



Lumos Diagnostics Holdings Limited

Q2 FY26 Presentation

3 February 2026

Financial information is shown in USD unless otherwise stated.

www.lumosdiagnostics.com

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

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 by end Q1 CY2026 (31 March 2026)
- 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,¹ 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 ASX-listed diagnostics company



> 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
- 100% Medicare reimbursement achieved across all 7 MACs. Focus shifts to private payors



Commercial Services Division

- Licensing/IP agreements add recurring high-margin revenue
- Hologic: US\$10M IP licensing + US\$7.0M development agreement for next-gen fFN women's health test
- Additional US\$1.9M Aptatek contract advancing in-home PKU monitoring test



Revenue Growth & Margin Strength

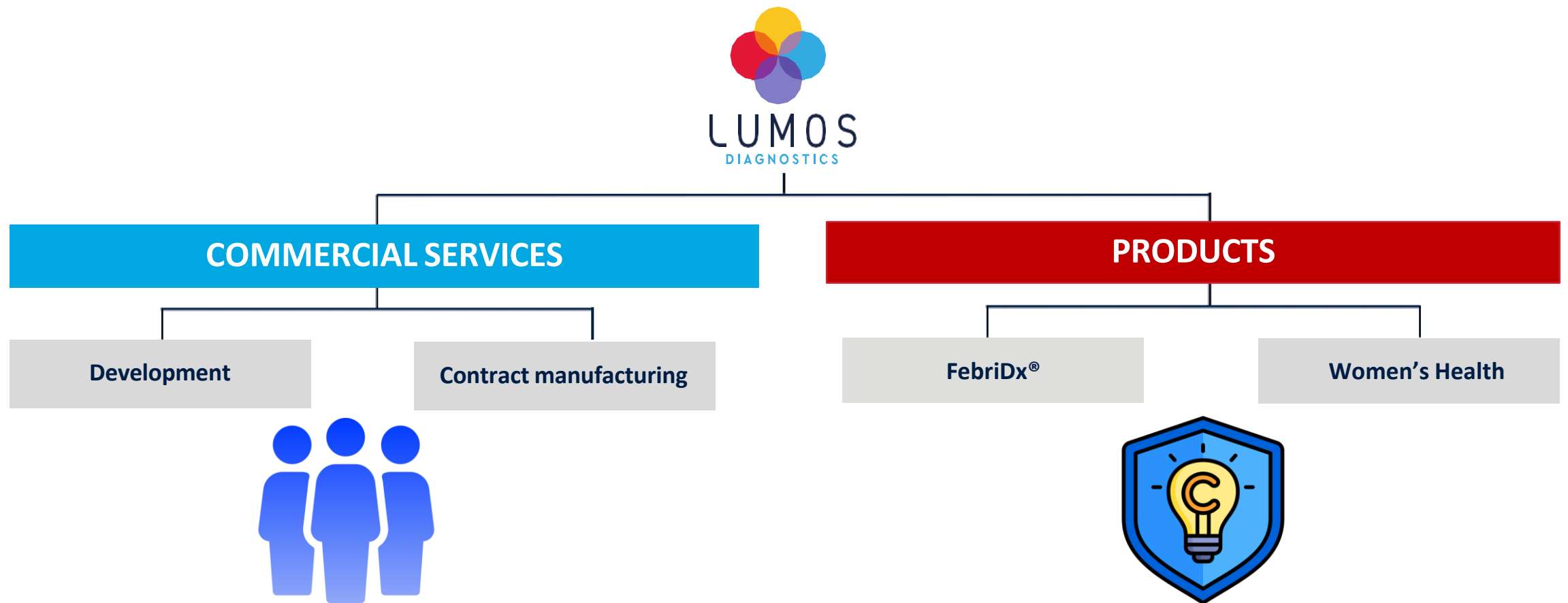
- FY25 revenue US\$12.4M (up 12% yoy), gross profit margin at 63%, and EBITDA loss narrowed to US\$3.4M (showing operating leverage as scale builds)
- Q2 FY26 revenue of US\$2.7M (Product US\$0.5M and Services US\$2.2M), bringing 1H FY26 revenue to US\$6.1M
- FebriDx sales in Q2 were >4x the prior corresponding period



Strong Funding Partnerships, No Debt, No Royalties Payable

- BARDA: US\$8.3M non-dilutive funding (for FebriDx CLIA waiver + paediatric studies)
- A\$5M loan facility available with Tenmile and Ryder Capital (drawdowns at Lumos discretion – with no drawdowns to-date)

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.

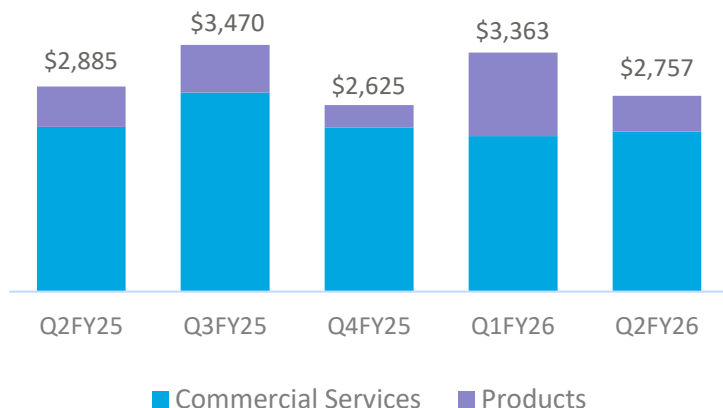
Financials Summary – Quarterly

- In Line with Expectations

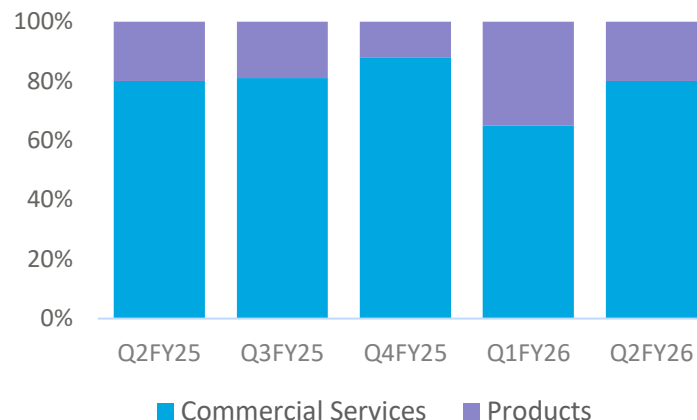
(Quarterly, US\$ in thousands)



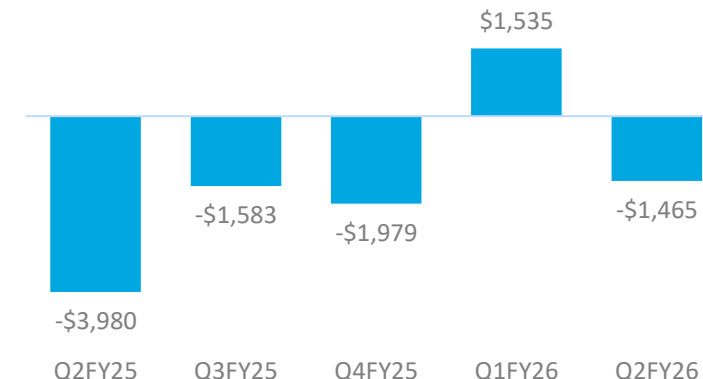
Revenue (\$'000)



Revenue Mix



Net Cash Generation (\$'000)*



Commentary

- **Revenue** – \$2.7 million in Q2 FY26, consistent with the prior corresponding quarter in Q2 FY25 (pcp). 1H FY26 Revenue \$6.1 million.
- **Services** revenue was \$2.2 million in Q2 FY26, across 12 projects, similar to the pcp, with a strong contribution from development services under the Hologic fFN Development Agreement + additional SOWs and the intellectual property licensing revenue associated with the IP Agreement.
- **Products** revenue was \$0.5 million in Q2 FY26 vs. \$0.6 million in pcp. Benefiting from a 4.3x increase in product sales for FebriDx®, which has backfilled the discontinuation of ViraDx® sales.
- **Net cash outflow** of \$1.5 million in Q2 FY26, equivalent to \$0.5 million per month. Significant improvement over the \$4.0 million cash outflow in the pcp.
- **Cash balance as at 31 December** of \$3.0 million. Loan Facility of A\$5.0 million has not been used.

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

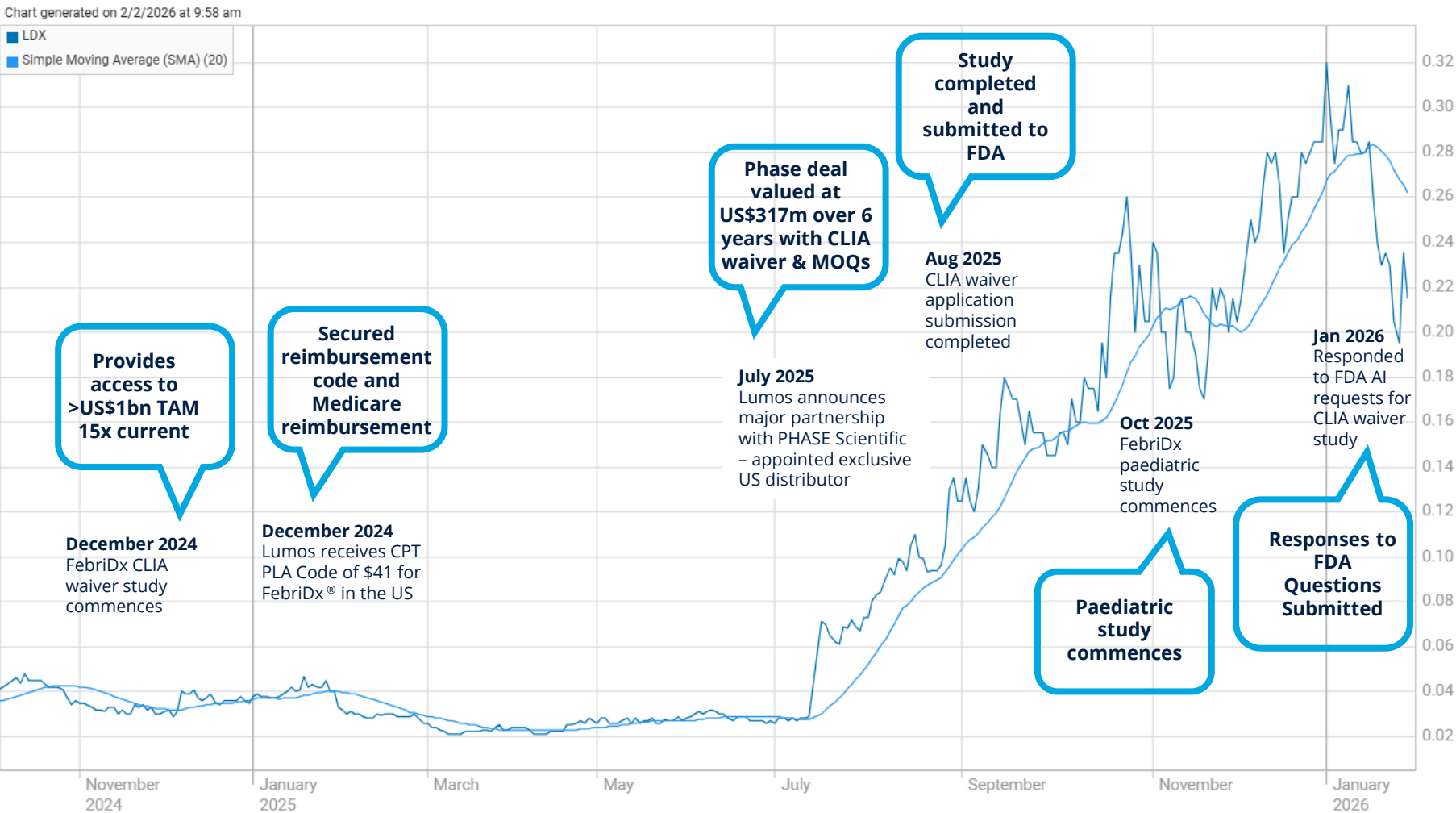
Products Division

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FebriDx Recent Achievements



Journey To Transform The Practice Of Medicine



Future Anticipated Events

By end Q1 CY2026
FDA grant of CLIA waiver anticipated

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

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 bacterial infection



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



Aids doctors to confidently and appropriately prescribe antibiotics as required

>40%

Of antibiotic prescriptions for patients with acute respiratory infections are unnecessary

>US\$1B

80M patients per annum presenting with acute respiratory infection

FebriDx[®] market opportunity in the U.S. > \$1 Billion



A CLIA waiver grant enables facilities (e.g., physician offices, stand alone urgent care centers) to perform diagnostics without laboratory oversight

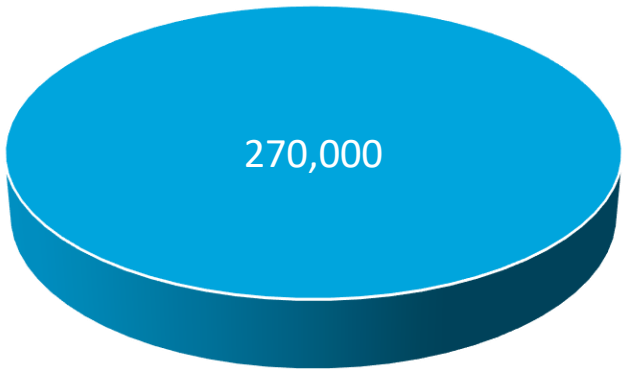
MODERATE COMPLEXITY LIMITATION

Potential U.S. customer sites



CLIA WAIVER EXPANDS ADDRESSABLE MARKET

Potential U.S. customer sites



Moderate complexity settings ~7% (5.6 million patient interactions)

CLIA waiver enables 100% market coverage (80 million patient interactions)

Acute respiratory infections in U.S. annually: 80 million (potential FebriDx[®] patient opportunities for use)¹

FebriDx® CLIA waiver Study Update



BARDA partnership agreement announced in October 2024

- BARDA partnership agreement: non-dilutive funding of US\$3.0 million committed to support CLIA waiver study (US\$2.5 million received so far, balance of US\$0.5 million due on grant of CLIA waiver)
- Biomedical Advanced Research and Development Authority (BARDA) is part of US Federal Department of Health and Human Services.

CLIA waiver clinical study commenced in December 2024

- The CLIA waiver study is designed to demonstrate that the FebriDx® test is simple to perform with a low risk of erroneous results when performed by untrained users in expanded user settings (i.e. GP clinics, Urgent Care centers)

CLIA waiver study update as at 29 January 2026

- Study completed and submitted to the FDA on 18 August 2025, with performance endpoints being exceeded (99%+ concordance between trained & untrained users)
- Lumos received feedback from the FDA at the 90-day time frame from submission. FDA asked a number of questions, for minor changes to instructions and for a small usability assessment. All now completed and responses submitted to FDA in late January.
- Remain on-track and expect CLIA waiver decision by end of Q1 CY2026 or earlier.



FebriDx Paediatric Study Update



- FebriDx® is currently FDA-cleared for use in patients aged 12-64 years presenting to urgent care or emergency care settings for evaluation of acute respiratory infection
- In late October 2025, Lumos commenced the FebriDx® paediatric study in the U.S. for use on children 2-12 years of age in a CLIA-waived setting
- BARDA to support study through a US\$6.2 million non-dilutive funding package. Milestone payments from BARDA to Lumos triggered upon the achievement of twelve milestone events through to FDA 510(k)/CLIA waiver grant.
- Study expected to run for around 12 months, through the 2025/26 US respiratory season to November 2026
- Completed Milestones 1–3 (initial subcontractor contracting, 15 site contracts, and ethics approvals) and Milestone 5 (first patient in), totalling US\$1.2 million in milestone payments received. By the end of December, 90 patients had been enrolled

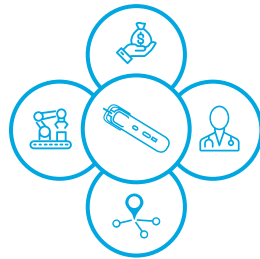
The path to commercial adoption



Clinical Benefit



Only test that distinguishes between bacterial and non-bacterial acute respiratory infections at the point-of-care, enabling physicians to prescribe antibiotics appropriately and support antimicrobial stewardship.

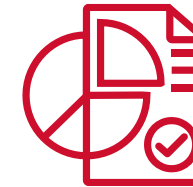


Economic Benefit



Reimbursed under PLA code at \$41.38 per test, creating sustainable margins for Lumos, distributors, and physicians while incentivizing adoption across the care network.

100% Medicare reimbursement achieved with MACs. Focus now shifts to private payors.

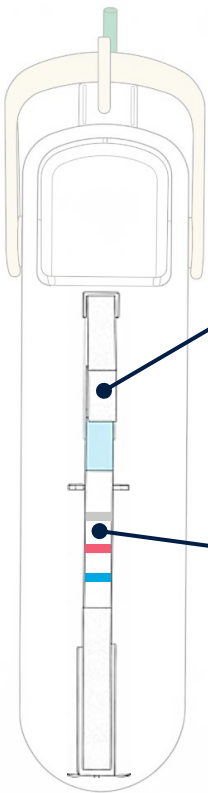


Operational Efficiency



Easily integrated alongside COVID/Flu combo tests without disrupting clinic workflow or patient throughput. Simple finger-prick test performed in under 10 minutes at triage.

FebriDx IP



On-strip cell lysis

- Blood cell lysis chemical formulation
- Detection of intracellular and extracellular biomarkers

Bacterial/non-bacterial biomarker combinations

- CRP and MxA used in existing FebriDx product
- CRP and MxA precursors to block new entrants
- CRP, MxA and Procalcitonin to block new entrants and expand product offering
- CRP and alternate viral biomarkers to block new entrants
- MxA and alternate bacterial biomarkers to block new entrants

Lumos FebriDx Patents

- 59 FebriDx patents, 4 patent families
- 17 countries
- 50 granted, 9 pending
- Core MxA/CRP patent life in USA to 2038

Lumos Trademarks

- FebriDx is a registered trademark in the USA, EU and UK

Patent Family	WO2010033963A2	AU2014226173B2, AU2020233741B2, BR112015021199A2, DK2909331T3, EP2335072B1, EP2909331B1, EP3591397A1, ES2666350T3, HK1214308A1, JP5859854B2, JP6521525B2, JP6892890B2, KR102209489B1, KR102322094B1, KR102489679B1, US8614101B2, US8962260B2, US9372192B2, US9910036B2, US9933423B2, US10379121B2, US10408835B2
	WO2010033963A2	US8614101B2, US9797898B2, US9804155B2, US11002734B2, US20210302419A1
	WO2017070419A1	AU2016342268B2, AU2022228181A1, CA3041458A1, EP3365459A1, ES2976232T3, HK1260059B, US10808287B2, US20250154609A1
	WO2021127374A1	AU2020407110A1, CA3165294A1, CN114846331A, EP4077657A4, US12078636B2
Trademarks		4837134, 011690881, UK00911690881

Lumos Future Products

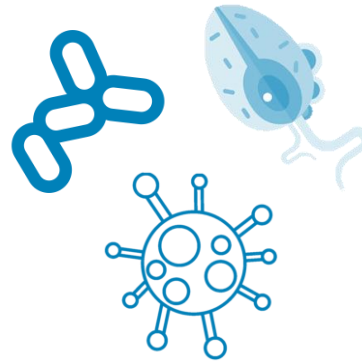


Women's Sexual Health - \$10B



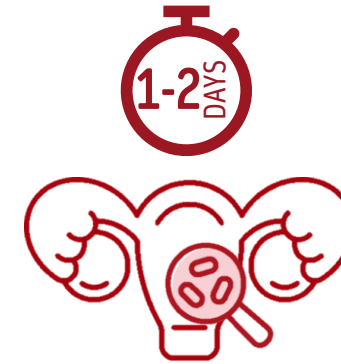
Prevalence

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



Clinical Need

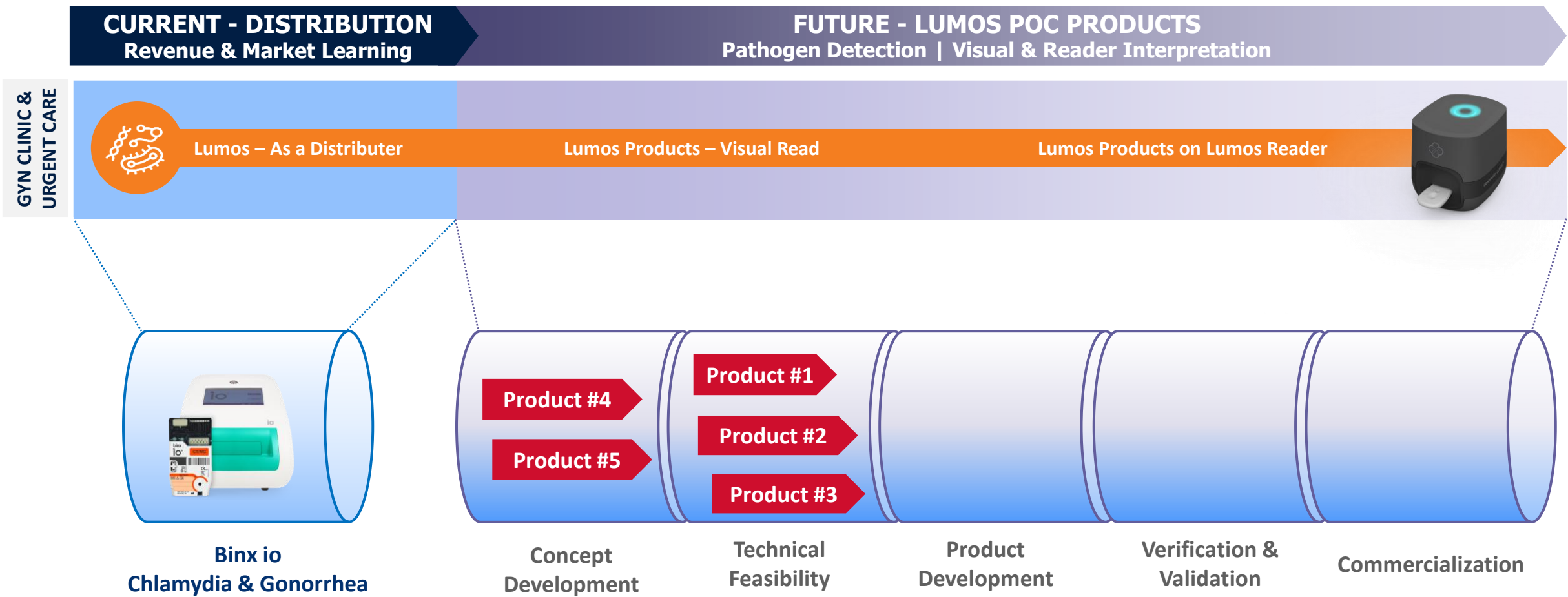
Multiple infectious organisms.
Similar symptoms / hard to diagnose.
Different treatments for each. Patient samples currently sent to the core lab and can take days for results that potential mean delayed or incorrect diagnosis or treatment



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



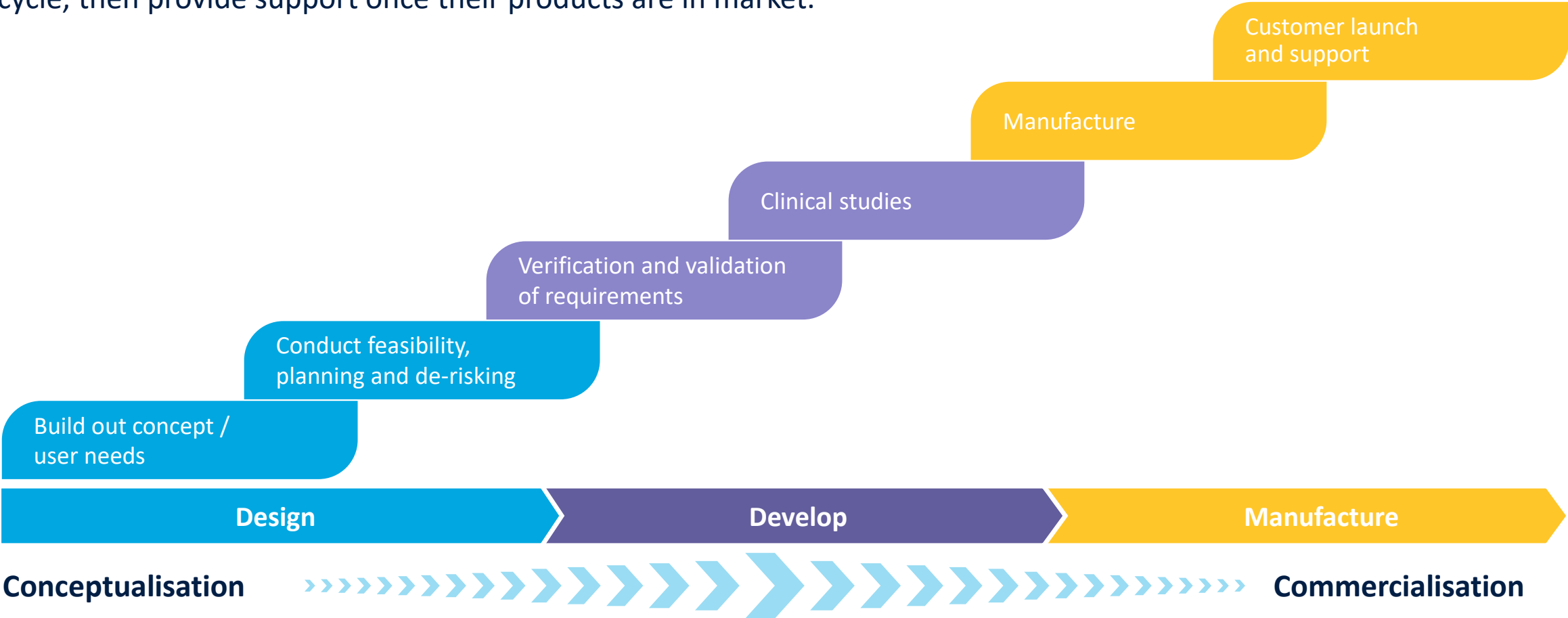
Commercial Services Division

A horizontal bar composed of several small squares in a rainbow color gradient (yellow, orange, red, purple, blue, green).

How we add value to partners



We work with partners through the whole diagnostic product development cycle, then provide support once their products are in market.



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\$17.0 million. Has two components:
 - IP - US\$10.0m
 - Development – US\$7.0m
- **US\$13.6 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 in-home monitoring device to next stage of clinical development and commercial readiness, plus manage recent IRB approved multi-centre study. Total \$1.9 million total current contract value, 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
 - Managing the IRB approved multi-centre study to advance to FDA submission
- **Future Opportunity** - PheCheck™ test and reader manufacturing

Key Priorities



FDA decision on the CLIA waiver for FebriDx® is expected by 31 March 2026 or earlier.



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



Progress FebriDx paediatric 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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