

FebriDx CLIA waiver submission

NEED TO KNOW:

- LDX submits its application for CLIA waiver.
- Strategic partnership enhances FebriDx market access.
- Lumos Diagnostics specialises in rapid diagnostic testing.

LDX submits its application: Lumos Diagnostics has completed its clinical study and submitted a CLIA waiver application to the US FDA for its FebriDx test. This test showed over 98% concordance between trained and untrained operators, highlighting its simplicity and ease of use. Approval could significantly expand its market opportunity in the US.

Strategic partnership for market access: Lumos has partnered with US-based consultancy PRO-spectus to strengthen FebriDx's market access. While FebriDx is already reimbursed by Medicare, the goal is to expand coverage among private insurers, who make up 60% of the US market.

Lumos Diagnostics' expertise: Lumos specialises in rapid diagnostic testing solutions, particularly in point-of-care diagnostics. They develop and manufacture custom assay solutions and diagnostic platforms for various applications, including infectious disease detection and inflammatory markers.

INVESTMENT VIEW

Growing demand for rapid diagnostics: The global healthcare system increasingly prioritises rapid diagnostic solutions, especially for infectious disease management. Lumos' technology addresses this need by offering point-of-care solutions that reduce diagnosis and treatment times.

Proprietary technology and diversification: Lumos leverages advanced immunoassay technology, providing improved sensitivity and ease of use. The ability to develop both proprietary and partner-based tests offers diversified revenue streams across multiple health conditions.

Commercialisation strategy in progress: Lumos is advancing its commercialisation strategy by expanding FebriDx into global markets and broader clinical settings. Strategic partnerships and regulatory approvals are crucial for revenue scalability and long-term profitability.

RISKS TO INVESTMENT VIEW

Key risks to the company include regulatory challenges, commercialisation difficulties, reimbursement issues, technological disruption, and reliance on distributors.

VALUATION

The valuation of Lumos Diagnostics is A\$223m, or A\$0.22 per fully diluted share. This valuation is based on 748.5m shares and 157.4m options, assuming a

Lumos Diagnostics Holdings Ltd

CLASSIFICATION 19 SEP 2025

Pre-Profit

Stock Overview

ASX code	LDX
Price at Review (19 Sep 2025)	\$0.17
GICS Sector	Health Care
Market Cap (AUD\$m)	\$134m

Source: LSEG

Financial Forecast

Year	JUN US\$m	2023	2024	2025E	2026E	2027E
Revenue		11	11	13	17	26
EBIT		-8	-7	-5	0	1
Pre-tax Profit		-9	-9	-6	-1	-1
Net Profit		-9	-9	-6	-1	-1
EPS (cps)		-3.82	-1.85	-0.82	-0.11	-0.16
PE (x)		-0.3	-1.6	-20.7	-155.0	-104.8
DPS (cps)		0	0	0	0	0
Dividend Yield (%)		-	-	-	-	-

Source: LSEG, MST Financial

Share Price



Source: LSEG, Sandstone Insights. Index rebased into share price terms

Company Description

Lumos Diagnostics is a company specializing in rapid diagnostic testing solutions, particularly in point-of-care (POC) diagnostics. They develop and manufacture custom assay solutions, reader technologies, and diagnostic platforms for various applications, including infectious disease detection, inflammatory markers, and other health conditions. Lumos also works in food and environmental testing.

US\$5m capital raise in FY27. The change in valuation reflects an increased probability of success for the FebriDx CLIA waiver trial from 80% to 95%.

CATALYSTS

1QFY26: Milestone in Hologic fFN agreement

3QFY26: Update on CLIA waiver submission

1HFY26: Women's health diagnostic update

2HFY26: Completion of Hologic fFN agreement

Emerging Companies Equities Research Methodology.

Sandstone Insights Emerging Companies Research provides equity research coverage on companies outside the S&P/ASX 300 index. Our analysts, most with over 15 years of institutional equity research experience, have provided their views, opinions, and valuation estimates for each company. In addition, we provide a summary financial forecasts for each company under coverage.

CLASSIFICATION METHODOLOGY

Our Classification Methodology relies on a blend of historical financials and our forward estimates/and projections. Financial estimates are subject to change, which may impact a Company's Classification. Estimates of future performance are based on assumptions that may not be realised. Past performance is not indicative of future performance.

Each company is classified into four primary classifications, according to where they are in their life cycle, as measured by the both the proximity to earnings, and the strength of earnings:

Pre-Revenue	The Company is not currently generating any sales revenue and is not forecast to generate sales revenue over the next 12 months. The Company is therefore reliant on cash reserves and or external capital over the short-medium term.
Pre-Profit	The revenue base has been established but is not at a sufficient level to generate positive measures of profit (Earnings Before Interest Tax Depreciation and Amortisation (EBITDA), Profit Before Tax (PBT), Net Profit After Tax (NPAT), and or positive operating cash flow). The Company is likely to continue to be reliant on cash reserves and or external capital over the next 12 months.
Profitable	The Company is generating profits (EBITDA, PBT, NPAT, and or positive operating cash flow) reducing or eliminating the need for reliance on cash reserves and or external capital. The Company is forecast to continue to be profitable over the medium term.

DISCLAIMER AND DISCLOSURES

Dividend Capacity

The level of profitability is sufficient to allow the Company to pay ongoing dividends to shareholders from operating earnings (or undertake other forms of capital management). The Company is expected to be able to continue to pay dividends over the medium term.

SANDSTONE INSIGHTS VALUATION

For each Company under Sandstone Insights Emerging Companies Coverage, a Valuation estimate is provided. The Valuation is our estimate of what the Company's shares could be worth under our base case scenario for the Company, discounted back to the publication date of this report.

The base case scenario includes a risk-weighted assessment of each company's ability to achieve its strategic plans over the short to medium term, whilst considering the Company's ability to fund its strategic plans.

A range of valuation techniques is used which can include Discounted Cash Flow (DCF), Sum Of The Parts (SOTP), Net Asset Backing, multiple-based valuation techniques (examples include Price to Sales, Price to earnings), and comparable company-based valuation. For Companies without any revenue, an assessment of future market penetration and cash-flow generation are considered. Industry-specific valuations are also used (examples include EV/Resources, EV/Reserves, and EV/2P Reserves).

Company valuations are subject to change depending on; a) the success or otherwise of the Company's ability to execute its strategic plans; b) external market factors, including interest rates, investor sentiment, prevailing growth rates valuations of peer group Companies.

Many companies under Sandstone Insights Emerging Companies Coverage are still building out their businesses. Therefore, both the range and variability of outcomes are much wider than in larger, more mature companies.

Sandstone Insights Valuation estimates are not static and may be updated as information and or view changes.