

# **Lumos Diagnostics Holdings Limited**

1H FY24 Financial Results Presentation

28 February 2024

lumosdiagnostics.com

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### **Contents**



- Company Overview
- 1H FY24 Financial Results
- Product Update
- Services Update
- Looking Ahead
- Questions



### **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 and Post Reporting – Highlights\*





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



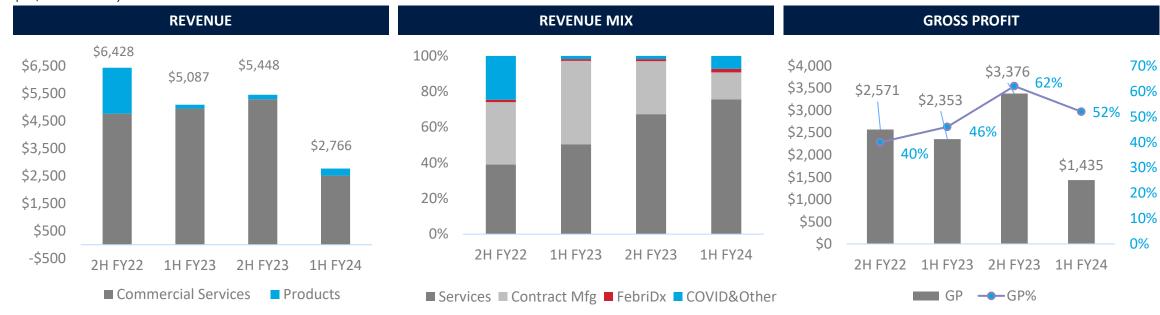
Pro-forma cash balance of \$6.4 million as at 31 January 2024 + additional \$5.0 million committed by June 2024

<sup>\*</sup> 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

70%

60%

40%

30%

20%

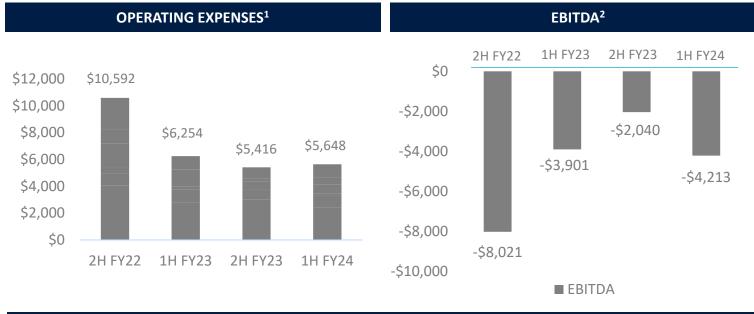
10%

0%

### **OPEX & EBITDA**



(US\$ in thousands)



	1H FY24	1H FY23
	\$'000	\$'000
Underlying EBITDA Loss	(4,213)	(3,901)
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Depreciation & Amortisation	(1,248)	(1,949)
Impairment of Current Assets	-	(627)
Share based payments expense	(150)	129
Finance Costs - convertible notes	(498)	-
Finance Costs - other	(304)	(216)
Income Tax Expense	-	-
Net Loss After Tax	(6,413)	(6,564)

NPAT<sup>3</sup>

#### **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

<sup>1</sup>Operating Expenses prior to impairments & non-recurring costs.

<sup>2</sup> Underlying EBITDA loss before impairments & non-recurring costs.

<sup>3</sup> Statutory NPAT per HY Report.

### **Cash Flow**



(US\$ in thousands)

#### OPERATING INVESTING FINANCING & CASH BALANCE

	1H FY24	1H FY23
	\$'000	\$'000
Cash flows from operating activities		
Receipts from customers	2,438	2,974
Payments to employees and suppliers	(7,401)	(8,738)
Proceeds from government grant	471	-
	(4,492)	(5,764)
Interest received	19	-
Interest and other finance costs paid	(368)	(171)
Net cash (used in) operating activities	(4,841)	(5,935)

	1H FY24	1H FY23
	\$'000	\$'000
Cash flows from investing activities		
Payments for plant and equipment	(9)	(19)
Payments for clinical trials and development	(9)	(24)
Proceeds from disposal of property, plant & equipment	-	-
Net cash from/(used in) investing activities	(18)	(43)

	1H FY24	1H FY23
	\$'000	\$'000
Cash flows from financing activities		
Proceeds from issue of shares, net of costs	4,999	-
Redemption of convertible notes	(1,110)	-
Payment of lease liabilities	(679)	(1,095)
Net cash from/(used in) financing activities	3,210	(1,095)
Net increase/(decrease) in cash	(1,649)	(7,073)
Cash at the beginning of the financial year	3,015	7,978
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	30 Jun 2023
	\$'000	\$'000
Assets		
Current assets		
Cash and cash equivalents	1,379	3,015
Trade and other receivables	1,000	1,489
Inventories	1,338	1,063
Prepayments and other assets	593	397
Total current assets	4,310	5,964
Non-current assets		
Plant and equipment	354	611
Right-of-use assets	7,857	7,953
Intangibles	10,531	10,891
Total non-current assets	18,742	19,455
Total Assets	23,052	25,419

	31 Dec 2023	30 Jun 2023
	\$'000	\$'000
Liabilities		
Current liabilities		
Trade and other payables	2,051	2,882
Convertible notes	-	1,346
Lease liabilities	906	692
Employee benefits	1,968	1,540
Contract liabilities	1,279	1,714
Total current liabilities	6,204	8,174
Non-current liabilities		
Lease liabilities	7,621	7,747
Total non-current liabilities	7,621	7,747
Total Liabilities	13,825	15,921
Net Assets	9,227	9,498

	31 Dec 2023 \$'000	30 Jun 2023 \$'000
Equity		
Issued capital	98,228	92,468
Reserves	(296)	(678)
Accumulated losses	(88,705)	(82,292)
Total Equity	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)



### FebriDx Launch- US product sales



### **Commenced sales & marketing activities to initial key customers**

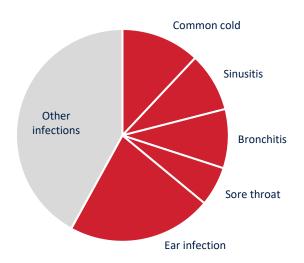
- Commenced selling FebriDx in the US in January 2024
- Agreements with 14 customers/distributors in place
- Henry Schein distribution agreement executed February 2024
  - 50 lab specialists; Providing exposure to 600 account managers
- Pathway established with FDA to pursue CLIA waiver for FebriDx
- 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



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

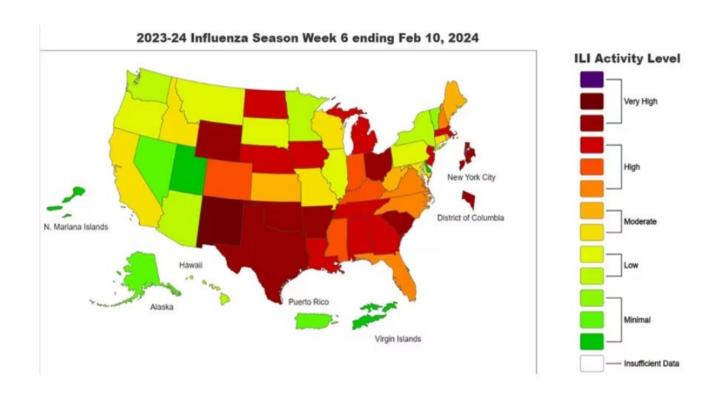
<sup>&</sup>lt;sup>2</sup> Unnecessary Antibiotics for Acute Respiratory Tract Infections: Associations with Care Setting and Patient Demographics, 2016

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

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

# **US - CDC flu map**





# 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





# **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.

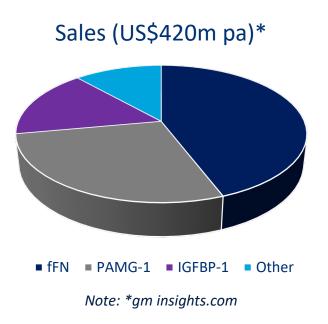
<sup>\*</sup> ASX announcements from 11 and 16 January 2024 provide additional information.

# 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



### 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**



# 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

### **Next generation test concept (mock-up)**



# **Hologic – the opportunity ahead**





**Verification and validation** 



**Clinical study** 



Manufacturing



**Second test development and IP** 





# **Promising Outlook**



66

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





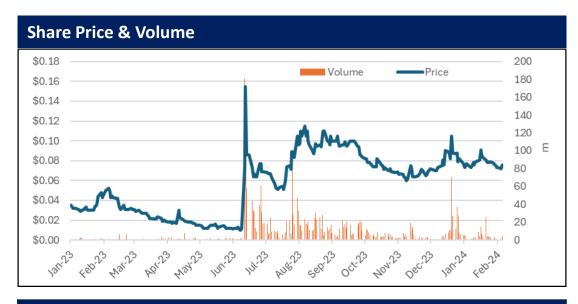
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# **Company snapshot**



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%	



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

# 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 Premedicine 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

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.

## Lumos has a compelling and highly competitive offering



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



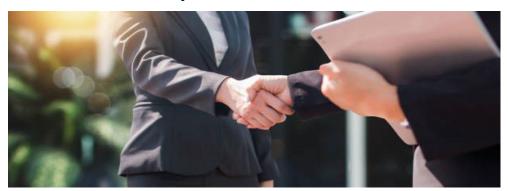
### 2. Proprietary reader platform for use in different settings







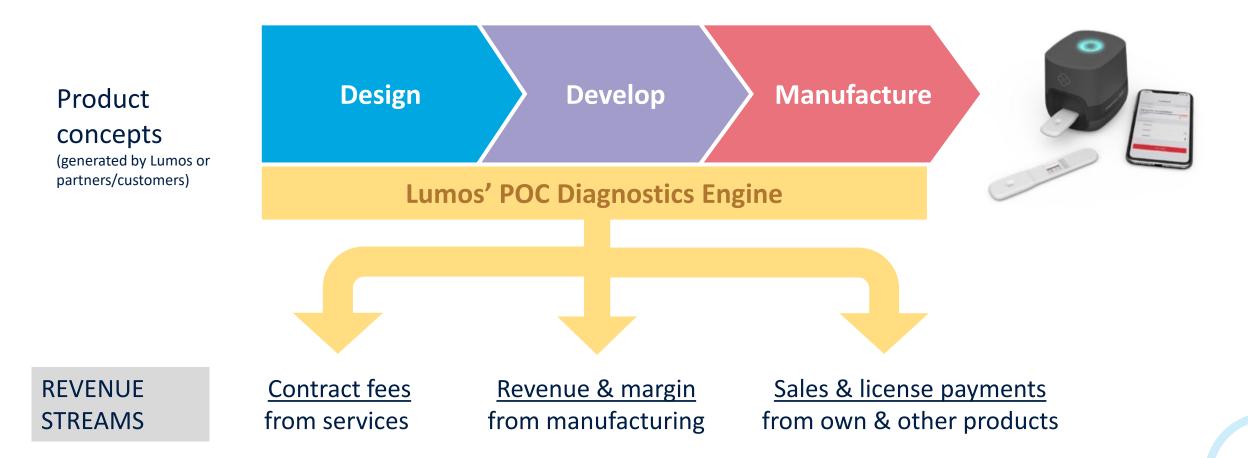
### 4. Business development / commercialisation



# Lumos' POC diagnostic test development engine



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



# 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

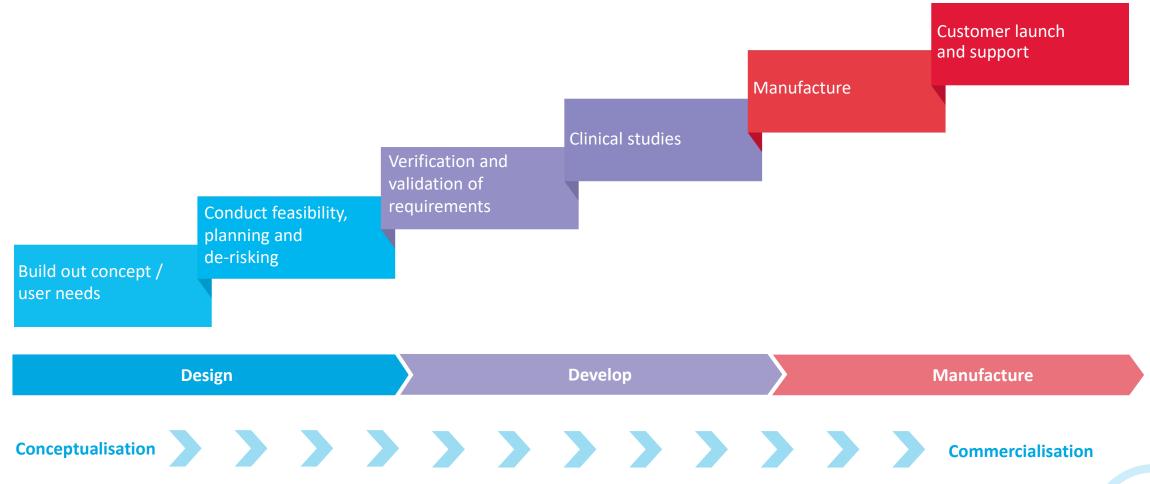
- Multiple projects—reduced transaction costs with repeat business
- Project extensions—as products migrate through stages of the development process
- New projects—creating and developing new products for strategic partners
- Next gen products—extending commercial life of partner's products as market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



## 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





lumosdiagnostics.com