

# Lumos Diagnostics Holdings Limited Annual General Meeting – CEO Presentation

24 October 2025

Financial information is shown in USD unless otherwise stated.

www.lumosdiagnostics.com

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# **Board of Directors**





**Sam Lanyon**Non-Executive
Chair



Doug Ward
CEO and
Managing Director



**Bronwyn Le Grice**Non-Executive
Director



**Lawrence Mehren**Non-Executive
Director



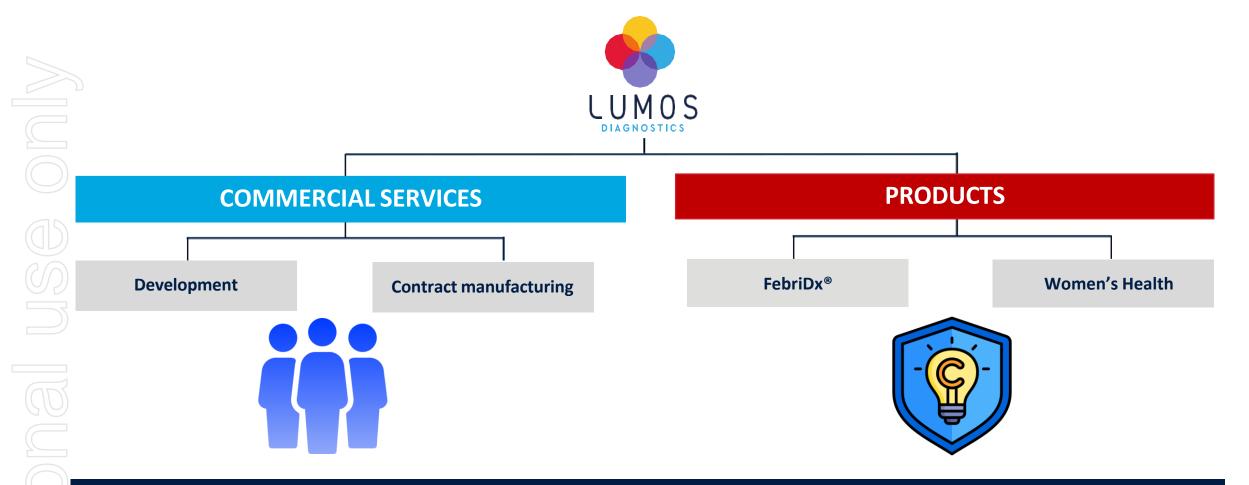
Catherine Robson
Non-Executive
Director



Lumos develops, manufactures and distributes innovative diagnostic products – delivering actionable information, in real time, at the point-of-care.

## **Lumos Business Overview**





People and Capability drive value - able to leverage R&D, IP, manufacturing scale, medical, quality and regulatory skillset across

Lumos' Products and Commercial Services business.

## **Investor Takeaways**





# First in Class Product FebriDx® Nearing Major US Breakthrough

- CLIA waiver study exceeded performance targets (99%+ concordance)
- FDA submission lodged 18 Aug 2025, decision expected Nov 25 - Feb 26
- FebriDx® protected by a broad global patent estate covering method, device, and biomarkers



# Transformational US\$317M (A\$487M) Distribution Deal

- With PHASE Scientific for the US market over 6 years,<sup>1</sup> assuming FebriDx® granted CLIA waiver and minimum order quantities (MOQ's) are achieved
- Initial US\$5M prepaid order triggered at CLIA waiver grant
- One of the largest POC distribution deals for an ASXlisted diagnostics company



#### **Revenue Growth & Margin Strength**

- FY25 revenue up 12% to US\$12.4M; product sales up 46%
- Gross margin stable at 63%
- EBITDA loss narrowed by 12% to US\$3.4M (showing operating leverage as scale builds)



#### > US\$1.0 Billion p.a. TAM for FebriDx

- CLIA waiver unlocks >80M patient interactions annually in the US
- 0442U: proprietary PLA Code assigned for FebriDx®
- CMS established rate on CLFS (Clinical Lab Fee Schedule) for FebriDx at US\$41.38 per test



#### **Commercial Services Division**

- Licensing/IP agreements add recurring high-margin revenue
- Hologic: US\$10M IP licensing + US\$6.4M development agreement for next-gen fFN women's health test
- Additional US\$1.5M Aptatek contract advancing inhome PKU monitoring



# Strong Funding Partnerships, No Debt, No Royalties Payable

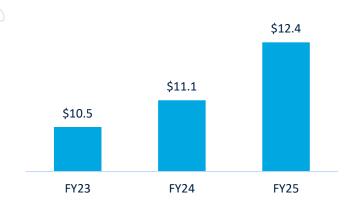
- BARDA: US\$8.3M non-dilutive funding (CLIA waiver + pediatric study)
- A\$5M loan facility available with Tenmile and Ryder Capital (drawdowns at Lumos discretion)

<sup>1</sup>AUD:USD of 0.651 as at 15 July 2025

# **Financials Summary - Annual**



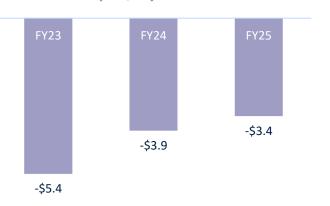




#### Gross Profit (US\$M) & Margin



#### Adjusted EBITDA (US\$M)



# **Financial Highlights**



**Revenue Growth** 

US\$12.4M

FY25, up 12% YoY. Products up 46% YoY



Gross Profit & Margin Consistent & Healthy

US\$7.8M

GM at 63% for FY25



EBITDA Loss Reducing with Scale

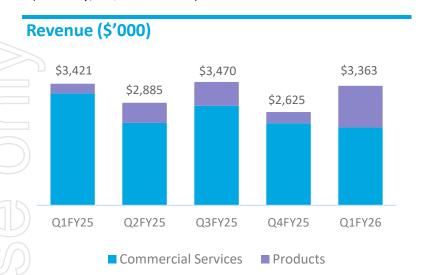
US\$3.4M

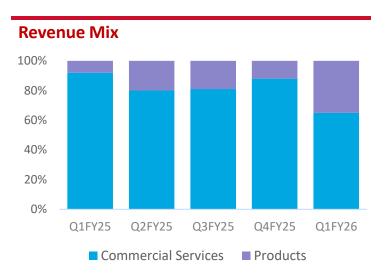
Future revenue growth to drive profits

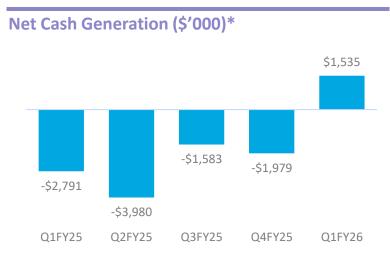
# **Financials summary - Quarterly**



(Quarterly, US\$ in thousands)







#### Commentary

- Revenue \$3.4 million in Q1 FY26, consistent with the prior corresponding quarter in Q1 FY25 (pcp).
  - Services revenue was \$2.2 million in Q1 FY26, down 29% on pcp, with a large contribution from development services under the Hologic fFN Development Agreement and the intellectual property licensing revenue associated with the IP Agreement. Reduction due to extended project timeline.
  - **Products** revenue was \$1.2 million in Q1 FY26, up five-fold on the pcp. Benefiting from the PHASE Scientific \$1.0 million exclusivity fee and increasing product adoption for FebriDx<sup>®</sup>.
  - Net cash inflow of \$1.5 million in Q1 FY26, before the proceeds from the exercise of options of \$1.0 million.
- Cash balance as at 30 September of \$4.5 million.

\*Net cash generation comprised of operating and investing cash flow, plus lease payments.

### **The Unmet Medical Need – Respiratory Infections in Primary Care**

"Patients want answers. Doctors need certainty. FebriDx® delivers both."







#### FebriDx® Supports Antibiotic Stewardship and Combats Antimicrobial Resistance

>99%

Accuracy for ruling out bacterial infection

>90%

Accuracy in differentiating viral vs >40%bacterial infection

Of antibiotic prescriptions for patients with acute respiratory infections are unnecessary



Aids doctors to confidently and appropriately prescribe antibiotics as required



Result after 10 min. Patients leave with actionable plan of trust

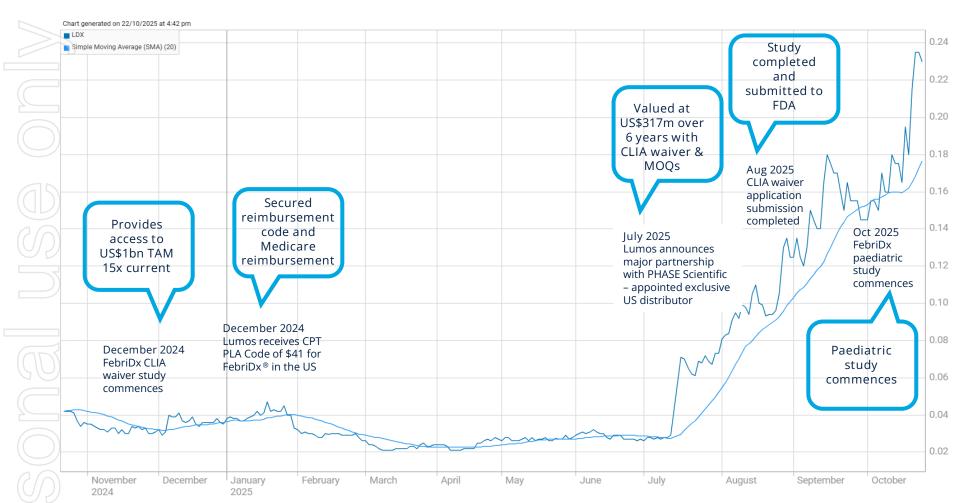
>US\$1B

80M patients per annum presenting with acute respiratory infection

## **FebriDx Recent Achievements**



#### **Journey To Transform The Practice Of Medicine**



# Future Anticipated **Events**

By Q1 CY2026 FDA grant of CLIA waiver anticipated

> By Q1 CY2026 Phase Scientific US\$5.0m pre-paid purchase order triggered on CLIA waiver

### **Lumos Future Products**

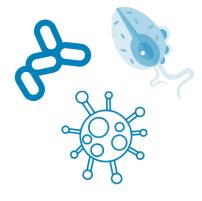
Women's Sexual Health - \$10B





#### **Prevalence**

Affects 30%-40% of women globally. >10M heath care visits annually in the US



#### **Clinical Need**

Multiple infectious organisms.

Similar symptoms / hard to diagnose.

Different treatments for each. Patient samples currently sent to the core lab and can take days for results that potential mean delayed or incorrect diagnosis or treatment

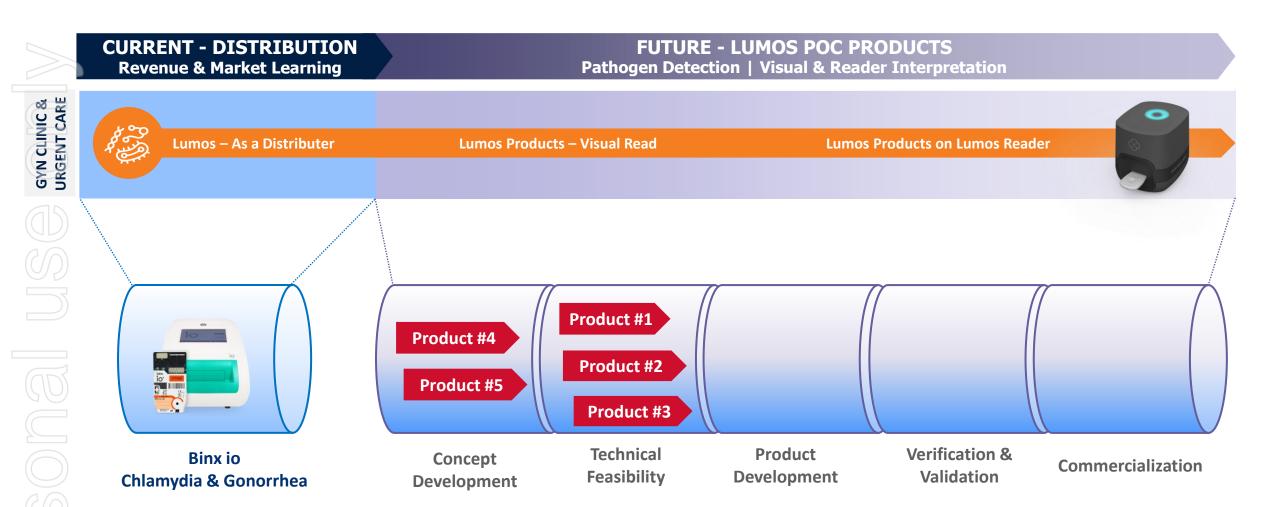


#### **POC Diagnostic Opportunity**

Rapid & accurate testing close to the patient is needed. With a POC test(s), physicians can identify & treat at first patient visit. Easy to use & trusted by clinic staff

# **Lumos Product Roadmap | Women's Sexual Health**





# **Commercial Services - Partnership Examples**



#### **Hologic – Fetal Fibronectin (fFN)**

- fFN is a biomarker indicating a heightened risk of pre-term delivery and is the largest segment of the pre-term birth diagnostic kit market
- Project Development of an improved version of one of Hologic's leading in-market women's health products, Fetal Fibronectin (fFN), including adapting it for use on Lumos' proprietary reader platform.
- Agreement signed January 2024. Currently valued at US\$16.4m. Has two components:
  - IP US\$10.0m
  - Development US\$6.4m
- US\$13.2 million received to date
- Future Opportunity validation and verification, clinical study, manufacturing, additional products

#### **Aptatek – PKU in-home monitoring**

- PKU affects 1 in 12,000 newborns, leading to neurological complications if un-checked
- Agreement secures follow-on contract to move PKU inhome monitoring device to next stage of clinical development and commercial readiness. \$1.5 million contract commencing September, to be charged on time-and-materials basis
- Project Lumos to focus on:
  - Maturing the design of the tests
  - Blood processing unit and readers
  - Formal verification testing to ensure the device meets product requirements for clinical trials and FDA submission
- Opportunity anticipated through support of clinical trials and ongoing instrument manufacturing in subsequent phases of the partnership

# **Key Priorities**





FDA decision on the CLIA waiver for FebriDx® is expected between November 2025 and February 2026.



Implement agreement with PHASE Scientific, advance national payer coverage through our partnership with Pro-spectus, and plan for volume scale-up.



Progress FebriDx pediatric study – fully funded with US\$6.2M by BARDA - addresses important clinical market for 2 -12 yr olds and expands U.S. market by approx. 20%



Deliver on Hologic fFN development milestones additional milestone 3 studies from Phase 2 & Phase 3 milestones 4 -9



Progress to formal product development on the first Lumos branded women's health diagnostics test



# Thank You

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