



# Lumos Diagnostics Holdings Limited Annual General Meeting

14 November 2024

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

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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

# Summary of Achievements



Signed US\$14.7 million IP and Development Agreements with leading women's health company Hologic – inline with strategy to focus on point-of-care women's health market



FebriDx & ViraDx achieve US FDA clearance. Sales commence in the US



FebriDx distribution agreements - expanded Henry Schein into Spain, Portugal, Netherlands & US. Post year-end Henry Schein expanded into Belgium, Australia/New Zealand. Thermo Fisher and MediGroup US agreements signed



Revenue for FY24 of US\$11.1 million - up 6% compared to the prior year. Second half revenue up 196% on pcp



Positive net cash from operations for FY24 of US\$0.9 million - cash balance at fiscal year end - US\$6.5 million



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

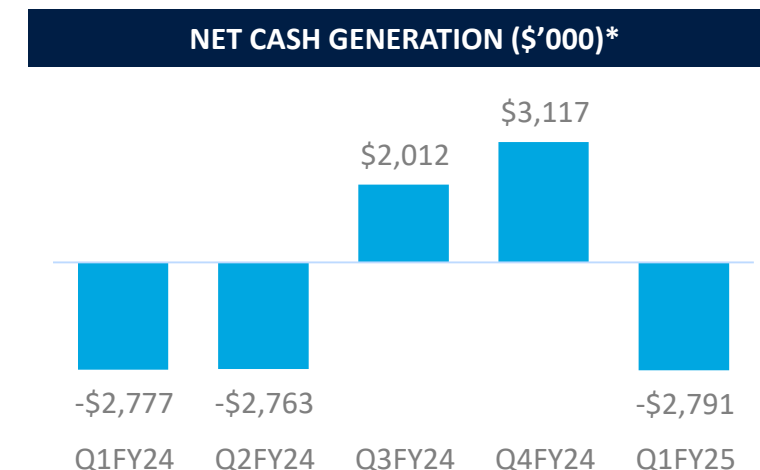
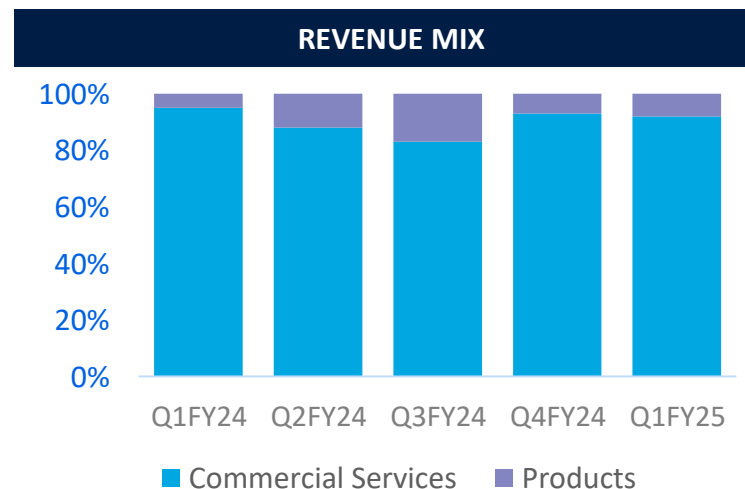
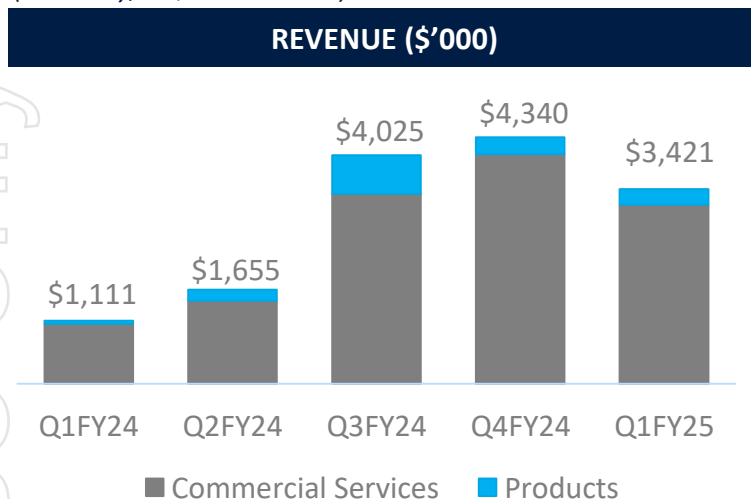


BARDA partnership announced in October 2024 to support US FebriDx CLIA waiver and pediatric studies with non-dilutive funding up to US\$8.3 million

# Financials Summary (to 30 September)



(Quarterly, US\$ in thousands)



## COMMENTARY

- **Revenue** – FY24 revenue of US\$11.1 million, up 6% on prior year.
- **Services** revenue was US\$9.9 million in FY24, with a strong contribution from development services under the Hologic fFN Development Agreement and the intellectual property licensing revenue associated with the IP Agreement.
- **Products** revenue was US\$1.2 million in FY24, up 289% on the prior year. Quarterly revenue contributions were driven by timing of the sales launch of recently cleared products, ViraDx and FebriDx and also influenced by seasonal demand for the products in the US.
- **Net cash generation** was an outflow of US\$0.4 million in FY24, a significant improvement over FY23 outflow of US\$11.6 million
- **1Q FY25** – continued revenue from the Hologic agreements. Product sales up 200% on pcp, driven by additional ViraDx sales.
- **Pro-forma cash balance as at 30 September** of US\$9.8 million (including receipt of all capital raise funds)

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

# Post Reporting: Equity Raising of A\$10m Successfully Completed – Oct 2024

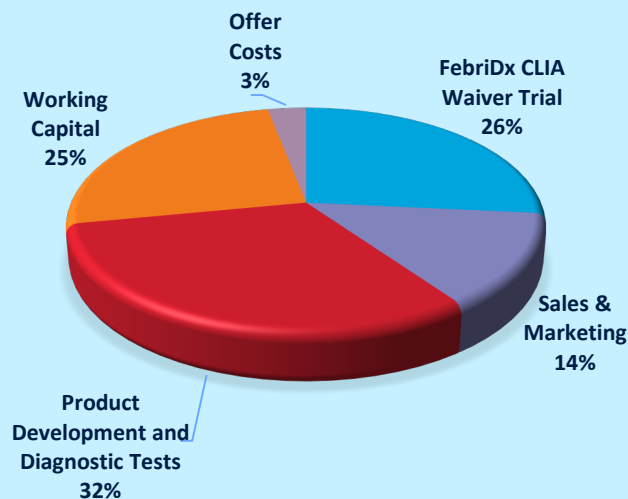


## Key highlights

- Successfully completed A\$10.0m equity raising at A\$0.038 per share on 8 October 2024, including:
  - A\$3.1m institutional component; and
  - A\$6.9m retail entitlement offer.
- Pleased to welcome dedicated health technology investment business Tenmile, part of Tattarang, one of Australia’s largest private investment groups to the share register with a holding of 19.9%
- Strong ongoing support from long-standing shareholder Ryder Capital with increased holding from 5.3% to 17.0%

Proceeds will be used to progress the FebriDx CLIA waiver trial in the US to enable an extension to the existing label; initiate the development of additional proprietary products for sale by Lumos or licensing to strategic partners; for sales & marketing activities, to support the Lumos Services business, and for general working capital purposes.

## Uses of Funds



# FebriDx Update

- **Reimbursement amount: PLA code update**
  - Positive momentum - CMA Panel presentation in June was well received, final decision expected December 2024 with publishing date of January 2025
- **Partnerships**
  - 27 FebriDx partnerships to-date through to Q1 FY25: regional distributors and end-user customers
  - Thermo Fisher and MediGroup appointed US distributors in Q1 FY25
- **CLIA waiver clinical trial**
  - Trial commencing December 2024 with FDA application by Q4 FY25
  - CLIA waived labelling to expand market by 15 times current moderate complex opportunity (market size >US\$ 1 billion)
- **BARDA partnership**
  - To support CLIA waiver and pediatric studies: non-dilutionary funding up to US\$8.3m





# 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 regulatory and commercial update:

- **Distribution<sup>1</sup>**
  - 23 ViraDx partnerships through to Q1 FY25
- **Infection rates**
  - US summer: elevated acute respiratory infections (Covid)
- **Stocking orders**
  - Although infection rates are currently low in the US, sales growth is being realized for ViraDx thus far into FY25 due to distributor stocking orders and new end user customers



<sup>1</sup>ASX announcement 1 August 2024

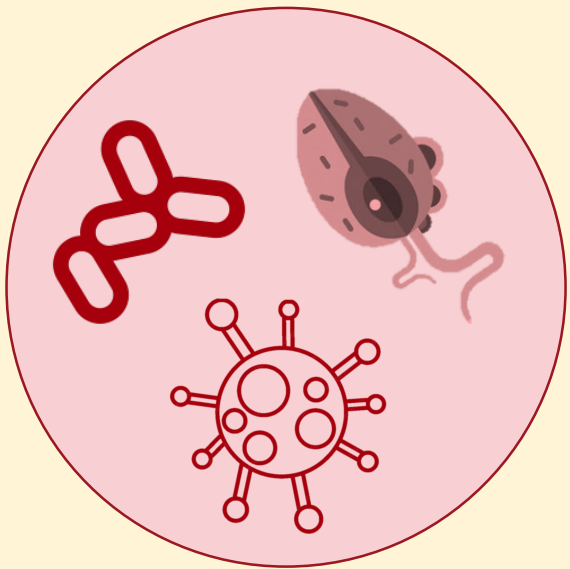


# Lumos Product Roadmap | Women's Sexual Health - \$10B



## **PREVALENCE**

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



## **CLINICAL NEED**

Multiple infectious organisms  
Similar symptoms  
Different treatments



## **POC DIAGNOSTIC NEED**

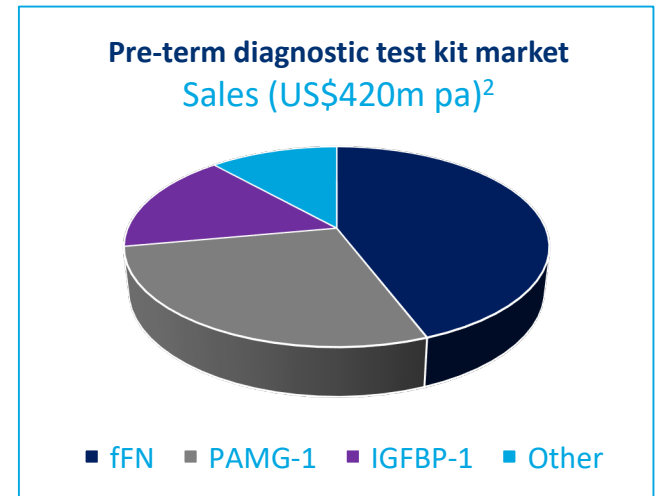
Rapid testing on site  
Identify & treat at patient visit  
Easy to use by clinic staff

# Hologic - Strategic Partnership



## 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 18 - 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 – commenced 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](http://www.gminsights.com)

# 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

# Service Partnerships - Other

## Burnet Diagnostics Initiative

- Extension of agreement with the Burnet Diagnostics Initiative (BDI) to manufacture a lateral flow test developed at the BDI and develop and manufacture customized Lumos readers to monitor liver function in an upcoming clinical trial
- The point-of-care test will provide rapid, near-patient measurement of blood levels of the liver biomarker, Alanine Transaminase (ALT) that when elevated can indicate liver injury, possibly from a drug reaction
- The ALT point-of-care test builds on feasibility work conducted in 2023, to develop a point-of-care prototype for evaluation of clinical specimens
- Lumos will provide development, regulatory and manufacturing services to BDI over the next 9-12 months, generating fees between US\$0.7 million and US\$1.0 million

## Health & Environmental Monitoring

- Lumos completed pivotal pre-clinical study for Aptatek Biosciences to demonstrate in field use and performance of its phenylketonuria (PKU) monitoring test developed by Lumos. The Aptatek test utilizes a Lumos reader to enable home testing by PKU patients to calculate phenylalanine levels and assist in managing disease.
- Lumos has extended its manufacturing agreement with Huvepharma, a privately-held global company specializing in the development and manufacturing of human and animal health and nutritional products, to ramp up production of a Lumos developed test that detects a specific antibiotic in animal feed.



# Priority Catalysts for Growth



“

*With a strong pipeline of projects & partnerships and balance sheet strength, supported by the recent capital raise, we are 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**



**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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