ASX ANNOUNCEMENT

US FDA Grants CLIA Waiver for FebriDx®

Key Highlights

- **510(k) clearance with CLIA waiver for FebriDx® issued by the US FDA**
- **Triggers key milestone payments of US$5.0 million from Phase Scientific and US$0.5 million from BARDA**
- **Unlocks a US$1.0+ billion market opportunity, representing a 15x market expansion for FebriDx[1,2]**
- **Expands addressable market to approximately 80 million patients per annum[2]**
- **Allows for use in over 300,000 US locations[1]**
- **Expands applicability to primary care physician offices, urgent care clinics, retail health & pharmacy clinics and community health centres that hold a Certificate of Waiver**

MELBOURNE, Australia (27 March 2026) – The US FDA has granted a Clinical Laboratory Improvement Amendments (CLIA) waiver for Lumos Diagnostics' (ASX:LDX, "Lumos" or "the Company") flagship point-of-care test, FebriDx®, following its 510(k) clearance [K260787].

A transformative moment for the Company, the clearance and granting of the CLIA waiver triggers milestone payments of US$5.5 million under agreements with PHASE Scientific and the Biomedical Advanced Research and Development Authority (BARDA) and expands the applicability of FebriDx® to over 80 million US patients per annum and a total market opportunity of US$1.0+ billion, representing a 15-fold increase on the market opportunity prior to CLIA waiver[1,2].

Lumos has an exclusive distribution agreement for the US market for FebriDx with Phase Scientific valued at US$317 million (ASX: 16 July 2025). Under this agreement, the granting of CLIA waiver triggers an immediate payment of US$5.0 million from Phase. Additionally, Lumos will receive a US$507,377 milestone payment under its contract with BARDA for achieving FDA CLIA waiver. These combined receipts will further strengthen Lumos' balance sheet and provide additional funding to support the broader US commercial rollout of FebriDx®.

The CLIA waiver expands the applicability of FebriDx® to over 300,000 locations across the US[1], covering a broad range of healthcare settings, spanning primary care physician offices, urgent care clinics, retail health & pharmacy clinics and community health centres that hold a Certificate of Waiver. This milestone

marks a significant commercial achievement for Lumos, positioning FebriDx® to reach tens of millions more patients without the need for complex laboratory infrastructure or specialised training.

This expanded opportunity aligns with Lumos' US commercial strategy, which includes support from the Company's partnerships with PRO-spectus, AcuityMD and PHASE Scientific. The focus remains on driving broader market adoption through healthcare provider education, integration into outpatient clinic workflows, and securing reimbursement from private payors.

Prior to the granting of CLIA waiver, FebriDx® usage was limited to moderate complexity clinical settings, restricting it primarily to hospital and laboratory environments. With the CLIA waiver now granted, FebriDx® can be deployed more broadly, potentially reaching 80 million patients[2] per annum in the US who present with acute respiratory infections at primary care and urgent care centres. This unlocks a US$1.0+ billion market opportunity, approximately 15 times larger than the market opportunity available to the Company under the previous moderate-complexity classification.

Doug Ward, CEO of Lumos Diagnostics, said: *"The FDA's granting of a CLIA waiver for FebriDx® marks a transformative moment for Lumos and for the management of acute respiratory infections in the US healthcare system. This approval opens access to a vastly larger market - allowing healthcare professionals in outpatient clinics to deliver rapid and accurate results at the time of the consultation to deliver more effective patient outcomes."*

"This milestone also highlights the invaluable support of our partner, BARDA, whose continued collaboration underscores the importance of public-private collaboration in combating antimicrobial resistance and enhancing patient care."

"Looking ahead, with the continued support of BARDA, we are excited with the opportunity to further broaden patient access to FebriDx®, through our pediatric study. If successful, this important initiative would enable the use of FebriDx® in younger patient populations, extending the benefits to children 2 to 12 years of age and supporting more informed antibiotic prescribing across a wider age group."

This CLIA waiver project was funded in whole or in part with federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA) 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 after 10 minutes, supporting more informed clinical decision-making and potentially reducing unnecessary antibiotic prescribing.

About Lumos Diagnostics

Lumos Diagnostics is a leading point of care diagnostics company focused on improving the diagnosis and management of acute infectious and inflammatory conditions. Lumos develops and commercialises rapid, clinically actionable tests that are designed to deliver results in minutes and support more targeted treatment decisions at the point of care. The company combines proprietary assay technologies, connected digital reader platforms and scalable manufacturing capabilities to provide end to end solutions for its own Lumos branded products as well as for leading healthcare and life sciences partners worldwide. Lumos generates value through a diversified portfolio of products and partnered programs aimed at addressing significant unmet needs in primary and acute care settings.

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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References

1. Division of Clinical Laboratory Improvement and Quality Centers for Medicare & Medicaid services, March 2024 (CMS CLIA Database).
2. Precision Business Insights, US Acute Respiratory Infections, 2024.