

Pacific Edge

Advances in bladder cancer diagnosis

Pacific Edge is driving the commercial launch of its molecular diagnostic Cxbladder_{detect} in the US in 2014. The advantage of the test is its greater accuracy in detecting cancer, particularly at the early stages, than established methods, and it is a faster, less invasive, more cost-effective option. It is also preparing to launch line extension Cxbladder_{triage} in Q314 as an additional tool for urologists. The market opportunity for Cxbladder_{detect} in the US alone is greater than NZ\$600m.

Clinically validated and differentiated diagnostic test

Cxbladder_{detect} is a gene-based diagnostic, designed to detect the presence of bladder cancer in patients presenting with haematuria, blood in the urine. In a 485-patient clinical study, the test demonstrated 82% overall sensitivity (true negatives) and 85% specificity (true positives) vs cytology, the gold standard (56% and 95% respectively). The test detected 100% of stages Tis and T1 to T3 tumours and 97% of high-grade tumours, outperforming the benchmark tests in the study. A new product, Cxbladder_{triage}, is due for launch in Q314 as a test with high sensitivity and negative predictive value, which physicians could use to rule out the presence of a tumour.

Progress in the US is central

The key catalyst in 2014 will be further evidence of commercial progress in the US. Cxbladder_{detect} was launched in the US in July 2013. Pacific Edge has agreements with four US national provider networks and is negotiating reimbursement with large commercial payers and with the Center for Medicare and Medicaid Services (CMS). Pacific Edge is growing out its US direct sales force focusing on high-volume specialists; over one million patients per year present for urine testing with haematuria. Cxbladder_{triage} would be commercialised through the same channels.

Financial flexibility

Pacific Edge reported a 187% increase in FY13 trading revenue to NZ\$0.5m. The net cash position on 31 March 2014 was NZ\$20.4m, after completing a NZ\$20.5m (gross) rights issue in December 2013. The proceeds will be invested in building sales and marketing infrastructure and developing the pipeline during 2014/15.

Valuation: US launch of Cxbladder is the key driver

The shares have underperformed the NZX All Index during the calendar year to date, having risen over 60% after signing an agreement with three of the key US national provider networks in 2013. There is scope for further re-ratings as Pacific Edge delivers on its growth strategy. We will publish a full initiation report in due course.

Historical financials

Year end	Revenue (NZ\$m)	PBT (NZ\$m)	EPS (NZ\$)	DPS (NZ\$)	P/E (x)	Yield (%)
03/13	0.18	(6.9)	(0.03)	0.0	N/A	N/A
03/14	0.52	(10.0)	(0.03)	0.0	N/A	N/A

Source: Pacific Edge. Note: Revenue only includes trading revenue.

Pharma & biotech

15 July 2014

Price NZ\$0.76
Market cap NZ\$242m

Share price graph



Share details

Code PEB
Listing NZSX
Shares in issue 318.6m

Business description

Pacific Edge develops and sells molecular diagnostic tests based on biomarkers for the early detection and management of cancer. The first, Cxbladder_{detect}, is commercially available in New Zealand, Australia and the US. There are two other bladder cancer tests in the pipeline, plus tests for colorectal and gastric cancers.

Bull

- The test has been clinically validated and widely adopted in New Zealand and Australia.
- Agreements signed with four US national provider networks.
- Technology is applicable for other tests: a bladder cancer triage test to be launched in 2014; pipeline of diagnostic tests in colon and gastric cancers.

Bear

- Healthcare specialists can have a conservative attitude towards adopting new technologies.
- Revenues for Cxbladder in Europe dependent on partners.
- Potential competition from unknown diagnostic tests in development.

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