

Pacific Edge

Rights offer to support expansion

Pacific Edge raised NZ\$35.3m in a rights issue, which completed in early July. Funds are to be used mainly to provide cash for continued commercialisation of its Cxbladder diagnostics tests in its primary US market, as well as to fuel international expansion. The company also recently announced its first User Programme in South-East Asia with the completion of an agreement with Singaporean hospital Tan Tock Seng representing the start of its stated intent to capture the significant South-East Asian market. Pacific Edge also reported full-year results at the end of May, largely in line with our expectations.

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	8.4	(15.2)	(4.1)	0.0	N/A	N/A
03/17e	27.8	1.4	0.3	0.0	N/A	N/A

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

Rights offer supports worldwide marketing

Pacific Edge has raised NZ\$35.3m (uptake 100%) in the form of a fully underwritten rights offer, completing early July. Eligible shareholders received two new shares for every 11 held at a price of NZ\$0.61 per share. The proceeds are to be used to reinforce the balance sheet, increase the salesforce in the US (from 12 to 18 people), and support expansion into the South-East Asian market, including initial launch of operations in Singapore. Funds will also be used for the commercialisation of its next two products in the Cxbladder franchise, Cxbladder Monitor and Cxbladder Predict.

Singapore and entry into South-East Asia

Pacific Edge recently announced a newly-signed User Programme with Tan Tock Seng Hospital in Singapore (TTSH). TTSH is one of Singapore's largest hospitals with 40 clinical and allied health departments and ~7,000 staff tending to ~2,000 patients per day. Initially, TTSH will trial Cxbladder Detect in those patients presenting with hematuria. The User Programme with TTSH represents a first move into a potentially significant market. The company is also in the process of employing a sales and marketing staff in the region to pursue commercial roll-outs in Bangkok and Taipei.

Valuation: NZ\$487m from NZ\$380

Our valuation increases to NZ\$487m (\$1.29/share) from NZ\$379.6m (NZ\$1.19/share). Our fair value is increased primarily on the strength of the US dollar and the NZ\$35m in proceeds from the rights offer. These increases are partially offset by the company's planned increase in expenditure. We expect cash holdings, shored up by the newly raised funds, to carry the company through to profitability in fiscal year 2017.

Successful rights issue

Pharma & biotech

17 August 2015

Price **NZ\$0.61**

Market cap **NZ\$230m**

NZ\$1.51/US\$

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

Shares in issue 376.5m

Free float 74%

Code PEB

Primary exchange NZX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (6.2) (15.8) (11.0)

Rel (local) (6.7) (14.9) (17.7)

52-week high/low NZ\$0.93 NZ\$0.64

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

Cxbladder Monitor launch 2015

Completion of SCPMG user programme 2015

Preliminary H116 results Dec 2015

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Headway on geographic and product growth

Completion of NZ\$35.3m rights offer

Following the reporting of its full-year results ending March 2015, Pacific Edge announced the completion of a rights offer to support the ongoing international commercialisation of the Cxbladder franchise. The company raised NZ\$35.3m in the form of a fully underwritten pro rata renounceable rights offer, which was 100% subscribed. Eligible shareholders were offered two new shares for every 11 held at a price of NZ\$0.61 per share (the share price was NZ\$0.72 on 28 May when the offer was announced). The offer, which opened 12 June, completed on 9 July.

The company has specified uses of funds from the raising, which in addition to the reinforcement of its balance sheet, include the increase of the salesforce in the US (from 12 to 18 people), continued assessment of the South-East Asian market including initial launch of operations in Singapore and the commercialisation of its next two products in the Cxbladder franchise, Cxbladder Monitor and Cxbladder Predict.

Expansion into Asia through Singapore

Pacific Edge is currently evaluating the South-East Asian market opportunity. In early June, the company announced its first entry into South-East Asia with the completion of a User Programme agreement with Tan Tock Seng Hospital (TTSH) in Singapore, a move we consider a significant strategic step for the company. TTSH is one of Singapore's largest hospitals with 40 clinical and allied health departments and a more than 7,000 strong staff which is tending to over 2,000 patients per day. Initially, the programme will trial Cxbladder Detect in those patients presenting with hematuria, however there is also considerable future potential for testing with Cxbladder Triage in conjunction with a total workup for patients, particularly for the increasing numbers of medical tourists coming to TTSH seeking annual wellness check-ups. We note that approximately one million medical tourists are visiting Singapore annually, which according to Pacific Edge is projected to exceed 1.3 million visits by 2018. This tourist patient population regularly pays out of pocket, thereby lowering any reimbursement hurdles.

The user programme with TTSH represents a first move into a potentially significant market. In this targeted growth region, the company anticipates work with additional hospitals and clinics in Singapore and other areas of South-East Asia, with the goal of adding three additional key user programmes by year end. The company is also in the process of employing a sales and marketing staff in the region to pursue commercial roll-outs in Bangkok and Taipei. Financial support for the programme will be provided by the recently announced grant from New Zealand Trade and Enterprise (NZTE). The three-year \$600,000 grant to aid in the evaluation of the South-East Asia market opportunity will be dispersed on the basis of milestones and Pacific Edge will match the NZTE funding.

While, in our view, the signing-on of TTSH represents a significant milestone, we remain conservative and do not yet include potential sales into the region, awaiting the completion of Pacific Edge's evaluation and clarity on sales potential, particularly that stemming from the potentially large medical tourist community.

Progress with public & private healthcare organisations in the US

Pacific Edge is making steady inroads into what is a well-established US market for the workup of those patients with hematuria. Management are targeting the completion of the Veteran's Administration (VA) process by the end of calendar 2015, having recently submitted its dossier for

the Federal Supply Schedule¹ application for commercial access to the VA. Progress has also been made in the negotiation process with the Centers for Medicare and Medicaid Services (CMS) with the conclusion of discussions expected by year end. Volumes are likely to be significant with these organisations although reimbursement will be somewhat below that of the ~\$600 per test anticipated in the private sector.

Also in the US, a key user programme with Southern California Permanente Medical Group has recently begun recruiting approximately 2,000 patients for the evaluation of the Cxbladder Triage. Conclusion of the pilot programme is anticipated by the end of calendar 2015 or early-2016. We also await the potential full adoption of Cxbladder Detect in the coming quarters with healthcare providers from three ongoing user programmes in the US.

Exhibit 1: Pacific Edge upcoming newsflow – Cxbladder franchise

Event	Timing (calendar year)
Launch Cxbladder triage US	Q315
Outcome of Kaiser Permanente user programme	End-2015/early-2016
Decisions on commercialisation VA/CMS	End-2015/early-2016
Initiate up to four key user programmes South-East Asia	2015/2016
Cxbladder Monitor launch in New Zealand	2015
Cxbladder Predict launch in New Zealand	2016
Source: Edison Investment Research	

Scientific journals supports Cxbladder test accuracy

A recent study completed by a consortium of authors with support from the Auckland University of Technology followed prior findings as to the advantages of Cxbladder Detect versus other non-invasive urinary cancer diagnostics. The data confirmed previous peer-reviewed trials. In mid-May, the scientific journal Biomed Central Medical Research Methodology ranked four non-invasive bladder cancer diagnostic tests based on a study of 939 patients including nine with urinary carcinoma, across five data sets. Data compared Pacific Edge's Cxbladder Detect with three tests – UroVysion fluorescence in situ hybridization (FISH) assay (molecular test widely used in the US and reimbursed by most major players), cytology and NMP22 – on three measures of accuracy; sensitivity, signal-to-noise (SNR) and cross-validation error rates. Overall, Cxbladder Detect outperformed other tests. Data showed Cxbladder Detect ranking higher than FISH and other tests when SNR analyses were performed, also ranking highest on sensitivity while urine cytology ranked highest on specificity.² We expect these positive results and validation of the Cxbladder technology to support and enhance the ongoing marketing effort in the commercialisation of the Cxbladder franchise.

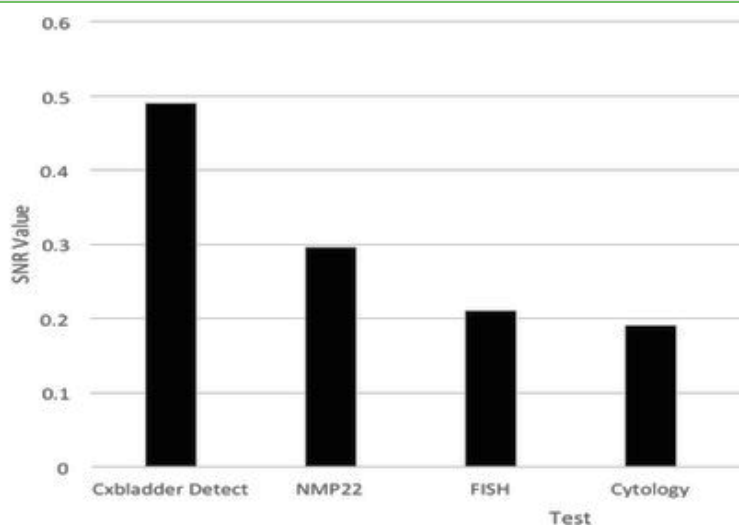
Exhibit 2: Sensitivity/specificity urinary cancer diagnostic tests

	Sensitivity % (95% CI)	Specificity % (95% CI)
Cxbladder Detect	73.6 (65.1-81.7)	81.7 (78.7-84.4)
Cytology	46.0 (36.3-55.8)	95.3 (93.7-96.6)
NMP22	45.9 (35.9-56.3)	88.0 (85.5-90.2)
FISH	47.7 (31.5-63.3)	87.7 (84.7-90.3)
Source: Breen et al. BMC Medical Research Methodology 2015		

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

² Sensitivity = % of sick people who are correctly identified as having the condition. Specificity = % of healthy people correctly identified as not having the condition.

Exhibit 3: SNR ranking of urinary cancer diagnostic test



Source: Breen et al. BMC Medical Research Methodology 2015

We also highlight the publication of research in BMC Urology on Cxbladder Triage in April. The journal presented the findings of a study using the segregation index applied by Cxbladder Triage which combines phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to segregate those patients with microhematuria with a low probability of urothelial cancer. The data revealed that 80% of those patients with microhematuria who did not have urothelial cancer were correctly triaged out using the G&P index and were therefore able to bypass a full urological work-up. The findings highlight the opportunity for physicians to triage out patients not requiring a full urological work-up in an effort to reduce diagnostic costs and patient inconvenience.

Valuation

Our valuation for Pacific Edge is adjusted upwards to NZ\$487m (NZ\$1.29 per share) from NZ\$379.6m (NZ\$1.19 per share). The change in our fair value market capitalisation primarily reflects the continued dollar strength and the recent capital raise. The US dollar has increased to NZ\$1.51 vs NZ\$1.30 in our last report, adding 24% to our valuation (98% of our projected sales are expected to come from the US in the coming years). New funds from the capital increase are partially offset by a change in our forecasts on the back of the announced step-up in expected expenditure in 2016. Additionally, our fair value per share is affected by the 18% dilution on the increase of 57.9m new shares in conjunction with the capital raise. As detailed, the new funds have been earmarked mainly for use in the marketing of current and soon to be launched products and for continued international expansion. Our valuation is derived from a discounted cash flow utilizing our standard 12.5% discount rate which includes sales of Cxbladder Detect and Cxbladder Triage in the US, New Zealand and Australia. We do not include forecasts for new product launches within the Cxbladder franchise or for tests in the pipeline on follow-on cancer indications.

Financials

Full year results meet our forecasts

- Generally in line with our expectation, Pacific Edge reported sales (ordinary revenue) of NZ\$3.35 million for the full year end-March 2015, of which 57% were product sales. As expected, product sales in H215 of NZ\$1.2m showed a marked step-up from NZ\$715k in H115

on throughput of several thousand tests. Current sales are only scratching the surface of what we believe is a significant revenue opportunity, as ongoing user programmes convert into fully-paid contracts in coming quarters. Management has reiterated its goal of achieving NZ\$100m in sales in its fifth full year of trading, ie in FY18, a number which we conservatively model to be reached in FY20.

- The company reported a net trading loss of NZ\$7.7m for the full year with the net loss of NZ\$3.9m in H2 roughly in line with H1 at NZ\$3.6m. Nearly all cash flow expenses for the year were from SG&A and R&D at an estimated NZ\$6.3m and NZ\$4.0m respectively.
- The company ended 2015 with cash and short-term deposits on hand of NZ\$7.8m. The company's projected net cash outflow in fiscal 2016 of approximately NZ\$15m will be funded via the NZ\$35.3m rights offer which we anticipate should carry the company through to profitability in 2017.

The table below shows our P&L forecast for 2016 and 2017 pre- and post-preliminary 2015 results. Changes are primarily related to the projected stepped up planned expenditures as provided by the company and currency fluctuations.

Exhibit 4: Changes to estimates									
NZ\$	Sales			Operating income			Net income		
	Old	New	% change	Old	New	% change	Old	New	% change
2016e	8,369	8,369	0.0%	-6,694	-15,008	-124.2%	-6,223	-15,157	-143.6%
2017e	27,805	27,805	0.0%	9,970	1,237	-87.6%	8,974	1,256	-86.0%
Source: Edison Investment Research									

Exhibit 5: 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	3,714	8,369	27,805
Cost of Sales		0	0	(588)	(980)	(2,951)
Gross Profit		178	523	3,125	7,389	24,854
EBITDA		(6,960)	(9,311)	(10,530)	(14,500)	1,696
Operating Profit (before GW and except.)		(7,155)	(9,579)	(10,838)	(14,947)	1,332
Intangible Amortisation		0	(116)	(151)	(61)	(96)
Exceptionals		0	0	0	0	0
Operating Profit		(7,155)	(9,695)	(10,989)	(15,008)	1,237
Other		(92)	(571)	(750)	(750)	(750)
Net Interest		330	315	510	540	802
Profit Before Tax (norm)		(6,917)	(9,835)	(11,079)	(15,157)	1,384
Profit Before Tax (FRS 3)		(6,917)	(9,951)	(11,229)	(15,218)	1,289
Tax		0	0	0	0	(129)
Profit After Tax (norm)		(6,917)	(9,835)	(11,079)	(15,157)	1,256
Profit After Tax (FRS 3)		(6,917)	(9,951)	(11,229)	(15,218)	1,160
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)	0.3
EPS - FRS 3 (c)		(2.5)	(3.4)	(3.5)	(4.2)	0.3
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	30,209	31,501
Stocks		0	242	623	725	1,000
Debtors		132	574	2,584	2,584	2,584
Cash		10,676	20,444	7,819	26,746	27,763
Other		204	166	245	154	154
Current Liabilities		(1,078)	(953)	(1,930)	(1,167)	(1,296)
Creditors		(922)	(953)	(1,930)	(1,167)	(1,296)
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	30,334	31,494
CASH FLOW						
Operating Cash Flow		(6,710)	(9,524)	(13,048)	(16,475)	671
Net Interest		0	0	510	540	802
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	0	0
Net Cash Flow		(7,283)	9,749	(12,965)	18,626	1,017
Opening net debt/(cash)		(17,959)	(10,676)	(20,444)	(7,819)	(26,746)
HP finance leases initiated		0	0	0	0	0
Other		0	20	340	300	(0)
Closing net debt/(cash)		(10,676)	(20,444)	(7,819)	(26,745)	(27,763)

Source: Company accounts, Edison Investment Research

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