



# Lumos Diagnostics Holdings Limited

## Investor Briefing

16 July 2025

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

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

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# Today's presenters



**Doug Ward**  
CEO & Managing Director  
Lumos Diagnostics



**Barrie Lambert**  
Chief Financial Officer  
Lumos Diagnostics



**Paul Kase**  
SVP of Commercial Operations  
Lumos Diagnostics



**Bob Gergen**  
VP of Commercial Operations  
PHASE Scientific

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

# 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 - up to **US\$317 million (A\$487 million<sup>1</sup>)** over 6 years,<sup>2</sup> 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.

# 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<sup>®</sup> with PHASE Scientific International



Partnership potential - up to **US\$317 million (A\$487 million<sup>1</sup>)** over 6 years,<sup>2</sup> assuming FebriDx<sup>®</sup> 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		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 up to 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<sup>®</sup>: Lumos' first-of-its-kind point of care test



FebriDx<sup>®</sup> 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 cases<sup>1</sup>



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



FebriDx<sup>®</sup> 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<sup>®</sup> addresses a major need: antibiotic overprescription



## ANTIBIOTICS PRESCRIBED (U.S.)

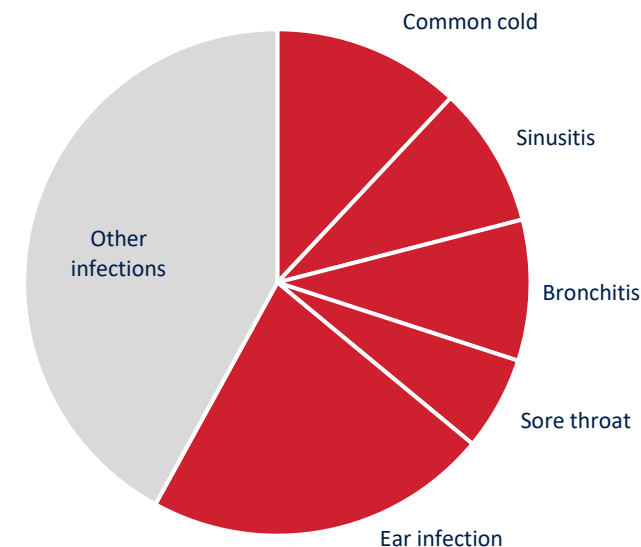


**211M** antibiotic prescriptions issued in outpatient settings each year <sup>1</sup>

**44%** of antibiotic prescriptions are written to treat patients with ARIs <sup>2</sup>

**40%** of these are unnecessary <sup>3</sup>

## ANTIBIOTICS PRESCRIBED IN THE U.S. BY TYPE



Acute respiratory infections  
may account for

**58%**

of all antibiotics prescribed <sup>4</sup>

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

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

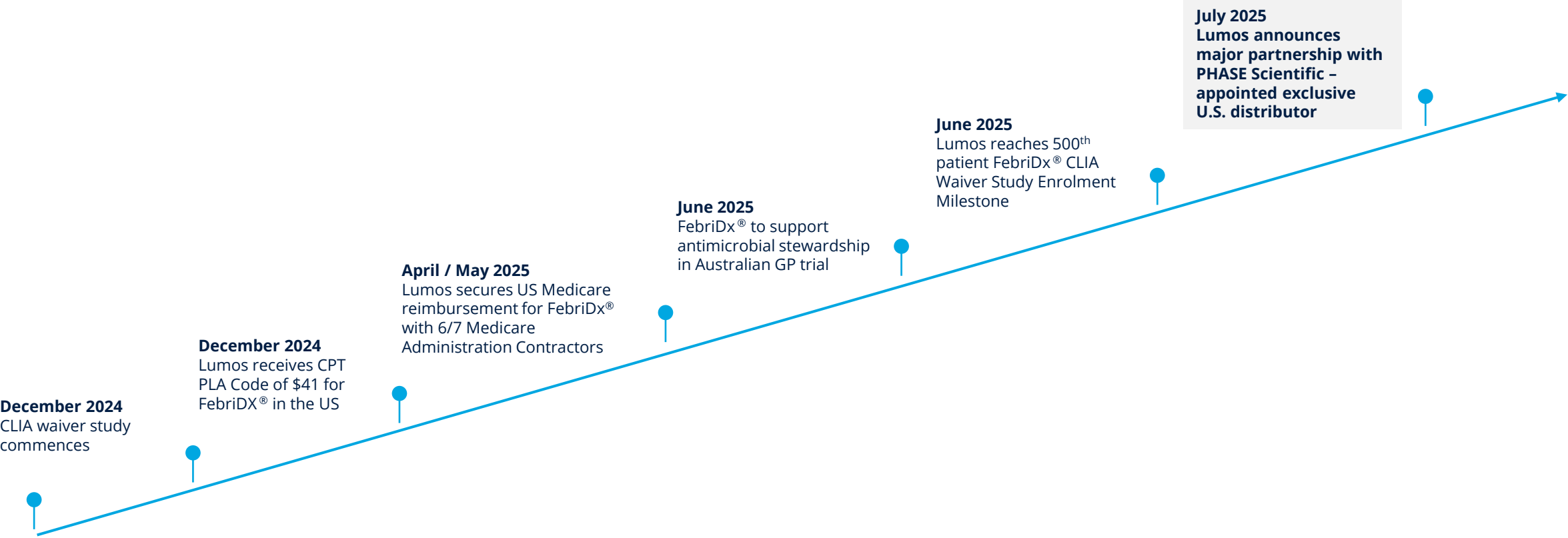
<sup>3</sup> Tse, J.; Near, A. *et al*; Antibiotics 2022, 11, 1058. <https://doi.org/10.3390/antibiotics11081>.

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

# FebriDx<sup>®</sup> journey to transform the practice of medicine



Recent achievements forming the critical commercialisation backbone for FebriDx<sup>®</sup>



# FebriDx<sup>®</sup> 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

## **CLIA waiver clinical study commenced in December 2024**

- The CLIA waiver study is designed to demonstrate that the FebriDx<sup>®</sup> 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**

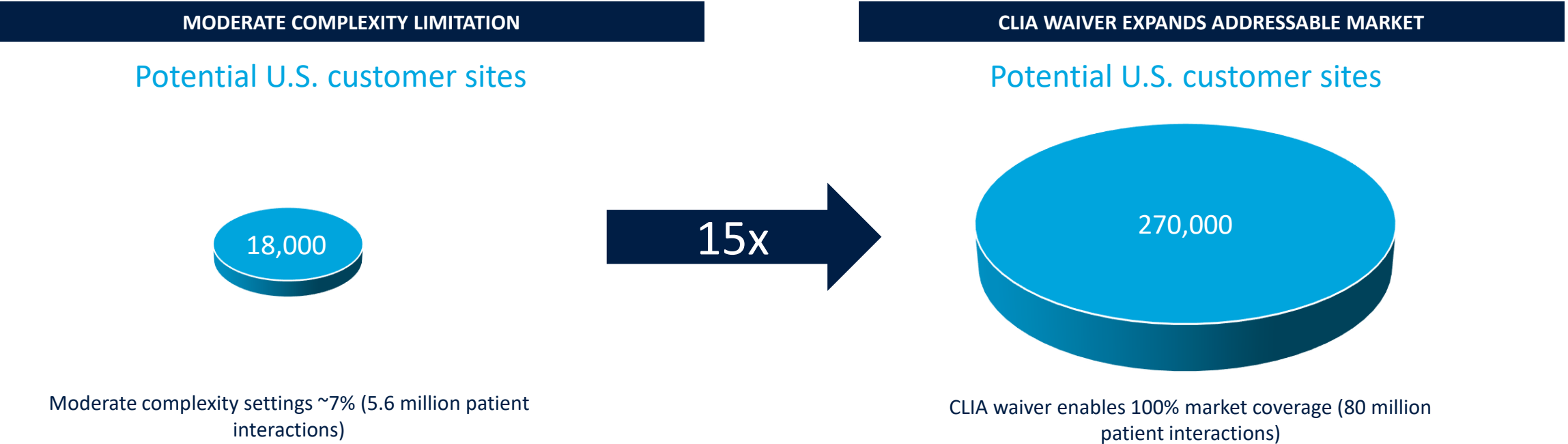
- 105 bacterial positive patients have been enrolled to-date out of the targeted 120 bacterial-positive patient results required for the study
- At the current accrual rate, study completion anticipated during August
- FDA CLIA waiver application expected to be submitted within the next three months.



# FebriDx<sup>®</sup> 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<sup>®</sup> patient opportunities for use)<sup>1</sup>

# 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](https://phasescientific.com)





# PHASE Scientific commercial strategy



- **Contract with National and Regional Med Surg Distributors (3,000+ sales reps)**
- **Continue to deploy contract sales group MedPro Partners (60 sales reps)**
- **Sales strategy with current PHASE call points:**
  - 10 direct sales personnel: Urgent Care, Student Health, Retail Health, Worksite Health and targeted alternate markets
  - Distribution: Physician Office Lab market
  - Inside sales
- **Target existing and under- penetrated segments, innovators, early adopters, high volume users and opinion leaders:**
  - Sustain and expand Lumos' commercial footprint and market impact
  - Leverage INDICAID customers to drive FebriDx® utilization and adoption
- **Marketing: Customer–first messaging:**
  - Focus on “why it matters” for the end users (patients, providers, pharmacists)
  - Proof through people: Case studies, testimonials, behind-the-scenes scientist/KOL spotlights
  - Multi-channel narrative: Consistent voice across packaging, social media, sell sheets, landing pages/ website.

# Key Priorities



Complete CLIA waiver study and submit application to FDA



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



Initiate the BARDA paediatric study in coming months - addresses important clinical market and expands U.S. market by approx. 20%



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



**Coming roadshow dates:**

21 July 2025	Brisbane
22 - 23 July 2025	Sydney
24 July 2025	Melbourne

**For more information or to  
arrange a meeting, please contact:**

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