BELL POTTER

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Speculative

See key risks on Pages 5-6 and Biotechnology Risk Warning on Page 9. Speculative securities may not be suitable for Retail Clients.

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Lumos Diagnostics

Steps in the right direction

Recommendation
Buy (Buy)
Price
$0.14
Target (12 months)
$0.28 (previously $0.75)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**95.5%**
Dividend yield	**0**
Total expected return	**95.5%**

Company Data & Ratios	
Enterprise value	**$14.9**
Market cap	**$27.0m**
Issued capital	**192.7m**
Free float	**99%**
Avg. daily val. (52wk)	**$0.23m**
12 month price range	**$12.5-$1.41**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.26	0.39	na
Absolute (%)	-46.63	-63.99	na
Rel market (%)	-37.75	-54.29	na

Absolute Price

SOURCE: IRESS

A flurry of activity for LDX

Lumos has announced their cost-cutting measures in the US have been successful and resulted in scaled capacity and personnel ahead of near-term requirements at both of their US facilities (in Florida and California). The company has targeted a monthly cash burn of less than US $1.0M by the end of FY22.

They have also appointed Doug Ward, previous CEO of PGDx, and most recently, VP of Strategy and Business Development for Hologic (HOLX: NASDAQ)– the large diagnostics, surgery, and medical imaging devices company.

LDX successfully completed an institutional entitlement offer in June 2022, raising A$8m via the placement of 41.9 million shares. A retail component of the capital raise, aiming for a further A$3m, is currently still open until June 23rd 2022.

The company has provided information regarding the FDA approval process for their FebriDX asset, confirming that they were required to submit responses to a number of queries relating to the categorisation of the test. Their formal response was submitted on 9 May 2022. The FDA is expected to provide Lumos with an indicative clearance decision within 58 days of filing.

Finally, today Lumos announced that the company has secured an initial development services contract with New Jersey-based Aptatek Biosciences, Inc. for a point-of-care test for phenylketonuria (PKU).

Investment view: Valuation $0.28, Retain Buy (Spec.)

We maintain our Buy (Spec.) rating and have reduced our valuation to $0.28 from $0.75 per share. The valuation is DCF driven and we have adjusted (increased) the WACC from 11.5% to 17% to reflect the current macro environment. The dilutive effect of the new issuance of shares is also reflected in the new valuation.

Table 1 - Earnings Forecast

June Year End	FY21	FY22e	FY23e	FY24e
Revenues (A$m)	25.1	13.7	15.5	21.5
EBIT (A$m)	-14.6	-9.9	-7.5	-2.5
NPAT (A$m)	-20.1	-12.9	-10.5	-5.5
EPS (cps)	-76.4	-8.3	-5.8	-1.3
EPS growth (%)	nm	nm	nm	nm
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	0.0	0.0	0.0	0.0
Franking	0.0	0.0	0.0	0.0
Yield (%)	0.0	0.0	0.0	0.0
ROE (%)	-0.3	-0.2	-0.2	-0.1

SOURCE: BELL POTTER SECURITIES ESTIMATES

A flurry of activity for LDX

Cutting costs works a treat

Lumos has announced their cost-cutting measures in the US have been successful and resulted in scaled capacity and personnel ahead of near-term requirements at both of their US facilities (in Florida and California). The company has targeted a monthly cash burn of less than US $1.0M per calendar month by the end of FY22. LDX indicated these measures were part of the forward looking activities the company was undertaking to keep costs in line with current requirements.

Appointment of new CEO

Following an extensive executive search, Lumos announced they have appointed Mr Dough Ward, an experienced strategy and business developer in the diagnostics and life sciences sector. Mr Ward is based in the US and has held various senior commercial roles with Roche/Ventana Medical, GE, Siemens, Bayer, Chiron and Hologic, and was the CEO of well-known diagnostics company, PGDx. He has extensive experience in securing regulatory clearances and launching new diagnostic products onto the commercial market.

Update on the FDA approval process for FebriDX

FebriDx® remains, in our view, LDX's most important asset - a test that first confirms an acute upper respiratory tract infection and neatly differentiates between a viral or bacterial infection.

Both FebriDx® and ViraDx® (that tests for flu and COVID-19) remain under review by the FDA, with wait times significantly affected by both the COVID-19 pandemic and some additional questions posed by the FDA that appear to be primarily focused on the appropriate CLIA categorisation for FebriDx .

Lumos indicate they have submitted a formal supplementary response that was acknowledged by the FDA on 9 May 2022. The FDA is expected to provide Lumos with an indicative clearance decision within 58 days of filing this formal response (ie 6 July 2022). An indicative clearance still requires further time for refining of label claims and creating and finalizing the package insert. If FebriDX is approved by the FDA, Lumos will be allowed to commence marketing activities for FebriDx in the USA.

Share placement effects

LDX raised A$8m and issued 41.9 million shares via an institutional placement in June 2022. This capital raise and associated increase in shares on issue has had a material effect on our forecasts as follows (Table 2):

Table 2 - Effects of capital raise on cash balance and forecasts

Cash

A$m	FY20	FY21	FY22e	FY23e	FY24e
Previous	1.2	59.7	24.8	9.5	0.2
New	1.2	59.7	32.2	16.9	7.6
Change %	0.0%	0.0%	29.8%	78.3%	3529.4%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Note that LDX intends to raise a further A$3.2 million via a retail entitlement offer that is currently open and expected close on Thursday, 23 June 2022.

The company has indicated the capital raise will fully fund the company's activities until the end of CY22.

Lumos have provided guidance on the expected use of these funds as outlined in Figure 1. Briefly, the funds are intended for the following purposes:

- progress the current applications for regulatory clearances of FebriDx, ViraDx and CoviDx;
- Initiate the commercial launch of these products;
- support the development of Lumos' contract development and manufacturing business; and
- Working capital purposes.

Figure 1 - Expected use of funds

Sources of funds[1,2]	(US$ million)
Proceeds of Entitlement Offer	7.9
Cash at bank (as at 30 April 2022)	5.0
Total Sources	**12.9**

Expected Uses of funds[1]	(US$ million)
Infrastructure and Capacity Expansion	0.1
Sales and Marketing	3.1
Regulatory, Clinical and Quality	2.3
Development of Test Pipeline	1.0
Technology Platform Development	0.5
Working Capital	5.5
Offer Costs	0.4
Total Uses	**12.9**

[1] Assumes AUD / USD exchange rate of 0.7. [2] Assumes the Entitlement Offer is fully subscribed

SOURCE: COMPANY

New development services contract with Aptatek

Lumos today announced that the company has secured an initial development services contract with New Jersey-based Aptatek Biosciences, Inc. for a point-of-care test for phenylketonuria (PKU). PKU is a rare, inherited disorder characterized by the absence of an enzyme called phenylalanine hydroxylase (PAH). PAH is responsible for processing the amino acid phenylalanine (found in most high protein foods), and without this enzyme, phenylalanine accumulates in the body, affecting brain development and resulting in severe intellectual disabilities. In the US (and Australia), newborns are screened for PKU at the hospital (ever wondered why the nurse takes a few drops of blood from your baby's heel a day or two after birth?), yet many countries do not have such a screening program. Any patients with PKU must continually measure their phenylalanine levels and usually do this at a pathology collection centre.

The Aptatek product, developed under contract with Lumos, aims to provide a point-of-care/at-home screening test to allow PKU patients to directly measure their phenylalanine levels as often as they like. The product has achieved breakthrough status from the FDA, which should accelerate its approval timeframe.

This initial phase of the partnership with Aptatek is expected to generate at least US$0.5 million in revenue for LDX, and there is potential for further revenue in the future from additional development activities and ongoing instrument manufacturing.

Lumos Diagnostics (LDX)

COMPANY DESCRIPTION

Lumos was established in 2015 and merged with RPS diagnostics in 2019. RPS developed a variety of diagnostic tests across multiple indications. The Company's core competency lies in their proprietary assay development technology for rapid, point-of-care tests. They have three ready for use products and are in early development phases for at least two more that are not included in our forecasts due to the development stage they are at. These include a urinary tract infection (UTI) detection kit and a sepsis detection kit.

Lumos also maintains a services business that currently underpins the Company's existing earnings base. The Services business was established in 2015 and includes key customers including Diabetomics, Hitachi, DiaSorin, Merck, among others

KEY RISKS

Key risks we consider to be specific to LDX include, but are not limited to:

Commercial risk: Our forecasts assume revenue growth from both the product sales segment of the business, and from the ability of Lumos to grow contract revenues for its services business. Failure to achieve growth from either division of the revenue base would could see the company's earnings differ from both our forecasts and the company's forecasts. We note that a component of commercial risk is contingent on the ability to secure additional reimbursement codes in the US, which, if not achieved, could impede the uptake rates.

Competitive risk: There are a number of companies with tests that operate at 'point of care' for individual illnesses, including COVID 19, influenza and strep throat (group A Streptococcus), among others. These may be viewed as competition to LDX in certain instances, especially when patients present to their healthcare provider with unknown underlying aetiology. Although we understand the rationale for using a broader test like FebriDx® ahead of a more specific test, this will require somewhat of a shift in clinical practice. This may take time and is susceptible to some hesitancy from clinicians. Our view is that LDX offers a much broader diagnostic tool that can provide the gateway to more extensive testing on an as-needed basis, and is not limited by the small proportion of cases that might require more dedicated tests. The MeMed BV™ test is currently the only other available rapid test in the US capable of distinguishing between a viral and bacterial acute upper respiratory infection. MeMed signed a licensing agreement with DiaSorin to co-develop and commercialise the MeMed BV™ test in 1H21 and received FDA 510(k) approval in 2021. They are still completing their launch and roll-out. Other options all still require samples to be sent to laboratories and are not suitable for use in the point of care setting.

Clinical and regulatory risk: Lumos has shown positive clinical data with regard to the accuracy and precision of their tests including FebriDx® and CoviD®x. Lumos continues to anticipate 510k approval for FebriDx®, and we do not anticipate any major setbacks for this approval given the derisking Health Canada and CE mark approvals, as well as FDA confirmation that FebriDx® is comparable to another approved product on the US market. We also note an element of clinical risk with FebriDx®, which has not been tested

rigorously in patients with significant comorbidities. This could add an element of downstream clinical and regulatory risk for the product.

Distributor risk: The success of commercialization becomes highly dependent on the level of commitment from the distributor (currently Henry Schein Healthcare Distributor and Lumos is working to gain more contracts with others) to promote Lumos specifically, as a part of their more general point of care testing portfolio. A lack of prioritization for distributors to promote Lumos products could see sales figures differ significantly from our forecasts.

Reimbursement risk: FebriDx® and CoviDx® are expected to achieve reimbursement under existing reimbursement codes in the US. For FebriDx®, these codes provide reimbursement of $16-18/test, for MxA, with the potential for adding $5 for CRP, and will be confirmed following approval. For CoviDx®, the COVID-19 antigen test reimbursement is established at $35/test. Our view is that US reimbursement at current levels, within existing code structure, is de-risked, especially given the high sensitivity and specificity of the test vs traditionally used tests including CRP and white blood cell count. In Europe and other single-payor systems, pricing and reimbursement will need to be backed by the health economic argument put forward by Lumos with regard to the long term benefit of accurate and timely diagnosis. Our long term forecasts for FebriDx®, especially in the US, rely on additional reimbursement being secured, which drives improved levels of market share and market access. This can be a complex process that can take 18-24 months to achieve, following approval.

Financial risk: Lumos is currently a loss-making business, and is expected to continue to incur losses until FY24. The large upturn in revenue from CoviDx® over the past 12 months and the ongoing revenue from the services arm of the company should cover the operating costs, although there is always the risk that the current cash position may not be sufficient to fund this level of ongoing operating loss, and the business may require additional capital injections in the future.

Lumos Diagnostics
as at 17 June 2022

Recommendation	Buy, Speculative
Price	$0.14
Valuation	$0.28

Table 1 - Financial summary

A$m	FY20	FY21	FY22e	FY23e	FY24e
Year Ending 30 June					
Revenue	**8.4**	**25.1**	**13.7**	**15.5**	**21.5**
Change	*0%*	*198%*	*-45%*	*13%*	*39%*
Cost of sales	- 4.8	- 13.5	- 13.5	- 13.5	- 13.5
Gross profit	**3.6**	**11.5**	**0.2**	**2.0**	**7.9**
Gross margin	*43%*	*46%*	*1%*	*13%*	*37%*
Other income/(expense)	2.7	0.2	0.3	0.3	0.3
Expenses (excl. D&A, int.)	**- 19.2**	**-26.3**	**-10.3**	**-9.7**	**-10.7**
% of revenue	*-228%*	*-105%*	*-75%*	*-63%*	*-50%*
EBITDA	**- 12.1**	**-14.1**	**-7.7**	**-5.3**	**-0.4**
Depreciation and amortisation	- 0.7	-0.5	-2.2	-2.2	-2.1
EBIT	**- 12.8**	**-14.6**	**-9.9**	**-7.5**	**-2.5**
Net interest (expense)/revenue	- 0.7	-5.5	-3.0	-3.0	-3.0
Pre-tax profit	**- 13.5**	**-20.1**	**-12.9**	**-10.5**	**-5.5**
Income tax expense	0.1	0.0	0.0	0.0	0.0
NPAT	**- 13.4**	**-20.1**	**-12.9**	**-10.5**	**-5.5**

Cashflow (A$m)	FY20	FY21	FY22e	FY23e	FY24e
EBITDA	-12.1	-14.1	-7.7	-5.3	-0.4
Change in w orking capital	6.7	5.9	-16.7	0.5	1.6
Gross cash flow	**-5.4**	**-8.2**	**-24.4**	**-4.8**	**1.2**
Interest received	0.0	0.0	0.0	0.0	0.0
Interest paid	0.0	-0.3	-1.5	-1.5	-1.5
Operating cash flow	**-5.4**	**-8.5**	**-25.9**	**-6.3**	**-0.3**
Payments for PPE	-0.4	-10.6	-2.5	-2.5	-2.5
Payments for trials and development	-9.0	-3.2	-5.0	-5.0	-5.0
Investing cash flow	**-9.4**	**-13.7**	**-7.5**	**-7.5**	**-7.5**
Proceeds from issue of convertible notes	0.0	24.2	0.0	0.0	0.0
Proceeds from issue of shares	12.0	34.4	7.4	0.0	0.0
Proceeds from sell dow n of shares	0.0	23.4	0.0	0.0	0.0
Repayment of leases	-0.2	-1.1	-1.5	-1.5	-1.5
Financing cash flow	**11.8**	**80.9**	**5.9**	**-1.5**	**-1.5**
Net change in cash	**-3.1**	**58.6**	**-27.5**	**-15.3**	**-9.3**
Cash at start of period	4.4	1.2	59.7	32.2	16.9
Exchange rate impact	0.0	-0.2	0.0	0.0	0.0
Cash at end of period	**1.2**	**59.7**	**32.2**	**16.9**	**7.6**

Balance Sheet (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Cash	1.2	59.7	32.2	16.9	7.6
Current receivables	1.4	5.7	2.1	2.3	3.2
Inventories	0.7	6.1	1.0	1.2	1.6
Other current assets	2.0	4.6	4.6	4.6	4.6
PPE	0.9	8.3	8.8	9.3	9.8
Intangibles	31.4	34.4	39.2	44.1	48.9
Right-of-use assets	6.0	11.5	11.5	11.5	11.5
Total assets	**43.9**	**130.5**	**99.7**	**90.1**	**87.5**
Payables	4.6	32.3	6.9	7.7	10.7
Current Lease Liabilities	1.3	1.0	1.0	1.0	1.0
Employee Benefits	0.6	2.5	2.5	2.5	2.5
Contract Liabilities	0.7	7.5	7.5	7.5	7.5
Non-Current lease liabilities	4.7	9.6	9.6	9.6	9.6
Total liabilities	**11.8**	**52.8**	**27.4**	**28.3**	**31.3**
Net Assets	**32.1**	**77.7**	**72.3**	**61.8**	**56.2**
Share capital	50.7	116.2	123.6	123.6	123.6
Other reserves	1.5	1.7	1.7	1.7	1.7
Accumulated losses	(20.0)	(40.2)	(53.0)	(63.5)	(69.0)
Total shareholders' equity	**32.1**	**77.7**	**72.3**	**61.8**	**56.2**

Valuation Ratios (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Reported EPS (cps)	-60.6	-76.4	-8.3	-5.8	-1.3
Normalised EPS (cps)	-60.6	-76.4	-8.3	-5.8	-1.3
EPS grow th (%)	0.0	nm	nm	nm	nm
PE(x)	nm	nm	nm	nm	nm
EV/EBIT (x)	nm	nm	nm	nm	nm
Total assets	43.9	130.5	93.6	87.2	89.6
Net Assets	32.1	77.7	65.3	56.6	54.7
NTA	0.7	43.4	26.1	12.5	5.7
NTA/share cps	1.4	28.9	17.4	8.4	3.8
Book value per share	0.0	0.0	0.0	0.0	0.0
P/NTA (x)	28.1	1.4	2.3	4.8	10.4
Book Value Per Share (cps)	61.7	51.8	43.5	37.7	36.4
Price/Book (x)	0.6	0.8	0.9	1.1	1.1
DPS (cps)	0.0	0.0	0.0	0.0	0.0
Payout ratio %	0.0	0.0	0.0	0.0	0.0
Dividend Yield %	0.0	0.0	0.0	0.0	0.0
Franking %	0.0	0.0	0.0	0.0	0.0
FCF yield %	nm	nm	nm	nm	nm
Net debt/(Cash)	0.0	0.0	0.0	0.0	0.0
Net debt/Equity	0.0	0.0	0.0	0.0	0.0
Net debt/Assets	0.0	0.0	0.0	0.0	0.0
Gearing	0.0	0.0	0.0	0.0	0.0
Net debt/EBITDA (x)	Net Cash	Net Cash	Net Cash	Net Cash	Net Cash
Interest cover (x)	na	na	na	na	na

Segmentals (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Revenue					
Sale of Goods	0.5	2.3	5.3	5.8	7.5
Services Income	7.9	22.7	8.4	9.7	14.0
Total revenue	8.4	25.1	13.7	15.5	21.5
Growth					
Sales of goods	0%	365%	128%	10%	28%
Services income	0%	188%	-63%	15%	45%
Total growth	**0%**	**198%**	**-44%**	**13%**	**39%**

Interim Results	1H21	2H21	1H22	2H22e
Revenues	8.4	16.6	5.2	8.5
EBIT	-2.5	-12.1	-10.9	1.0
NPAT	-3.4	-16.9	-11.1	-1.8

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

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The fact that the intellectual property base of a typical biotechnology company lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek U.S. FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other diseases not previously diagnosed. Furthermore, the Australian exchange listed biotechnology sector is subject to influence by the global biotechnology sector, particularly that in the USA. Consequently, Australian exchange listed biotechnology stocks can experience sharp movements, both upwards and downwards, in both valuations and share prices, as a result of a re-rating of the sector both globally and in the USA, in particular. Investors are advised to be cognisant of these risks before buying such a stock.

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