

Pacific Edge

CMS coverage pending

Company outlook

Pacific Edge continues to make progress commercialising its Cxbladder suite of bladder cancer diagnostics products, with three of the four Cxbladder tests available in the US market. Cxbladder was recently included in the National Comprehensive Cancer Network (NCCN) guidelines for bladder cancer. The company also submitted an updated evidence dossier to its Medicare Administrative Contractor (MAC), which may decide in Q2 CY20 whether Cxbladder will be included in a Local Coverage Determination (LCD) by the US Centers for Medicare and Medicaid Services (CMS). This will be a key milestone for the company as approximately 47% of US lab throughput for the company is for patients covered by CMS.

Year end	Revenue (NZ\$m)	PBT* (NZ\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/18	4.6	(19.6)	(4.5)	0.0	N/A	N/A
03/19	4.8	(17.8)	(3.7)	0.0	N/A	N/A
03/20e	5.2	(18.7)	(3.1)	0.0	N/A	N/A
03/21e	19.1	(5.8)	(0.8)	0.0	N/A	N/A

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

Getting closer to CMS reimbursement

Pacific Edge has completed two of the three components necessary for national reimbursement in the US, namely CPT codes and a national price of US\$760 per test. The final milestone is to gain inclusion in an LCD, which would enable consistent payments from CMS (which covers patients representing about 47% of US lab throughput for Cxbladder tests) and likely be transformational for the company from a test adoption, revenue and cash flow standpoint.

Cxbladder sales increased 12.4% in H120

The company reported an increase in Cxbladder sales of 12.4% in the first half of FY20 with a 10.1% increase in total laboratory throughput. Sales in the rest of the world (primarily Australia, New Zealand and Singapore) were particularly strong and were up 53.6% compared to the same period last year.

Raising additional funds

Pacific Edge recently completed an integrated placement and fully subscribed rights offering, which raised a total of NZ\$20.1m for the company in two parts (NZ\$7.0m in a private placement in November and NZ\$13.1m in a rights offering in December) through the issuance of approximately 178.1m shares.

Valuation: NZ\$231m or NZ\$0.33 per share

Our DCF-based valuation has been adjusted to NZ\$231m (NZ\$0.33/share) from NZ\$219m (NZ\$0.43/share). The total value has been increased due to higher net cash post-offering and due to rolling forward our DCF. This was partially offset due to lower near-term sales expectations. The per-share value fell due to an increased share count.

Healthcare equipment & services

6 January 2020

Price **NZ\$0.12**

Market cap **NZ\$83m**

NZ\$1.56/US\$

Net cash (NZ\$m) at 30 September 2019 + offerings 24.8

Shares in issue (estimated) 689.7m

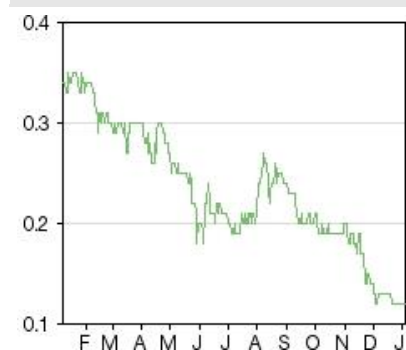
Free float 89.1%

Code PEB

Primary exchange NZX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (9.6) (34.9) (61.1)

Rel (local) (12.4) (38.9) (69.7)

52-week high/low NZ\$0.33 NZ\$0.12

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, Australia and Singapore.

Next events

LCD inclusion Q2 CY20

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Pacific Edge is a research client of Edison Investment Research Limited

Investment summary

Company description: Cancer diagnostic testing

Pacific Edge was formed in August 2001 to develop molecular diagnostic and prognostic tools in cancer. Its headquarters are in Dunedin, New Zealand, and it has two wholly owned subsidiaries commercialising Cxbladder: Pacific Edge Diagnostics NZ in Dunedin and Pacific Edge Diagnostics USA (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. 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 such as Cxbladder Triage, to rule out patients who do not have cancer, Cxbladder Monitor, which monitors for disease recurrence, and Cxbladder Resolve, which segregates lower-grade tumours from higher grade ones.

Valuation: NZ\$231m (NZ\$0.33 per share)

Using a DCF methodology, we value Pacific Edge at NZ\$231m (NZ\$0.33/share). We forecast overall peak sales of NZ\$164m for the Cxbladder franchise in 2025. As the US is by far the largest market the company is targeting, inclusion in an LCD to gain coverage from CMS is necessary for the company to meet our forecasts. The MAC may decide in Q2 CY20 whether Cxbladder will be included in an LCD by the CMS.

Financials: H120 results and capital raises

Pacific Edge reported an increase in Cxbladder sales of 12.4% in the first half of FY20 with sales in the rest of the world (primarily Australia, New Zealand and Singapore) particularly strong, up 53.6% compared to the same period last year. The company recently completed an integrated placement and fully subscribed rights offering, which raised a total of NZ\$20.1m and had net cash of NZ\$4.7m at 30 September 2019 (which does not include cash from the capital raises). Based on our estimates the post-offering net cash level should be enough to fund the company through forecast profitability in FY22.

Sensitivities: CMS is key

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. Especially key will be the timing of the LCD inclusion that will drive reimbursement from CMS, which covers around 47% of the tests conducted by the company in the US. Obtaining inclusion in an LCD would improve test adoption, lead to timely payment for tests and also may result (subject to negotiation with the agency) in a one-off payment from CMS for the backlog of 19,361 Cxbladder tests (as of 30 September 2019) for CMS patients that have yet to be reimbursed. In the longer term, 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 its portfolio of products serves as a formidable barrier to entry.

Pacific Edge: A suite of tests for bladder cancer

Pacific Edge develops and commercialises molecular tests for the detection and better management of urothelial cancers (UC). 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 number of current, repetitive and invasive diagnostic tests and procedures for UC, and an improvement in accuracy over those tests currently in the market.

A one-stop shop to detect and manage bladder cancer

Pacific Edge's Cxbladder products are regulated in the US as laboratory-developed tests (LDTs) 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 can be removed from requiring a full clinical workup for UC and for the better and faster identification of patients who should go on for more invasive testing. In New Zealand, Cxbladder has replaced the use of cystoscopy in all patients with hematuria being evaluated for UC. It is more accurate, faster, less invasive and more cost-effective than the existing tests and procedures that include cytology, NMP22 BladderChek (Abbott through the acquisition of Alere), NMP22 ELISA (Fisher Scientific) and UroVysion FISH (Abbott).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 evaluated and tested 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 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 using its high sensitivity and high negative predictive value. Follow on tests Cxbladder Monitor and Cxbladder Resolve 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 Resolve	Classifies tumours as low or high grade.	Launched in New Zealand (2016) with US roll-out upcoming.	Prognostic test with sensitivity and high specificity to patients with high-grade and late-stage disease.
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.

Source: Pacific Edge

Bladder cancer is the fourth most common cancer in men in the US according to the National Cancer Institute and has the highest per patient medical cost of any cancer.² There will be an

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.

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

estimated 80,470 new cases diagnosed in the US in 2019. 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

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.

Cxbladder Detect also compares favourably against Abbott's UroVysion looking at separate large-scale clinical trials, each with over 400 patients. By comparison, UroVysion was launched 2001 as an aid in monitoring bladder cancer and in 2005 to aid diagnosis, using 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 has been 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 (Abbott) 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, both metrics essential to an effective rule-out test.

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.

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 the 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, and until Cxbladder, none has been shown to be more accurate than the existing benchmark. Hence, many of the commercially available IVD tests are not used by mainstream urology practices.

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 other 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 College of American Pathologists (CAP) 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.

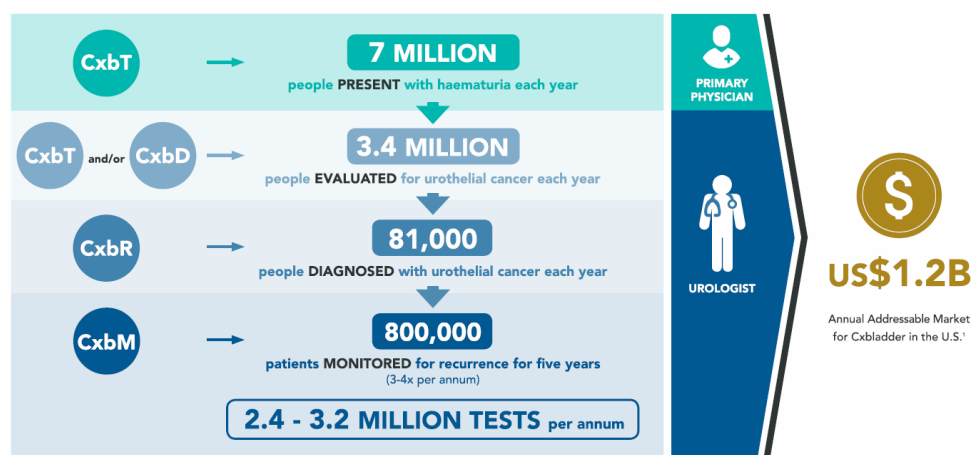
Pacific Edge management intends to focus on bladder cancer diagnostics in the short to medium term. Further out, the company may pursue other portfolio opportunities that include gastric, colorectal and endometrial cancers and melanoma. However, the company plans to first concentrate on building on the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

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 Department of Veterans Affairs (VA), which provides healthcare to veterans; TRICARE, which provides healthcare to members of the armed services and their families; the 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 an analysis by Ernst and Young sponsored by Pacific Edge (see Exhibit 5), the annual addressable market for Cxbladder is US\$1.2bn with 3.4 million being evaluated for urothelial cancer each year. An additional 800,000 are monitored for recurrence three to four times per year.

Exhibit 5: The addressable market opportunity



1. EY-Parthenon business review of the annual addressable market opportunity for Cxbladder in the U.S. completed February 2018

Source: Pacific Edge

The salesforce actively markets its tests to private paying integrated healthcare providers and urologists (c 13,000 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 has been converting those clinicians trialling the tests on User Programmes into fee-paying customers. A number of large academic institutions have started using Cxbladder commercially and an additional 15 are currently evaluating Cxbladder for commercial use.

Exhibit 6: Select healthcare institutions commercially using Cxbladder

Institutions	
Johns Hopkins Medicine	University of Pennsylvania
Carolina Urologic Research Center	University of Southern California
Cleveland Clinic	University of Rochester
Fox Chase Cancer Center	University of Oklahoma
Penn State Medical Center	City of Hope
University of California-Los Angeles	Thomas Jefferson University
University of Minnesota	University of California-San Diego
Mount Sinai Hospital	University of California-San Francisco
Source: Pacific Edge	

Drivers of healthcare decisions by clinicians in the US include the avoidance of a large number of unnecessary tests and procedures, averting malpractice suits on missed tumours, clinical utility and minimising co-payments for 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 seen in the adoption cycle of most emerging medical technologies. 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. Several LUGs have successfully completed User Programmes and are placing commercial orders.

US public healthcare groups, most notably include the VA,⁴ TRICARE⁵ and the CMS,⁶ with potentially significant volumes. In March 2016, its dossier for Cxbladder Detect was approved for addition to the Federal Supply Schedule,⁷ enabling commercial access to 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. 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, who accounted for 106 million outpatient visits in 2017 in 55 military hospitals and 373 military medical centres. The company is leveraging existing relationships with high-volume sites in key areas.

CMS provides healthcare services to the elderly (age 65 and above) and those on a lower income in the US and, according to Pacific Edge, represents a notable 47% of its current US test volume, which if anything may understate the eventual demand from CMS patients once reimbursement is obtained as the average age at diagnosis is 73. The company is continuing to work with CMS to gain inclusion in an LCD. An LCD is a document that includes the coverage decisions of the MAC. An LCD would provide the conditions of the coverage as well as the price, guidance on

⁴ The Veterans Administration is a federal agency providing services to 20 million US veterans and their families.

⁵ TRICARE is a federal programme that provides medical care to members of the US Department of Defense.

⁶ 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.

⁷ Enables provision of goods and services to government entities and enterprises.

reimbursement and coding information. Unfortunately, historically there has been little transparency from the MACs in the LCD inclusion process, and in many ways, it is the epitome of arbitrary bureaucracy. LCD inclusion is also a multi-year process, although the company may be nearing a decision. The company has submitted an updated evidence dossier to its MAC, which may decide in Q220 on LCD inclusion for Cxbladder based on an estimate provided by the company's LCD consultant. The updated evidence dossier includes two recent peer-reviewed publications and, importantly, the inclusion of Cxbladder into the NCCN guidelines under a category 2B recommendation (see Exhibit 7).

Exhibit 7: NCCN guideline categories

NCCN Category	Level of evidence and consensus
1	Based on high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based on lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based on lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based on any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Source: NCCN. Note: 'Uniform NCCN consensus' is defined as a panel vote where at least 85% of a panel agrees, while 'NCCN consensus' is defined by a panel vote where at least 50% but less than 85% of the panel agrees.

Once an LCD inclusion is attained, reimbursement from CMS should become consistent and timely. Besides this immediate benefit of new tests being covered by CMS, the company may finally receive payment for old tests previously conducted. Pacific Edge has not sought payment for tests provided to patients covered by CMS until LCD inclusion so there could be a multi-year backlog of test revenue that is recognised in a single reporting period post-inclusion, subject to negotiation with CMS. In addition, private payers often base their own coverage decisions and reimbursement levels on the coverage listed in an LCD, so a success here could lead to increased success nationally for the company.

Integrated healthcare providers combine insurance, hospital and medical group functions into a coordinated healthcare model. Pacific Edge is targeting integrated healthcare providers 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. 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 a number of networks in the US, including FedMed, ACPN, Stratos and MultiPlan, thereby establishing a fixed retail price to patients insured by NPN clients.

Marketing outside the US

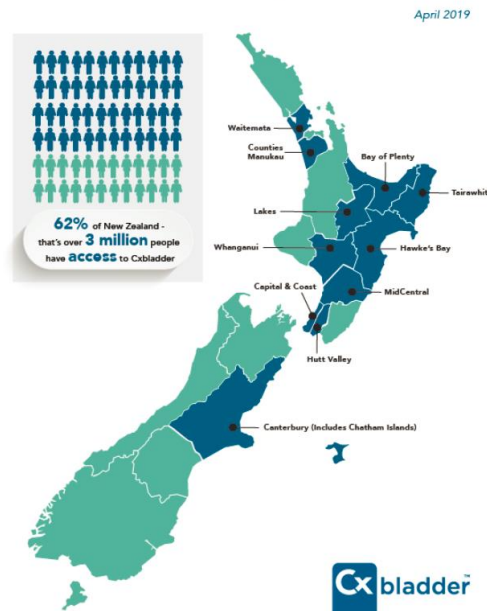
In addition to the US, Pacific Edge is dedicated to the commercialisation of Cxbladder in its home market of New Zealand, Australia and Singapore while pursuing other worldwide opportunities. The markets in New Zealand and Australia are measurably smaller, with the number of urologists a small fraction of the 13,000 in the US (according to the American Urological Association). Australia, for example, has only around 450 registered urologists. 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 public healthcare providers. In late 2018, Cxbladder was adopted into guidelines replacing the gold standard cystoscopy for all hematuria patients being evaluated for UC. Around 62% of the population has access to Cxbladder (as the company has signed 11 of 20 public healthcare providers) and the Cxbladder Triage product (used to rule out low-risk patients and reduce the numbers of cystoscopies) is especially popular. Growth in New Zealand is a major reason for the sales in the rest of the world (primarily Australia, New Zealand and Singapore) going up 53.6% in H120 to NZ\$0.3m compared to the same period last year. The company believes it can bring the New Zealand subsidiary to a cash flow positive position in the near term.

Exhibit 8: Cxbladder contract coverage in New Zealand

Contract Coverage of New Zealand's Population Using Cxbladder



Source: Pacific Edge

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 were projected to visit Singapore in 2018. This tourist patient population regularly pays out of pocket, thereby lowering any reimbursement hurdles.

The company is seeking to transition its User Programmes into commercial customers and is progressing discussions with potential strategic partners. We await additional clarity on sales

potential, particularly stemming from the potentially large medical tourist community, before including South-East Asia into our model.

Sensitivities

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. Especially key will be the timing of the LCD inclusion that will drive reimbursement from CMS, which covers around 47% of the tests conducted by the company in the US. Obtaining inclusion in an LCD would improve test adoption, lead to timely payment for tests and may result (subject to negotiation with the agency) in a one-off payment from CMS for the backlog of 19,361 Cxbladder tests for CMS patients that have yet to be invoiced. In the longer term, in the cancer diagnostic arena, competition from new entrants remains a risk. However, clinical validation will be critical for new competitive technologies and the long lead time to commercial adoption for Pacific Edge as well as its portfolio of products serves as a formidable, high barrier to entry.

Valuation

Our DCF-based valuation has been adjusted to NZ\$231m (NZ\$0.33/share) from NZ\$219m (NZ\$0.43/share). The total value has been increased due to higher net cash post-offering and rolling forward our DCF. This was partially offset due to lower near-term sales expectations. The per-share value fell due to an increased share count.

Exhibit 9: Valuation based on DCF

Discounted cash flow (NZ\$000)	206,053
Net cash (NZ\$000) 30 September 2019 + NZ\$20m raised in November and December offerings	24,837
Valuation (NZ\$000)	230,890
Number of shares (m) as of 30 September 2019 + shares from November and December offerings	689.7
Value per share (NZ\$)	0.33

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 (however, we continue to believe that the US is by far the largest addressable market for Cxbladder and represents around 94% of our peak sales forecast for 2025, compared to 87% currently). 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.

Financials

The company recently published interim (half-year) FY20 results. Pacific Edge reported operating revenue of NZ\$2.3m, up 12.4% compared to the first half of FY19. Laboratory throughput (which includes both User Programmes and commercial tests) rose 10.1% compared to last year. R&D expenses were NZ\$2.0m, up 18.7% compared to the first half of the prior year. Reported SG&A expenses were NZ\$7.5m, up 1.7%. For the full-year FY20, the company has guided for operating expenses to be in line with FY19. Due to these results, we have made changes to our financial forecasts (see Exhibit 10). We have lowered our revenue estimate for FY20 by NZ\$0.7m due to a

lower run rate than our forecasts. We have also lowered our FY21 revenues as LCD inclusion is not expected until the first quarter of FY21 and we had modelled reimbursement for the entire year.

Exhibit 10: Financial forecast changes

	FY20e		FY21e	
	Old	New	Old	New
Revenue (NZ\$m)	5.9	5.2	24.5	19.1
PBT (normalised) (NZ\$m)	(17.4)	(18.7)	(0.2)	(5.8)
EPS (NZ\$)	(0.03)	(0.03)	(0.00)	(0.01)

Source: Edison Investment Research

The company recently completed an integrated placement (NZ\$7m through issuance of c 46.7m shares at NZ\$0.15 per share) and fully subscribed rights offering (NZ\$13.14m through issuance of c 131.4m shares at NZ\$0.10 per share), which raised a total of NZ\$20.1m, and had net cash of NZ\$4.7m at 30 September 2019 (which does not include cash from the capital raises). Based on our estimates the post-offering net cash level should be enough to fund the company through forecast profitability in FY22.

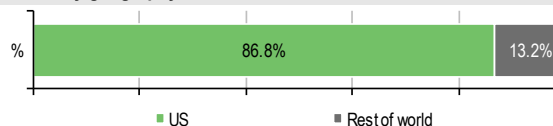
Exhibit 11: Financial summary

	NZ\$'000s	2018	2019	2020e	2021e
Year end 31 March		NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS					
Revenue		4,642	4,807	5,195	19,127
Cost of Sales		(4,619)	(4,594)	(5,230)	(5,753)
Gross Profit		23	213	(35)	13,375
EBITDA		(19,500)	(17,840)	(17,661)	(4,781)
Operating Profit (before amort. and except.)		(19,816)	(18,077)	(18,961)	(6,341)
Intangible Amortisation		(188)	(154)	(116)	(139)
Exceptionals		46	(4)	2	0
Operating Profit		(19,958)	(18,235)	(19,075)	(6,480)
Other		0	0	0	0
Net Interest		231	323	230	494
Profit Before Tax (norm)		(19,585)	(17,754)	(18,731)	(5,847)
Profit Before Tax (FRS 3)		(19,727)	(17,912)	(18,845)	(5,986)
Tax		0	(9)	0	0
Profit After Tax (norm)		(19,585)	(17,763)	(18,731)	(5,847)
Profit After Tax (FRS 3)		(19,727)	(17,921)	(18,845)	(5,986)
Average Number of Shares Outstanding (m)		438.4	481.2	600.4	717.1
EPS - normalised (c)		(4.5)	(3.7)	(3.1)	(0.8)
EPS - FRS 3 (c)		(4.5)	(3.7)	(3.1)	(0.8)
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		1,135	1,002	2,262	2,106
Intangible Assets		281	233	180	103
Tangible Assets		854	769	582	503
Other		0	0	1,500	1,500
Current Assets		18,530	15,564	19,171	15,620
Stocks		752	842	828	828
Debtors		1,064	1,265	952	952
Cash		16,242	12,847	16,468	12,917
Other		472	610	923	923
Current Liabilities		(2,999)	(2,624)	(4,521)	(4,521)
Creditors		(2,926)	(2,572)	(3,372)	(3,372)
Short term borrowings		0	0	0	0
Short term leases		(73)	(52)	(1,149)	(1,149)
Other		0	0	0	0
Long Term Liabilities		(26)	(32)	(352)	(352)
Long term borrowings		0	0	0	0
Long term leases		(26)	(32)	(352)	(352)
Other long term liabilities		0	0	0	0
Net Assets		16,640	13,910	16,560	12,852
CASH FLOW					
Operating Cash Flow		(18,331)	(17,830)	(15,703)	(3,897)
Net Interest		231	323	0	494
Tax		0	0	0	0
Capex		(335)	(156)	(142)	(148)
Acquisitions/disposals		0	0	0	0
Financing		21,318	14,569	20,100	0
Dividends		0	0	0	0
Other		(1,261)	(275)	(612)	0
Net Cash Flow		1,622	(3,369)	3,643	(3,551)
Opening net debt/(cash)		(14,564)	(16,143)	(12,763)	(14,967)
HP finance leases initiated		(99)	15	(1,417)	0
Other		56	(26)	(22)	(0)
Closing net debt/(cash)		(16,143)	(12,763)	(14,967)	(11,416)

Source: Edison Investment Research, company accounts

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Revenue by geography

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: 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 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	16.40
Westpac Banking	9.53
AMP	5.01
K One W One	4.51
Masfen Securities	2.43
Norges Bank	1.91
Leveraged Equities Finance	1.59

Companies named in this report

Thermo Fischer Scientific (TMO), Abbott (ABT)

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