

Pacific Edge

Early signs of revenue traction

H114 results

Pacific Edge has reported encouraging headline results for its fiscal H115 ending in September. Sales reached NZ\$1.59m, of which NZ\$714k was attributed to trading revenue, a 774% increase from the previous year. The net loss of NZ\$4.9m in the six months to September was roughly in line with the previous six-month period, indicating continued lean management and cost control. Additionally, the company has announced the launch of complementary bladder test Cxbladder Triage in New Zealand. We value Pacific Edge at NZ\$369m (previously NZ\$338m).

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	3.2	(8.0)	(2.5)	0.0	N/A	N/A
03/16e	15.7	0.9	0.3	0.0	N/A	N/A

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

H115 headline figures show sales on course

Headline sales, while still small at an absolute level, showed a marked increase, providing reassurance as to the initial acceptance and adoption of the company's first product to market, Cxbladder Detect, launched in the US in mid-2013. We await the conclusion of key user programmes in the US beginning in 2015. The NZ\$4.9m net loss was only slightly higher than our forecast, but we continue to forecast that net cash (NZ\$14.7m as at September 2014) is sufficient to support operations into 2016. We await full and detailed fiscal H1 results in December.

Business expansion underway

Management has also provided colour on its recent progress via its press release and conference call. The company's near-term strategic focus remains on the Cxbladder franchise in the US, Australia and New Zealand, whereby Cxbladder Triage has just been made available in New Zealand (US launch planned for early 2015). Management also continues to evaluate potential geographic expansion with its eyes on South-East Asia. Ground work with partner Oryzon Genomics is ongoing in preparation for the launch of Cxbladder Detect into Spain and Portugal. A recent patent approval for Pacific Edge's colorectal cancer prognostic technology also indicates progress in furthering the company's pipeline products beyond the Cxbladder franchise.

Valuation: NZ\$369m from NZ\$338m

In conjunction with the headline interim results, we increase our fair value to NZ\$369m from NZ\$338m (NZ\$1.16 per share from NZ\$1.06). The increase is based primarily on the strength of the US dollar and slightly higher than expected interim trading sales offset by a slightly higher than forecast net loss in the period (we await detailed half year results in the coming weeks). We base our valuation on a discounted cash flow for the company (discount rate 12.5%), incorporating sales for Pacific Edge's two lead products only, Cxbladder Detect and Cxbladder Triage.

Pharma & biotech

16 December 2014

Price **NZ\$0.83**

Market cap **NZ\$264m**

NZ\$1.29/US\$

Cash as at September 2014 NZ\$14.7m

Shares in issue 318.6m

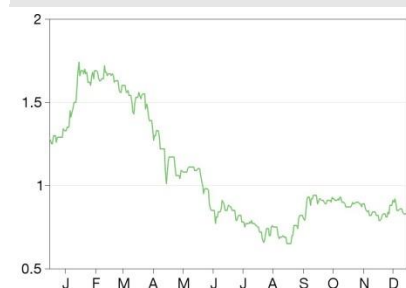
Free float 74%

Code PEB

Primary exchange NZX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 1.2 (6.7) (35.2)

Rel (local) 1.5 (10.1) (41.9)

52-week high/low NZ\$1.74 NZ\$0.65

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 early 2015). The pipeline includes additional tests in bladder, colorectal and gastric cancers.

Next events

Preliminary FY15 results May 2015

Completion of SCPMG user programme Mid-2015

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Early signs of traction in the US

Half year headline results: Encouraging top line

Pacific Edge recently announced headline results for the first six months of its fiscal year ending September 2014. Most notably, the company was able to report sales of NZ\$1.0m (~US\$0.8m) excluding ~NZ\$0.6m interest and foreign exchange gains. The NZ\$714k in user programme study tests and commercial sales in the period compares to NZ\$128k in trading sales in the six months previously, a 774% increase. Laboratory throughput nearly doubled in the US. Management has indicated that the step up in turnover was supported by progress in the US following its launch of Cxbladder Detect in mid-2013. However, solid sales growth was also reportedly achieved in its other two markets, New Zealand and Australia, albeit from very small bases. In conjunction with the results, Pacific Edge has also confirmed the company's longer-run sales target of NZ\$100m in the fiscal year following five full years of trading, ie FY19. We continue to err on the side of caution, forecasting sales of NZ\$100m one year later in FY20.

Pacific Edge finished H115 with cash on hand of NZ\$14.7m, which, on our forecast cash burn, should bring the company through the first quarter of 2016. However, future cash burn is dependent on the pace of the expected ramp-up in sales over the next year following the conclusion of initial user programmes and the results of negotiations with key public health organisations. Pacific Edge reported a net loss of NZ\$4.9m in the first six months, with expenditure principally related to investment in the workforce, intellectual property, market expansion and product development. We note the company has remained mindful of costs. We expect the increase in cash burn in the first six months at NZ\$6.1m, up from NZ\$4.3m in the previous year, was in large part to support the ramp-up of sales in the US including the building of the sales force.

Appointment of new CFO

Pacific Edge announced the appointment of a new CFO on 13 November, rounding out the management team. Kate Rankin comes to Pacific Edge with significant corporate experience in the US, Asia and the UK. Having lived and worked abroad, she brings international financial management expertise to the company. Her role is additive to the company whereby we expect this additional seat on the executive board will provide it with further skill and experience.

Commercialisation of diagnostic testing on track

Pacific Edge remains on schedule for the commercialisation of its leading product franchise, Cxbladder. In addition to the promising sales development in the first six months of the year, management confirmed in its conference call following interim 2015 results that negotiations are ongoing with public healthcare organisations, including the Center for Medicaid and Medicare Services (CMS), and that steady progress is being made with major healthcare organisations. Management intends to continue to grow its number of user programmes. Two new programmes have recently been signed in Australia, while in the US to date four healthcare providers are undertaking user programmes for Cxbladder Detect, each having been signed following an initial evaluation period of three to nine months. Most recently, the company entered into a key user programme agreement in August with integrated healthcare provider Southern California Permanente Medical Group, which employs more than 5,500 physicians. Management reported that this programme will be enrolling an estimated 2,000 patients presenting with haematuria (blood in urine) over the next few months. The programme, expected to conclude in 2015, will evaluate the performance of its newer complementary product, Cxbladder Triage, in the clinical setting and we

expect the outcome will be an important indicator of greater sales potential for the Cxbladder suite of products.

Pacific Edge launched Cxbladder Triage in New Zealand in early December and will launch the test in the US in early CY15. The test is designed to enable clinicians and physicians to accurately segregate patients who present with haematuria (blood in the urine), who have a low probability of having bladder cancer. Cxbladder Triage is designed as a complement to Cxbladder Detect and is potentially a means to save many patients from undergoing an expensive and invasive investigation for bladder cancer. In New Zealand Cxbladder Triage is targeted at physicians and clinicians evaluating patients with haematuria in the primary care setting. In the US, the American Urological Association recently made changes to its clinical primary evaluation guidelines, now urging patients identified with low levels of blood in their urine to undergo more extensive testing. We expect the new recommendations will eventually lead to a significant increase in the number of people required to be tested for urinary tract carcinomas in a patient population ideally suited for the Cxbladder products.

The sales force continues to focus on large urology groups (LUGs) and other sizeable urology networks. In accordance with plans, the sales team has expanded in recent months from four to 12 people in the US, enabling coverage of 11 of the 19 high-density, large urban urology areas. Management will continue to monitor its sales force requirements as it works toward its intermediate goal of coverage of all 19 targeted urology areas. A sales force of 20 reps is envisioned, although this will depend on take-up, initial sales and the number of accounts that can ultimately be serviced by one salesperson.

Following its initial launch in New Zealand, the US and Australia, Pacific Edge has also indicated its intention to expand the market reach of its diagnostics products further in the near to medium term, having identified additional market opportunities globally, including South-East Asia, a relatively medically progressive region, and Japan.

Patents received for colorectal and melanoma cancer tests

In late November, the European Intellectual Property Office awarded Pacific Edge a patent for its colorectal cancer prognostic technology in all members of the EU and eight additional countries. This followed the issue of a patent for the company's colorectal technology in Japan in September, a market where colorectal ranks overall as the most prevalent of cancers. While the roll-out of the Cxbladder platform remains the current priority for the company, we note that management remains proactive in moving forward with its medium-term objective to further additional technologies in preparation for next market launches. Pacific Edge's colorectal test is designed to provide the clinician with a novel diagnostic to determine the aggressiveness and progression of Stage II and Stage III colorectal cancer, allowing for a more tailored treatment. A successful launch of the diagnostic could represent a considerable opportunity, given that well over one million cases of colorectal cases occur globally each year. Additionally, Pacific Edge was granted a patent in the US in September covering technology that will be used to develop a test that distinguishes aggressive and life-threatening melanomas from those not as aggressive.

We do not yet account for the potential of future products beyond Cxbladder in our valuation or forecasts for the company given the lack of a yet to be communicated commercialisation strategy and timeline. However, we note the current progress Pacific Edge has made in its patent estate provides an indication as to the potential of follow-on products and the company's overall capabilities in molecular diagnostics testing.

Sensitivities

Execution risk remains an important hurdle. While Cxbladder Detect has yet to fully prove itself commercially, the initial sales traction and first adoption of Pacific Edge's first product, Cxbladder Detect, in fiscal H115 is an important step toward the realisation of the product's much larger potential.

Success in the key US market will be the primary driver of Pacific Edge's valuation. The US accounts for c 95% of our projected sales in 2021. Healthcare specialists in the US (and worldwide) can have a conservative attitude towards adopting new technologies and the selling process for molecular diagnostics is normally protracted. Continuing to convert those organisations with current user programmes to fee-paying customers will be critical for the company. However, we expect Pacific Edge to be on the verge of meaningful conversions in the US. Management reports early signs of acceptance from clinicians and we are encouraged by first payments beginning to feed through. Ongoing and large user programmes in the US are expected to conclude in 2015 and, assuming positive evaluation, unleash significant sales potential from these sizeable organisations (eg Kaiser Permanente Southern California with its 3.7 million members).

Pacific Edge runs the risk of potential competition from any new diagnostic test not yet in the public domain. However, we do not expect a near-term competitive threat to the Cxbladder technology. Clinical validation will be critical for potential new tests, while the long lead time to commercial adoption serves as a high barrier to entry.

Valuation

Our fair valuation for Pacific Edge increases from NZ\$338m to NZ\$369m (or NZ\$1.06 to NZ\$1.16 per share). The increase is mainly due to the strength of the US dollar (given that the vast majority of our forecast sales are in the US market), as well as the slightly higher than expected reported interim 2015 trading sales. This is offset by the tweaking of our forecasts based on the company's reported interim headline 2015 results. An increase in our forecast net loss for FY15 follows the slightly higher than expected reported interim 2015 costs, which we expect is primarily due to a step-up in marketing and R&D to support future sales; however, we await detailed accounts expected in December for more elucidation. Our valuation is derived using a DCF methodology using a discount rate of 12.5% and using forecast free cash flows. We include sales for Cxbladder Detect and Cxbladder Triage, conservatively excluding additional pipeline products in our forecasts. We also forecast sales into the US, New Zealand and Australia only and do not factor in potential added value for the company's technology.

Exhibit 1: Pacific Edge financial summary

	NZ\$000s	2011	2012	2013	2014	2015e	2016e
Year end 31 March		NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS							
Revenue		202	280	178	523	3,192	15,701
Cost of Sales		0	0	0	0	(460)	(1,990)
Gross Profit		202	280	178	523	2,731	13,711
EBITDA		(3,115)	(4,176)	(6,960)	(9,311)	(7,963)	1,074
Operating Profit (before GW and except.)		(3,227)	(4,354)	(7,155)	(9,579)	(8,408)	675
Intangible Amortisation		0	0	0	(116)	(48)	(81)
Exceptionals		0	0	0	0	0	0
Operating Profit		(3,227)	(4,354)	(7,155)	(9,695)	(8,456)	593
Other		(1)	(96)	(92)	(571)	0	0
Net Interest		82	339	330	315	409	212
Profit Before Tax (norm)		(3,147)	(4,111)	(6,917)	(9,835)	(7,999)	886
Profit Before Tax (FRS 3)		(3,147)	(4,111)	(6,917)	(9,951)	(8,047)	805
Tax		0	0	0	0	0	0
Profit After Tax (norm)		(3,147)	(4,111)	(6,917)	(9,835)	(7,999)	886
Profit After Tax (FRS 3)		(3,147)	(4,111)	(6,917)	(9,951)	(8,047)	805
Average Number of Shares Outstanding (m)		172.2	232.0	275.4	291.3	318.6	318.6
EPS - normalised (c)		(1.8)	(1.8)	(2.5)	(3.4)	(2.5)	0.3
EPS - FRS 3 (c)		(1.8)	(1.8)	(2.5)	(3.4)	(2.5)	0.3
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	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	N/A
BALANCE SHEET							
Fixed Assets		544	396	1,210	1,305	1,325	1,374
Intangible Assets		0	0	0	193	325	424
Tangible Assets		544	396	1,081	1,112	1,000	949
Other		0	0	129	0	0	0
Current Assets		2,751	18,250	11,013	21,426	13,443	14,582
Stocks		0	0	0	242	341	1,472
Debtors		264	207	132	574	2,361	11,614
Cash		2,486	17,959	10,676	20,444	10,575	1,329
Other		1	84	204	167	167	167
Current Liabilities		(604)	(997)	(1,078)	(953)	(1,037)	(1,420)
Creditors		(411)	(803)	(922)	(953)	(1,037)	(1,420)
Short term borrowings		0	0	0	0	0	0
Short term leases		0	0	0	0	0	0
Other		(194)	(194)	(156)	0	0	0
Long Term Liabilities		0	0	0	0	0	0
Long term borrowings		0	0	0	0	0	0
Long term leases		0	0	0	0	0	0
Other long term liabilities		0	0	0	0	0	0
Net Assets		2,691	17,650	11,145	21,778	13,731	14,536
CASH FLOW							
Operating Cash Flow		(2,918)	(3,605)	(6,710)	(9,524)	(9,764)	(8,928)
Net Interest		0	0	0	0	409	212
Tax		0	0	0	0	0	0
Capex		(277)	(30)	(1,009)	(497)	(513)	(530)
Acquisitions/disposals		0	0	0	0	0	0
Financing		4,884	20,128	445	21,002	0	0
Dividends		0	0	0	0	0	0
Other		(159)	(1,020)	(9)	(1,232)	0	0
Net Cash Flow		1,530	15,473	(7,283)	9,749	(9,869)	(9,246)
Opening net debt/(cash)		(956)	(2,486)	(17,959)	(10,676)	(20,444)	(10,575)
HP finance leases initiated		0	0	0	0	0	0
Other		0	0	0	19	0	0
Closing net debt/(cash)		(2,486)	(17,959)	(10,676)	(20,444)	(10,575)	(1,329)

Source: Edison Investment Research, Pacific Edge accounts

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