EDISON

Pacific Edge

Test sales up 43% in H119

Financial update

Pharma & biotech

Pacific Edge recently reported H119 results, including 43% growth in Cxbladder sales compared to H118. These sales exclude tests for patients covered by the US Centers for Medicare and Medicaid Services (CMS), which currently account for 47% of lab throughput. The company is in the process of gaining inclusion in the CMS's local coverage determination (LCD), which will enable reimbursement and negotiation for payment of more than 14,000 tests previously performed on patients covered by CMS.

Year end	Revenue (NZ$m)	PBT* (NZ$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/17**	4.4	(22.4)	(5.9)	0.0	N/A	N/A
03/18	4.6	(19.6)	(4.5)	0.0	N/A	N/A
03/19e	5.0	(17.5)	(3.5)	0.0	N/A	N/A
03/20e	10.2	(13.2)	(2.6)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. Note: **FY17 restated for IFRS15.

CMS reimbursement process two-thirds of the way

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 company continues to work with CMS to gain inclusion in an LCD, which would enable consistent payments from CMS as well as reduce the lag time between the test being performed and receipt of cash. Timing is uncertain but typically it can take up to five years to gain inclusion in a LCD and Pacific Edge has been in the process since 2014.

12% increase in billable test volume

Billable test volume increased 12% over a very strong H118. Total laboratory throughput increased 3.9% as the number of non-billable tests fell. The company believes that it will be able to achieve growth between 10.7% and 17.7% (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.

Raising funds

Pacific Edge completed a private placement of shares to raise proceeds of around NZ$7m through the issuance of around 20m shares at $0.35 each. Following the completion of the placement it intends to allow New Zealand resident shareholders to purchase up to NZ$5m at $0.35 per share as well via a share purchase plan.

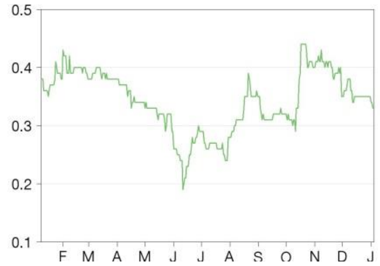
Valuation: NZ$255m or NZ$0.52 per share

Our DCF-based valuation has been reduced to NZ$255m (NZ$0.52/share) from NZ$348m (NZ$0.75/share). This reflects a combination of lower near-term estimates to reflect a more conservative view of the sales ramp for the Cxbladder franchise in the US and delayed cash inflow from product sales in the US. We continue to expect profitability in FY21. We estimate the financing needs of the company to be NZ$10m in FY20 following completion of the private placement.

7 January 2019

Price	**NZ$0.33**
Market cap	**NZ$163m**
	NZ$1.45/US$
Net cash (NZ$m) at 30 September 2018	10.1
Shares in issue post-offering (estimate)	494.8m
Free float	89.9%
Code	PEB
Primary exchange	NZX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(10.7)	6.4	(13.0)
Rel (local)	(9.3)	13.1	(13.0)
52-week high/low		NZ$0.44	NZ$0.19

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 and Australia.

Next events

LCD inclusion	CY19
Kaiser Permanente commercial agreement	CY19

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Edison profile page

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CMS and Kaiser negotiations ongoing

The company is continuing to work with CMS to obtain reimbursement. So far, 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. Typically the process can take up to five years to gain an LCD inclusion so while Pacific Edge has been in this process for around four years, it is within the normal timeframe.

Once an LCD inclusion is attained, reimbursement from CMS (which currently represents approximately 47% of Cxbladder test volume) 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 14,000 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 is recognised in a single reporting period post-inclusion. 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.

Pacific Edge is also in discussions with Kaiser Permanente regarding a commercial relationship and is working with Kaiser's staff to ensure that commercial tests can begin shortly after an agreement is reached. Commercial adoption by Kaiser could provide a significant ramp in sales. However, management confirms that it is taking longer than anticipated for Kaiser to work through its internal processes and to finalise the Kaiser agreements.

Additionally, the company recently announced that Johns Hopkins Medicine, an $8 billion healthcare system, has commenced a commercial evaluation of Cxbladder with a select group of urologists at the world-class institution. With regards to its home market in New Zealand, 62% of the population of New Zealand currently have coverage for Cxbladder through their healthcare providers, up from just 36% a year ago.

Valuation

Our DCF-based valuation has been reduced to NZ$255m (NZ$0.52/share) from NZ$348m (NZ$0.75/share). This reflects a combination of lower near-term estimates to reflect a more conservative view of the sales ramp for the Cxbladder franchise in the US and delayed cash inflow from product sales in the US. We will revisit these estimates once agreements are completed with CMS and Kaiser Permanente and we have greater clarity on the ramp-up once reimbursement is in place. CMS reimbursement is especially important 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 1: Valuation based on DCF

Discounted cash flow (NZ$000)	238,189
Net cash (NZ$000) at 30 September 2018 + private placement	17,060
Valuation (NZ$000)	**255,249**
Number of shares (m) at 30 September 2018 + private placement (estimate)	494.79
Value per share (NZ$)	**0.52**

Source: Edison Investment Research

Financials

The company recently published H119 results with operating revenue growth of 42.7% from NZ$1.4m in H118 to NZ$2.0m. As a reminder, the company previously announced that it had adopted the new revenue recognition accounting standard, NZ IFRS 15, which means that revenue from US customers will only be recognised once cash payment is received (previously the company recognised tests that had been billed but not yet paid). Using the prior accounting standard, the company would have reported NZ$5.6m in sales for the period, 33% growth over H118.

Billable test volume increased 12% over a very strong H118. Total laboratory throughput increased 3.9% as the number of non-billable tests fell. The company currently believes that it will be able to achieve approximately 14.2% growth in total laboratory throughput in FY19, exclusive of any major changes from new customers (like Kaiser Permanente) or CMS LCD inclusion. Operating expenses for H119 were reported as NZ$11.4m, a 6% decrease compared to H118.

With this in mind we have lowered our FY19 and FY20 revenues estimates to be more in line with guidance and the run rate for sales. Our FY19 revenue estimate is now NZ$5.0m compared to NZ$7.8m previously and our FY20 estimate has been changed from NZ$12.7m to NZ$10.2m. Conversely, we have reduced our R&D expenses by NZ$1.2m for FY19 and by NZ$1.7m for FY20 due to a lower than expected run rate. Also, we have reduced our SG&A expense estimates by NZ$3.4m for FY19 and NZ$3.1m for 2020 for the same reason. We continue to expect profitability in FY21.

Exhibit 2: Financial forecast changes

	FY19e		FY20e	
	Old	New	Old	New
Revenue (NZ$m)	7.8	5.0	12.7	10.2
PBT (normalised) (NZ$m)	(17.7)	(17.5)	(14.2)	(13.2)
EPS (NZ$)	(0.04)	(0.04)	(0.03)	(0.03)

Source: Edison Investment Research

The company had net cash of NZ$10.1m at 30 September 2018 thanks in part to a NZ$2.6m share raise with Manchester Management Company, a US-based fund specialising in life sciences. The company has just completed an additional private placement of shares to raise proceeds of around NZ$7m through the issuance of around 20m shares at $0.35 each. Following the completion of the placement it intends to allow New Zealand resident shareholders to purchase up to NZ$5m at $0.35 per share as well in a share purchase plan. That offering is expected to open on 10 December and close on 25 January.

We estimate the financing needs of the company to be NZ$10m (which we show as illustrative long-term debt) following the completion of the private placement and will be lower once the share purchase plan is completed.

Exhibit 3: Financial summary

NZ$'000s	2017	2018	2019e	2020e
Year end 31 March	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS				
Revenue	4,432	4,642	4,986	10,219
Cost of Sales	(1,446)	(4,619)	(4,759)	(5,235)
Gross Profit	2,986	23	227	4,984
EBITDA	(22,293)	(19,500)	(17,563)	(13,162)
Operating Profit (before amort. and except.)	(22,646)	(19,816)	(17,795)	(13,426)
Intangible Amortisation	(189)	(188)	(158)	(66)
Exceptionals	(43)	46	(5)	0
Operating Profit	(22,878)	(19,958)	(17,958)	(13,492)
Other	0	0	0	0
Net Interest	249	231	338	259
Profit Before Tax (norm)	(22,398)	(19,585)	(17,457)	(13,166)
Profit Before Tax (FRS 3)	(22,629)	(19,727)	(17,620)	(13,233)
Tax	0	0	0	0
Profit After Tax (norm)	(22,398)	(19,585)	(17,457)	(13,166)
Profit After Tax (FRS 3)	(22,629)	(19,727)	(17,620)	(13,233)
Average Number of Shares Outstanding (m)	382.5	438.4	491.9	511.6
EPS - normalised (c)	(5.9)	(4.5)	(3.5)	(2.6)
EPS - FRS 3 (c)	(5.9)	(4.5)	(3.6)	(2.6)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	1,166	1,135	925	781
Intangible Assets	329	281	265	345
Tangible Assets	837	854	660	436
Other	0	0	0	0
Current Assets	16,541	18,530	11,230	8,900
Stocks	824	752	846	846
Debtors	663	1,064	836	836
Cash	14,564	16,242	8,636	6,306
Other	490	472	912	912
Current Liabilities	(2,734)	(2,999)	(2,861)	(12,861)
Creditors	(2,734)	(2,926)	(2,771)	(2,771)
Short term borrowings	0	0	0	(10,000)
Short term leases	0	(73)	(90)	(90)
Other	0	0	0	0
Long Term Liabilities	0	(26)	(48)	(48)
Long term borrowings	0	0	0	0
Long term leases	0	(26)	(48)	(48)
Other long term liabilities	0	0	0	0
Net Assets	14,973	16,640	9,246	(3,228)
CASH FLOW				
Operating Cash Flow	(18,086)	(18,331)	(17,284)	(12,403)
Net Interest	249	231	338	259
Tax	0	0	0	0
Capex	(479)	(335)	(180)	(186)
Acquisitions/disposals	0	0	0	0
Financing	8,750	21,318	9,623	0
Dividends	0	0	0	0
Other	(91)	(1,261)	(66)	0
Net Cash Flow	(9,657)	1,622	(7,569)	(12,330)
Opening net debt/(cash)	(24,160)	(14,564)	(16,143)	(8,498)
HP finance leases initiated	0	(99)	(39)	0
Other	61	56	(37)	0
Closing net debt/(cash)	(14,564)	(16,143)	(8,498)	3,832

Source: Edison Investment Research, company accounts

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