ASX ANNOUNCEMENT

Lumos Achieves Key "Phase 1 Milestone" in Hologic fFN Development Agreement

Key Highlights

- Lumos has completed the first phase of its Development Agreement to develop a new fetal fibronectin (fFN) test for leading women's health company, Hologic, Inc. (NASDAQ: HOLX)
- Phase 1 of the Development Agreement, focusing on Product Definition and Planning, was valued at US$0.4 million, with US$0.2 million recognized in Q3 FY2024 and the remaining US$0.2 million to be booked in Q4 FY2024
- With this critical Phase 1 now complete, Lumos will move onto Phase 2 - the Assay Feasibility phase of the Development Agreement, which has a value of US$0.6 million.

All amounts are in USD, the Company's reporting currency, unless otherwise stated.

MELBOURNE, Australia (6 May 2024) – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") a leader in rapid point-of-care diagnostic technologies, is pleased to announce that it has successfully completed the first phase of its Development Agreement to develop a new fetal fibronectin (fFN) test for leading women's health company, Hologic, Inc. (NASDAQ: HOLX).

On 11 January 2024, Lumos announced that it had signed two new Agreements with US based women's health company, Hologic. An Intellectual Property agreement valued at US$10.0 million, and a Development Agreement valued at US$4.7 million. The Agreements focus on the development of a next generation version of Hologic's on-market fFN diagnostic product for pre-term birth, a women's health product for which Hologic is the only manufacturer globally. A key focus of the development program is to adapt the test for use on the Lumos proprietary reader platform and provide improved connectivity options.

First Phase Complete

As previously announced, the body of work under the Development Agreement is being conducted across three phases, providing total milestone payments of up to US$4.7 million, structured as follows:

- Phase 1 - Product Definition and Planning: define the parameters for the product and establish a project plan - US$0.4 million;
- Phase 2 - Assay Feasibility: conduct work to demonstrate the assay can detect the biomarkers - US$0.6 million; and
- Phase 3 - System Prototype Delivery: deliver a working prototype of the system - US$3.7 million.

Hologic has confirmed that Lumos has now successfully completed Phase 1 of the agreement. Phase 1, focused on Product Definition and Planning, was valued at US$0.4 million, with US$0.2 million recognized in Q3 FY2024 and the remaining US$0.2 million to be booked in Q4 FY2024. The US$0.4 million will be paid by Hologic in approximately 45 days.

Lumos CEO and Managing Director, Doug Ward commented, *""We are very pleased to have completed this critical first phase of this Development Agreement with Hologic. Achieving milestone approval from Hologic is excellent validation of the project work completed by the Lumos team, whilst providing additional strength to the company balance sheet through further project funding and a positive outlook on the likelihood of Lumos delivering on subsequent phases.*

As Hologic is the only global manufacturer of this important prenatal test, we feel a strong responsibility toward successfully developing the next generation of the test on the Lumos reader platform."

With Phase 1 complete, Lumos is now preparing to commence Phase 2 of the Development Agreement, entitled Assay Feasibility which is designed to demonstrate that the assay can detect the biomarkers associated with the new fFN test.

The fFN test is the largest segment in the pre-term diagnostic test kit market in the United States. The test is focused on the fFN protein which is found at the maternal-fetal interface. As delivery approaches, fFN is increasingly detectable and detection of fFN (in pregnancy weeks 22 – 35) can indicate that a woman is at higher risk of preterm delivery. A positive fFN result indicates an increased risk of delivery in the next 14 days. The US annual pre-term birth total addressable market is approximately 2.5 million tests per annum and the US reimbursement rate for fFN, CPT Code 82731 is US$64.41 per test.

Lumos will continue to keep the market updated as we progress through the Development Agreement.

-Ends-

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.

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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