



Lumos Diagnostics Holdings Limited



Equity Capital Raise Presentation

4 September 2024

The consolidated entity's presentation currency is US Dollars.

Financial information is shown in USD unless otherwise stated.

Entitlement Offer and Share Price information is shown in AUD, as the parent entity is an Australian entity listed on the Australian Stock Exchange.

Where conversions are shown, an FX rate of 1 AUD : 0.67 USD is used.

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You acknowledge and agree that determination of eligibility of investors for the purposes of the Offer is determined by reference to a number of matters, including legal and regulatory requirements, logistical and registry constraints and the discretion of the Company and the Lead Managers and each of the Company and the Lead Managers (and their respective related bodies corporate, affiliates, officers, directors, employees, agents and advisers) disclaim any duty or liability (including for negligence) in respect of the exercise or otherwise of that discretion, to the maximum extent permitted by law. For the avoidance of doubt, the Offer is partially underwritten.

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- Pro-Forma Balance Sheet
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Executive Summary



Raising ~A\$10m via Entitlement Offer to fully fund FebriDx CLIA waiver trial anticipated to read out in the middle of 2025. A successful trial and submission in Aug/Sep 2025 would likely expand the market for FebriDx in the US by more than 15x.

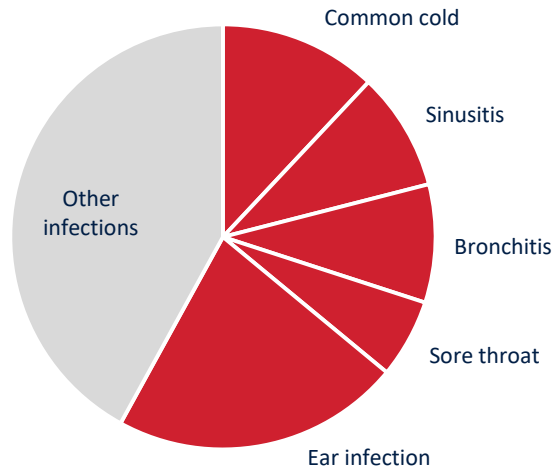
Significant operational progress achieved in the last 12 months	<ul style="list-style-type: none"> • FY24 revenue of US\$11.1 million, up 6% over the prior year • Positive net operating cash flow for FY24 of US\$0.9 million • Closing cash as at 30 June 2024 of US\$6.5 million • FY24 adjusted EBITDA loss was US\$3.9 million, an improvement of US\$1.5 million, 28%, over prior year
Significant momentum made in commercial services business	<ul style="list-style-type: none"> • FY24 revenue of US\$9.9 million for Services • Strategic partnership with Hologic strengthened further with new transformative development and IP agreements for their on market fFN test to the total value of US\$14.7 million • Pipeline of other commercial services projects in health, veterinary, food safety and molecular diagnostics
US regulatory clearance awarded for FebiDx® and ViraDx	<ul style="list-style-type: none"> • FY24 revenue of US\$1.2 million for Products, up 289% over the prior year • FebriDx is a point-of-care test to aid to the diagnosis of acute bacterial respiratory infections • FebriDx cleared in the US in July 2023, and commercialization commenced in January 2024 • The US is the largest market opportunity for FebriDx with 211 million antibiotics prescriptions p.a., with 58% related to ARI • ViraDx, a point-of-care test for COVID/Flu A/B EUA in the US in September 2023, with sales commencing in December
Capital raising, Tenmile investment, and underwritten retail Entitlement Offer	<ul style="list-style-type: none"> • 1 for 1.82 Accelerated Non-Renounceable Entitlement Offer to raise approximately A\$10.0 million at A\$0.038 per share. • The retail entitlement offer will be underwritten up to approximately A\$6.0 million. Including entitlement offer and sub-underwriting commitments from key institutional shareholders, Tenmile Ventures and Ryder Capital for up to approximately A\$7.5 million • On 3 September 2024, Tenmile Ventures Pty Ltd, the healthcare investment arm of Tattarang, purchased 45.0 million shares to become a 9.3% shareholder of Lumos. It is anticipated that following completion of the entitlement offer, Tenmile will be the largest shareholder of Lumos. • Funds raised under the Entitlement Offer are intended to be used to (amongst other things) complete the FebriDx CLIA waiver trial in the US, where a successful FDA clearance in 2024/25 significantly expands the market for FebriDx sales in the US • Funds also to be used for product development, sales & marketing activities and provide general working capital

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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 ⁴

ANTIBIOTICS PRESCRIBED



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

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

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

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

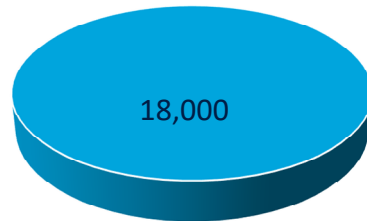
⁴ Centers for Disease Control and Prevention. MMWR, 2011, 60:1153-6

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FebriDx Market Opportunity in the US > \$1Billion

MODERATE COMPLEXITY LIMITATION

Potential Customer Sites

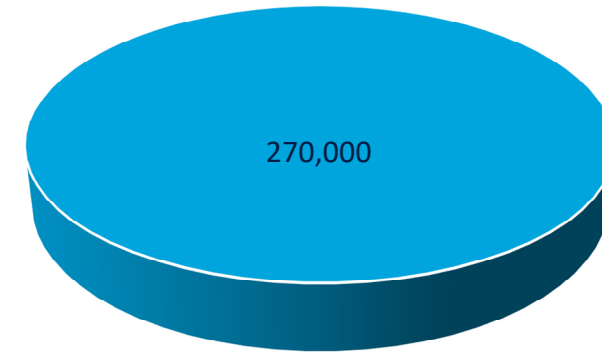


■ Moderate Complex

- 18,000² potential customer sites in US
- Acute Respiratory Infections (ARI) in US Annually: 80 million (potential FebriDx patient opportunities for use)¹
- Moderate complex settings ~7% (5.6 million patient interactions)
- Assume distributor sell price to end customers of US\$21.00 (CPT codes for reimbursement is US\$29.55)
- TAM US\$118 million p.a.

CLIA WAIVER EXPANDS ADDRESSABLE MARKET

Potential Customer Sites



■ CLIA Waived

- 270,000² potential customer sites in US
- Acute Respiratory Infections (ARI) in US Annually: 80 million (potential FebriDx patient opportunities for use)¹
- CLIA waiver enables 100% market coverage (80 million patient interactions)
- Assume distributor sell price to end customers of US\$21.00 (CPT codes for reimbursement is US\$29.55)
- TAM US\$1.7 billion p.a.



¹ Source from 2024 Precision Business Insights Report for periods 2026-2030.

² Division of Clinical Laboratory Improvement and Quality Centers for Medicare & Medicaid Services, March 2024 (CMS CLIA Data base)

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FebriDx CLIA Waiver Study



What is the study for...what is CLIA?

- The Clinical Laboratory Improvement Amendment (CLIA) waiver study will 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.
- A CLIA waiver certificate enables facilities (e.g., physician offices, stand alone urgent care centers) to perform diagnostics without laboratory oversight.

Why?

- A successful study will enable Lumos to market FebriDx to waived settings which expands the TAM 15X and to over \$1Billion.

How?

- A method comparison study will be conducted comparing the performance of untrained operators to trained operators in a multi-center study across the US, consisting of physician offices (majority) and standalone urgent care clinics who will enroll around 500-900 patients.

When?

- The study may start in Sept/Oct of 2024 and the submission is planned for May/June 2025. Based on FDA review times, the waived status designation may be expected by Sept/Oct 2025¹.

Risks?

- Success Criteria: FDA criteria for obtaining CLIA waiver is very high (small number of errors).
- Timeline: low prevalence of bacterial infection in the respiratory season could result in the need to sign on additional sites to enroll or could lead to a longer than expected enrollment timeline.

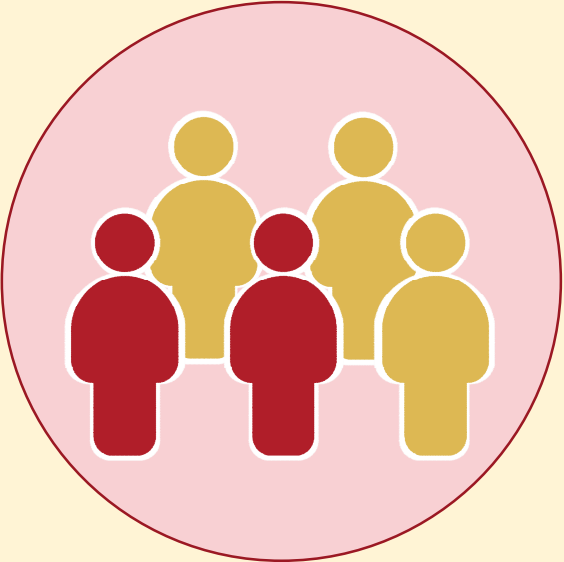
¹These timelines are indicative only and subject to change without notice.

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

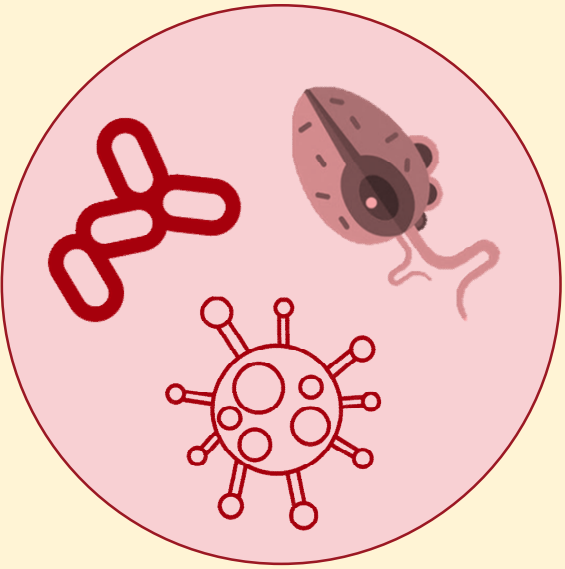


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PREVALENCE

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



CLINICAL NEED

Multiple infectious organisms
Similar symptoms
Different treatments



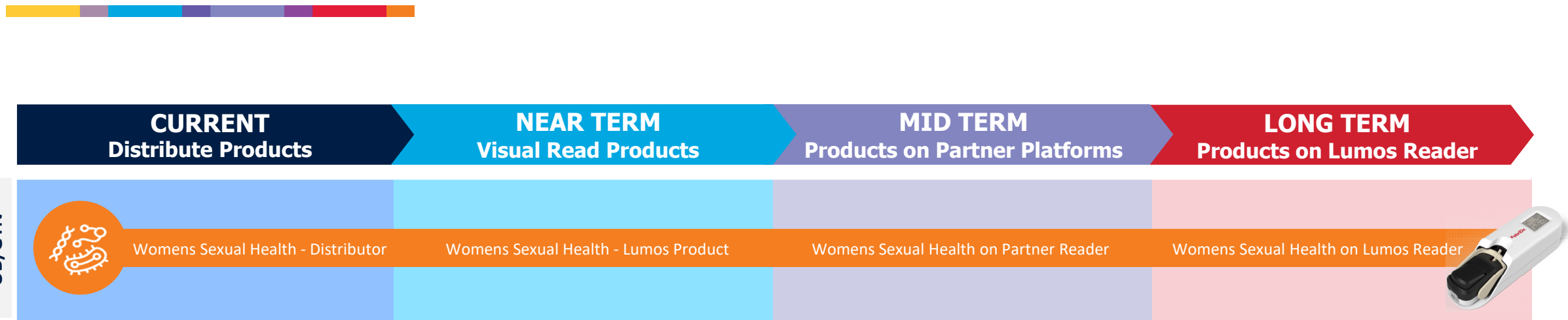
POC DIAGNOSTIC NEED

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

Women's Sexual Health Products – Product “One*” Program



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 HOSPITAL &
 DECENTRAL
 OB/GYN
 Product “One”
 Timeline*



Year 1		Year 2		Year 3	
Feasibility	Development	Verification			
	Obtain clinical samples	Pilot study	Clinical trial	FDA review	

*Not actual product name.

Visual read product.

Priority Catalysts for Growth

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There is little doubt in my mind that point-of-care diagnostic tests are going to become an ever-increasing part of our lives.

With its unique capabilities, technology and products, Lumos has an important and valuable role to play in that future. I look forward to making that happen.

Doug Ward
MD & Chief Executive Officer
Lumos Diagnostics



Monetize the Lumos 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.

Capital Raising



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Capital Raising Details



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Entitlement Offer	<ul style="list-style-type: none"> • A 1 for 1.82 pro-rata accelerated non-renounceable entitlement offer to eligible shareholders of LDX to raise approximately A\$10.0 million ('Entitlement Offer'), comprising; <ul style="list-style-type: none"> • An Institutional Entitlement Offer anticipated to raise approximately A\$4.0 million; Firm commitments from Tenmile and Ryder received to take up A\$1.5 million • A Retail Entitlement Offer anticipated to raise approximately A\$6.0 million. The Retail Entitlement Offer is underwritten up to A\$6.0 million • The Entitlement Offer is non-renounceable & entitlements will not be tradeable or otherwise transferable • Approximately 264.5 million new fully paid ordinary shares in LDX (New Shares) to be issued under the Offer, representing approximately 54.9% of existing ordinary shares on issue in LDX
Offer Price	<ul style="list-style-type: none"> • New Shares issued under the Offer will be issued at a price of A\$0.038 (3.8 cents) per new share ("Offer Price"), representing a: <ul style="list-style-type: none"> – 17.4% discount to the last close price on 3 September 2024 of A\$0.046 – 12.0% discount to 5 trading day VWAP up to and including 3 September 2024 of A\$0.0432
Institutional Offer	<ul style="list-style-type: none"> • The institutional component of the Entitlement Offer will be conducted on Wednesday, 4 September 2024 and Thursday, 5 September • Entitlements not taken up and those of shareholders who are ineligible to participate in the Institutional Entitlement Offer will be sold at the Offer Price
Retail Entitlement Offer	<ul style="list-style-type: none"> • The retail component of the Entitlement Offer will open on Wednesday, 11 September 2024 and will close at 5.00pm on Wednesday, 2 October 2024 (Retail Entitlement Offer) • Only eligible shareholders of LDX with an address on the LDX share register in Australia may participate in the Retail Entitlement Offer. Under a Top-Up Offer, Eligible shareholders who take up all of their entitlement will be able to apply for additional New Shares up to 100% in excess of their entitlement.
Record Date	<ul style="list-style-type: none"> • 7:00pm (Sydney, Australia time) on Friday, 6 September 2024
Use of Funds	<ul style="list-style-type: none"> • Funds raised under the Offer are intended to be used to complete the FebriDx CLIA waiver trial in the US, product development, sales & marketing activities and provide general working capital (and costs of the offer).
Ranking	<ul style="list-style-type: none"> • The New Shares issued under the Offer will rank equally with existing LDX shares on issue on the relevant issue date
Lead Manager & Underwriter	<ul style="list-style-type: none"> • Bell Potter Securities Limited
Sub-underwriters	<ul style="list-style-type: none"> • Tenmile Ventures and Ryder Capital ("Sub-underwriters") will be acting as sub-underwriters to the retail entitlement offer for up to approximately A\$6.0 million and taking up their full entitlement of A\$1.5 million, approximately A\$7.5 million in aggregate • The sub-underwriters will receive a sub-underwriting fee of approximately 31.1 million unlisted options each, with an exercise price of A\$0.07 and expiry date of around 30 September 2026, and a 1% cash fee payable on approx. A\$1.3 million of the sub-underwriting. The options will be issued under the Company's existing Placement capacity under ASX Listing Rule 7.1. Each of the Sub-underwriters will also have the right (but not the obligation) to appoint a director to the Company's board for so long as they hold at least 10% of the voting shares in the Company.

Expected Use of funds



The funds raised under the Entitlement Offer provides balance sheet flexibility and drive strategic and targeted growth initiatives.

- Lumos expects to have pro-forma net cash as at 30 June 2024 of approximately US\$13.2 million¹—post completion of the Entitlement Offer to raise approximately A\$10.0 million (US\$6.7 million¹)
- The proceeds from the capital raise will be used to:
 - progress the FebriDx CLIA waiver trail to enable an extension to the existing label;
 - Initiate the development of additional proprietary products for sale by Lumos or licensing to strategic partners
 - Provide sales & marketing funds to progress the commercial launch of these products in the relevant jurisdictions;
 - support the development of Lumos' contract development and manufacturing business; and
 - Working capital purposes (and costs of the offer).

Sources of funds ¹	(US\$ million)
Proceeds of Entitlement Offer	6.7
Cash at bank (as at 30 June 2024)	6.5
Total Sources	13.2

Expected Uses of funds ¹	(US\$ million)
FebriDx CLIA Waiver Trial	3.5
Sales and Marketing	1.8
Product Development of Diagnostics Tests	4.2
Working Capital	3.3
Offer Costs	0.4
Total Uses	13.2

¹ Assumes AUD / USD exchange rate of 0.67. Note: The above represents a statement of the Company's current intentions as at the date of this Presentation. Investors should note that this may change depending on a number of factors, including the changes in the competitive environment, business performance, strategic and operational considerations, regulatory developments, and market and general economic conditions.

Timetable

Event¹	Sydney, Australia time
Trading Halt	Wednesday, 4 September 2024
Announcement of the Offer	Wednesday, 4 September 2024
Institutional Entitlement Offer Opens	Wednesday, 4 September 2024
Announcement of results of Institutional Entitlement Offer and trading halt lifted	Friday, 6 September 2024
Record Date for Entitlement Offer	7:00pm Friday, 6 September 2024
Settlement of Institutional Entitlement Offer	Wednesday, 11 September 2024
Retail Entitlement Offer opens and Retail Offer Booklet despatched	Wednesday, 11 September 2024
Issue of New Shares under the Institutional Entitlement Offer	Thursday, 12 September 2024
Retail Entitlement Offer closes	Wednesday, 2 October 2024
Results of the Retail Entitlement Offer announced	Tuesday, 8 October 2024
Settlement of Retail Entitlement Offer	Tuesday, 8 October 2024
Allotment of Retail Entitlement Offer Securities	Wednesday, 9 October 2024
Commencement of trading of New Shares issued under the Retail Entitlement Offer	Thursday, 10 October 2024

¹ The above timetable is indicative only and subject to change. Subject to the requirements of the Corporations Act, the ASX Listing Rules and any other applicable laws, Lumos in consultation with the Lead Manager, reserves the right to amend this timetable and withdraw the offer at any time.

Company Overview

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

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Company Overview

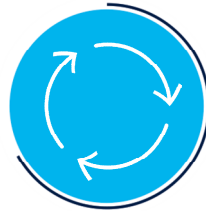


Lumos is a developer and manufacturer of connected instrumentation and rapid point-of-care tests for the diagnostics and healthcare industries



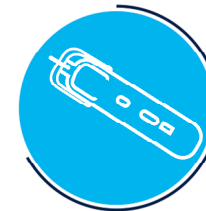
Experienced leadership team

- Led by Doug Ward (CEO/MD) - 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



Commercialised proprietary point-of-care diagnostic products

- FebriDx US – aid in the diagnosis of bacterial v non-bacterial etiology for acute respiratory infection
- FebriDx International – aid in the diagnostics of bacterial v viral acute respiratory infection
- ViraDx – test for key respiratory infections (COVID/Flu A/B)



Distribution

- Lumos has distribution rights for the sale of women's health and sexual health products in the US



Transformational Hologic agreements

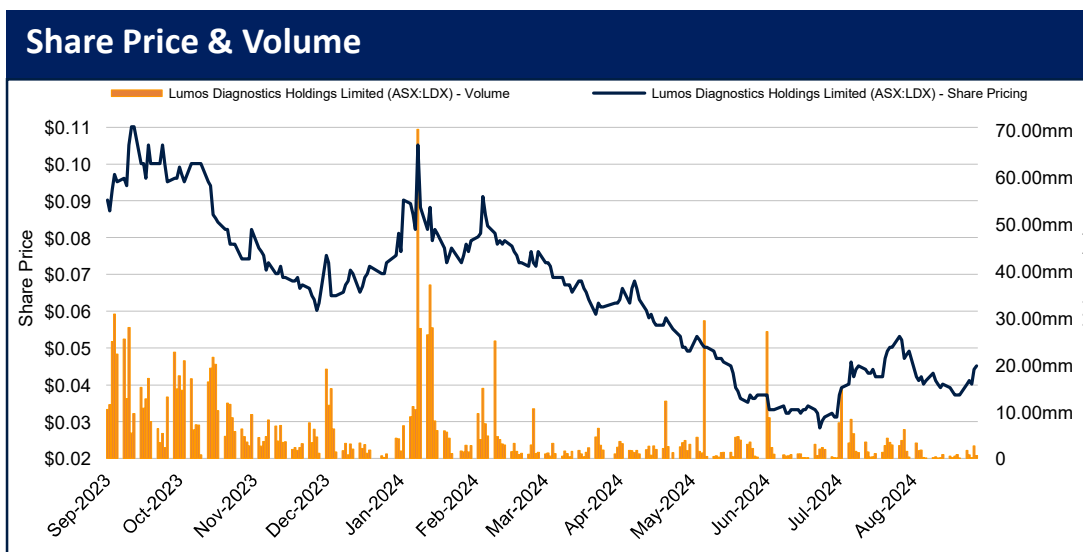
- Strategic relationship with US-based women's health leader Hologic – expanded in January 2024 with the signing of a Development Agreement for up to US\$4.7 million and IP Agreement for US\$10.0 million

Company Snapshot



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Issued Capital	
Shares	481.3m
Options	81.7m
Market Capitalization (AUD)	
Share price ¹	A\$0.046
Market value	A\$22.1m
Pro-forma Cash (30 June 2024 – in AUD) ²	A\$19.7m
Enterprise value	A\$41.8m
Substantial shareholders	
Perennial Value Management	14.6%
Tenmile Ventures	9.3%
Ryder Capital	5.3%



Board and Management

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

¹As at 3 September 2024

² Assumes a capital raising of A\$10.0 million, excluding offer costs. USD FX rate of 0.67 used.

Board of Directors



Sam Lanyon

Non-Executive
Chair



Bronwyn Le Grice

Non-Executive
Director



Lawrence Mehren

Non-Executive
Director



Catherine Robson

Non-Executive
Director



Doug Ward

Managing
Director & CEO

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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 25 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 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.



Sacha Dopheide, PhD
Chief Technology Officer

Sacha 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.

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Product Portfolio Approach



Be a leader in point-of-care testing for women's health and sexual health, offering a portfolio of assays for visual read out and on a suite of differentiated, automated and connected platforms.



Focus on verticals with existing markets / reimbursement / transition from Core Lab to point-of-care / and ability to secure channel access.



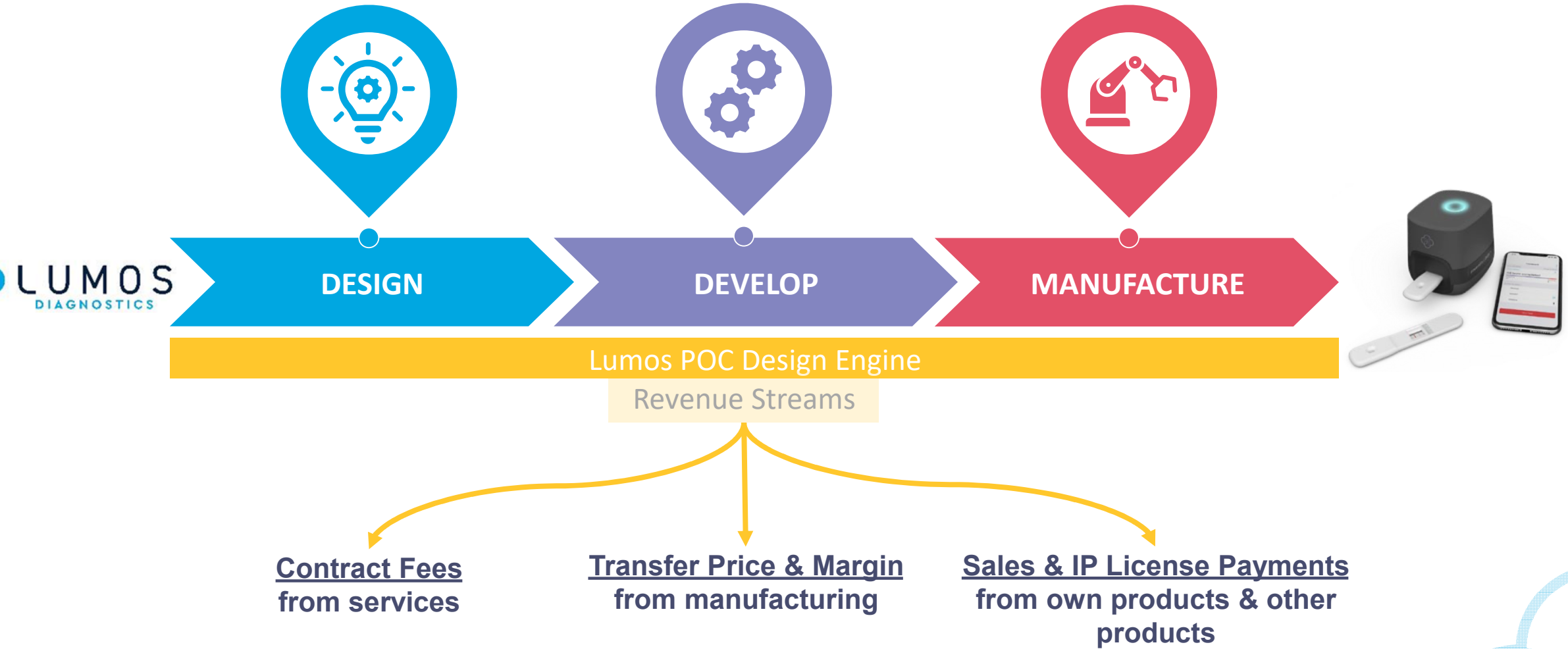
Leverage broad partnering strategy to secure content, share costs, and drive commercial success.

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Lumos Point-of-Care Diagnostic Test Development Engine



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FY24 Highlights



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Key Highlights from FY24



FebriDx & ViraDx achieve US FDA clearance 1H FY24

Commercialised and commenced early sales part way through US 2023-24 flu season



Hologic IP and Development Agreement

Non-refundable IP Agreement valued at US\$10.0 million and Development Agreement of US\$4.7 million. Phase 1 completed; Phase 2 underway



Expanded Henry Schein FebriDx distribution agreements

In FY24, Spain, Portugal, Netherlands & US. Post year-end expanded to Belgium, Australia/New Zealand



Revenue of US\$11.1 million

Up 6% compared to the prior year. Second half revenue up 196% on pcp



Positive net cash from operations of US\$0.9 million

Cash balance at year end - \$6.5 million



Repaid Convertible Notes in full

No debt on the balance sheet at 30 June 2024

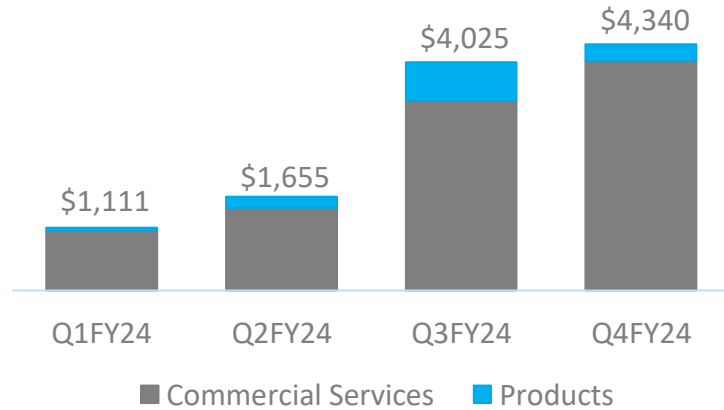
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Financials – Summary FY24 - Quarterly

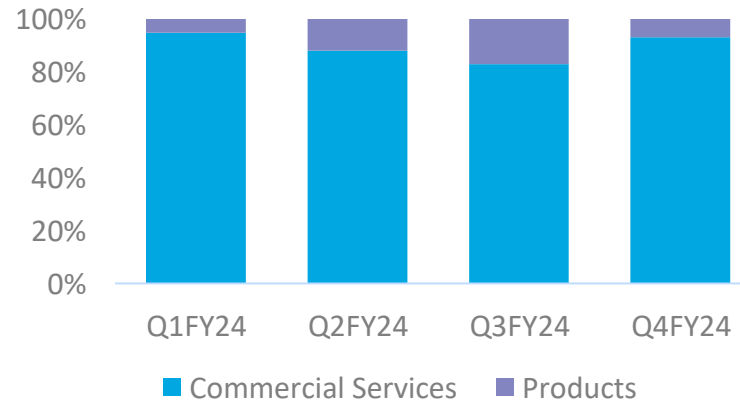


(US\$ in thousands)

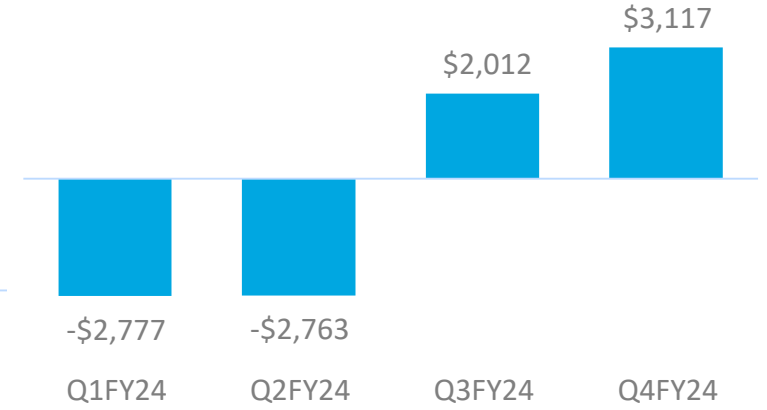
REVENUE (US\$'000)



REVENUE MIX



NET CASH GENERATION (US\$'000)*



COMMENTARY

- **Revenue** – FY24 revenue of US\$11.1 million, up 6% on prior year. Progressive quarterly growth across the year.
- **Services** revenue was US\$9.9 million in FY24, with a strong contribution from development services under the fFN Development Agreement and the intellectual property licensing revenue associated with the Hologic 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 launch of the products and also influenced by seasonal demand from ViraDx and FebriDx in the US.
- **Net cash generation** – final two quarters delivered positive net cash flows of US\$5.1 million combined
- **Cash balance** of US\$6.5 million at year end.

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

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Product Update



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FebriDx: First-of-its-Kind Point-of-Care 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)¹
- 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 the US², Europe, UK, Australia and other markets
- Clearance to market FebriDx in the US awarded in July 2023, as “moderate-complex” test
- Selling and partnering opportunities for FebriDx in cleared markets
- Henry Schein³ now appointed as distributor for FebriDx in UK, Spain, Portugal, Netherlands, Australia/NZ and Belgium



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

² ASX announcement 3 July 2023

³ Refer to various ASX announcements

FebriDx Update

- **Reimbursement amount: PLA code update¹**
 - Positive momentum - CMA Panel presentation in June was well received, final decision expected Sept 2024
- **Partnerships¹**
 - 25 FebriDx partnerships in FY24: regional distributors and end-user customers
 - Immediate impact witnessed in university student health market
- **FebriDx customer resources delivered**
 - Validation panels
 - Proficiency sample protocol (API)
- **Clinical trial outcome**
 - To extend the label in the US for FebriDx from the current moderately-complex to include CLIA waived settings would greatly expand market in the US



¹ASX announcement 1 August 2024

Henry Schein Distribution Agreements



- **FebriDx** is a rapid point-of-care respiratory test which delivers results after 10 minutes from a fingerstick blood sample.
- **Henry Schein** is the world's largest provider of health care solutions to office-based dental and medical practitioners.
- In February 2024¹, Lumos signed an agreement with Henry Schein, Inc. (Nasdaq: HSIC) to distribute FebriDx® in the United States.
 - Customer adoption has commenced and is ramping
- New Henry Schein distribution agreements were executed for Australia and New Zealand² on 4 July 2024, and an expansion agreement to sell into Belgium³ was enacted on 9 July 2024.
 - Ready to commence sales immediately into Australia/New Zealand for the current flu season.



¹ASX announcement 12 February 2024.

² ASX announcement 4 July 2024.

³ ASX announcement 9 July 2024.

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:

- **Distribution¹**
 - 19 ViraDx partnerships FY25
 - 3 new distribution agreements in Q4 FY24
- **Infection rates**
 - US summer: elevated acute respiratory infections (Covid)
 - Purchase orders have already provided a robust start to FY25
- **Stocking orders**
 - Full season v half season (due to timing of EUA) in FY24
 - Current partnerships can be leveraged
 - September/October timeframe for stocking orders



¹ASX announcement 1 August 2024

Services Update

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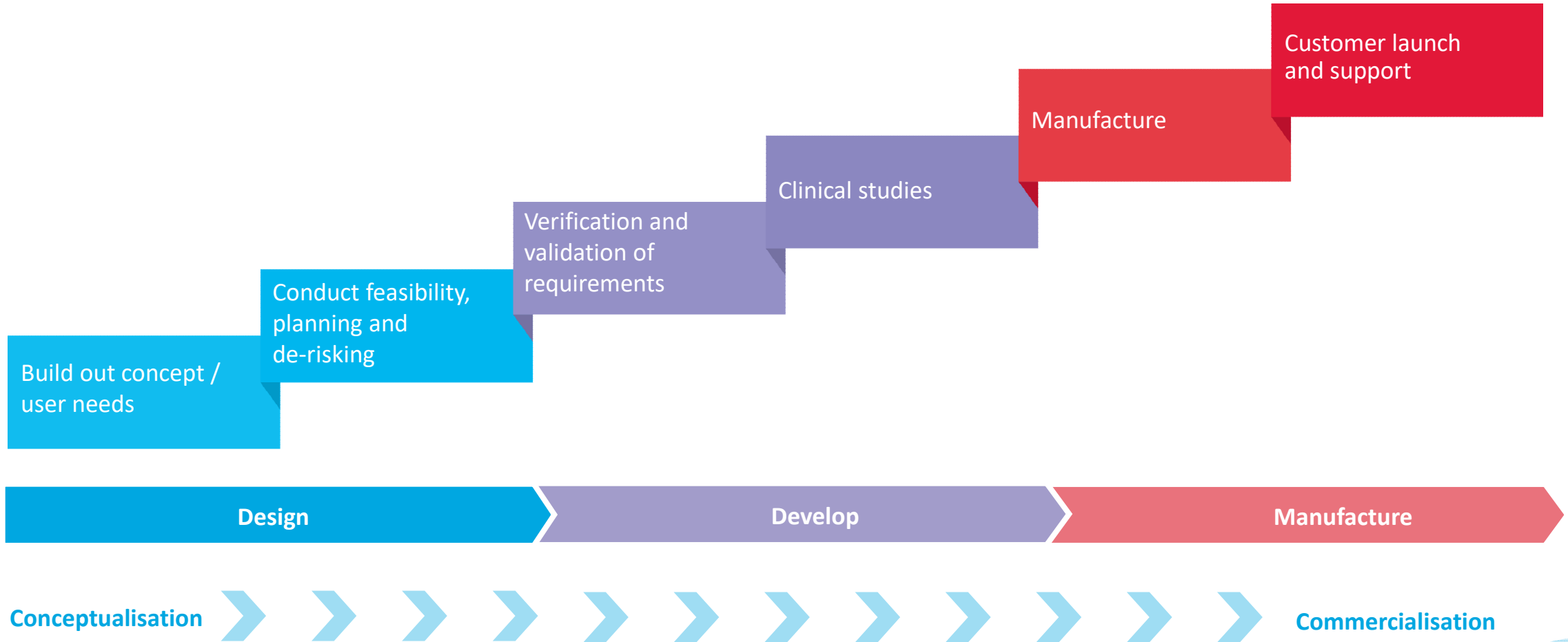
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How we add value to Partners

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

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Hologic - Strategic Partnership

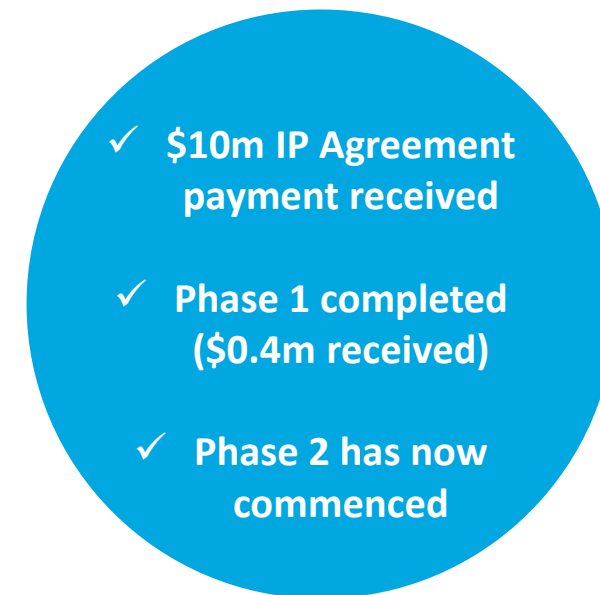


Hologic is a recognized global leader in women's health based in Massachusetts, US

- 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
- Two new agreements signed for the development of an improved version of one of Hologic's leading in-market women's health products, including adapting it for use on Lumos' proprietary reader platform¹
- 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 product¹
- **Development Agreement** valued at up to US\$4.7M in payments over an 18-24 month period, dependent on the achievement of specified milestones, outlined below¹:
 - **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 – in progress; and
 - **Phase 3: System Prototype Delivery** – deliver a working prototype of the system - US\$3.7 million – not commenced

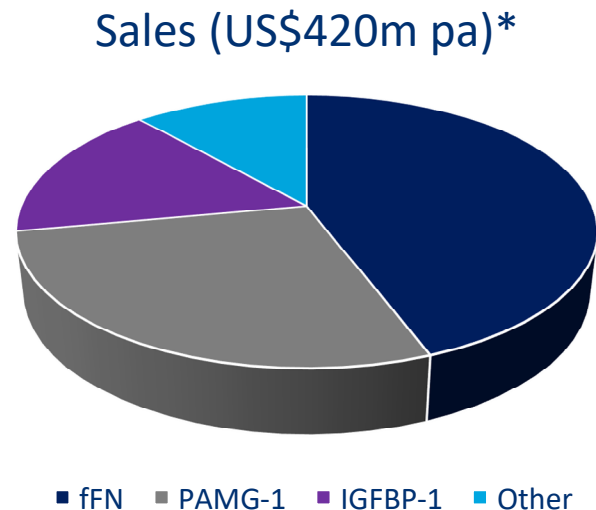


¹ASX announcements 11 January 2024, 15 January 2024, 16 January 2024, 6 May 2024, 4 June 2024, 19 June 2024

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



Note: *Global Market Insights,
www.gminsights.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: US\$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

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Verification and validation



Clinical study



Manufacturing



Second test development and IP



Other Items

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Summary Pro-Forma Balance Sheet

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Summary Pro-forma Balance Sheet

US\$ million	30-Jun-24 (Audited) ³ (US\$ million)	Impact of equity raising ^{1,2} (US\$ million)	30-Jun-24 Pro-forma (US\$ million)
Cash and cash equivalents	6.5	6.3	12.8
Other current assets	3.0		3.0
Total Current Assets	9.5	6.3	15.8
Total Non-Current Assets	17.3		17.3
Total Assets	26.8	6.3	33.1
Total Current Liabilities	12.6		12.6
Total Non-Current Liabilities	7.1		7.1
Total Liabilities	19.7		19.7
Equity	7.1	6.3	13.4

¹ Assumes AUD / USD exchange rate of 0.67.

² Illustrates impact of Entitlement Offer to raise approximately A\$10.0m (US\$6.7 million), after costs.

³ Refer to the Appendix 4E and Annual Report for FY2024.

Key Risks

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Key risks



This section discloses some of the key risks attaching to an investment in Lumos. The Company is subject to risks that are specific to the Company and the Company's business activities, as well as general risks. Before investing or increasing your investment in Lumos, you should consider whether this investment is suitable for you having regard to publicly available information and your personal circumstances and following consultation with your professional advisors. The risks in this section are not and should not be considered to be or relied on as, an exhaustive list of the risks relevant to an investment in Lumos. The risks are general in nature and regard has not been had to the investment objectives, financial situation, tax position or particular needs of any investor.

Regulatory Approvals and Responsibilities

For each country in which Lumos wishes to distribute its Products, Lumos may be required to obtain manufacturing permissions, product clearances or approvals prior to marketing the product and is required to maintain an up to date product registration with appropriate governmental authorities and regulatory bodies, for example, by the FDA in the United States.

Unsuccessful applications for or the revocation of these approvals, accreditations, registrations or listings (or a failure to obtain additional required clearances of this nature) would likely materially impact Lumos' ability to fulfil its contracts and produce or distribute its own products or services, which would have a negative impact on Lumos' financial performance, position and prospects.

Underwriting risk

The Company has entered into an underwriting agreement with the Lead Manager who have agreed to underwrite the Retail Entitlement Offer up to approximately A\$6.0 million, subject to certain terms and conditions. If certain conditions are not satisfied or certain events occur, the Lead Manager may terminate the Underwriting Agreement. There is a risk that the Underwriting Agreement may terminate before the Retail Entitlement Offer has settled. If the Underwriting Agreement is terminated and the Retail Entitlement Offer does not proceed or does not raise the funds required for the Company to meet its stated objectives, the Company would be required to find alternative financing to meet its objectives. In those circumstances, there is no guarantee that alternative funding could be sourced in the quantum and at the price sought.

Successful commercialisation

Lumos' operating and financial performance is dependent on its ability to develop and successfully commercialise its product portfolio. Lumos will need to manage and optimally develop its business model and global presence to support the commercialisation of its existing and future product portfolio. Should Lumos not be materially successful in one or more of these areas, there is risk of a loss of commercial opportunities essential for the achievement of the long-term strategy which may lead to the inability to realise, or the inability to retain, value.

Competition

Lumos operates in a competitive market against a number of other diagnostic technology companies, with the market being further disrupted by new technologies and products. Many of Lumos' existing competitors have significantly more resources and greater market access than Lumos. These competitors may use aggressive marketing campaigns, new product formats, product improvements, acquisitions or price discounting to secure market share which could impact on Lumos' revenue and margins.

Lumos' competitors or new market entrants may develop or market devices and products that are more effective than Lumos' products and new therapies or diagnostic devices could be developed that replace or reduce the need for Lumos' products. Lumos may also fail to anticipate or adequately respond to changing opportunities, technology, or standards, or more broadly to customer requirements, as quickly as Lumos' competitors.

Lumos' commercial success is dependent on the continued advancement of existing products and the generation and acceptance of new products that utilise Lumos' technology through its investment in research and development. Developing new products is expensive and often involves an extended period of time to achieve a return on investment, if a return is achieved at all.

Key risks cont.



Reliance on Distributors

The success of Lumos' Products business relies on its ability to attract, retain, support and motivate distributors. The loss of, or any significant decrease in business from these distributors may negatively impact Lumos' financial performance.

If product distributors or end customers do not continue to purchase Lumos' products, terminate the existing contracts or do not increase their usage over time, the growth in Lumos' revenue may slow or decline, which will have an adverse impact on Lumos' operating and financial performance.

Reliance on suppliers

Lumos is reliant on some third-party suppliers for the development and manufacture of outsourced commercial services customer products and the manufacture of some components within Lumos' own product portfolio, including some specific single source parts. Many of these suppliers are located outside of the United States, whilst the raw materials Lumos requires may be in high demand globally. A number of single source parts may be difficult to replace with alternative parts and may require significant development, time and effort to remediate. Any disruption to third party businesses or supply chains or in the supply of single source parts that Lumos relies on for its development and manufacturing activities could have a material impact on the availability of Lumos' products for distribution.

Early termination of customer contracts

A number of Lumos' direct contracts with Commercial Services clients allow for termination based on a specified notice period. While Lumos has established relationships with many of these clients, should a customer decide to terminate its contract with Lumos for convenience (i.e., by providing the requisite prior notice), Lumos may suffer a loss of the customer revenue associated with that contract, and would need to sign up additional clients to replace that revenue.

Reliance on key personnel

Lumos relies heavily on the existing senior leadership team who have intimate knowledge of the business and its products. If a member of Lumos' senior leadership team were to resign or leave the business there is no certainty that Lumos could attract a suitable replacement, or how long it may take to do so.

Lumos' internal policies governing recruitment, succession planning and incentive programs to assist recruitment and staff retention may not be sufficient to retain key personnel or to attract new personnel in a timely manner. Lumos has included non-competition and non-solicitation clauses in certain employee's contracts where the applicable jurisdictions permit such restrictive covenants, however these may not always be enforceable, and the movement of any key personnel to a competitor may negatively impact Lumos' competitive advantage.

Intellectual Property

The value of Lumos' own Products depends in part on its success in obtaining and maintaining issued patents, trademarks and other intellectual property rights and protecting Lumos' proprietary technology. If Lumos' intellectual property and proprietary technology are not adequately protected, competitors may be able to use the technologies and replicate Lumos' Products or Commercial Services offering and consequently erode or negate any competitive advantage Lumos may have, which could harm Lumos' commercial position and viability.

The issue of a patent is not conclusive as to its validity or its enforceability and it may not provide Lumos with adequate proprietary protection or competitive advantages against competitors with similar products. The granting of a patent does not guarantee that competitors will not develop competing intellectual property that misappropriates, circumvents or works around the patent. Lumos' competitors may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with Lumos' ability to make, use and sell its products.

Key risks cont.



Reimbursement and coverage

Third-party payers, whether U.S. or non-U.S., or governmental or commercial, are developing increasingly sophisticated methods of controlling rising healthcare costs. These include, evaluating the cost-effectiveness and economic impact of using different procedures, products and services when making coverage and payment decisions. Payers continually review new and existing technologies and can, without notice, deny or reverse coverage or alter pre-authorisation requirements for new or existing procedures, products or services

The significant adoption of tests (including those offered by Lumos) requires either government payment or third-party reimbursement payments including governmental payers (such as the Medicare and Medicaid programs in the U.S.), managed care organisations and private health insurers, particularly for example in the U.S. and some countries in Europe. In other countries with national health services, a material cost saving may be required in order for the tests to be readily adopted.

Sufficiency of funding

Lumos' financial resources are limited and Lumos may be required to raise additional funds from time to time to finance the development of its Products and Commercial Services businesses. The ability to raise additional funding is subject to factors beyond Lumos' control and Lumos can give no assurance that it will be able to secure future funding on favourable terms, or at all.

Currency movements may be unfavourable

Lumos currently conducts the majority of its business in the United States with a majority of revenue and costs denominated in USD, with capital raisings being made predominantly in Australia in AUD. As such, unfavourable movements in the exchange rate between the Australian dollar and the U.S. dollar, or other foreign currencies in which Lumos conducts business, may cause Lumos to incur foreign currency losses.

IT system failure and cyber security risks

Any information technology system is potentially vulnerable to interruption and/or damage from a number of sources, including but not limited to computer viruses, cyber security attacks and other security breaches, power, systems, internet and data network failures, and natural disasters.

Litigation risk

In the ordinary course of its business, Lumos may be subject to the risk of litigation and other disputes with its clients, employees, consultants, lessors, regulators and other third parties. Proceedings may result in high legal costs, adverse monetary judgements and/or damage to Lumos' reputation, which ultimately is likely to have an adverse effect on Lumos' financial performance.

Appendix – Underwriting Agreement

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Underwriting Key Terms



The Company has entered into an underwriting agreement (**Underwriting Agreement**) with Bell Potter Securities Limited (**Lead Manager**) who has agreed to act as lead manager and bookrunner to the Offer and underwriter to the Retail Entitlement Offer up to a maximum aggregate amount of A\$6.0 million. The Company is required to pay the Lead Manager the following fees for the performance of their services under the Underwriting Agreement: a management and selling fee of 6.0% of the proceeds raised.

Further, in connection with the Underwriting Agreement, the Company will be required to issue an aggregate of approximately 62.2 million unquoted options to sub-underwriters having an exercise price of A\$0.07 (7 cents) per option and an expiration date of around 30 September 2026 utilising its existing Listing Rule 7.1 placement capacity.

The Company must also reimburse the Lead Manager for their reasonably incurred expenses, including legal costs, out-of-pocket expenses, stamp duty, transfer taxes, withholding taxes (or similar) incurred in relation to the Offer. The Underwriting Agreement contains customary representations, warranties and indemnities in favour of the Lead Manager.

The obligations of the Lead Manager under the Underwriting Agreement are conditional on the satisfaction or waiver of customary and typical conditions, including receipt by the Lead Manager of various usual reports, sign-offs and consents. If any of the condition's precedent are not satisfied or waived, the Lead Manager may terminate the Underwriting Agreement, in which case, the Lead Manager would no longer be required to underwrite the Offer.

The Lead Manager may terminate the Underwriting Agreement (and be released from its underwriting obligations) without cost or liability on the occurrence of certain unqualified termination events including (without limitation – in summary form only):

- (a) **(Certificate and New Circumstances Certificate)** a certificate or new circumstances certificate which is required to be furnished by the Company under the Underwriting Agreement is not furnished by the time specified or any statement in a certificate or new circumstances certificate is untrue, inaccurate, incomplete or misleading or deceptive in any material respect;
- (b) **(unable to issue New Shares)** the Company is prevented from issuing the New Shares within the time required by the ASX Listing Rules, applicable laws, an order of a court of competent jurisdiction or a government agency;
- (c) **(Offer Documents to comply)** the offer booklet, investor presentation, cleansing notice and related documents (collectively, Offer Documents) or any aspect of the Offer does not comply in any material respect with the *Corporations Act 2001* (Cth) (Corporations Act) or the ASX Listing Rules or any other applicable law including due to a statement in the Offer Documents which is or becomes misleading or deceptive or likely to mislead or deceive in a material respect, or omit any information that is required and any forecasts, expressions of opinion, intention or expectation expressed in the Offer Documents, are not, in all material respects, based on reasonable assumptions;
- (d) **(Supplementary disclosure):** an obligation arises on the Company to give ASX Limited (ASX) a notice in accordance with section 708AA(12) of the Corporations Act (as modified by *ASIC Corporations (Non-Traditional Rights Issues) Instrument 2016/84*) or any adverse events or circumstances occur or become known that would, in the reasonable opinion of the Lead Manager, have required the Company to give ASX such a notice had the cleansing notice in respect of the Offer been lodged on the date the Offer is announced (Announcement Date) on the basis of information known at that time;

Underwriting Key Terms



- e. **(withdrawal)** the Company withdraws the Offer or any part of it;
- f. **(corrective notice)** the Company becomes required to give or gives a correcting notice under subsection 708AA(10) other than as a result of a new circumstance arising;
- g. **(market fall)** the S&P/ASX 300 Index falls by 12.5% or more below the level of the S&P/ASX 300 Index on the business day before the Announcement Date, at the close of trading:
 - (i) for at least two (2) consecutive business days in the period between (and including) the Announcement Date and the business day immediately prior to the settlement date for the retail component of the Offer (Retail Offer Settlement Date);
 - (ii) on the business day immediately prior to the settlement date for the institutional component of the Offer (Institutional Offer Settlement Date); or
 - (iii) on the business day immediately prior to the Retail Offer Settlement Date;
- h. **(ASIC action):** the Australian Securities and Investments Commission (ASIC) commences any investigation or hearing, applies for certain orders or make certain applications in respect of the Offer or Offer Documents or gives notice of intention to prosecute the Company or its directors which is not withdrawn within 2 business days after it is made, or where it is made less than 2 business days before the Institutional Offer Settlement Date or Retail Offer Settlement Date, it is not withdrawn before such date;
- i. **(regulatory action)** there is an application to a government agency (including, without limitation, the Takeovers Panel) for an order, declaration (including, in relation to the Takeovers Panel, of unacceptable circumstances) or other remedy, or a government agency commences any investigation or hearing or announces or notifies its intention to do so, in each case in connection with the Offer (or any part of it) or any agreement entered into in respect of the Offer (or any part of it);
- j. **(legal proceedings)** the commencement of material legal proceedings against the Company, any other related body corporate or controlled entity of the Company (each, a **Group Member** and collectively, the **Group**) or against any director of the Company or any other Group Member in that capacity, or there is a materially adverse development from the perspective of the Company, any other Group Member or any director of the Company or any other Group Member in relation to any existing legal proceedings or any regulatory body conducts any new material inquiry or public action against a Group Member or makes, or communicates any intention to make, any materially adverse finding, ruling, order or determination against a Group Member;
- k. **(change of control)** a transaction is announced, whether by the Company or by another person, which, if implemented, would result in a person and their associates acquiring voting power in the Company of 50% or more and which in the opinion of the Lead Manager has reasonable prospects of success;
- l. **(listing)** ASX announces that the Company will be removed from the official list or that any Company shares will be delisted or suspended from quotation by ASX;
- m. **(offences by directors)** a director of the Company is charged with an indictable offence, any government agency commences any public action against a director of the Company or announces that it intends to take any such action or any director of the Company is disqualified from managing a corporation under the Corporations Act;
- n. **(insolvency)** the Company or a Group Member is insolvent or there is an act or omission which may result in the Company or a Group Member becoming Insolvent;

Underwriting Key Terms



- o. **(adverse change)** there is a material adverse effect, or an event occurs which is likely to give rise to a material adverse effect;
- p. **(capital structure)** the Company alters its capital structure or constitution without the prior written consent of the Lead Manager;
- q. **(ASX approval)** unconditional approval (or conditional approval, provided such condition would not, in the reasonable opinion of the Lead Manager, have a material adverse effect on the success or settlement of either component of the Offer) by the ASX for official quotation of the New Shares is refused or not granted or withdrawn by the relevant allotment date (or ASX makes an official statement that such quotation will not be granted); or
- r. **(Timetable)** any event specified in the timetable is delayed for more than 2 business days without the prior written consent of the Lead Manager.

The Lead Manager may also terminate the Underwriting Agreement (and be released from its underwriting obligations) without cost or liability on the occurrence of certain materiality qualified termination events where the Lead Manager holds the reasonable opinion that the event has, or is likely to have, a material adverse effect including (without limitation) on the success of, the ability of the Lead Manager to market or settle, or the value of Company shares or willingness of investors to subscribe under, the Offer (or the performance on the secondary market of such shares); or has given or could reasonably be expected to give rise to a contravention by, or a liability of, the Lead Manager, under any law or regulation, including (without limitation – in summary form only):

- (a) **(disclosures in Public Information)** the Company's public information includes a statement which is or becomes misleading or deceptive or likely to mislead or deceive or any forecasts, expressions of opinion, intention or expectation which are not based on reasonable assumptions;
- (b) **(disclosures)** any information supplied by or on behalf of the Company to the Lead Manager is or becomes misleading or deceptive, including by way of omission;
- (c) **(hostilities)** hostilities not presently existing commence (whether war has been declared or not) or a major escalation in existing hostilities occurs (whether war has been declared or not) involving any one or more of the United States, Australia, Russia, Ukraine, New Zealand, the United Kingdom, North Korea, South Korea, the People's Republic of China, Japan, Singapore, Iran, Israel or a member state of the European Union or the declaration by any of these countries of a national emergency or war or a major terrorist act is perpetrated anywhere in the world;
- (d) **(change of law)** there is introduced, or there is a public announcement of a proposal to introduce, into the Parliament of Australia or any State of Australia, or any Federal or State authority of Australia adopts or announces a proposal to adopt a new policy (other than a law or policy which has been announced before the date of the Underwriting Agreement), any of which does or is likely to prohibit or regulate the Offer, capital issues or stock markets or adversely affects the Group or investors in it;
- (e) **(compliance with regulatory requirements)** a contravention by the Company or a Group Member of the Corporations Act, the Company's constitution, the ASX Listing Rules or any other applicable law;
- (f) **(Material financing arrangements)** any Group Member breaches or defaults under any provision, undertaking, covenant or ratio of any material financing arrangement or an event of default, potential event of default or review event which gives a lender or financier the right to accelerate or require repayment of the debt or financing or other similar event occurs under or in respect of any material financing arrangement;

Underwriting Key Terms



- g. **(breach)** the Company fails to perform or observe any of its obligations under the Underwriting Agreement or a representation or warranty is or becomes untrue;
- h. **(market or trading disruption) there is:**
 - (i) a suspension or material limitation in trading in securities generally or any adverse change or disruption to the existing financial markets, political or economic conditions of Australia, Japan, Hong Kong, Singapore, the People's Republic of China, the United Kingdom, the United States of America, Germany, France, Spain, Italy, or the international financial markets or any change in national or international political, financial or economic conditions;
 - (ii) a general moratorium on commercial banking activities is declared by the relevant central banking authority in any of the countries referred to in the sub-paragraph immediately above; or
 - (iii) any adverse change or disruption to the existing financial markets, political or economic conditions of Australia, Japan, Hong Kong, Singapore, the People's Republic of China, the United Kingdom, the United States of America, Germany, France, Spain, Italy or the international financial markets or any change in national or international political, financial or economic conditions;
- i. **(change in management)** a change in the Chief Executive Officer or the Chief Financial Officer of the Company or in the board of directors of the Company is announced or occurs without the Lead Manager's prior written consent;
- j. **(adverse change)** there is an adverse change, or an event occurs which is likely to give rise to an adverse impact of an amount equal to or greater than 10% of the assets, liabilities, revenue, profits, operations or prospects of the Group when compared to what the assets, liabilities, revenue, profits, operations or prospects of the Group would have been if not for that adverse change or event; or
- k. **(new circumstances)** in the reasonable opinion of the Lead Manager, a new circumstance arises that would have been required to be disclosed in the Offer Documents had it arisen before the Offer Documents were lodged with ASX; and

The Lead Manager may appoint sub-underwriters at its discretion (at its sole cost and expense).

Appendix – Foreign Selling Restrictions

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International Offer Restrictions



Hong Kong

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Glossary

A horizontal bar with a multi-colored gradient consisting of yellow, cyan, purple, and red segments.

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Glossary



- **ASIC** means the Australian Securities and Investments Commission.
- **ASX** means ASX Limited ACN 008 624 691 or the financial market known as the 'Australian Securities Exchange' operated by it, as the context requires.
- **ASX Listing Rules** means the official listing rules of the ASX as amended or waived.
- **CLIA** means the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations which include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease.
- **Company** or **Lumos** means Lumos Diagnostics Holdings Limited ACN 630 476 970.
- **CPT Codes** means Current Procedural Terminology, being a medical code set that is used to report medical, surgical, and diagnostic procedures and services.
- **CRP** means C-reactive protein.
- **Eligible Institutional Shareholder** means a shareholder who is an Institutional Investor and who the Company determines may receive an offer under the Institutional Entitlement Offer.
- **Eligible Retail Shareholder** means a person who: was registered as the holder of Shares as at 7.00pm (Sydney time) on the Record Date; has a registered address in Australia; is not in the U.S. nor acting for the account or benefit of a person in the U.S. or elsewhere outside Australia; and does not hold Shares on behalf of another person who resides outside Australia (unless they hold Shares in another eligible capacity).
- **FDA** means the U.S. Food and Drug Administration.
- **FDCA** means the Federal Food, Drug, and Cosmetic Act.
- **FebriDx** means Lumos' point-of-care diagnostic test that is able to rapidly identify patients with a microbial infection and, if positive, determine if that infection is caused by a virus or bacteria.
- **Institutional Entitlement Offer** means the offer of New Shares to Eligible Institutional Shareholders.
- **IVD** means in vitro diagnostics.
- **MDSAP** means Medical Device Single Audit Program.
- **MxA** means Myxovirus resistance protein A.
- **New Shares** means the new Shares offered under the Entitlement Offer.
- **Offer Booklet** means the offer booklet in respect of the Offer announced to the ASX on or about the date of this Presentation.
- **Option** means the right of the holder to be issued one New Share on payment of the applicable exercise price.
- **OTC** mean over the counter.
- **POC** means point of care.
- **Retail Entitlement Offer** means the the offer of New Shares to Eligible Retail Shareholders.
- **Share** means a fully paid ordinary share in the capital of the Company.
- **TGA** means the Therapeutic Goods Administration.
- **Top Up Facility** means the facility under which Eligible Retail Shareholders may apply for additional New Shares if there is a shortfall under the Retail Entitlement Offer.
- **U.S.** means the United States of America.

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