ASX ANNOUNCEMENT

Lumos secures follow-on contract with Aptatek Biosciences to manage clinical study to progress to FDA clearance for PheCheck™ device

Key Highlights

- **Lumos secures follow-on contract to manage the IRB approved multi-center study to advance PKU in-home monitoring device to progress to FDA clearance**
- **Contract value of approximately US$0.4 million, commencing January 2026 and expected to run for 6 months**
- **PKU affects 1 in 12,000 newborns, leading to neurological complications if un-checked.**

MELBOURNE, Australia (19 January 2026) – Lumos Diagnostics Holdings Ltd (ASX: LDX, "Lumos" or the "Company"), a leader in rapid, point-of-care diagnostic technologies, is pleased to announce it has secured the next phase of the project with New Jersey-based Aptatek Biosciences, Inc. (Aptatek) to advance the PheCheck™ aptamer-based, in-home monitoring tool for the screening and management of phenylketonuria (PKU).

Under the agreement, Lumos will manage an Institutional Review Board (IRB) approved multi-center clinical study intended to obtain US Food and Drug Administration (FDA) clearance for the PheCheck™ device. The study will leverage Lumos's extensive in-house medical affairs and regulatory capabilities, reflecting the breadth of Lumos's services offering beyond product development and manufacturing, and extending into clinical and regulatory affairs. Lumos will provide comprehensive clinical study support services throughout the study lifecycle, from startup through to close-out, including compilation and statistical analysis of the results and generation of the clinical study report for submission to the FDA.

In parallel, Lumos will continue to complete product development activities and undertake the required formal verification studies commenced in September 2025 (ASX announcement: 1 September 2025) which followed the initial development services contract with Aptatek announced on 17 June 2022.

This new contract is valued at approximately US$0.4 million, to be charged on a time-and-materials basis. The study is expected to commence in Q2 CY26 and run for around 6 months.

Subject to the successful study and achievement of FDA clearance, Lumos expects to pursue additional revenue opportunities with Aptatek, including PheCheck™ test and reader manufacturing.

PKU is a rare inherited disorder affecting approximately 1 in 12,000 newborns. It causes a build-up of the amino acid phenylalanine in the body, which, if untreated, can lead to intellectual disabilities, seizures, behavioral issues, and mental health disorders. The Aptatek device, developed in collaboration with Lumos, is designed to enable PKU patients to measure their phenylalanine levels in real time from home or at the point of care, enabling faster detection and improved ongoing management. The product has been granted FDA Breakthrough Device designation, which is expected to expedite its regulatory review.

Commenting on the announcement, Doug Ward, CEO of Lumos Diagnostics said*: "We are excited to continue partnering with Aptatek as this project matures into the clinical trial phase. We look forward to progressing PheCheck™ through to commercialization and supporting Aptatek at every stage of the journey"*

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This announcement has been approved by the Lumos Disclosure Committee.

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.

About Aptatek

Aptatek is a mobile health company developing innovative systems combining novel sensing technology and innovative digital health tools to enable detection and monitoring of small molecule targets on a portable platform. The privately held company is commercializing technology developed by Columbia scientists and licensed from Columbia University by Aptatek and is based in Princeton, New Jersey.

For more information visit aptatek.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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