



# Lumos Diagnostics Holdings Limited

## Q3 FY25 Investor Briefing

6 May 2025

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

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## Company Overview

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**Who is Lumos  
and why  
do we exist?**

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

**Improve the practice of medicine.**

# Unique Value Creation



## Solving Unmet Medical Needs



Developed and launched one of a kind proprietary point-of-care diagnostic product - FebriDx



Transformational development agreements with the world's leading global women's health company – Hologic

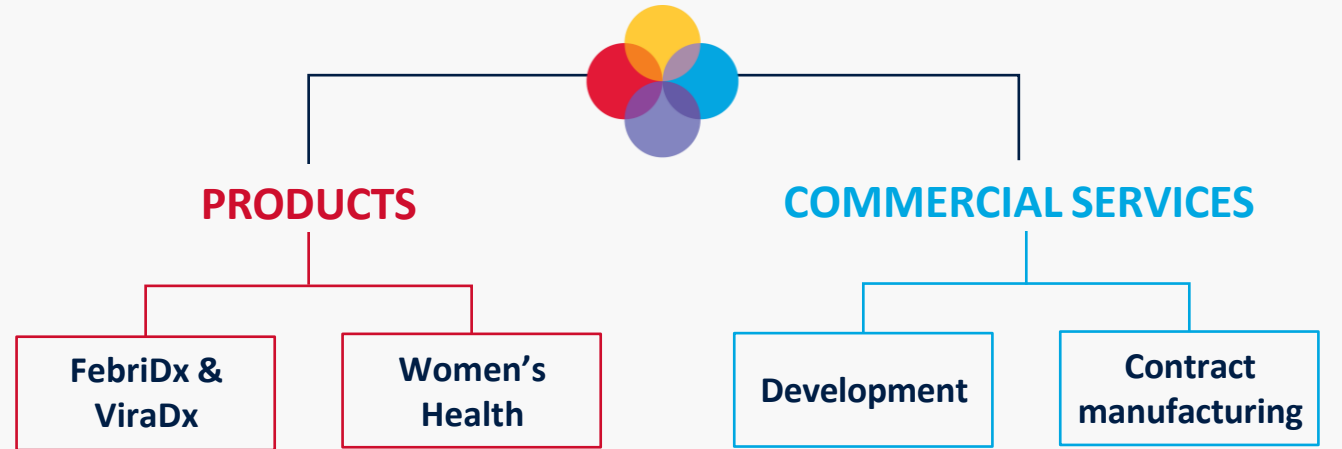


Currently developing women's health and sexual health point-of-care products for use at the point of care

# Lumos Business Overview



Lumos offers end-to-end point of care (POC) diagnostic test development, from initial assay creation to high-volume manufacturing. We develop and sell our own tests and also create tests for customers under commercial contracts.



Proprietary and in-licensed POC diagnostic tests and systems for commercial sale

POC diagnostic tests, digital reader formats and digital applications developed for customers under commercial contracts

**Able to leverage R&D, manufacturing scale, quality and regulatory skillset across Lumos' Products and Commercial Services divisions**

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## Key Q3 FY25 Highlights

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# Key Highlights from Q3 FY25



Revenue of US\$3.5 million for the quarter, up 21% compared to prior quarter (Q2 FY25 - US\$2.9 million). YTD revenue of US\$9.8 million, up 44% on PCP.



Product revenue was up 17% and Services revenue was up 22% on Q2 FY25.



Additional FebriDx<sup>®</sup> agreements completed in the U.S. 1) MedPro Associates and 2) U.S. Defense Logistics Agency (DLA) awarded FebriDx a Distribution and Pricing Agreement (DAPA) which authorizes sales representatives to promote to the US Military Services.



FebriDx - CLIA Waiver study continues with around 351 patients tested to-date and 37 bacterial positives. Study completion and FDA application anticipated in 2H CY2025.



Hologic fFN project scope of work expansion signed and expected to generate an additional US\$0.6 - US\$0.8 million in fee revenue.



Post Reporting Date: Medicare payor coverage adoption commences – FebriDx<sup>®</sup> added to Medicare Fee Schedule of four Medicare Administration Contractors (MACs) at \$41.38 per test, effective April 2025. Discussions with the three remaining MACs progressing.

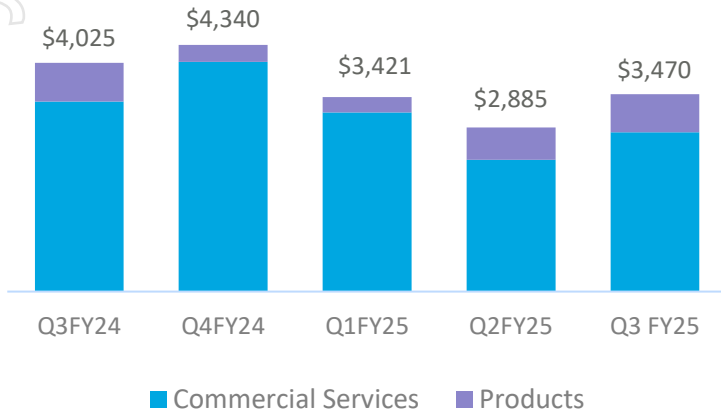


# Financials Summary

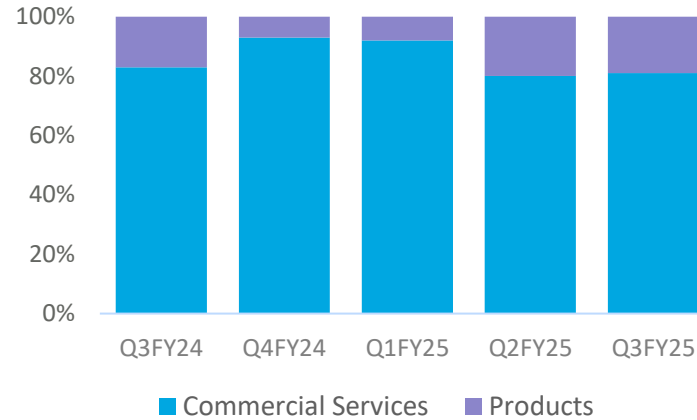


(Quarterly, US\$ in thousands)

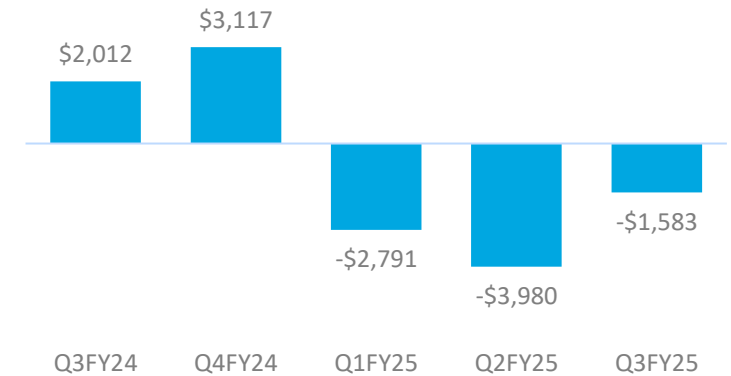
## Revenue (\$'000)



## Revenue Mix



## Net Cash Generation (\$'000)\*



## Commentary

- **Revenue** – US\$3.5 million in Q3 FY25, up 21% on prior quarter. YTD revenue is US\$9.8 million, up 44% on the PCP.
- **Services** revenue was US\$2.8 million in Q3 FY25, up 22% on prior quarter, with a large 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\$0.7 million in Q3 FY25, up 17% on prior quarter. Major contribution from ViraDx, plus increasing contribution from FebriDx in UK & US and small but growing Binx adoption.
- **Net cash outflow** of US\$1.6 million in Q3 FY25, significant reduction on US\$4.0 million outflow in Q2 FY25. Lower costs associated with inventory build up for US flu season, pre-clinical trial costs and other general operating costs.
- **Cash balance as at 31 March** of US\$4.0 million.

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

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# Products Division



# FebriDx<sup>®</sup> Update

## Distribution agreements

Two new distribution agreements signed in the US with:

- MedPro Associates – across national hospital and primary care markets.
- U.S. Defense Logistics Agency (DLA) awarded FebriDx a Distribution and Pricing Agreement (DAPA) which authorizes sales representatives to promote to the US Military Services.

## Medicare Benefits Schedule application

- In late March, Lumos completed and lodged an application with the Australian Government Department of Health and Aged Care for the inclusion of FebriDx<sup>®</sup> on the Medicare Benefits Schedule.

## Extended supply agreement with Atomo Diagnostics

- During April, contract extended for Atomo's Pascal cassette, which is used in the FebriDx<sup>®</sup> test. The amended agreement extends the contract until 30 June 2031 and retains exclusivity for a CLIA waived product.



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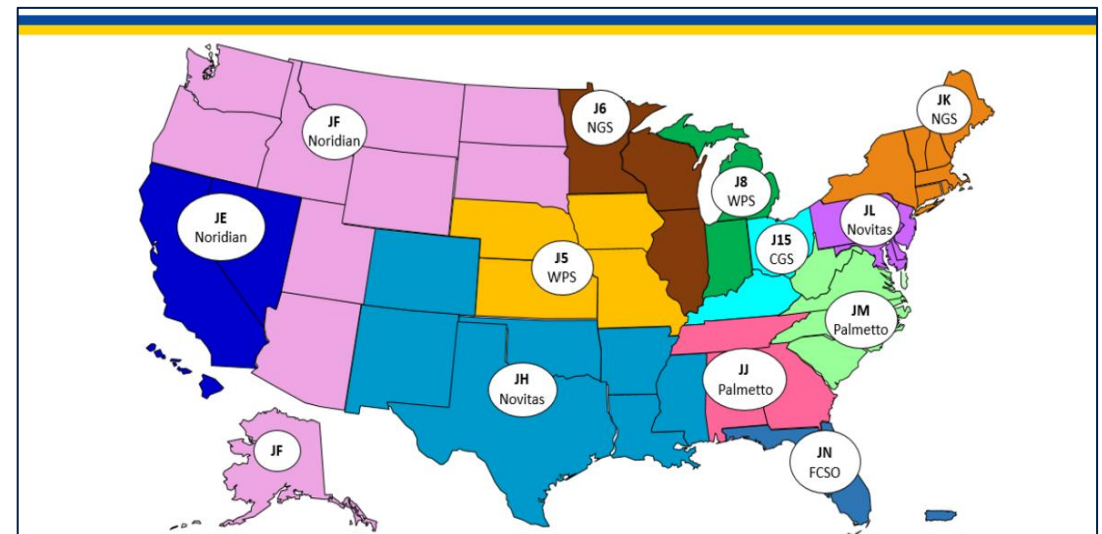
# FebriDx<sup>®</sup> Update ...cont'd



## Medicare US payor coverage adoption

- Effective from April 2025, FebriDx<sup>®</sup> has been added to the Medicare Fee Schedule in four of the seven Medicare Administration Contractors (MACs) regions - Palmetto, Novitas, First Coast Service Options and Noridian at US\$41.38 per test.
- These four represent over 55% of the total US Medicare payment coverage.
- In discussions with the remaining three MACs.
- All seven MACs represent 20%-24% of the US payor mix

Map of US MAC Jurisdictions



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# FebriDx® CLIA Waiver Update

## BARDA partnership agreement | October 2024

To support CLIA waiver and pediatric studies:  
non-dilutive funding up to US\$8.3m

- US\$3.0m to support CLIA waiver study
- US\$5.3m to support pediatric study (children under 12yrs old)
- Payments based on achieving certain milestones
- Next milestone payment is 500<sup>th</sup> patient, US\$0.3 million

## CLIA waiver clinical study commenced | December 2024

- Trial commenced on 19 December 2024 - first patient tested
- Around 351 patients tested to-date, with 37 bacterial positive (120 required)
- Bacterial prevalence lower than expected, at 10.5%
- Implementing patient enrollment “enrichment” plan
- Anticipate completion in 2H CY2025
- CLIA waiver enables access to a TAM of greater than US\$1 billion in the US



# 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

- ViraDx made up the majority of product sales during Q2 and Q3, with stocking orders received in October in preparation for the US flu season
- US flu season commenced some 6 – 8 weeks later than expected, now winding down
- ViraDx has achieved customer adoption due to the infection rates and great utility of the test - despite the US market experiencing significant competition from international organizations, with very aggressive pricing, at times below our COGS
- We are looking at alternative product distribution opportunities to sell a product that is competitive financially.



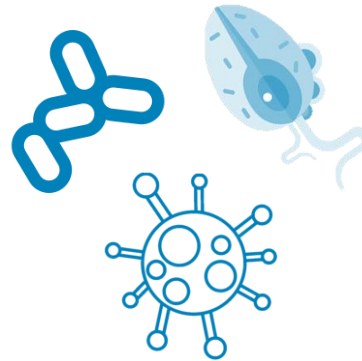
# Lumos Future Products

Women's Sexual Health - \$10B



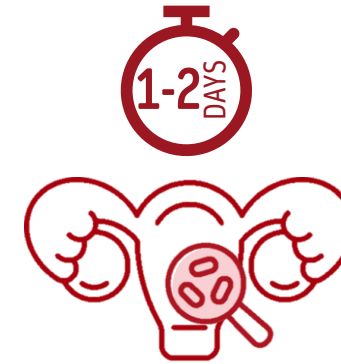
## Prevalence

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.

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# Women's Sexual Health – The Opportunity

## IN CLINIC TESTING

### Physical Exam



### Microscopic Exam



### Pathogen Testing



## EXTERNAL LAB TESTING

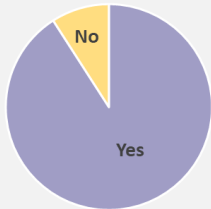
### Pathogen Testing



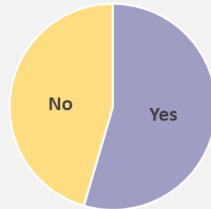
1-5  
DAYS

Current  
Practice

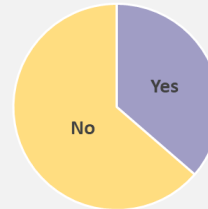
### Physical Exam



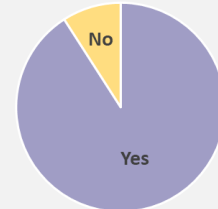
### Microscopy



### Pathogen Testing



### Pathogen Testing



Majority of clinics do not have in house testing of sexual health pathogens, due to test complexity, overheads and cost.

Instead, clinics send out testing to external labs, delaying patient diagnosis and treatment.



Lumos Women's Sexual Health POC tests will be run by existing staff, cost effective and provide rapid and accurate results.

Reimbursement codes are available today.

# Lumos Product Roadmap | Women's Sexual Health



**CURRENT - DISTRIBUTION**  
Revenue & Market Learning

**FUTURE - LUMOS POC PRODUCTS**  
Pathogen Detection | Visual & Reader Interpretation



Lumos – As a Distributer

Lumos Products – Visual Read

Lumos Products on Lumos Reader



GYN CLINIC & URGENT CARE



**Binx io**  
Chlamydia & Gonorrhea



Product #3

Product #4

Product #5

Product #1

Product #2

Concept  
Development

Technical  
Feasibility

Product  
Development

Verification &  
Validation

Commercialization

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# Commercial Services Division

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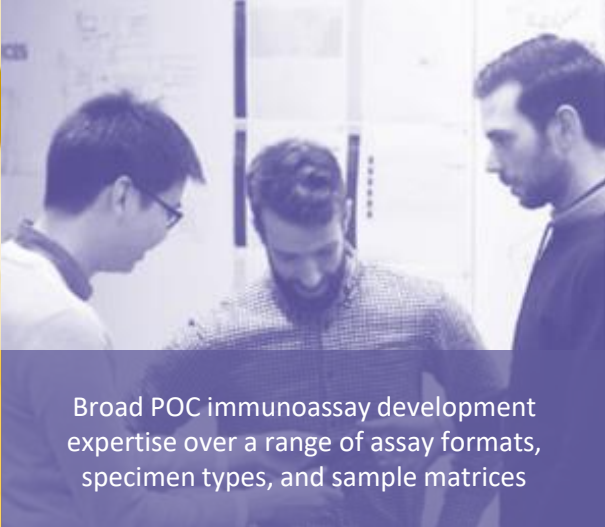
# Commercial Services Overview



Lumos works directly with clients to develop and deliver custom built, commercially viable point-of-care (POC) test solutions that meet business and end user needs.



Deep POC market insight



Broad POC immunoassay development expertise over a range of assay formats, specimen types, and sample matrices



Diverse proprietary digital reader platforms and cloud based technologies



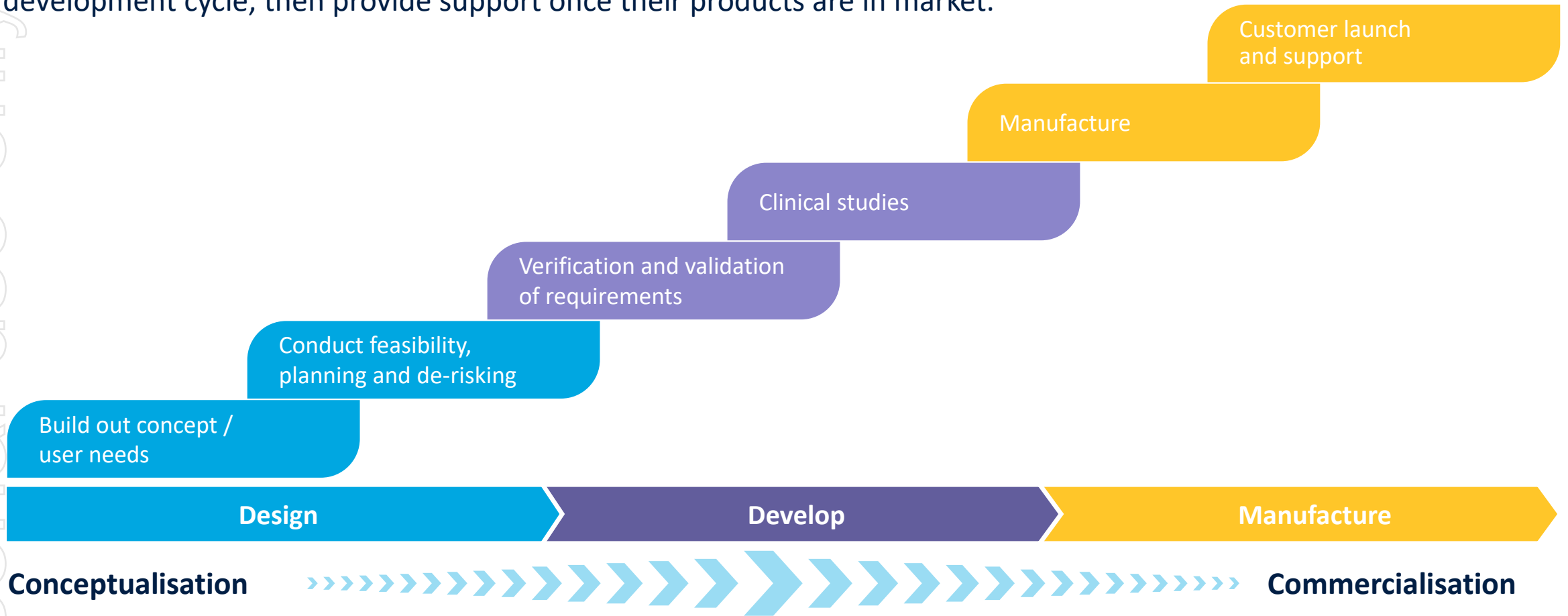
Full in-house ISO 13485 compliant manufacturing including test strip manufacturing, assembly, kitting, and packaging



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# How we add value to partners

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



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# Hologic - Strategic Partnership



## Fetal Fibronectin (fFN)<sup>1</sup>

- fFN is a biomarker indicating a heightened risk of pre-term delivery and is the largest segment of the pre-term birth diagnostic test kit market of US\$420m p.a.<sup>2</sup>
- Two agreements signed in FY24 for the development of an improved version of Hologic's leading in-market women's health product, Rapid fFN TLIQ, including adapting it for use on Lumos' proprietary reader platform
  - **IP Agreement** - US\$10.0m - exclusive license to the Lumos proprietary reader and POC technologies for next generation fFN product – **received in FY24**
  - **Development Agreement** - up to US\$5.5m over an estimated 24-month period for the following milestones:
    - **Phase 1:** Product Definition and Planning - US\$0.4m - **completed**
    - **Phase 2:** Assay Feasibility - US\$0.6m – milestone 1 **completed** / milestone 2 **in-progress (expect to complete in May)**
    - **Phase 3:** System Prototype Delivery – US\$3.7m – 6 milestones – **commenced**
    - **Expanded HW scope of work** – announced Mar 2025 - US\$0.6 – US\$0.8m for delivery of new hardware features - **commenced**

<sup>1</sup>ASX announcements 11 January 2024, 15 January 2024, 16 January 2024, 6 May 2024, 4 June 2024, 19 June 2024. 3 March 2025 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

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## Key Priorities



# Key Priorities



Continue to monitor and implement strategies to maintain and improve the rate of bacterial positive patients enrolled in the FebriDx CLIA waiver trial



Incorporate FDA feedback from the FDA pre-submission for FebriDx pediatric study in April 2025 into an updated study protocol



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



Continue to drive FebriDx product awareness and sales into US urgent care centers while expanding payor coverage with both US government and private insurance companies



Deliver on Hologic fFN development milestones - milestone 2 from Phase 2 & Phase 3 milestones

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