

# Pacific Edge

Launches continue to progress

Pacific Edge continues to make progress in the commercialisation of its bladder cancer diagnostics tests in the US, with three tests currently available in the US market. The company signed a contract with Tricare, which handles the healthcare for uniformed service members and their families, and successfully completed a User Programme with Kaiser Permanente (KP), validating the performance of the Cxbladder Triage and the Cxbladder Detect tests. Additionally, the company's newest test, Cxbladder Resolve, has been launched in New Zealand.

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	9.4	(20.9)	(5.4)	0.0	N/A	N/A
03/18e	24.4	(2.5)	(0.4)	0.0	N/A	N/A

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

## Tricare and VA sales push ongoing

Pacific Edge recently announced a contract signing with Tricare, which handles the healthcare for a total of 9.4 million beneficiaries (uniformed service members and their families as well as some veterans) with a total of 70.5 million outpatient visits in 2015. Coupled with its previous agreement with the Veterans Administration (VA), with approximately 20 million people under coverage, and the continued discussions with the Centers for Medicare and Medicaid Services (CMS), the potential for a significant sales ramp exists.

## Positive Kaiser Permanente User Programme data

Kaiser Permanente, a managed care provider that serves 10.6 million members, had been evaluating the Cxbladder Triage and Detect tests in a large, blinded User Programme. According to Pacific Edge, the findings were positive, compelling and equivalent to the previously published data. The data will be submitted for scientific and clinical publication once KP completes its own analysis, after which the company will work on transitioning Kaiser into a large commercial customer.

## Cxbladder Monitor US launch underway

The Cxbladder Monitor test, which is meant for use in the ongoing monitoring of bladder cancer in order to check for recurrence, has been launched in the US. The company is expanding on its earlier targeted efforts and recently published a paper in the Journal of Urology to reach out to the broader network of urologists.

## Valuation: NZ\$422m (NZ\$1.10 per share)

Our valuation for Pacific Edge moves from NZ\$448m (NZ\$1.19 per share) to NZ\$422m (NZ\$1.10/share) primarily due to a decrease in FY17 sales estimates as well as an increase in expense estimates that resulted in a delay in expected profitability from FY18 to FY19. This was partly offset by rolling forward our estimates. Net cash of NZ\$14.6m should fund operations into forecast profitability. We believe evidence of commercial success will serve as a driver of the valuation.

Earnings update

Healthcare equipment  
& services

13 February 2017

Price **NZ\$0.51**

Market cap **NZ\$195m**

NZ\$1.47/US\$

Net cash (NZ\$m) at 30 September 2016 14.6

Shares in issue 381.7m

Free float 74%

Code PEB

Primary exchange NZX

Secondary exchange N/A

### Share price performance



%	1m	3m	12m
Abs	(13.8)	8.7	19.1
Rel (local)	(14.6)	3.5	5.1

52-week high/low NZ\$0.67 NZ\$0.40

### 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

Updates on product launches 2017

### Analysts

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## A broad bladder cancer franchise

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Pacific Edge develops and commercialises molecular tests, three of which are being commercialised in the US, 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 brand 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. Cxbladder Monitor targets patients that are currently undergoing follow-up surveillance for UC and was recently (December 2016) launched in the US. Cxbladder Triage is designed for undiagnosed patients that present with hematuria.

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.

## 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), NMP22 ELISA (Fisher Scientific) and UroVysion FISH (Abbot).<sup>1</sup> 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; the company's newest test, Cxbladder Resolve, can be used to classify existing tumours by grade and was launched in New Zealand in December 2016.

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. Follow on tests Cxbladder Monitor and Cxbladder Resolve (formerly Predict) are aimed at different value propositions in the evaluation and monitoring of UCs detailed below.

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<sup>1</sup> Breen V, et al. (2015) A holistic comparative analysis of diagnostic tests for urothelial carcinoma: a study of Cxbladder Detect, UroVysion FISH, NMP22 and cytology based on imputation of multiple datasets. *BMC Med. Res. Methodol.* 15, 45.

**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 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) and the US (2016).	High sensitivity and high negative predictive value to determine patients who should receive follow-up tests.
Cxbladder Resolve (formerly Predict)	Classifies tumours as low or high grade.	Launched in New Zealand (2016) with US roll-out in 2018	Prognostic test with high sensitivity and high specificity to patients with high-grade and late-stage disease.
Source: Pacific Edge			

## US commercialisation continues

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 2016 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. The company subsequently published a paper in December 2016 in the high-impact Journal of Urology detailing the performance of the Cxbladder Monitor test (93% sensitivity and 97% negative predictive value) and its capacity to reduce unnecessary cystoscopies.<sup>2</sup>

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 four sales executives, with a current total of 19 canvassing 19 earmarked regions clustered around metro centres. In addition to public payers – CMS, Tricare 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

<sup>2</sup> Kavalieris L, et al. (2016) Performance Characteristics of a Multigene Urine Biomarker Test for Monitoring for Recurrent Urothelial Carcinoma in a Multicenter Study. *J. Urol.* 16, 31930-31939.

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 serves over 10.6million members. In the large User Programme with KP, patients presenting with haematuria for the evaluation of the Cxbladder Triage were enrolled in the large, blinded study. With the successful conclusion of the programme, the previously published Cxbladder triage data (sensitivity of 95.1% and a negative predictive value of 98.5% according to the BioMed Central Urology Journal) has been validated in a real-world clinical setting, based on the company's analysis. Commercial adoption by KP could provide a significant ramp in sales.

**US public healthcare groups** most notably include Tricare, which provides healthcare to members of the armed services and their families, the Veterans Administration (VA), which provides healthcare to veterans, and the Centers for Medicare and Medicaid Services (CMS), which covers 35% of Americans. Pacific Edge is making steady progress in the US public sector. In March 2016, its dossier for Cxbladder Detect was approved for addition to the Federal Supply Schedule (VA FSS)<sup>3</sup> 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 20 million veterans and their families in a network of clinics, hospitals and healthcare centres across the US.

Pacific Edge was approved as a provider and negotiated a contract price for tests with Tricare in October 2016. Tricare covers 9.4 million beneficiaries who accounted for 70.5 million outpatient visits in 2015 in 55 military hospitals and 373 military medical centres.

CMS provides healthcare services to the elderly and those on a lower income in the US. 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.

## Marketing in Australia/New Zealand

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

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<sup>3</sup> Enables provision of goods and services to government entities and enterprises.

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<sup>4</sup> plan. In September 2016, nib Health Insurance, a private health insurance provider, approved reimbursement for a six-month period for Cxbladder diagnostic tests. Then in October, the Waitemata District Health Board approved a programme in which selected low-risk patients previously diagnosed and treated for bladder cancer will receive a Cxbladder Monitor test. The company's newest test, Cxbladder Resolve, was launched in the region in December 2016.

In Australia, Pacific Edge partnered with Tolmar Australia earlier this year; Tolmar is a specialist uro-oncology company that provides healthcare to men with advanced prostate cancer. It has a specialist salesforce of nine 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 South-East Asia**

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. 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. Then in November of 2016 a User Programme agreement with Singapore General Hospital (SGH), the country's largest hospital, was signed. SGH has a team of 10,000 staff and serves over one million patients a year. We note that approximately one million medical tourists visit Singapore each year, which according to Pacific Edge is projected to exceed 1.3 million by 2018. This tourist patient population regularly pays out of pocket, thereby lowering any reimbursement hurdles.

The User Programmes with TTSH and SGH represent an initial move into a potentially significant market. In this targeted growth region, the company anticipates work with additional hospitals and clinics in 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 and SGH on represent significant milestones, 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.

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<sup>4</sup> 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.

## Valuation

Our valuation for Pacific Edge moves from NZ\$448m (NZ\$1.19 per share) to NZ\$422m (NZ\$1.10/share) primarily due to a decrease in FY17 sales estimates as well as an increase in expense estimates that resulted in a delay in expected profitability from FY18 to FY19. This was offset by rolling forward our estimates. We believe ongoing commercial success, aided by sales staff accessing VA and military centres directly and adoption by KP, will serve as a driver of the valuation.

### Exhibit 2: Valuation based on DCF

Discounted cash flow(NZ\$000)	407,009
Net cash (NZ\$000)	14,604
Valuation (NZ\$000)	421,613
Number of shares (m)	381.74
Value per share (NZ\$)	1.10

Source: Edison Investment Research

## Financials

Our FY17 estimates have been revised downwards due to a slower sales ramp though our estimates for future years remain the same due to the company's success in the KP User Programme as well as the new contract with Tricare. In the first half of FY17 (ended 30 September 2016), Pacific Edge reported sales of NZ\$3.0m, up significantly from NZ\$1.8m in the first half of FY16, although down sequentially from the NZ\$3.2m reported for the second half of FY16. The reason for the weakness is seasonal in nature as the first half of its fiscal year includes the summer months in the US market. Laboratory throughput increased 72% compared to the first half of FY16. We expect sales will remain modest until converting larger-scale User Programmes to commercial use begins feeding through to the top line in CY17. Our models include sales of NZ\$24m in 2018 and NZ\$105m in 2020, peaking at NZ\$296m in 2025.

### Exhibit 3: Changes to estimates

NZ\$000s	Revenue			Operating profit			Profit after tax		
	Old	New	% change	Old	New	% change	Old	New	% change
2017e	11,361	9,384	(17.4%)	(7,194)	(20,314)	182%	(7,441)	(20,908)	181%
2018e	24,379	24,379	0%	4,139	(1,578)	N/A	2,629	(1,602)	N/A

Source: Edison Investment Research

We have also increased our expense expectations following the results for the first half of FY17, which had a higher expense run rate than we modelled. We now expect profitability in FY19 instead of FY18. Net cash of NZ\$14.6m should sufficiently fund operations into forecast profitability.

**Exhibit 4: Financial summary**

	NZ\$'000s	2015	2016	2017e	2018e
Year end 31 March		NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
<b>PROFIT &amp; LOSS</b>					
Revenue		3,622	6,431	9,384	24,379
Cost of Sales		(588)	(1,047)	(1,810)	(2,300)
Gross Profit		3,034	5,384	7,574	22,079
EBITDA		(10,530)	(14,899)	(19,967)	(1,225)
Operating Profit (before GW and except.)		(10,838)	(15,246)	(20,314)	(1,578)
Intangible Amortisation		(151)	(159)	(194)	(74)
Exceptionals		154	223	(262)	0
Operating Profit		(10,835)	(15,182)	(20,770)	(1,652)
Other		(750)	(1,034)	(1,145)	(1,145)
Net Interest		510	762	551	219
Profit Before Tax (norm)		(11,078)	(15,518)	(20,908)	(2,505)
Profit Before Tax (FRS 3)		(11,075)	(15,453)	(21,364)	(2,579)
Tax		0	0	0	903
Profit After Tax (norm)		(11,078)	(15,518)	(20,908)	(1,602)
Profit After Tax (FRS 3)		(11,075)	(15,453)	(21,364)	(1,676)
Average Number of Shares Outstanding (m)		318.6	376.5	385.6	401.0
EPS - normalised (c)		(3.5)	(4.1)	(5.4)	(0.4)
EPS - FRS 3 (c)		(3.5)	(4.1)	(5.5)	(0.4)
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
<b>BALANCE SHEET</b>					
Fixed Assets		1,362	1,237	1,181	1,277
Intangible Assets		244	248	297	474
Tangible Assets		1,118	990	884	803
Other		0	0	0	0
Current Assets		11,271	31,093	14,899	20,158
Stocks		623	707	600	600
Debtors		2,584	5,730	6,427	6,427
Cash		7,819	24,160	7,292	11,649
Other		245	496	580	1,483
Current Liabilities		(1,930)	(2,523)	(1,994)	(1,543)
Creditors		(1,930)	(2,523)	(1,994)	(1,543)
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	14,086	19,893
<b>CASH FLOW</b>					
Operating Cash Flow		(13,048)	(17,715)	(16,156)	4,211
Net Interest		510	762	0	219
Tax		0	0	0	451
Capex		(427)	(325)	(504)	(524)
Acquisitions/disposals		0	0	0	0
Financing		0	35,336	0	0
Dividends		0	0	0	0
Other		1	(1,936)	(10)	0
Net Cash Flow		(12,964)	16,123	(16,670)	4,357
Opening net debt/(cash)		(20,444)	(7,819)	(24,160)	(7,292)
HP finance leases initiated		0	0	0	0
Other		340	218	(198)	0
Closing net debt/(cash)		(7,819)	(24,160)	(7,292)	(11,649)

Source: Pacific Edge accounts, Edison Investment Research

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