

Pacific Edge

Moving towards key decision points

Pacific Edge continues to make progress commercialising its bladder cancer diagnostics tests as key user programmes move towards critical junctures. We anticipate the company will convert user programmes into full commercial contracts over the next year, while new programmes continue to be initiated. We also expect decisions on a go-ahead for commercialisation with key public health organisations in the US, while laboratory throughput of Cxbladder tests continues to move upwards, reflecting steadily growing adoption by new customers and the expansion of testing through user programmes. Our fair value is amended slightly to NZ\$496m due to exchange rate movements.

Year end	Revenue (NZ\$m)	PBT* (NZ\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/14	0.5	(9.8)	(3.4)	0.0	N/A	N/A
03/15	3.7	(11.1)	(3.5)	0.0	N/A	N/A
03/16e	8.5	(15.1)	(4.1)	0.0	N/A	N/A
03/17e	28.2	1.7	0.4	0.0	N/A	N/A

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

Judgment time ahead in the US

Pacific Edge awaits approval for use of its bladder cancer diagnostics tests from two major public organisations in the US, the Veteran's Administration (VA) and Centers for Medicare and Medicaid Services (CMS), each representing major market opportunities. The company is now in the final stages of a lengthy review process with the VA to gain access to the Federal Supply Schedule that will enable sales to VA urologists. Management expects discussions with the CMS on approval and reimbursement for Cxbladder tests to conclude in mid-2016. CMS, according to Pacific Edge, represents c 40% of its total target market.

Converting user programmes to sales

In early November, Pacific Edge reported semi-annual laboratory throughput numbers – a figure combining both user programmes test kits and commercial sales worldwide. Cxbladder tests increased 19% in the six months to 30 September from the prior six months (185% y-o-y). A number of user programmes are underway in the US with the potential to convert to commercial sales over the next year, including with the sizeable Southern California Permanente Medical Group.

Valuation: Edges up to NZ\$496m

Our valuation for Pacific Edge edges upwards to NZ\$496m (NZ\$1.32 per share) from NZ\$487m (NZ\$1.29/share) purely on the back of a slight strengthening of the US dollar (>95% of our forecast sales are derived from the US). Following the NZ\$35m rights offer in July, the company looks to have sufficient liquidity to fund operations into 2017, at which time we expect Pacific Edge to become profitable.

Commercial update

Pharma & biotech

17 November 2015

Price **NZ\$0.42**

Market cap **NZ\$158m**

NZ\$1.53/US\$

Net cash (NZ\$m) at 30 March 2015 7.8

Shares in issue 376.5m

Free float 74%

Code PEB

Primary exchange NZX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (8.7) (26.3) (48.4)

Rel (local) (10.8) (28.3) (50.2)

52-week high/low NZ\$0.91 NZ\$0.41

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 2015

Decision on Commercialisation VA/CMS Early/mid-2016

Cxbladder Monitor launch New Zealand 2015

Interim results 26 November 2015

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Working towards full commercialisation

Pacific Edge is moving towards fully commercialising its molecular diagnostics testing with a steady increase in sales from existing customers, albeit off a low base, and with healthcare organisations' ongoing testing through user programmes. A number of these programmes are underway in the US where we await news on the slightly delayed recruitment for the sizeable Southern California Permanente Medical Group. In Singapore, the first user programme at Tan Tock Seng hospital is testing the potential for Cxbladder products in South-East Asia for patients needing testing for bladder cancer as well as those coming to SEA for routine medical check-ups. Sales in the smaller New Zealand market are slowly building, where a third product, Cxbladder Monitor, is targeted for launch by the year end. In Australia an announcement is expected on a new commercial partnership to drive sales forwards after the company ended its agreement with Healthscope earlier this year.

Exhibit 1: Pacific Edge upcoming newsflow – Cxbladder franchise

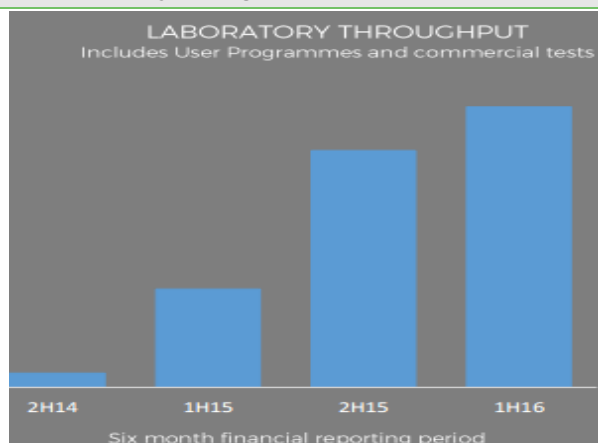
Event	Timing (calendar year)
Formal launch Cxbladder Triage US	2015
Enrolment into completion of Kaiser Permanente user programme	Mid-2016
Decisions on commercialisation VA/CMS	Early/mid-2016
Initiate up to four key user programmes in South-East Asia	2015/16
Cxbladder Monitor launch in New Zealand	2015
Cxbladder Predict launch in New Zealand	2016

Source: Edison Investment Research

Continued growth in laboratory throughput

In conjunction with a recent company update for investors issued earlier this month, Pacific Edge released its semi-annual laboratory throughput numbers, which include both user programmes and commercial sales worldwide. Absolute numbers are not provided, but the company reported an increase in the number of Cxbladder tests processed through Pacific Edge Laboratories of 19% in the six months to 30 September and an increase of 185% y-o-y. Management also indicated that laboratory throughput continued to grow strongly in September and October following the traditional seasonal downturn in the US.

Exhibit 2: Semi-annual laboratory throughput



Source: Edison Investment Research, company reports

Making inroads with US public and private healthcare organisations

Pacific Edge is making steady progress in the US public sector. Earlier this year, the company submitted its dossier for Cxbladder Detect for approval and addition to the Federal Supply Schedule (VA FSS)¹ to gain commercial access to the VA. The company is now in the final stages of a lengthy review process with the VA to gain access to the Federal Supply Schedule that will enable sales to VA urologists. The VA is an organisation that represents a considerable market providing care to approximately nine million veterans and their families. Progress has also been made in the negotiation process with the CMS, and management expect the conclusion of discussion on approval and reimbursement to provide a significant lift in revenue/lab throughput for Cxbladder tests in the coming months. CMS provides healthcare services to the elderly and lower income in the US and, according to Pacific Edge, represents 40% of its total target market. Volumes with the VA and CMS are likely to be significant (although prices fetched will be somewhat lower than that anticipated in non-public markets).

In the private sector, the company's large user programme with Southern California Permanente Medical Group is currently recruiting an approximate 2,000 patients for the evaluation of the Cxbladder Triage. Recruitment of the pilot programme has been somewhat slower than our expectations but a more rapid ramp-up is expected following the imminent finalisation of a new patient consenting electronic platform and full recruitment is anticipated by mid-2016. We believe a successful conclusion of the programme will provide a critical validation of the Cxbladder technology and its usefulness in clinical workups for those patients with bladder cancer and/or those at risk. We also expect other ongoing US user programmes to conclude and transition to full commercial adoption in the coming quarters.

Pacific Edge is also moving ahead in the US on other fronts. Management plans to hire an extra two sales executives in addition to the current four in the coming months. The new hires will augment the 16 sales specialists, which are canvassing 19 earmarked regions. Meanwhile, a soft launch of the company's second bladder cancer test, Cxbladder Triage, was completed in the US in July with a formal launch planned by year end following the anticipated final CLIA regulatory approval.

Valuation

Our fair value for Pacific Edge is adjusted only slightly to NZ\$496m (NZ\$1.32 per share) from NZ\$487m (NZ\$1.29 per share) in August 2015 on the edging up of the US dollar against the New Zealand dollar (to NZ\$1.53 from NZ\$1.51). We derive our valuation by applying our standard 12.5% discount rate, which includes only the sales of Cxbladder Detect and Cxbladder Triage in the US, New Zealand and Australia. We exclude forecasts for potential additional product launches in the Cxbladder franchise, tests in the pipeline for follow-on cancer indications and sales in additional regions, including South-East Asia where Cxbladder is currently in beta testing in Singapore.

Financials

Our short-term estimates have been revised slightly upwards since our last [update](#) in August 2015 on exchange rate fluctuations only. The company will publish interim (half-year) results at the end of November, at which time we will revisit our forecasts. In the second half of fiscal 2015 (ending 30 March), Pacific Edge reported product sales of NZ\$1.2m on throughput of several thousand tests,

¹ Enables provision of goods and services to government entities and enterprises.



up significantly from NZ\$715m in H115. We expect sales will remain modest until converting larger-scale user programmes to commercial use begins feeding through to the top line in the latter part of 2016. We currently model sales to top NZ \$100m in 2020, more conservative than management's communicated estimate of reaching NZ\$100m by 2018.

Management projects a cash outflow of approximately NZ\$15m in 2016 and we are slightly more conservative, forecasting NZ\$16.4m. Current cash holdings estimated at NZ\$34m at end September – boosted earlier this year by a NZ\$35m rights offer – should carry the company through to profitability in 2017.

Exhibit 3: Financial summary

	NZ\$000s	2013	2014	2015	2016e	2017e
Year-end 31 March		NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS						
Revenue		178	523	3,737	8,470	28,157
Cost of Sales		0	0	(588)	(980)	(2,951)
Gross Profit		178	523	3,148	7,489	25,206
EBITDA		(6,960)	(9,311)	(10,508)	(14,400)	2,048
Operating Profit (before GW and except.)		(7,155)	(9,579)	(10,816)	(14,847)	1,684
Intangible Amortisation		0	(116)	(151)	(61)	(96)
Exceptionals		0	0	0	0	0
Operating Profit		(7,155)	(9,695)	(10,966)	(14,908)	1,588
Other		(92)	(571)	(750)	(750)	(750)
Net Interest		330	315	510	540	806
Profit Before Tax (norm)		(6,917)	(9,835)	(11,056)	(15,057)	1,740
Profit Before Tax (FRS 3)		(6,917)	(9,951)	(11,207)	(15,118)	1,645
Tax		0	0	0	0	(164)
Profit After Tax (norm)		(6,917)	(9,835)	(11,056)	(15,057)	1,576
Profit After Tax (FRS 3)		(6,917)	(9,951)	(11,207)	(15,118)	1,480
Average Number of Shares Outstanding (m)		275.4	291.3	318.6	366.0	376.5
EPS - normalised (c)		(2.5)	(3.4)	(3.5)	(4.1)	0.4
EPS - FRS 3 (c)		(2.5)	(3.4)	(3.5)	(4.1)	0.4
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		1,210	1,305	1,362	1,292	1,289
Intangible Assets		0	193	244	382	491
Tangible Assets		1,081	1,112	1,118	910	797
Other		129	0	0	0	0
Current Assets		11,012	21,426	11,271	30,332	31,980
Stocks		0	242	623	725	1,000
Debtors		132	574	2,584	2,584	2,584
Cash		10,676	20,444	7,819	26,869	28,242
Other		204	166	245	154	154
Current Liabilities		(1,078)	(953)	(1,930)	(1,167)	(1,332)
Creditors		(922)	(953)	(1,930)	(1,167)	(1,332)
Short term borrowings		0	0	0	0	0
Short term leases		0	0	0	0	0
Other		(156)	0	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		11,145	21,778	10,703	30,457	31,937
CASH FLOW						
Operating Cash Flow		(6,710)	(9,524)	(13,026)	(16,374)	1,023
Net Interest		0	0	510	540	806
Tax		0	0	0	0	0
Capex		(1,009)	(497)	(427)	(438)	(456)
Acquisitions/disposals		0	0	0	0	0
Financing		445	21,002	0	35,000	0
Dividends		0	0	0	0	0
Other		(9)	(1,232)	1	23	0
Net Cash Flow		(7,283)	9,749	(12,942)	18,750	1,373
Opening net debt/(cash)		(17,959)	(10,676)	(20,444)	(7,819)	(26,869)
HP finance leases initiated		0	0	0	0	0
Other		0	20	317	300	23
Closing net debt/(cash)		(10,676)	(20,444)	(7,819)	(26,869)	(28,265)

Source: Pacific Edge accounts, Edison Investment Research

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