



Lumos Diagnostics Holdings Limited

Investor Briefing

21 July 2025

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.**

Company Overview



Experienced leadership team



Comprehensive & integrated offering from product concept design through to manufacture and distribution



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



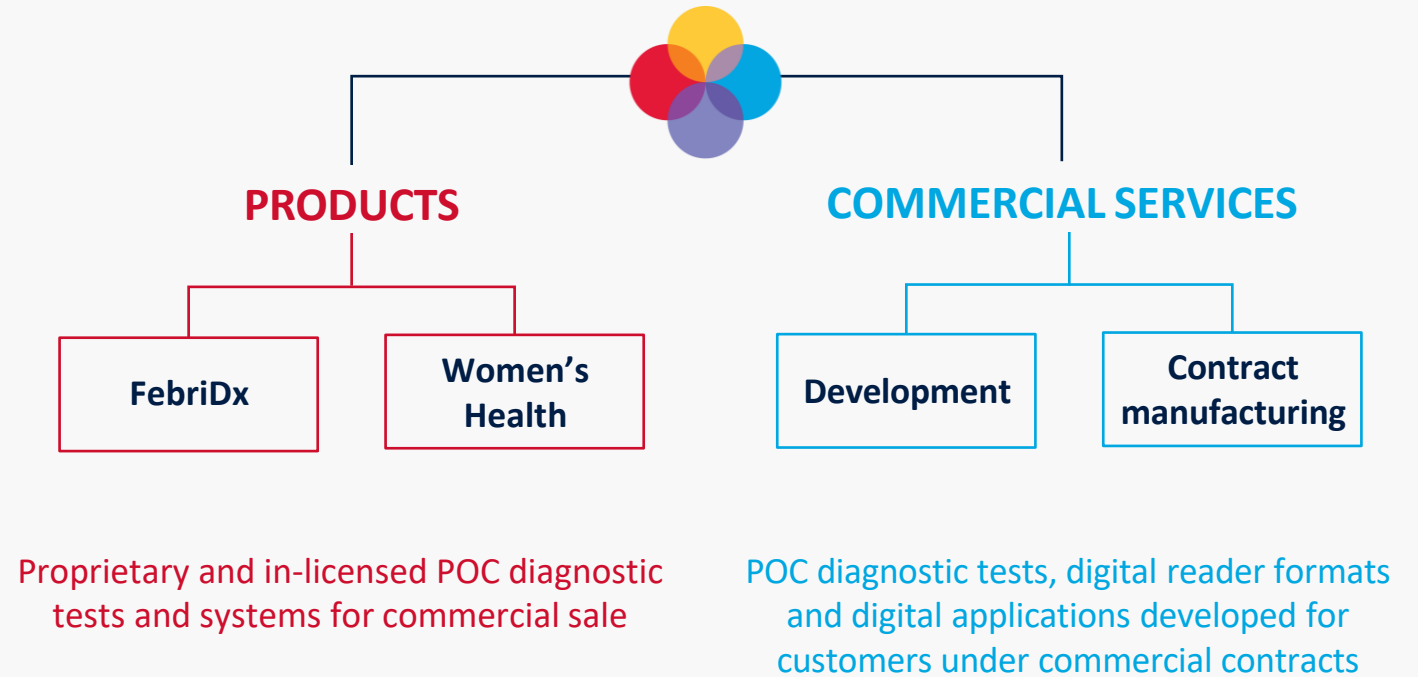
Transformational development agreements with world's leading global women's health company – Hologic



Currently developing proprietary women's health and sexual health point-of-care products

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.



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

Investment Highlights



Proprietary product

FebriDx® (bacterial v non-bacterial test) generating sales in market

Pivotal distribution contract

Major agreement signed with PHASE Scientific for the U.S. market – for **US\$317 million (A\$487 million¹)** over 6 years,² assuming FebriDx® granted CLIA waiver and minimum order quantities (MOQ's) are achieved

CLIA waiver study

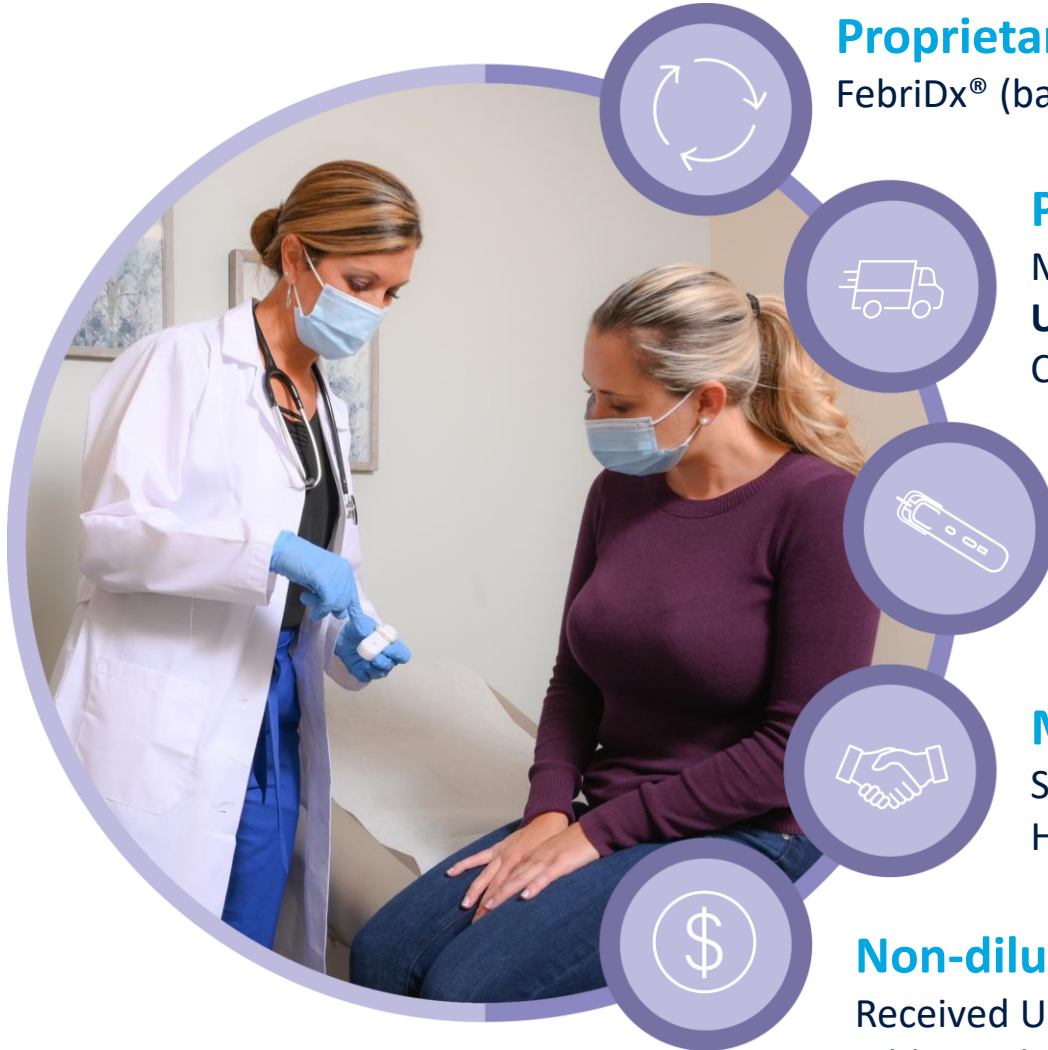
Progressing well - FDA CLIA waiver application submission expected within three months

Major services agreement

Strategic relationship with U.S. based women's health leader, Hologic to develop next-gen fFN test

Non-dilutive funding

Received US\$15.6 million in non-dilutive funding in the last 2 years and an additional US\$7.1 million committed under BARDA partnership.



Key Q4 FY25 Highlights

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

Key highlights from Q4 FY25 & post reporting date



Revenue of \$12.4 million for the year, up 12% compared to prior year (FY24 - \$11.1 million). Q4 FY25 revenue of \$2.6 million, down 26% on prior quarter due to end of U.S. flu season.



Major distribution agreement signed with PHASE Scientific for the U.S. market - for **US\$317 million (A\$487 million)** over 6 years,² assuming FebriDx® granted CLIA waiver and minimum order quantities (MOQ's) are achieved.



Lumos U.S. Medicare payor coverage for FebriDx®, representing 20%-24% of the reimbursement payor mix, reaches 85% of Medicare, following the onboarding of six of the seven Medicare Administrative Contractor's (MAC's).



FebriDx - CLIA Waiver study continues with 105 of targeted 120 bacterial positive patients enrolled. Expected completion August, with **FDA application submission within three months.**



Hologic fFN project continues to progress, with Phase 2 work completed. Hologic requested additional studies on milestone 3, assay feasibility, which will delay Phase 3 by approx. 3 months.



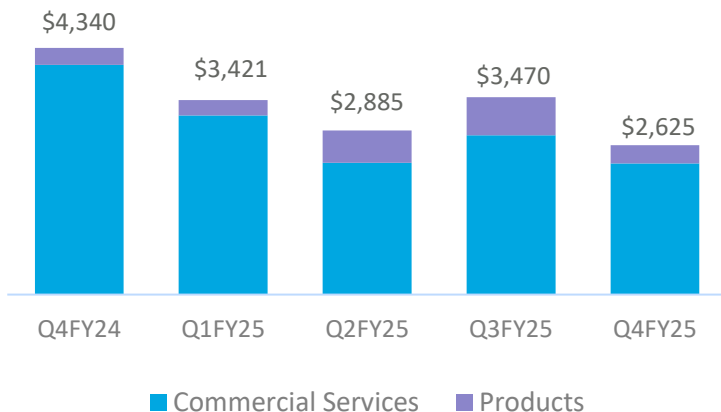
Binding term sheet for A\$5.0 million loan facility, with drawdowns as needed, to support working capital until after anticipated CLIA waiver grant for FebriDx.

Financials summary

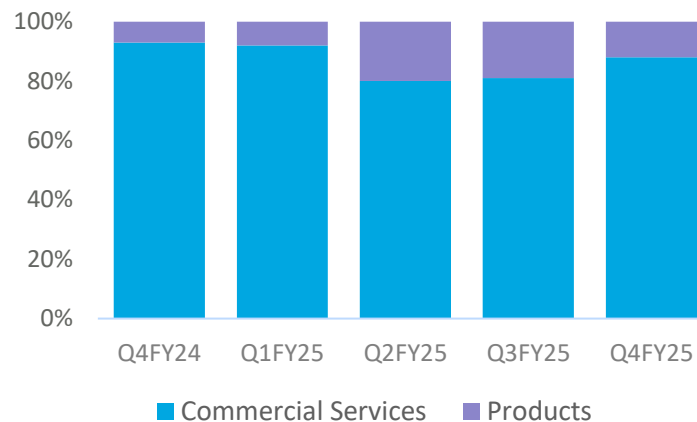
(Quarterly, US\$ in thousands)



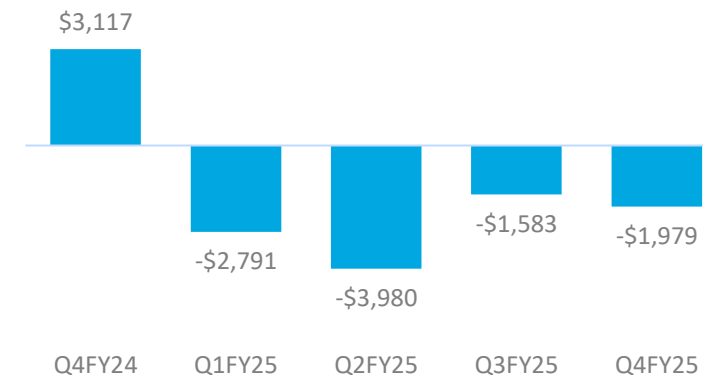
Revenue (\$'000)



Revenue Mix



Net Cash Generation (\$'000)*



Commentary

- **Revenue** – FY25 revenue of US\$12.4 million, up 12% compared to FY24 of US\$11.1 million. Revenue \$2.7 million in Q4 FY25, down 26% on prior quarter.
- **Services** revenue was \$2.3 million in Q4 FY25, down 18% on prior quarter, with a large contribution from development services under the Hologic fFN Development Agreement and the licensing revenue associated with the IP Agreement. Extended project timeline of 3 months reduced revenue.
- **Products** revenue was \$0.3 million in Q4 FY25, down 57% on prior quarter. Influenced by seasonal demand for ViraDx in the quarter.
- **Net cash outflow** of \$2.0 million in Q4 FY25.
- **Cash balance as at 30 June** of \$2.0 million.

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

Binding term sheet for loan facility – 17 July 2025



Binding term sheet signed with supportive major shareholders Tenmile and Ryder Capital



Funding of up to A\$5.0 million, as required, on 12-month term, with option to extend by a further 12-months



Subject to completing a definitive loan agreement and ASX waiver



Anticipate a loan agreement to be executed by mid-August 2025



In conjunction with cash receipts from PHASE Scientific distribution agreement and expected milestone payments from partners, cash inflows should meet working capital requirements through to anticipated grant of CLIA waiver

The loan is designed to provide short term funding with limited equity dilution, while Lumos works toward a CLIA waiver for its flagship product, FebriDx®.

Products Division

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PHASE Scientific partnership



A pivotal agreement - one of the largest distribution deals of its type to be done by an ASX-listed point of care diagnostics company



Exclusive U.S. distribution agreement signed for FebriDx[®] with PHASE Scientific International



Partnership potential – for **US\$317 million (A\$487 million¹)** over 6 years,² assuming FebriDx[®] is granted CLIA waiver and minimum order quantities (MOQ's) are achieved



PHASE Scientific **MOQ's to ramp up significantly** from years 2 through to 6 of the agreement.



PHASE Scientific exclusive FebriDx® U.S. distribution agreement



Summary of anticipated payments (US\$)

Milestones	Payment Timing	With CLIA waiver
Exclusivity fee	On signing	1.0m
Pre-paid purchase order	On signing	1.0m
Pre-paid purchase order	On CLIA waiver application submission	1.5m
Prep-paid purchase commitment	On grant of CLIA waiver	5.0m
Aggregated minimum order quantities (Yrs 2-6)	On delivery of product	308.5m
Total		US\$317.0m

Summary of key terms

- Six-year term, with option to extend
- Exclusive rights to distribute and commercialise FebriDx® under the Lumos brand in the U.S.
- Possible co-branding at a later date
- Lumos retains all IP rights, manufacturing, quality control and product compliance
- Initial contract value of US\$317 million - assuming CLIA waiver is granted and all MOQ's are achieved.
- Contract value without grant of CLIA waiver up to US\$25.0 million
- Regular business reviews to assess performance
- At three years after granting of CLIA waiver – modify commercial terms if the MOQ's are not achieved or modify the terms after good faith discussions.

About FebriDx[®]: Lumos' first-of-its-kind point of care test



FebriDx[®] is an aid for healthcare providers to improve patient care and antibiotic stewardship



The majority of acute respiratory infections are caused by viruses and do not require antibiotics, yet antibiotics are prescribed in up to 50% of cases¹



Overprescription of antibiotics can result in adverse patient reactions and contribute to antimicrobial drug resistance



FebriDx[®] is a rapid point-of-care test that uses a fingerstick blood sample to aid in the differentiation between bacterial and non-bacterial infections



Rapid results at point of care can increase confidence in whether or not to prescribe an antibiotic.



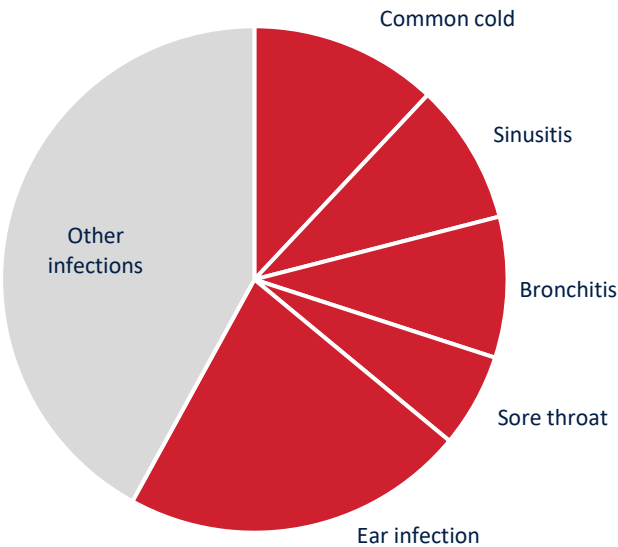
FebriDx[®] addresses a major need: antibiotic overprescription



ANTIBIOTICS PRESCRIBED (U.S.)



ANTIBIOTICS PRESCRIBED IN THE U.S. BY TYPE



211M antibiotic prescriptions issued in outpatient settings each year ¹

44% of antibiotic prescriptions are written to treat patients with ARIs ²

40% of these are unnecessary ³

Acute respiratory infections may account for
58%
of all antibiotics prescribed ⁴

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¹ Outpatient Antibiotic Prescriptions—United States 2021: <https://www.cdc.gov/antibiotic-use/data/report-2021.html>

² Unnecessary Antibiotics for Acute Respiratory Tract Infections: Associations with Care Setting and Patient Demographics, 2016

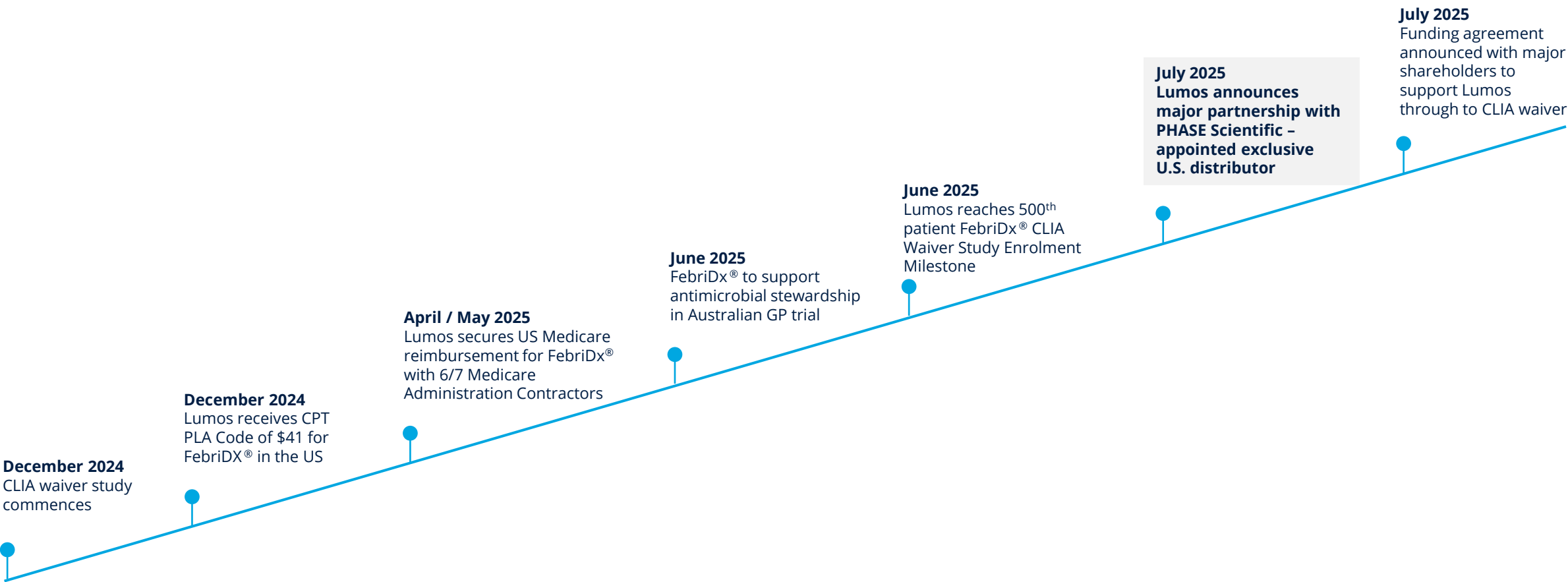
³Tse, J.; Near, A. *et al*; Antibiotics 2022, 11, 1058. <https://doi.org/10.3390/antibiotics11081>.

⁴ Centers for Disease Control and Prevention. MMWR, 2011, 60:1153-6

FebriDx[®] journey to transform the practice of medicine



Recent achievements forming the critical commercialisation backbone for FebriDx[®]



FebriDx® CLIA waiver study update



BARDA partnership agreement announced in October 2024

- BARDA partnership agreement: non-dilutive funding up to US\$8.3 million committed to support CLIA waiver and pediatric studies (US\$3.0m for CLIA waiver study and US\$5.3m for pediatric study)

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

CLIA waiver study update as at 9 July 2025

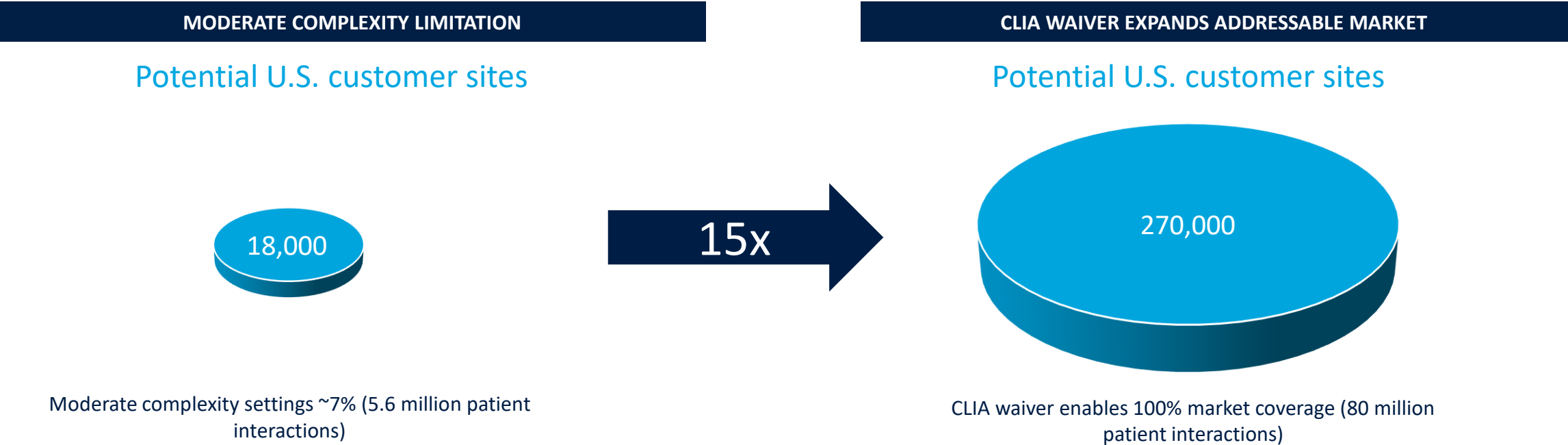
- 105 bacterial positive patients have been enrolled to-date out of the targeted 120 bacterial-positive patient results required for the study
- At the current accrual rate, study completion anticipated during August
- FDA CLIA waiver application expected to be submitted within the next three months.



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



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

Why partner with PHASE Scientific?



Expertise and understanding of the POC market in the U.S.



Highly regarded, well respected commercial leadership



Financial commitment to a robust go-to-market launch for FebriDx®



Strong network of sub- distributors and end user customers.



Our Approach

Better health information helps better decision-making, for both patients and healthcare providers

Introducing PHASE Scientific

- Operations in the U.S., mainland China, and Hong Kong
- Delivering novel diagnostic tools and services for cancer and infectious diseases using proprietary technologies
- Products/services: received certifications from the U.S. Food and Drug Administration (FDA), the European Union CE, and regulatory agencies in various countries, providing over 100 million testing products and services in more than 30 countries worldwide
- Recently completed a US\$34 million Series A funding round
 - ▶ Largest Series A raise in Asia's diagnostic technology sector since 2019
- Other supporters include Gates Foundation, and U.S. governmental agencies, National Science Foundation and National Institute of Health.

For more information visit phasescientific.com



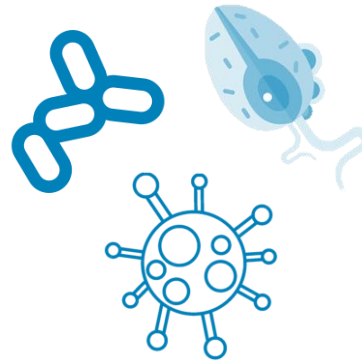
Lumos Future Products

Women's Sexual Health - \$10B



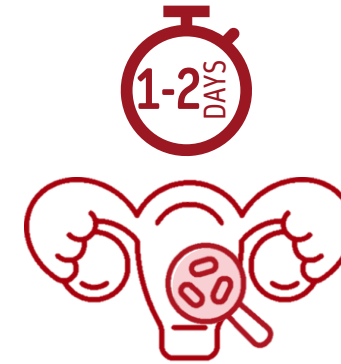
Prevalence

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.

Women's Sexual Health – The Opportunity



IN CLINIC TESTING

Physical Exam



Microscopic Exam



Pathogen Testing



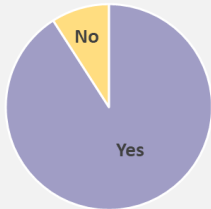
EXTERNAL LAB TESTING

Pathogen Testing

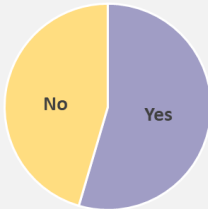


Current Practice

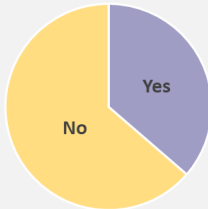
Physical Exam



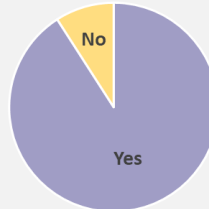
Microscopy



Pathogen Testing



Pathogen Testing



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

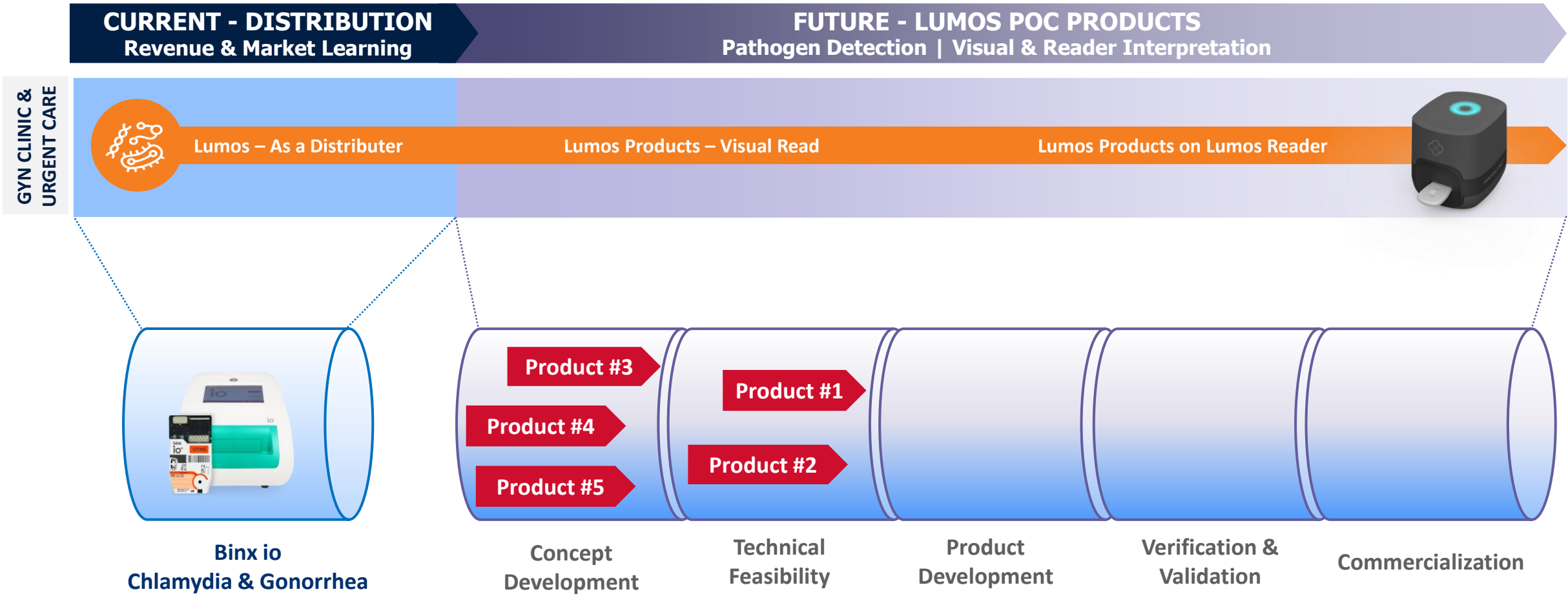
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Reimbursement codes are available today.

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 Product Roadmap | Women's Sexual Health



Commercial Services Division

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Commercial Services Capabilities



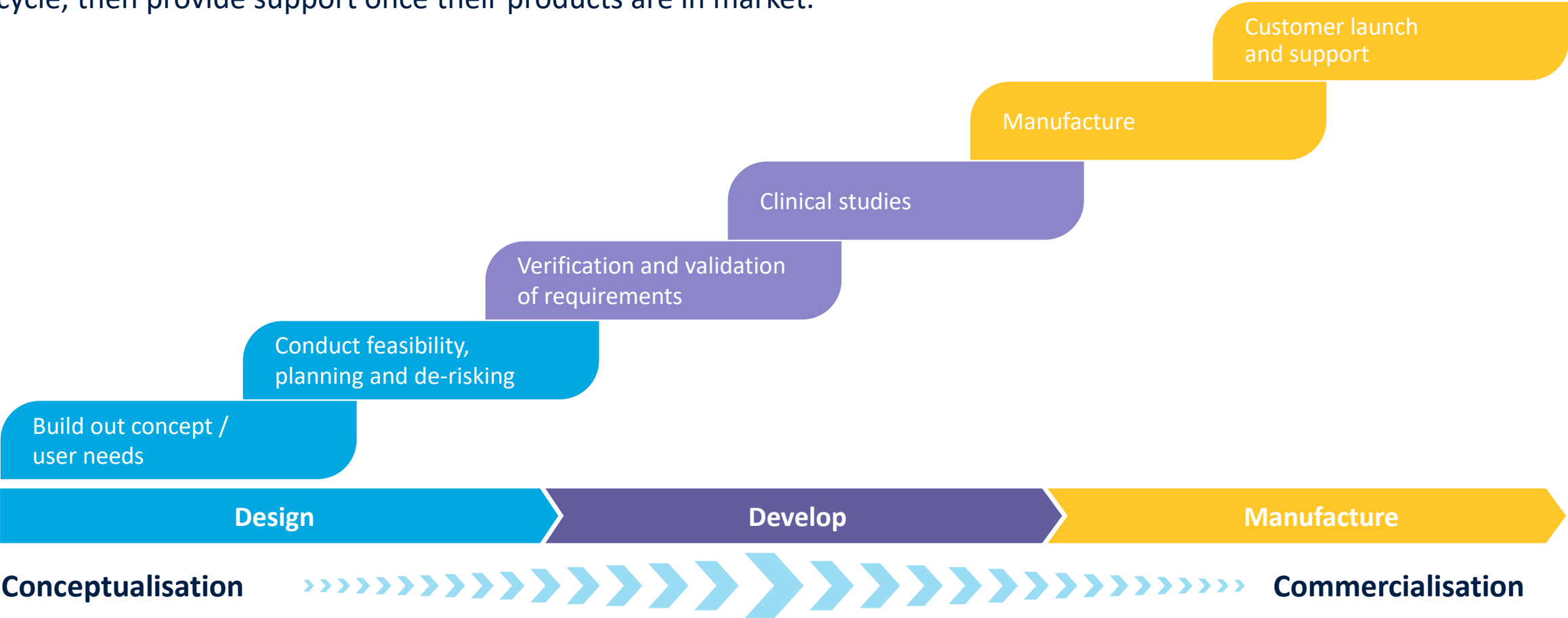
Lumos offers the full range of in-house expertise required to deliver a complete, commercially ready solution.

DEVELOPMENT & MANUFACTURING			PLATFORM TECHNOLOGIES		
ASSAY			READERS		
			EMR & CONNECTIVITY		

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.



Hologic - strategic partnership

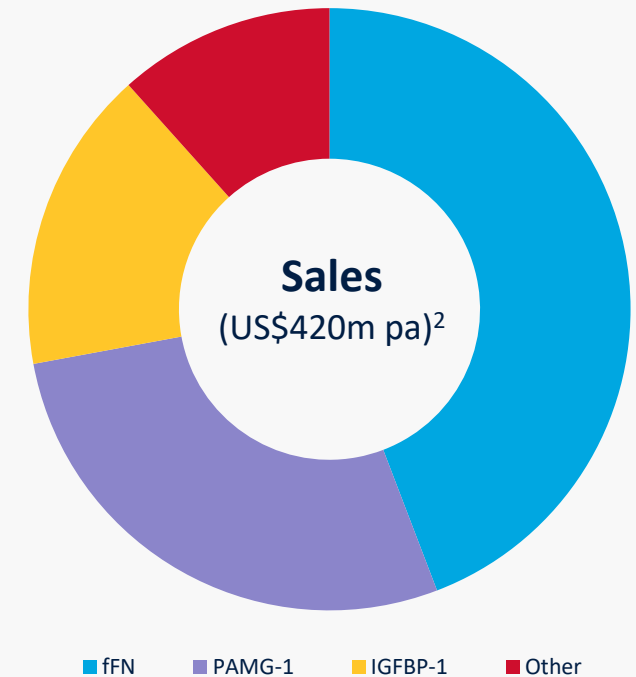
Fetal Fibronectin (fFN)¹

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

- Two 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
 - **IP Agreement** - US\$10.0m - exclusive license to the Lumos proprietary reader and POC technologies for next generation fFN product - **received**
 - **Development Agreement** - up to US\$5.5m over an estimated 27-month period for following milestones:
 - **Phase 1: Product Definition and Planning** - US\$0.4m - **completed**
 - **Phase 2: Assay Feasibility** - US\$0.6m – milestone 1 **completed** / milestone 2 **completed**
Additional assay studies requested by Hologic, estimated to take 3 months
 - **Phase 3: System Prototype Delivery** – US\$3.7m – 6 milestones – **commenced milestones 4 & 5**, now delayed pending additional assay studies
 - **Expanded hardware scope of work** – announced Mar 2025 - US\$0.6 - 0.8m for delivery of new hardware features - **commenced**
- **Expected Development Agreement completion by March 2026**



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



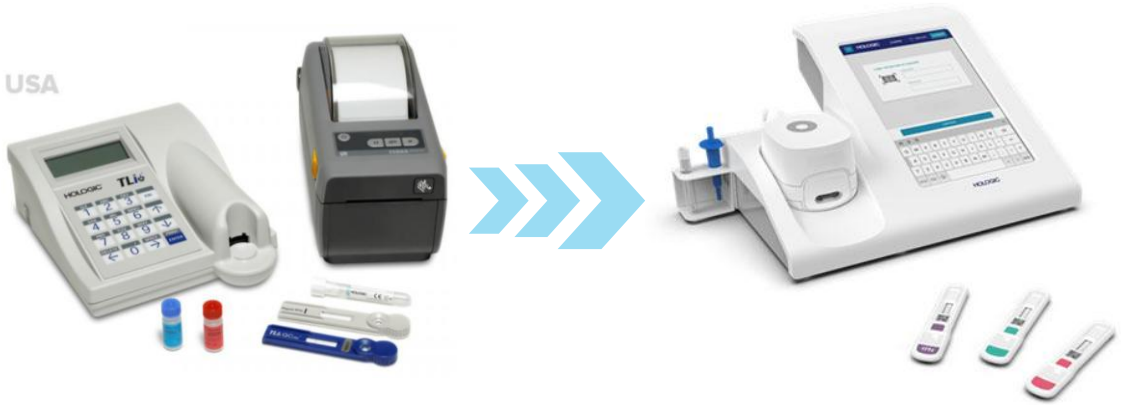
¹ASX announcements 11 January 2024, 15 January 2024, 16 January 2024, 6 May 2024, 4 June 2024, 19 June 2024. 3 March 2025 2. Global Market Insights, www.gminsights.com

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

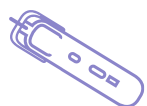


Manufacturing



Second test
development and IP

Key Priorities



Complete CLIA waiver study for FebriDx and submit application to FDA within the next 3 months



Implement agreement with PHASE Scientific, drive reimbursement coverage, and plan for volume scale-up.



Initiate FebriDx pediatric study in coming month's – fully funded by BARDA - addresses important clinical market and expands U.S. market by approx. 20%



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



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



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