# Lumos Diagnostics

**LDX.AX**

MST Access
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# FebriDx CLIA waiver submission

## NEED TO KNOW

- **LDX submits its application for CLIA waiver**
- **Strategic partnership enhances FebriDx market access**

**CLIA waiver application submission for FebriDx:** Lumos (LDX) has announced that it has completed its clinical study and submitted a CLIA waiver application to the US Food & Drug Administration (FDA) for its rapid point-of-care test, FebriDx. The study demonstrated 99.1% concordance for bacterial-positive and 98.4% for non-bacterial patients between trained and untrained operators. This highlights the test's simplicity and ease of use. The FDA submission triggers milestone payments of about US$1.3m from BARDA and a US$1.5m product purchase prepayment from PHASE Scientific, with additional payments due upon CLIA waiver approval. LDX expects FDA feedback by end-1Q2026. If approved, the US market opportunity for FebriDx could expand 15X to over US$1.0bn.

**PRO-spectus to accelerate market access and reimbursement for FebriDx:** LDX has also partnered with US-based consultancy PRO-spectus to strengthen market access for FebriDx. While FebriDx is currently reimbursed by Medicare, LDX aims to expand coverage of the product among private insurers, which constitute 60% of the US market. PRO-spectus will provide strategic consulting, a reimbursement helpline, and field-based support integrated with LDX's sales operations.

## Investment Thesis

**Market demand for rapid point-of-care diagnostics:** The global healthcare system is increasingly prioritising rapid diagnostic solutions, particularly in infectious disease management and antibiotic stewardship. LDX's proprietary technology addresses this need with point-of-care solutions that reduce the time to diagnosis and treatment. Stricter antimicrobial stewardship guidelines and government support for point-of-care testing could drive adoption.

**Proprietary technology and diversified business:** LDX's reader-based and reader-free diagnostics leverage advanced immunoassay technology, offering improved sensitivity and ease of use compared to traditional methods. The company's ability to develop and commercialise both proprietary and partner-based tests provides diversified revenue streams across multiple indications.

**Commercialisation underway:** LDX is advancing its commercialisation strategy by expanding FebriDx into global markets and broader clinical settings in the US, and extending its labelling to paediatric populations. Strategic partnerships and regulatory approvals will be key drivers of revenue scalability and long-term profitability in the diagnostics sector.

## Valuation/Risks

We raise our valuation of LDX to A$223m ($0.22 per fully diluted share) from A$176m ($0.10) using DCF methodology, following an increase in our assumed probability of success to 95% (from 80% previously). Our valuation is based on the 748.5m shares on issue and 157.4m options, and assumes a US$5m capital raise in FY27, which adds a further 80m new shares priced at current levels of ~A$0.10 per share (vs A$0.03 previously) to our fully diluted calculation. In the highly competitive diagnostics market, LDX's key risks are regulatory, commercialisation, reimbursement, technology and distribution.


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LUMOS DIAGNOSTICS

Lumos Diagnostics is a company specialising 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. https://lumosdiagnostics.com

| | |
|---|---|
| Valuation | **A$0.22** *(from A$0.10)* |
| Current price | **A$0.10** |
| Market cap | **A$75m** |
| Cash on hand | **US$2m** *(30 June 2025)* |

### Upcoming Catalysts / Next News

| Period | |
|---|---|
| 1QFY26 | Milestone in Hologic fFN agreement |
| 3QFY26 | Update on CLIA waiver submission |
| 1HFY26 | Women's health diagnostic update |
| 2HFY26 | Completion of Hologic fFN agreement |

### Share Price (A$)


*Source: FactSet, MST Access.*

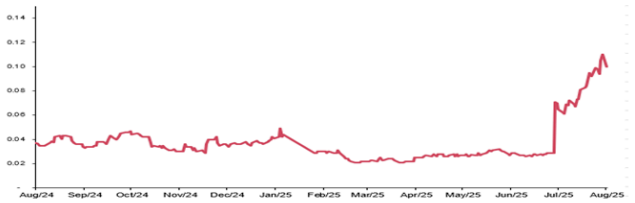
## Lumos Diagnostics — LDX-AU

**Year end 30 June, USD unless otherwise noted**

### MARKET DATA

| | | |
|---|---|---|
| **Price** | **A$** | **0.10** |
| 52 week high / low | A$ | 0.02-0.11 |
| **Valuation** | **A$** | **0.22** |
| Market capitalisation | A$m | 75.0 |
| **Shares on issue (basic)** | **m** | 828.7 *(incl ~80m new shares from forecast cap raise in FY27)* |
| Options / rights | m | 157.4 *(unlisted options and performance rights)* |
| Other equity | m | 0.0 |
| **Shares on issue (diluted)** | **m** | **986.1** |

### 12-MONTH SHARE PRICE PERFORMANCE (A$)




| INVESTMENT FUNDAMENTALS | | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|---|
| Reported NPAT | $m | (9.0) | (8.6) | (6.1) | (0.8) | (1.2) |
| **Underlying NPAT** | **$m** | **(9.0)** | **(8.6)** | **(6.1)** | **(0.8)** | **(1.2)** |
| Reported EPS (diluted) | ¢ | (3.8) | (1.9) | (0.8) | (0.1) | (0.2) |
| **Underlying EPS (diluted)** | **¢** | **(3.8)** | **(1.9)** | **(0.8)** | **(0.1)** | **(0.2)** |
| Growth | % | | | | | |
| **Underlying PER** | x | **nm** | **nm** | **nm** | **nm** | **nm** |
| Operating cash flow per share | ¢ | (3.1) | 0.2 | (0.5) | 0.2 | 0.2 |
| Free cash flow per share | ¢ | (1.7) | 0.2 | (0.5) | 0.2 | 0.2 |
| **Price to free cash flow per share** | **x** | **nm** | **56.8** | **nm** | **46.3** | **53.3** |
| FCF Yield | % | nm | 1.8% | nm | 2.2% | 1.9% |
| **Dividend** | ¢ | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** |
| Payout | % | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| **Yield** | **%** | **0.0%** | **0.0%** | **0.0%** | **0.0%** | **0.0%** |
| Franking | % | nm | nm | nm | nm | nm |
| **Enterprise value** | **$m** | **72.0** | **68.5** | **73.6** | **70.0** | **67.9** |
| EV/EBITDA | x | (13.3) | (17.6) | (27.9) | 27.1 | 26.5 |
| EV/EBIT | x | (8.8) | (9.2) | (15.1) | 159.6 | 127.5 |
| Price to book (NAV) | x | 3.3 | 6.8 | 77.5 | 515.6 | (77.5) |
| Price to NTA | x | (22.2) | (18.7) | (9.9) | (18.2) | (31.1) |

| KEY RATIOS | | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|---|
| Gross Margin | % | 54.2 | 63.0 | 59.1 | 50.5 | 63.6 |
| EBITDA margin | % | nm | nm | nm | 12.2 | 10.0 |
| EBIT margin | % | nm | nm | nm | 2.1 | 2.1 |
| NPAT margin | % | nm | nm | nm | nm | nm |
| ROE | % | nm | nm | nm | nm | nm |
| ROA | % | nm | nm | nm | nm | nm |
| Net tangible assets per share | $ | (0.0) | (0.0) | (0.0) | (0.0) | (0.0) |
| Book value per share | $ | 0.0 | 0.0 | 0.0 | 0.0 | (0.0) |
| Net debt/(cash) | $m | (3.0) | (6.5) | (1.4) | (5.0) | (7.1) |
| Interest cover/ (EBIT/net interest) | x | nm | nm | nm | (0.3) | (0.3) |
| Gearing (net debt/EBITDA) | x | nm | nm | nm | nm | nm |
| Leverage (net debt/(net debt + equity | x | nm | nm | nm | nm | nm |

| DUPONT ANALYSIS | | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|---|
| Net Profit Margin | % | nm | nm | nm | nm | nm |
| Asset Turnover | x | 0.4 | 0.4 | 0.7 | 0.9 | 1.0 |
| Return on Assets | % | nm | nm | nm | nm | nm |
| Leverage | x | 2.7 | 3.8 | 21.8 | 167.5 | (25.1) |
| **Return on Equity** | % | nm | nm | nm | nm | nm |

| KEY PERFORMANCE INDICATORS | | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|---|
| **Revenue** | | | | | | |
| Branded products | $m | 0.3 | 1.2 | 1.5 | 5.0 | 13.3 |
| Contract services | $m | 10.2 | 9.9 | 11.2 | 11.7 | 12.3 |

| HALF YEARLY DATA | | 2H22 | 1H23 | 2H23 | 1H24 | 2H24 |
|---|---|---|---|---|---|---|
| Total Revenue | $m | 6.4 | 5.1 | 5.4 | 2.8 | 8.4 |
| Operating expenses | $m | (37.4) | (8.9) | (6.5) | (7.9) | (8.0) |
| EBITDA | $m | (7.9) | (4.4) | (1.0) | (4.4) | 0.5 |
| EBIT | $m | (34.2) | (6.3) | (1.8) | (5.6) | (1.9) |
| PBT | $m | (34.6) | (6.6) | (2.4) | (6.4) | (2.2) |
| **Reported NPAT** | $m | (45.7) | (6.6) | (2.4) | (6.4) | (2.2) |

*Source: Company reports, MST Access estimates*

| PROFIT AND LOSS | | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|---|
| **Revenue** | **$m** | **10.5** | **11.1** | **13.0** | **16.7** | **25.7** |
| Other income | $m | 0.5 | 0.1 | 1.0 | 4.4 | 0.1 |
| **Total Revenue** | **$m** | **11.0** | **11.3** | **14.0** | **21.1** | **25.7** |
| Gross profit | $m | 6.0 | 7.1 | 8.3 | 10.7 | 16.4 |
| Operating expenses | $m | (15.4) | (15.8) | (15.5) | (15.9) | (17.6) |
| **EBITDA** | **$m** | **(5.4)** | **(3.9)** | **(2.6)** | **2.6** | **2.6** |
| Depreciation & Amortisation | $m | (3.7) | (2.6) | (2.3) | (2.1) | (2.0) |
| **EBIT** | **$m** | **(8.2)** | **(7.5)** | **(4.9)** | **0.4** | **0.5** |
| Net interest | $m | (0.8) | (1.1) | (1.3) | (1.3) | (1.7) |
| **Pretax Profit** | **$m** | **(9.0)** | **(8.6)** | **(6.1)** | **(0.8)** | **(1.2)** |
| Tax expense | $m | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Reported NPAT** | **$m** | **(9.0)** | **(8.6)** | **(6.1)** | **(0.8)** | **(1.2)** |
| **Underlying NPAT** | $m | **(9.0)** | **(8.6)** | **(6.1)** | **(0.8)** | **(1.2)** |
| Year end shares | m | 309.4 | 481.3 | 748.5 | 748.5 | 828.7 |

| GROWTH PROFILE | | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|---|
| Revenue | % | (9.4) | 5.7 | 16.9 | 28.4 | 53.6 |
| EBITDA | % | nm | nm | nm | nm | nm |
| EBIT | % | nm | nm | nm | nm | nm |
| Reported NPAT | % | nm | nm | nm | nm | nm |

| BALANCE SHEET | | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|---|
| Cash | $m | 3.0 | 6.5 | 1.4 | 5.0 | 7.1 |
| Receivables | $m | 1.5 | 0.7 | 0.8 | 1.0 | 1.5 |
| Other | $m | 1.5 | 2.4 | 2.5 | 2.8 | 3.4 |
| **Current assets** | **$m** | **6.0** | **9.6** | **4.8** | **8.9** | **12.1** |
| PPE | $m | 0.6 | 0.3 | 0.3 | 0.2 | 0.2 |
| Intangible assets | $m | 10.9 | 9.7 | 8.5 | 7.5 | 6.6 |
| Right-of-use assets | $m | 8.0 | 7.3 | 7.5 | 7.7 | 7.9 |
| Other | $m | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Non current assets** | **$m** | **19.5** | **17.3** | **16.3** | **15.5** | **14.7** |
| **Total assets** | **$m** | **25.4** | **26.8** | **21.1** | **24.3** | **26.8** |
| Trade and other payables | $m | 2.9 | 2.4 | 2.8 | 3.6 | 5.5 |
| Borrowing and lease liabilities | $m | 0.7 | 1.0 | 1.0 | 1.0 | 1.0 |
| Other | $m | 4.6 | 9.3 | 9.3 | 9.3 | 9.3 |
| **Current liabilities** | **$m** | **8.2** | **12.6** | **13.0** | **13.8** | **15.7** |
| Borrowing and lease liabilities | $m | 7.7 | 7.1 | 7.1 | 7.1 | 7.1 |
| Other liability | $m | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Non current liabilities** | **$m** | **7.7** | **7.1** | **7.1** | **7.1** | **7.1** |
| **Total liabilities** | **$m** | **15.9** | **19.7** | **20.1** | **20.9** | **22.8** |
| **Net assets** | **$m** | **9.5** | **7.1** | **1.0** | **3.4** | **3.9** |
| Share capital | $m | 92.5 | 98.2 | 98.2 | 98.2 | 98.2 |
| Retained earnings | $m | (82.3) | (90.9) | (97.0) | (97.8) | (99.0) |
| Other | $m | (0.7) | (0.3) | (0.3) | (0.3) | (0.3) |
| **Total equity** | **$m** | **9.5** | **7.1** | **1.0** | **0.1** | **(1.1)** |

| CASH FLOW | | FY23A | FY24A | FY25E | FY26E | FY27E |
|---|---|---|---|---|---|---|
| **Profit/(net loss) for period** | **$m** | **(9.0)** | **(8.6)** | **(6.1)** | **(0.8)** | **(1.2)** |
| Depreciation & Amortisation | $m | 3.7 | 2.6 | 2.3 | 2.1 | 2.0 |
| Changes in working capital | $m | (3.9) | 5.4 | 0.2 | 0.3 | 0.7 |
| Other | $m | (0.4) | 1.5 | (0.0) | 0.0 | 0.0 |
| **Operating cash flow** | **$m** | **(9.6)** | **0.9** | **(3.7)** | **1.6** | **1.6** |
| Payments for PPE | $m | (0.2) | (0.1) | (0.1) | (0.0) | (0.0) |
| Other | $m | 4.5 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Investing cash flow** | **$m** | **4.3** | **(0.1)** | **(0.1)** | **(0.0)** | **(0.0)** |
| Payment of lease liabilities | $m | (1.8) | (1.3) | (1.3) | (1.3) | (1.3) |
| Proceeds from issued shares | $m | 0.0 | 5.0 | 0.0 | 0.0 | 5.0 |
| Proceeds from borrowings | $m | 0.0 | 0.0 | 0.0 | 3.3 | (3.3) |
| Dividends paid | $m | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Financing cash flow** | **$m** | **0.7** | **2.6** | **(1.3)** | **2.0** | **0.5** |
| **Cash year end** | **$m** | **3.0** | **6.5** | **1.4** | **5.0** | **7.1** |
| **Free cash flow** | **$m** | **(5.3)** | **0.8** | **(3.8)** | **1.6** | **1.6** |

## LDX Advances FebriDx with CLIA Waiver Submission

LDX has submitted a CLIA waiver application to the FDA for FebriDx.

The clinical study exceeded performance criteria, triggering US$1.3m in milestone payments from BARDA and US$1.5m from PHASE Scientific. LDX expects FDA feedback by the end of 1QCY26. If approved, the US addressable market for FebriDx could expand 15X to over US$1.0bn.

The FebriDx clinical study aimed to demonstrate usability and accuracy for CLIA waiver candidacy, achieving 99.1% concordance for bacterial-positive cases and 98.4% for non-bacterial cases between trained and untrained operators. The study's design supported FDA requirements, focusing on device safety, simplicity, and low error probability as used in typical healthcare environments.

Support from BARDA played a crucial role during the FebriDx trial. Following key milestones of final patient enrolment and the waiver application submission, LDX expects immediate payments totalling US$1,253,520. Approval will trigger an additional US$507,377 payment. PHASE Scientific will pay a further US$5.0m, post-waiver approval, per the distribution agreement. These payments demonstrate the important support of LDX's strong partners for FebriDx.

## Enhancing FebriDx Market Preparedness, Reimbursement Partnership with PRO-spectus

LDX has also entered a strategic partnership with US-based consultancy PRO-spectus to drive market access and reimbursement for FebriDx through December 2026. With reimbursement now secured under US Medicare, LDX aims to expand FebriDx coverage among private payors, who insure 60% of the US population. The initiative combines LDX's rapid, point-of-care diagnostic capabilities with PRO-spectus' expertise in market access, targeting both major insurance firms and smaller payors to maximise patient and provider reach. The collaboration enhances market preparedness, contingent upon successful completion of the CLIA waiver process.

Under the agreement, PRO-spectus will provide the following key deliverables:

- **Market access consulting services:** Strategic collateral to communicate FebriDx's clinical and economic benefits for multiple healthcare settings.
- **Reimbursement helpline team**: Dedicated support for FebriDx coding, coverage, and payment inquiries from internal and external stakeholders.
- **Access and reimbursement manager services**: Field team focused on supporting provider adoption of FebriDx, delivering education on reimbursement, navigating payor requirements, and solving site-specific billing and coding issues.

# Thesis: End-to-End Point-of-Care Diagnostic Player

LDX is an Australian-based, publicly traded medical technology company which develops and commercialises rapid, point-of-care (POC) diagnostic tests. LDX aims to establish a competitive advantage by integrating high-performance lateral flow assays (LFAs) with sophisticated reader technology and a supporting suite of applications. This strategy aims to provide a balance of speed, accuracy, and connectivity at the point of care, competing with traditional laboratory testing in terms of cost, time and convenience.

## Offering: rapid tests, advanced readers, custom solutions

LDX offers a range of proprietary commercially available POC tests and contract services. However, its contract services are typically not provided directly to healthcare providers. Instead, these services are contracted by third-party clients, including diagnostic and pharmaceutical companies, food and environmental testing companies, startups, and universities. LDX's expertise supports these clients as they develop, manufacture and commercialise diagnostic products.

LDX's portfolio of platforms covers several areas (readers, cassettes, app): see Figure 1 (image labels correspond with bullets below). These are provided to clients and customised to meet individual needs.

**Rapid diagnostic tests (lateral flow assays and other tests) (Figure 1 – A):** LDX has developed a number of proprietary LFAs, which assess a sample and determine whether a particular analyte is present, thereby diagnosing specific conditions. Its suite of tests includes flagship product FebriDx, which can differentiate between viral and bacterial infections in patients with acute respiratory infections after 10 minutes (notably, the ex-US claim distinguishes viral from bacterial infections, whereas the US claim differentiates bacterial from non-bacterial infections). The company also develops LFAs and other diagnostic tests for its partners.

**Reader platforms (Figure 1 – B):** LDX's reader platforms are POC devices used to analyse, interpret and transmit the results of diagnostic tests. These include the following, which are each customisable for specific assay types and user scenarios in terms of portability, connectivity and output format:

- Single-use Disposable Reader – fully integrated with test strip in single-use, disposable system
- Multi-use Disposable Reader – facilitates easy drop-in of test strips, customisable for various needs
- Leelu Reader – research-use-only benchtop reader for assay development and quality control
- Hand-Held Camera Reader (also called 'Portable Camera Reader') – uses a high-performance camera system (also used on the Leelu Reader) to detect test strip signals and provide numerical results, with options for Bluetooth connectivity and barcode reading.

**Desktop app and smartphone app (Figure 1 – C):** Companion apps enhance the functionality of LDX's reader devices by integrating with cloud platforms, enabling the user-friendly capture of data.

**Figure 1: LDX portfolio of platforms**


*Source: LDX.*

**Figure 2: Product portfolio overview**

| **Product division** | **Division contribution: 11% of FY24 revenue; projected revenue CAGR (FY24–29): 308%** |
|---|---|
| *Lateral flow assays, including:* | |
| FebriDx® | Rapid, all-in-one point-of-care test that diagnoses acute respiratory infections and differentiates between bacterial and viral respiratory infections |
| ViraDx™ | Rapid point-of-care test that diagnoses and distinguishes between acute viral respiratory infections caused by COVID-19, Influenza A and Influenza B |
| **Contract Services division** | **Division contribution: 89% of FY24 revenue; projected revenue CAGR (FY24–29): 7%** |
| *Services contracted by third parties (e.g. healthcare organisations and biotechs), including:* | |
| Assay development | Offers comprehensive services encompassing the development of diagnostic tests, from reagent sourcing to verification, validation, and design transfer |
| Reader development | Customises reader platforms based on client needs, including disposable and reusable readers, as well as off-the-shelf product solutions |
| Supporting technology and services, including: | |
| • App and cloud services | Develops applications and cloud-based solutions to support data management and connectivity for diagnostic devices |
| • Manufacturing | Conducts full-scale manufacturing of diagnostic reagents, cartridges, and test kits, with capabilities for manufacturing transfer and process validation |
| • Medical affairs | Supports all stages of product development and commercialisation, including clinical trials and medical communications |
| • Quality and regulatory affairs | Assists with quality management systems and regulatory compliance throughout the product lifecycle |

*Source: LDX.*

## Technology: proprietary platform underpins product development

LDX's technology platform uniquely positions the company to offer tailored, innovative, and efficient POC diagnostic solutions across various healthcare settings. Highlights of the platform are as follows:

- **Portfolio of proprietary tests:** LDX develops its own branded POC tests (FebriDx and ViraDx), targeting infectious and inflammatory diseases and focusing on rapid results. By integrating its development process, LDX benefits from synergy gains in optimising costs and maximising profit margins. Additionally, LDX is building a strong intellectual property portfolio, giving it a stronger competitive edge in the diagnostics market.
- **End-to-end development services:** LDX provides a comprehensive development process, from feasibility studies using the Leelu R&D Reader to clinical validation and design transfer for commercial-scale manufacturing. This reduces development timelines, costs, and risks.
- **Rapid development of assays:** LDX's rapid prototyping capabilities enable it to develop assays at an accelerated pace compared with competitors.
- **Versatile reader portfolio:** LDX's readers range from single-use disposables to reusable camera-based systems, and are adaptable to various assay chemistries and formats. Test strips can be seamlessly integrated with digital readers. Custom assay-specific algorithms can be uploaded to readers for qualitative or quantitative results. Readers can be branded and customised with application-specific features, alternate form factors, and connectivity options (e.g., Bluetooth).
- **Digital ecosystem (apps and cloud integration) supporting the LDX offering:** LDX offers companion mobile and desktop apps for workflow guidance and data management, analytics and visualisation. Connectivity options enable real-time reporting, integrating with laboratory information systems. Cloud platforms capture key data such as test results, device usage, and patient metrics.
- **Regulatory-compliant manufacturing:** Readers are manufactured to ISO 13485 standards, ensuring readiness for regulatory trials and compliance with international quality requirements.

# Market opportunity and competitive advantages

## Overall market: point-of-care diagnostics

**Opportunity – growing point-of-care diagnostics market (10% CAGR):** LDX operates within the POC diagnostics sector, a rapidly expanding healthcare segment. This market is projected to grow to US$65.9 bn by 2029 from US$44.24 bn in 2023 (see References: 1), a compound annual growth rate (CAGR) of ~10.2%. The COVID-19 pandemic significantly accelerated the adoption of POC diagnostics, driving demand for rapid, decentralised testing beyond traditional hospital settings.

**Competitive advantages:** Competitors in the POC diagnostics space include both large multinationals and innovative startups. Molecular POC testing has surged post–COVID-19, with platforms such as Abbott ID NOW and Cepheid GeneXpert gaining widespread use. AI-powered, digital POC solutions and at-home testing have become mainstream, while regulatory fast-tracking has improved market access.

LDX has meaningful advantages over its competitors in this space, including:

- **customisable LFAs,** allowing partners to tailor tests for specific biomarkers and applications
- **superior accuracy** due to integrated digital reader technology: Integrated digital readers provide quantitative and semi-quantitative results, improving accuracy over traditional visual LFAs
- **ability to assess multiple biomarkers in one test:** Some of LDX's solutions can detect multiple biomarkers in one test, improving diagnostic efficiency compared to single-marker LFAs. This allows a more detailed snapshot of a patient's condition and the capture of more information on various targets in parallel and is particularly valuable for complex diseases where multiple factors may be relevant for diagnosis or prognosis
- **less expensive and faster** than PCR and other lab tests: While less sensitive than PCR testing, LDX's solutions are lower cost and enable rapid decision-making (for example, FebriDx provides results in ~10 minutes). These features are particularly useful in decentralised healthcare settings
- **global market access:** With regulatory approvals in multiple regions (specifically, FebriDx has FDA clearance and CE marking), LDX has a stronger international market foothold than many competitors.

## Immediate and critical market opportunity: differentiating bacterial vs. viral infections at point of care

**Opportunity – combatting antibiotic overuse with flagship product, FebriDx:** LDX's immediate market opportunity rests with FebriDx, specifically with respect to the overuse of antibiotics in the treatment of acute respiratory infections (ARIs) – a well-documented contributor to the escalating global challenge of antimicrobial resistance among bacterial pathogens. Put simply, by identifying whether an ARI is bacterial or not at the point of care, the prescriber can choose the right treatment and – where appropriate – avoid the use of antibiotics.

Although ARIs are mostly caused by viruses, US healthcare providers in outpatient settings issued approximately 211 million antibiotic prescriptions for ARIs in 2021 – a rate of 636 prescriptions per 1,000 individuals. The CDC estimates that up to 28% of these prescriptions were unwarranted.

**Competitive advantages:** MeMed is the only real direct competitor to LDX in the host-response biomarker-based POC diagnostics space. Both tests differentiate bacterial from viral infections, positioning them uniquely in the POC market. However, we see FebriDx as having meaningful competitive advantages over MeMed. FebriDx:

- **is smaller (instrument-free) and thus more portable** (MeMed requires the use of an instrument)
- **is stored at room temperature** (MeMed requires cold chain storage)
- **is less expensive**
- **requires a smaller volume of blood for the test** (fingerstick for FebriDx vs. blood draw for MeMed)
- **provides clearer, definitive results** (in MeMed's algorithm, 30% of patients can fall into an equivocal zone).

# Valuation

We raise our valuation of LDX to A$223m ($0.22 per fully diluted share) from A$176m ($0.10) using DCF methodology, following an increase in our assumed probability of success to 95% (from 80% previously). Our valuation is based on the 748.5m shares currently on issue and 157.4m options, and assumes a US$5m capital raise in FY27, which adds 80m new shares priced at current levels of ~A$0.10 per share (vs A$0.03 previously).

## Key inputs

- WACC of 12.5% using beta of 1.25 (FactSet)
- Long-term gross margin of around 64%
- Terminal growth rate beyond 2034 of 2%
- Net debt position of negative US$50k as at 30 June 2025 (pro-forma basis includes BARDA payment of US$1.3m, debt facility of A$5m and cash at 30 June of US$2m)
- Assumed probability of success (POS) in FebriDx CLIA waiver trial of 95% (up from 80%) with clearance in 2HFY26
- FebriDx unit sale price of US$11 in the United States
- ViraDx unit sale price of US$6
- Commercial services business revenue growth of around 5%

**Figure 3: DCF valuation and key metrics**

| | | Jun-24 2024 | Jun-25 2025 | Jun-26 2026 | Jun-27 2027 | Jun-28 2028 | Jun-29 2029 | Jun-30 2030 | Jun-31 2031 | Jun-32 2032 | Jun-33 2033 | Jun-34 2034 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| EBIT | US$m | (8.6) | (6.1) | (0.8) | (1.2) | 3.6 | 8.2 | 12.9 | 17.5 | 22.7 | 28.0 | 35.8 |
| Tax at standard rate | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Post-tax EBIT** | US$m | **(8.6)** | **(6.1)** | **(0.8)** | **(1.2)** | **3.6** | **8.2** | **12.9** | **17.5** | **22.7** | **28.0** | **35.8** |
| Depreciation & Amortization | US$m | (2.6) | (2.3) | (2.1) | (2.0) | (1.9) | (1.9) | (1.8) | (1.7) | (1.7) | (1.6) | (1.6) |
| **Post-tax cash flow** | US$m | **(11.2)** | **(8.4)** | **(3.0)** | **(3.2)** | **1.7** | **6.4** | **11.1** | **15.8** | **21.0** | **26.4** | **34.2** |
| Less capex | US$m | (0.1) | (0.1) | (0.0) | (0.0) | (0.0) | (0.0) | (0.0) | (0.0) | (0.0) | (0.0) | (0.0) |
| Less change in working capital | US$m | 5.4 | 0.2 | 0.3 | 0.7 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 1.1 |
| **Free cash flow** | US$m | **(5.9)** | **(8.3)** | **(2.7)** | **(2.5)** | **2.4** | **7.1** | **11.8** | **16.6** | **21.8** | **27.2** | **35.4** |
| Discount coefficient | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| **Discounted cash flow** | US$m | | **(7.4)** | **(2.1)** | **(1.8)** | **1.5** | **3.9** | **5.8** | **7.3** | **8.5** | **9.4** | **10.9** |
| Sum of discount streams | US$m | 36.1 | | | | | | | | | | |
| Terminal growth | % | 2.0% | | | | | | | | | | |
| Future value into perpetuity | US$m | 343.5 | | | | | | | | | | |
| NPV of terminal value | US$m | 107.9 | | | | | | | | | | |
| PV of cash flows | US$m | 144.0 | | | | | | | | | | |
| PLUS: Value of investments | US$m | - | | | | | | | | | | |
| LESS: Net debt | US$m | (0.050) | | *(Proforma basis includes BARDA payment of US$1.3m, debt facility of A$5m and cash at 30 June of US$2m)* | | | | | | | | |
| **Equity value** | US$m | **144.0** | | | | | | | | | | |
| **Equity value** | **A$m** | **221.6** | ***0.65*** | ***AUD:USD*** | | | | | | | | |
| Ordinary shares | m | 843.7 | | *(includes ~80m new shares from forecast cap raise in FY27 and 15m shares issued to debt lenders for establishement fee)* | | | | | | | | |
| Options | m | 157.4 | | *(includes 13.7m of performance rights)* | | | | | | | | |
| **Value per share (fully diluted)** | **A$** | **0.22** | | | | | | | | | | |

*Source: MST Access.*

## Near-term catalysts

- 1QFY26: Milestone in Hologic fFN agreement
- 3QFY26: Update on FebriDx CLIA waiver trial
- 1HFY26: Women's health diagnostic update
- 2HFY26: Completion of Hologic fFN agreement

# Sensitivities and risks

## Synergies

Notwithstanding operational risk related to coordination, LDXs business model creates synergies between its contract development and proprietary diagnostic products. LDX's assay development expertise enhances its in-house pipeline, optimising design, regulatory pathways, and commercialisation. This integration accelerates expansion beyond FebriDx, de-risking product development while strengthening market positioning and revenue growth in the diagnostics sector. Failure to effectively manage the operational and strategic coordination required to optimise and exploit these synergies may expose the company to increased sensitivity and potential negative impact.

## Competition

LDX operates within a highly competitive and dynamic market for diagnostic technologies. This sector is characterised by continuous disruption through emerging technologies and novel product offerings. The competitive landscape is dominated by well-established entities possessing substantially greater resources and market penetration compared to LDX.

## Commercialisation and reliance on distributors

LDX's strategic focus going forward on branded products, such as FebriDx, relies on consistently identifying, developing, and commercialising unique products. Market adoption of new diagnostic tests, particularly in the US, also depends on securing favourable reimbursement policies, gaining acceptance from healthcare providers, and increasing patient awareness. The company also currently relies on distributors' marketing efforts to promote products in various geographies. Inadequate promotion or regulatory non-compliance could negatively impact LDX's operational and financial results.

## Regulatory

Regulatory approval involves obtaining clearances, maintaining registrations, and complying with ongoing requirements in each target market. Failure to meet these obligations could result in severe consequences, including product recalls, fines, production suspensions, approval denials or withdrawals, and even criminal penalties. Such outcomes, potentially enforced by authorities such as the FDA or EU regulators, could significantly impair LDX's ability to produce, sell, or market its products. Delay or failures in obtaining approvals in new geographies or for new products could significantly impact the company's timeline and financial projections.

## Reimbursement landscape

The importance of reimbursement for diagnostic tests, particularly in the US healthcare system, cannot be overstated. For tests such as FebriDx, current reimbursement levels within the existing code structure appear to be relatively secure, especially considering the test's high sensitivity and specificity compared to traditional methods. However, in European and other single-payer healthcare systems, the pricing and reimbursement landscape differs significantly. Changes in healthcare policies and reimbursement models can represent risks in these jurisdictions.

## Technological disruption

The diagnostics field is constantly evolving driven by advances in molecular biology, artificial intelligence, miniaturisation, and automation. New technologies could emerge, rendering LDX's platform obsolete.

## Funding

LDX must effectively manage its operations, scale its manufacturing, and allocate capital across both its growing branded products and commercial service divisions respectively. The company is still loss making and as such is vulnerable to volatility in cash flows and funding shortfalls.

## Intellectual property

Intellectual property is critical for LDX, as it protects its proprietary reader and POC technologies, enables lucrative licensing agreements such as the US$10m deal with Hologic, and underpins the value of its products and partnerships in the competitive diagnostics market. The company has 88 patents (issued or pending), and as such we consider the risk to IP as low.

# References

(1) https://www.globenewswire.com/news-release/2024/11/26/2987324/28124/en/Point-of-Care-Diagnostics-Technologies-and-Market-Research-Report-2024-2029-Opportunities-in-Increasing-R-D-Budgets-AI-and-ML-Integration-Emerging-Economies.html

# Personal disclosures

Chris Kallos, CFA received assistance from the subject company or companies in preparing this research report. The company provided them with communication with senior management and information on the company and industry. As part of due diligence, they have independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in this report. They have taken care to maintain honest and fair objectivity in writing this report and making the recommendation. Where MST Financial Services or its affiliates has been commissioned to prepare content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid has, or will, directly or indirectly impact the content provided in this report.

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The companies and securities mentioned in this report, include:

Lumos Diagnostics (LDX.AX) | Price A$0.10 | Valuation A$0.22;

*Price and valuation as at 19 August 2025 (* not covered)*

# Additional disclosures

This report has been prepared and issued by the named analyst of MST Access in consideration of a fee payable by: Lumos Diagnostics (LDX.AX)

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