EDISON

# Pacific Edge

Company update

## On the road to full US commercialisation

Pharma & biotech

**Pacific Edge has made solid progress in recent months toward the start of broad commercialisation of its bladder cancer diagnostics tests in the US, with a third test becoming available there in mid-2016. In February, the Veterans Administration (VA) handed down a positive decision on its Cxbladder testing technology just as large-scale User Programmes in the US near completion. The Kaiser Permanente (KP) pilot is expected to be completed by the end of 2016 and could result in significant sales traction.**

| Year end | Revenue (NZ$m) | PBT* (NZ$m) | EPS* (c) | DPS (c) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 03/15 | 3.6 | (11.1) | (3.5) | 0.0 | N/A | N/A |
| 03/16 | 6.4 | (15.5) | (4.1) | 0.0 | N/A | N/A |
| 03/17e | 11.4 | (7.4) | (1.9) | 0.0 | N/A | N/A |
| 03/18e | 24.4 | 4.0 | 0.6 | 0.0 | N/A | N/A |

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

## Progress with public healthcare organisations

In February, Pacific Edge received approval of its bladder cancer diagnostics tests from the VA, a major public organisation in the US. Access to the Federal Supply Schedule was given following a lengthy review process, opening the door for the company's sales staff to market directly to urologists within the VA. The VA represents a considerable market providing care to 10.2 million veterans in addition to their families in a network of clinics, hospitals and healthcare centres across the US. We believe the approval represents a significant validation of the Cxbladder testing technology. Discussions with CMS on approval and reimbursement are currently underway though this process is likely to be long and iterative.

## User Programmes well under way in the US

Given the need for extensive user testing, there is a long lead time to commercialisation, and conversion of large customers trialling the test into fee-paying customers has progressed, but is relatively slow. However, we expect that the conclusion of a number of trial User Programmes (pilot testing) over the next 12 months should begin to translate into meaningful sales. The largest User Programme with KP has completed recruiting patients presenting with haematuria for the evaluation of Cxbladder Triage and the conclusion of the pilot is targeted for later in 2016. Adoption by KP would result in significant sales traction.

## Valuation: NZ$448m (NZ$1.19 per share)

Our valuation for Pacific Edge moves to NZ$448m (NZ$1.19 per share) from NZ$496m (NZ$1.32/share) as a push back of sales in the US and a negative currency impact are partly offset by the inclusion of Cxbladder Monitor in our forecasts, as well as rolling forward our model to FY17. Net cash of NZ$24.2m (March 2016) should sufficiently fund operations into our forecast profitability in FY18. We believe ongoing commercial success, aided by sales staff accessing VA centres directly and adoption by KP, will serve as a driver of the share price.

**27 June 2016**

| | |
|---|---|
| **Price** | **NZ$0.57** |
| **Market cap** | **NZ$215m** |
| | NZ$1.47/US$ |
| Net cash (NZ$m) at 31 March 2016 | 24.2 |
| Shares in issue | 376.5m |
| Free float | 74% |
| Code | PEB |
| Primary exchange | NZX |
| Secondary exchange | N/A |

### Share price performance


| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | (9.5) | (13.6) | (9.5) |
| Rel (local) | (7.9) | (14.9) | (20.0) |
| 52-week high/low | NZ$0.7 | | NZ$0.4 |

### Business description

Pacific Edge develops and sells a portfolio of molecular diagnostic tests based on biomarkers for the early detection and management of cancer. Tests utilising its Cxbladder technology for detecting and monitoring bladder cancer are sold in the US, New Zealand and Australia.

### Next events

| | |
|---|---|
| US launch of Cxbladder Monitor | H216 |
| NZ launch of Cxbladder Predict | H216 |

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# Investment summary

## Company description: Cancer diagnostic testing

Pacific Edge Ltd. (PEB) was formed in August 2001 to develop molecular diagnostic and prognostic tools, in cancer. It is headquartered in Dunedin, New Zealand, and has two wholly-owned subsidiaries commercialising Cxbladder, Pacific Edge Diagnostics NZ Ltd. in Dunedin and Pacific Edge Diagnostics USA Ltd. (PED USA) in Hershey, Pennsylvania. The company also has laboratories in both locales with Dunedin being CLIA-certified and IANZ accredited, while Hershey is CLIA-certified and CAP accredited. Pacific Edge joined the NZX in February 2002 and has raised total funds of c NZ$95m to date. Its first product was approved in New Zealand in 2011.

Cxbladder Detect, the first of the company's three products, is a non-invasive urine-based test that detects bladder cancer in people presenting with haematuria (blood in urine). It was rolled out initially in New Zealand and Australia, and subsequently launched in the US in July 2013. The company has since launched additional bladder cancer tests focusing on differing value propositions identified by physicians and clinicians to provide a one-stop-shop offering. In 2015, Cxbladder Triage was launched in New Zealand with a soft launch in the US, while Cxbladder Monitor was launched in New Zealand in late 2015 and targeted for launch in the US in mid-2016. 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: NZ$448m (NZ$1.19 per share)

Using a DCF methodology, we value Pacific Edge at NZ$448m (NZ$1.19 per share), down from the prior $496m (NZ$1.32 per share), as slower than expected inroads into the US market and the negative impact of currency fluctuations are offset by the first-time inclusion of sales of Cxbladder Monitor into our forecasts, as well as rolling forward our model to FY17. We forecast overall peak sales of NZ$296m for the Cxbladder franchise in 2025. In the midst of a somewhat protracted global roll out for its initial products, we note there is still some uncertainty as to the full sales potential of the group, particularly given the complexities and vast size of its target market.

## Financials: Steady growth ahead of expected ramp up

Pacific Edge is now ramping up sales efforts in the commercialisation of its Cxbladder franchise in the US. The company raised NZ$35m in capital in July 2015 and had net cash of NZ$24.2m at 31 March 2016. We forecast positive cash flow in FY18 (without additional capital), when we expect the company will realise significant sales. We note that a large portion of the company's remaining cost base is variable as it outsources manufacturing, billing and reimbursement. Current laboratory facilities have the capacity to accommodate our forecast sales to 2031.

## Sensitivities: Clinical acceptance

Pacific Edge has made considerable inroads on its way to full commercialisation in the crucial US market. Wider acceptance of its Cxbladder products in the US will be driven by the rate of conversion of ongoing User Programmes into fee-paying customers. Cxbladder products are now undergoing evaluation by a number of clinicians and key opinion leaders and a large User Programme in Southern California should complete by year end. Negotiations are proceeding with key organisations including the Centers for Medicare and Medicaid Services (CMS) (which covers c 30% of the US population) and other large private healthcare providers. We do not see a near-term competitive threat to the Cxbladder portfolio of products. Further out, the company runs the risk of potential competition from new diagnostics tests. However, clinical validation will be critical for new competitive technologies and the long lead time to commercial adoption for Pacific Edge serves as a formidable, high barrier to entry.

# Pacific Edge: Nearing broad adoption

Pacific Edge develops and commercialises molecular tests for the detection and better management of urothelial cancers (UC) and is the only company worldwide to offer multiple molecular diagnostic tests for bladder cancer. The company has created 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 aims are to meet the 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.

Pacific Edge is working towards fully commercialising its bladder cancer testing, reporting a steady increase in volumes from existing customers in recent quarters, albeit off a low base and including healthcare organisations' testing through User Programmes. A number of these User Programmes are under way in the US, most notably a large-scale testing by Kaiser Permanente. In Singapore, the first User Programme at Tan Tock Seng Hospital is trialling the potential for Cxbladder products in South-East Asia (SEA) 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 building slowly. A third product, Cxbladder Monitor, was launched in NZ at the end of FY16. In Australia, Pacific Edge recently entered into a new commercial partnership with Tolmar Australia to drive sales forwards after ending its agreement with Healthscope earlier this year.

**Exhibit 1: Pacific Edge upcoming newsflow – Cxbladder franchise**

| Event | Timing (calendar year) |
|---|---|
| Cxbladder Monitor launch in US | Mid-2016 |
| Cxbladder Predict launch in New Zealand | H216 |
| Completion of Kaiser Permanente User Programme | End-2016 |
| Expansion in South-East Asia | 2016/2017 |

Source: Edison Investment Research

## Suite of tests offers one-stop-shop to detect and manage bladder cancer

Pacific Edge's first product, Cxbladder Detect, is regulated in the US as a laboratory-developed test that can be used for detecting bladder cancer in patients who present with haematuria in conjunction with standard urological work-up, a patient population of around seven million annually 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). Cxbladder Detect 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 cancer biomarkers 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.

Its next product, Cxbladder Triage, was first launched in New Zealand in December 2014 and targets physicians in the primary and secondary care of patients who present with haematuria in New Zealand and Australia and urologists in the United States. Cxbladder Triage includes the same five genomic biomarkers as Cxbladder Detect adding four phenotypic variables to give a new algorithm. Cxbladder Triage is used to rule out cancer by its high sensitivity and high negative

predictive value. Notably, the company recently announced that the Canterbury District Health Board (CDHB) in New Zealand has agreed to replace cytology with Cxbladder Triage. Follow on tests Cxbladder Monitor and Cxbladder Predict are aimed at different value propositions in the evaluation and monitoring of UCs detailed below.

**Exhibit 2: 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 since 2013. | Non-invasive laboratory test for the detection of bladder cancer. Adjunct to cystoscopy. |
| Cxbladder Triage | Segregates patients without bladder cancer. | Commercially available in NZ (2014), Australia and the US (2015). | High sensitivity and high negative predictive value. |
| Cxbladder Monitor | Ongoing monitoring to check for recurrence of bladder cancer. | Commercially available in NZ (2015); slated for US launch in 2016 and other markets in 2016/17. | High sensitivity and high negative predictive value to determine patients who should receive follow-up tests. |
| Cxbladder Predict | Classifies tumours as low or high grade. | Expected launch in NZ in 2016. | Prognostic test. |

Source: Pacific Edge

Bladder cancer is the sixth most common cancer worldwide and has the highest per patient medical cost of any cancer.[1] There will be an estimated 77,000 new cases diagnosed in the US in 2016. 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 a 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.

Cxbladder Detect is clinically validated by 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 and sensitivity (true positives) and specificity (true negatives) compared to cystoscopy as a reference.

**Exhibit 3: Sensitivity of urine detection tests in multicentre clinical study of 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 Cxbladder Detect to be 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 also completed an 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

[1] World J Urol. 2009 Jun; 27(3); 295-300.

clinical study. 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.

Cxbladder Detect also compares favourably against Abbott's UroVysion looking at 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 detecting 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.

There are a number of commercially available in-vitro diagnostic (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 a number diagnostics tests in the market in development for detecting and monitoring UCs, underpinning the attractive opportunity. All are in early stages of development 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.

The Cxbladder portfolio is being developed as laboratory-developed tests (LDTs). The CMS 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. The company has also received the CAP (College of American Pathologists) signification approval in the US. Pacific Edge management continues to explore the pathway to full FDA approval for the Cxbladder portfolio, which would enable the company to directly market to consumers. However, CLIA certification is sufficient for direct selling to physicians given the tests are processed in the company's own lab.

Pacific Edge management intends to focus on bladder cancer diagnostics in the short to medium term. Further out, the company may pursue other portfolio opportunities that include gastric, colorectal and endometrial cancers and melanoma. However, the company plans to first focus on building on the current momentum of the Cxbladder products and franchise.

## Commercialisation in the US gains momentum

Pacific Edge's US operations are run through its wholly owned subsidiary, Pacific Edge Diagnostics USA Ltd., in Hershey, Pennsylvania. The company's cancer testing technology is steadily gaining recognition by key thought leaders in the field as it nears the completion of critical User Programmes. In early May the company was granted a prestigious plenary presentation at the Annual Conference of the American Urological Association (AUA2016) in San Diego for the debut of its third product in the Cxbladder portfolio, Cxbladder Monitor. Dr Yair Lotan, US urologist and lead author of a Cxbladder scientific paper recently submitted for publication, will present at the meeting.

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

Pacific Edge's sales organisation in the US 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 has continued to expand its commercialisation efforts in the US with the recent hiring of an additional three sales executives, with a current total of 18 canvasing 19 earmarked regions clustered around metro centres. In addition to public payers – CMS and the VA are described below – the salesforce also actively markets its tests to private paying integrated healthcare providers and urologists (c 11,000 in the US). The company has made good headway in establishing sales channels and building relationships with payers and clinicians. However, the sales cycle is relatively long for the new technology, as for most molecular diagnostic tests, and the main challenge remains converting those clinicians trialling the tests on User Programmes into fee-paying customers. A number of User 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 directly covers the first two and, more indirectly, the third. Urologists 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. Its User Programmes offer clinicians the opportunity to trial the product in 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 who are introduced to Cxbladder tests recognise the potential value in the technology and are interested in trialling the product before entry into commercial relationships.

Key decision makers driving sales in the US are described below.

**Large urology group practices (LUGs)** comprise approximately 15% of US urologists and Pacific Edge has made positive inroads with a number of select LUGs. Selling to these organisations began 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)** combine insurance, hospital and medical group functions into a coordinated healthcare model. Pacific Edge targets integrated healthcare providers such as Kaiser Permanente, which has circa nine million members as strategic partners. In the private sector, the company's large User Programme with KP has completed recruiting patients presenting with haematuria for the evaluation of the Cxbladder Triage. Due to the instalment of a new patient-consenting electronic platform the recruitment of the pilot programme has been somewhat slower than our expectations but a more rapid ramp-up is expected mid-2016. We believe a successful conclusion of the programme targeted for the end of this year will provide a critical acknowledgement as to the usefulness of the Cxbladder technology in clinical workups for those patients with bladder cancer and/or those at risk. The outcome of this large-scale programme promises to be a key indicator for the success of not only Cxbladder Triage but the entire Cxbladder suite of products. Commercial adoption by KP, which covers approximately 9.5 million people under its plan, would provide a significant clinical validation for other User Programmes evaluating the Cxbladder technology.

**US public healthcare groups** most notably include the Centers for Medicare and Medicaid Services (CMS)[2] and the Veterans Administration (VA)[3] with potentially significant volumes. Pacific Edge is making steady progress in the US public sector. In March of this year, its dossier for Cxbladder Detect was approved for addition to the Federal Supply Schedule (VA FSS)[4] enabling commercial access to the VA urologists and expedited payment following a lengthy review process. The government-funded VA, one of the largest healthcare programmes in the US, is an organisation that represents a considerable market providing care to approximately 8.8 million veterans and their families in a network of clinics, hospitals and healthcare centres across the US. Pacific Edge awaits imminent receipt of the Award Package at which time sales reps can begin marketing to and building awareness with high-volume sales representatives of Cxbladder, in some cases through User Programmes.

CMS provides healthcare services to the elderly and lower income in the US and, according to Pacific Edge, represents a notable 40% of its total target market. Progress has also been made in the negotiation process with the CMS and management expects the conclusion of discussion on approval and reimbursement to provide a significant lift in revenue/lab throughput for Cxbladder tests, though exact timing is uncertain as the process is long and iterative.

**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 NPN clients.

[2] 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.

[3] The Veterans Administration is a federal agency providing services to US veterans.

[4] Enables provision of goods and services to government entities and enterprises.

## Marketing outside of the 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 while also pursuing other worldwide opportunities. The markets in New Zealand and Australia are measurably smaller, with 300 urologists in both countries together, which is less than 3% of the c 11,000 in the US. The CLIA-certified New Zealand facility services these territories and can also serve as backup to the US. Annual capacity for tests is 35,000 and scalable, and on our base-case forecasts is sufficient to accommodate Pacific Edge sales through to 2031.

In New Zealand, Pacific Edge is seeing steadily increasing adoption of Cxbladder products by publicly and privately funded health organisations. Launched in 2011 in New Zealand, the sales effort there 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. Labtests in Auckland is the exclusive sales and marketing partner for the Auckland and Northland regions, which account for c 40% of all tests in the country. Cxbladder has been commercially adopted by Urotech, which provides urological services to two additional DHBs. More recently the company signed an agreement with Canterbury District Health Board to provide Cxbladder testing for primary referral in the evaluation of haematuria through Canterbury DHB's HealthPathways[5] plan. Initially, a total 200 tests will be performed to evaluate the technology. This is a significant milestone, marking the first time an organisation has moved forward with the intended replacement of cytology with Cxbladder testing.

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 the 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 site is designed to increase patient compliance and provide easy access for rural GPs. Regulatory clearance for this new sales channel in New Zealand was cleared through TAPS (Therapeutic Advertising Pre-vetting System of the Advertising Standard Authority).

In Australia, Pacific Edge partnered with Tolmar Australia earlier this year, a specialist uro-oncology company that provides healthcare to men with advanced prostate cancer. Tolmar has a specialist salesforce of eight people with strong relationships with urologists throughout Australia who will encourage the use of Cxbladder tests through User Programmes, replicating the marketing approach in the US and New Zealand.

### Expansion into Asia through Singapore

Pacific Edge is evaluating the South-East Asian market opportunity. In early June 2015, 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 tends to over 2,000 patients per day. Initially, the programme will trial Cxbladder Detect in those patients presenting with haematuria, 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 visit Singapore each year, which according to Pacific Edge is projected to

[5] The Canterbury HealthPathways are the main source of assessment, management and referral information about Canterbury health services for community healthcare providers, and used by 80% of general practitioners more than six times per week.

exceed 1.3 million 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. The company is also employing 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 a grant from New Zealand Trade and Enterprise (NZTE). The three-year NZ$600,000 grant to aid the evaluation of the South-East Asian market opportunity will be dispersed on the basis of milestones and Pacific Edge will match NZTE funding.

While we believe signing TTSH on represents a significant milestone, we do not yet include potential sales in the South-East Asian region. We await the completion of Pacific Edge's evaluation and clarity on sales potential, particularly that stemming from the potentially large medical tourist community.

## Sensitivities

First acceptance of Cxbladder products has confirmed the utility of the technology associated with the franchise. The diagnostic test has been validated through various User Programmes and is now seeing its first sales in New Zealand, Australia and the US. However, execution risk remains an important hurdle as the Cxbladder tests have yet to be proven on a full commercial scale. The US accounts for more than 90% of our projected sales in 2020. Healthcare specialists in the US (and worldwide) are typically highly conservative in their adoption of 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. We believe Pacific Edge is on the tipping point of potential meaningful conversions in the US. The nod of approval from the VA for Pacific Edge to sell to VA urologists is a considerable stepping stone towards wider acceptance by the greater medical community. Additionally, management reports early interest and willingness to explore the potential of the products from numerous clinicians. We expect the successful negotiation of contracts with four national provider networks to provide additional support. While 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

Our fair value for Pacific Edge moves down to NZ$448m (NZ$1.19 per share) from that of NZ$496m (NZ$1.32 per share) in November 2015. The downward adjustment is affected by pushing out sales from the Cxbladder franchise given the more protracted time frame than anticipated for traction on commercialisation in the US and has led us to delay projected profitability from 2017 to 2018. Currency fluctuations of the US dollar against the New Zealand dollar (to NZ$1.47 from NZ$1.51 since our last report in November 2015) also negatively impact our fair value. At the same time, our valuation is positively influenced by the addition of sales from Cxbladder Monitor, now included in our forecasts, as well as rolling forward our model to FY17. We assume Cxbladder will be used for the ongoing monitoring of those patients diagnosed with bladder cancer (tested by Cxbladder Predict or Triage), calculate average testing of twice annually for Cxbladder Monitor and account for an average 75% five-year survival rate of patients. We project

that the company will be able to achieve NZ$296m in peak sales in 2025 through a mix of the three products with the average price in the US starting at US$663 per test in 2016.

**Exhibit 5: Valuation based on DCF**

| | |
|---|---|
| Discounted cash flow (NZ$000) | 423,614 |
| Net cash (NZ$000) | 24,160 |
| Valuation (NZ$000) | 447,774 |
| Number of shares (m) | 376.54 |
| Value per share (NZ$) | 1.19 |

Source: Edison Investment Research

We derive our valuation by applying our standard 12.5% discount rate to our estimates, which include the sales of the Cxbladder Detect, Triage and Monitor in the US, New Zealand and Australia. We do not include forecasts for potential additional product launches in the Cxbladder franchise (including Cxbladder Predict), tests in the pipeline for follow-on cancer indications and sales in additional regions, including South-East Asia where Cxbladder is in beta testing in Singapore.

# Financials

Our short-term estimates have been revised downwards since our last update in November 2015 due to a slower sales ramp as well as exchange rate fluctuations. In FY16 (ended 31 March 2016), Pacific Edge reported product sales of NZ$5.0m, up significantly from NZ$1.9m in FY15, although below the NZ$8.5m we expected as of our last published note. Laboratory throughput increased 114% compared to the previous year. We expect sales will remain modest until converting larger-scale User Programmes to commercial use begins feeding through to the top line in early CY17. Our models include sales of NZ$24m in 2018 and NZ$105m in 2020, peaking at NZ$296m in 2025.

**Exhibit 6: Changes to estimates**

| NZ$000s | Revenue | | | Operating profit | | | Profit after tax | | |
|---|---|---|---|---|---|---|---|---|---|
| | Old | New | % change | Old | New | % change | Old | New | % change |
| 2017e | 28,157 | 11,361 | (59.7%) | 1,588 | (7,194) | N/A | 1,576 | (7,441) | N/A |
| 2018e | N/A | 24,379 | N/A | N/A | 4,319 | N/A | N/A | 2,629 | N/A |

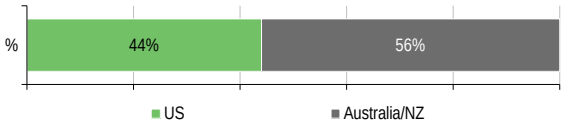
Source: Edison Investment Research

Given our current expectations for a loss of NZ$7.4m in FY17, current cash holdings and investments estimated at NZ$24.2m at end March 2016 – boosted by a NZ$35.3m rights offer in mid-2015 – should carry the company through to profitability in 2018.

**Exhibit 7: Financial summary**

| NZ$000s | 2015 | 2016 | 2017e | 2018e |
|---|---|---|---|---|
| Year end 31 March | NZ GAAP | NZ GAAP | NZ GAAP | NZ GAAP |
| PROFIT & LOSS | | | | |
| Revenue | 3,622 | 6,431 | 11,361 | 24,379 |
| Cost of Sales | (588) | (1,047) | (1,400) | (2,300) |
| Gross Profit | 3,034 | 5,384 | 9,961 | 22,079 |
| EBITDA | (10,530) | (14,899) | (6,736) | 4,713 |
| Operating Profit (before GW and except.) | (10,838) | (15,246) | (7,132) | 4,407 |
| Intangible Amortisation | (151) | (159) | (62) | (88) |
| Exceptionals | 154 | 223 | 0 | 0 |
| Operating Profit | (10,835) | (15,182) | (7,194) | 4,319 |
| Other | (750) | (1,034) | (1,034) | (1,034) |
| Net Interest | 510 | 762 | 725 | 625 |
| Profit Before Tax (norm) | (11,078) | (15,518) | (7,441) | 3,998 |
| Profit Before Tax (FRS 3) | (11,075) | (15,453) | (7,503) | 3,910 |
| Tax | 0 | 0 | 0 | (1,369) |
| Profit After Tax (norm) | (11,078) | (15,518) | (7,441) | 2,629 |
| Profit After Tax (FRS 3) | (11,075) | (15,453) | (7,503) | 2,542 |
| Average Number of Shares Outstanding (m) | 318.6 | 376.5 | 391.6 | 407.3 |
| EPS - normalised (c) | (3.5) | (4.1) | (1.9) | 0.6 |
| EPS - FRS 3 (c) | (3.5) | (4.1) | (1.9) | 0.6 |
| Dividend per share (c) | 0.0 | 0.0 | 0.0 | 0.0 |
| Gross Margin (%) | N/A | N/A | N/A | N/A |
| EBITDA Margin (%) | N/A | N/A | N/A | N/A |
| Operating Margin (before GW and except.) (%) | N/A | N/A | N/A | N/A |
| BALANCE SHEET | | | | |
| Fixed Assets | 1,362 | 1,237 | 1,117 | 1,074 |
| Intangible Assets | 244 | 248 | 351 | 434 |
| Tangible Assets | 1,118 | 990 | 766 | 641 |
| Other | 0 | 0 | 0 | 0 |
| Current Assets | 11,271 | 31,093 | 24,904 | 30,594 |
| Stocks | 623 | 707 | 1,000 | 1,000 |
| Debtors | 2,584 | 5,730 | 2,584 | 2,584 |
| Cash | 7,819 | 24,160 | 20,824 | 26,515 |
| Other | 245 | 496 | 496 | 496 |
| Current Liabilities | (1,930) | (2,523) | (2,523) | (3,208) |
| Creditors | (1,930) | (2,523) | (2,523) | (3,208) |
| Short term borrowings | 0 | 0 | 0 | 0 |
| Short term leases | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 |
| Long Term Liabilities | 0 | 0 | 0 | 0 |
| Long term borrowings | 0 | 0 | 0 | 0 |
| Long term leases | 0 | 0 | 0 | 0 |
| Other long term liabilities | 0 | 0 | 0 | 0 |
| Net Assets | 10,703 | 29,807 | 23,498 | 28,461 |
| CASH FLOW | | | | |
| Operating Cash Flow | (13,048) | (17,715) | (3,723) | 6,101 |
| Net Interest | 510 | 762 | 725 | 625 |
| Tax | 0 | 0 | 0 | (684) |
| Capex | (427) | (325) | (338) | (351) |
| Acquisitions/disposals | 0 | 0 | 0 | 0 |
| Financing | 0 | 35,336 | 0 | 0 |
| Dividends | 0 | 0 | 0 | 0 |
| Other | 1 | (1,936) | 0 | 0 |
| Net Cash Flow | (12,964) | 16,123 | (3,336) | 5,690 |
| Opening net debt/(cash) | (20,444) | (7,819) | (24,160) | (20,824) |
| HP finance leases initiated | 0 | 0 | 0 | 0 |
| Other | 340 | 218 | 0 | (0) |
| Closing net debt/(cash) | (7,819) | (24,160) | (20,824) | (26,515) |

Source: Company accounts, Edison Investment Research

| Contact details | Revenue by geography |
|---|---|
| Centre for Innovation<br>87 David Street<br>PO Box 56<br>Dunedin, New Zealand, 9016<br>+64 (0)3 479 5800<br>www.pacificedge.co.nz |  |

## Management team

| CEO: David Darling | CEO, Pacific Edge Diagnostics USA Ltd: Jackie 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 brings to the company extensive leadership experience commercialising medical technologies in the US and a strong general management background. Before joining Pacific Edge, Jackie held senior executive positions at OSspray, Ondine Biomedical and Dentsply International, a NASDAQ-100 company. |
| **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 | (%) |
|---|---|
| Harbour Asset Management | 10.1 |
| Salt Funds Management | 9.35 |
| Devon Funds Management | 6.42 |
| BT Investment Management | 6.33 |
| Stephen Robert Tindhall | 5.39 |
| Superlife Investments | 5.11 |

## Companies named in this report

Thermo Fischer Scientific (TMO), Abbott (ABT), Alere (ALR)