

Pacific Edge

Company update

User programmes underway

Pacific Edge's bladder cancer diagnostics tests have been available in the US, New Zealand and Australia for over a year and initial sales indicate a steady ramping-up of adoption in both new customers embarking on User Programmes, as well as initial evaluations and commercial sales from existing customers. We expect news related to the conversion of these programmes into full commercial contracts in the next year. Negotiations are also well underway with key public health organisations in the US – CMS (Centers for Medicare & Medicaid Services) and the VA (Veteran's Administration). Meanwhile, the company continues to build a world-wide patent estate around its additional genetic-based cancer diagnostic tests.

Year end	Revenue (NZ\$m)	PBT* (NZ\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/13	0.2	(6.9)	(2.5)	0.0	N/A	N/A
03/14	0.5	(9.8)	(3.4)	0.0	N/A	N/A
03/15e	3.5	(8.2)	(2.6)	0.0	N/A	N/A
03/16e	8.4	(6.2)	(2.0)	0.0	N/A	N/A

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

Upcoming newsflow

Stepped-up throughput of Cxbladder Detect testing, as recently reported by the company, points to increasing usage of the tests in the many User Programmes currently evaluating the diagnostic ahead of full commercial adoption. We expect news related to the success of these programmes over the next 12 months, which should begin to translate into first meaningful sales. Meanwhile, Kaiser Permanente S. California, will be enrolling more than 2,000 patients in a large User Programme evaluating follow-on diagnostic test Cxbladder Triage for use across all of Kaiser Permanente (9.5m patients). A positive outcome of this high-profile assessment would be a key endorsement for the Cxbladder franchise.

Expanding patent estate

Our company valuation includes sales of bladder cancer testing products only and is limited to three markets – the US, New Zealand and Australia. Pacific Edge continues to announce the filing and granting of a steady stream of patents covering its molecular diagnostics technology. Patents span a number of highly prevalent cancers, including colorectal and gastric cancers, in numerous countries and regions, including India, South-East Asia and the EU, highlighting the significant longer-term potential of its technological capabilities.

Valuation: Increases to NZ\$380m

Our valuation for Pacific Edge increases to NZ\$379.6m (NZ\$1.19/share) from NZ\$369m (NZ\$1.16/share) due to the strength of the US dollar (>95% of our forecast sales are derived from the US), and the rolling forwards of our DCF by one year, offset primarily by the slower start to the SC User Programmes by about six months impacting the top line. We anticipate the company has sufficient liquidity to fund operations into 2016.

Pharma & biotech

14 May 2015

Price **NZ\$0.73**

Market cap **NZ\$234m**

NZ\$1.30/US\$

Net cash (NZ\$m) at Sept 2014 14.7

Shares in issue 318.6m

Free float 74%

Code PEB

Primary exchange NZX

Secondary exchange N/A

Share price performance



Business description

Pacific Edge develops and sells molecular diagnostic tests based on biomarkers for the early detection and management of cancer. Cxbladder Detect is sold in New Zealand, Australia and the US and complementary product Cxbladder Triage was launched in New Zealand in December (US launch planned mid 2015). The pipeline includes additional tests in bladder, colorectal and gastric cancers.

Next events

US launch Cxbladder Triage	Mid-2015
Preliminary FY15 results	May 2015
Cxbladder Monitor launch	2015
Completion of SCPMG User Programme	H215/H116

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A steady stream of newsflow

At the end of last year, Pacific Edge reported encouraging fiscal half-year results (to September), at which time confirmation of successful initial uptake of its Cxbladder Detect was highlighted and sales of NZ\$1m reported excluding interest and foreign exchange gains. Based on steadily climbing throughput in the US for Cxbladder Detect via User Programmes, we expect continued sales momentum for FY15 end-March will be reported when the company announces full-year results this coming May. We anticipate continued announcements related to new User Programmes in the US, New Zealand, Australia and potentially in South-East Asia. We also point to critical newsflow in the coming quarters related to the potential full commercial adoption of Cxbladder Detect with healthcare providers from three ongoing user programmes in the US.

A fourth User Programme with Southern California Permanente Medical Group is due to start enrolling an estimated 2,000 patients mid-year to evaluate the performance of the company's complementary product, Cxbladder Triage. The outcome of this large-scale programme, expected to conclude at the end of 2015/early 2016 promises to be a key indicator for the Cxbladder suite of products. Cxbladder Triage enables clinicians to segregate patients who have presented with haematuria (blood in urine), who have a low probability of bladder cancer. Its clinical performance was detailed in the most recent publication of medical journal, BioMed Central Urology, serving as both a critical endorsement for the diagnostic as well as widespread news dissemination to a large audience of clinicians. Commercial adoption by Kaiser Permanente, which covers approximately 9.5 million people under its plan, would provide a significant clinical validation for those other ongoing user programmes currently evaluating the Cxbladder technology.

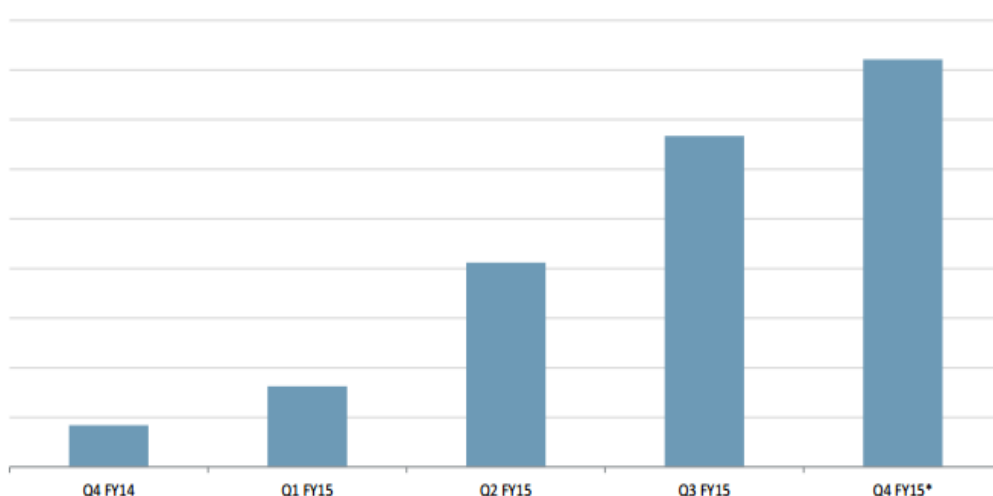
Exhibit 1: Pacific Edge upcoming newsflow – Cxbladder franchise

Event	Timing (calendar year)
Launch of Cxbladder Triage US	H115
Outcome Kaiser Permanente user programme	End 2015/early 2016
Decisions on commercialisation of VA CMS	End 2015/early 2016
Initiate up to four key user programmes, SE Asia	2015/16
Cxbladder Monitor launch	2015
Cxbladder Predict launch	2016
Source: Edison Investment Research	

The chart below shows a steady lab throughput through March of 2015 in the US, in its second year of commercialisation. Sales in the US are supported by a growing salesforce of dedicated specialists, currently at 12 people.

Exhibit 2: Lab throughput US

Lab throughput showing significant improvements



Source: Company presentation, March 2015 * Forward forecast of Q4 FY15 throughput.

Progress with federal programmes

The conclusion of discussions with the Centers for Medicare & Medicaid Services (CMS) and Veteran's Administration (VA) – both with significant patient numbers – is anticipated in calendar 2015. Management reports that negotiations are ongoing with these major public healthcare organisations and that good headway has been made in the negotiation processes. Tests are currently being processed for the CMS. We note volumes are potentially significant for these programmes; however, reimbursement will likely be below our estimated \$600 price per treatment in the private sector. Pacific Edge has previously stated its reimbursement range to be US\$550 to \$650 for the private sector.

New patents securing future full product offering

The roll-out of Cxbladder is the pressing priority for the company; however, management continues to actively pursue its medium-term goal to round out the product portfolio with additive technologies in additional cancer indications, including colorectal and stomach. The company has steadily built a portfolio of patents in new and existing markets across the Americas, Asia, Europe and Australasia. Pacific Edge has continually announced newly-granted patents and patent filings (see Exhibit 3 below for those most recent). The breadth and scope of these patents demonstrate the potential for Pacific Edge to expand geographically and across cancer types also displaying the company's overall capabilities in molecular diagnostics testing.

Exhibit 3: Recent patents granted across cancer indications

Technology	Countries	Existing patents	Date
Stomach cancer prognostic technology	Issue of a patent in Japan	NZ, Australia, China, EU	March 2015
Cxbladder Predict technology	Mexico		March 2015
Cxbladder technology	European patent office grants patent		February 2105
Cxbladder technology	Patent protection granted in India	Europe, US, Australia, NZ	
Gastric cancer technology	European patent office grants patent		
Colorectal cancer prognostic technology	European Intellectual Property Office awards patent in the EU and eight additional countries		November 2014
Colorectal cancer prognostic technology	Issue of a patent in Japan		September 2014
Melanomas	Patent granted in the US for technology to develop a test distinguishing life-threatening melanomas from those not as aggressive		September 2014

Source: Edison Investment Research

Valuation

Our 2015 forecasts, including R&D and SG&A expenses, remain largely unchanged since our [last published update](#) on 16 December 2014, which followed announced preliminary half-year results ending September 2014. Our valuation increases to NZ\$379.6m from NZ\$369.4m (NZ\$1.19 per share from NZ\$1.16) on dollar strength and the rolling forward of our discounted cash flows by one year offset by a slower ramping up of sales due primarily to a later start to the SCPMG User Programme than first anticipated (from early to mid-2015). We price the company through the discounting of free cash flows at a rate of 12.5% and include sales of Cxbladder Detect and Cxbladder Triage only in the three markets where the tests are currently or imminently commercially available – the US, New Zealand and Australia. We do not factor in potential follow-on cancer indications, although we believe the company has considerable scope to expand geographically.

Exhibit 2: Financial summary

	NZ\$'000s	2012	2013	2014	2015e	2016e
Year end 31 March		NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS						
Revenue		280	178	523	3,422	8,369
Cost of Sales		0	0	0	(460)	(1,103)
Gross Profit		280	178	523	2,962	7,266
EBITDA		(4,176)	(6,960)	(9,311)	(8,532)	(6,171)
Operating Profit (before GW and except.)		(4,354)	(7,155)	(9,579)	(8,843)	(6,624)
Intangible Amortisation		0	0	(116)	(96)	(69)
Exceptionals		0	0	0	0	0
Operating Profit		(4,354)	(7,155)	(9,695)	(8,940)	(6,694)
Other		(96)	(92)	(571)	0	0
Net Interest		339	330	315	613	402
Profit Before Tax (norm)		(4,111)	(6,917)	(9,835)	(8,230)	(6,223)
Profit Before Tax (FRS 3)		(4,111)	(6,917)	(9,951)	(8,327)	(6,292)
Tax		0	0	0	0	0
Profit After Tax (norm)		(4,111)	(6,917)	(9,835)	(8,230)	(6,223)
Profit After Tax (FRS 3)		(4,111)	(6,917)	(9,951)	(8,327)	(6,292)
Average Number of Shares Outstanding (m)		232.0	275.4	291.3	318.6	318.6
EPS - normalised (c)		(1.8)	(2.5)	(3.4)	(2.6)	(2.0)
EPS - FRS 3 (c)		(1.8)	(2.5)	(3.4)	(2.6)	(2.0)
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets		396	1,210	1,305	1,410	1,418
Intangible Assets		0	0	193	277	388
Tangible Assets		396	1,081	1,112	1,133	1,029
Other		0	129	0	0	0
Current Assets		18,250	11,013	21,426	13,078	7,240
Stocks		0	0	242	341	816
Debtors		207	132	574	2,532	6,190
Cash		17,959	10,676	20,444	10,040	67
Other		84	204	167	167	167
Current Liabilities		(997)	(1,078)	(953)	(1,037)	(1,498)
Creditors		(803)	(922)	(953)	(1,037)	(1,198)
Short term borrowings		0	0	0	0	(300)
Short term leases		0	0	0	0	0
Other		(194)	(156)	0	0	0
Long Term Liabilities		0	0	0	0	0
Long term borrowings		0	0	0	0	0
Long term leases		0	0	0	0	0
Other long term liabilities		0	0	0	0	0
Net Assets		17,650	11,145	21,778	13,451	7,159
CASH FLOW						
Operating Cash Flow		(3,605)	(6,710)	(9,524)	(10,504)	(10,144)
Net Interest		0	0	0	613	402
Tax		0	0	0	0	0
Capex		(30)	(1,009)	(497)	(513)	(530)
Acquisitions/disposals		0	0	0	0	0
Financing		20,128	445	21,002	0	0
Dividends		0	0	0	0	0
Other		(1,020)	(9)	(1,232)	0	0
Net Cash Flow		15,473	(7,283)	9,749	(10,404)	(10,273)
Opening net debt/(cash)		(2,486)	(17,959)	(10,676)	(20,444)	(10,040)
HP finance leases initiated		0	0	0	0	0
Other		0	0	19	0	0
Closing net debt/(cash)		(17,959)	(10,676)	(20,444)	(10,040)	233

Source: Edison Investment Research

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