and contract manufacturing projects, with the recent signing of a new contract with Aptatek and other potential partnerships in the concluding stages of negotiation. We believe this pipeline will provide a foundation for future growth leveraging Lumos' proprietary technology platform of connected readers for diagnostic tests in FY23.

A key focus for Lumos during FY22 was advancing the commercialisation of its own POC diagnostic tests. The benefits of Lumos' FebriDx[®] test as an aid to differentiate bacterial from viral infection by identifying a host immune response was recognised in key markets during the year. This reflects the growing awareness of the need for improved antibiotic stewardship in the face of increasing resistance to antimicrobial drugs – a global problem that only got worse during the SARS-CoV-2 pandemic.

FebriDx received regulatory clearance in Brazil and the United Arab Emirates. In addition, the test was incorporated in plans for the Pharmacy First trial to be conducted in Liverpool, UK, to enable rapid diagnoses and appropriate antibiotic prescribing – without the need for a general practitioner (GP) appointment first. A number of studies on FebriDx[®], including a U.S. healthcare economic study, were published in peer-reviewed journals and highlighted the international interest in this test and its utility in the clinic. In view of this, Lumos was both surprised and disappointed with the FDA's decision, announced subsequent to the end of the financial year, not to provide clearance to market FebriDx[®] in the U.S. The Company is currently working towards potentially securing U.S. clearance for FebriDx[®] through filing an appeal or a new submission.

During the year, Lumos secured authorisation to market its CoviDx[™] test in Canada. CoviDx[™] is a rapid, point-of-care test for the identification of SARS-CoV-2. Following the initial outbreak of the omicron strain of SAR-CoV-2, Lumos received and fulfilled several orders for CoviDx[™] during FY22 from its distributors and a large-scale healthcare provider, in Canada which generated US\$1.7 million in revenue in total.

With changes across the POC diagnostics industry at large, Lumos undertook an extensive operational review and cost reduction program during the year to improve its alignment with current market conditions. This resulted in a significant reduction of Lumos' operational cash burn and ensured that the Company's resources are aligned with its focused commercial and business objectives. At the end of FY22, Lumos also undertook a A\$11.2 million (US\$7.9 million) capital raising to strengthen its balance sheet.

In-light of the Company's current market capitalisation, its balance sheet, recent restructuring activities and on the advice from the company's auditors, the Company has decided to record one-off impairments and reserves totalling US\$24.1 million for the financial year FY22. The impairment of intangible assets of US\$12.6 million primarily relates to goodwill and intellectual property recorded as part of the acquisition of RPS by Lumos Diagnostics. In addition, Lumos has incurred one-off costs associated with restructure and facility rationalisation of US\$5.5 million. The remaining US\$6.0 million impairment and reserves relate to inventory write-downs, doubtful debts and financial assets.

The Lumos Board of Directors and management are satisfied that with these impairments and reserves, the Company's balance sheet reflects the current state of its financial position and that future write downs or impairments should not be expected. From this position, the business and the Company can move forward with confidence on building a resilient and growing business from a solid financial foundation.

Changes to Management and Incentives

During FY22, Rob Sambursky resigned as CEO and from the Lumos Board of Directors. Subsequent to Rob Sambursky's resignation, Sam Lanyon acted as Interim CEO until the appointment of industry veteran, Doug Ward as CEO in June 2022. With Doug Ward's appointment and strong leadership, Sam Lanyon intends to transition to a non-executive Director role on the Lumos Board following the Company's FY22 Annual General Meeting.

As part of Doug Ward's remuneration package announced to the market on 6 June 2022, he is entitled to receive 7.5 million options with an exercise price of A\$0.30 vesting over a period of 4 years. Given the importance of Doug's on-going leadership to the company, the Board intends to issue a further 3.0 million options to Doug Ward, with an exercise price determined by the 30-day VWAP from the date of grant and which vest on a pro-rata basis over a 2 year period.

In addition, as part of transitioning from an executive to non-executive Director role, the Board intends to issue a further 2.2 million incentive and retainer options to Sam Lanyon, subject to shareholder approval, with the same exercise price as those options issued to Doug Ward above and which vest on a pro-rata basis over a 2 year period.

Finally, following the Company restructure and rationalisation to focus its operations at the Carlsbad facility, the Board intends to issue a further 3.2 million incentive and retainer options to staff and senior management with an exercise price determined by the 30-day VWAP from the date of grant and which vest over a 6 – 24 month period.

All options that the Board intends to issue are within the available placement capacity for the Company.

Business Outlook

During FY23, 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 and partnerships for its Commercial Services business unit. 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.

In addition, Lumos intends to commercially progress its portfolio of Lumos-branded point-of-care diagnostics products including FebriDx[®], ViraDx[™] and CoviDx[™] through securing regulatory clearances in key markets and selling directly or via distributors.

With the recent announcement to close its Sarasota facility to consolidate its operations at the Carlsbad, CA, site, Lumos intends to maintain an ongoing focus on prudent cost management and investment directed at near-to-medium commercial opportunities.

Investor webinar – 11am AEST today

Lumos Diagnostics invites shareholders and other interested parties to a webinar hosted by Executive Chair Sam Lanyon with CEO Doug Ward and CFO Barrie Lambert discussing today's results announcement.

The webinar will be held today, Friday 26 August 2022 at 11am AEST.

For the Q&A session, investors are encouraged 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_Yq0jnwcrQfCOXr-Yz2FBtw

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

This announcement has been approved by the Lumos Disclosure Committee

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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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