EDISON

Pacific Edge

Company outlook

Anticipating commercial growth

Healthcare equipment & services

Pacific Edge continues to make progress commercialising its suite of bladder cancer diagnostics products, with three tests currently available in the US market. An uplift in sales is expected as TRICARE and the Veterans Administration (VA) are under contract, although the exact timing of a sales ramp is unknown. In addition, the company's discussions with Kaiser Permanente are nearing a final decision and progress has been made with achieving inclusion in the local coverage determination (LCD) by the US Centers for Medicare and Medicaid Services (CMS).

Year end	Revenue (NZ$m)	PBT* (NZ$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/16	6.4	(15.5)	(4.1)	0.0	N/A	N/A
03/17	9.3	(20.8)	(5.4)	0.0	N/A	N/A
03/18e	12.3	(14.0)	(3.2)	0.0	N/A	N/A
03/19e	21.2	(3.9)	(0.9)	0.0	N/A	N/A

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

Forthcoming US sales

US sales are expected to increase by around 50% in 2018 driven by increasing sales from large urology practices and a contribution from TRICARE, which handles the healthcare of 9.4 million beneficiaries (uniformed service members and their families as well as some veterans) and the Veterans Administration (VA), which covers approximately 20 million people, are under contract with Pacific Edge. Inclusion in the LCD by CMS would also help improve reimbursement and usage.

Kaiser Permanente commercial relationship expected

Kaiser Permanente, a managed care provider that serves 11.8 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 company remains in final discussions with Kaiser regarding a commercial relationship.

US launch of Cxbladder Resolve coming up

The company launched its fourth test, Cxbladder Resolve, in New Zealand in December 2016 and expects a soft launch in the US by the end of the first half of FY19 (Q318 on a calendar basis). Resolve classifies tumours as high or low grade. With their portfolio of tests, Pacific Edge is becoming known as the one-stop shop to detect and manage bladder cancer through non-invasive urine tests.

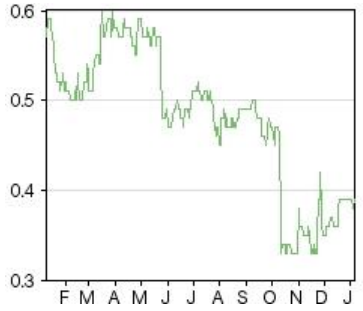
Valuation: NZ$434m or NZ$0.93 per share

Our DCF-based valuation has been reduced to NZ$434m (NZ$0.93/share) from NZ$449m (NZ$1.12/share). This is mainly due to a more conservative view of the sales ramp for the Cxbladder franchise in the US, following a slower than expected first half of the year. We have also pushed back profitability to FY20 from FY19. Pacific Edge recently raised NZ$21.3m in an offering and we expect that no additional capital will be required to fund operations into forecast profitability.

8 January 2018

Price	**NZ$0.39**
Market cap	**NZ$182m**
	NZ$1.48/US$
Net cash (NZ$m) at 30 September 2017	4.0
Shares in issue	466.3m
Free float	92%
Code	PEB
Primary exchange	NZX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	8.3	(16.7)	(33.6)
Rel (local)	4.8	(21.0)	(43.0)
52-week high/low	NZ$0.6		NZ$0.3

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 Resolve	Q318

Analysts

Maxim Jacobs	+1 646 653 7027
Nathaniel Calloway	+1 646 653 7036

healthcare@edisongroup.com

Edison profile page

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 over NZ$100m to date. Its first product was approved in New Zealand in 2011.

Cxbladder Detect, the first of the company's four products, is a non-invasive urine-based test that detects bladder cancer in people presenting with hematuria (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 comprehensive diagnostic toolkit. In December 2016, Cxbladder Monitor was launched in the US while its fourth product, Cxbladder Resolve, was launched in New Zealand. 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$434m (NZ$0.93 per share)

Using a DCF methodology, we value Pacific Edge at NZ$434m (NZ$0.93/share). We forecast overall peak sales of NZ$256m 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 completed a capital raise of NZ$21.3m in November 2017 and had net cash of NZ$4.0m at 30 September 2017 (which does not include cash from the November raise). We forecast profitability in FY20, which is a delay from FY19 previously due to a slower than expected sales ramp in the US. 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. Negotiations are proceeding with key organisations including the Centres for Medicare and Medicaid Services (CMS) (which covers c 35% of the US population) and other large private healthcare providers, which may take longer than expected. 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 as well as their portfolio of products serves as a formidable, high barrier to entry.

Pacific Edge: Nearing greater 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 68% increase in US sales for the year ended 31 March 2017, albeit off a low base and including healthcare organisations' testing through User Programmes. A number of these User Programmes are underway in the US, most notably a large-scale testing by Kaiser Permanente, which concluded in November 2016 and demonstrated positive results. In Singapore, three hospitals, including Tan Tock Seng Hospital and Singapore General Hospital, have commenced User Programmes and are 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 steadily. In August of this year, Pacific Edge announced its third commercial contract in New Zealand with the MidCentral District Health Board to integrate the entire suite of Cxbladder tests into the standard of care for UC diagnosis and monitoring.

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

Pacific Edge's Cxbladder products are regulated in the US as laboratory-developed tests that can be used for detecting bladder cancer in patients who present with hematuria 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. In New Zealand, Cxbladder has replaced the use of cystoscopy for some of the low risk patients. 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).[1] 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 second 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 hematuria 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

[1] 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.

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.

Exhibit 1: Summary of the Cxbladder pipeline

Product name	Function	Status	Notes
Cxbladder Detect	Detects bladder cancer in patients with hematuria.	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	Classifies tumours as low or high grade.	Launched in New Zealand (2016) with US roll-out in 2018.	Prognostic test with sensitivity and high specificity to patients with high-grade and late-stage disease.

Source: Pacific Edge

Bladder cancer is the sixth most common cancer worldwide and has the highest per patient medical scost of any cancer.[2] There will be an estimated 79,000 new cases diagnosed in the US in 2017. Patients who present with non-muscle-invasive bladder cancer experience high recurrence rates of 15-61% and 31-78% after one and five years, respectively.[3] Consequently, the American Urological Association (AUA), National Comprehensive Cancer Network (NCCN), and European Association of Urology (EAU) guidelines suggest intensive surveillance procedures involving cytology (manual examination of a urine sample under a microscope), which tends to have low sensitivity (true positives), particularly at the earlier stages of cancer, and is subject to user variability, as well as cystoscopy (insertion of a flexible scope into the urinary tract) every few months for several years after primary treatment.[4]

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 2: 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. 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.

---

2 World J Urol. 2009 Jun; 27(3); 295-300.

3 Van der Heijden, A. G., & Witjes, J. A. (2009). Recurrence, Progression, and Follow-Up in Non–Muscle-Invasive Bladder Cancer. *European Urology Supplements , 8*, 556-562.

4 Lotan, Y., et al. (2017). Clinical comparison of noninvasive urine tests for ruling out recurrent urothelial carcinoma. *Urologic Oncology: Seminars and Original Investigations, 35*(8). doi:10.1016/j.urolonc.2017.03.008

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 hematuria. 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.

In 2017, Pacific Edge published two clinical studies evaluating Cxbladder Monitor. Cxbladder Monitor for UC recurrence is internally clinically validated by a multicentre US study, which analysed 1,036 voided urine samples from 763 patients undergoing routine surveillance, including cystoscopy, from October 2012 to November 2015. The independent clinical validation of Cxbladder Monitor showed a validated sensitivity of 93%, a negative predictive value (NPV; true negative) of 97%, and a test negative rate of 34%. For all high-grade disease and low-grade stage T1 or greater, sensitivity was 95%, while sensitivity was 85% for low-grade Ta disease. Furthermore, of the 1,036 individual samples used in the development and validation of Cxbladder Monitor, 1,016 samples (from 748 patients) collected were used for clinical comparison to non-invasive tests that include cytology, NMP22 ELISA (Fischer Scientific), and NMP22 BladderChek (Alere) for ruling out recurrent UC. The study showed Cxbladder Monitor to be more accurate than cytology and NMP22 tests across all stages and grades as demonstrated by high sensitivity and high NPV, which is essential to an effective rule-out test.

Exhibit 3: Sensitivity of urine detection tests in multicentre study of 748 patients

Tumour stage	Cxbladder monitor	Cytology	NMP22 ELISA	NMP22 BladderChek
Ta	89%	16%	21%	5%
Tis	97%	31%	41%	31%
≥T1	100%	26%	32%	11%
High grade tumours	97%	23%	29%	14%
Low grade tumours	84%	13%	20%	4%
Overall sensitivity	91%	22%	26%	11%

Source: Pacific Edge trial published in *Urologic Oncology: Seminars and Original Investigations*, Vol 35, 531.e15- 531.e22

Additionally, Abbott's UroVysion FISH was performed on 145 samples because of either atypical local cytology, physician request, or performed independently of cytology analysis. UroVysion FISH demonstrated a sensitivity of 33% and an NPV of 92%, consecutive cytology and UroVysion FISH yielded a sensitivity of 38% and an NPV 93%, in comparison to Cxbladder Monitor, which showed a sensitivity and NPV of 93% and 98%, respectively. However, the UroVysion FISH test was not part of principal pathologic review and the data was obtained from a comparatively low sample size.

There are a number of commercially available in-vitro diagnostic (IVD) tests to detect and monitor bladder cancer in hematuria 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 and monitor bladder cancer with hematuria

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 hematuria 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

Of the many diagnostic tests currently in development for detecting and monitoring UCs, 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 concentrate on building on the current momentum of the Cxbladder products and franchise.

Progression continues in the US

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 in the field as it has completed critical User Programmes with the Veterans Administration (VA), which provides healthcare to veterans; TRICARE, which provides healthcare to members of the armed services and their families; the Centres for Medicare and Medicaid Services (CMS), which covers 35% of Americans; and Kaiser Permanente (KP), an integrated healthcare provider that serves 11.8 million members.

The US market for hematuria testing and monitoring represents a noteworthy commercial opportunity. According to Pacific Edge, an estimated US$1bn is spent investigating hematuria each

year, with approximately 1.5 million people presenting to their healthcare provider a year in the US.[5] 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 a total of 18 sales executives canvasing 19 earmarked regions clustered around metro centres. The salesforce actively markets its tests to private paying integrated healthcare providers and urologists (c 11,000 in the US) as well as public payers including CMS and the VA. 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 hematuria. 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.

US public healthcare groups most notably include the Veterans Administration (VA)[6], TRICARE[7], and the Centres for Medicare and Medicaid Services (CMS)[8], with potentially significant volumes. In March 2016, its dossier for Cxbladder Detect was approved for addition to the Federal Supply Schedule (VA FSS)[9] 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. The company is currently targeting five large VA clinics and early sales have already begun in two of them. It also expects to set up User Programmes at larger sites so that healthcare providers can trial the tests. In October 2016, Pacific Edge was approved as a provider and negotiated a contract price for tests with TRICARE. TRICARE covers 9.4 million beneficiaries

5 Zholudev, V., Laganosky, D., Safir, I., Dear, M., Lindelow, J., Goodgame, B., Issa, M. (2017). Mp32-19 Cost Analysis For Initial Evaluation Of Hematuria: Impact Of Tele-Urology Clinics. *The Journal of Urology, 197*(4). doi:10.1016/j.juro.2017.02.994

6 The Veterans Administration is a federal agency providing services to US veterans.

7 TRICARE is a federal program that provides medical care to members of the US Department of Defense.

8 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.

9 Enables provision of goods and services to government entities and enterprises.

who accounted for 70.5 million outpatient visits in 2015 in 55 military hospitals and 373 military medical centres. The company is currently leveraging existing relationships with high-volume sites in key areas. As in other areas, it anticipates User Programmes at the larger sites so that healthcare providers can trial the tests. CMS provides healthcare services to the elderly and those on a lower income in the US, and, according to Pacific Edge, represents a notable 40% of its total target market. Progress has 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.

Integrated healthcare providers (IHPs) combine insurance, hospital and medical group functions into a coordinated healthcare model. Pacific Edge is targeting IHPs such as Kaiser Permanente (KP), which serves over 11.8 million members. In the large User Programme with KP, patients presenting with hematuria for the evaluation of the Cxbladder Triage were enrolled in a large, blinded study. With the successful conclusion of the programme, the previously published Cxbladder Triage data (sensitivity of 95.1%, specificity of 45%, 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. The company is now in final discussions with Kaiser regarding a commercial relationship. Commercial adoption by KP could provide a significant ramp in sales.

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 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). In August of this year, the company signed its third commercial agreement with MidCentral District Health Board, joining Canterbury and Waitemata DHBs, to incorporate Cxbladder testing into the standard of care across the bladder cancer pathway from initial diagnosis to post-treatment observation for patients throughout the Manawatu-Whanganui region. Among private health insurance providers, nib Health Insurance and Sovereign Health have approved reimbursement for Cxbladder diagnostic tests. The company's latest test, Cxbladder Resolve, was launched in New Zealand in December 2016.

In Australia, Pacific Edge partnered with Tolmar Australia in February 2016; 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.

Singapore as a beachhead to South-East Asia

Pacific Edge is evaluating the South-East Asian market opportunity and has set up Singapore as a base to do so. In early June 2015, the company announced its first entry into South-East Asia with the commencement 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. In November 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. According to Pacific Edge, 1.3 million medical tourists are projected to visit Singapore in 2018. This tourist patient population regularly pays out of pocket, thereby lowering any reimbursement hurdles.

A third User Programme has recently commenced in Singapore and the company anticipates additional User Programmes in hospitals and clinics in South-East Asia will commence in the second half of the year. Additionally, one of the three User Programmes in Singapore is expected to transition into a commercial agreement in the near future. The company is also employing sales and marketing staff in the region to pursue commercial rollouts 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 that the signing of three User Programmes in Singapore 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 95% 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 DCF-based valuation has been reduced to NZ$434m (NZ$0.93/share) from NZ$449m (NZ$1.12/share). This is mainly due to a more conservative view of the sales ramp for the Cxbladder franchise in the US following a slower than expected first half of the year. We have also pushed back profitability to FY20 from FY19. The impact on a per-share basis was more pronounced than on the absolute valuation due to the dilution related to the NZ$21.3m November 2017 capital raise. The effect of these reductions was mitigated by lower operating expense estimates due to lower than expected spending on R&D and SG&A. With the recent capital raise, we expect that no additional capital will be required to fund operations into forecast profitability.

Exhibit 5: Valuation based on DCF

Discounted cash flow (NZ$000)	408,294
Net cash (NZ$000) 30 September 2017 + NZ$21.3m raised in the November offering	25,297
Valuation (NZ$000)	**433,591**
Number of shares (m)	466.32
Value per share (NZ$)	**0.93**

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 Resolve), 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

The company recently published interim (half-year) results. Pacific Edge reported operating revenue of NZ$4.2m, up 41% compared to the first half of the prior year, although this is down 17% compared to the sequential half-year due to summer seasonal weakness in the US. Laboratory throughput (which includes both User Programmes and commercial tests) rose 26% compared to last year, though this is a slight deceleration from the 35% growth seen in the previous full year. R&D expenses were NZ$1.8m, down 29% compared to the first half of the prior year. SG&A expenses were NZ$7.7m, down 8% compared to the prior year as that period included expenses related to winding up the incentive scheme for employees. Due to these results, we have made changes to our financial forecasts (see Exhibit 6).

Exhibit 6: Financial forecast changes

	2018e Old	2018e New	2019e Old	2019e New
Revenue (NZ$m)	18.5	12.3	41.8	21.2
PBT (normalised) (NZ$m)	(9.2)	(14.0)	11.2	(3.9)
EPS (NZ$)	(0.02)	(0.03)	0.02	(0.01)

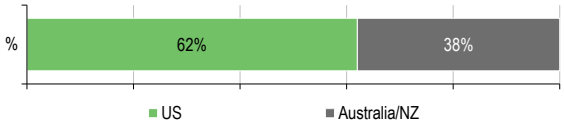
Source: Edison Investment Research

The company completed a capital raise of NZ$21.3m in November 2017 and had net cash of NZ$4.0m at 30 September 2017 (which does not include cash from the November raise). We forecast profitability in FY20, which is a delay from FY19 previously due to a slower than expected sales ramp in the US.

Exhibit 7: Financial summary

NZ$'000s	2015	2016	2017	2018e	2019e
Year end 31 March	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS					
Revenue	3,622	6,431	9,286	12,271	21,197
Cost of Sales	(588)	(1,047)	(996)	(1,350)	(2,000)
Gross Profit	3,034	5,384	8,290	10,921	19,197
EBITDA	(10,530)	(14,899)	(19,620)	(13,074)	(3,164)
Operating Profit (before GW and except.)	(10,838)	(15,246)	(19,973)	(13,409)	(3,505)
Intangible Amortisation	(151)	(159)	(189)	(180)	(107)
Exceptionals	154	223	(67)	(220)	0
Operating Profit	(10,835)	(15,182)	(20,229)	(13,809)	(3,612)
Other	(750)	(1,034)	(1,067)	(1,067)	(1,067)
Net Interest	510	762	249	437	689
Profit Before Tax (norm)	(11,078)	(15,518)	(20,792)	(14,039)	(3,883)
Profit Before Tax (FRS 3)	(11,075)	(15,453)	(21,048)	(14,439)	(3,990)
Tax	0	0	0	0	0
Profit After Tax (norm)	(11,078)	(15,518)	(20,792)	(14,039)	(3,883)
Profit After Tax (FRS 3)	(11,075)	(15,453)	(21,048)	(14,439)	(3,990)
Average Number of Shares Outstanding (m)	318.6	376.5	382.5	434.7	452.1
EPS - normalised (c)	(3.5)	(4.1)	(5.4)	(3.2)	(0.9)
EPS - FRS 3 (c)	(3.5)	(4.1)	(5.5)	(3.3)	(0.9)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets	1,362	1,237	1,166	1,281	1,350
Intangible Assets	244	248	329	428	608
Tangible Assets	1,118	990	837	852	742
Other	0	0	0	0	0
Current Assets	11,271	31,093	22,397	32,641	32,129
Stocks	623	707	824	1,014	1,014
Debtors	2,584	5,730	6,519	8,027	8,027
Cash	7,819	24,160	14,564	22,955	22,443
Other	245	496	490	645	645
Current Liabilities	(1,930)	(2,523)	(2,734)	(2,658)	(2,658)
Creditors	(1,930)	(2,523)	(2,734)	(2,589)	(2,589)
Short term borrowings	0	0	0	0	0
Short term leases	0	0	0	(69)	(69)
Other	0	0	0	0	0
Long Term Liabilities	0	0	0	(54)	(54)
Long term borrowings	0	0	0	0	0
Long term leases	0	0	0	(54)	(54)
Other long term liabilities	0	0	0	0	0
Net Assets	10,703	29,807	20,829	31,210	30,767
CASH FLOW					
Operating Cash Flow	(13,048)	(17,715)	(18,086)	(12,727)	(683)
Net Interest	510	762	249	438	689
Tax	0	0	0	0	0
Capex	(427)	(325)	(479)	(498)	(517)
Acquisitions/disposals	0	0	0	0	0
Financing	0	35,336	8,750	21,394	0
Dividends	0	0	0	0	0
Other	1	(1,936)	(91)	(17)	0
Net Cash Flow	(12,964)	16,123	(9,657)	8,591	(512)
Opening net debt/(cash)	(20,444)	(7,819)	(24,160)	(14,564)	(22,832)
HP finance leases initiated	0	0	0	(123)	0
Other	340	218	61	(200)	0
Closing net debt/(cash)	(7,819)	(24,160)	(14,564)	(22,832)	(22,320)

Source: Company accounts, Edison Investment Research

Contact details	Revenue by geography
PO Box 56 Dunedin, New Zealand, 9016 +64 (0)3 479 5800 www.pacificedge.co.nz	

Management team

CEO: David Darling

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.

CEO, Pacific Edge Diagnostics USA Ltd: Jackie Walker

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

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: Jimmy Suttie

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	10.62
Salt Funds Management	10.62
Westpac Banking	8.65
BNP Paribas	5.23
Devon Funds Management	5.01

Companies named in this report

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