ASX ANNOUNCEMENT

Lumos and BARDA partner to undertake an additional clinical study to evaluate use of FebriDx® in U.S. CLIA-waived pediatric settings

Key Highlights

- **Lumos to commence FebriDx® pediatric study to evaluate use on 2–12 years of age in CLIA-waived settings**
- **BARDA to support study with US$6.198 million non-dilutive funding package**
- **Study launch anticipated to commence in Q3 CY2025 to run through the 2025/26 U.S. respiratory season**

MELBOURNE, Australia (1 September 2025) – Lumos Diagnostics Holdings Ltd (ASX: LDX, "Lumos" or the "Company"), a leader in rapid, point-of-care diagnostic technologies, is pleased to announce that the Biomedical Advanced Research and Development Authority (BARDA) has exercised its option to support Lumos in conducting a clinical study and regulatory submission aimed at expanding the age eligibility for FebriDx® use to include 2–12 years in Clinical Laboratory Improvement Amendments (CLIA)-waived settings (the "pediatric study").

Currently, FebriDx® is FDA 510(k)-cleared for use in patients aged 12–64 years presenting to urgent care or emergency care settings for evaluation of acute respiratory infection who have had symptoms for less than 7 days and within 3 days of fever onset. On 15 August 2025, Lumos—supported by BARDA—submitted an application to the U.S. Food and Drug Administration (FDA), seeking to expand FebriDx® use from moderately complex settings into CLIA-waived settings. If a CLIA waiver is granted, this expansion would increase Lumos' U.S. total addressable market 15-fold to over US$1 billion, providing access to 270,000 clinical sites (currently 18,000), and covering around 80 million annual acute respiratory consultations.[1,2] The proposed age eligibility extension would enable clinicians, including the 60,000 clinicians treating children 2–12 years of age, to access an additional diagnostic aid for differentiating bacterial acute respiratory infections from non-bacterial causes.

Upon the completion of the CLIA-waiver study on patients aged 12-64 years, BARDA exercised the option to commence the pediatric study and evaluate FebriDx® use on children from 2–12 years of age in CLIA-waived settings. The study is anticipated to enroll the first patient in the fall of 2025 (Q3 CY2025), with the target to complete enrolment within a single 12-month respiratory season, followed by dual 510(k)/CLIA waiver submission. The value of this option is US$6,198,459, which increases the overall total value of the contract to $9,183,030, upon completion of all milestones.

1. CMS, CLIA Database, 2024 (number of waived sites) and
2. Precision Business Insights, US Acute Respiratory Infections, 2024 (80 million annual acute respiratory consultations).

Milestone payments from BARDA to Lumos will be triggered upon the achievement of twelve milestone events, including clinical trial set-up, patient recruitment, FDA application submission, and FDA granting of 510(k) clearance and CLIA-waiver categorization for children 2–12 years of age.

Doug Ward, CEO of Lumos Diagnostics, said: *"We greatly appreciate BARDA's continued support—both in the recently completed CLIA waiver study and now in advancing this important pediatric study. We look forward to working closely with BARDA once again to deliver this study and further expand the accessibility of FebriDx® to pediatric patients across the United States."*

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 the first and only rapid, instrument free all-in-one point-of-care test utilizing fingerstick blood 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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