FOSTER STOCKBROKING

**EQUITY RESEARCH**

**Healthcare**

5 November 2025

# Lumos Diagnostics Holdings Ltd (LDX.ASX)

*FebriDx to hit fever pitch*

## Event:

- **We initiate research coverage on Lumos Diagnostics Holdings (LDX).**

## Investment Highlights:

- **Point-of-care (POC) diagnostic test provider.** LDX is a healthcare POC diagnostic test company offering both its own products, and services to third-parties such as product development, underpinned by its technology platform. The POC diagnostic market is growing at 11% CAGR driven by rapid results and low costs.
- **FerbiDx the game changer.** LDX's key product is FebriDx, which can rapidly identify with high confidence whether patients' acute respiratory infections (ARIs) are bacterial or viral. The product is a simple blood fingerstick test which delivers results in around 10 minutes.
- **Reducing unnecessary antibiotic prescriptions.** Detrimental impacts of overprescribing antibiotics include adverse side effects, and antimicrobial resistance, which can be disastrous for public health, plus significant costs to healthcare and the economy. Use of FebriDx can help alleviate these issues.
- **80M patients p.a. suffer ARIs in US.** FebriDx is FDA-approved for diagnosing ARIs in 12-64 years age cohort, about 59% of the US population, in a moderate complex setting. However, it is currently undergoing a pediatric trial (2-12 years) which would expand coverage to 72% of population. About 80M patient visits pa in the US are for ARIs.
- **US$2.4b opportunity if CLIA-waiver granted**. LDX has applied for FebriDx to obtain grant of CLIA-waiver, meaning no requirement for a trained professional to administer the test, increasing the market to all 277k US healthcare settings. At reimbursement of US$41.38/test, this means a potential US$2.4b market for FebriDx. Our estimate of LDX's share is US$0.6b, the balance split between distributors and healthcare providers such as primary care physician offices.
- **Well ahead of competitors.** The few competitors to FebriDx have a number of disadvantages, including no CLIA-waiver, requiring a separate and large reader, venous blood draw as opposed to fingerstick, and result times ≥15 minutes.
- **Exclusive distributor Phase to spearhead rollout**. LDX has a US$317M distribution deal with Phase Scientific (Phase) for the exclusive distribution rights for FebriDx in the US. Phase has experience with POC products such as its own INDICAID brand. The agreement is underpinned by minimum order quantities.
- **Services and womens' health products.** LDX Service business has a number of customers, the most notable being major healthcare provider Hologic for which it is assisting developing a new test. The company is also developing its own products, focusing on womens' health, which represents significant upside.

## Earnings and Valuation:

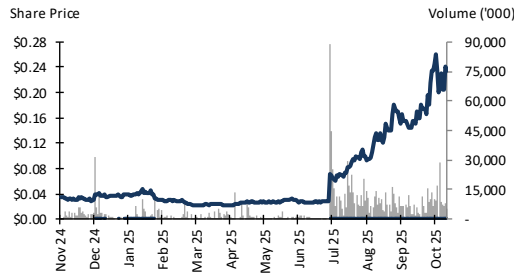
- **We value LDX at $0.42/share using $NPV_{10}$ (nominal)**. Assumptions include FebriDx CLIA-waiver grant, long-term US market share of 10% of ARI patients, FebriDx sales equaling Phase MOQs over next six years, and gross margin of 65%.

## Recommendation:

- **We initiate on LDX with a Buy and 12-month price-target of $0.42,** based on risked valuation. Catalysts include CLIA-waiver, successful pediatric trial, rising FebriDx sales, and progress of own womens' health products.

| Disclosures | | | | |
|---|---|---|---|---|
| **The analyst owns 179,000 LDX shares. Foster Stockbroking, staff, and Cranport own 1.0% of LDX shares on issue.** | | | | |
| **Recommendation** | | | | **Buy** |
| Previous | | | | n/a |
| Risk | | | | Medium |
| **Price Target** | | | | **$0.42** |
| Previous | | | | n/a |
| **Share price (A$)** | | | | **$0.2350** |
| ASX code | | | | LDX |
| 52 week low-high | | | | $0.019-0.28 |
| **Valuation - risked (A$/share)** | | | | **$ 0.42** |
| Methodology | | | | risked NPV |
| **Capital structure** | | | | |
| Shares (M) | | | | 787 |
| Market cap (A$M) | | | | 185 |
| Net cash (debt) (A$M) | | | | 8 |
| Performance rights (M) | | | | 38 |
| Options (M) | | | | 120 |
| Diluted EV (A$M) | | | | 214 |
| Ave daily volume ('000) | | | | 4,279 |
| **Earnings US$M y/e Jun** | **FY25a** | **FY26e** | **FY27e** | **FY28e** |
| Sales | 12 | 13 | 22 | 42 |
| EBITDA adj | -5 | -7 | -3 | 7 |
| NPAT reported | -7 | -8 | -6 | 4 |
| **NPAT adj** | **-8** | **-10** | **-6** | **4** |
| **EPS adj. $*** | **-0.01** | **-0.01** | **-0.01** | **0.00** |
| **PE x** | **nm** | **nm** | **nm** | **44x** |
| EV/EBITDA x | nm | nm | nm | 17x |
| ** Adj =underlying* | | | | |
| **Substantial shareholders** | | | | |
| Tenmile Ventures | | | | 19.9% |
| Ryder Capital | | | | 17.0% |
| **Board** | | | | |
| Sam Lanyon | | | | Non-Executive Chair |
| Doug Ward | | | | CEO &MD |
| Bronwyn Le Grice | | | | Non-Executive Director |
| Lawrence Mehren | | | | Non-Executive Director |
| Catherine Robson | | | | Non-Executive Director |

**Share price graph**





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## Lumos Diagnostics Holdings (LDX)

Full Year Ended 30 June

| Profit and Loss US$M | 2025a | 2026e | 2027e | 2028e |
|---|---|---|---|---|
| Revenue | 12 | 13 | 22 | 42 |
| Operating costs adj. | 18 | 20 | 26 | 34 |
| **EBITDA adj.** | **-5** | **-7** | **-3** | **7** |
| D&A | 3 | 2 | 3 | 4 |
| EBIT adj. | -8 | -10 | -6 | 3 |
| Net Interest expense/(income) | 1 | 0 | 0 | 0 |
| PBT adj. | -8 | -10 | -6 | 4 |
| Tax expense/(benefit) | 0 | 0 | 0 | 0 |
| **NPAT adj.** | **-8** | **-10** | **-6** | **4** |
| Non-recurring items | 1 | 2 | 0 | 0 |
| **NPAT reported** | **-7** | **-8** | **-6** | **4** |
| | | | | |
| **EPS diluted adj. ($)** | **-0.01** | **-0.01** | **-0.01** | **0.00** |

| Financial Metrics | 2025a | 2026e | 2027e | 2028e |
|---|---|---|---|---|
| EBITDA margin % | -44% | -54% | -15% | 17% |
| EBIT margin % | -64% | -78% | -27% | 8% |
| Gearing ND/(ND+E) % | -47% | -326% | nm | nm |
| Interest cover (EBIT/net int exp) x | -15 | 32 | 59 | -22 |
| Average RoE % | -128% | -155% | -77% | 33% |
| Average RoA % | -33% | -46% | -25% | 12% |
| Wtd ave shares M | 680 | 838 | 890 | 890 |
| Wtd ave shares diluted M | 837 | 995 | 1,047 | 1,047 |

| Valuation multiples | 2025a | 2026e | 2027e | 2028e |
|---|---|---|---|---|
| **P/E x** | **-15x** | **nm** | **nm** | **43x** |
| **EV/EBITDA x** | nm | nm | nm | 17x |

| Cashflow US$M | 2025a | 2026e | 2027e | 2028e |
|---|---|---|---|---|
| EBITDA adj | -5 | -7 | -3 | 7 |
| Chng in working capital | -5 | 1 | 0 | 0 |
| Net interest | -1 | 0 | 0 | 0 |
| Tax | 0 | 0 | 0 | 0 |
| Shares-based payments | 0 | 0 | 0 | 1 |
| Other | 1 | 2 | 0 | 0 |
| **Operating cashfow** | **-9** | **-3** | **-3** | **8** |
| | | | | |
| PPE | 0 | -1 | -1 | -1 |
| Acquisitions | 0 | 0 | 0 | 0 |
| Investment | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 |
| **Investing cashflows** | **0** | **-1** | **-1** | **-1** |
| | | | | |
| Equity issue | 6 | 8 | 8 | 0 |
| Debt proceeds | 0 | 0 | 0 | 0 |
| Debt repayments | 0 | 0 | 0 | 0 |
| Other | -1 | -1 | -1 | -1 |
| **Financing cash flow** | **5** | **7** | **6** | **-1** |
| | | | | |
| **Net cash flows** | **-4** | **3** | **3** | **6** |

| Company Valuation | Unrisked | | Risked | |
|---|---|---|---|---|
| **Segment** | **A$M** | **A$/share** | **A$M** | **A$/share** |
| FebriDx | 409 | $0.41 | 409 | $0.39 |
| Other products | 13 | $0.01 | 13 | $0.01 |
| Services | 31 | $0.03 | 31 | $0.03 |
| Corporate | -54 | -$0.05 | -54 | -$0.05 |
| Net cash | 8 | $0.01 | 8 | $0.01 |
| Options-in-money at valuation | 9 | $0.01 | 9 | $0.01 |
| Cash from future raising | 23 | $0.02 | 23 | $0.02 |
| **Equity value** | **439** | **$0.44** | **439** | **$0.42** |
| | | | | |
| Shares | 787 | | 787 | |
| Performance rights | 38 | | 38 | |
| Options-in-money at valuation | 117 | | 117 | |
| Shares from future raising* | 52 | | 110 | |
| **Diluted shares** | **995** | | **1,053** | |

**Risked assumes future shares raised at valuation, unrisked at near current share price.*

| Balance Sheet US$M | 2025a | 2026e | 2027e | 2028e |
|---|---|---|---|---|
| Cash | 2 | 5 | 8 | 14 |
| Receivables | 1 | 1 | 2 | 4 |
| Inventories | 1 | 1 | 1 | 2 |
| PPE | 0 | 0 | 0 | 0 |
| Right-of-use assets | 6 | 6 | 6 | 6 |
| intangibles | 8 | 8 | 8 | 8 |
| Other | 3 | 3 | 0 | 0 |
| **Total Assets** | **21** | **24** | **25** | **34** |
| | | | | |
| Payables | 3 | 3 | 4 | 5 |
| Provisions | 2 | 2 | 2 | 2 |
| Debt | 0 | 0 | 0 | 0 |
| Lease liabilities | 7 | 7 | 7 | 7 |
| Contract liabilities | 0 | 3 | 0 | 0 |
| Other | 0 | 3 | 4 | 7 |
| **Total Liabilities** | **12** | **17** | **17** | **21** |
| | | | | |
| Capital | 104 | 113 | 121 | 121 |
| Reserves | 0 | 0 | 0 | 0 |
| Retained earnings | -98 | -106 | -112 | -109 |
| **Equity** | **6** | **7** | **9** | **13** |

| Capital structure | M |
|---|---|
| Shares | 787 |
| Performance rights | 38 |
| Options | 120 |
| **Diluted shares** | **945** |

*Source: Company; Foster Stockbroking estimates.*

## POC DIAGNOSTIC TEST PROVIDER

- Lumos Diagnostics Holdings (LDX) is a developer, manufacturer and distributor of rapid point-of-care (POC) diagnostic tests. Activities span various stages, including from early initial concept, clinical validation and verification, to commercial manufacture and sales. The company was founded in 2015 and listed by IPO on the ASX in July 2021. Corporate headquarters are in Melbourne, Victoria, and its main operating facility in Carlsbad, California.

### POC - Convenient, simple, quick tests

- POC diagnostic tests facilitate convenient and relatively accurate testing, providing results to patients and physicians quickly (typically 5 to 30 minutes), allowing for immediate clinical decisions. The tests are also compact, and relatively simple to conduct, by patient alone or with the presence of a physician or nurse. No laboratory facility testing is required, especially useful where there is no or limited access to it, as well as saving significant time in obtaining results.
- POC diagnostic tests can be utilised across a wide range of healthcare settings, including hospital and critical care centres, community sites, GP offices, specialist and outpatient clinics, home care, rehabilitation facilities, community centres, pharmacies, and aged care. Hospitals, which have ready access to labs, still often use POC tests for regular monitoring of patients, rapid results for fast diagnosis, and timely decision-making.
- A wide range of health conditions diagnosed by POC tests including diabetes, infectious diseases, influenza, HIV, tuberculosis, sexually transmitted diseases, hepatitis, cardiac health, blood, cholesterol, urinary, respiratory conditions, and pregnancy**.**

### Market size with high growth

- The global POC diagnostic testing market was US$14.3b in 2023 and growing at CAGR 8.5% to US$22.6b in 2029 (*MarketandMarkets*), with infectious diseases a major market segment. Covid19 highlighted several benefits of POC tests, including convenient rapid results, immediate patient management, diagnosis in different environments including home, and generated greater attention, when globally many people used them for the first time.

**Driver of POC diagnostic tests**

- Timely decision-making;
- Consumer education, autonomy, and privacy for home testing;
- Telehealth and other decentralisation of healthcare services;
- Test simplicity;
- Rapid results;
- Relatively low-cost;
- Supportive regulatory and reimbursement environment; and
- Growing incidence of healthcare conditions that can be tested.

**LDX's technology platform the centre of its IP**

- LDX's POC diagnostic test technology platform is its intellectual property (IP), comprising its patents, design, know-how, and in-house expertise. It's the basis for LDX's customised development and manufacture of the tests for its own products and those of third-parties. Key components of the platform are:
    - **Test strips:** These are membranes or physical matrices on which the test, typically rapid lateral flow assay or immunoassay, is conducted, analysed, and the result displayed. Lateral flow and immunoassay tests comprise about 80% of the POC diagnostic test market.
    - **Cassettes.** These are physical containers which house the test strips for storage, usage, and protection. The cassette may include functionality associated with conducting the test, such as dispensing and applying assay detector reagents, or interfacing with a digital test reader.
    - **Readers.** These capture, analyse, interpret, and transmit test results, with measurements typically using colorimetric or fluorescent signals, including sensing with high precision camera optics that analyse strips. Readers can be formatted to have a range of different functions depending on the test. Types include disposable single-use only and simple qualitative yes/no (positive/negative) tests; multi-use disposable providing single-use test strips with limited re-use; and high-performance desktop offering multiple tests, applicable for higher volume and complexity that report results quantitatively.
    - **Digital Applications.** Digital readers can interface with cloud and electronic medical records, integrating into patient workflows.
- LDX's patents cover many of the above features, including trademarks, housings, drawings, test procedures, software applications, manufacturing, quality control, clinical trials, verification, and validation procedures.

**Figure 1: LDX POC Diagnostic Technology**

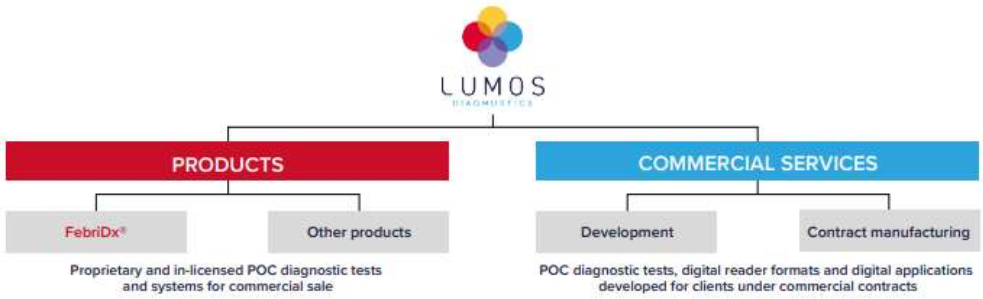

*Source: Company.*

## BUSINESS DIVISIONS

### Products and services

- LDX'S business comprises two divisions, Products and Commercial Services. The former encompasses development, manufacture, distribution, and sales of the company's own proprietary and in-licensed POC tests, while Services provides development and manufacture of POC diagnostic tests for third-party clients under fee-based commercial contracts, including contract manufacturing.

**Figure 2: LDX Business Divisions**




*Source: Company.*

## PRODUCTS

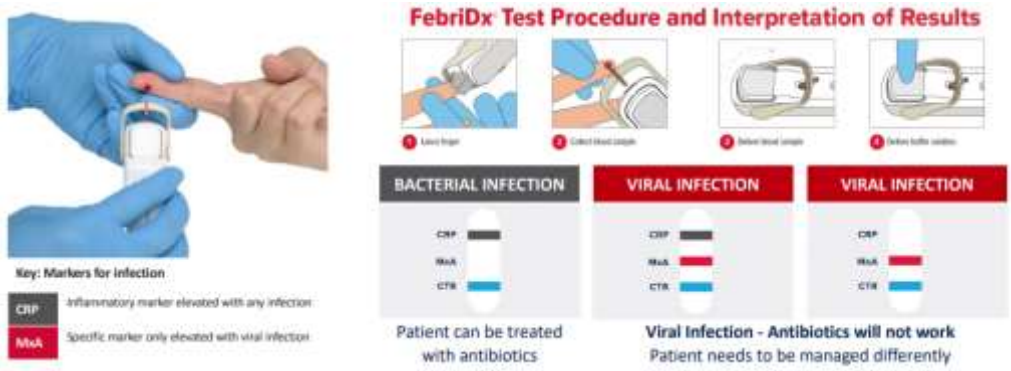
### FebriDx – the key product

- LDX's major product is FebriDx, a POC diagnostic test able to rapidly identify whether patients suffering acute respiratory infection (ARI) symptoms, such as sore throat, acute cough, and sinus congestion, have a microbial infection, and if positive, whether the infection is caused by a viral or bacterial pathogen. It was first launched commercially in FY20 and gained US FDA 510(k) clearance for use in 12-64 year-old patients in a moderate-complex setting in 2023.

### How it works

- FebriDx uses a simple lateral-flow assay, a procedure that qualitatively assesses a compound or its effects on identified molecular, cellular, or biochemical targets. FebriDx's assay detects targeted analytes in complex mixture samples, based on a proprietary combination of two biomarkers that are produced by the human body in response to infection - a host-response test that measures the patient's immune response to an infection, rather than directly detecting the infecting microbe itself. FebriDx evaluates the level of two human immune proteins that become elevated in a patient's bloodstream when they have a microbial infection:
    - C-reactive protein (CRP) – a general or non-specific marker for inflammation and infection; and
    - Myxovirus resistance protein A (MxA) - a marker specific for viral infections.
- FebriDx is a disposable test in the form of a cassette that collects a patient's blood by fingerstick while housing the test strip. It is a relatively inexpensive, all-in-one, instrument-free, compact, and portable test. Results can be delivered after ten minutes.

**Figure 3: FebriDx Test**




*Source: Company.*

- LDX manufactures FebriDx at its Carlsbad facility, including test strip, assembly, and packaging. The company's IP covers the use of the MxA marker, the combination of MxA and CRP, and the threshold levels to determine a positive test result. The company has a supply and exclusive licensing agreement with Atomo Diagnostics to 2033 for its all-in-one Pascal cassette used in FebriDx.

## Advantages of FebriDx biomarkers

- **Detects wide range of bacterial or viral pathogens.** FebriDx's host-response test clinically detects significant infections caused by a range of bacterial or viral pathogens, whereas pathogen-specific tests may be limited to identifying one pathogen and its related infection only.
- **Detects only active infections.** FebriDx will only detect active infections, which are the most likely to require medical intervention. Tests relying on detecting the pathogen itself cannot distinguish between an active infection that may require treatment and a benign microbial colonisation that does not require any.

## Clinical studies back up positive results

- Numerous clinical studies have been undertaken on FebriDx, published in over ten peer -review scientific journals, and tests on over 2,000 patients. These have found positive results for FebriDx including:
    - 90% reduction in unnecessary antibiotic prescriptions, including 80% in ARI patients;
    - A 99% NPV (negative predictive value) for bacterial infections in patients that present with a fever, meaning doctors can be highly confident, or 99% certain, that a patient does not have bacterial infection.
    - High sensitivity (95%) of the test for bacterial infection, reflecting the ability to correctly identify true positives (patients who have the condition and record a positive result);
    - High specificity (94%) for bacterial infection, the ability to identify true negatives (patients who do not have the condition and record a negative result);
    - 95% sensitivity and 94% specificity for viral infections;

## ANTIBIOTIC MISUSE

- When a patient presents with ARI, it is often difficult to distinguish between a bacterial or viral ARI as they often have similar symptoms. Consequently, many patients are prescribed antibiotics as a cautionary measure so as not to accidently miss possible bacterial infection. However, antibiotics are specifically designed to kill bacteria, and do not work against other microbial pathogens such as viruses, fungi, or parasites which require other drugs. Evidence of misuse includes:
    - 40% of prescriptions for outpatients are unnecessary, patient not possessing a bacterial infection; and
    - While the majority of ARIs are caused by viruses and only 10-15% from bacteria, antibiotics are prescribed in up to 50% of cases (US Centres for Diseases Control and Prevention, CDC).

### Negative effects

- Unnecessary antibiotic prescribing has major negative effects:
- **Immediate side-effects.** 1-in-10 patients can experience side-effects or allergic reactions to antibiotics, some of which can be life-threatening and require additional medical interventions or hospitalisation, e.g. anaphylactic reactions (NHS).
- **Antimicrobial resistance (AMR).** The misuse and overuse of antibiotics in humans are the main drivers of drug-resistant pathogens, that no longer respond to the drugs. AMR make infections harder to treat and medical procedures such as surgery, caesarian sections, and cancer chemotherapy riskier. AMR bacteria can be transmitted to across communities.
- Some key findings on AMR from World Health Organisation (WHO) include:
    - AMR is one of the ten greatest public health threats facing humanity.
    - A person with resistant bacteria will doubles their chance of developing serious health issues and triple their chances of death.
    - AMR was directly responsible for 1.27M deaths globally in 2019 and contributed to 4.95M deaths and if no steps are taken to reduce it, AMR may be responsible for up to 10M deaths worldwide by 2050.
- **Incorrect diagnosis adverse effects.** Conversely not prescribing an antibiotic because of misdiagnosing a viral infection can cause the untreated bacterial infection to cause health complications, potentially progressing to sepsis.
- **Major cost to healthcare system.** Antibiotic resistant infections, which often occur in hospitals, require expensive healthcare resources to treat including more doctor visits, lengthier recovery, prolonged hospital stays, and patients experiencing a higher incidence of long-term disabilities and fatality. The CDC estimates antibiotic resistance in US can add US$1,400 to a patient's hospital bill for the treatment of bacterial infections. The World Bank estimates AMR could result in US$1 trillion additional healthcare costs by 2050, and US$1-3.4 trillion GDP losses per year by 2030.

### How FebriDx can be crucial in fights again antibiotic misuse

- Reduces side effects from unnecessary antibiotic prescriptions
- Reduces misdiagnosis and follow-up visits
- Saves time for patient and healthcare professionals
- Saves costs for insurers and government
- Quicker and more effective decision-making by healthcare professionals
- Reduces antimicrobial resistance and its adverse effects on population health

## THE MARKET FOR FEBRIDX

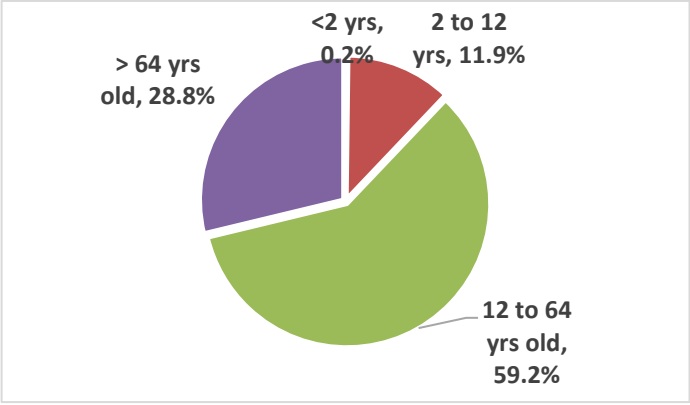
### US the major target market

- FebriDx has regulatory approvals in the USA, UK, Europe, Australia, UAE, Turkey, Pakistan, Singapore, Malaysia, and New Zealand. However, sales in these regions to date have been small, due to the need for government reimbursement to drive market adoption, given it is the major payer of health. This presents its own unique bureaucratic challenges.
- In contrast to other developed economies, the private reimbursement system is the major payer of health in the US, and presents a larger but easier opportunity for FebriDx, being more open to adopt new healthcare products if savings can be demonstrated.
- In the US FebriDx can be currently marketed for use by healthcare professionals as an aid in diagnosing bacterial infection from non-bacterial etiology with patients aged 12-64 years presenting in urgent care or emergency care settings. These include ARI symptoms, such as acute respiratory tract infections (ARTI), such as the common cold, influenza, and Covid 19.

### Pediatric trial to expand target demographic to 2-64 years

- The FDA-approved target age group of 12-64 years represents about 59% of the US demographic. However, the company recently commenced a pediatric study for authorised use of FebriDx in children 2-12 years, expected to be over 12 months duration of a full respiratory season. Successful approval by FDA would expand FebriDx's target market from 59% to 72% of the US population.

**Figure 4: US age cohort, % of patient visits**




*Source: US CDC; US census; Foster Stockbroking estimates.*

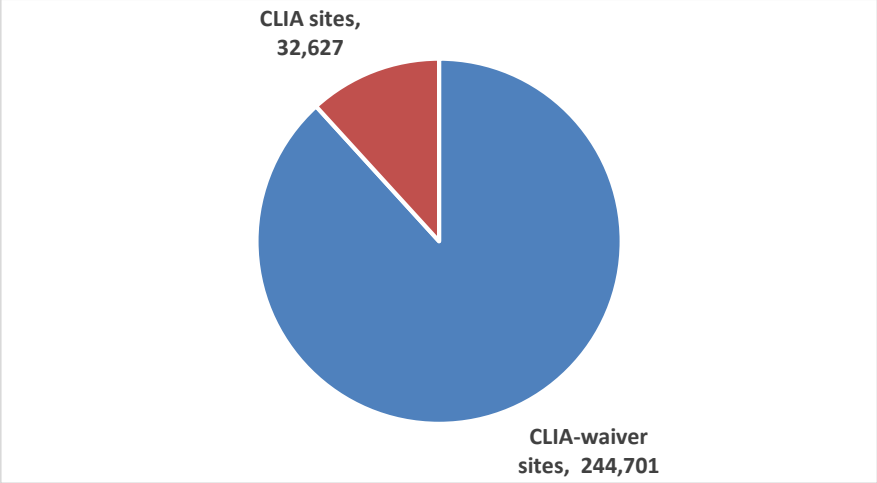
### 80M visits pa for ARI

- The number of annual US ARI patient visits across all healthcare settings varies, with estimates varying from 35M to 150M. We think LDX's own estimate of 80M, based on Precision Business Insights, a reputable source is a sound estimate, while incidentally also lying near the mid-point of the 35-150M range.

### CLIA-waiver to expand FebriDx market to all US healthcare settings

- FebriDx is subject to the Clinical Laboratory Improvement Amendments (CLIA), a US law that sets quality standards for lab tests. Under CLIA, every facility must be certified according to the complexity of the test undertaken: CLIA-waived – simple test with low risk of errors; Moderate Complexity - more steps, training and QC required; and High Complexity - requiring skilled personnel, stringent oversight, and inspections. Currently FebriDx is authorised for use in a non-CLIA waiver setting as a Moderate Complex test, meaning only authorised sites with a trained person can administer test.
- The total number of healthcare settings in the US are over 277k. However, FebriDx is currently applicable to only 33k (CLIA), or 12% of total market, usually limited to large urgent care and emergency centres. However, there are 245k clinical settings in the US that are CLIA-waived, including mostly physician offices and stand-alone care providers that can perform diagnostics without laboratory oversight.

**Figure 5: CLIA-waiver and CLIA healthcare sites**




*Source: Centers for Medicare & Medicaid Services. CLIA sites include Compliance and Accreditation Certificates. Excludes CLIA Exempt and Provider Performed Microscopy.*

### CLIA-Waiver trial's positive results

- LDX completed a clinical trial to extend the label for FebriDx to include CLIA-waived settings, the trial undertaken in partnership with Biomedical Advanced Research And Development Authority (BARDA), part of the US Department of Health and Human Services Administration for Strategic Preparedness and Response, which provided LDX US$2.5M in funding, as well as regulatory expertise and support of the application to the FDA to obtain CLIA waiver.
- The results demonstrated FebriDx possessed insignificant risk of erroneous results from untrained users, with 99.1% concordance between trained and untrained operators testing bacterial positive patients, and a 98.4% concordance for non-bacterial patients. We believe these key metrics should satisfy the FDA.

- LDX submitted is application 18 August 2025. We expect 18 November 2025 as the earliest approval date, while the company has guide to a November – February window, including any 60-day extension due to questions from the FDA.
- BARDA is also supporting LDX's pediatric trial with US$6.2M funding. The study will target around 500 patients, including approximately 72 bacterial positives. Milestone payments will be triggered upon 12 significant events, including clinical trials set up, patient recruitment, FDA application and FDA clearance for of 510(k) and CLIA waiver for children 2-12 years.

### Reimbursement implies US$2.4b market for FebriDx, US$0.6b for LDX

- POC diagnostic test reimbursement rates are set by US Government's Medicare, based on a physician fee schedule, assigning a unique code and payment rate. This sets a precedent for private payers, and influencing both the use and wholesale price of POC diagnostic tests, encouraging widespread use of a procedure where the patient has minimal or no out-of-pocket expenses. Private payers and insurers comprise about 61% of reimbursement, while the Center for Medicare and Medicaid Services (CMS) comprise 39%, the latter covering individuals aged >65 years and people with disabilities.
- FebriDx has a unique reimbursement identifier from the CMS which is the Current Procedure Terminology (CPT) Proprietary Laboratory Analyses (PLA) code 0442U at a reimbursement rate of US$41.38/test, providing a unique billing pathway for claims tracking, and allowing LDX to engage US private and government payers to establish reimbursement and coverage policies for FebriDx.
- Assuming annual ARI patient visits of 80M p.a. and 72% of these, or 57.6M, being FebriDx's target market of 2-64 years, the reimbursement of US$41.38/test, implies a total addressable market (TAM) of US$2.4b p.a. for FebriDx. Assuming LDX sells FebriDx for US$11/test, its share of the TAM would be US$633M, the balance of the TAM to be shared between distributors and healthcare providers, such as physicians, administering the test.

### Progress with Medicare and insurers

- LDX has secured FebriDx coverage with six of the seven Medicare Administration Contractors (MACs) that support reimbursement processing in the US, and is currently negotiating with the seventh MAC, National Government Services, which we expect will provide coverage shortly.
- The company also partnered with PRO-spectus, a US market access consultancy, to support marketing, market access, and reimbursement of FebriDx, including reimbursement helpline team, and manager services to help navigate payer payments, resolve specific coding challenges. Gradually, precedents for build across pilot sites and customers, aligning with payer policies and adoption of the FebriDx code, expanding coverage and increasing demand, especially as CLIA-waiver is granted.

## DISTRIBUTION - PHASE SCIENTIFIC PARTNERSHIP

### >US$300M FebriDx orders

- By far, LDX's most important US FebriDx distribution partnership is with PHASE Scientific International Ltd (Phase), having signed a transformative six-year exclusive agreement worth up to US$317M for Phase to exclusively distribute FebriDx in the US.

- LDX has received US$3.5M to date from Phase, comprising a US$1M exclusivity fee, US$1M pre-payment for a FebriDx order, and US$1.5M pre-paid order upon its CLIA waiver application to the FDA. A further US$5M is payable upon receipt of the CLIA waiver. The balance of US$308.5M will be paid to LDX from minimum order quantities (MOQs) of FebriDx over years 2 to 6, essentially 2026 to 2030, as Phase gradually ramps up roll-out of the product.

**Phase focusing on sales and marketing, LDX on supply**

- Phase will undertake sales, marketing, and distribution of FebriDx, while LDX will focus on manufacturing, marketing and reimbursement support, compliance, quality control, and regulatory, while importantly retain intellectual property relating FebriDx and any possible co-branded product.
- Phase will be incentivised to satisfy MOQs, especially if FebriDx has CLIA waiver, otherwise LDX has the option to pursue other distribution methods. If LDX doesn't get CLIA waiver, there are MOQs still in place but only up to a value of US$25M as opposed to US$317M, reflecting the narrower slice of about 8% of the TAM.

**FebriDx provides differentiation for Phase**

- Phase is Hong Kong company with offices in US and China, founded in 2015, with expertise in the US POC diagnostic market from its INDICAID brand products, which have sold over 100M tests, including RATs such as Covid, Flu A, B, and RVS. As these tests are somewhat commoditised in the market, Phase is seeking to offer more differentiated, innovative, and unique products, such as for cancer and infectious diseases with proprietary technologies. Examples include a HPV-urine test, for which it raised US$34M at a reported valuation of US$525M. Value Partners Group, one of Asia's largest independent asset managers, the Gates Foundation, National Science Foundation, and National Institute of Health (NIH) have been investors.
- We believe Phase is highly attracted to the uniqueness of FebriDx where there is little to no competing product, and offers an opportunity to take significant market position. Its keenness is reflected entering a committed agreement pre-CLIA waiver, whereas larger distributors likely would have conservatively preferred to wait

**Other US partners to be sub-distributors to Phase**

- Phase has a strong network of sub-distributors and end-user customers for its existing diagnostic products, including major distributors like McKesson and Henry Schein. We expect LDX's previously appointed national and regional distributors will place orders for FebriDx through Phase, effectively becoming sub-distributors, covering over 3,000 sales representatives. LDX had multiple distributors and direct customers for FebriDx, ranging from large nationwide entities like Henry Schein and Thermo Fisher Scientific to smaller, localised, and regional players such as Atlantic Medical Solutions and CLIA Waived Inc.
- LDX also has partnered with MediGroup, the largest non-acute care group purchasing organisation (GPO) in the US, with 30k members, including mix of moderately complex labs and CLIA waived settings, and the US Defense Logistics Agency (DLA).

### Marketing and sales

- Phase will target customers across a wide range of settings and sectors - urgent care, physician offices, surgery centres, home health agencies, retail/pharmacy, worksite, correctional health, Indian health, student health, concierge medicine, and government. Areas especially sought out will be under-penetrated markets, innovators, early adopters, high volume users, and opinion leaders. Phase will leverage its existing INICAID customer relationships to drive FebriDx utilisation and cross-selling strategies.
- First US sales of FebriDx was in January 2024, and the largest sale single sale to date has been to iMedical Inc for US$126k in May 2025, while this month urgent care chain WellStreet began rollout of FebriDx at one of its facilities, the with the chain procuring FebriDx through Phase.

## THE FEBRIDX EARNINGS CHAIN

### We estimate gross margin of 65%, but could be higher

- We envisage a single FebriDx test's US$41.38 to be approximately split across the various healthcare system participants as follows:

  - Manufacturer (LDX). R&D, IP, regulatory, and production. Sells to distributor at cost-of-test plus margin. LDX expects that under the Phase agreement the FebriDx gross margin will meet or exceed that previously reported, which over the past couple of years has ranged from 55% to 67%. We assume a sale price of US$11/test and gross 65% margin, which results in US$185M gross profit for FebriDx over the six year-period based on MOQs. However, there is upside to the margin due to scale benefits in the latter part of the period as sales ramp up.
  - Distributor. Sales to healthcare providers, logistics, warehousing, and inventory. Buys product from LDX, sells to healthcare providers at cost plus margin, or splits margin with sub-distributors.
  - Healthcare providers including physicians. Use test for diagnosis and treatment monitoring. Administer tests and receive US$41.38/test either from patient or reimbursed from Medicare/private insurer. The provider's margin is difference between reimbursement fee and price from paid to distributor for purchase.
  - Patients. Receive test without payment., or reimbursed by private health insurer/Medicare for US$41.38, offering limited out-of-pocket expense.
  - Payers: Determine coverage, reimbursement policies, and premiums.

## COMPETITION

### FebriDx well ahead of peers

- There are two main competing products to FebriDx in the US market – MeMed BV and Inflammatix Triverity. However, these have significant drawbacks compared to FebriDx:
  - **Require separate readers** to display the test result, which are much larger than the cassette, making the whole test less portable and compact (Figure 7).
  - **They are not fingerstick tests**, instead drawing blood venously which is more uncomfortable for the patient.

- **Longer wait times of 15-30 minutes** for test results.
- **They are not CLIA-waived**, limited to use in emergency care and hospital inpatients.

- MeMed is developing a fingerstick blood version of its MeMed BV product called MeMed BV Flex, but this product is still in development, with a clinical trial required, and still requires a separate reader. We suspect the product is at least two years behind that of FebriDx.

**Figure 6: FebriDx and Competing Products**

| Product | FebriDx | MeMed BV | MeMed BV Flex | Triverity |
|---|---|---|---|---|
| Company | LDX | MeMed | MeMed | Inflammatix |
| Separate reader not required | ✓ | x | x | x |
| Compact | ✓ | x | x | x |
| Fingerstick test | ✓ | x | ✓ | x |
| Result time | 10 mins | 15 mins | 15 mins | <30 mins |
| Bacterial infection NPV | 99% | 96% | n/a | 95% |
| FDA clearance | ✓ | ✓ | x (in development) | ✓ |
| CLIA-waiver | submitted | x | x | x |
| Low cost/reimbursement fee | $41.38 | $260.50 | x | n/a |

*Source: Companies; Foster Stockbroking estimates.*

**Figure 7: Competitor Products Requiring Separate Readers vs FebriDx**


*Source: Company.*

## OTHER PRODUCTS

### Womens Health in development

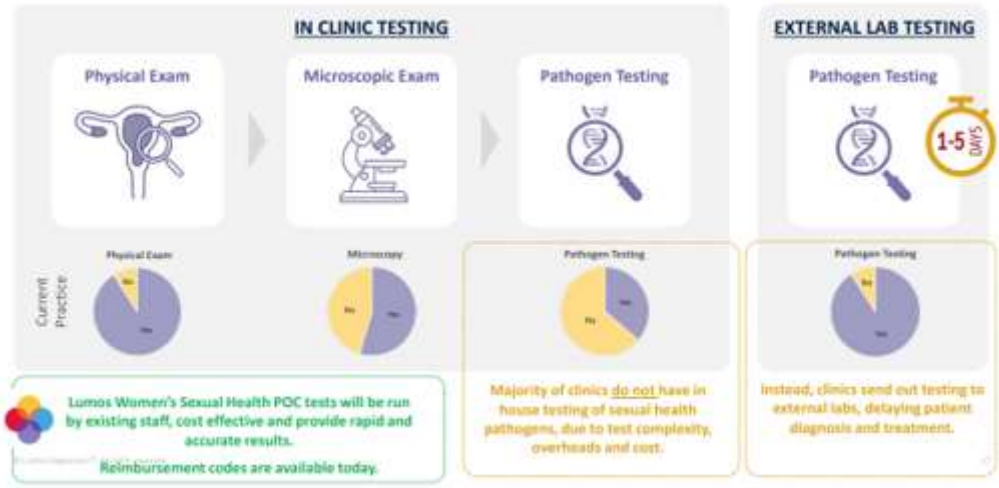
- LDX is seeking to expand its sales of POC diagnostic tests with a pipeline of new proprietary products under development, focusing on womens health, including sexual health. The company is exploring five potential products aimed at addressing unmet needs, with three in the concept development stage and two advancing to technical feasibility. LDX is targeting the transition of at least one of these products into formal product development within the next 6-8 months. Timeline is:
  - Feasibility and development on clinical samples in year 1,
  - Verification, pilot study and clinical trial in year 2,
  - FDA review in year 3.

### Need for fast test results

- The womens sexual health market tis US$10b, with >10M health care visits annually. Clinical needs are where multiple infectious organisms yield similar symptoms but require different

treatments – somewhat analogous to how similar symptoms are displayed by infectious and viral infections in ARI. Current practice requires microscopy and pathogen testing, with results taking one to five days. A POC diagnostic test needed for rapid testing on-site to identify and treat patient at visit, and easy to use by clinic staff.

**Figure 8: Womens Sexual Health Opportunity for LDX**




*Source: Company.*

**Binx and CorDx**

- LDX also has small sales (<US$1M pa) from CorDx and Binx, the former a Flu A/B & Covid-19 multiple tests at a competitive price point, and the latter a molecular POC tests for rapid detection of chalmydia and gonorrhea. Both products are CLIA-waived and licensed from third parties.

## COMMERCIAL SERVICES

### Servicing third parties

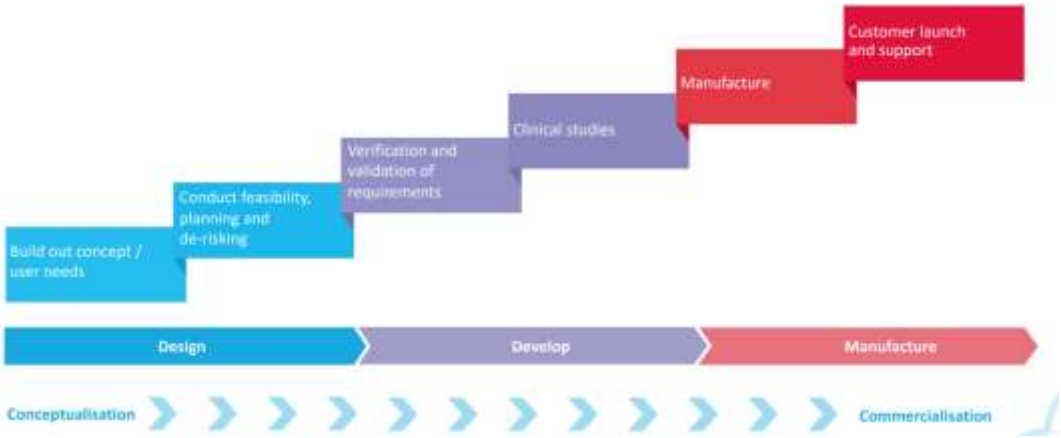
- LDX's Commercial Services division offers a range of start-to-finish POC diagnostic test services for clients, spanning all development stages from early concept to commercial-scale manufacture, including development of assays, digital readers, software applications, and contract manufacturing. The services are usually project-based and may be lumpy in revenue, but can include multi-year contract manufacturing agreements with MOQs. Revenue usually comprises both upfront and milestone-based fees. Details of stages include:

- **Product concept.** This encompasses developing a product concept or innovation, including evaluating commercial potential, assay chemistry for measuring and detecting a relevant diagnostic marker, initial studies to measure diagnostic markers in human tissues samples, and initial trial of the tests on one or more diagnostic readers.

- **Development and manufacturing.** Includes engineering a digital reader into a commercial-ready form by optimising test performance, either as a visually read test or in combination with one or more reader formats; customisation and supply of digital readers across a range of formats including size, cost, and complexity, including multi-disposable and desktop readers; and development of a commercially scalable manufacturing process.

- **Validation and commercial manufacturing.** This includes clinical and quality data to support applications for regulatory clearance, such as clinical verification and product evaluation; and undertaking commercial POC diagnostic test manufacturing and post-launch support for clients.

**Figure 9: LDX Commercial Services – Pathway from Concept to Commercial Product**




*Source: Company.*

## CLIENTS

- Commercial Services has a diverse client base from across industries such as human diagnostics and wellbeing, food safety and quality, and animal health. Product concept and development tests the company has recently worked on, or is currently involved, include liver health, cancer screening., hormone monitoring, maternal fetal health, anemia, nutrition, animal health, food safety, and molecular diagnostics. Current customers include Hologic, Aptatek BioSciences Inc, Burnett Diagnostics Initiative, Huvepharma, and TeleMedVet.

### Hologic key customer

- Hologic, a leading global womens' healthcare provider, is LDX's largest services customer. LDX's current work for Hologic stems from two agreements in 2024 for providing IP, development, and exclusive licencing for a fetal fibronectin (fFN) diagnostic product for pre-term birth, with LDX's proprietary reader and POC technology to be incorporated in the Hologic's next generation product, adding the benefits of latest technology with reader platform and connectivity for improved digital patient record management.

**Figure 10: LDX-Hologic fFN POC Diagnostic Test Development**


*Source: Company.*

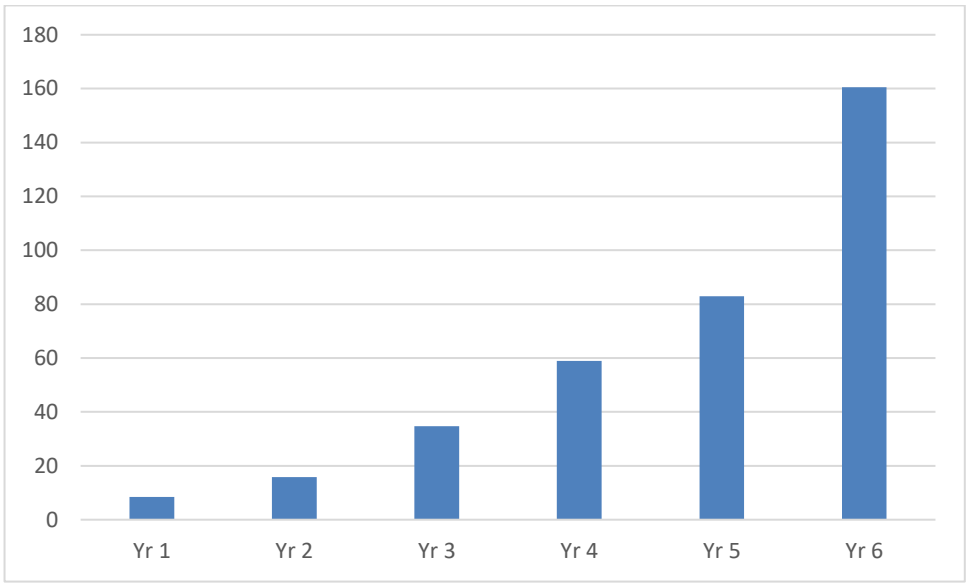
- fFN is the largest segment in the pre-term diagnostic market, and is a biomarker indicating a heightened risk of pre-term delivery when present in cervicovaginal secretions. It is found at the maternal–fetal interface and as delivery approaches, becomes increasingly detectable. Detection of fFN in pregnancy weeks 22-35 can indicate that woman is at higher risk of preterm delivery. US annual term birth TAM is 2.5M tests pa at reimbursement rate for fFN at US$64.41/test, implying size of US$160M pa.
- The Hologic IP agreement was worth US$10M, and was paid to LDX in 2024. The Hologic Development Agreement is valued up to US$6.4M payable over 32 months (January 2024 to around August 2026), for milestones achieved over the period. These include:
    - Phase 1 (milestone 1, US$0.4M): Production definition and Planning. Defining parameters for product and establish a project plan. Completed.
    - Phase 2 (milestones 2-3, US$2.7M): Assay feasibility. Demonstrate the assay is able to detect the biomarkers which has been completed. Hologic has also requested additional studies for assay feasibility, and will provide LDX a scope of work, expected to take 3-4 months. US$1.8M has been received so far.
    - Phase 3 (milestones 4-9, US$3.3M): System prototype delivery. A working prototype of the system. US$3.7M across six milestones. Work has started on first and second milestones. US$1.0M has been received so far in payments.
    - Expanded scope of hardware. Commenced. US$0.8M for new hardware features in the proprietary reader technology.
- There are potential opportunities for LDX ahead with Hologic once the current scope of work is completed in 2026. This could include verification and validation, clinical studies, manufacturing, and a second test and IP development:

## EARNINGS FORECASTS

### Key assumptions

- Our LDX earnings forecasts are based on following assumptions:
    - FebriDx CLIA-waiver received by end 2025.
    - FebriDx sales equalling Phase's MoQs over its six-year period (Figure 11).
    - FebriDx long-term market penetration is 10% of total US patient ARI visits, including 14% of patients aged 12-64 years.
    - LDX sale price of FebriDx US$11/test and gross-margin of 65%.
    - Other products (ex-FebriDx) and Services long-term growth of 2%.
    - LDX group long-term EBIT margin 22%.
    - Maiden NPAT in FY28 (refer page 2 for detailed earnings forecasts).

**Figure 11: Forecast FebriDx Sales to Phase (US$M)**




*Year 1 corresponds from date of LDX-Phase agreement (July 2025); Years 2-6 from grant CLIA-waiver (FSBe: November 2025). Source: Company; Foster Stockbroking estimates.*

## VALUATION

### LDX risked valuation $0.42/share

- We derive a risked NPV of $0.42/share for LDX, based on a DCF model using 10% nominal discount rate and a terminal growth rate of 2%. The valuation is based on our aforementioned earnings assumptions.
- We assume an equity raising of US$15M near the current share price in our risked valuation, as company ramps up working capital for FebriDx commercialisation on in the US. The company also has a loan facility of US$3.3M for working capital which is currently undrawn. LDX had US$4.9M end September 2025 and nil debt.

**Figure 12: LDX Valuation**

| | Unrisked | | Risked | |
|---|---|---|---|---|
| **Segment NPV** | **A$M** | **A$/share** | **A$M** | **A$/share** |
| FebriDx | 409 | $0.42 | 409 | $0.39 |
| Other products | 13 | $0.01 | 13 | $0.01 |
| Services | 31 | $0.03 | 31 | $0.03 |
| Corporate | -54 | -$0.06 | -54 | -$0.05 |
| Net cash | 8 | $0.01 | 8 | $0.01 |
| Options-in-money at valuation | 9 | $0.01 | 9 | $0.01 |
| Cash from future raising | 23 | $0.02 | 23 | $0.02 |
| **Equity value** | **439** | **$0.44** | **439** | **$0.42** |
| | | | | |
| Shares | 787 | | 787 | |
| Per Rights | 38 | | 38 | |
| Options-in-money at valuation | 117 | | 117 | |
| Shares from future raising* | 52 | | 110 | |
| **Diluted shares** | **995** | | **1,053** | |

**Shares from future raising assumed issued at valuation in unrisked case, and at near current share price in risked case.*

*Source: Foster Stockbroking estimates*

### Upside from womens' sexual health products

- We believe the largest upside to our LDX valuation is from other products that the company has in development, mostly concerning womens' sexual health. These have the scope to provide significant valuation uplift lit as LDX successfully advances their progress.

## RECOMMENDATION

### Buy, price-target of $0.42

- We initiate with a Buy recommendation on LDX with a 12-month price target of $0.42, based on our risked valuation. Catalysts for the share price include:
    - CLIA-waiver approval from the FDA for FebriDx;
    - Progress in womens' health products
    - Increasing FebriDx sales; and
    - Increase in services business.

## KEY PERSONNEL

- **Doug Ward. MD & CEO**. Over 30 years' career in diagnostic and life sciences industry. Held roles with Roche/Ventana Medical, GE, Siemens, Bayer, Chiron, PGDx, and Hologic. Included expanding Ventana's companion diagnostics growing revenue to US$50M over two years. Was CEO of PGDx, establishing key genomic IVD tests which formed basis for acquisition by Labcorp in 2022 for US$575M, and VP of Strategy and Business Development at Hologic.
- **Paul Kase. Chief Commercial Officer.** Paul re-joined LDX in 2020 after previous tenure as Senior Director of US sales for Rapid Pathogen Screening (RPS) in 2017, which had focused on development and commercialisation of FebriDx, and merged with LDX in 2019. Over 27 years' experience in medical sales and POC diagnostic markets. Responsible for North American sales and implementing marketing strategies, customer relationships, and engaging end-user demand.

## RISKS

The following risks may negatively impact the LDX share price:

- **Sovereign risk**. Any change in government, policy, legislation, or fiscal policy of the US or Australia, may markedly impact the company's products or its corporate profitability.
- **Regulatory risk.** Failure to receive CLIA-waiver approval for FebriDx, or other regulatory approval for products in development, and in complying with regulatory standards may limit the company's profitability.
- **Clinical validation risk.** Negative trial outcomes of future products or the FebriDx pediatric trial may negatively impact ability to commercially launch product or expand markets.
- **Financing risk.** To fund its Arcadia project the company may raise equity which may dilute shareholders, and/or borrow debt which it may not be able to service.
- **Economic and market risk.** Should global economic growth decline or share markets fall, or demand or growth slow for POC diagnostic tests, this would negatively impact LDX earnings.
- **Distribution risk**. Termination of its agreement with Phase, or any other distributor or sub-distributors, may slow down market adoption of FebriDx or other LDX products.
- **Client risk.** Commercial Services clients such as Hologic may decide to fully use their own internal resources for product development, negatively impacting LDX.
- **Supplier risk.** Loss of supply of key components and inputs into LDX's products and services business may negatively impact FebriDx or other LDX products and services,
- **Intellectual property risk**. LDX's patents may be infringed or challenged, and the company may incur material legal costs in challenges and defence.
- **Reimbursement risk**. Change in healthcare funding, laws or insurer policies can negatively impact products sales.
- **Product risk**. Competitors and regulation may make LDX products and services obsolete or reduce demand.

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