EDISON

Pacific Edge

On the edge of glory

Initiation of coverage

Healthcare equipment & services

Pacific Edge (PEB) launched Cxbladder$_{detect}$, the first of its portfolio of urothelial cancer diagnostic tests, into the key US market in mid-2013. Sales from paying customers are beginning to feed through following the conclusion of initial user programmes and negotiations are fully underway with key public health organisations. We expect meaningful sales from Cxbladder$_{detect}$ in calendar 2015 and positive cash flow for the company in calendar 2016. We value Pacific Edge at NZ$1.16 per share.

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	2.6	(6.8)	(2.3)	0.0	N/A	N/A
03/16e	14.4	1.4	0.5	0.0	N/A	N/A

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

Cxbladder$_{detect}$ offers benefit to standard treatment

Cxbladder$_{detect}$ is a molecular diagnostic for the early detection and management of bladder cancer in patients with haematuria (blood in urine), a non-invasive adjunct to cystoscopy. It can replace other urine-based tests to identify more accurately those patients who should receive additional and more invasive testing. It is more accurate, less invasive and more cost-effective than standard testing.

Raising awareness in the key US market

Several large-scale US-based user programmes have been initiated in the 12 months Cxbladder$_{detect}$ has been on the US market. Pacific Edge has also signed agreements with four national provider networks and several large commercial payers. However, lead time to payment can be long and the key challenge will be to convert those trialling the test (mostly Pacific Edge funded) into fee-paying customers. Execution risk therefore remains an important hurdle and we expect proof of commercial success to serve as a compelling driver of the share price.

Portfolio of cancer diagnostics products

Pacific Edge is creating a franchise of products that can be commercialised through the same channels under the Cxbladder banner. The company plans to first focus on urothelial diagnostics with three products in development. Cxbladder$_{triage}$ is used to rule out bladder tumours and aimed at primary care physicians. Launch is planned in New Zealand by year end and in the US in mid-2015.

Valuation: DCF valuation of NZ$338m

Our valuation of Pacific Edge is based on a DCF using free cash flow and a WACC of 12.5%. We incorporate Pacific Edge's two lead products only into our valuation, forecasting peak sales of NZ$162m for Cxbladder$_{detect}$ and NZ$23m for Cxbladder$_{triage}$ by 2025. We see considerable scope for a re-rating of the shares as evidence of successful commercialisation emerges.

29 September 2014

Price	**NZ$0.91**
Market cap	**NZ$265m**

Net cash (NZ$m) as of March 2014	20.4
Shares in issue	291.3m
Free float	74%
Code	PEB
Primary exchange	NZX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	23.0	12.4	67.7
Rel (local)	23.5	11.4	58.6

52-week high/low	NZ$1.74	NZ$0.46

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

Next events

H115 results	December 2014
FY15 results	July 2015

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Edison profile page

Investment summary

Company description: Cancer diagnostics company

Pacific Edge Limited (PEB) was formed in August 2001 to develop molecular diagnostic and prognostic tools, in cancer. Pacific Edge is headquartered in Dunedin, New Zealand, and has two wholly-owned subsidiaries commercialising Cxbladder, Pacific Edge Diagnostics NZ Ltd in Dunedin and Pacific Edge USA (PED_{USA}) in Hershey, Pennsylvania. The company also has CLIA-regulated laboratories in Dunedin, NZ, and Hershey, PA. Pacific Edge joined the NZX in February 2002, when it raised NZ$3m. The company has raised total funds of c NZ$60m to date.

Pacific Edge launched its first product in 2011: $Cxbladder_{detect}$, a non-invasive urine based test that detects bladder cancer in people presenting with haematuria. $Cxbladder_{detect}$ was rolled out initially in New Zealand and Australia, and subsequently launched in the US in July 2013. The company has additional bladder cancer tests in the pipeline focusing on different value propositions identified by physicians and clinicians along the clinical pathway to provide a one-stop-shop offering. Pacific Edge plans to launch its second product, $Cxbladder_{triage}$, in New Zealand before the end of the year and into the US market in mid-2015. Pacific Edge runs its own product development programmes and has first rights to any new discoveries from the University of Otago's Cancer Genetics Laboratory.

Valuation: Attractive following pullback in price

We value Pacific Edge at NZ$338m (NZ$1.16 per share) using a DCF methodology based on free cash flow projections. We forecast peak sales of NZ$162m for $Cxbladder_{detect}$ and NZ$23m for $Cxbladder_{triage}$ by 2025. Now in the middle of the commercial roll-out of its first product, there is some ambiguity as to the full sales potential of the group, particularly given the complexities and vast size of its target market. Our sensitivity analysis suggests a value for Pacific Edge of NZ$0.46-3.91 per share based on the outcomes of two key variables, US average pricing and US market penetration for $Cxbladder_{detect}$.

Financials: Commercialisation is underway

Pacific Edge is on its way to realising the commercialisation of its first product in the US after more than a decade of research and product development on five cancers. Following a NZ$20m capital raise in October 2013, the company had cash and cash equivalents of NZ$20.4m and no debt at 31 March 2014. We forecast positive cash flow in FY17, without needing to issue new equity, when we expect Pacific Edge will begin to realise its first significant sales. Current laboratory facilities have the capacity to accommodate our forecast sales through to 2031. Much of the company's remaining cost base is variable as Pacific Edge outsources manufacturing, billing and reimbursement.

Sensitivities: Adoption by clinicians

Pacific Edge has successfully passed a number of milestones on the way to commercialisation in the crucial US market. Critical next steps toward wider-spread acceptance of $Cxbladder_{detect}$ in the US will be the conversion of ongoing user programmes into fee-paying customers and the closing of process with public agencies. $Cxbladder_{detect}$ is now undergoing evaluation by a number of clinicians and key opinion leaders and the first of the user programmes has converted to paying customers. Negotiations are proceeding with key organisations including the CMS (the federal agency administering to c 30% of the US population) and some larger private healthcare providers. Further out, Pacific Edge runs the risk of potential competition from new diagnostics tests. We do not see a near-term new competitive threat to $Cxbladder_{detect}$ or the Cxbladder portfolio of products. Clinical validation will be critical for new competitive technologies and the long lead time to commercial adoption serves as a high barrier to entry.

Outlook: On the edge of glory

Pacific Edge is focused on commercialising molecular tests for the detection and better management of urothelial cancers (UC). The company is working towards creating a franchise of products that can be commercialised through the same channels under the Cxbladder banner to meet a series of unmet needs along the same clinical pathway. The underlying principles are to meet clinical needs of urologists, notably a reduction in the length of current, repetitive and invasive diagnostic testing for UC and an improvement in accuracy over those tests currently in the market. The first test in the range, $Cxbladder_{detect}$, has been shown in clinical studies to be more accurate than benchmark tests at all stages and grades.

$Cxbladder_{detect}$ is regulated in the US as a laboratory-developed test that can be used for the detection of bladder cancer in patients that present with haematuria in conjunction with standard urological work-up, a patient population of around seven million pa in the US. The Cxbladder technology is gene-based and can be used as a non-invasive adjunct to cystoscopy or to replace other urine-based tests to identify more accurately those patients who should go on for more invasive testing. It is more accurate, faster, less invasive and more cost-effective than standard methods that include cytology, NMP22 BladderChek (Alere) and NMP22 ELISA (Fisher Scientific).

The test quantitatively measures the expression of five mRNA biomarkers in a small sample of the patient's urine that has been collected non-invasively. Pacific Edge has developed a set of algorithms that combine these biomarkers, CDC2, HOXA13, MDK, IGFBP5 and CXCR2, into a single score to detect and characterise bladder cancer. The urine sample is screened using a quantitative Polymerase Chain Reaction validation, a process that amplifies a small RNA sample. This system indicates a score-based probability of urothelial carcinoma – 0-0.12 normal; 0.12-0.23 elevated; and 0.23-1.0 high, based on gene expression.

Pacific Edge first launched $Cxbladder_{detect}$ in New Zealand and Australia in 2011. Subsequently, the company launched in the US in July 2013, initially targeting the higher-volume urology clinics. Its next product, $Cxbladder_{triage}$, is due to be launched over the next year in New Zealand the US and will also target physicians in the primary setting. There are two additional tests to follow. These tests are aimed at different value propositions in the evaluation and monitoring of UCs.

Exhibit 1: Summary of the Cxbladder pipeline

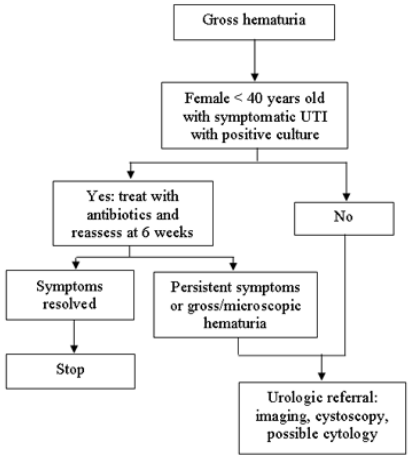
Product name	Function	Status	Notes
$Cxbladder_{detect}$	Detects bladder cancer in patients with haematuria.	Commercially available in NZ, Australia and the US.	Non-invasive laboratory test for the detection of bladder cancer. Adjunct to cystoscopy.
$Cxbladder_{triage}$	Used to rule out bladder cancer.	Preparing for commercial launch in NZ in H214.	High sensitivity and high negative predictive value.
$Cxbladder_{predict}$	Determines the severity of bladder cancer.	Clinical validation.	Prognostic test.
$Cxbladder_{monitor}$	Ongoing monitoring to check for recurrence.	Clinical validation.	High sensitivity and high negative predictive value to determine patients who should receive follow-up tests.

Source: Pacific Edge

Bladder cancer is the sixth most common cancer worldwide and has the highest per patient medical costs of any cancer. There will be an estimated 75,000 new cases diagnosed in the US in 2014 at an incidence rate of approximately 3%. Over 90% of bladder cancers are transitional cell carcinomas. Haematuria can be continuous or intermittent and either visible (gross) or microscopic. Screening studies have shown that in up to 20% of cases of gross haematuria, patients go on to be diagnosed with UC, while only 5% of cases of microscopic haematuria turn out to be UCs such that the 2001 American Urological Association (AUA) Best Practice Policy on Asymptomatic Microscopic Haematuria recommends that all patients presenting with gross haematuria, particularly those without evidence of infections, should undergo full urologic work-up. This procedure includes provision of a urine sample for testing with cytology (manual examination under a microscope) in conjunction with cystoscopy (insertion of a flexible scope into the urinary tract). Some patients are

also examined by means of upper tract imaging, typically with a CT scan or ultrasound imaging. Cytology tends to have low sensitivity (true positives), particularly at the earlier stages of cancer, and is subject to user variability.

Exhibit 2: Clinical pathway for detection/treatment of bladder cancer



Source: Medscape

Clinical validation

Cxbladder$_{detect}$ has been validated by means of a multicentre clinical study in 485 patients in Australasia, which compared the test to the benchmark urine tests. Pacific Edge has also completed a further blinded user study in 178 patients, which showed an equivalent rate of performance. Voided urine samples were analysed using Cxbladder, NMP22 Elisa and NMP22 Bladderchek and urine cytology. These patients were checked at the three-month stage by means of biopsy and histopathological examination. The sensitivity and specificity of each test was compared to cystoscopy as a reference.

Exhibit 3: Sensitivity of urine detection tests in multicentre clinical study in 485 patients

Tumour stage	Cxbladder$_{detect}$	Cytology	NMP22 BladderChek	NMP22 ELISA
Tis	100%	100%	0%	0%
Ta	68%	35%	38%	35%
T1	100%	69%	50%	75%
T2	100%	100%	22%	67%
T3	100%	100%	50%	100%
High grade tumours	97%	83%	38%	69%
Upper tract tumours	100%	50%	0%	75%
Overall sensitivity	82%	56%	38%	50%
Specificity	85%	96%	96%	88%

Source: Pacific Edge trial published in Journal of Urology, Vol 188, 741-747.

The study showed that Cxbladder$_{detect}$ was more accurate than cytology and NMP22 tests across all stages and grades at a pre-specified specificity of 85% including stage Ta, which is a potential advantage given the low sensitivity of other tests for early-stage bladder cancer. Pacific Edge has also completed independent clinical validation of Cxbladder$_{detect}$ in 178 patients in a New Zealand-based user performance study, which showed equivalent performance to that seen in the published clinical study. With a specificity rate of 90% and overall sensitivity at 73%, Cxbladder $_{detect}$ consistently outperformed the benchmark tests. Furthermore, Cxbladder$_{detect}$ identified five UCs that had not been diagnosed by cystoscopy, but were subsequently confirmed in a 12-month follow-up. The results were published in the International Journal of Urology in September 2012.

Edison analysis showed Cxbladder$_{detect}$ comparing favourably against Abbott's Urovysion in separate large-scale clinical trials, each with over 400 patients. Urovysion was launched 2001 as an aid in monitoring bladder cancer and in 2005 to aid diagnosis. The test uses Abbott's FISH fluorescence technology to detect chromosomal abnormalities. In a trial conducted by Abbott,

Urovysion showed an overall sensitivity of 68.6% and specificity of 77.7% in the detection of bladder cancer in 479 patients presenting with haematuria. This compared with a sensitivity of 82% and specificity of 85% for Cxbladder$_{detect}$ in the separate study detailed above. We note some caution must be used with the comparisons given tests were not compared head to head.

Competition

There are a number of commercially available IVD tests to detect bladder cancer in haematuria patients, although the specificity and sensitivity of such tests is variable. NMP22 has been widely adopted as an adjunct to cytology. However, no other test is being used as standard, as none has been shown to be more accurate than the existing benchmark.

Exhibit 4: Landscape of approved IVD tests to detect bladder cancer with haematuria

Test/distributor	Methodology	Advantages	Limitations	Notes
UroVysion/Abbott	FISH fluorescence in situ hybridisation assay – detects chromosomal abnormalities.	Higher sensitivity than cytology across all stages and grades.	Requires a large specimen sample. Poor positive predictive value.	Detects bladder cancer in voided urine sample in cases of gross and micro haematuria and in patients with a history of bladder cancer.
NMP22 ELISA	Measures levels of protein NMP22, which is elevated in bladder cancer sufferers.	Higher sensitivity than cytology for grade I/II.	Low specificity – interference from benign urinary tract conditions.	Has not been adopted for standard use in urologic work-up.
NMP22 BladderChek	Point-of-care (POC) test with 30-minute turnaround.	Improves detection vs cytology in cases of recurrent cancer.	Relatively high rate of false positives.	Improves accuracy in combination with cystoscopy, but will not replace it.
BTA Stat/Polymedco	POC, detects human complement factor H-related protein.	Immediate result.	High rate of false positive results in cases of co-existing genitourinary conditions.	FDA approved for monitoring bladder cancer in conjunction with cystoscopy.
BTA Trak/Polymedco	Lab-based immunoassay.	Higher sensitivity than cytology for low-grade tumours.	High rate of false positive results in cases of co-existing genitourinary conditions.	Used for monitoring rather than for diagnosis – high rate of false positives.
ImmunoCyt	Lab-based immunofluorescence assay.	Relatively high sensitivity in some patient groups.	High rate of false positive results in cases of co-existing genitourinary conditions.	Approved for monitoring bladder cancer in conjunction with cystoscopy.
UBC/IDL Biotech	Measures soluble fragments of cytokeratins 8 and 18. Cytokeratins are characteristic of epithelial cells.	More accurate at detecting CIS than cytology.	Overall performance not superior to cytology. Ongoing testing.	Available as UBC ELISA (2 hr test) and UBC IRMA (POC).

Source: Edison Investment Research

There are also currently a number diagnostics tests in the market in development for the detection and monitoring of UCs, underpinning the attractive opportunity. All are in earlier stages of development than Cxbladder$_{detect}$ and none, as yet, has shown equivalent or better overall accuracy. Given the long lead time for the commercialisation of UC tests, which can span a number of years, we believe that Pacific Edge has a considerable leg-up on would-be competitors.

Exhibit 5: Range of developing molecular diagnostics for urothelial carcinomas

Product/company	Key features	Method	Notes
UroSens	Proprietary assay platform ELISA and POC format – long term will adapt for other oncology tests.	Detects levels of Mcm5 protein in urine.	Targets urologist and primary care settings, minimally invasive.
OncoCyte Corporation	PanC-Dx bladder cancer markers.	Based on a set of biomarkers.	Initiated a multicentre clinical trial in comparison to cystoscopy. Aims to expand as a POC test.
Micromedic Technologies	CellDetect detects and monitors recurrence of bladder cancer.	Proprietary staining technology.	Used for cervical cancer diagnosis.
Cytosystems	CytoSol-B – diagnosis of primary and recurrent UC.	Antibody detects Mcm2 – maintenance protein 2.	700-pt user study across five UK centres – test is now in large performance evaluation study.
Sienna Cancer Diagnostics	Lead product SCD-A7 – in combination with standard UC workup.	SCD-A7 reagent detects telomerase biomarker, up regulated in cancers.	Aims to out-license the reagent to US pathology labs during H214.

Source: Edison Investment Research

The Cxbladder range is being developed as laboratory-developed tests (LDTs). LDTs are a class of in vitro diagnostic test manufactured, developed and validated for use in a single laboratory. The CMS (Centers for Medicare and Medicaid Services) regulates clinical laboratories that carry out diagnostic testing through the authority of CLIA (Clinical Laboratory Improvement Amendments),

which establishes quality standards for clinical lab testing and a certification programme for labs that perform testing using IVD devices. Under CLIA requirements, the analytical validity of the LDT is evaluated, whereas the FDA's PMA requirements assess the clinical validity of a test. The distinction is that analytical validity defines the ability of the test to detect or measure the analytes in question, whereas clinical validity is the ability to accurately diagnose or predict the risk of a particular clinical outcome. In 2013 Pacific Edge received CLIA regulatory approval for its Hershey, PA laboratory as well as its lab in Dunedin, New Zealand. The company has also received the CAP (College of American Pathologists) signification approval in the US. Pacific Edge management is currently exploring the pathway to full FDA approval for the Cxbladder portfolio, which would enable the company to directly market to consumers. At this stage CLIA certification is sufficient for direct selling to physicians given the tests are processed in the company's own lab.

Pacific Edge's next product, $Cxbladder_{triage}$, includes the same five biomarkers as $Cxbladder_{detect}$, adding four phenotypic variables to give a new algorithm. $Cxbladder_{triage}$ is to be used to rule out cancer by its high sensitivity and high negative predictive value. With a similar pricing strategy, the test will target primary clinicians and physicians; in particular primary care physicians could use this technology to triage out patients who do not need a referral for a full urological work-up.

Pacific Edge management intends to focus on bladder cancer diagnostics in the short to medium term. Further out, the company will pursue other portfolio opportunities that include gastric, colorectal and endometrial cancers and melanoma. Pacific Edge is developing a product, Cxcolorectal, which predicts the aggressiveness of a tumour in patients with Stage II or III colorectal cancer. However, the company plans to first focus on building on the current momentum of the Cxbladder products and franchise.

Commercial strategy – penetrating the US market

Pacific Edge operates with a franchise system through wholly-owned subsidiaries and licensing partners in New Zealand, Australia, Spain and the US. Pacific Edge's US operations are run through its wholly-owned subsidiary, Pacific Edge USA, in Hershey, Pennsylvania.

US market

The market for haematuria testing and monitoring represents a noteworthy commercial opportunity. In the US, an estimated US$1bn is spent investigating haematuria each year with approximately one million people presenting to their healthcare provider annually. A high recurrence rate means continual monitoring at an estimated extra cost of US$1-2bn for those requiring regular follow-on testing.

$Cxbladder_{detect}$ is still in an early launch phase in the US, but appears to be making progress towards commercialisation with the steady build of product awareness. Initial groundwork is being carried out that includes the establishment of sales channels, building relationships with payers and clinicians and the initiation of user programmes to allow for trial and evaluation of the product. All this takes time and translates into a relatively long selling cycle. The main challenge will be converting those clinicians trialling $Cxbladder_{detect}$ on user programmes into fee-paying customers. Pacific Edge management is encouraged by early feedback on $Cxbladder_{detect}$ from urologists and healthcare providers and has started generating revenue in Australia, New Zealand and the US.

Pacific Edge began recruiting and training its sales force in July 2013. The sales force has grown to eight people to date and will be built up to approximately 20 in the medium term, targeting key user groups to support its targeted NZ$100m in sales by 2019. The group includes an MSL (medical scientific liaison) for technical support and an experienced sales executive specialising in deal closing. All members of the sales staff have experience in selling high technology medical products including molecular diagnostics products.

Pacific Edge's initial sales strategy in the US will focus on 19 distinct sales territories clustered around metro centres. These areas cover around 60% of the US urologist market. In addition to public payers – CMS and the Veteran's Administration A are described below – the sales force is now actively marketing Cxbladder$_{detect}$ to private paying integrated healthcare providers and Urologists (c 11,000 in the US).

A number of user group programmes are underway in the US and most comprise large prospective customer groups of up to 100 urologists. Drivers of healthcare decisions by clinicians in the US include the avoidance of malpractice suits on missed tumours, the clinical utility of the product and minimising co-payments to the patients, thereby boosting patient retention rates. Cxbladder$_{detect}$ handily covers the first two and, more indirectly, the third. Urologists currently need a large number of tools for the clinical work-up of patients presenting with haematuria. The sales team has therefore placed much emphasis on the end-user – the urologists – of whom there are currently more than 11,000 in the US. Pacific Edge's user programmes offer clinicians the opportunity to trial the product in their clinical settings by trying it out on their patients. This process serves to garner a sufficient comfort level with the test to reduce the high level of pre-purchase dissonance. Pacific Edge management reports those specialists that are introduced to Cxbladder$_{detect}$ recognise value in the test and are interested in trialling the product prior to entry into commercial relationships.

Focus is now on driving and realising commercial sales volumes. The key challenge will be timely acceptance from the clinicians given the typical protracted decision-making process in the adoption of most molecular diagnostics tests. We expect key decisions from large buying groups and corresponding sales should create frequent share price inflection points for Pacific Edge over the coming months and years. The key decision makers driving sales are described below.

Large urology group practices (LUGs)

The large urology group practices (LUGs) make up c 15% of US urologists and Pacific Edge has made positive inroads with select LUGs. Selling to these organisations commenced in mid-2013, as with other significant but smaller urology practices. Several LUGs have successfully completed user programmes and are placing commercial orders.

Integrated healthcare providers (IHPs)

Insurance, hospital and medical group functions are combined with the IHP model. Pacific Edge targets integrated healthcare providers such as Kaiser Permanente, which has circa nine million members as strategic partners. Negotiations with these groups are ongoing and the company has recently announced the signing of the Kaiser Southern Urology Group to a large user programme. The first commercially sold Cxbladder kits are currently in process with private healthcare providers.

CMS[1] (Center for Medicaid and Medicare services) and Veteran's Administration (VA)[2]

CMS coverage is paramount to successful commercialisation in the US. The reimbursement and approval process for Cxbladder$_{detect}$ is underway and CMS and Pacific Edge management believe the conclusion of negotiations will likely occur later this calendar year or in the early part of 2015. Currently tests are being processed and invoiced. Once negotiations on a contract are complete, these can be billed, at which time we can expect a sales windfall for Pacific Edge as the backlog is processed. Advanced discussions are also underway with the Veteran's Administration (VA).

Healthcare providers

The relatively large number of tests processed through healthcare providers would serve as a relatively time efficient and welcome support and validation for Cxbladder$_{detect}$.

1 CMS is the US federal agency that administers Medicare and Medicaid and will reimburse Pacific Edge for all patients who utilise Cxbladder. Approximately 35% of Americans are covered by Medicare and Medicaid.

2 The Veteran's Administration is a federal agency providing services to US veterans.

National Provider Networks (NPNs)

National Provider Networks (NPNs) provide a contracted price network that links providers and payers. The NPNs consist of clinicians, hospitals, laboratories and other specialists that contract with the provider to offer services to the patients of their clients, which are private insurers, large employers and third-party administrators. In addition to a negotiated price, approved coverage of a product or service by the NPN encourages its acceptance and adoption by clinicians. To date, Pacific Edge has signed agreements with four networks in the US: FedMed, ACPN, Stratos and MultiPlan, thereby establishing a fixed retail price to patients insured by clients of the NPN.

Pacific Edge management has set clear goals for the US roll-out of the Cxbladder portfolio. Plans for the current fiscal year ending March 2015 include the increase of sales presence and the continued roll-out of user programmes to targeted clinical groups and urologists. The company also aims to close more agreements with national and regional provider networks (see below). Pacific Edge management targets sales of US$100m in the US after five years of trading (FY19). We believe this goal is attainable given the size of the market, advantages of the Cxbladder portfolio over current competitive diagnostics and work done to date on the introduction of Cxbladder$_{detect}$ in the US. Cxbladder$_{detect}$ is priced at a premium to existing cytology tests, which we believe is justified given the test's heightened sensitivity and specificity and product differentiation. However, our own forecasts are more cautious on timing and we model US$100m to be reached in FY21. The company processed its first commercial product in the US in October 2013.

Exhibit 6: Sales forecast Cxbladder$_{detect}$ in the US

Year end March	2014	2015e	2016e	2017e	2018e	2019e	2020e	2021e	2022e	2023e	2024e	2025e
US sales (NZ$m)	-	2.32	11.97	24.66	44.47	65.44	94.39	118.07	135.95	147.43	151.88	156.47
US sales (US$m)	-	2.0	10.1	20.9	37.7	55.5	80.0	100.1	115.2	124.9	128.7	132.6
Price (US$)	650	650	663	676	690	704	718	732	747	762	777	792
Number of tests	-	3,030	15,302	30,909	54,632	78,826	111,460	136,697	154,307	164,053	165,693	167,350
Penetration	0%	0.2%	1.0%	2.0%	3.5%	5.0%	7.0%	8.5%	9.50%	10.0%	10.0%	10.0%
Patients in US (m)	1.50	1.52	1.53	1.55	1.56	1.58	1.59	1.61	1.62	1.64	1.66	1.67

Source: Edison Investment Research

Given a typical slow conversion cycle from user programmes to adoption, the timing of the sales ramp-up of the Cxbladder portfolio is challenging to forecast. The conversion of each new provider from user programme to adoption for Cxbladder$_{detect}$ will provide an incremental boost to revenue in the coming years. We cautiously forecast sales of NZ$180m (US$152m) in 2025 for the Cxbladder franchise based on conservative expectations on pricing and a penetration rate of about 12% (10% for Cxbladder$_{detect}$ alone). However, the potential of the franchise could be significantly greater if the technology achieves more widespread use.

Focus is currently on the roll-out of Cxbladder$_{detect}$ into the US market. However, Pacific Edge has developed adjunct tests to meet the requirements of clinicians at different points in the assessment process and plans follow-on launches of its three additional bladder cancer tests over the coming years through the same selling channels.

Ex-US

In addition to the US, Pacific Edge is dedicated to the commercialisation of Cxbladder in its home market of New Zealand and in Australia. These markets are measurably smaller, with 300 urologists in both countries together, compared with c 11,000 in the US. We estimate the Cxbladder test market in New Zealand and Australia to be less than 5% of that in the US.

Pacific Edge has begun to make progress in New Zealand with the adoption of Cxbladder$_{detect}$ by publicly and privately funded health organisations. Launched in 2011 in New Zealand, the sales effort in New Zealand has focused primarily on the district health boards (DHBs). An agreement has been signed with the government's Health Innovation Hub (HIH) to make Cxbladder$_{detect}$ available to four of the 20 DHBs in New Zealand. Labtests in Auckland is the exclusive sales and marketing partner for the Auckland and Northland regions, with these regions accounting for c 40% of all tests

in New Zealand. Cxbladder has also been commercially adopted by Urotec, which provides urological services to two additional DHBs.

Driving demand from the patient, Pacific Edge has launched its e-commerce site in New Zealand, whereby the patient can order a urine sampling system directly. Under the system, the patient nominates a healthcare provider and results are then sent to a specialist. This direct sampling eliminates an initial healthcare consultation and can be bought by healthcare professionals for use in their clinic. The new site is expected to increase patient compliance and provide easy access for rural GPs. Pacific Edge recently received regulatory clearance for this new sales channel in New Zealand from TAPS (Therapeutic Advertising Pre-vetting System of the Advertising Standard Authority).

In Australia, Pacific Edge has partnered with Healthscope, which is actively targeting $Cxbladder_{detect}$ to the large Australian hospital network and major urology specialists. A user programme is also underway in Queensland to evaluate replacement of ultrasound in a clinical setting with $Cxbladder_{detect}$.

The CLIA-certified New Zealand facility can serve as back up. Capacity is 35,000 and is scalable. On our base case forecasts this is sufficient to accommodate Pacific Edge sales through to 2031.

Sensitivities

The initial acceptance of its first product, $Cxbladder_{detect}$, has confirmed the technology associated with the Cxbladder group of products. $Cxbladder_{detect}$ effectively finished first clinical evaluation with the publication of a large-scale trial. The diagnostic test has been validated through various user programmes and is now seeing its first sales in New Zealand, Australia and the US.

Execution risk remains an important hurdle. $Cxbladder_{detect}$ has yet to prove itself commercially. Success in the key US market will be the primary driver of Pacific Edge's valuation. The US accounts for c 90% 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. It will be critical for the company to continue to convert those organisations with current user programmes to fee-paying customers. The company is likely to be on the verge of meaningful conversions in the US. Management reports early signs of acceptance from clinicians as the first payments begin to feed through. We expect the successful negotiation of contracts with four national provider networks to provide additional support.

Pacific Edge also faces the potential threat of a new regulatory hurdle in the US. On 31 July 2014 the FDA provided notice of its intent to issue draft guidance providing a risk-based framework for new regulatory requirements of LDTs such as $Cxbladder_{detect}$. In practice the enactment could take time. According to the framework, the new requirements for LDTs are to be phased in over several years. 'High-risk' LDTs would be targeted first. We expect Pacific Edge diagnostic tests, such as $Cxbladder_{detect}$, would be categorised as Class II (moderate risk). As such, review requirements for Cxbladder tests would begin after the high-risk (Class III) LDTs are completed, which is expected to take five years after the FDA finalises the guidance. The Class II LDTs would then be reviewed sequentially over a subsequent four-year phase in period. Once reviewed, a product would likely be judged on its safety and would then be required to either follow a formal pre-market approval (PMA) registration process or an optional registration. Given the long notice period, we expect Pacific Edge will have adequate time and resources to prepare for this.

Pacific Edge runs the risk of potential competitive products from those known diagnostic tests that have not yet published data and those not yet in the public domain. We do not expect a near-term competitive threat to the Cxbladder technology. Clinical validation will be critical for would-be new tests, while the long lead time to commercial adoption serves as a high barrier to entry.

Valuation

We arrive at a value of NZ$338m for Pacific Edge using a DCF methodology based on forecast free cash flow. We model sales and cash flow up until 2031 when the first of an estate of patents on Cxbladder$_{detect}$ expires. Our forecast includes sales of Cxbladder$_{detect}$ reaching NZ$162m by 2025. We also factor in conservative sales estimates for Cxbladder$_{triage}$ of NZ$23m given uncertainty of market acceptance for this yet-to-be-launched test and some potential overlap of the customer base. We do not include additional pipeline products in our forecasts. We forecast sales into the US, New Zealand and Australia only and do not include added value for the technology of the company. Applying a WACC of 12.5%, we value Pacific Edge at NZ$1.16 per share.

Exhibit 7: Valuation based on DCF

Cash flow value (NZ$k)	317,693
Net cash (NZ$k)	20,444
Valuation (NZ$k)	337,656
Number of shares	291.27
Value per share (NZ$)	1.16

Source: Edison Investment Research

Sensitivity analysis on price and market penetration

Our sensitivity analysis suggests a value range of NZ$0.46-3.91/share depending on price and penetration in the US; in our base case we assume pricing of US$650 and 10% market penetration for Cxbladder$_{detect}$. Pacific Edge is at the start of the commercial roll-out and, as such, there is still considerable uncertainty as to the full sales potential in the coming years. We consider the chief variables are the level of market penetration that can be achieved, particularly in the US, and average pricing. Our base case is on the conservative side in both regards, therefore we expect significant upside potential on our forecasts if Pacific Edge's performance exceeds our cautious expectations. The prospective share prices based on the two key variables are detailed below.

Exhibit 8: Sensitivity of Pacific Edge share price (NZ$) based on pricing and US penetration

		Penetration rate (%)				
		5%	10%	15%	20%	25%
US$ pricing	600	0.46	1.03	1.60	2.17	2.74
	650	0.54	1.16	1.78	2.41	3.03
	700	0.61	1.29	1.97	2.65	3.32
	750	0.69	1.42	2.15	2.88	3.62
	800	0.77	1.55	2.34	3.12	3.91

Source: Edison Investment Research

Financials

Pacific Edge had cash and cash equivalents of NZ$20.4m as of FY14, which represented an increase from NZ$10.7m from a year earlier after the NZ$20m capital raise in October 2013. This was primarily for a build-out of the sales force for the initial product roll-out of Cxbladder$_{detect}$ in the US. Pacific Edge has no debt. It will continue to invest in the commercial opportunity for its Cxbladder products in the US throughout FY15. We forecast it will become cash generative in FY17 and will not need to issue additional equity.

We expect first significant top-line growth to commence this year on the back of the continued roll-out of Cxbladder$_{detect}$. We model sales of NZ$2.6m for FY15 increasing to NZ$14m in FY16 and first positive free cash flow and earnings in FY17. Our sales forecasts are based on gross retrievable revenue (GRR) from insurance companies averaging US$650 per test in the US to start (the retail price is unpublished and is likely to be significantly higher). We expect GRR will move upwards as a growing portion of private payers in the sales mix move off user programmes to full reimbursement status. Based on progress to date in the US market, Pacific Edge management's target of

NZ$100m in sales by FY19 or the group looks attainable. However, we err on the side of caution and model revenue of NZ$100m two years later in FY21. We factor in NZ$2m of initial costs by FY16 2016 for the start-up of the sales force. We do not include potential sales outside Australasia and the US now, preferring to wait for more news of progress on partnership agreements. Pacific Edge outsources manufacturing, billing and reimbursement, so much of its cost base is variable. We include the cost of building a sales force into our model.

Exhibit 9: 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	2,599	14,439
Cost of Sales	0	0	0	0	(384)	(1,990)
Gross Profit	202	280	178	523	2,215	12,449
EBITDA	(3,115)	(4,176)	(6,960)	(9,311)	(7,006)	1,420
Operating Profit (before GW and except.)	(3,227)	(4,354)	(7,155)	(9,579)	(7,450)	1,021
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)	(7,499)	939
Other	(1)	(96)	(92)	(571)	0	0
Net Interest	82	339	330	315	613	367
Profit Before Tax (norm)	(3,147)	(4,111)	(6,917)	(9,835)	(6,837)	1,388
Profit Before Tax (FRS 3)	(3,147)	(4,111)	(6,917)	(9,951)	(6,886)	1,306
Tax	0	0	0	0	0	0
Profit After Tax (norm)	(3,147)	(4,111)	(6,917)	(9,835)	(6,837)	1,387
Profit After Tax (FRS 3)	(3,147)	(4,111)	(6,917)	(9,951)	(6,886)	1,306
Average Number of Shares Outstanding (m)	172.2	232.0	275.4	291.3	291.3	291.3
EPS - normalised (c)	(1.8)	(1.8)	(2.5)	(3.4)	(2.3)	0.5
EPS - FRS 3 (c)	(1.8)	(1.8)	(2.5)	(3.4)	(2.4)	0.4
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	14,586	16,244
Stocks	0	0	0	242	284	1,472
Debtors	264	207	132	574	1,923	10,681
Cash	2,486	17,959	10,676	20,444	12,213	3,925
Other	1	84	204	167	167	167
Current Liabilities	(604)	(997)	(1,078)	(953)	(1,018)	(1,420)
Creditors	(411)	(803)	(922)	(953)	(1,018)	(1,1420)
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	14,893	16,198
CASH FLOW						
Operating Cash Flow	(2,918)	(3,605)	(6,710)	(9,524)	(8,331)	(8,124)
Net Interest	0	0	0	0	613	366
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	(8,231)	(8,288)
Opening net debt/(cash)	(956)	(2,486)	(17,959)	(10,676)	(20,444)	(12,213)
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)	(12,213)	(3,925)

Source: Edison Investment Research, Pacific Edge accounts

Contact details	Revenue by geography
Centre for Innovation 87 St David Street PO Box 56 Dunedin, New Zealand, 9016 +64 (0)3 479 5800 www.pacificedge.co.nz	N/A

CAGR metrics		Profitability metrics		Balance sheet metrics		Sensitivities evaluation	
EPS 11-15e	N/A	ROCE 14e	N/A	Gearing 14e	N/A	Litigation/regulatory	◖
EPS 11-15e	N/A	Avg ROCE 11-15e	N/A	Interest cover 14e	N/A	Pensions	○
EBITDA 11-15e	N/A	ROE 14e	N/A	CA/CL14e	N/A	Currency	●
EBITDA 11-15e	N/A	Gross margin 14e	N/A	Stock days 14e	N/A	Stock overhang	○
Sales 11-15e	N/A	Operating margin 14e	N/A	Debtor days 14e	N/A	Interest rates	○
Sales 11-15e	N/A	Gr mgn / Op mgn 14e	N/A	Creditor days 14e	N/A	Oil/commodity prices	○

Management team

CEO: David Darling	CEO, PED USA: Jacqueline Walker
David Darling became CEO in 2003, joining from Rubicon where he was director of biotech business development. He also led the development and management of Fletcher Challenge's tree breeding and biotechnology business and was involved in the start-up of US-based biotechnology business ArborGen.	Jackie Walker became CEO of Pacific Edge Diagnostics USA in May 2012. She is COO of Hanson Technologies and has been the president of Ondine Biopharma (USA) since 2006. She was COO of Ondine Biopharma, where she scaled up operations for the successful commercialisation of Periowave.
Chief Scientific Officer: Dr Parry Guilford	**COO: Jimmy Suttie**
Parry Guilford is a principal investigator in the Cancer Genetics Laboratory in the University of Otago, and co-founder of Pacific Edge. He is a senior inventor of Pacific Edge patents including Cxbladder. He is VP of the New Zealand Society for Oncology.	COO at Pacific Edge since January of 2012, Jimmy Suttie has a range of executive experience in the management of science and technology in New Zealand. Having worked across a number of sectors, he has specialised in the development of science for commercialisation. Jimmy has served as director at several plant and animal biotechnology companies.

Principal shareholders	(%)
K One W One	6.4
University of Otago	6.6
Harbour Asset Management	7.5
Westpac Banking Corp	5.2
Salt Funds Management Ltd	5.2

Companies named in this report

Abbott, Cytosystems Ltd., IDL Biotech, Micromedic Technologies, Oncocyte Corporation, Polymedco, Urosens Ltd, Sienna Cancer Diagnostics

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