



# Lumos Diagnostics Holdings Limited Annual General Meeting

14 November 2024

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

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

ersonal use only

# Disclaimer and Important Information



**This presentation (Presentation) has been prepared solely for informational purposes by Lumos Diagnostics Holdings Limited (Company).**

The information contained in this document ("Document") has been prepared by Lumos Diagnostics Holdings Limited (referred to as "Lumos" or "Company"). This Document is current as at the date of this Document and should be read in conjunction with other Lumos periodic and continuous disclosure announcements filed with the Australian Securities Exchange (ASX), available at [www.asx.com.au](http://www.asx.com.au).

The information in this Document is not intended to form the basis of any investment decision in relation to the Company or its assets and should not be considered as a recommendation to the Recipient to acquire securities in the Company. This Document is not a prospectus, profile statement or disclosure document and does not constitute an offer or invitation to acquire securities or otherwise invest in the Company, and no agreement to subscribe for securities will be entered into on the basis of this Document.

No representation or warranty, expressed or implied, is or will be made, and no responsibility or liability is or will be accepted by the Company, any of their respective officers, servants, agents or advisers (collectively "Limited Parties") as to or in relation to the accuracy, reasonableness, completeness or reliability of the information in this Document or any other written or oral information made available to any Recipients or their advisers. Any liability therefore is hereby expressly disclaimed. In particular, no representation or warranty is given as to the achievability or reasonableness of any future projections, management estimates or plans, prospects, returns or forecasts.

To the fullest extent permitted by law, the Limited Parties will not have any responsibility or liability for any loss or damage (whether foreseeable or not), however arising (including as a result of negligence), in relation to or in connection with the provision of this Document, the Recipient's or any other person's purported reliance on this Document, the failure to provide information of which any of the Limited Parties becomes aware or any errors in or omissions from this Document.

None of the Limited Parties makes or gives any representation, warranty or guarantee, express or implied, that the information in this Document is accurate, current, reliable or complete, has been or will be audited or independently verified, or that reasonable care has been taken in compiling, preparing or furnishing it. Various statements in this Document constitute statements relating to intentions, future acts and events including forecast financial information ("Forward Looking Statements"). Forward Looking Statements involve subjective judgment and analysis, known and unknown risks, uncertainties and other important factors that may cause those future acts, events and circumstances to differ from the way or manner in which they are expressly or impliedly portrayed herein.

The Limited Parties do not make or give any representation, warranty or guarantee, express or implied, that any Forward Looking Statements will be achieved or proven correct, or that any assumptions or projections on which the Forward Looking Statements are based are reasonable. No historical financial information, forecast financial information, estimates or projections contained in this Document or any other financial information derived from that information, can be relied upon as a promise or representation, as to the past, present or the future. Past performance is not necessarily a guide to future likelihood of achievement or reasonableness of any Forward Looking Statement, forecast financial information or other forecast. The Limited Parties do not undertake any obligation to (and expressly disclaim any obligation to) provide the Recipients with access to any additional information or to correct any inaccuracies herein which may become apparent or to disseminate any updates or revisions to any Forward Looking Statements in this Document to reflect any change in expectations in relation to any such statements or any change in events, conditions or circumstances on which any such statement is based.

This document also contains statistics, data and other information relating to markets, market sizes, market shares, market positions and other industry data pertaining to the Lumos business and markets. Such information is generally based on independent market and industry data or research. Lumos has not independently verified and cannot give any assurances as to the accuracy and completeness of the information sourced from market and industry data or research contained herein. Accordingly, the accuracy and completeness of such information is not guaranteed. There is no assurance that any of the forecasts or projections contained in the independent market and industry data or research will be achieved. Forecasts and projections involve risks and uncertainties and are subject to change based on various factors. You should note that market data and statistics are inherently predictive and subject to uncertainty and not necessarily reflective of actual market conditions.

Neither the receipt of this Document by any person nor any information contained in it or supplied with it or subsequently communicated to any person in connection with a proposed investment in the Company constitutes, or is to be taken as constituting, the giving of investment or financial product advice (or any other advice) to any such person. Each such person should make their own independent assessment of the merits or otherwise of investing in the Company and should seek their own professional advice in respect of any future investment opportunity and not act on the basis of any matter contained in this Document. In providing this Document, the Company has not considered the objectives, financial position, taxation situation or other needs of any particular Recipient.

The distribution of this document in jurisdictions outside Australia may be restricted by law. Persons who come into possession of this document who are not in Australia, should seek advice on and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws. In particular, this document does not constitute an offer to sell, or a solicitation of an offer to buy, any securities in the United States.

## **Non-IFRS financial measures**

Recipients should note that certain financial data included in this Document is not recognised under the AAS and is classified as 'non-IFRS financial information' under Regulatory Guide 230 'Disclosing non-IFRS financial information' published by ASIC. The Company believes that this non-IFRS financial information provides useful information to users in measuring the financial performance and condition of Lumos. The non-IFRS financial measures do not have standardised meanings under AAS, and therefore may not be comparable with similarly titled measures presented by other entities, nor should these be interpreted as an alternative to other financial measures determined in accordance with AAS. Investors are cautioned not to place undue reliance on any non-IFRS financial information, ratios and metrics included in this Document.

# 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

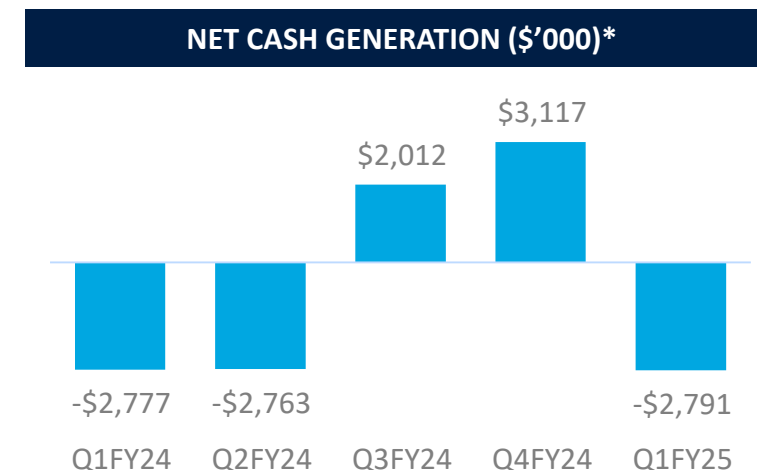
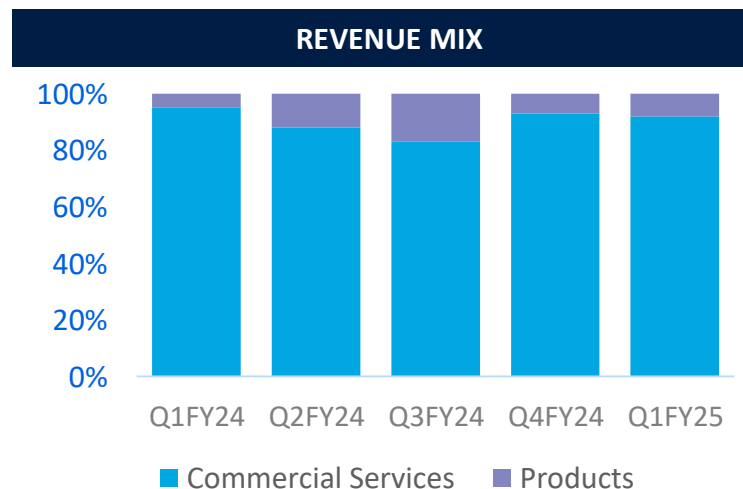
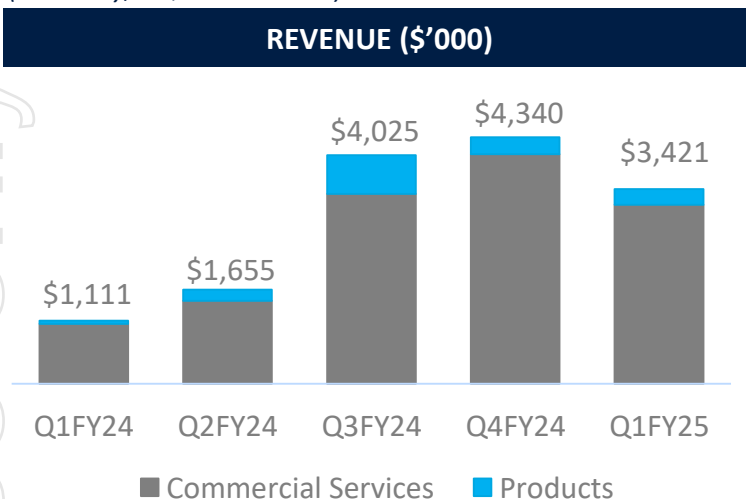


BARDA partnership announced in October 2024 to support US FebriDx CLIA waiver and pediatric studies with non-dilutive funding up to US\$8.3 million

# 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

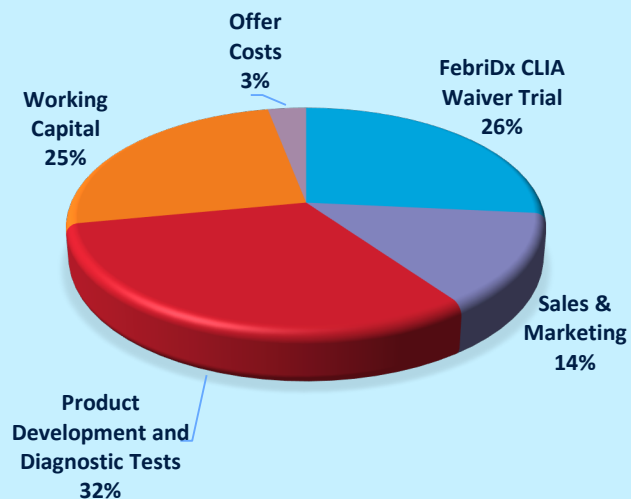


## Key highlights

- 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

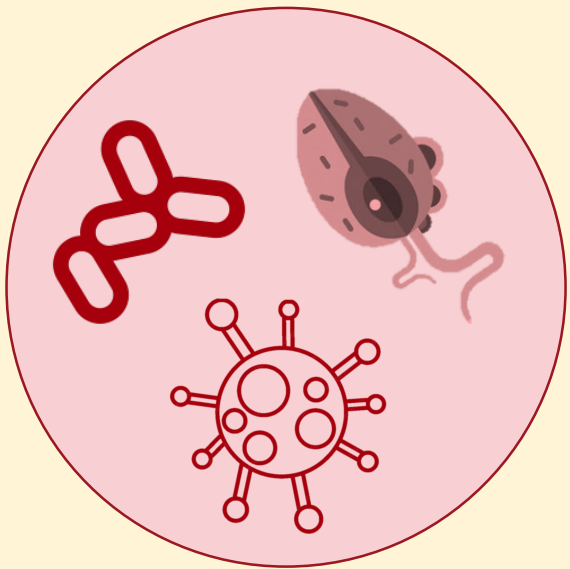


# Lumos Product Roadmap | Women's Sexual Health - \$10B



## **PREVALENCE**

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



## **CLINICAL NEED**

Multiple infectious organisms  
Similar symptoms  
Different treatments



## **POC DIAGNOSTIC NEED**

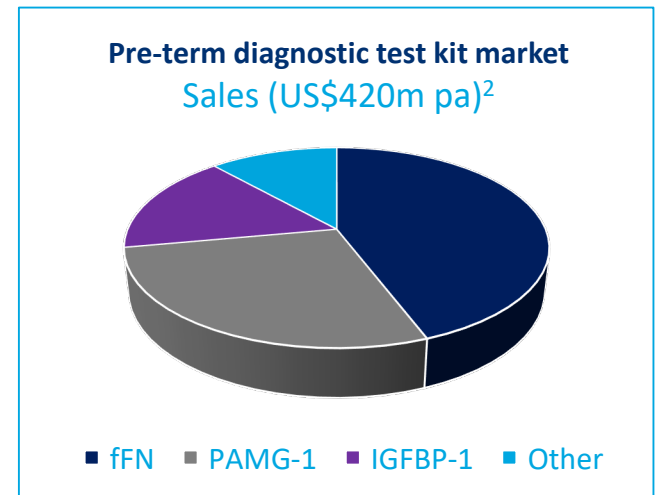
Rapid testing on site  
Identify & treat at patient visit  
Easy to use by clinic staff

# 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.**

ersonal use only



LUMOS  
DIAGNOSTICS

[www.lumosdiagnostics.com](http://www.lumosdiagnostics.com)