



**PACIFIC EDGE**  
Cancer Diagnostic Company

**FY19 Results Presentation**  
**For the year ended 31 March 2019**  
**and Outlook for FY20**

29 May 2019

# PACIFIC EDGE IS IN A UNIQUE GLOBAL POSITION (PEB.NZX)



- **First to market for 17 years:** Four proprietary, commercial diagnostic tests (Cxbladder) addressing large, under-served urothelial cancer markets globally.
- **Proven model:** Answering clinical questions that matter; disrupting “gold standard” of care; resolving diagnostic uncertainty with additional clinical utility; reducing healthcare costs and patient fatigue.
- **Strong clinical validation:** Growing pool of clinical evidence supporting Cxbladder in top-tier international journals; facilitating test adoption and reimbursement.
- **Strong momentum:** Growth rates accelerating; addressing a large global market opportunity.
- **Future Pipeline in Other Cancers:** Identified biomarkers and IP supporting new product development and long term growth.

# CXBLADDER

World class diagnostic tests validated by international physicians

The first new diagnostic tests for bladder cancer to be made commercially available in the US market in 17 years, disrupting clinical pathways and standards of care.

Four high performance Cxbladder products in use by clinicians and now being integrated into standards of care and guidelines.

- Non-invasive
- Simple to use
- Extensive market access
- Fast laboratory turnaround
- Increases clinical resolution
- Reduces healthcare spend

Ongoing clinical validation continues to demonstrate the outperformance of Cxbladder compared to other commonly used diagnostics. Third party clinical outcomes now being published support the transition into commercial reality.



# FIRST MOVER ADVANTAGE IN A GLOBAL OPPORTUNITY IN HAEMATURIA AND BLADDER CANCER

The US and NZ markets dominate our commercial focus

Approx. 7 million people present with haematuria annually in the USA	70% recurrence rate leads to many clinical procedures	17 years of R&D and validation
79,000+ new bladder cancer cases in USA every year	Highest medical cost of any cancer; up to US\$240k per patient lifetime	Primary focus is the USA; the world's largest healthcare market
9 <sup>th</sup> most common cancer in the world; 4 <sup>th</sup> most common in men	Suite of four Cxbladder tests	Commercial partnerships in USA, NZ, Australia and Singapore

**Pacific Edge's addressable market in the USA alone has been calculated to be worth up to US\$1.2 billion per annum.**

Validated by EY-Parthenon review\*

\*EY Parthenon, a leading international consulting firm, has endorsed Pacific Edge's USA market strategy and confirmed the addressable market for Cxbladder in the USA to be more than US\$1.2 billion per annum

# FY19 PROGRESS

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# FY19 HIGHLIGHTS AND MILESTONES

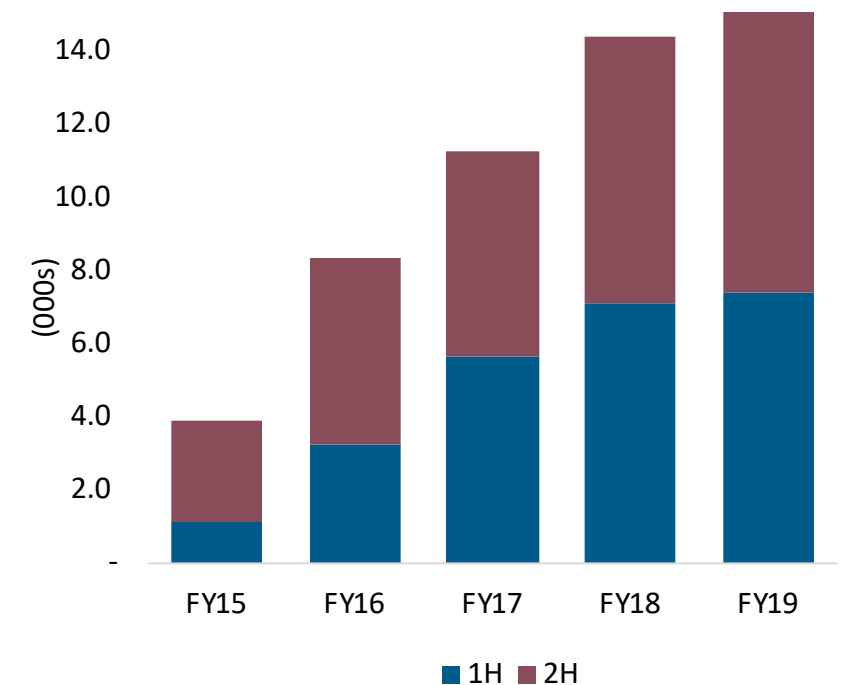
- Growth in commercial sales and billable test volumes:
  - Strong growth in NZ and US commercial sales achieved in Q419.
- Several US reimbursement milestones successfully attained:
  - National price for all Cxbladder tests (US\$760 per test)
  - National product specific CPT codes for Cxbladder Detect and Cxbladder Monitor.
- Increasing global pool of clinical evidence for Cxbladder facilitating test adoption and reimbursement.
- Addition to public healthcare provider guidelines in New Zealand.
- Continued adoption and use in the USA; initial commercial sales in Southeast Asia.
- Improvement in Net Operating Cash Outflow and Net Loss.
- Successful \$12m capital raise with several new investors welcomed to the register.

# TOTAL LABORATORY THROUGHPUT

- Total laboratory throughput grew to 15,697 tests in FY19, a 9% increase on FY18.
- Total billable tests grew to 12,744 tests in FY19, a 7% increase on FY18.
- CMS related tests accounted for approximately 50% of total laboratory throughput in FY19 and cumulatively totalled in excess of 17,000 tests as at 31 March 2019.
- Rest of World (ROW) total laboratory throughput increased 83% y/y, primarily driven by strong demand from NZ public healthcare providers.

**LABORATORY THROUGHPUT**  
(Commercial tests and User Programmes)

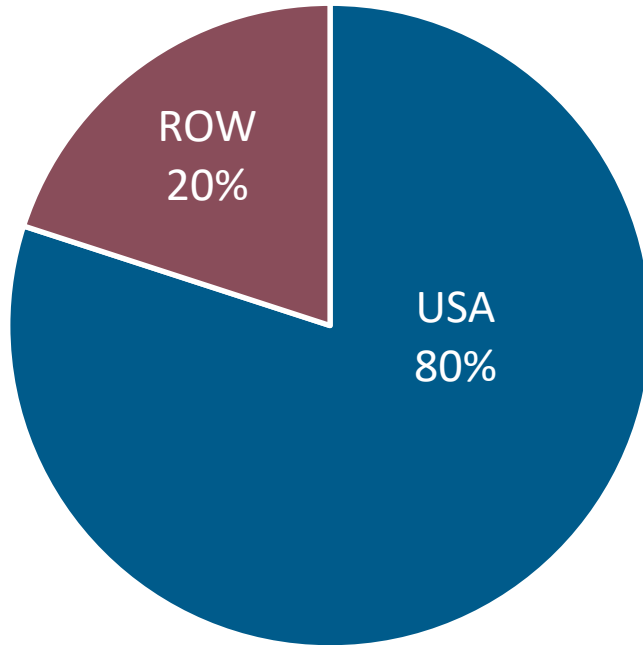
**81% of FY19 tests were billable**



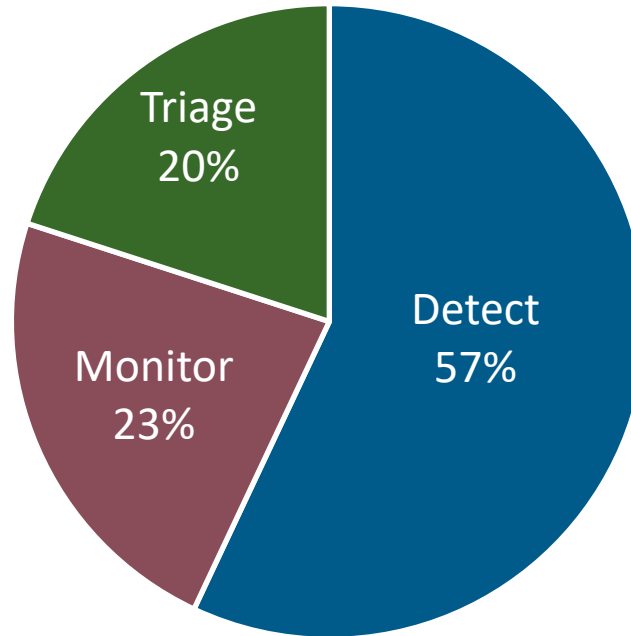
See slide 24 for further detail on FY17 to FY19 total laboratory throughput

# TOTAL LABORATORY THROUGHPUT BY REGION AND TEST TYPE

**Total Laboratory Throughput  
(by region)**



**Total Laboratory Throughput  
(by test type)**



Regional Throughput by Test	USA	NZ
Cxbladder Detect	66%	20%
Cxbladder Monitor	26%	12%
Cxbladder Triage	8%	68%

Test usage determined by length of time in market for each product.



# TOTAL LABORATORY THROUGHPUT

## ACCELERATED GROWTH RATES IN Q419; POSITIVE TRENDS HAVE CONTINUED INTO Q120

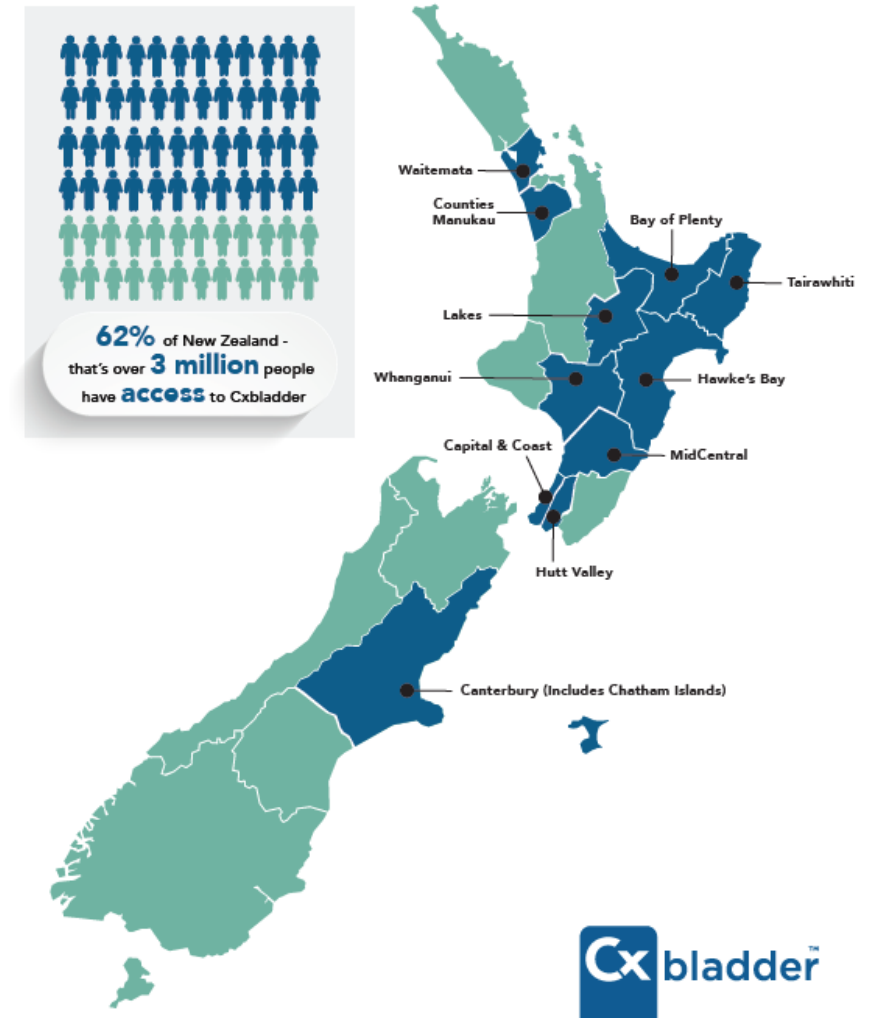
	Q419 compared to Q418	Q419 compared with Q319
Total laboratory throughput	+26%	+12%
ROW laboratory throughput	+126%	+32%
USA laboratory throughput	+10%	+7%

# GROWING COMMERCIAL ADOPTION IN HOME MARKET (NEW ZEALAND)

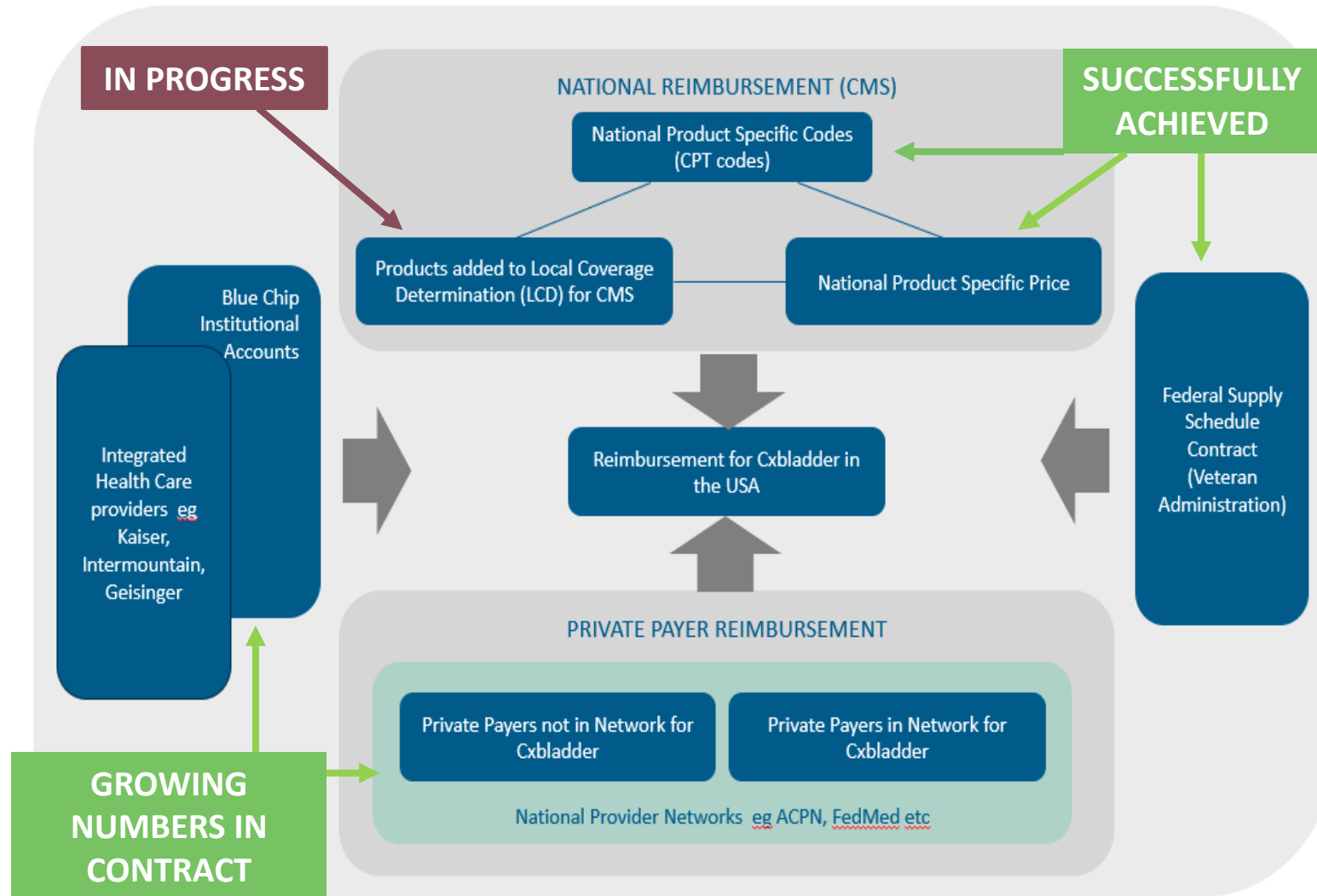
- New Zealand's public healthcare providers are leading the global adoption of Cxbladder.
- Majority have now adopted Cxbladder into their standard of care and, in some cases, their clinical guidelines, replacing the gold standard cystoscopy
- Demand from NZ public healthcare providers exceeded expectations with strong growth from new and existing customers, particularly in Q419.
- Counties Manukau, Tairāwhiti, Capital & Coast and Hawkes Bay District Health Boards all signed commercial agreements in FY19 bringing total contract coverage of New Zealand's population to more than 60%.
- Canterbury DHB's comprehensive 12 month commercial look-back over 12 months of use is currently in peer review for publication.
- Demand from New Zealand's public healthcare providers is expected to continue to grow in FY20.

## Contract Coverage of New Zealand's Population Using Cxbladder

April 2019



# CONTINUED REIMBURSEMENT SUCCESS IN THE USA



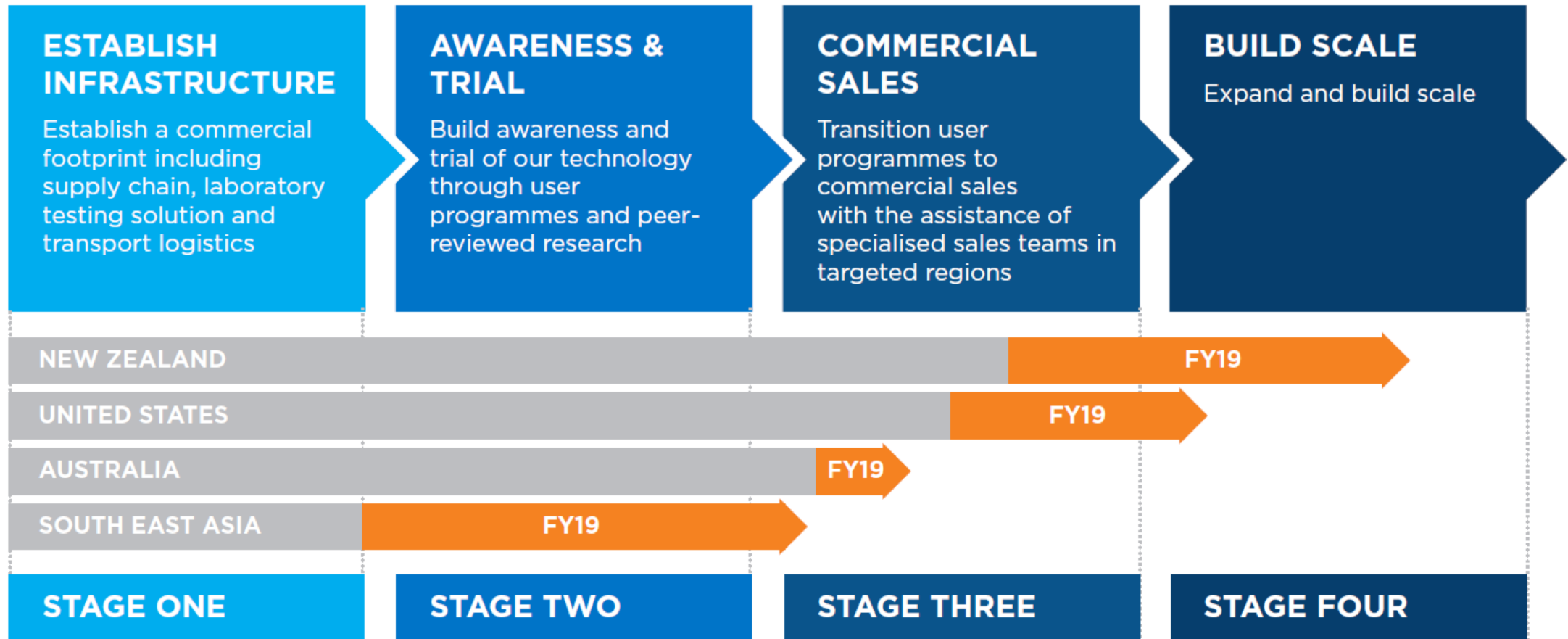
**Two of the three milestones required for national public reimbursement in the US were completed in FY19:**

- Receipt of product specific CPT codes for Cxbladder Detect and Cxbladder Monitor (effective from 1 January 2019)
- Notification of a national price for all Cxbladder tests of \$760 per test in October 2018.

Allows Pacific Edge to move into contract negotiations with private payers.

Progress being made with the third and final milestone, to have Cxbladder included in a Local Coverage Determination (LCD), which will allow for reimbursement by CMS.

# COMMERCIAL PROGRESS BY REGION IN FY19



# FOCUS ON INSTITUTIONAL HEALTHCARE ORGANISATIONS IN ALL MARKETS

- Building on success achieved with large public healthcare providers in New Zealand.
- Ongoing commercial negotiations and start up processes with multiple targeted institutional customers in the USA.
- Commencement of commercial evaluation with John Hopkins Medicine, a US\$8 billion integrated global health enterprise and one of the leading health care systems in the USA.

While these customers can take longer to bring to completion, once commercial agreement is reached they can provide significant volume, require lower sales maintenance and deliver more sustainable, longer term growth opportunities.

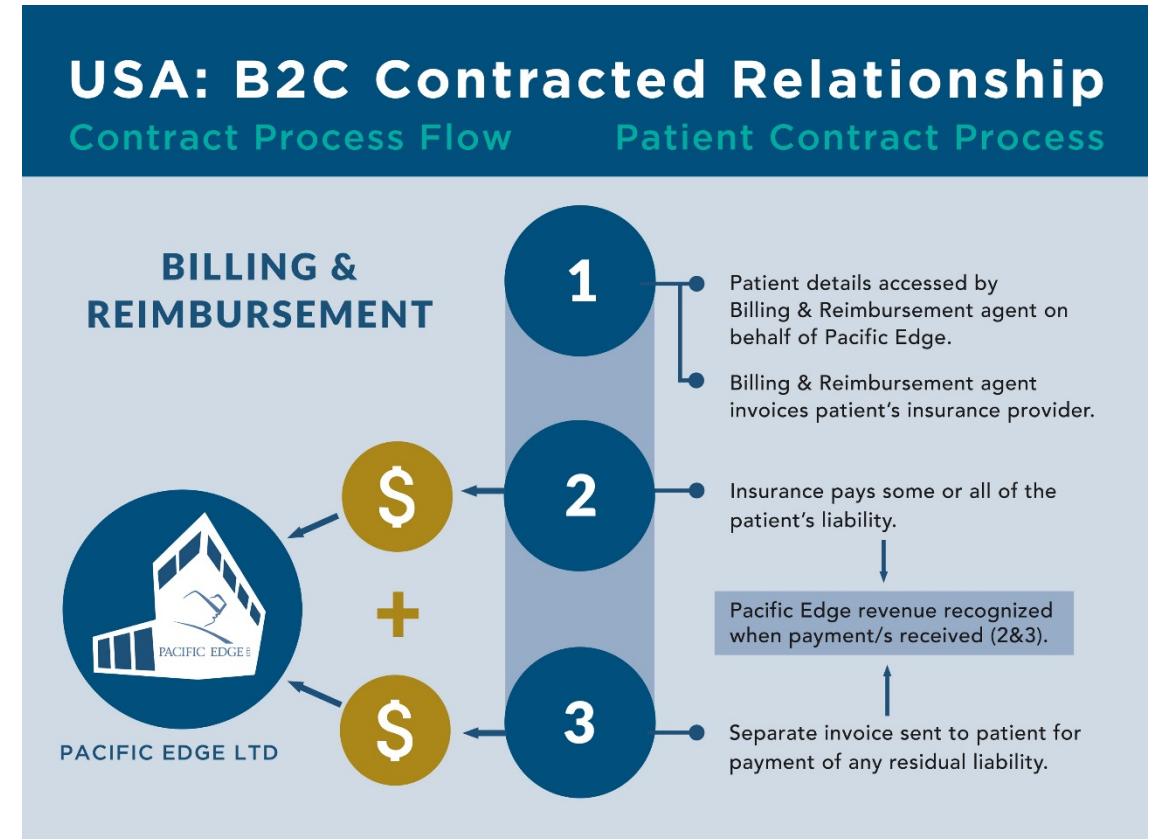


# FY19 FINANCIAL PERFORMANCE

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# USA B2C REIMBURSEMENT PROCESS

- The US reimbursement system is complex.
- Currently, approx. 60% of Pacific Edge customers are directly with the patient (B2C relationship).
- Payment can take anywhere from 1 to 24 months to be received as the majority involves payment by either private or public insurance, with the bulk of cash receipts coming within 7 to 12 month period.
- Commercial agreements with large institutions and private insurance companies will increase collectability of revenue.
- The Centers for Medicare and Medicaid Services are seen as reimbursement leaders. attaining a Local Coverage Determination and price will provide payment for tests provided to patients covered by the CMS and faster collection times.
- LCD and price setting for the CMS tests facilitate Pacific Edge’s commercial negotiations with other insurance payers.
- Pacific Edge sales teams increase focus on institutional healthcare organisations.



# FY19 FINANCIAL RESULT SNAPSHOT

(NZ\$'000)	FY19	FY18	% Change
Operating Revenue <sup>1</sup> (test sales)	3,817	3,400	12%
Other Revenue	1,312	1,602	(18%)
Total Revenue	5,129	5,002	3%
Operating Expenses	23,038	24,646	(7%)
Total Comprehensive Loss	17,921	19,727	(9%)
Net Operating Cash Outflow	17,507	18,100	(3%)
Cash on hand as at 31 March 2019 (cash, cash equivalents and short term deposits)	12,847	16,242	(21%)

- ✓ Operating revenue from test sales up 12% y/y to \$3.8m, with total revenue for the period of \$5.1m
- ✓ Total operating expenses reduced to \$23.0m for the year, a 7% decrease on FY18
- ✓ Net loss of \$17.9m for the year, an improvement of 9% on FY18
- ✓ Net operating cash outflow reduced to \$17.5m for the year, a 3% decrease on FY18
- ✓ \$12.9m in cash, cash equivalents and short term deposits as at 31 March 2019

1: Revenue excludes tests sold in the US for which cash payment has yet to be received, as well as tests completed for patients covered by the CMS. CMS tests account for approximately 47% of annual US laboratory throughput and Pacific Edge will seek reimbursement for these when it is included in the CMS's Local Coverage Determination (LCD). As at 31 March 2019, Pacific Edge has completed and invoiced a total of 17,015 tests for CMS patients in the USA, for which we are yet to be reimbursed.



# OPERATING CASHFLOW

NET OPERATING CASHFLOWS (NZ\$'000)	FY19	FY18	% Change
Receipts from:			
- Customers	3,734	3,420	9%
- Grant providers	755	944	(20%)
Interest Received	376	115	227%
Payments to Suppliers and Employees	22,431	22,575	(0.6%)
Net Cash Flows from Operating Activities	(17,507)	(18,100)	(3%)

- Cash receipts from customers increased 9% y/y to \$3.7m – with a large portion of the cash received in FY19 being for tests sold in FY18
- Net operating cash outflow reduced to (\$17.5m), a 3% decrease on FY18
- US payment terms currently average between 7 to 12 months from completion of test to payment by relevant US payer (insurer).
- The introduction of national product specific CPT codes for Cxbladder Detect and Cxbladder Monitor in the USA from 1 January 2019 had a positive impact on cash collection rates in Q419. This positive trend is expected to continue in 1H20
- Cash, cash equivalents and short term deposits of \$12.9m as at 31 March 2019

**The New Zealand business is expected to reach a cashflow positive position in FY20.**

# FY20 OUTLOOK

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# KEY OBJECTIVES FOR FY20

## SUCCESS WITH THESE OBJECTIVES WILL ADD SIGNIFICANT GROWTH TO OUR BUSINESS

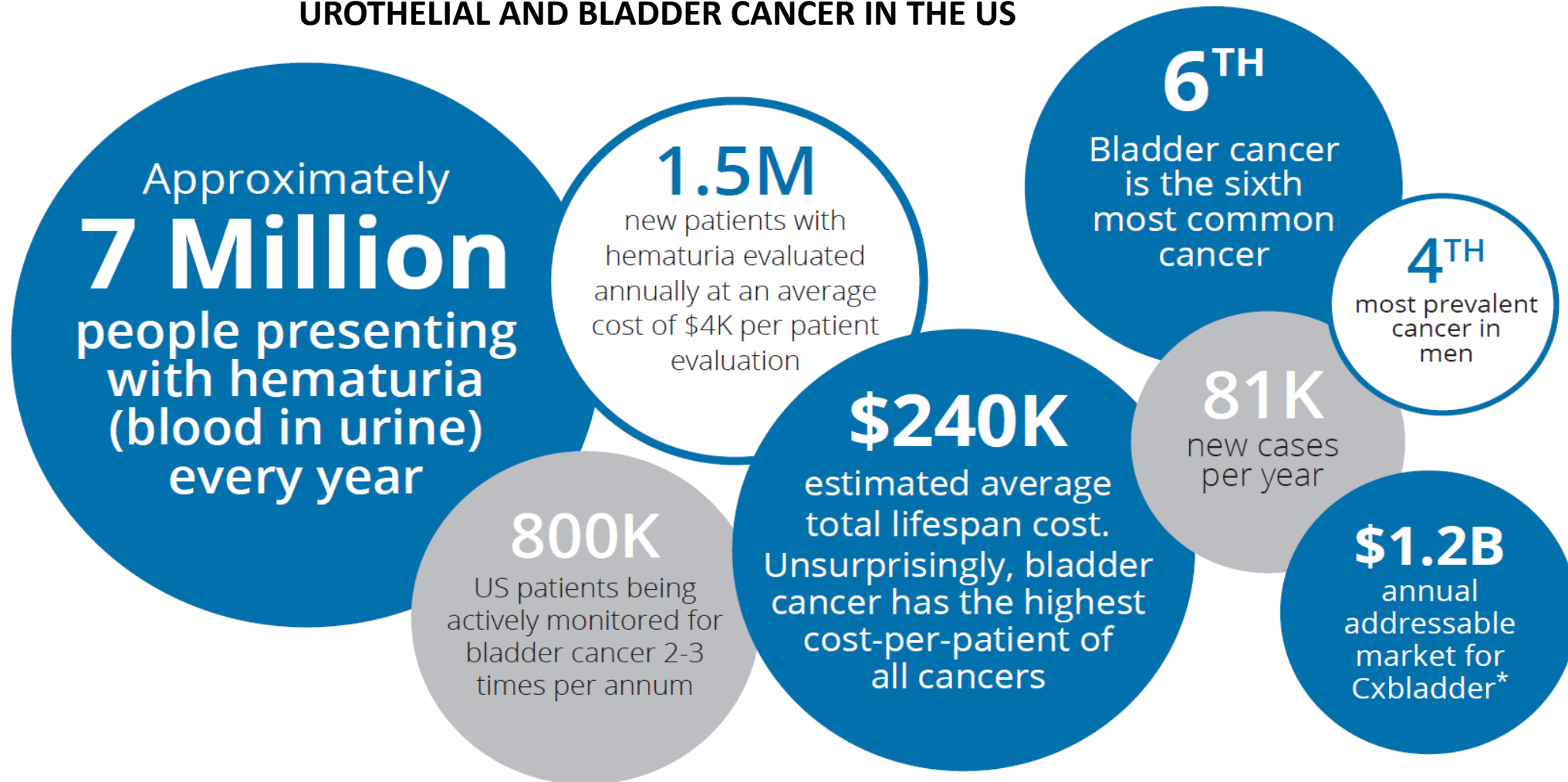
- **GLOBAL REACH:** Grow the number of large institutional healthcare customers globally and build on initial sales to these organisations.
- **USA:** Successfully achieve the third and final USA reimbursement milestone to gain inclusion in the LCD, upsell additional Cxbladder tests to contracted customers, and build on initial sales to the VA and other organisations.
- **NEW ZEALAND:** Further accelerate the roll out of Cxbladder in New Zealand to obtain widespread contract coverage with public health care providers (DHBs), upsell additional Cxbladder tests to each of the contracted DHBs, and bringing Pacific Edge's New Zealand business to a cashflow positive position.
- **AUSTRALIA:** Replicate the successful NZ sales and marketing model in Australia to drive sales.
- **SE ASIA:** transition User Programmes in Singapore into commercial customers, and progress discussions with potential strategic partners in South East Asia.
- **TEST ADOPTION:** Increase the commercial adoption of Cxbladder in the USA, Australia and South East Asia by leveraging the clinical validation and commercial success of Cxbladder in New Zealand.
- **CLINICAL EVIDENCE:** Continue to build out the evidence portfolio to drive further positive reimbursement decisions.

# OUR PRIMARY FOCUS REMAINS THE USA MARKET

A SCALE OPPORTUNITY IN BOTH THE EVALUATION OF HAEMATURIA AND MONITORING FOR RECURRENCE



## UROTHELIAL AND BLADDER CANCER IN THE US



\*EY-Parthenon business review of the US market opportunity

# GROWING CLINICAL EVIDENCE FOR CXBLADDER

- Publication of peer-reviewed papers is key to gaining coverage and positive reimbursement decisions.
- Library of comprehensive clinical evidence for physicians, healthcare payers (reimbursement) and healthcare providers alike.
- Application to have Cxbladder included in a LCD has been supported by the recent publication of further compelling clinical evidence expanding the clinical utility of Cxbladder.
- Cxbladder already in guidelines for some NZ public healthcare providers.



# PEER REVIEWED JOURNAL PUBLICATION DEMONSTRATES SIGNIFICANT CLINICAL UTILITY OF CXBLADDER




- Diagnostic outperformance published in global number one\* ranked urology journal, European Urology, in May 2019.
- Cxbladder providing enhanced diagnostic outcomes not currently available from existing technology.
- Enables physicians to remove the diagnostic dilemma faced, when existing gold standard tests and procedures are not able to determine a clear diagnostic outcome.
- Use of Cxbladder minimises the need for patients to have further unnecessary tests and procedures.
- Use of Cxbladder resulted in 35% of patients avoiding cystoscopies.

**This real world outcome positions Cxbladder for consideration for inclusion in other international guidelines**

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available at [www.sciencedirect.com](http://www.sciencedirect.com)  
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European Association of Urology

**Bladder Cancer**

**Evaluation of Cxbladder and Adjudication of Atypical Cytology and Equivocal Cystoscopy**

Badrinath Konety<sup>a,\*</sup>, Neal Shore<sup>b</sup>, Andrew Karim Kader<sup>c</sup>, Sima Porten<sup>d</sup>, Siamak Daneshmand<sup>e</sup>, Tony Lough<sup>f</sup>, Yair Lotan<sup>g</sup>

<sup>a</sup>Department of Urology, University of Minnesota, Minneapolis, MN, USA; <sup>b</sup>Carolina Urologic Research Center, Myrtle Beach, SC, USA; <sup>c</sup>Department of Urology, UC San Diego, La Jolla, CA, USA; <sup>d</sup>Department of Urology, UC San Francisco, San Francisco, CA, USA; <sup>e</sup>USC Institute of Urology, USC/Norris Comprehensive Cancer Center, University of Southern California, Los Angeles, CA, USA; <sup>f</sup>Pacific Edge Ltd, Dunedin, New Zealand; <sup>g</sup>University of Texas Southwestern Medical Center, Department of Urology, Dallas, TX, USA

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<b>Article info</b>	<b>Abstract</b>
<b>Article history:</b> Accepted April 24, 2019	<b>Background:</b> Cxbladder diagnostic tests combine genomic information from urinary mRNA with phenotypic information to either rule out low-risk individuals or identify patients at a high risk of urothelial carcinoma (UC).
<b>Associate Editor:</b> James Catto	<b>Objective:</b> To evaluate the performance of Cxbladder and urine cytology, and Cxbladder's adjudication of atypical cytology and equivocal cystoscopy.
<b>Statistical Editor:</b> Andrew Vickers	<b>Design, setting, and participants:</b> This is a retrospective analysis of pooled data from three prospective Cxbladder clinical trials and one real-world clinical study. Physicians were blinded to Cxbladder results, and Cxbladder providers were blinded to clinical results. This study analyzed diverse urology practices in the USA, Australia, and New Zealand. A total of 1784 consecutive, prospectively recruited patients with hematuria or previously diagnosed UC provided 852 samples with both local cytology and Cxbladder results; 153 had atypical cytologies and 14 had both atypical cytology and equivocal cystoscopy.
<b>Keywords:</b> Cytology Atypical cytology Equivocal cystoscopy Cxbladder Urothelial carcinoma Diagnosis	<b>Outcome measurements and statistical analysis:</b> Negative predictive value (NPV) and proportion of tumors missed for Cxbladder and local cytology, and evaluation of Cxbladder for adjudicating atypical cytology and equivocal cystoscopy.
	<b>Results and limitations:</b> Cxbladder ruled out 35% of patients and NPV 97% (95% confidence interval [CI] 94-98%) compared with 93% (95% CI 91-94%) for cytology. Cxbladder missed 8.5% and cytology missed 63% of tumors. UC was diagnosed in 26/153 cases of atypical cytology (17%). Cxbladder correctly adjudicated all these patients including those with both atypical cytology and equivocal cystoscopy; these patients had a positive Cxbladder result and were diagnosed with UC by pathology. The incidence of patients with both atypical cytology and equivocal cystoscopy is low.
	<b>Conclusions:</b> Cxbladder correctly adjudicated all patients diagnosed with UC among

\*European Urology - has an Impact Factor Rating of 17.58 and is currently read by more than 20,000 urologists across the globe.

# POSITIVE GROWTH OUTLOOK FOR FY20

- Continued growth in commercial sales expected from new and existing customers.
- Demand from public healthcare providers in New Zealand is expected to grow strongly and positively impact on laboratory throughput volumes.
- New Zealand business expected to be cashflow positive in FY20.
- Total operating expenses are expected to remain in line with FY19.
- USA demand is expected to be positively impacted from having national product specific CPT codes for Cxbladder and a national CMS reimbursement price in place.
- Compelling clinical evidence published in top tier international journals is expected to facilitate test adoption, coverage and reimbursement in FY20.





# LABORATORY TEST THROUGHPUT

## HALF YEAR COMPARATIVES

(Number of Tests)	1H17	2H17	FY17	1H18	2H18	FY18	1H19	2H19	FY19
<b>Total Laboratory Throughput</b>	5,622	5,624	11,246	7,119	7,329	14,448	7,397	8,300	15,697
<b>Billable Tests</b>	4,112	4,185	8,297	5,439	6,427	11,866	6,078	6,666	12,744
<b>% of total</b>	73%	75%	74%	76%	88%	82%	82%	80%	81%
<b>Non-billable Tests</b>	1,510	1,439	2,949	1,680	902	2,582	1,319	1,634	2,953
<b>% of total</b>	27%	25%	26%	24%	12%	18%	18%	20%	19%

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