



Lumos Diagnostics Holdings Limited FY2022 Half Year Update

28 February 2022

www.lumosdiagnostics.com

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1H FY22 at a Glance

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We have been strategically navigating the pandemic to maximize opportunities while making every effort to mitigate the risks.

Lumos experienced the same supply chain, labour and regulatory timing issues felt by companies across the global healthcare industry.

Our team is fully prepared to launch two new products in the U.S. market pending regulatory approvals expected in FY22, which has the potential to create strong shareholder value in FY23.

Rob Sambursky, MD
President & CEO
Lumos Diagnostics



US\$5.2M total revenue in 1H FY22 ▶ 38% decrease vs 1H FY21



US\$4.2M Commercial Services business unit revenue in 1H FY22 ▶ 42% decrease vs 1H FY21



Launched Contract Manufacturing in 2H FY21 ▶ US\$1.0M revenue in 1H FY22



US\$1.1M Products business unit revenue in 1H FY22 ▶ 16% decrease vs 1H FY21



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



Commercial sales of CoviDx™ with material orders from Canada

Company Overview

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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



SARASOTA, FL USA



CARLSBAD, CA USA¹

¹ Move to new facility planned for 1H FY23.

Lumos Business Model

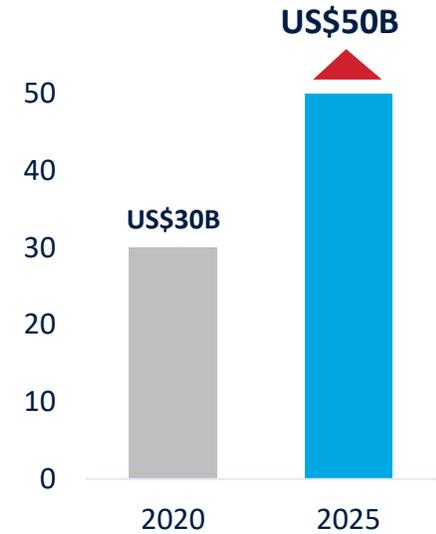


Lumos is a fully integrated innovator, developer and manufacturer of rapid POC diagnostic solutions that allow clinicians and patients to make important medical decisions quickly and accurately.



GLOBAL POC DIAGNOSTIC TEST SALES¹

(US\$ in billions)



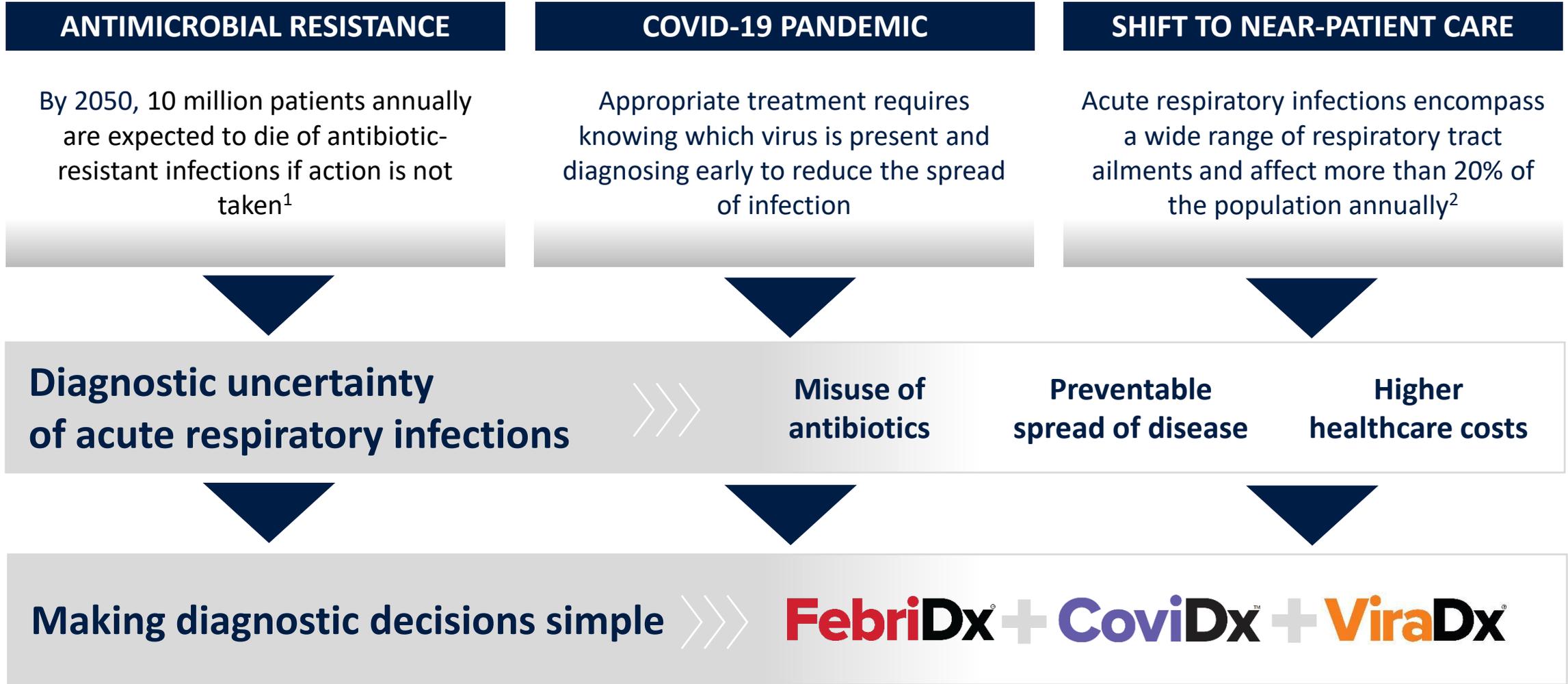
11.5% 5-year CAGR for North America & Europe

¹ MarketsandMarkets Report, 2021

The Healthcare Dilemma

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Positioned to Address Major Healthcare Challenges



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1 World Health Organization

2 Nelson KE, Williams C. *Infectious disease epidemiology: theory and practice*. 3rd ed. Jones & Bartlett Learning; 2014.

Products Business Unit

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Products Business Unit

Product Business Operating Highlights



FebriDx[®]

BACTERIAL VS VIRAL INFECTION

- The FebriDx application for U.S. FDA 510(k) clearance is under review with a decision expected in FY22.
- FebriDx received market clearance in the United Arab Emirates (UAE).
- FebriDx[®] was featured in two highly regarded peer-reviewed medical journals:
 - The Journal of Health Economics & Outcomes Research (JHEOR)
 - The British Medical Journal (BMJ)
- In January, NHS Liverpool Clinical Commissioning Group and Community Pharmacy Liverpool, UK, announced that they had launched a new clinical service at more than 100 pharmacies.

CoviDx[™]

SARS-COV-2 RAPID ANTIGEN TEST

- In November, CoviDx was granted Interim Order (IO) authorization from Health Canada.
- In December, Lumos generated orders and commercial momentum for CoviDx in Canada via new distribution partners and direct sales to a large healthcare organization.
- In January, Lumos announced that it received \$5 million in purchase orders for CoviDx.
- In February, the Victorian State Government announced intent for a support package to establish a manufacturing capability in rapid antigen tests in Victoria, which is subject to requirements, including Australian TGA approval for CoviDx self-test.

ViraDx[®]

3-IN-1 COVID-19/FLU A/FLU B TEST

- In December, Lumos completed all product validation and verification work for the 3-in-1 ViraDx test.
- In December, ViraDx was submitted to the U.S. FDA for Emergency Use Authorization (EUA).
- In February, ViraDx was submitted to Health Canada for Interim Order authorization.

FebriDx®: A Validated Rapid Test for Microbial Infection



FOR FEBRILE PATIENTS PRESENTING WITH SYMPTOMS AND SIGNS OF ARI ²

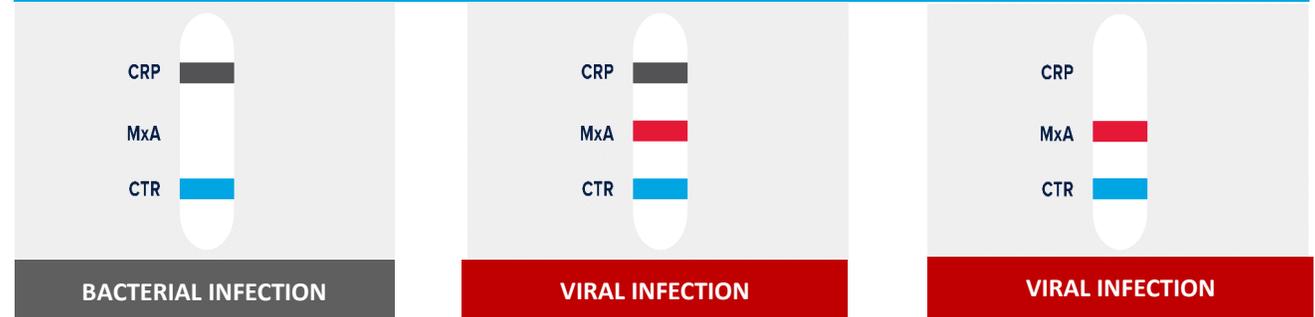
Bacterial	Sensitivity	93-95%
	Specificity	88-91%
	NPV	97-99%
Viral	Sensitivity	70-77%
	Specificity	85-90%
	PPV	90-92%

Markers for infection

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

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.

FebriDx U.S. CLINICAL EVALUATION



Can treat patient with antibiotics

*Antibiotics will not be effective
Patient needs to be managed differently*



- 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 evidence to support confirmation of microbiological 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.

FebriDx[®] Path to Commercialisation in the U.S.

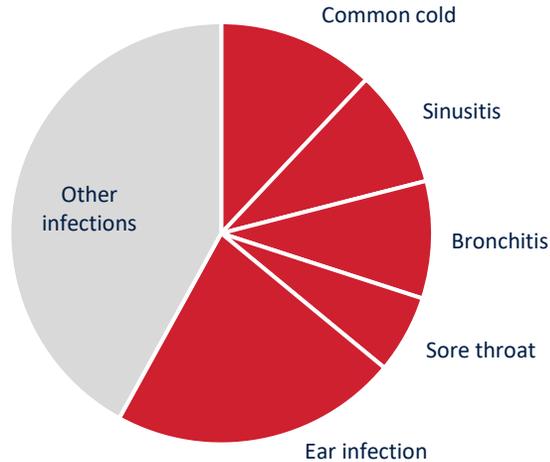


¹ Pending U.S. FDA 510(k) clearance
² Current Procedural Terminology (CPT) is a medical code set that is used to report medical, surgical and diagnostic procedures and services to entities such as physicians, health insurance companies and accreditation organizations
³ Typically takes 18-24 months

FebriDx[®]: Large U.S. Market Opportunity



ANTIBIOTICS PRESCRIBED IN THE U.S. BY TYPE



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

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ANTIBIOTICS PRESCRIBED



260M antibiotic prescriptions issued in outpatient settings each year³

44% of antibiotic prescriptions are written to treat patients with ARIs

but **50%** of these are unnecessary

FebriDx[®] is applicable for **150M** patient interactions each year^{1,2}



¹ <https://www.jucm.com/improving-appropriate-antibiotic-use-common-clinical-conditions-urgent-care>.

² Unnecessary Antibiotics for Acute Respiratory Tract Infections: Associations with Care Setting and Patient Demographics, 2016.

³ Centers for Disease Control and Prevention. Outpatient antibiotic prescriptions, United States, 2017.

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

CoviDx™: COVID-19 Rapid Antigen Test



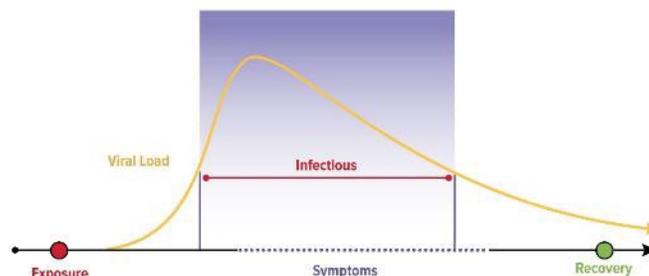
SIMPLE TEST PROCEDURE → RESULTS IN 15 MINUTES



- Launched into Canada 1H FY22 and will enter into Australia pending regulatory approval
- Initial sales commenced in Europe
- Used in conjunction with FebriDx for diagnosing acute respiratory infection patients
- Manufactured in the U.S.
- Clinically and commercially synergistic with FebriDx

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



STRONG US 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%)		

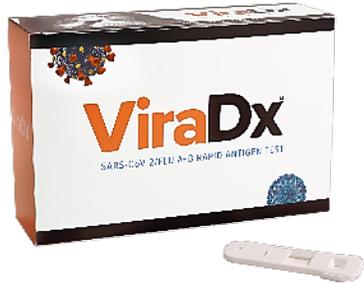
¹ Adapted from Crozier A. Put to the test: Use of rapid testing technologies for Covid-19. *Br Med J.* 2021;372:n208. <https://doi.org/10.1136/bmj.n208>

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

ViraDx: 3-in-1 COVID/Flu A/Flu B Rapid Antigen Test



ONE SAMPLE → THREE RESULTS IN 15 MINUTES



Professional use at the point of care with results in 15 minutes



Suspected respiratory viral infection consistent with COVID-19 within 5 days

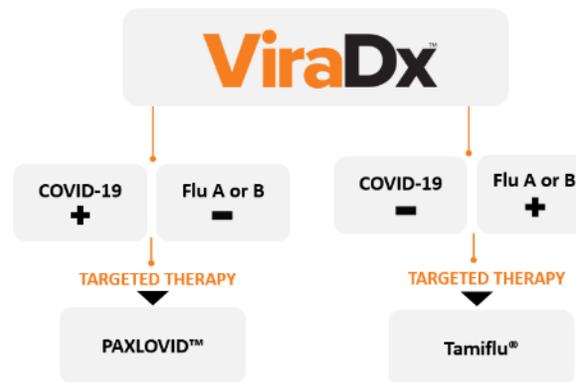


Nasal or nasopharyngeal swab



Patients 1 year of age or older

COVID-19 and influenza symptoms are nearly identical.



Easy to use and interpret

Simple test procedure for outpatient & inpatient settings

No instruments or lab equipment required

Diagnostic confidence

COVID-19: Sensitivity 93.4%; Specificity 100%

Flu A: Sensitivity 91.4%; Specificity 95.7%

Flu B: Sensitivity 87.6%; Specificity 95.9%

MARKET OPPORTUNITY

Under review with U.S. FDA for Emergency Use Authorization (EUA)

Under review with Health Canada for Interim Order authorization

Manufactured in the U.S.

Clinical and commercial synergies with FebriDx

Dedicated CPT code with \$31 reimbursement

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			
 FebriDx	 CoviDx	 Lumos Readers	
Test to differentiate bacterial from viral acute respiratory infection	COVID-19 rapid antigen test	A suite of proprietary digital reader formats including connectivity options	
PIPELINE			
 ViraDx	 FebriDx Digital	 FebriDx Multi-Use	UriDx™ SepsiDx™
3-in-1 Flu A/B and COVID-19 rapid antigen test	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 clearances.

Commercial Services Business Unit

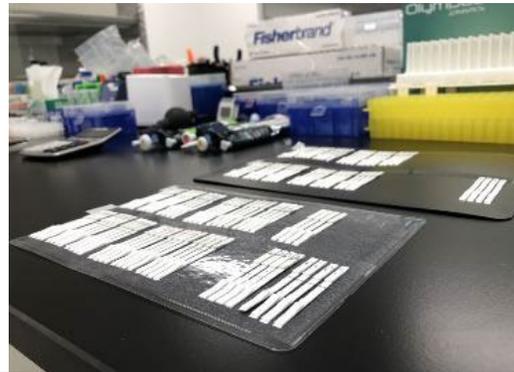
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Commercial Services Operating Highlights

Contract services provide consistent revenue that mitigates against product regulatory delays and seasonality while supporting better product margins and increased capacity.



Research & Development



Pilot-to-Commercial Scale Manufacturing Capabilities



CONTRACT DEVELOPMENT

- Lumos' Services has eleven (11) active contract development service programs in various stages of development including:
 - Early feasibility and development
 - Advanced verification and validation
 - Transfer to manufacturing

CONTRACT MANUFACTURING

- Launched contract-based, commercial scale manufacturing to meet client demand for end-to-end solutions
 - Long-term revenue stream with existing clients
 - Attractive capacity for large scale manufacturing
 - Solid margins across all products expected to improve with scale
- Lumos' commercial partner, Diabetomics, secured U.S. FDA EUA for its CovAb™ COVID-19 antibody test.
 - Lumos is performing full scale contract manufacturing of the CovAb test in its Sarasota, FL facility
 - Monthly production volumes grew in 1H FY2022 in conjunction with demand for the test

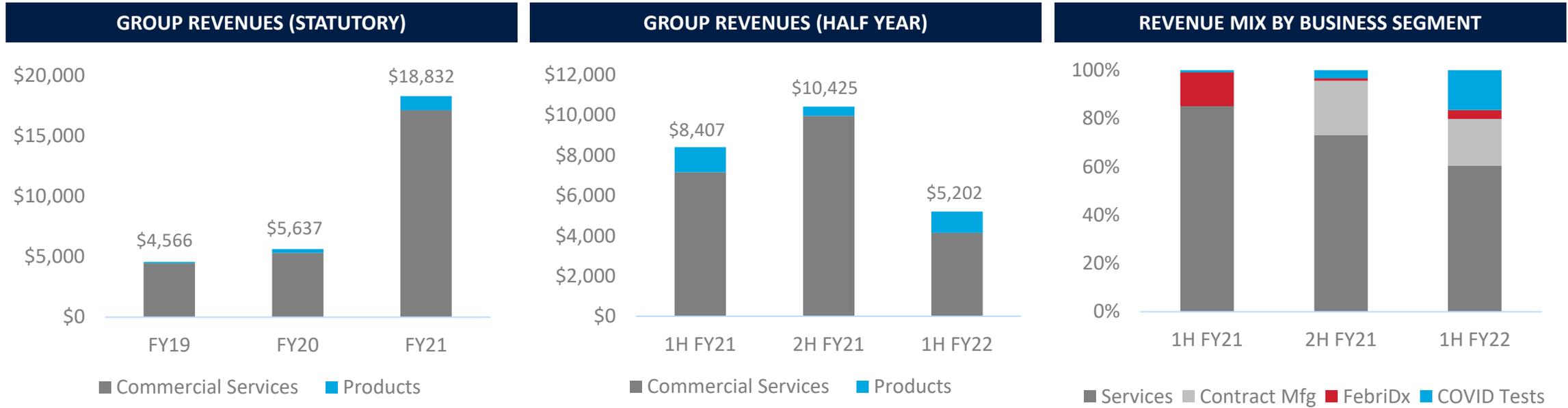
Financial Highlights

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Revenue



(US\$ in thousands)



COMMENTARY

A year of transition

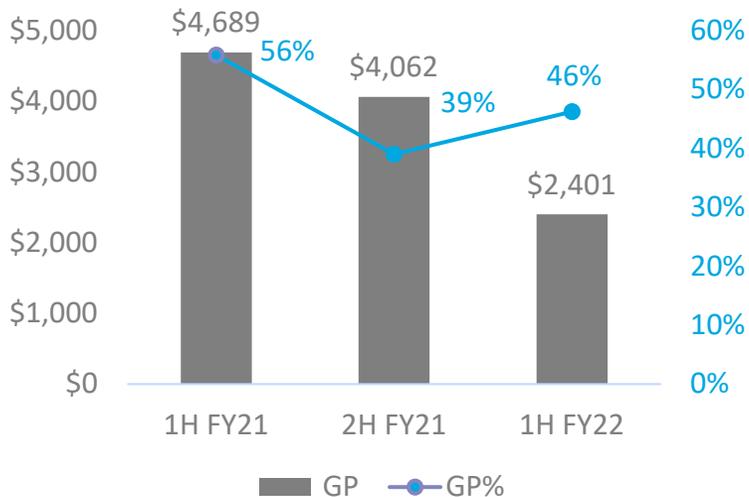
- Lumos reporting group revenues of \$5.2M, down 38% from 1H FY2021
- Commercial Services revenue being driven by 11 ongoing development programs in various phases
- Contract development revenue weakened as a result of lower COVID-related development activities
- Contract manufacturing established with \$1.0M in revenue
- Product revenue driven by initial CoviDx sales in Canada; FebriDx revenue in U.S. gated by regulatory approval
- Increasing diversification of revenue mix

Gross Profit, OPEX & EBITDA

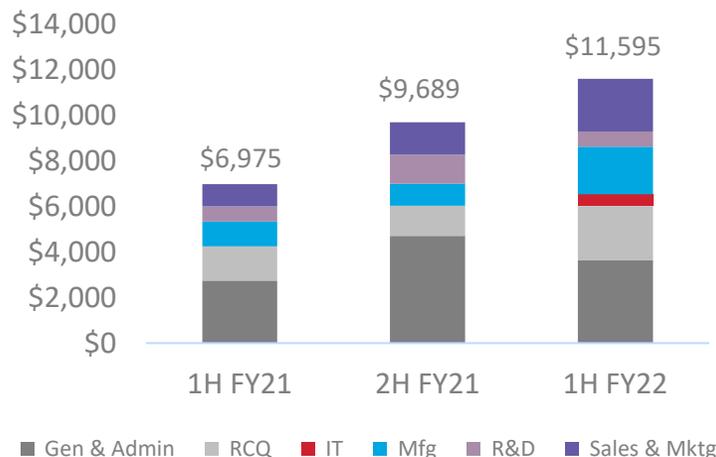


(US\$ in thousands)

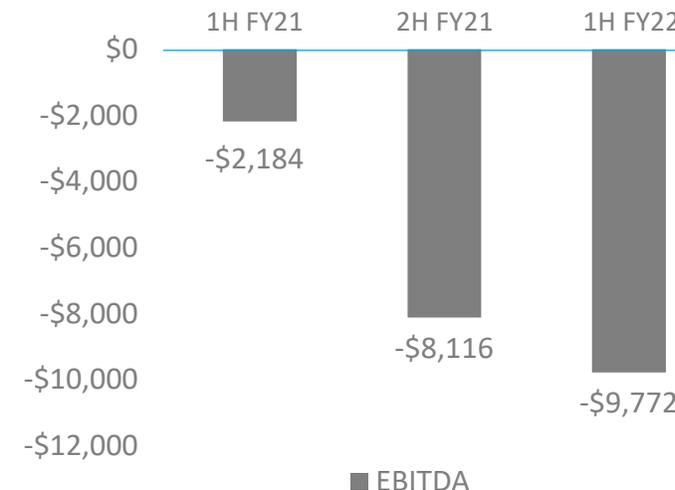
GROSS PROFIT (PRO FORMA)¹



OPERATING EXPENSES (PRO FORMA)²



EBITDA (STATUTORY)³



COMMENTARY

Gross profit evolving with revenue mix

- Improving gross margins with contract manufacturing and product focus
- Higher FY21 margin in contract development 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

- Operating expenses (adj. for IPO/non-recurring costs) reduced G&A, investment in S&M and manufacturing establishment to support future growth
- EBITDA loss reflects investment to position the business for future growth
- DISRUPT clinical trial completed and FebriDx® under review for U.S. FDA 510(k) clearance

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

² Adjusted for IPO & non-recurring costs.

³ Statutory EBITDA as per HY accounts restated to US currency subject to FY22 audit completion .

1H FY22 Corporate 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 A\$1.25 per share.

In January, Lumos changed its presentation currency from Australian dollars to U.S. dollars reflecting that the majority of the Company's revenues and costs are incurred in U.S. dollars.

EXPANDED U.S. OPERATIONS & LAUNCH OF CONTRACT MANUFACTURING

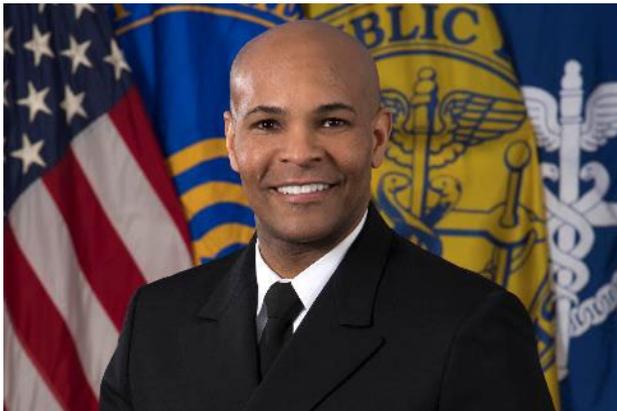


Commenced operations at its new manufacturing facility in Sarasota, Florida, USA capable of producing up to 10 million POC test strips per month.

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

Performed full scale contract manufacturing for Diabetomics.

DR. JEROME ADAMS, 20TH U.S. SURGEON GENERAL



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

In November, Lumos launched a significant campaign to promote Antimicrobial Resistance (AMR) with Dr. Adams as primary spokesperson, which delivered national media coverage.

FEBRIDX MARKET DEVELOPMENT



FebriDx[®] was featured in two highly regarded peer-reviewed medical journals: The Journal of Health Economics & Outcomes Research (JHEOR) and The British Medical Journal (BMJ).

FebriDx received market clearance from the UAE and is under review for U.S. FDA 510(k) with a decision expected in FY22.

Promising 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 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



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

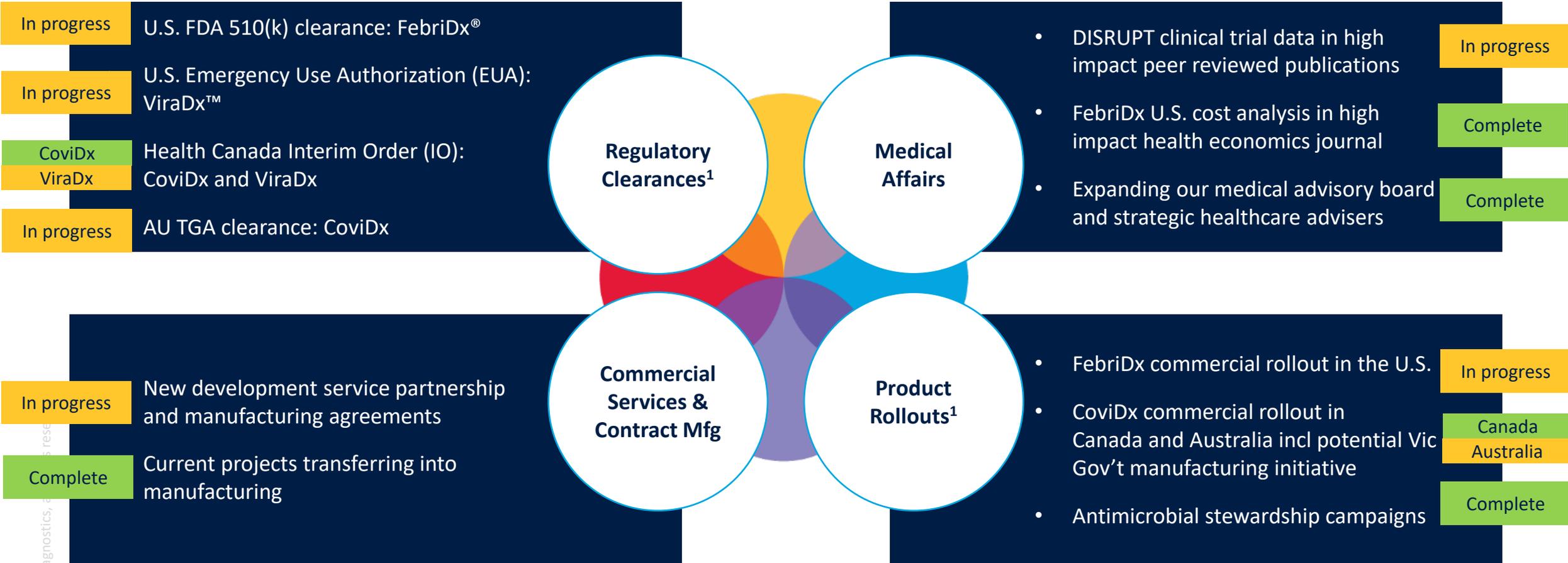


Product portfolio expansion with broader market access and expected launches of CovidX and ViraDx



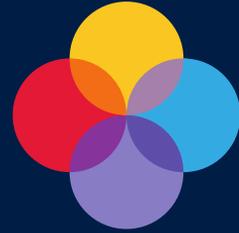
Expanded sales of Lumos-branded POC diagnostic products through existing distribution channels

FY22 Milestones & Achievements – Progress Update



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¹ Pending required regulatory approvals in each country



LUMOS
DIAGNOSTICS

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