Lumos Diagnostics Holdings Limited
FY21 Results Briefing

30 August 2021

www.lumosdiagnostics.com

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Lumos Diagnostics (ASX:LDX)

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

Company Overview

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

(A$ in millions)

KEY COMPANY DATA				SHARE REGISTER BREAKDOWN		
Share Price[1]	Shares on Issue	Market Cap[1]	Cash Balance[2]	Institutions	Corporate	Retail
$1.20	150M	$186.0M	$59.7M	38%	37%	25%

SARASOTA, FL USA

CARLSBAD, CA USA[3]

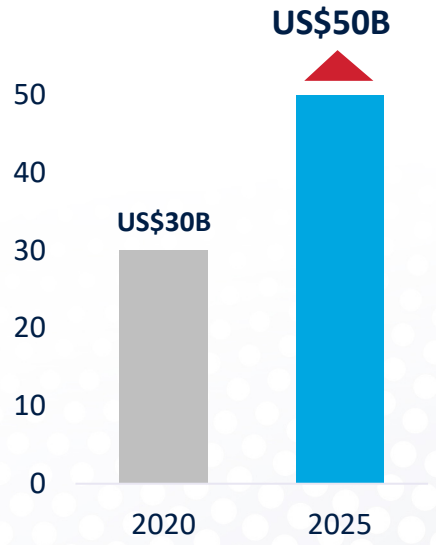
[1] As of close of trade on 27 August 2021
[2] Cash balance on 30 June 2021 includes IPO proceeds net of costs and includes funds for settlement of sell-down of A$25M
[3] Move to new facility begins in 2H FY22

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 SALES[1]

(US$ in billions)



11.5% 5-year CAGR for North America & Europe

[1] MarketsandMarkets Report, 2021

Products Business Unit

Product Business Operating Highlights

- Revenue of A$2.3M from product sales, up significantly from FY20
- Majority of product revenues from sale of FebriDx® in the UK, Germany and Canada
  - Limited ability to target primary care users during FY21 due to COVID-19 restrictions
  - Offset by opportunistic sales to hospitals using FebriDx as screening tool
    - Rapid identification of patients with potential COVID-19 infection
    - Faster results than PCR to identify an underlying viral infection that may benefit from additional pathogen confirmation
    - Four clinical studies on FebriDx as a screening tool published in peer-reviewed journals
    - Accelerated awareness of FebriDx, which will support future marketing efforts
- Initial launch sales of CoviDx™ in European market
  - Rapid COVID-19 antigen test based on in-licensed technology and reagents
  - High sensitivity and specificity compared to the highest performing PCR molecular tests
  - Integrated with Lumos digital reader platform in partnership with DiaSorin

FebriDx®: A Validated Rapid Test for Microbial Infection

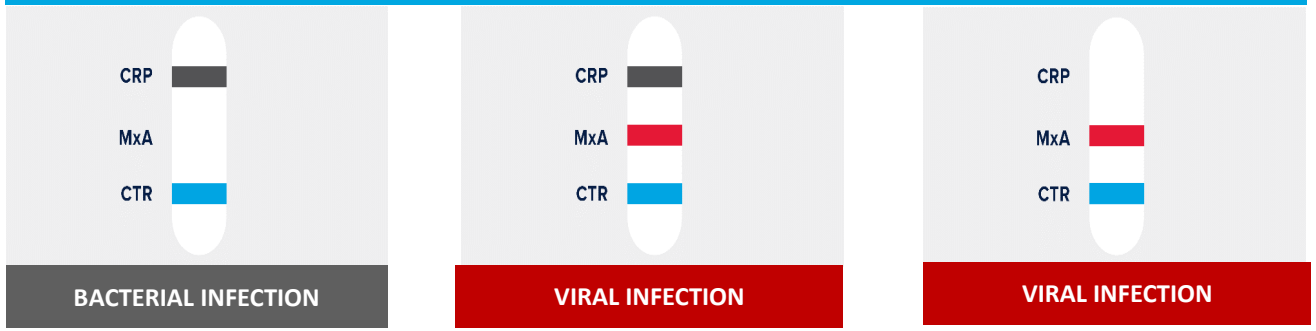
FOR FEBRILE PATIENTS PRESENTING WITH SYMPTOMS AND SIGNS OF ARI [2]		
Bacterial	Sensitivity	95%
	Specificity	91%
	NPV	**97%**
Viral	Sensitivity	77%
	Specificity	85%
	PPV	**92%**

Markers for infection

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

FebriDx® 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 performance for microbiologically confirmed infection and final clinical diagnosis

[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.

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

- U.S. commercial launch in FY22 pending U.S. FDA 510(k) clearance
- Initial launch focus on the US$500M+ specialty outpatient markets not reliant on reimbursement
  - Developed a hybrid sales strategy based on immediate direct and future distribution sales
  - Built a sales and marketing foundation for future milestone-driven growth
  - Established a world class multi-specialty medical advisory board
- Leveraged the DISRUPT clinical trial sites to initiate pilot programs in target markets to support future reimbursement that unlocks the full US$2-3B TAM in FY23-24
- Ability to bundle FebriDx with a COVID-19 antigen or COVID/Flu to maximise product sales and physician reimbursement

Launch in the U.S. market[1] in FY22

Focus on markets not reliant on reimbursement

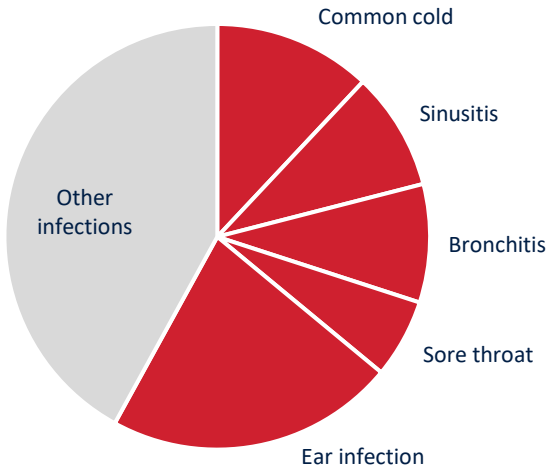
Commercial pilots support reimbursement strategy

CTP codes[2] enable reimbursement[3]

[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 still account for 58% of all antibiotics prescribed.[4]

ANTIBIOTICS PRESCRIBED

260M antibiotic prescriptions issued in outpatient settings each year[3]

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.

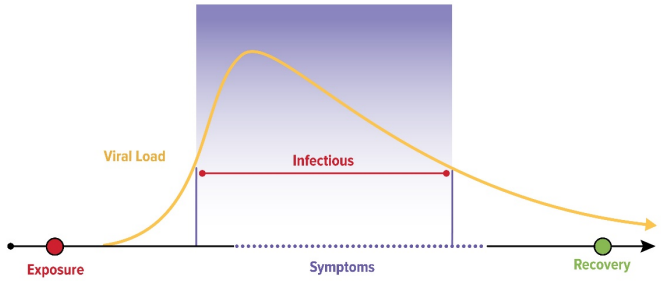
CoviDx™: Rapid COVID-19 Antigen Test Solution

SIMPLE TEST PROCEDURE → RESULTS IN 15 MINUTES

- Initial sales commenced into Europe
- Launch in the U.S., 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

SARS-CoV-2 Viral Load Over Course of Infection[1]

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



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%)		

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

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

CURRENT PRODUCTS[1]

Differentiate viral from bacterial acute respiratory infection

COVID-19 antigen

A suite of proprietary digital reader formats including connectivity options

PIPELINE

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

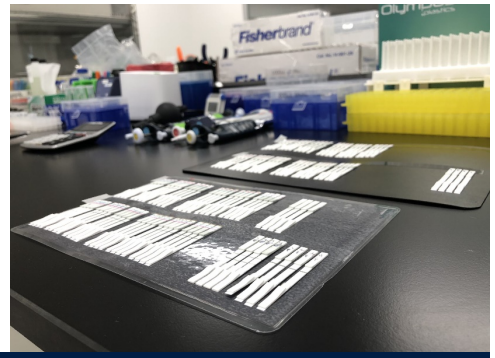
SepsiDx™
Blood stream infections

[1] In various global markets based on required regulatory approvals

Commercial Services Business Unit

Commercial Services Operating Highlights

- Record revenue of A$22.7M in FY21, up 188% from FY20
- Success winning contracts with new and existing clients
  - Won 30 contracts spanning 10 development programs in FY21
- Strong demand for POC diagnostic tests R&D services continues
  - Non-COVID and COVID-related growth
  - Broad range of clients across multiple markets
- 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



Research & Development

Pilot-to-Commercial Scale Manufacturing Capabilities

Financial Results Overview

FY21 Profit & Loss

(A$ in millions)

FY21 RESULTS vs FORECAST (PRO FORMA)

	FY19A	FY20A	FY21A	Prospectus	Variance
Product revenue	0.2	0.5	2.3	2.9	(0.6)
Services revenue	6.2	7.9	22.7	20.9	1.8
Revenue	**6.5**	**8.4**	**25.0**	**23.8**	**1.2**
Cost of sales [1]	(4.2)	(5.2)	(13.7)	(12.5)	(1.2)
Gross Profit	**2.3**	**3.2**	**11.3**	**11.2**	**0.1**
Sales and marketing expenses [2]	(2.8)	(2.6)	(3.2)	(3.2)	-
General and administrative expenses [3]	(10.1)	(15.7)	(19.8)	(20.5)	0.7
Research and development expenses [4]	(0.3)	(2.5)	(2.4)	(2.0)	(0.4)
Total Operating Expense	**(13.2)**	**(20.9)**	**(25.4)**	**(25.8)**	**0.4**
EBITDA before non-operating items	**(11.0)**	**(17.7)**	**(14.1)**	**(14.6)**	**0.5**
Non-operating items	0.1	-	0.3	(0.1)	0.4
EBITDA	**(10.9)**	**(17.7)**	**(13.8)**	**(14.7)**	**0.9**
Depreciation and amortisation	(0.8)	(0.7)	(0.7)	(0.5)	(0.2)
EBIT	**(11.7)**	**(18.4)**	**(14.5)**	**(15.8)**	**1.3**
Net finance costs	-	-	-	(0.2)	0.2
Profit (loss) before taxation	**(11.7)**	**(18.4)**	**(14.5)**	**(16.0)**	**1.5**

[1] The pro forma historical and forecast cost of sales includes a pro forma adjustment to the direct labour costs associated with the provision of Commercial Services to reflect the additional costs that would have been incurred by Lumos had the Amended Planet Innovation MSA (which will become effective on 1 July 2021) been in place since 1 July 2018.

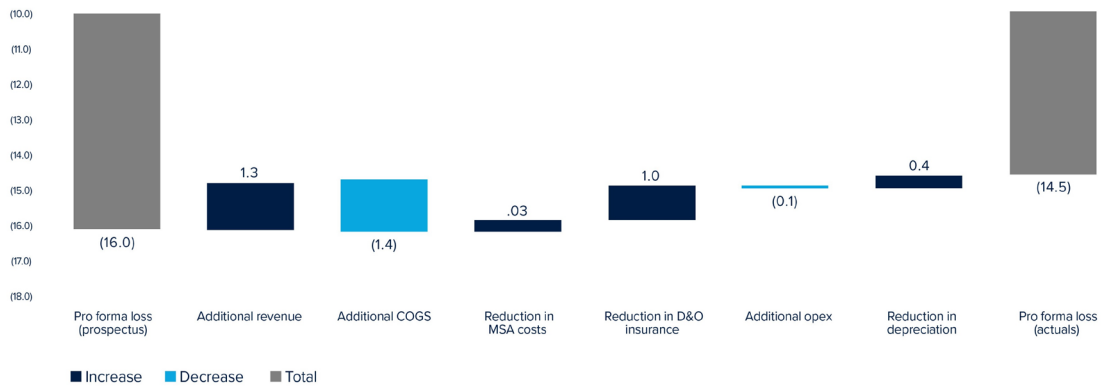
[2] Includes business development, marketing and sales which includes both labour and associated overheads

[3] Includes administrative, manufacturing and clinical/quality overhead which includes both labour and associated overheads

[4] Predominately includes personnel costs

COMMENTARY

FY21 Pro Forma Loss Bridge – Prospectus > Annual Report

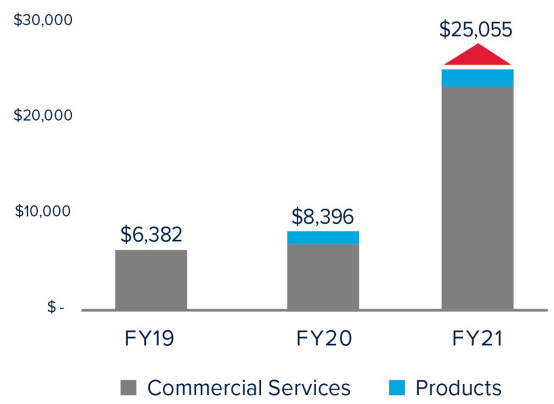


- Revenue growth of 198%
- EBITDA better than prospectus forecast
- Products revenue as a % of total revenue increasing. Variance to prospectus due to CM timing (orders into FY22)
- Gross margin has further scope to improve as product revenue increases
- Sales and marketing expenses increases reflect investment into future growth
- Research and development expense relatively stable over FY20 and FY21
- General and administrative expenses include regulatory, clinical affairs, quality and manufacturing establishment
- Clinical trials expenses (DISRUPT) incurred over FY20 and FY21

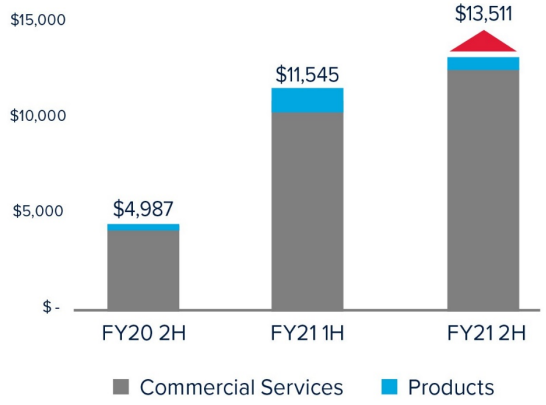
FY21 Revenue

(A$ in thousands)

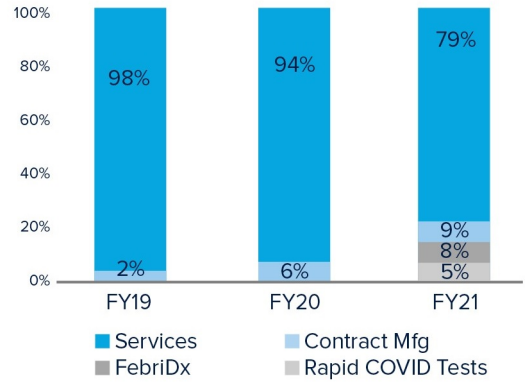
GROUP REVENUES (STATUTORY)



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

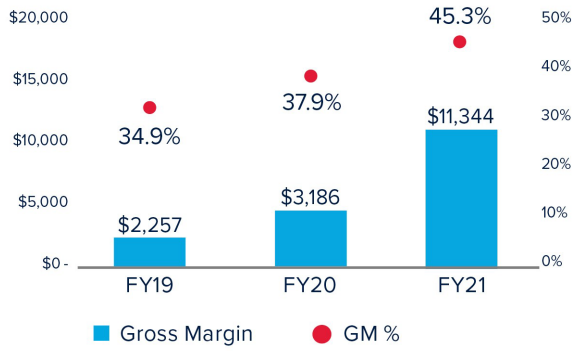
Strong demand for services during FY21

- 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

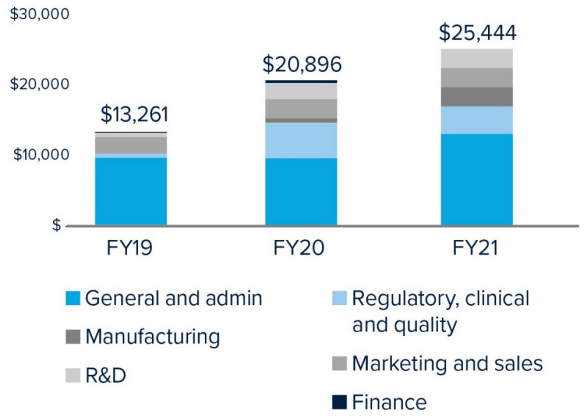
FY21 Margin, OPEX & EBITDA

(A$ in thousands)

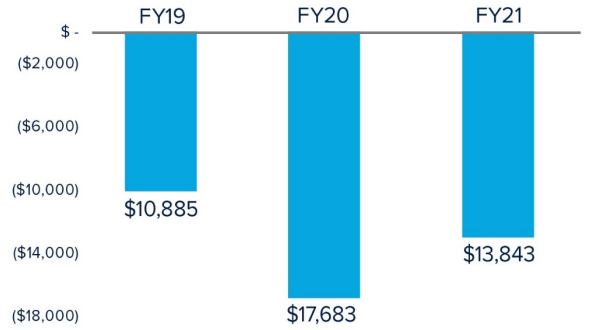
GROSS MARGIN (PRO FORMA)[1]



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.

FY21 Cash Flows

(A$ in millions)

CONSOLIDATED PRO FORMA HISTORICAL CASH FLOWS, PRO FORMA PROSPECTUS CASH FLOWS

	FY19A	FY20A	FY21A	Prospectus	Variance
EBITDA before non-operating items	(11.1)	(17.7)	(14.1)	(14.6)	0.5
Adjustments to EBITDA[1]	1.0	1.4	0.9	1.2	(0.3)
Non-operating revenue / expenses	0.1	-	0.3	0.2	0.1
Changes to working capital[2]	1.8	0.8	2.8	1.1	1.7
Operating cash flow	**(8.1)**	**(15.5)**	**(10.2)**	**(12.1)**	**1.9**
Capital expenditure	(0.9)	(0.4)	(10.6)	(10.8)	0.2
Payments for investment[3]	(0.3)	-	-	-	-
Capitalised development cost[4]	(4.3)	(5.6)	(3.5)	(3.4)	(0.1)
Free cash flow	**(13.6)**	**(21.6)**	**(24.3)**	**(26.3)**	**2.0**

[1] Adjustments to EBITDA: Includes non-cash items including share-based payments, bad debts, inventory write-offs and unrealised foreign currency gains/(losses).

[2] Changes in working capital: Are impacted by changes in trade receivables, trade payables, inventory levels, prepayments, accrued income, unearned income and employee provisions.

[3] Payment for purchase of business, net of cash acquired: Relates to the RPS Acquisition in FY19, of which the costs associated have been removed as a pro forma adjustment to reflect the one-off nature of the costs.

[4] Capitalised development costs: Includes a pro forma adjustment to the direct labour costs associated with the provision of Commercial Services to reflect the additional costs associated with PI MSA.

COMMENTARY

- Underlying EBITDA improvement over forecast ($0.5M) due to higher revenues and lower than anticipated operating expenditure in prospectus forecast
- Increased capital expenditure represents investment in new Sarasota, Florida facility to increase capacity
- Majority of capital expenditure related to Sarasota manufacturing establishment complete
- Capitalised development costs relate to ongoing R&D investment in technology platform (hardware and software) which is carried out in Australia
- Financing cashflows are detailed in the annual report and relate to net proceeds from Pre-IPO and IPO fundraisings completed in FY22

Balance Sheet

(A$ in millions)

	Statutory 30 June 2020	Statutory 30 June 2021
Assets		
Current assets		
Cash and cash equivalents	1.2	59.7
Trade and other receivables	1.4	5.7
Inventories	0.7	6.1
Prepayment and other assets	2.0	4.6
Total current assets	**5.3**	**76.1**
Non-current assets		
Financial assets held at cost	0.3	0.3
Deferred tax assets	0.1	-
Right-of-use assets	5.9	11.5
Property, plant and equipment	0.9	8.3
Intangibles	31.4	34.4
Total non-current assets	**38.6**	**54.5**
Total assets	**43.9**	**130.5**
Liabilities		
Current Liabilities		
Trade and other payables	4.5	32.3
Lease liabilities	1.3	1.0
Employee benefits	0.6	2.5
Contract liabilities	0.7	7.5
Total current liabilities	**7.1**	**43.2**
Non-current liabilities		
Lease liabilities	4.7	9.6
Total non-current liabilities	**4.7**	**9.6**
Total liabilities	**11.8**	**52.8**
Net Assets	**32.1**	**77.7**
Equity		
Ordinary shares	23.1	116.2
Preference shares	27.5	-
Reserves	1.5	1.7
Accumulated losses	(20.0)	(40.2)
Total Equity	**32.1**	**77.7**

COMMENTARY

- **Cash balance** of $59.7M reflects IPO proceeds of $38.0M inclusive of $25.0M reserved for sell-down related to the IPO. The opposing sell down amount payable is within the $32.3M trade payable balance at year end.
- **Prepayments** of $4.6M largely relate to equipment being built on Sarasota facility. Increase in PPE of $7.0M largely relates to construction underway at the same facility.
- **Right of use asset** increase of approximately +$6.0M due to establishment of Carlsbad and Sarasota facilities in line with AASB 16. The lease liability balances of $9.6M correspond to these facilities as well.
- **Ordinary shares** increased to $116.2M during the period, being an increase of $93.1M attributable to:
    - Proceeds from IPO of $38.0M
    - Conversion of preference shares into ordinary shares of $29.5M
    - Conversion of convertible note into ordinary shares of $28.0M
    - Issue of shares on execution of options of $0.2M
    - Offset by cost of IPO and share issue of $2.6M
- **Reserves** increased by $0.2M, being an increase in the share-based payment reserve of $1.1M, offset by decrease in foreign currency reserve of $0.9M.

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

Regulatory Clearances[1]

- U.S. FDA 510(k) clearance: FebriDx®
- U.S. Emergency Use Authorization (EUA): CoviDx™ and ViraDx™
- Health Canada Interim Order (IO): CoviDx and ViraDx
- AU TGA clearance: CoviDx and ViraDx

Medical Affairs

- DISRUPT clinical trial data in high impact peer reviewed publications
- FebriDx U.S. cost analysis in high impact health economics journal
- Expanding our medical advisory board and strategic healthcare advisers

Commercial Services & Contract Mfg

- New development service partnership and manufacturing agreements
- Current projects transferring into manufacturing

Product Rollouts[1]

- FebriDx commercial rollout in the U.S.
- CoviDx commercial rollout in the U.S., Canada and Australia
- Antimicrobial stewardship campaigns

[1] Pending required regulatory approvals in each country

Q&A

LUMOS

DIAGNOSTICS

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