

Pacific Edge

2019 finishes strongly

Pacific Edge recently reported FY19 results, including 12.3% growth in Cxbladder sales compared to FY18. These sales exclude tests for patients covered by the US Centers for Medicare and Medicaid Services (CMS), which currently account for approximately 50% of lab throughput. Total lab throughput increased by 8.6% during the year, with Q419 up 26% compared to Q418 and up 12% compared to the prior quarter. Rest of world (ROW) throughput (which represents 20% of the total) increased by 126% in the quarter versus Q418, mainly due to strength in the New Zealand market.

Year end	Revenue (NZ\$m)	PBT* (NZ\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/18	4.6	(19.6)	(4.5)	0.0	N/A	N/A
03/19	4.8	(17.8)	(3.7)	0.0	N/A	N/A
03/20e	5.9	(17.4)	(3.4)	0.0	N/A	N/A
03/21e	24.5	(0.2)	(0.0)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Working on CMS reimbursement

Pacific Edge is in the process of gaining inclusion in the CMS's local coverage determination (LCD), which would enable reimbursement and negotiation for payment of more than 17,015 tests previously performed on patients covered by CMS as of the end of FY19. The company has completed two of the three components necessary for national reimbursement in the US, namely CPT codes and a national price of US\$760 per test.

12.3% increase in Cxbladder sales

Cxbladder sales were up 12.3% to NZ\$3.8m in FY19. Total laboratory throughput increased 8.6% over FY18 to 15,697 tests, while the total number of billable tests increased 7% to 12,744 (81.2% of the total). This is slightly lower than previous guidance from the company of growth between 10.7% and 17.7% growth (16,000 and 17,000 tests) in total laboratory throughput in FY19, exclusive of any major changes from new customers (like Kaiser Permanente) or CMS LCD inclusion.

New Zealand growth especially strong

ROW throughput was especially strong in the year, up 83%, with an especially strong fourth quarter where growth was 126% compared to Q418. This was mainly driven by New Zealand, where approximately 62% of the population have access to Cxbladder through public healthcare contracts.

Valuation: NZ\$219m or NZ\$0.43 per share

Our DCF-based valuation has been reduced from NZ\$255m (NZ\$0.52/share) to NZ\$219m (NZ\$0.43/share). This reflects a more conservative view of the sales ramp for the Cxbladder franchise in the US, a lower level of net cash and a greater number of shares outstanding. We now expect profitability in FY22 versus FY21 previously.

Financial update

Pharma & biotech

10 June 2019

Price NZ\$0.22 Market cap NZ\$112m

NZ\$1.54/US\$

 Net cash (NZ\$m) at 31 March 2019
 12.8

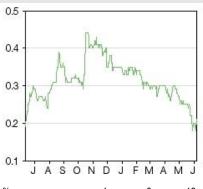
 Shares in issue
 510.8m

 Free float
 96%

 Code
 PEB

Primary exchange NZX
Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	(13.7)	(26.7)	(13.7)
Rel (local)	(13.6)	(30.2)	(20.9)
52-week high/low	NZ\$0.44		NZ\$0.18

Business description

Pacific Edge develops and sells a portfolio of molecular diagnostic tests based on biomarkers for the early detection and management of cancer. Tests utilising its Cxbladder technology for detecting and monitoring bladder cancer are sold in the US, New Zealand, Australia and Singapore.

Next events

LCD inclusion 2019/20

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Edison profile page

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FY19 results

During FY19, operating revenue grew 12.3% to NZ\$3.8m compared to the NZ\$3.4m in FY18. Total reported revenue was NZ\$5.1m in FY19, up from NZ\$5.0m in the previous year. Note that in our financial model we subtract out the interest income and foreign exchange gain (or loss) that the company reports as revenue (per New Zealand accounting practices) and place these items below the operating line in order to normalise across international accounting standards (revenues in our model totals NZ\$4.8m in FY19 and NZ\$4.6m in FY18). Total laboratory throughput increased 8.6% over FY18 to 15,697 tests, while the total number of billable tests increased 7% to 12,744 (81.2% of the total). The final quarter of the fiscal year finished especially strongly with total lab throughput up 26% compared to Q418 and up 12% compared to the prior quarter. Rest of world (ROW) throughput (which represents 20% of the total) increased by 126% in the quarter vs Q418 mainly due to strength in the New Zealand market, where 62% of the population have access to Cxbladder and the Cxbladder Triage product (used to rule out low-risk patients and reduce the numbers of cystoscopies) is especially popular. Importantly, the company expects the New Zealand business to be cash flow positive in FY20.

Exhibit 1: Cxbladder contract coverage in New Zealand

April 2019 Waitemata Counties Bay of Flenty Tairewhiti Lakes Whangamii Hewke's Bay Capital & Count Hutt Valley Canterbury (Includes Chathem Islands)

Contract Coverage of New Zealand's Population Using Cxbladder

Source: Pacific Edge

Note that the sales figures exclude the approximately 50% of tests for patients covered by CMS and that cumulatively 17,015 tests have yet to be booked (as of the end of FY19) as the company awaits an LCD. As a reminder, the company has completed two of the three components necessary for national reimbursement in the US, namely CPT codes and a national price of US\$760 per test. The final step will be to gain inclusion in an LCD. An LCD is a document that includes the coverage decisions of the Medicare Administrative Contractor (MAC). An LCD would provide the conditions of the coverage as well as the price, guidance on reimbursement and coding information. Unfortunately there is no set process for achieving an LCD and in many ways it is the epitome of arbitrary bureaucracy.



Once an LCD inclusion is attained, reimbursement from CMS should become consistent and timely. Besides this immediate benefit of new tests being covered by CMS, the company may finally receive payment on the more than 17,000 tests previously conducted for CMS patients. Pacific Edge has not received payment for tests provided to patients covered by CMS until LCD inclusion so there could be a multi-year backlog of test revenue that would be recognised in a single reporting period post-inclusion. Based on a price of US\$760 per test these payments could total US\$12.9m. In addition, private payers often base their own coverage decisions and reimbursement levels on the coverage listed in an LCD, so a success here is expected to lead to faster growth for the company.

Valuation

Our DCF-based valuation has been reduced from NZ\$255m (NZ\$0.52/share) to NZ\$219m (NZ\$0.43/share). This reflects a more conservative view of the sales ramp for the Cxbladder franchise in the US, a lower level of net cash and a greater number of shares outstanding. We will revisit these estimates once CMS reimbursement is in place, as once LCD inclusion occurs revenue recognition would normalise and the backlog of unpaid tests from previous years would provide a boost to revenue as they are paid.

Exhibit 2: Valuation based on DCF	
Discounted cash flow (NZ\$000)	219,393
Net cash at 31 March 2019 (NZ\$000)	12,847
Valuation (NZ\$000)	219,393
Number of shares (m) at 31 March 2019	510.82
Value per share (NZ\$)	0.43
Source: Edison Investment Research	

Financials

We have lowered our FY20 revenues estimate to NZ\$5.9m from NZ\$10.2m as a lack of CMS reimbursement appears to be continuing to restrain sales in the US, and have also increased our estimates for operating expenses by NZ\$0.3m as they came in slightly higher than expected. We are introducing FY21 estimates, which include NZ\$24.5m in product sales, which assumes LCD inclusion and CMS reimbursement, and we expect profitability in FY22 (previously FY21).

Exhibit 3: Financial forecast changes						
	FY20e		FY21e			
	Old	New	Old	New		
Revenue (NZ\$m)	10.2	5.9	N/A	24.5		
PBT (normalised) (NZ\$m)	(13.2)	(17.4)	N/A	(0.2)		
EPS (NZ\$)	(0.03)	(0.03)	N/A	(0.00)		
Source: Edison Investment Re	search					

The company had net cash of NZ\$12.8m at 31 March 2019 thanks to capital raises that brought in NZ\$14.6m to the company. These include a NZ\$2.6m share raise with Manchester Management Company, a US-based fund specialising in life sciences, an additional private placement of shares to raise proceeds of around NZ\$7m through the issuance of around 20m shares at NZ\$0.35 each, and a share purchase plan for New Zealand resident shareholders. We currently estimate the future financing needs of the company to be NZ\$10m, unchanged from our previous estimate despite these recent additional sources of capital, as our sales estimates are now reduced.



	NZ\$000s	2018	2019	2020e	2021
/ear end 31 March		NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAF
PROFIT & LOSS					
Revenue		4,642	4,807	5,942	24,49
Cost of Sales		(4,619)	(4,594)	(5,053)	(5,559
Gross Profit		23	213	889	18,93
EBITDA		(19,500)	(17,840)	(17,525)	(31
Operating Profit (before amort. and except.)		(19,816)	(18,077)	(17,833)	(400
ntangible Amortisation		(188)	(154)	(58)	(70
Exceptionals		46	(4)	0	
Operating Profit		(19,958)	(18,235)	(17,891)	(470
Other		0	0	0	
Net Interest		231	323	385	19
Profit Before Tax (norm)		(19,585)	(17,754)	(17,447)	(210
Profit Before Tax (FRS 3)		(19,727)	(17,912)	(17,506)	(279
Гах		0	(9)	0	
Profit After Tax (norm)		(19,585)	(17,763)	(17,447)	(210
Profit After Tax (FRS 3)		(19,727)	(17,921)	(17,506)	(279
Average Number of Shares Outstanding (m)		438.4	481.2	510.9	510.
EPS - normalised (c)		(4.5)	(3.7)	(3.4)	(0.0
EPS - FRS 3 (c)		(4.5)	(3.7)	(3.4)	(0.1
Dividend per share (c)		0.0	0.0	0.0	0.
Gross Margin (%)		N/A	N/A	N/A	N/.
EBITDA Margin (%)		N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/.
BALANCE SHEET					
Fixed Assets		1,135	1,002	798	52
ntangible Assets		281	233	284	32
Tangible Assets		854	769	514	20
Other		0	0	0	
Current Assets		18,530	15,564	9,079	9,90
Stocks		752	842	842	84
Debtors		1,064	1,265	1,265	1,26
Cash		16,242	12,847	6,362	7,18
Other		472	610	610	61
Current Liabilities		(2,999)	(2,624)	(12,624)	(12,624
Creditors		(2,926)	(2,572)	(2,572)	(2,572
Short term borrowings		0	0	(10,000)	(10,000
Short term leases		(73)	(52)	(52)	(52
Other		0	0	0	
Long Term Liabilities		(26)	(32)	(32)	(32
Long term borrowings		0	0	0	
ong term leases		(26)	(32)	(32)	(32
Other long term liabilities		0	0	0	
Net Assets		16,640	13,910	(2,779)	(2,226
CASH FLOW					
Operating Cash Flow		(18,331)	(17,830)	(16,709)	80
Net Interest		231	323	385	19
Гах		0	0	0	
Capex		(335)	(156)	(162)	(168
Acquisitions/disposals		Ó	Ó	Ó	,
Financing		21,318	14,569	0	
Dividends		0	0	0	
Other		(1,261)	(275)	0	
Net Cash Flow		1,622	(3,369)	(16,485)	82
Opening net debt/(cash)		(14,564)	(16,143)	(12,763)	3,72
HP finance leases initiated		(99)	15	0	0,12
Other		56	(26)	0	((
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