




Lumos Diagnostics Holdings Limited (LDX)

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Rob Sambursky, MD
CEO and President
Lumos Diagnostics

www.lumosdiagnostics.com

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Our Mission

To develop, manufacture and provide access to rapid, accurate and actionable diagnostic solutions for a diverse range of unmet needs in order to improve outcomes, reduce unnecessary treatments, minimise disease spread and contribute to more effective clinical management and therapeutic decisions.

About Lumos (LDX)



SARASOTA, FL USA



CARLSBAD, CA USA

Capable of manufacturing ~10M test strips per month

- Sarasota: ~75 FTEs (Primary manufacturing site with R&D transfer)
- Carlsbad: ~50 FTEs (Primary R&D site with pilot manufacturing)
- 42,000 ft across 2 leased facilities
- Geographically strategic locations and redundancy (supply chain access and international markets)
- Fully automated capabilities for test strips and assembly

MDSAP certified, ISO 13485 compliant and FDA compliant facilities

- Reducing the time and risk involved to take new diagnostic tests through development to manufacture and commercialisation.

FY21 At A Glance



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While FY20 was all about integration and transformation, FY21 represented strategic action and growth.

The Lumos team achieved major accomplishments this year across all aspects of our business.

Rob Sambursky, MD
President & CEO
Lumos Diagnostics



A\$25.0M total revenue in FY21 ▶ **198%** YoY increase



A\$22.7M Commercial Services business unit revenue in FY21 ▶ **188%** YoY increase



Global manufacturing capacity expanded up to **10 million** rapid diagnostics tests per month



A\$2.3M Products business unit revenue in FY21 ▶ significant YoY increase



FebriDx® U.S. multicentre clinical trail (DISRUPT) complete and U.S. FDA 510(k) submitted



Developed two **Lumos-branded POC diagnostic products** for launch in FY22

Lumos Business Model

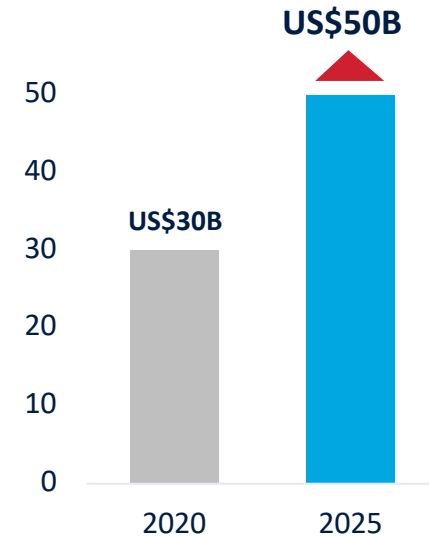


Lumos is a fully integrated innovator, developer and manufacturer of rapid POC diagnostic solutions that allow clinicians and patients to make important medical decisions quickly and accurately.



GLOBAL POC DIAGNOSTIC TEST SALES¹

(US\$ in billions)



11.5% 5-year CAGR for North America & Europe

¹MarketsandMarkets Report, 2021

Proprietary Readers: Different Settings

Lumos is developing a comprehensive digital reader platform designed to satisfy the specific needs of different customer groups.



SINGLE-USE DISPOSABLE

- Single use disposable tests
- Simple “yes/no” tests
- Out-of-clinic use
 - Over the counter
 - Consumers / at home testing



MULTI-USE DISPOSABLE

- 10-50 single use test strips
- Limited reuse disposable reader
- Lower volume clinical settings



DESKTOP

- High performance desktop reader
- Multiple tests using same reader
- Higher volume / higher complexity settings e.g. Electronic Medical Record / Lab Information System connectivity

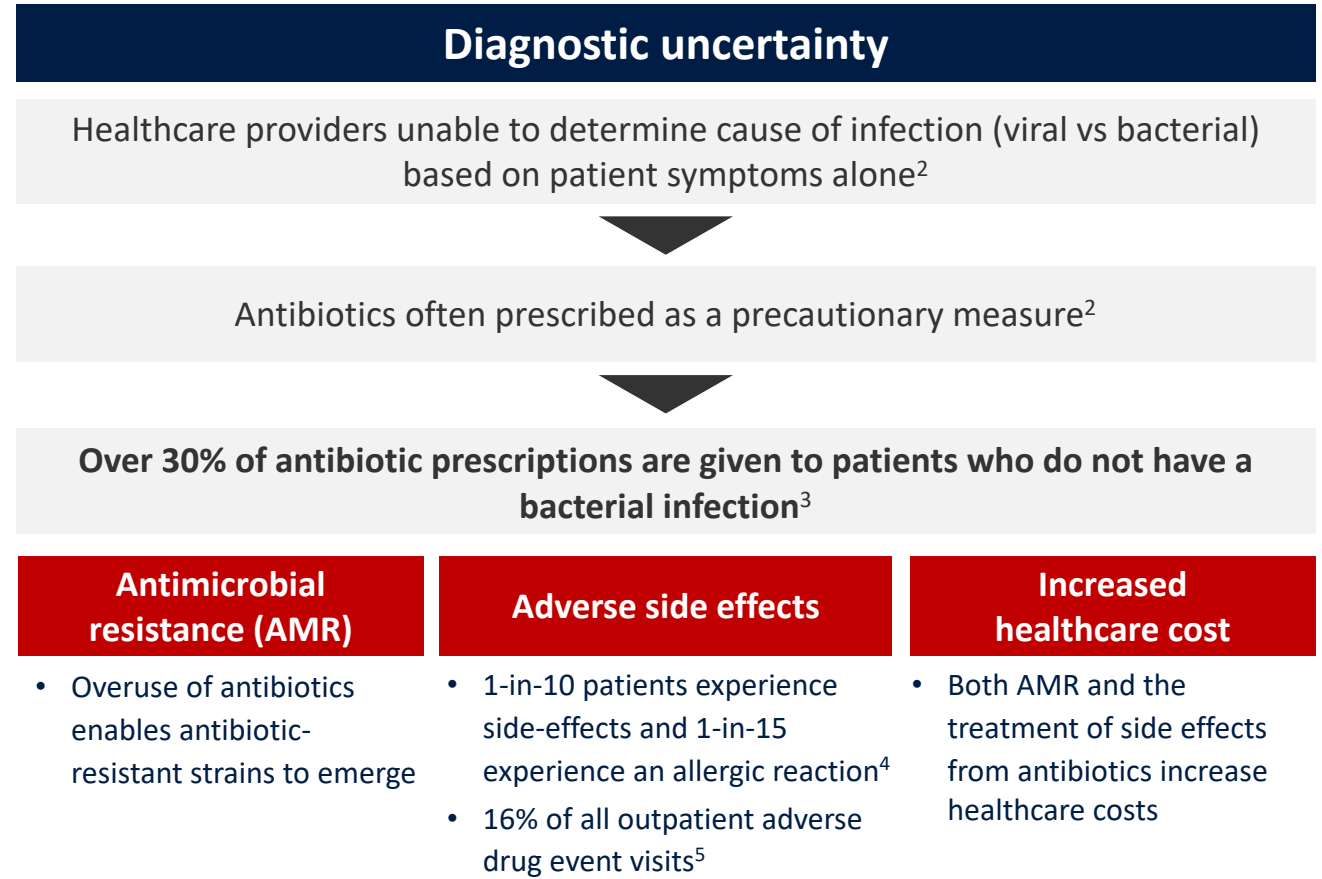
Lumos currently sells single use disposable readers. Multiuse disposable and desktop readers are under development.

Overuse of Antibiotics

Extensive inappropriate use of antibiotics is adversely impacting healthcare through the emergence of antimicrobial resistance, adverse side effects and increased costs to healthcare systems



- Antibiotics can only treat bacterial infections¹
- Hard to distinguish ARIs that are caused by viruses from those caused by bacteria based on symptoms alone because the symptoms are very similar¹
- Diagnostic uncertainty is one of the most common causes for the inappropriate prescribing of antibiotics²



1. The Pew Charitable Trust (2016), Antibiotic Use in Outpatient Settings. 2. Handle with care: Chief Public Health officer of Canada's 2019 spotlight report. 3. 2020 - Measuring Outpatient Antibiotic Prescribing. 4. NHS, Antibiotics side effects, published on May 2019. 5. National Estimates of Emergency Department Visits for Antibiotic Adverse Events Among Adults—United States, 2011–2015, (<https://doi.org/10.1007/s11606-018-4430-x>)N.

FebriDx®: A Simple Test For Microbial Infection

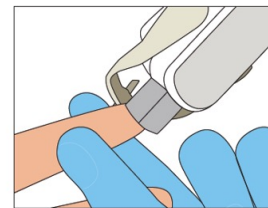
FebriDx can rapidly identify patients who have a microbial infection¹ and, if positive, determine if that infection is caused by a viral or bacterial pathogen.



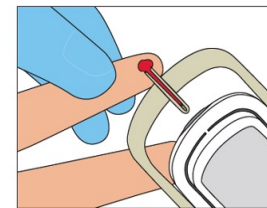
Key: Markers for infection

CRP	Inflammatory marker elevated with any infection
MxA	Specific marker only elevated with viral infection

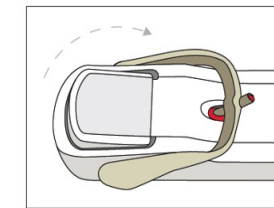
FebriDx® Test Procedure and Interpretation of Results



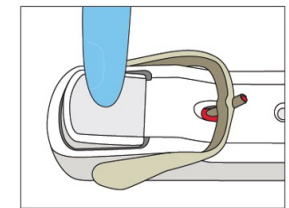
1 Lance finger



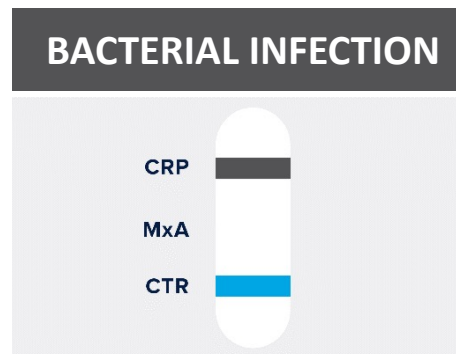
2 Collect blood sample



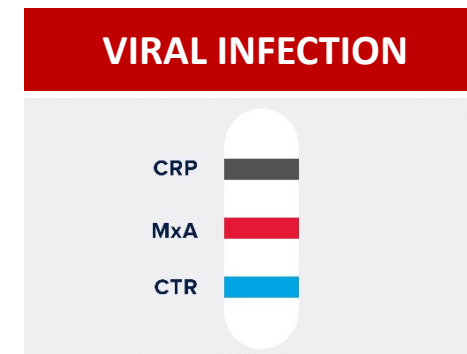
3 Deliver blood sample



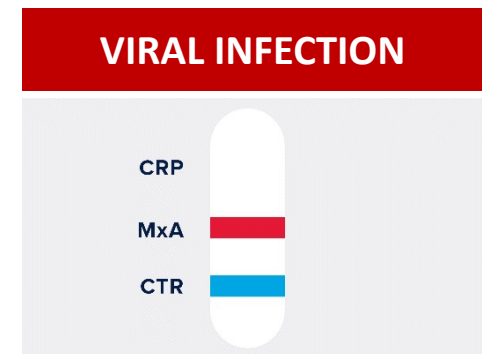
4 Deliver buffer solution



Patient can be treated with antibiotics



Viral Infection - Antibiotics will not work
Patient needs to be managed differently



1. Microbial infection is the invasion of infectious agents into the organism, their multiplication and the reaction of host tissue against these agents. Infectious agents include bacteria, virus, parasite and fungi.

FebriDx®: A Validated Rapid Test for Microbial Infection



FOR FEBRILE PATIENTS PRESENTING WITH SYMPTOMS AND SIGNS OF ARI ²		
Bacterial	Sensitivity	95%
	Specificity	91%
	NPV	97%
Viral	Sensitivity	77%
	Specificity	85%
	PPV	92%

Markers for infection

- CRP** Inflammatory marker elevated with any infection
- MxA** Specific marker only elevated with viral infection



- FebriDx completed clinical evaluation in a U.S. prospective multicentre clinical trial (DISRUPT)
- FebriDx achieved all U.S. FDA predetermined clinical performance criteria
- FebriDx submitted for U.S. FDA 510(k) clearance and is under active review
- Strong clinical performance for microbiologically confirmed infection and final clinical diagnosis

FebriDx® is a clinically validated,¹ patented, easy-to-use, point-of-care test that uses a unique combination of two different markers for infection.



¹ Diagnosis of bacterial or viral infections in Acute Respiratory Illness (ARI) patients

² Clinical data represents combined U.S. Pilot and DISRUPT clinical trial data.

CoviDx™: Rapid COVID-19 Antigen Test Solution



SIMPLE TEST PROCEDURE → RESULTS IN 15 MINUTES



- Initial sales commenced into Europe
- Launch in Canada and Australia in FY22 pending regulatory approvals
- Works with all variants including Delta
- Used in conjunction with FebriDx for diagnosing acute respiratory infection patients
- Manufactured in the U.S.
- Synergistic with FebriDx and will sell through same sales channels

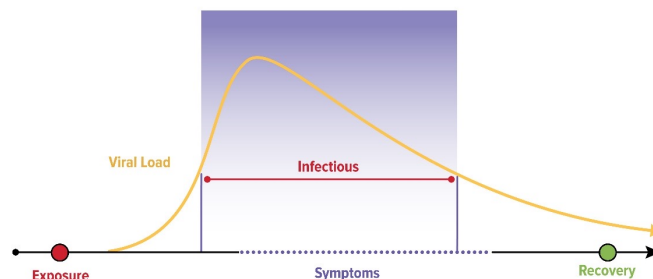
STRONG U.S. CLINICAL DATA AGAINST HIGH SENSITIVITY PCR

CoviDx Results vs. RT-PCR

CoviDx-SARS-CoV-2 Rapid Antigen Test	PCR Test		
	Ct ≤ 35		
	Positive	Negative	Total
Positive	40	5	45
Negative	0	96	96
Total	40	101	141
Positive Percent Agreement (PPA) Sensitivity	100% (95% CI: 91.2% - 100%)		
Negative Percent Agreement (NPA)	95% (95% CI: 88.9% - 97.9%)		

SARS-CoV-2 Viral Load Over Course of Infection¹

Frequent testing with antigen tests can identify people when their infection is most likely to be transmissible.²



¹ Adapted from Crozier A. Put to the test: Use of rapid testing technologies for Covid-19. *Br Med J.* 2021;372:n208. <https://doi.org/10.1136/bmj.n208>







² Mina MJ, Parker R, Larremore DB. Rethinking Covid-19 test sensitivity – A strategy for containment. *N Engl J Med.* 2020;383:e120. doi: 10.1056/NEJMp20256315

Promising Product Pipeline



Lumos is leveraging its expertise and infrastructure to expand the Lumos-branded family of POC diagnostic tests and readers.

Lumos has a growing portfolio of POC diagnostic solutions for healthcare providers in a variety of care settings.

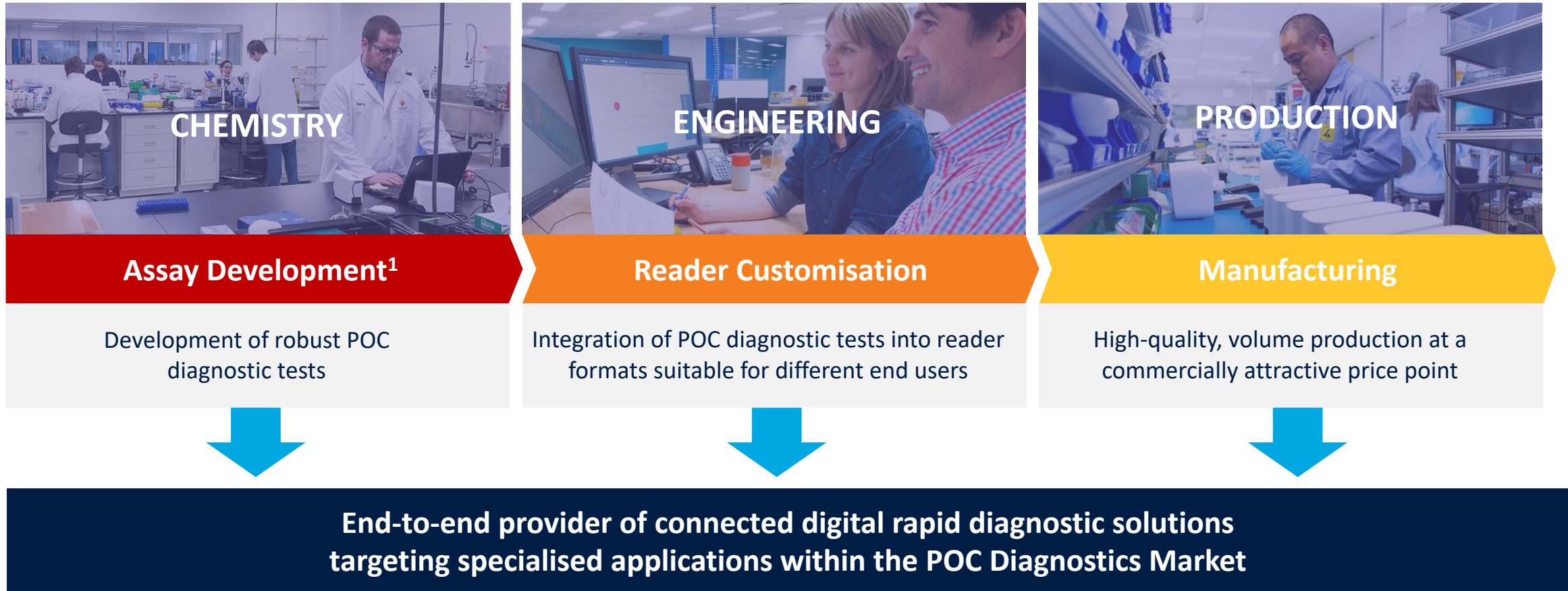
CURRENT PRODUCTS ¹			
 <p>FebriDx</p>	 <p>CovidDx</p>	 <p>Lumos Readers</p>	
Differentiate viral from bacterial acute respiratory infection	COVID-19 antigen	A suite of proprietary digital reader formats including connectivity options	
PIPELINE			
 <p>ViraDx™</p>	 <p>FebriDx® Digital</p>	 <p>FebriDx® Multi-Use</p>	<p>UriDx™</p> <p>SepsiDx™</p>
Influenza A/B and COVID-19 antigen	A connected, multi-use reusable platform to include FebriDx	Reusable, digitally read FebriDx results	UriDx™ Urinary tract infection SepsiDx™ Blood stream infections

¹ In various global markets based on required regulatory approvals

Lumos Commercial Services



Lumos' commercial services business provides clients with a complete, end-to-end POC solution



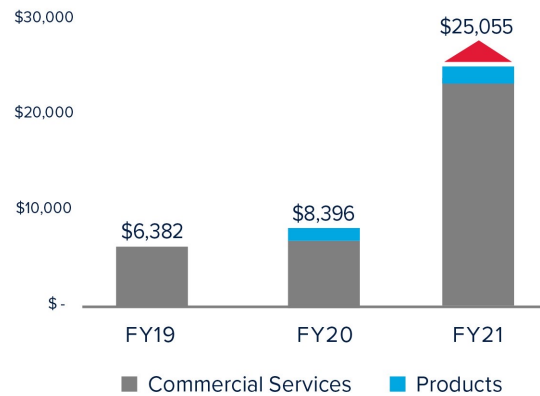
1. Assays are investigative procedures that qualitatively assess a compound or examine a compound's effects on identified molecular, cellular, or biochemical targets.

FY21 Revenue

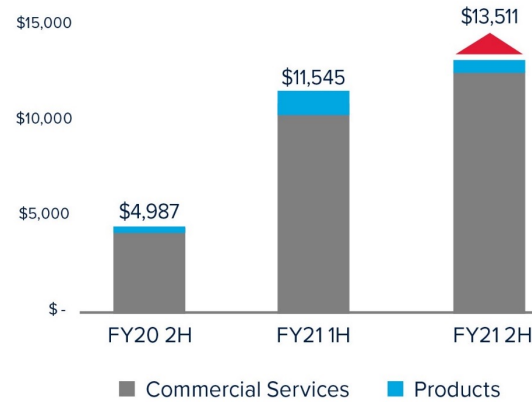


(A\$ in thousands)

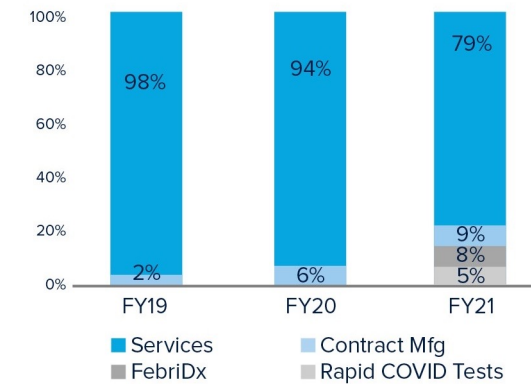
GROUP REVENUES (STATUTORY)



GROUP REVENUES (HALF YEAR)



REVENUE MIX BY BUSINESS SEGMENT



COMMENTARY

A record year

- Lumos reporting group revenues of A\$25.0M, up \$198% on FY20
- Commercial Services revenue of A\$22.7M, up 188% on FY20, 91% of group revenue
- Product revenue of \$2.3M with initial commercial sales of FebrIDx® in the UK, Germany and Canada
- Increasing diversification of revenue mix

Strong demand for services during FY21

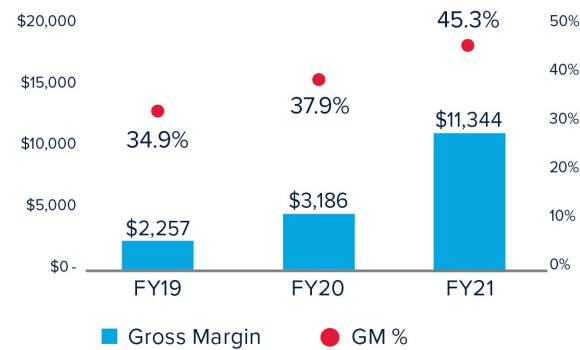
- High demand from partners for development and contract manufacturing services
- Won 30 proposals for work spanning 10 different programs
- High levels of staff utilisation (95%) with an aim to return to industry norm (80—85% utilisation) in FY22

FY21 Margin, OPEX & EBITDA

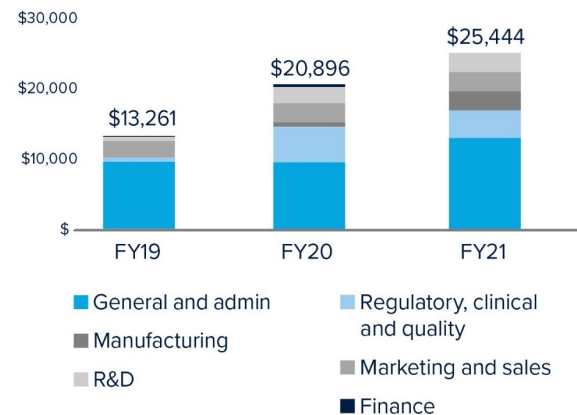


(A\$ in thousands)

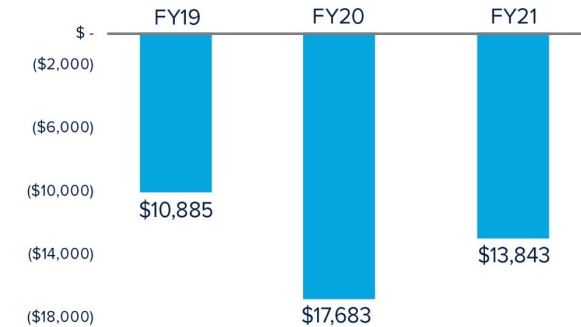
GROSS MARGIN (PRO FORMA)¹



OPERATING EXPENSES (PRO FORMA)



EBITDA (PRO FORMA)



COMMENTARY

Gross margin evolving with revenue mix

- Ahead of prospectus forecast
- Higher margin development services driven by pandemic demand
- Contract manufacturing margins remain strong as opportunities initiated in FY21 carry over in FY22
- Product margins expected to improve as sales volumes increase

Investment in growth and operations

- Actual EBITDA ahead of prospectus forecast by \$0.9M
- DISRUPT clinical trials to submit for U.S. FDA clearance for FebriDx®
- Addition of commercial manufacturing capacity able to produce 10 million tests per month
- Increased investment in European and North American sales and marketing infrastructure

¹ Pro-forma gross margin analysis in recent prospectus reflected impact of out-sourced reader development services under Planet Innovation MSA which is expected to reduce in FY22.

FY22 First Quarter Highlights



Listed on the ASX



Listed on the Australian Stock Exchange (ASX) on 5 July 2021 following a successful Initial Public Offering (IPO) that raised A\$63M at \$1.25 per share.

Appointed Strategic Healthcare Adviser



Appointed Dr Jerome Adams, immediate former U.S. Surgeon General, as a Strategic Healthcare Adviser on Lumos' Medical Advisory Board.

Expanded Operations



Commenced operations at its new manufacturing facility in Sarasota, Florida, USA capable of producing up to 10 million POC test strips per month.

Performed on 11 active R&D service contracts at various stages of development.

FebriDx Featured in Medical Journals



FebriDx® was featured in two highly regarded peer-reviewed medical journals:

The Journal of Health Economics & Outcomes Research (JHEOR)

The British Medical Journal (BMJ)

FY22 Outlook

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Lumos is well positioned as an emerging technology leader in the rapidly growing global POC diagnostics industry. Looking ahead, there are attractive near- and long-term growth opportunities in every segment of our business.

Rob Sambursky, MD
President & CEO
Lumos Diagnostics



Solid, **diversifying revenue mix** in FY22 driven by expansion of product business and contract manufacturing



Broader engagement with clients as a result of expanded Commercial Services offerings



New commercial scale manufacturing facility providing significant **new revenue stream** in FY22



FebriDx U.S. commercialisation following U.S. FDA 510(k) clearance and the follow-on publication of clinical trial results and U.S. cost analyses

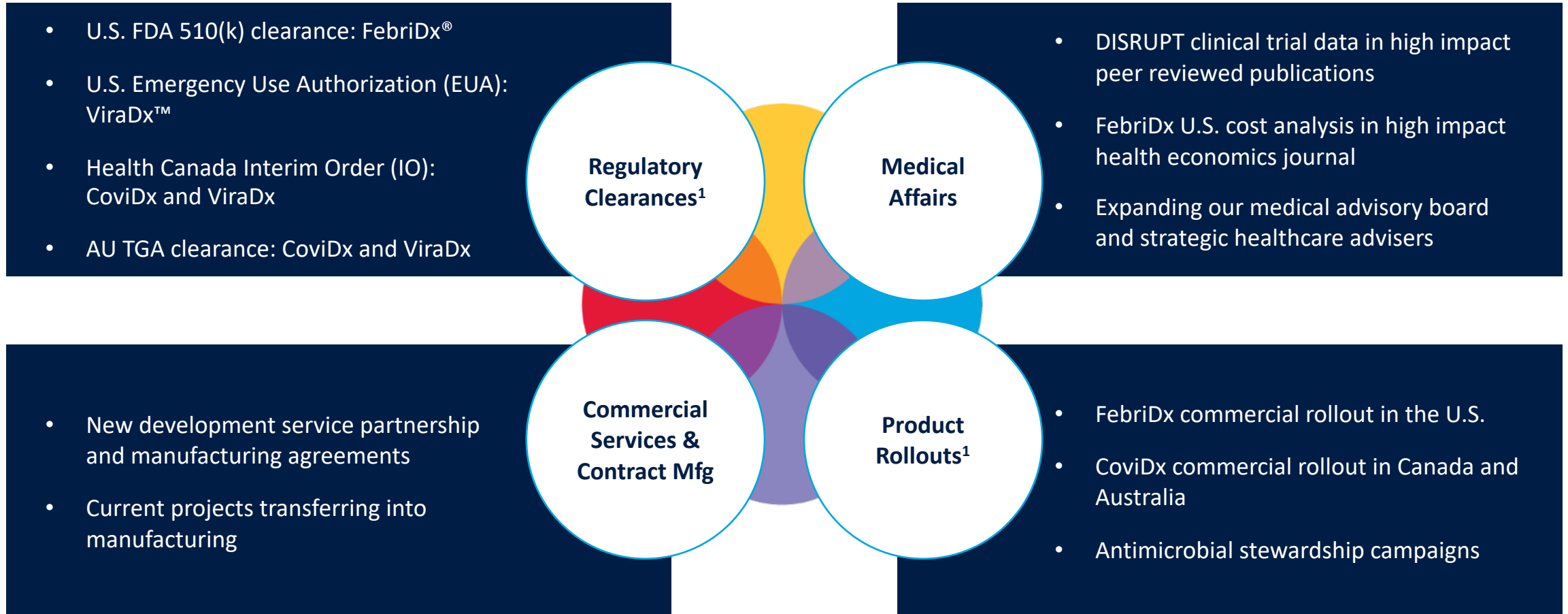


Product portfolio expansion with broader market access and expected launches of **CoviDx** and **ViraDx** in FY22



Expanded sales of **Lumos-branded digital POC diagnostic products** through existing distribution channels

FY22 Milestones & Achievements



¹ Pending required regulatory approvals in each country

Operational Leadership Team



Rob Sambursky, MD
CEO and Board Member

Founder of RPS Diagnostics. 25+ years in clinical, medical sciences, ophthalmology and infectious disease



Sacha Dopheide, PhD
Chief Technology Officer

Commercially driven biomedical scientist with a proven track record in IVD and POC diagnostics



Jill Thompson
Sr VP of Corporate Strategy and Development

25 years of experience in life science and diagnostics industry leading licensing, M&A, and business development



Aaron Erlandson, MBA
Sr VP of Finance

20+ years experience in diagnostics leading financial and accounting activities, including business planning, forecasting, compliance & audit functions



Jeff Bishop, PhD
Sr VP of Research and Development

25+ years as an R&D leader in the diagnostics space including deep expertise in point of care applications



Jennifer Christiansen
VP of Corporate Marketing and Communications



Jason Inman
VP of Information Technology

25+ years experience in the IT healthcare industry leading ERP and implementation to support sales, manufacturing & accounting



Kurt Phinney
Vice President of Operations

Experienced operations director with deep capability in infectious disease assay development and production



Sarah Glubka
Sr Director of Human Resources

17+ years of Human Resources experience developing business initiatives, fostering employee engagement and mobilizing talent



Annie Bell MSN, APN
Sr Director of Medical Affairs

15+ years managing clinical trial design and submission (FDA), and direct clinical practice in nursing



Sue Hibbeln, MS, RAC
Sr Director of Regulatory Affairs

15+ years of Regulatory Affairs and Quality Assurance experience in medical devices, including IVD devices, software, hardware, implants and sutures



Huan Tran
Director of Quality

18 years of experience in both Quality and Regulatory Affairs within the IVD industry including FDA QSR, ISO 13485, MDSAP and HIPAA

Lumos Board of Directors



■ Executive Directors

- Sam Lanyon (Chair)
- Rob Sambursky (CEO and President)

■ Non-Executive Directors

- **Larry Mehren**

Global business leader in healthcare including CEO/Exec roles at Accelerate Dx and Ventana

- **Catherine Robson**

20 years of financial leadership and audit committee experience

- **Bronwyn Le Grice**

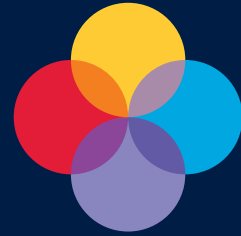
15+ years in health-tech and venture capital. Founder and Managing Director, ANDHealth

■ Company Secretary and Chief Financial Officer

- **Melanie Leydin**

25+ years of ASX-listed CFO and Company Secretary experience





LUMOS
DIAGNOSTICS

www.lumosdiagnostics.com