ASX ANNOUNCEMENT

Lumos Diagnostics Announces CLIA Waiver Application Submission for FebriDx®

Key Highlights

- **Lumos submits its application for CLIA waiver to the U.S. FDA for FebriDx®**
- **Clinical trial data exceeds performance targets**
- **Submission triggers approximately US$1.3 million in milestone payments from BARDA and US$1.5 million FebriDx product prepayment milestone with Phase Scientific**
- **FDA feedback expected by end of Q1 CY 2026**
- **If FebriDx® receives CLIA waiver categorization, the U.S. market opportunity will expand fifteen-fold to over US$1.0 billion.**

MELBOURNE, Australia (18 August 2025) – Lumos Diagnostics Holdings Ltd (ASX:LDX, "Lumos" or the "Company") a leader in rapid, point-of-care diagnostic technologies is pleased to announce the completion of the clinical study and submission of its application to the U.S. Food and Drug Administration (FDA) for Clinical Laboratory Improvement Amendments (CLIA) waiver classification for FebriDx®.

The clinical study demonstrated a 99.1% concordance between trained and untrained operators testing bacterial positive patients, and a 98.4% concordance for non-bacterial patients. Lumos planned and executed the clinical study to demonstrate the simplicity and ease of use of the FebriDx® device and to demonstrate that FebriDx® poses insignificant risk of erroneous results in the hands of untrained users – the key metric required to achieve CLIA waived categorization.

The Company acknowledges the substantial assistance provided by its partner, the Biomedical Advanced Research and Development Authority (BARDA), in preparing and supporting the study. Having achieved the key milestones of "last patient enrolled in the study" and "CLIA waiver application submission," Lumos expects to receive combined milestones payments of US$1,253,520 shortly from BARDA. A final milestone payment of $507,377 will be triggered if the FebriDx CLIA waiver is granted.

The CLIA waiver application submission also marks the achievement of a key milestone under the distribution agreement with PHASE Scientific, triggering a US$1,500,000 FebriDx product purchase prepayment to Lumos. An additional US$5.0 million, non-refundable, pre-paid FebriDx purchase commitment is payable by PHASE Scientific upon the granting of CLIA waiver.

Doug Ward, CEO of Lumos Diagnostics, said: *"We are very pleased with the successful results of our CLIA waiver study for FebriDx® and the timely submission of our application to the FDA. This milestone represents the culmination of significant effort from the Lumos team and our partners. I'd like to extend our sincere thanks to BARDA for their substantial support in helping us achieve this outcome."*

"We look forward to receiving the FDA's findings, which we expect to receive in the first quarter of the 2026 calendar year. The anticipated granting of CLIA waiver will expand our U.S. addressable market by around 15 times to over US$1.0 billion."

This project has been funded in whole or in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number 75A50124C00051.

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This announcement has been approved by the Lumos Disclosure Committee.

About FebriDx

FebriDx® is a rapid, point-of-care test that helps healthcare professionals differentiate between bacterial and non-bacterial respiratory infections in around 10 minutes, supporting more informed clinical decision-making and potentially reducing unnecessary antibiotic prescribing.

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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