



# Lumos Diagnostics Holdings Limited



Investor Presentation

February 2024

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

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# Company Overview

A horizontal bar composed of several colored segments: yellow, grey, cyan, purple, red, and orange.

# Company snapshot



Lumos is a developer and manufacturer of connected instrumentation and rapid point-of-care tests for the diagnostics and healthcare industries



## Experienced leadership

- Led by Doug Ward (CEO) - industry veteran with over 30 years' in diagnostics
- Experienced business/technical/commercial leaders also include Barrie Lambert (CFO); Sacha Dopheide (CTO) & Paul Kase (SVP Commercial Ops)



## Comprehensive / integrated offering

- Concept design, development, clinical, regulatory, commercial production
- Proprietary reader platforms providing connected use in different clinical settings
- Development and manufacturing facility located in Carlsbad, California



## Transformational Hologic agreements

- Strategic relationship with US-based women's health leader Hologic – expanded in January 2024 with two transformative new agreements



## Commercialised proprietary POC diagnostic products

- FebriDx – aid in the diagnosis of bacterial acute respiratory infection
- ViraDx – test for key respiratory infections

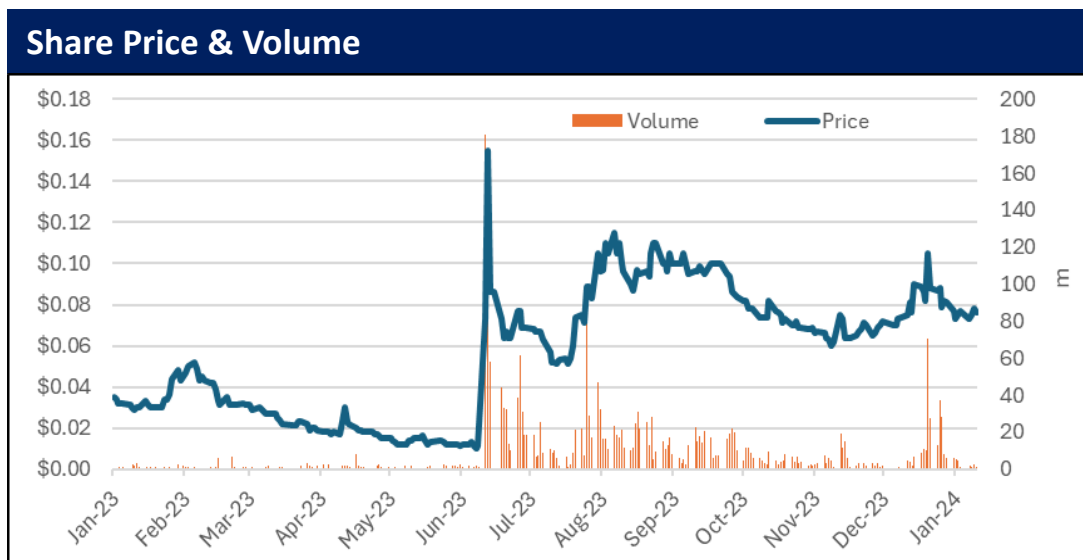


## Distribution

- Distributor of other women's health and sexual health products

# Company snapshot

Issued capital	
Shares	481.3m
Options	85.0m
Market capitalization (AUD)	
Share price	A\$0.079
Market value	A\$38.2m
Cash (pro-forma – Jan 24)	A\$9.7m
Enterprise value	A\$28.5m
Substantial shareholders	
Perennial Value Management	13.6%
Planet Innovation	14.1%
Ryder Capital	5.3%



### Board and management

Sam Lanyon	Non-Exec Chairman
Doug Ward	CEO & Managing Director
Bronwyn Le Grice	Non-Exec Director
Lawrence Mehren	Non-Exec Director
Catherine Robson	Non-Exec Director
Barrie Lambert	CFO

As at 2 February 2024

# Highly experienced leadership team



**Doug Ward**  
CEO & Managing Director

Doug Ward has more than 30 years of biotech and medical technology experience at notable global healthcare companies including Roche, GE, Siemens, Bayer, Chiron and Hologic.

With a deep understanding of the life sciences ecosystem, Mr. Ward excels at setting the strategic direction for global companies. He brings experience across all company functions, including Commercial Leadership, R&D, Operations, Quality, Regulatory, Service, and Support.

Mr. Ward earned his Bachelor of Arts in Pre-medicine Studies from Ohio Wesleyan University.



**Barrie Lambert**  
Chief Financial Officer

Barrie Lambert has more than 20 years of international experience in high growth companies from the medical device research and development services and manufacturing sector, as well other sectors. Prior to joining Lumos Diagnostics, he was CFO of Planet Innovation, one of the founding shareholders and current major shareholder of Lumos.

Mr. Lambert has a broad background in governance, strategy, finance, M&A, operations, technology and sales. He holds a BA in Accounting from the University of South Australia and an MBA from University of Sydney. He is a chartered accountant and a graduate of the Australian Institute of Company Directors.



**Sasha Dopheide, PhD**  
Chief Technology Officer

Sasha Dopheide, PhD has more than 15 years of experience in the in vitro diagnostic device industry, ranging from point-of-care devices to laboratory analyzers. She has held an executive leadership role within Lumos Diagnostics since its 2017 acquisition of Kestrel Bioscience.

Dr. Dopheide has experience managing the full range of product development for both immunoassays and their accompanying electronic readers from proof of concept through development, verification and external validation trials. She holds a BSc with First Class Honours in Biochemistry and Molecular Biology from Monash University. She received her PhD in Medicine in 2000, for which she was awarded the Victoria Fellowship for Excellence in Medical Research.



**Paul Kase**  
SVP of Commercial Operations

Paul Kase brings more than 28 years of medical sales and leadership experience in the point-of-care diagnostic testing market to Lumos Diagnostics.

Mr. Kase is a proven leader in coaching and developing best-in-class sales teams that consistently meet and exceed revenue goals. His experience also extends to overseeing customer and technical support divisions, commercial product launches, key opinion leader development, and the creation of distributor networks in the hospital and primary care markets.

Mr. Kase earned his Bachelors in Economics and English from Bucknell University.

# Lumos has a compelling and highly competitive offering



## 1. Fully-integrated—from design to manufacturing



## 2. Proprietary reader platform for use in different settings



## 3. Clinical validation, trial management, and regulatory

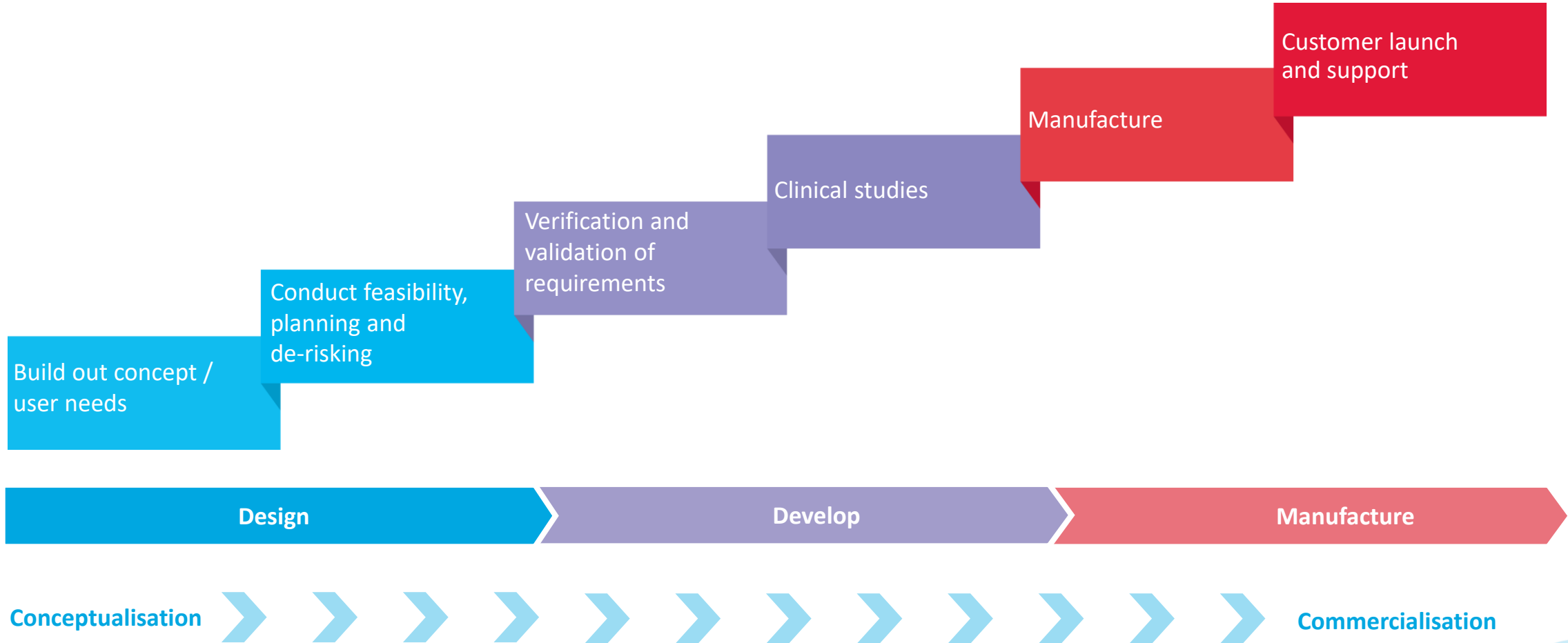


## 4. Business development / commercialisation



# 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

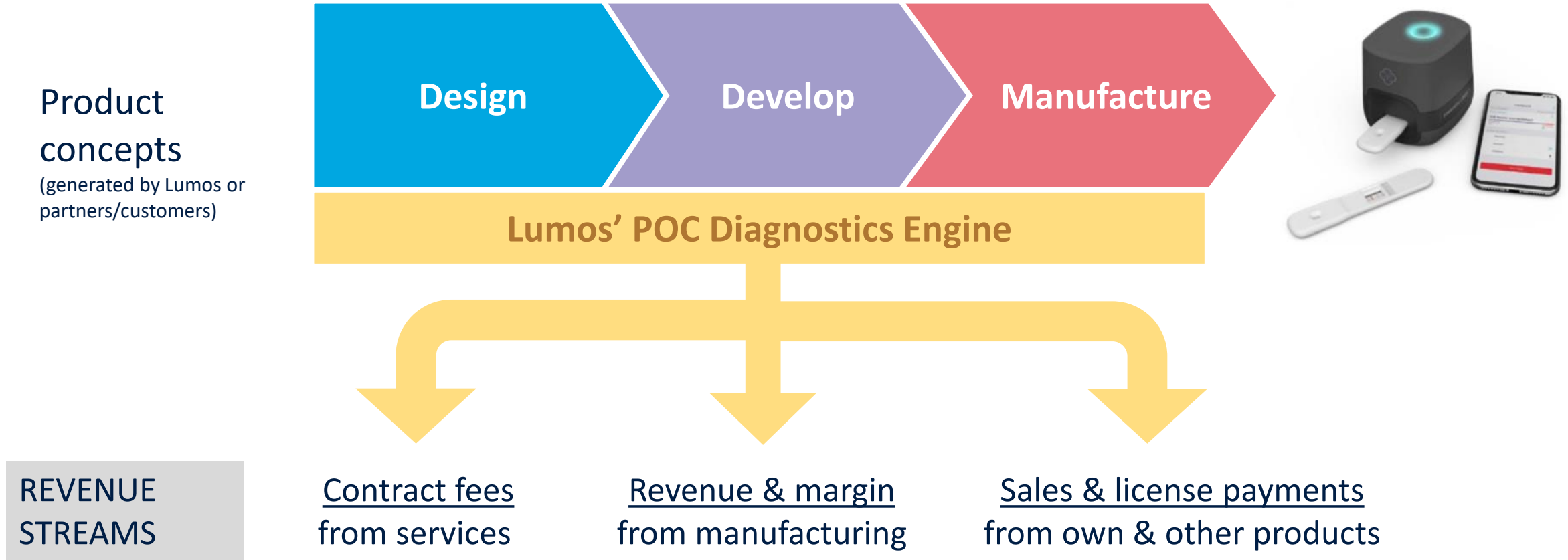




# Lumos' POC diagnostic test development engine



We are one of the few companies in the POC space that provides these integrated services to partners

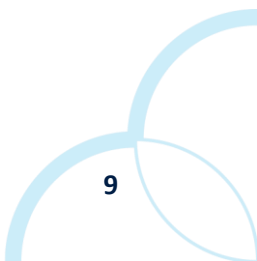


REVENUE STREAMS

Contract fees  
from services

Revenue & margin  
from manufacturing

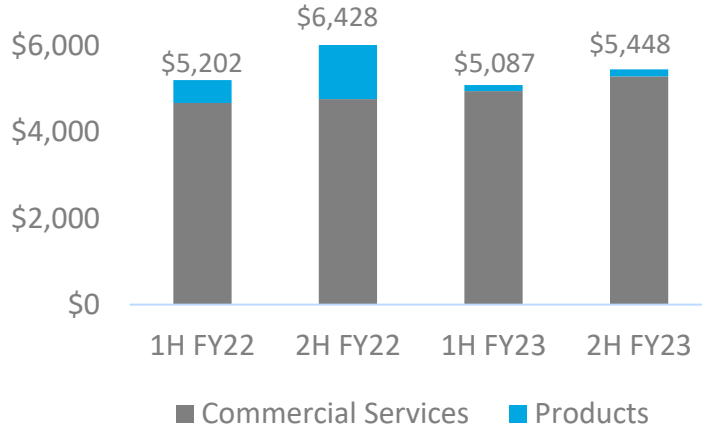
Sales & license payments  
from own & other products



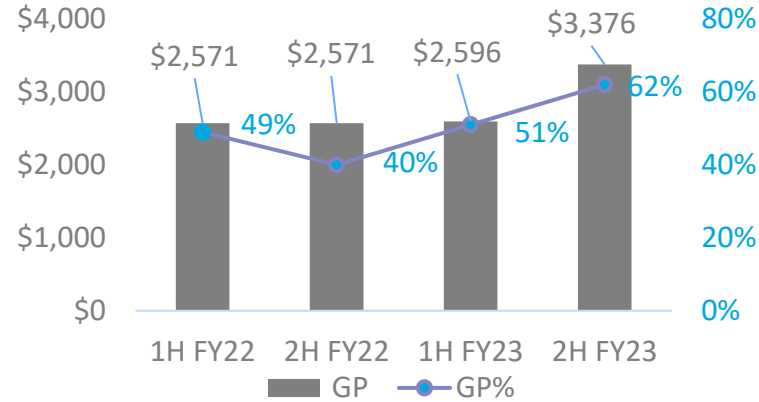
# Financials - summary

(US\$ in thousands)

## REVENUE



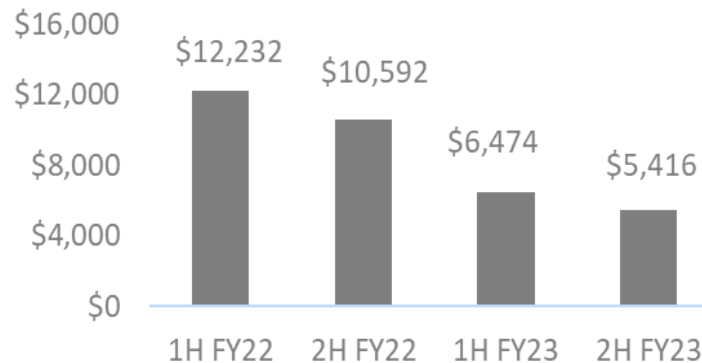
## GROSS PROFIT



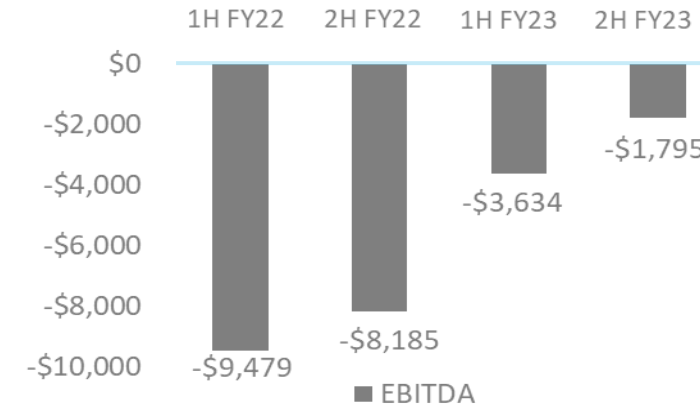
## COMMENTARY

- Q2 FY24 unaudited revenue of US\$1.7m, up 55% from Q1 of \$1.1m
- Implemented significant cost reduction initiatives over last 2 years
- Cash-burn in 1H FY24 at US\$0.9m per month, in line with previous guidance
- Cash at bank as at 31 Dec 23 of US\$1.4m
- Pro-forma cash including US\$5.0m received from recent Hologic IP Agreement is US\$6.4m
- Additional US\$5.0m Hologic IP payment committed by 30 June 24
- Up to US\$4.7m in milestone payments over next 18-24 months, under Hologic Development Agreement

## OPERATING EXPENSES<sup>1</sup>



## EBITDA<sup>2</sup>



<sup>1</sup> Operating Expenses prior to impairments & non-recurring costs. <sup>2</sup> Underlying EBITDA loss before impairments & non-recurring costs..

# Product Update



# FebriDx: Lumos' launches first-of-its-kind POC test



## FebriDx offers an aid for healthcare providers to improve patient care and antibiotic stewardship

- Antibiotics often prescribed for respiratory infections unnecessarily (ie. patient had no bacterial infection)<sup>1</sup>
- Can result in adverse patient reactions and contribute to antimicrobial drug resistance

## FebriDx regulatory clearances and commercial activities

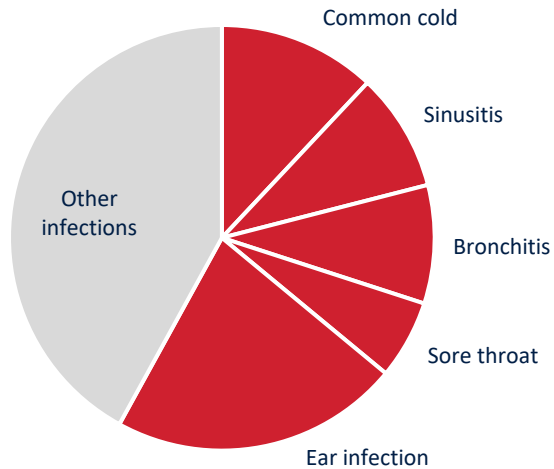
- 708-subject, multicentre clinical trial published in JAMA in 2022 — 98.7% NPV for bacterial infections
- FebriDx cleared in other markets including Europe, UK, Australia and other markets
- Clearance to market FebriDx in the US awarded in July 2023
- Selling and partnering opportunities for FebriDx in cleared markets
- Henry Schein now distributing FebriDx in UK, Spain, Portugal and the Netherlands



<sup>1</sup> Tse, J.; Near, A.M. et al; Antibiotics 2022, 11, 1058. <https://doi.org/10.3390/antibiotics11081058>

# FebriDx addresses a major need: antibiotic overprescription

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



Acute respiratory infections may account for **58%** of all antibiotics prescribed <sup>4</sup>

## ANTIBIOTICS PRESCRIBED



Acute respiratory infections may account for **58%** of all antibiotics prescribed <sup>4</sup>

**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>

## HOW WE'RE DRIVING MARKET ADOPTION

### Marketing and education

- Microbial testing prior to prescribing antibiotics not currently routine
- Assembling Medical Advisory Board of Urgent Care experts
- Program of communication through social media and KOLs

### Program of activities includes:

- Sales calls
- Distributor training
- Email campaigns
- Tradeshows
- Digital advertising
- PR
- Strategic partnerships
- Product education
- End user onboarding

<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 - commenced US product sales

## Commenced marketing activities to initial key customers

- Agreements with 14 customers/distributors
- Additional discussions with urgent care and relevant physician offices through Lumos' US sales channel
- Identified CPT codes (USD \$29.55) that are expected to provide reimbursement coverage for FebriDx
- Pathway established with FDA to pursue CLIA waiver for FebriDx
- Commenced commercial production of FebriDx to meet anticipated demand
- Inbound interest from potential customers at physicians' offices and urgent care clinics
- Commenced shipping and selling product in the US



# ViraDx™ – Lumos' POC test for key respiratory infections

## ViraDx highly relevant POC test for post-pandemic environment:

- SARS-CoV-2 pandemic increased consumer and healthcare POC testing
- ViraDx is a 3-in-1 test for COVID-19/flu A/flu B
- One of two tests available in market that provides visual read-out

## ViraDx regulatory and commercial update:

- US EUA authorisation awarded in September 2023 – includes CLIA waiver
- Additional studies will be required to transition for EUA to 510(k) clearance
- Scale-up of production of ViraDx has commenced
- Initial sales through Lumo's US sales channel
- Agreements with 16 customers/distributors
- First orders received and shipped



# Services Update

A horizontal bar composed of several colored segments: yellow, light blue, dark blue, purple, red, and orange.



# Strategic partnerships are a key pillar of Lumos' growth plan

## Lumos provides a compelling service offering for leading diagnostics companies

- **Fully-integrated offering**—from concept-to-clinic-to-commercial production
- **Proprietary reader platform**—integrate POC testing with electronic medical records
- **Track record**—successful delivery of products to recognised industry leaders

## Strategic partnerships will underpin long-term and durable revenue growth for Lumos

- **Multiple projects**—reduced transaction costs with repeat business
- **Project extensions**—as products migrate through stages of the development process
- **New projects**—creating and developing new products for strategic partners
- **Next gen products**—extending commercial life of partner's products as market evolves
- **Manufacturing**—ongoing revenue stream from commercial-stage products



# Hologic - strategic partnership



## Hologic is a recognized global leader in women's health based in Massachusetts, US

- NASDAQ: HOLX, Market Capitalization ~US\$18 billion
- FY2023 revenue of US\$4.0 billion with net income of US\$0.5 billion
- Diagnostic products account for ~50% of Hologic's revenue

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

- Multiple services contracts signed during FY2023
- Existing, marketed product
- US\$4.2 million in non-dilutive funding through sale and leaseback agreement



# Hologic - new major development and IP agreements\*

Focus on improving one of Hologic's leading on-market women's health products and adapting it for use on Lumos' proprietary reader platform.



## Collaboration

Builds on work jointly conducted over last 12+ months



## Fetal fibronectin

Focus on the development of next generation point of care technologies and intellectual property rights for custom reader



## IP agreement payments

Valued at US\$10M in two equal non-refundable payments by June 2024



## Development agreement payments

Valued at up to US\$4.7M in payments over an 18-24 month period upon achieving milestones

These new contracts strengthen Lumos' balance sheet and provide a pipeline of revenue generating partnerships in POC diagnostics.

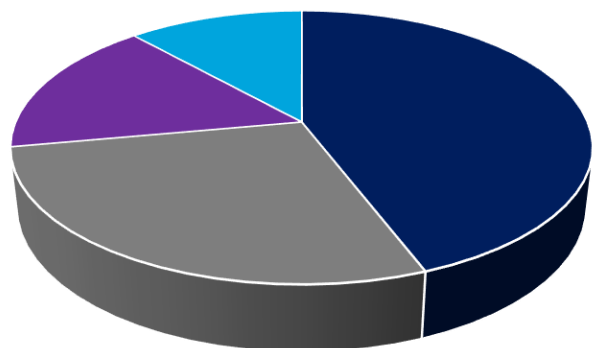
\* ASX announcements from 11 and 16 January 2024 provide additional information.

# Fetal Fibronectin (fFN) background

A biomarker indicating a heightened risk of pre-term delivery when present in cervicovaginal secretions

fFN is the largest segment in the pre-term diagnostic test kit market

Sales (US\$420m pa)\*



■ fFN ■ PAMG-1 ■ IGFBP-1 ■ Other

Note: \*gm insights.com

- **Background**

- fFN is protein found at the maternal-fetal interface. As delivery approaches, fFN is increasingly detectable
- Detection of fFN (in pregnancy weeks 22 – 35) can indicate that a woman is at higher risk of preterm delivery
- Positive fFN result indicates an increased risk of delivery in the next 14 days

- **Metrics**

- US annual pre-term birth TAM: Approx. 2.5m tests
- US reimbursement rate fFN, CPT Code 82731: USD\$64.41/test

# Hologic - fFN product development overview

Current test: Rapid fFN TLIQ



Next generation test concept (mock-up)



## Benefits of the new technology

- Latest state-of-the-art technology, with reader platform
- Connectivity for improved digital patient record management
- Developed and manufactured to latest GMP quality standards

# Hologic – the opportunity ahead



**Verification and validation**



**Clinical study**



**Manufacturing**



**Second test development and IP**



Looking ahead



# Key strategic priorities



Drive FebriDx and ViraDx sales in US market through expanded sales channels



Expand current partnerships and establish new strategic agreements



Hologic – deliver on development milestones over next 18-24 months



Improve operating cash flow through revenue growth and ongoing cost management





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DIAGNOSTICS

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