



## ASX ANNOUNCEMENT

### Q2 FY25 Results Investor Briefing Invitation

**MELBOURNE, Australia (5 February 2025)** – Lumos Diagnostics Holdings Ltd (ASX:LDX, “Lumos” or the “Company”) a leader in rapid, point-of-care diagnostic technologies, will be presenting its Q2 FY25 financial results today at 10:15am (AEDT). The accompanying presentation is attached to this release.

During the briefing, Chief Executive Officer, Doug Ward and Chief Financial Officer, Barrie Lambert will present an overview of the results and discuss recent progress. This will be followed by a Q+A session.

Participants can pre-register ahead of time via the following link:

[https://us02web.zoom.us/webinar/register/WN\\_v9-IXNkeQeS6lXOLiAUYCQ](https://us02web.zoom.us/webinar/register/WN_v9-IXNkeQeS6lXOLiAUYCQ)

Once the registration form is completed, investors will receive a confirmation email with details on how to access the briefing. If you would like to ask a question during the briefing, please send your question ahead of the session to: [george.kopsiaftis@irdepartment.com.au](mailto:george.kopsiaftis@irdepartment.com.au).

The Lumos team looks forward to welcoming those shareholders and potential investors who are able to attend.

**-Ends-**

***This announcement has been approved by the Lumos Company Secretary.***

#### **About Lumos Diagnostics**

*Lumos Diagnostics specializes in rapid and complete point-of-care (POC) diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customized assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes novel Lumos-branded POC tests that target infectious and inflammatory diseases.*

*For more information visit [lumosdiagnostics.com](http://lumosdiagnostics.com).*

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## Forward-Looking Statements

*This announcement contains forward-looking statements, including references to forecasts. Forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions, and other important factors, many of which are beyond Lumos' control and speak only as of the date of this announcement. Readers are cautioned not to place undue reliance on forward-looking statements.*

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# Lumos Diagnostics Holdings Limited

## Q2 FY25 Investor Briefing

5 February 2025

*Financial information is shown in USD unless otherwise stated.*

[lumosdiagnostics.com](https://lumosdiagnostics.com)

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## Key Highlights – Q2 FY25

A horizontal bar composed of several small, colored segments in yellow, blue, red, and purple, matching the LUMOS logo colors.

# Key Highlights - 2Q FY25



Unaudited revenue of US\$2.9 million for the quarter, up 71% compared to PCP (Q2 FY24 - US\$1.7 million).



Product revenue was up 200% over same period last year and Services revenue was up 53% on PCP



FebriDx - CPT PLA code approval in the US, effective 1 January 2025 – reimbursement rate of US\$41.38 per test



FebriDx - BARDA partnership announced in October 2024 to support CLIA waiver and paediatric studies with non-dilutive funding up to US\$8.3 million. CLIA Waiver study commenced 19 December 2024 with first patient tested



Successful A\$10.0 million capital raise completed October 2024 – well supported by Tenmile and Ryder Capital

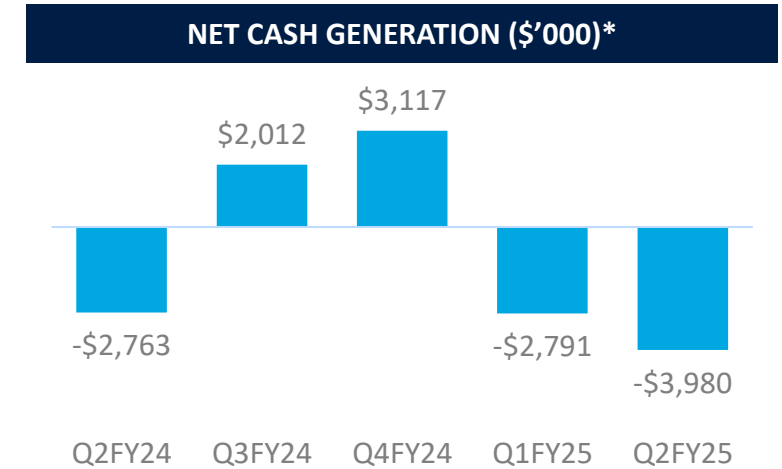
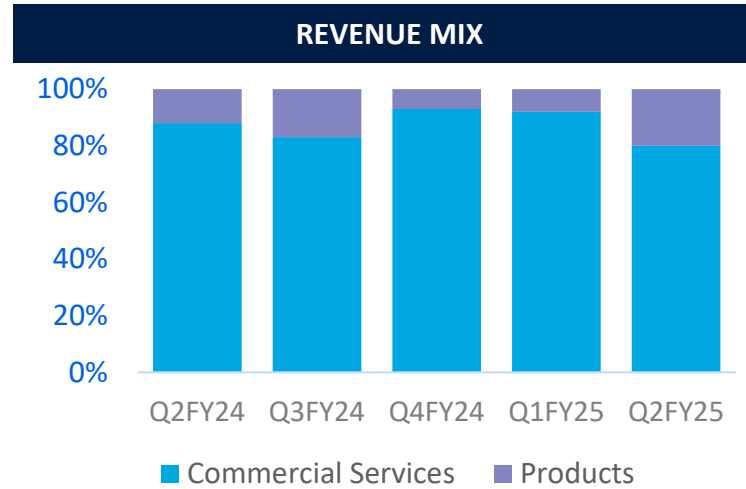
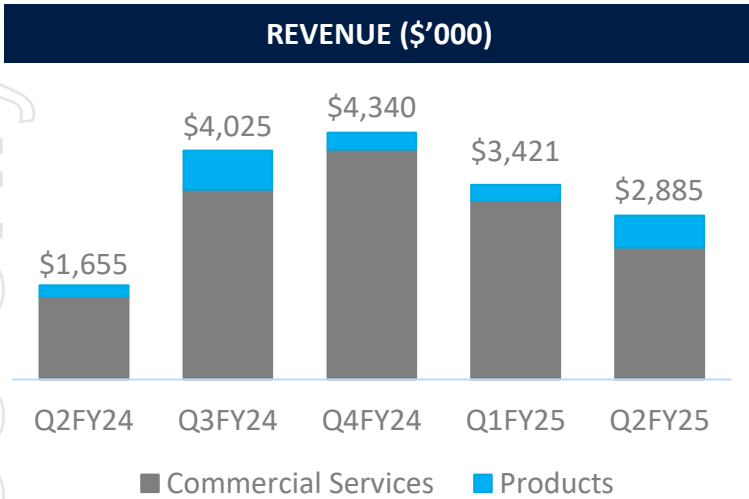


Cash balance of US\$5.5 million as at 31 December 2024, prior to receipt of BARDA milestone payments of US\$0.9 million in January 2025. Proforma cash balance of US\$6.4 million

# Financials Summary (to 31 December 2024)



(Quarterly, US\$ in thousands)



## COMMENTARY

- **Revenue** – US\$2.9 million in Q2 FY25, up 71% on pcp. Revenue for 1HY FY25 of US\$6.3 million, up 128% on 1HY FY24 of \$2.8 million
- **Services** revenue was US\$2.3 million in Q2 FY25, up 53% 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. Impacted by US\$0.59 million due to the extended timeline for the project from 20 to 24 months.
- **Products** revenue was US\$0.6 million in Q2 FY25, up 200% on pcp. Major contribution from ViraDx, plus increasing contribution from FebriDx.
- **Net cash outflow** of US\$3.9 million in Q2 FY25, affected by inventory stocking ahead of US flu season and FebriDx CLIA waiver study preparation costs.
- **Successfully completed retail entitlement component** on 8 October 2024 for A\$6.9 million, bringing the total capital raise to A\$10.0 million, strongly supported by new and existing shareholders, Tenmile and Ryder Capital.
- **Cash balance as at 31 December 2024** of US\$5.5 million. Pro-forma of US\$6.4 million (including receipt of BARDA milestone payments in Jan 25 of US\$0.9 million, which is reimbursement for costs incurred in Q1 and Q2).

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

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# Product Update

A decorative horizontal bar consisting of a series of small, colored squares in yellow, blue, purple, and red.



# FebriDx Update

- **Reimbursement amount: PLA code approval – Dec 2024**
  - The FebriDx PLA code has been approved and published on the Clinical Lab Fee Schedule and is effective from January 1, 2025. Reimbursement rate of US\$41.38 per test
- **BARDA partnership agreement - Oct 2024**
  - To support CLIA waiver and pediatric studies: non-dilutive funding up to US\$8.3m
- **CLIA waiver clinical study commenced – Dec 2024**
  - Trial commenced on 19 December 2024 - first patient tested
  - Anticipate completion by forthcoming US Spring season
  - CLIA waived labelling expands market by 15 times current moderate complex opportunity (market size >US\$ 1 billion)
- **Partnerships / Agreements**
  - **Post reporting date:** Lumos partners with MedPro Associates for FebriDx national contract sales coverage across hospital and primary care markets in the US
  - Awarded DAPA certification for procurement to US Military Services



# ViraDx™ – Point-of-Care test for key respiratory infections



## ViraDx highly relevant POC test for post-pandemic environment:

- SARS-CoV-2 pandemic increased consumer and healthcare point-of-care testing
- ViraDx is a 3-in-1 test for COVID-19/Flu A/Flu B

## ViraDx market update:

- **Stocking orders**
  - Majority of product sales during the quarter, with stocking orders received in October in preparation for the upcoming flu season
  - US flu season commenced some 6 – 8 weeks later than expected, impacting product sales in November and December
- **Competition**
  - ViraDx continues to see an increase in new customer adoption due to the rise in infection rates - despite the US market experiencing growing competition from international organizations, with aggressive pricing

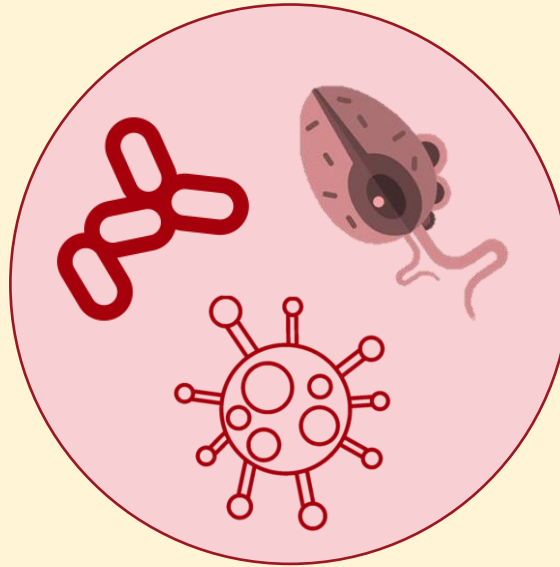


# Lumos Product Roadmap | Women's Sexual Health - \$10B



## PREVALENCE

30-40% of women  
>10M health care visits annually



## CLINICAL NEED

Multiple infectious organisms  
Similar symptoms  
Different treatments



## POC DIAGNOSTIC NEED

Rapid testing on site  
Identify & treat at patient visit  
Easy to use by clinic staff

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# Services Update

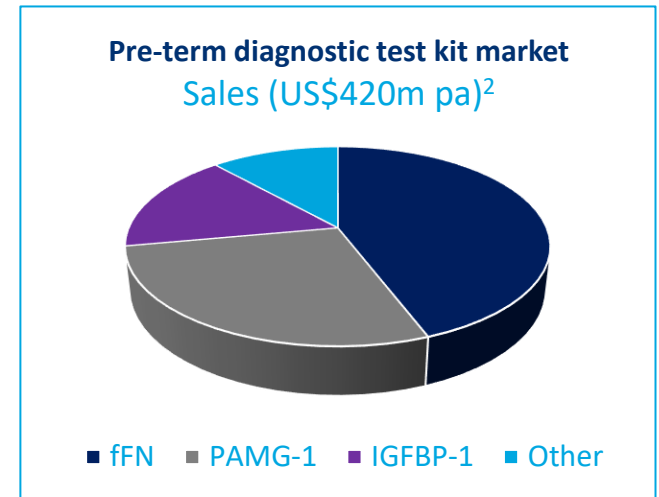
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# Hologic - Strategic Partnership - Recap



## Historic relationship with Lumos <> Hologic – working together at multiple levels

- Multiple services contracts signed during FY2023
- Two new agreements signed in FY24 for the 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<sup>1</sup>
- fFN is a biomarker indicating a heightened risk of pre-term delivery when present in cervicovaginal secretions and the largest segment in the pre-term diagnostic test kit market
- The **IP Agreement** for US\$10.0 million provides Hologic with an exclusive license in the field of fetal fibronectin to the Lumos proprietary reader and POC technologies that will be incorporated into the next generation product<sup>1</sup>
- **Development Agreement** valued at up to US\$4.7 million in payments over an estimated 24 month period, dependent on the achievement of specified milestones, outlined below<sup>1</sup>:
  - **Phase 1: Product Definition and Planning** - define the parameters for the product and establish a project plan US\$0.4 million - completed;
  - **Phase 2: Assay Feasibility** - conduct work to demonstrate the assay is able to detect the biomarkers US\$0.6 million – milestone 1 completed /milestone 2 in-progress; and
  - **Phase 3: System Prototype Delivery** – deliver a working prototype of the system - US\$3.7 million – contains 6 milestones, commenced milestone 1, planning and initial design activities



<sup>1</sup>ASX announcements 11 January 2024, 15 January 2024, 16 January 2024, 6 May 2024, 4 June 2024, 19 June 2024. 2. Global Market Insights, www.gminsights.com

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# Hologic - fFN product development overview and opportunity

## Current test: Rapid fFN TLiQ



## Next generation test concept (mock-up)



## Hologic – the opportunity ahead



Verification and validation



Clinical study



Manufacturing



Second test development and IP

# Services Division Updates



## Burnet Diagnostics Initiative

- Extension of existing agreement win in August 2024.
- Includes development, regulatory and manufacturing services over a 9 - 12 month period, generating fees between US\$0.7 million and US\$1.0 million.
- By the end of December 2024, successfully transferred the BDI Alanine Transaminase (ALT) lateral flow test formula into its Carlsbad, California manufacturing site and begun production of ALT test kits for BDI.
- Completed customization activities to its existing camera reader platform and started manufacturing readers for the BDI liver function test.
- BDI's US based clinical trial is expected to start in February 2025 and is likely to be expanded into Australian clinical trials later in 2025.

# Priority Catalysts for Growth



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*“With the successful recent capital raise completed, along with a strong pipeline of projects and partnerships, the Company is well-positioned for continued growth and success.”*

**Doug Ward**  
MD & Chief Executive Officer  
Lumos Diagnostics



**Monetize the Lumos-owned, cleared point-of-care test products: FebriDx and ViraDx, through sales, licenses and partnerships**



**Complete a successful CLIA waiver trial for FebriDx in the US, and achieve FDA label extension. Submit FDA pre-submission for paediatric study**



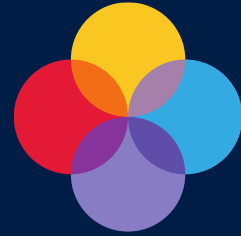
**Continue to build the foundation for long-term growth through strategic partnerships, and delivering on milestones relating to the Hologic fFN development agreement**



**Initiate product development on Lumos branded women's health diagnostics tests**



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