



ASX Announcement

30 March 2026

FebriDx® FDA CLIA wavier approval unlocks upside for Pascal

Pascal performance proven in US studies and compatible with many applications

SYDNEY, 30 March 2026, Australia - Atomo Diagnostics Limited (ASX:AT1) (Atomo) is pleased to note that Lumos Diagnostics (ASX:LDX) FebriDx® test has received CLIA waiver approval from the US Food and Drug Administration (FDA). FebriDx® has been exclusively commercialised in Atomo's patented Pascal cassette to deliver improved usability and reliability in the hands of untrained users, with the performance of Pascal playing a pivotal role.

CLIA waiver approval is estimated by Lumos to expand the US addressable market by around 15 times. In an agreement signed in July 2025 between Lumos and PHASE Scientific for supply of FebriDx® in the US, containing contracted Minimum Order Quantities (**MOQs**) of up to US\$313 million in FebriDx® revenues over the six-year term, subject to CLIA waiver which is now secured.

As previously disclosed, Atomo is the exclusive licensor, manufacturer and supplier of Pascal cassettes to Lumos for FebriDx, and each FebriDx® test sold to Phase requires Lumos order an assembled Pascal cassette from Atomo, under an agreement between the Parties which runs until 30 June 2031, Atomo supplies assembled cassettes to Lumos. (*AT1: ASX Announcement, 29th October 2025, Quarterly Activity Report Q1 FY26*). Under Atomo's exclusive supply agreement with Lumos which expires in June 2031, Lumos committed to purchase annual Pascal volumes to secure ongoing exclusivity arrangements for the Pascal cassette's use with FebriDx®, with a shortfall fee agreed if annual volumes are not met.



Atomo has received orders from Lumos for Pascal of ~A\$1.57 million since the signing of the agreement with Phase in July-25. Excluding IP licensing payments already made by Lumos, the agreement has committed Pascal revenues totalling US\$3.4m (A\$5.2m), based on FebriDx® securing CLIA waived status from the US FDA.

The agreement was entered into by the parties prior to Lumos's agreement with Phase and the volumes anticipated to be ordered to support the Phase agreement are a magnitude larger than the contract minimums in the agreement between Atomo and Lumos now that FebriDx® has received CLIA waiver.

Atomo Managing Director John Kelly said, *“We are delighted to see FebriDx® receive CLIA waiver approval and are proud of the critical role that Pascal played in that. We are now actively scaling up Pascal operations to support growing demand from Lumos and from other new pipeline customers, who have seen the outstanding performance that Pascal delivered for FebriDx, and its proven ability to support valuable CLIA waiver approvals in the US market.”*

For more information, please contact:

John Kelly
Atomo Diagnostics
john.kelly@atomodiagnostics.com
Phone: +61 401 922 279

This announcement was authorised by the Managing Director & CEO.

About Atomo

Atomo is an Australian headquartered medical device company supplying unique, integrated rapid diagnostic test (RDT) devices to the global diagnostic market. Atomo's unique patented devices simplify testing procedures, enhance usability and improve reliability across rapid point-of-care (POC) and at-home testing applications. The Company has successfully commercialised a number of products across international markets and has supply agreements in place for testing applications targeting infectious diseases including HIV, COVID-19, viral vs bacterial differentiation, as well as the early detection of pregnancy.

See more at www.atomodiagnostics.com