



## ASX ANNOUNCEMENT

### **Lumos Complete 1<sup>st</sup> Enrollment Milestone for Paediatric Study - Triggering a US\$720,000 Payment**

#### **Key Highlights**

- Lumos has completed Milestone 6 tied to total number of enrolled patients to-date in its BARDA-funded paediatric clinical study.
- Completion of the milestone triggers a milestone payment of US\$720,000.
- A total of US\$1,920,000 in milestone payments have been received for this study to-date.
- BARDA has committed non-dilutive funding total of US\$6,198,459 across the achievement of all 12 milestones within the study.
- A successful outcome will support the broadening of FebriDx<sup>®</sup>'s use in the U.S. to include patients aged 2-64 years.

**MELBOURNE, Australia (23 February 2026)** – Lumos Diagnostics Holdings Ltd (ASX: LDX, “Lumos” or the “Company”), a leader in rapid, point-of-care diagnostic technologies, is pleased to announce that it has completed an enrollment milestone (Milestone 6) in its ongoing Biomedical Advanced Research and Development Authority (BARDA)-funded paediatric clinical study.

Completion of this enrollment milestone triggers a US\$720,000 milestone payment under the Company’s contract with BARDA. Together with the previously achieved milestones, Lumos has generated a total of US\$1,920,000 in milestone payments to-date for the paediatric study. The total value of all milestone payments under this contract is US\$6,198,459 from BARDA to Lumos if all 12 milestone events, including clinical trial set-up, patient recruitment, U.S. Food and Drug Administration (FDA) submission, and FDA granting of 510(k) clearance and CLIA-waiver categorization for children, are achieved.

The study will assess the use of the FebriDx<sup>®</sup> device in children aged 2 to 12 years within CLIA-waived settings. The study is expected to run for approximately 12 months to meet statistical endpoints, following which a formal submission will be prepared for the FDA.

Currently, FebriDx<sup>®</sup> is FDA 510(k)-cleared for use in the U.S. 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 FDA, seeking to expand FebriDx® use from moderately complex settings into CLIA-waived settings. If a CLIA waiver is granted, the expansion will increase Lumos' U.S. total addressable market 15-fold to over US\$1.0 billion, providing access to 270,000 clinical sites (currently 18,000), and covering around 80 million annual acute respiratory consultations<sup>1,2</sup>.

This proposed age eligibility extension into paediatric settings would enable clinicians, including the 60,000 clinicians treating children 2 to 12 years of age, to access an additional diagnostic aid for differentiating bacterial acute respiratory infections from non-bacterial causes.

**Doug Ward, CEO of Lumos Diagnostics said:** *“Completing this enrollment milestone in our paediatric study is an important operational milestone on the path to lodging a formal submission. The team has mobilised quickly and has delivered strong enrolment momentum. We look forward to the day that we can better support clinicians in the assessment of acute respiratory infections in children through the use of FebriDx®.”*

Lumos will continue to provide updates as further milestones are achieved.

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.

**-Ends-**

***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](https://lumosdiagnostics.com).

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<sup>1</sup> CMS, CLIA Database, 2024 (number of waived sites) and

<sup>2</sup> Precision Business Insights, US Acute Respiratory Infections, 2024 (80 million annual acute respiratory consultations)

## 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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