



ASX ANNOUNCEMENT

Lumos Achieves First “Phase 2 Milestone” in Hologic fFN Development Agreement

Key highlights:

- Lumos has achieved the first milestone in the second phase of its Development Agreement to develop a new fetal fibronectin (fFN) test for leading women’s health company, Hologic, Inc. (NASDAQ: HOLX)
- Phase 2 of the Development agreement is focused on Assay Feasibility where Lumos is conducting work to demonstrate the assay can detect the biomarkers
- US\$0.3 million will be awarded to Lumos for achievement of the first of the Phase 2 milestones.
- Additional milestones are included within this section of the agreement, with the total Phase 2 program valued at US\$0.6 million.

MELBOURNE, Australia 20 September 2024 – Lumos Diagnostics (ASX: LDX), (“Lumos” or the “Company”) a leader in rapid, point-of-care (POC) diagnostic technologies, is pleased to announce that it has successfully completed a milestone under Phase 2 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 Milestone Under Phase 2 of Development Agreement 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 completed as announced on 6 May 2024;

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- Phase 2 - Assay Feasibility: conduct work to demonstrate the assay can detect the biomarker - 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 the first milestone under Phase 2 of the agreement. Phase 2, focused on Assay Feasibility where Lumos is conducting work to demonstrate the assay can detect the biomarker, is valued at US\$0.6 million, with US\$0.3 million awarded under achievement of this first milestone. The US\$0.3 million will be paid by Hologic in approximately 45 days.

Lumos CEO and Managing Director, Doug Ward commented, *“We are proud to receive this milestone payment, which demonstrates the strong progress the Lumos and Hologic are making in developing a new fetal fibronectin (fFN) test. We’re excited by the results of the work program to date and are pressing ahead with the remainder of the scoped work under Phase 2 of the agreement.”*

With the first milestone under Phase 2 complete, Lumos is now continuing to work on the remaining milestone work under this phase of the project.

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 remaining milestones under the Development Agreement.

-Ends-

This announcement has been approved by the Lumos Disclosure Committee.

About Lumos Diagnostics

Lumos Diagnostics specializes in rapid, cost-effective, and complete point-of-care (POC) diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customized assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes novel Lumos-branded POC 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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