



Lumos Diagnostics Holdings Limited



1H FY24 Financial Results Presentation

28 February 2024

lumosdiagnostics.com

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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

- 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)



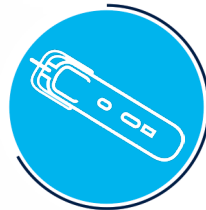
Comprehensive / integrated offering

- 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

1H FY24 Financial Results



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1H FY24 and Post Reporting – Highlights*



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“Having dedicated our limited resources to closing the Hologic deal, which impacted our near-term revenue, Lumos is now on solid foundations from which to grow.”

Doug Ward
Chief Executive Officer
Lumos Diagnostics

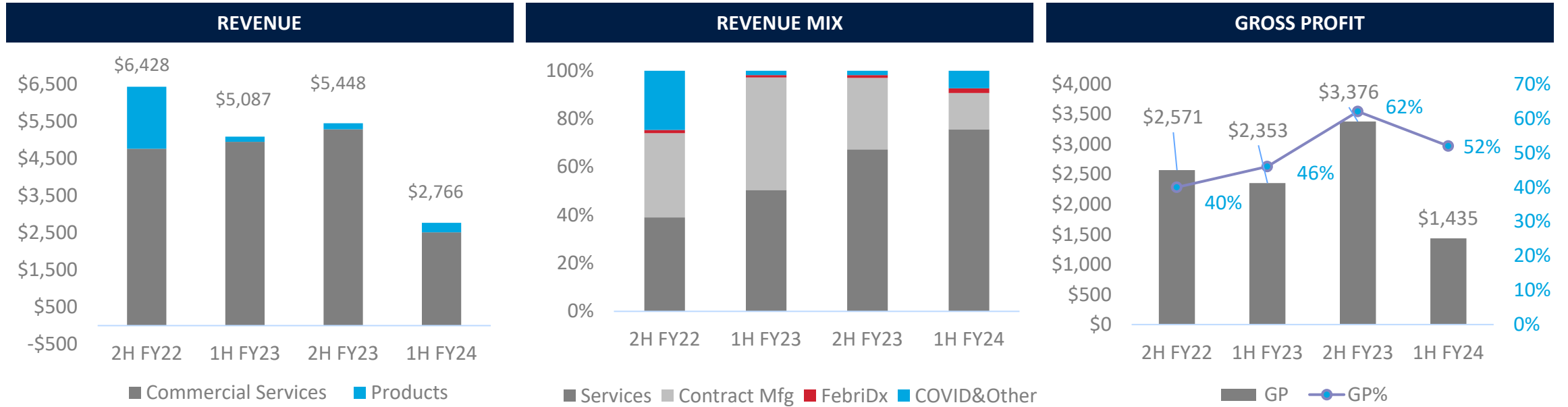
-  Revenue \$2.8 million (\$5.1 million 1H FY23) – resources focused on FebriDx/ViraDx launches and closing Hologic deal
-  Gross profit margin for 1H FY24 of 52%, an improvement of 6ppts over 1H FY23
-  Completed capital raise of A\$5.4 million in July 2023 – Placement + SPP
-  Repaid all Convertible Notes, A\$1.58 million in August 2023
-  Hologic Agreements signed – transformational deal + entry into women’s health – January 2024
-  Henry Schein signs FebriDx US distribution agreement – February 2024
-  Pro-forma cash balance of \$6.4 million as at 31 January 2024 + additional \$5.0 million committed by June 2024

* All amounts are in US\$ unless stated otherwise

Revenue & Gross Profit



(US\$ in thousands)



COMMENTARY

1H FY24, a focus on getting new products established:

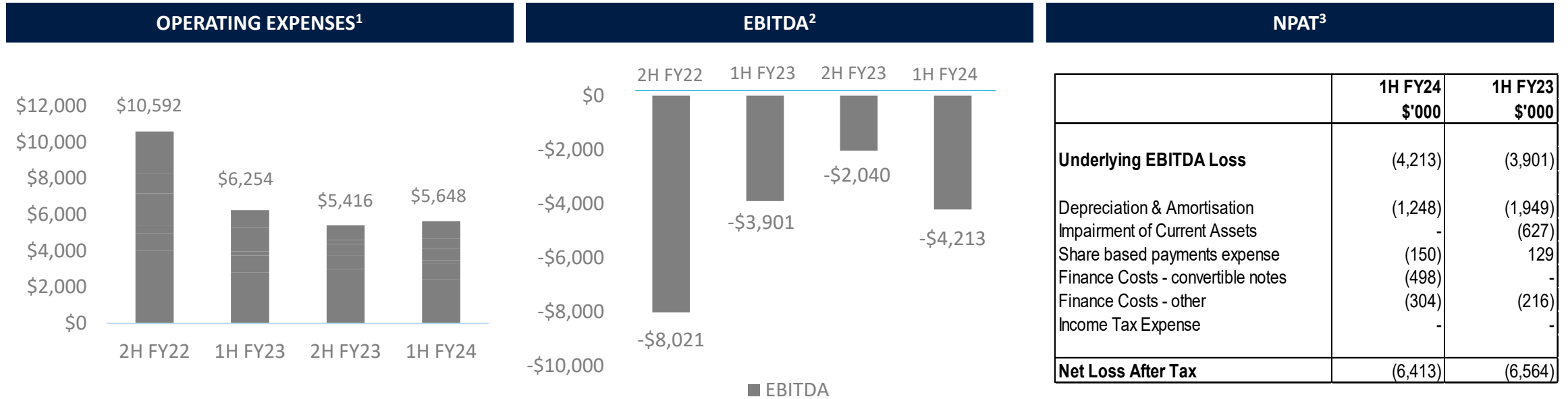
- Revenue of \$2.8M, down 46% from 1H FY23 of \$5.1M
- 1H revenue impacted by switching resources to internal non-billable product projects (FebriDx/ViraDx launches), and delay in starting new contracts with Hologic, plus 1H FY23 had some contract manufacturing work related to the COVID pandemic which was completed and did not carry over to the 1H FY24 period
- Gross profit margin for 1H FY24 of 52%, within our target range of 50% - 60% and 6ppts better than 1H FY23
- Services revenue of \$2.5M from both contract development and manufacturing services
- Commercial Services revenue driven by 12+ development programs in various phases
- Product revenue of \$0.3M, up 82% on 1H FY23. Driven by FebriDx sales outside the US, and some initial sales of ViraDx in the US

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OPEX & EBITDA



(US\$ in thousands)



COMMENTARY

1H FY24, ongoing cost control:

- Cost base after restructure and rightsizing in previous periods continues to hold steady
- Operating expenses steady at \$5.6M, which are down by 10% on 1H FY23, and up 4% on 2H FY23
- Underlying EBITDA loss of \$4.2M for 1H FY24, 8% higher than 1H FY23 EBITDA loss of \$3.9M (impacted by reduced revenue)
- Lower depreciation due to the sale and leaseback of PP&E with Hologic
- No impairments or reserves booked in the 1H FY24
- Finance costs higher due to the convertible notes, which were fully redeemed in August 2023
- NPAT loss for the 1H FY24 \$6.4M, which is similar to the 1H FY23 loss

¹ Operating Expenses prior to impairments & non-recurring costs.

² Underlying EBITDA loss before impairments & non-recurring costs.

³ Statutory NPAT per HY Report.

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Cash Flow

(US\$ in thousands)

OPERATING			INVESTING			FINANCING & CASH BALANCE		
	1H FY24 \$'000	1H FY23 \$'000		1H FY24 \$'000	1H FY23 \$'000		1H FY24 \$'000	1H FY23 \$'000
Cash flows from operating activities			Cash flows from investing activities			Cash flows from financing activities		
Receipts from customers	2,438	2,974	Payments for plant and equipment	(9)	(19)	Proceeds from issue of shares, net of costs	4,999	-
Payments to employees and suppliers	(7,401)	(8,738)	Payments for clinical trials and development	(9)	(24)	Redemption of convertible notes	(1,110)	-
Proceeds from government grant	471	-	Proceeds from disposal of property, plant & equipment	-	-	Payment of lease liabilities	(679)	(1,095)
	(4,492)	(5,764)	Net cash from/(used in) investing activities	(18)	(43)	Net cash from/(used in) financing activities	3,210	(1,095)
Interest received	19	-				Net increase/(decrease) in cash	(1,649)	(7,073)
Interest and other finance costs paid	(368)	(171)				Cash at the beginning of the financial year	3,015	7,978
Net cash (used in) operating activities	(4,841)	(5,935)				Effects of exchange rate changes on cash	13	(122)
						Cash at the end of the financial year	1,379	783

COMMENTARY

1H FY24, improved operating cash flow, and repayment of the convertible notes:

- Operating cash outflow for 1H FY24 \$4.8M, versus an outflow of \$5.9M in 1H FY23
- No spend on PP&E, product development or clinical trials
- Total cash usage (operating, capital expenditure, lease payments) was \$5.5M (\$0.9M per month), versus \$7.1M in 1H FY23 (\$1.2M per month)
- Capital raises in July and October 2023, resulted in net proceeds after costs of \$5.0M
- Payout of convertible notes in August 2023 of \$1.1M (A\$1.575M)
- Cash at 31 December \$1.4M, which increased to \$6.4M after the receipt of the first IP payment of \$5.0M from Hologic in January 2024 (second payment of \$5.0M due in June 2024)

Balance Sheet

(US\$ in thousands)

ASSETS			LIABILITIES			EQUITY		
	31 Dec 2023 \$'000	30 Jun 2023 \$'000		31 Dec 2023 \$'000	30 Jun 2023 \$'000		31 Dec 2023 \$'000	30 Jun 2023 \$'000
Assets			Liabilities			Equity		
Current assets			Current liabilities			Issued capital	98,228	92,468
Cash and cash equivalents	1,379	3,015	Trade and other payables	2,051	2,882	Reserves	(296)	(678)
Trade and other receivables	1,000	1,489	Convertible notes	-	1,346	Accumulated losses	(88,705)	(82,292)
Inventories	1,338	1,063	Lease liabilities	906	692	Total Equity	9,227	9,498
Prepayments and other assets	593	397	Employee benefits	1,968	1,540			
Total current assets	4,310	5,964	Contract liabilities	1,279	1,714			
Non-current assets			Total current liabilities	6,204	8,174			
Plant and equipment	354	611	Non-current liabilities					
Right-of-use assets	7,857	7,953	Lease liabilities	7,621	7,747			
Intangibles	10,531	10,891	Total non-current liabilities	7,621	7,747			
Total non-current assets	18,742	19,455	Total Liabilities	13,825	15,921			
Total Assets	23,052	25,419	Net Assets	9,227	9,498			

COMMENTARY

31 December 2023, clean balance sheet and new capital in July & October 2023, convertible notes redeemed:

- Some investment in inventory, related to launch of ViraDx and FebriDx in the US
- Improvement in receivables
- ROU Assets is property leases, and sale & leaseback. Intangibles is point-of-care reader platforms and IP related to FebriDx
- Reduction in contract liabilities as projects now delivered
- After conversions in July and August, the convertible notes were fully paid out in full in August for a cash outlay of A\$1.575M (US\$1.110M)

Product Update



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FebriDx Launch- US product sales

Commenced sales & marketing activities to initial key customers

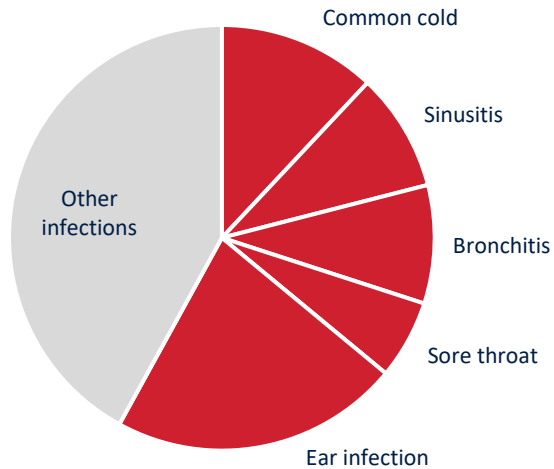
- Commenced selling FebriDx in the US in January 2024
- Agreements with 14 customers/distributors in place
- Henry Schein distribution agreement executed February 2024
 - 50 lab specialists; Providing exposure to 600 account managers
- Pathway established with FDA to pursue CLIA waiver for FebriDx
- Inbound interest from potential customers at physicians' offices, urgent care clinics, and health systems
- Manufacturer partnership discussions ongoing
- Reimbursement update: Existing CPT Codes 86332 (Immune complex measurement) and 86140 (Measurement C-reactive protein for detection of infection or inflammation) combine [86332: \$24.37 + 86140: \$5.18 = \$29.55). **PLA Code has been awarded. Code #0442U. Goes into affect 1 April 2024**
 - Proprietary code eliminates the uncertainty of pre-existing CPT codes as well as provides higher rate of reimbursement



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FebriDx: Addressing 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



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

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>.

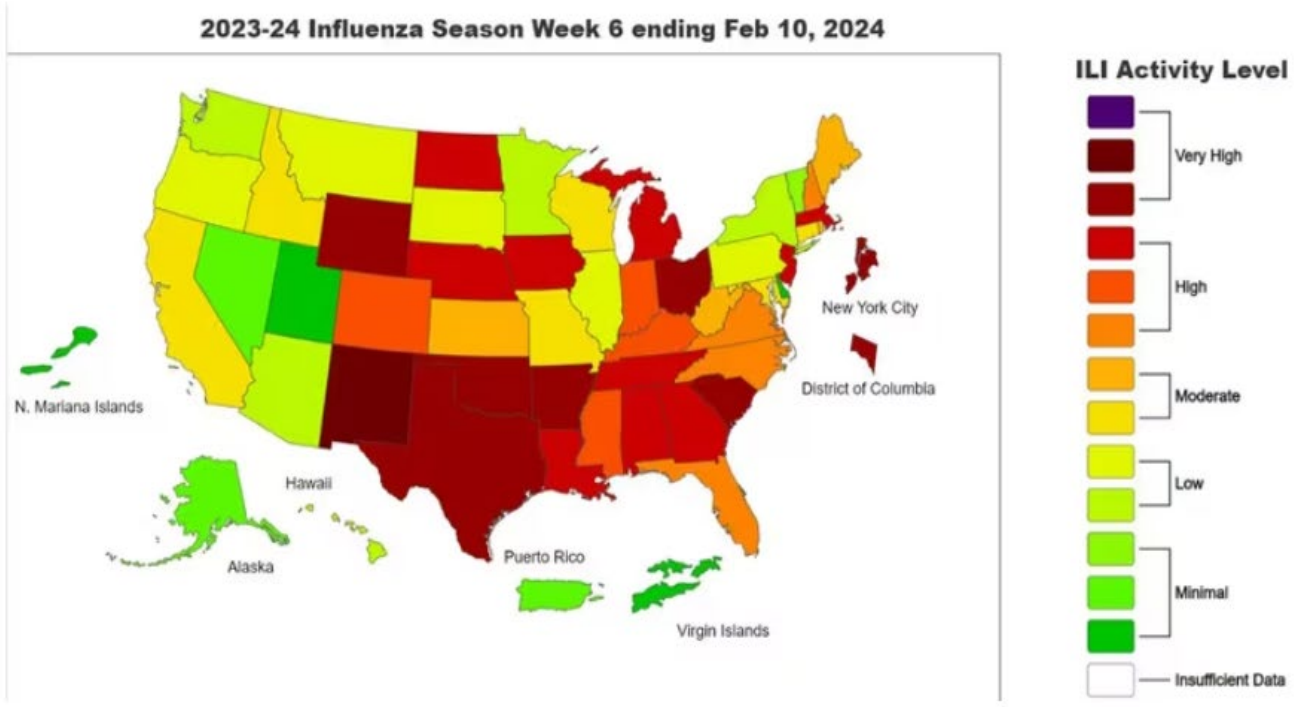
⁴ Centers for Disease Control and Prevention. *MMWR*, 2011, 60:1153-6

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US - CDC flu map



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Current flu season infections continue to increase in the US:

- Flu season expected to continue through to April 2024
- Sales windows for FebriDx and ViraDx extended

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
- Diagnosis aids in anti-viral therapeutic decision making, Paxlovid v Tamiflu

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
- Commenced selling of ViraDx in late November 2024
- Agreements with 17 customers/distributors in place
 - Revenue underpinned by ongoing demand across the flu season
 - Averaging 8 distributor orders/week



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Services Update

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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

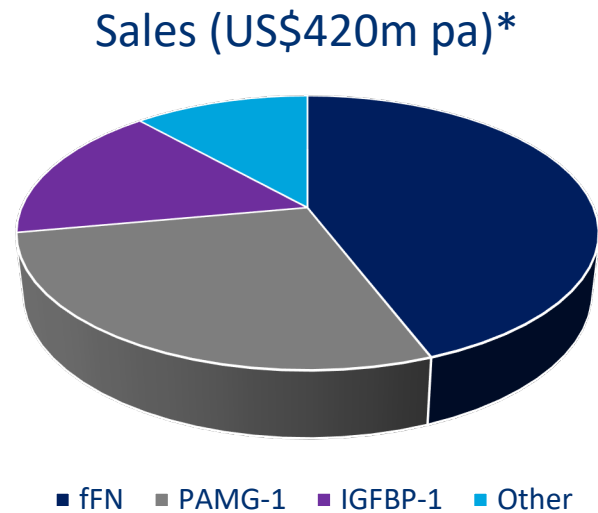
These new contracts strengthen Lumos' balance sheet and provide a pipeline of revenue generating partnerships in POC diagnostics.

* 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



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

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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

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Hologic – the opportunity ahead

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Verification and validation



Clinical study



Manufacturing



Second test development and IP



Looking ahead



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Promising Outlook

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Whilst our financial performance in 1H FY24 was below what we had planned, we achieved significant and transformative milestones in the services and products business which strengthen our balance sheet, lift revenue, and provide an exciting pipeline of opportunities.

I believe that the foundations established in the financial year to date will enable Lumos to accelerate the building and growth of its business.

Doug Ward
Chief Executive Officer
Lumos Diagnostics



Revenue will recover in 2H FY24 - Hologic IP payment, services income and product sales



Hologic product development commenced – milestone payments expected



FebriDx and ViraDx sales commenced – FebriDx US sales to be supported by Henry Schein



Improving operating cash flow through growing revenue streams and cost management



Strong foundations for growth assisted from balance sheet strength

Questions

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Appendices

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Company snapshot



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Issued capital	
Shares	481.3m
Options	85.0m
Market capitalization (AUD)	
Share price	A\$0.076
Market value	A\$36.6m
Cash (pro-forma – Jan 24)	A\$9.7m
Enterprise value	A\$26.9m
Substantial shareholders	
Planet Innovation	14.1%
Perennial Value Management	13.6%
Ryder Capital	5.3%

Share Price & Volume



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 27 February 2024

Highly experienced leadership team



Doug Ward
CEO & Managing Director

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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



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Lumos' POC diagnostic test development engine



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

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Product concepts
(generated by Lumos or partners/customers)



Lumos' POC Diagnostics Engine



REVENUE STREAMS

Contract fees
from services

Revenue & margin
from manufacturing

Sales & license payments
from own & other products

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

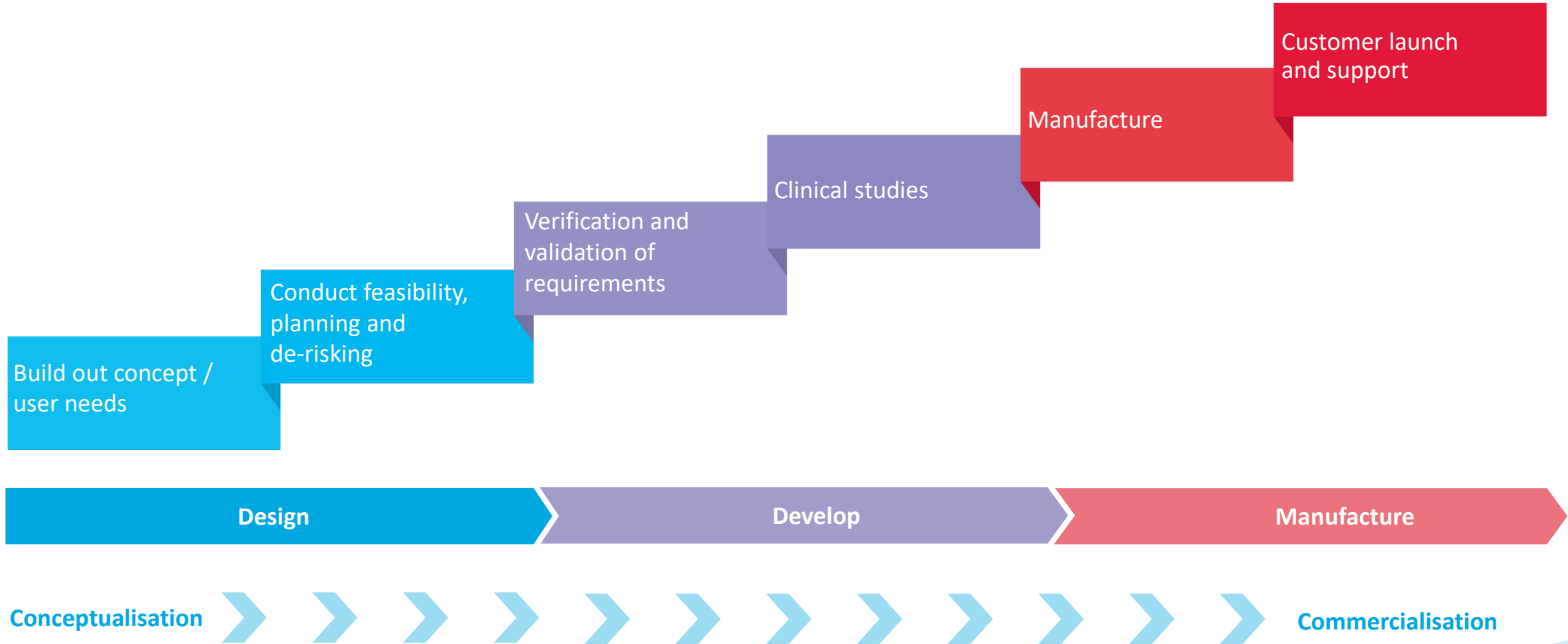


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How we add value to partners

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

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