

# FY20 Interim Result and Capital Raising Presentation

21 November 2019



**PACIFIC EDGE**  
CANCER DIAGNOSTICS COMPANY

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# About Pacific Edge and Cxbladder

# Pacific Edge Overview

## ✓ Global first mover advantage

Four class leading, proprietary, non-invasive, urine-based diagnostic tests (Cxbladder) for the detection and management of urothelial cancer (UC)<sup>1</sup> - the first new commercial tests for UC globally in 17 years<sup>2</sup>.

## ✓ Large global addressable market

Addressing a large, under-served global market opportunity; Annual Addressable Market (AAM) for Cxbladder in the U.S. of up to US\$1.2 billion.<sup>3</sup>

## ✓ Unique commercial proposition

First-to-market products targeting multiple clinician defined needs. Cxbladder provides enhanced diagnostic outcomes not currently available from existing technology, resulting in lower healthcare costs for payers and better health outcomes for patients.

## ✓ Proven model with compelling performance

Track record of successfully launching high-impact, high-value diagnostic products used by urologists and medical practitioners.

1. Urothelial cancer includes bladder cancer (which accounts for ~95% of all urothelial cancers).
2. The UroVysion FISH assay was the last diagnostic test to be made commercially available in 2002
3. EY-Parthenon review of the U.S market opportunity for Cxbladder completed in February 2018
4. CAP: College of American Pathologists
5. CLIA: Clinical Laboratory Improvement Amendments of 1988

## ✓ Large portfolio of published clinical evidence

Products are underpinned by extensive clinical validation and clinical utility evidence published in top-tier international journals; facilitating test adoption, reimbursement and NZ and U.S. guideline inclusion.

## ✓ Established lab and sales infrastructure

Commercial sales in New Zealand, Australia, Singapore and the U.S. underpinned by:

- Two proprietary CAP<sup>4</sup>-accredited, CLIA<sup>5</sup> certified laboratories (one in Dunedin, New Zealand and one in Pennsylvania, U.S.) with combined design capacity for 295,000 tests per annum;
- Dedicated sales force calling on urologists.

## ✓ Increasing commercial momentum

Test adoption and revenue are growing; continued reimbursement progress in the U.S. with both public and private payers; NZ and U.S. guideline inclusion; over 60% of New Zealand's population currently under coverage (up from 35% FY18).

## ✓ Future pipeline in other cancer biomarkers

Identified biomarkers and IP supporting new product development and long-term growth; IP portfolio across 4 different cancers.

# Pacific Edge<sup>1</sup> Investment Opportunity

Significant progress underpins reduction in risk profile and proximity to full reimbursement coverage

## ✓ Proximity to significant cash reimbursement event and consequential strong cash uplift

- Significant advances have been made in the last 12 months in clinical evidence for reimbursement approvals - including the CMS for consideration for inclusion in a Local Coverage Determination (LCD).
- Post a successful inclusion in a LCD, and in combination with the recent inclusion in guidelines, Pacific Edge expects a significant increase in test adoption, revenue growth and operating cash-flow.

## ✓ Competitive advantage continues to grow

- Cxbladder has recently been included in the NCCN guidelines in the U.S. and clinical guidelines in New Zealand providing a compelling opportunity for medical practitioners and urologists to use Cxbladder more extensively.
- Cxbladder's intellectual property and published evidence portfolio continues to grow globally supporting Pacific Edge's competitive advantage.

1. Pacific Edge is listed on the New Zealand Stock Exchange (PEB.NZX)

# Recent Achievements Highlight Accelerating Momentum and Adoption of Cxbladder

## ...progressing towards a transformational commercial inflexion point

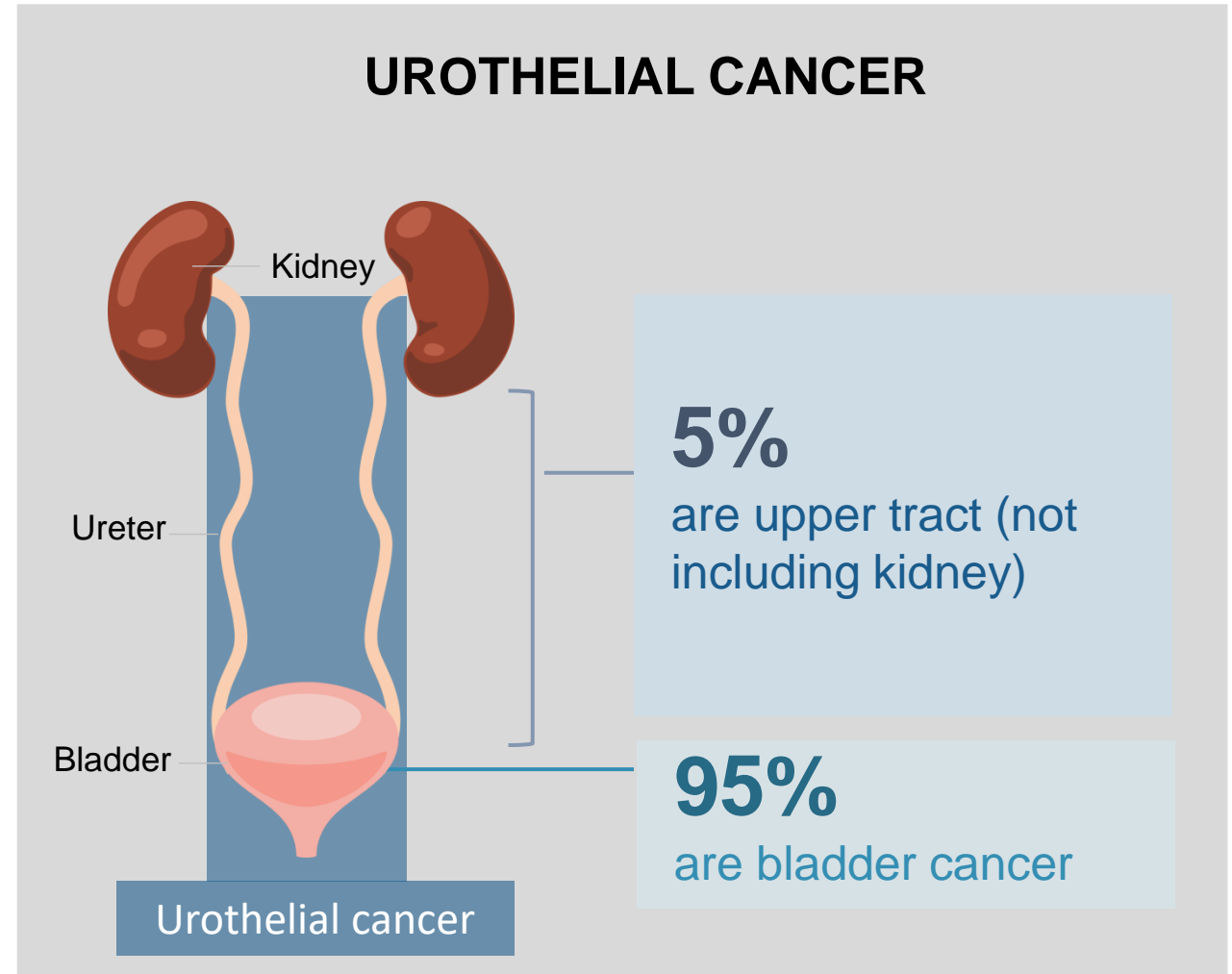
- **March 2018:** Notification of Product Specific CPT<sup>1</sup> codes from the American Medical Association for Cxbladder Detect and Cxbladder Monitor.
- **August 2018:** Public Healthcare Provider, Counties Manukau District Health Board (New Zealand) commercially adopts Cxbladder.
- **August 2018:** Public Healthcare Provider, Hauora Tairāwhiti District Health Board (New Zealand) commercially adopts Cxbladder.
- **October 2018:** Commencement of commercial evaluation of Cxbladder by Johns Hopkins Medicine (U.S.).
- **October 2018:** Notification of a National Price for all Cxbladder tests of US\$760 per test in the U.S. (effective 1 January 2019).
- **November 2018:** Public Healthcare Provider, Capital & Coast District Health Board (New Zealand) commercially adopts Cxbladder.
- **March 2019:** Public Healthcare Provider Hawkes Bay District Health Board (New Zealand) commercially adopts Cxbladder.
- **May 2019 and June 2019:** Publication of two more papers in peer-reviewed journals (including the world's number 1 ranked Urology Journal<sup>2</sup>) adding significant additional clinical utility evidence in support of Cxbladder.
- **July 2019:** Cxbladder referenced as a recommended clinical path for Urologists in the National Comprehensive Cancer Network (NCCN) Guidelines in the U.S.

1. Current Procedural Terminology (CPT) is a medical code set that is used to report medical, surgical, and diagnostic procedures and services to entities such as physicians, health insurance companies and accreditation organizations.

2. European Urology has an Impact Factor Rating of 17.58 and is read by more than 20,000 Urologists across the globe.

# Urothelial Cancer is a Significant Global Healthcare Challenge

- ~ 550,000 new cases in 2018<sup>1</sup>
- ~ 200,000 deaths annually<sup>1</sup>
- Globally 10<sup>th</sup> most common cancer but 6<sup>th</sup> most common in men<sup>1</sup>
- High recurrence rates (70% recurrence following treatment)
- Requires regular monitoring
- High detection and management costs with invasive tests and procedures
- Patient compliance low ~40% leading to an increase in disease progression



1. Bray et al. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 3 cancers in 185 countries. *Ca Cancer J Clin.* 2018;68:394-424.

# Urothelial Cancer is a Significant Healthcare Challenge in the U.S.

**~7 million patients** present with haematuria annually and **3.4 million** are worked up to look for bladder cancer<sup>1</sup>

**~4 million** cystoscopies were performed in 2018<sup>1</sup> (many of which are unnecessary and are replaceable with a non-invasive, accurate diagnostic test)

**More than 81,000** new bladder cancers are diagnosed every year in the U.S.<sup>2</sup>

**4<sup>th</sup> most common cancer in men in the U.S.**<sup>3</sup>

**1 in 42 people** will be diagnosed with bladder cancer in their lifetime<sup>4</sup>

**More than 800,000** people living with bladder cancer will **present annually up to 4 times a year** for up to 5 years for evaluation for the recurrence of urothelial cancer

**Average lifetime costs of US\$220,000 per patient** (recurrence rate of 70% with expensive surveillance)<sup>1</sup>

Direct costs associated with bladder cancer predicted to **reach US\$4.9 billion in 2020**<sup>1</sup>

Based on direct costs alone, bladder cancer has the highest per patient treatment costs of any cancer over the patient lifetime<sup>1</sup>

1. Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019

3. American Cancer Society, 2019

2. NIH National Cancer Institute, 2016

4. Bladder Cancer Advocacy Network, 2017



# Existing Tests and Procedures have Significant Shortcomings...

...they are expensive, invasive and have poor relative performance...providing significant opportunities for new diagnostic tests that are cheaper, non-invasive and more accurate...Cxbladder

	CYSTOSCOPY	CYTOLOGY	FISH
<b>USE</b>	Detection of bladder cancer	Identifying urothelial carcinoma	Conducted as a result of atypical cytology
<b>SOURCE MATERIAL</b>	Endoscopic procedure of the bladder	Whole cells that have sloughed off tumor and are caught in voided urine	Whole cells that have sloughed off tumor and are caught in voided urine
<b>RESULTS</b>	Performance does not meet the expectations of physicians; invasive and expensive	Subjective. High rate of atypical or suspicious findings	Quantitative (# of cells with aneuploidy.) Moderate rates of non-diagnostic results
<b>SENSITIVITY</b>	Sensitivity 71% and Specificity 65% <sup>2</sup>	Very low (32%-62%) <sup>1,2</sup>	Poor (39%) with high variability <sup>1</sup>

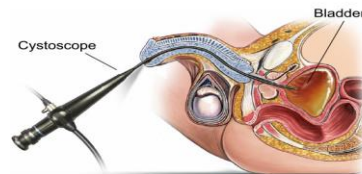
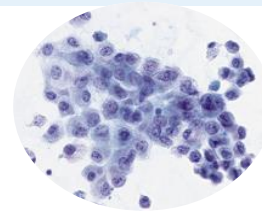
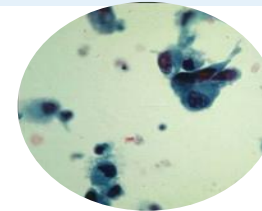


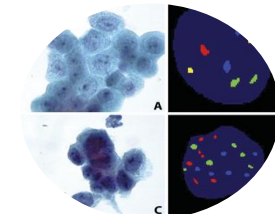
Figure 1  
A flexible cystoscopy



Normal



Cancer



1. BMC Urol. 2016.

2. Konety et al, European Urology, May 2019

# Cxbladder Revolutionises How Urologists Detect and Manage Urothelial Cancer

## World Class Diagnostic Tests Validated by International Urologists - Now in Guidelines

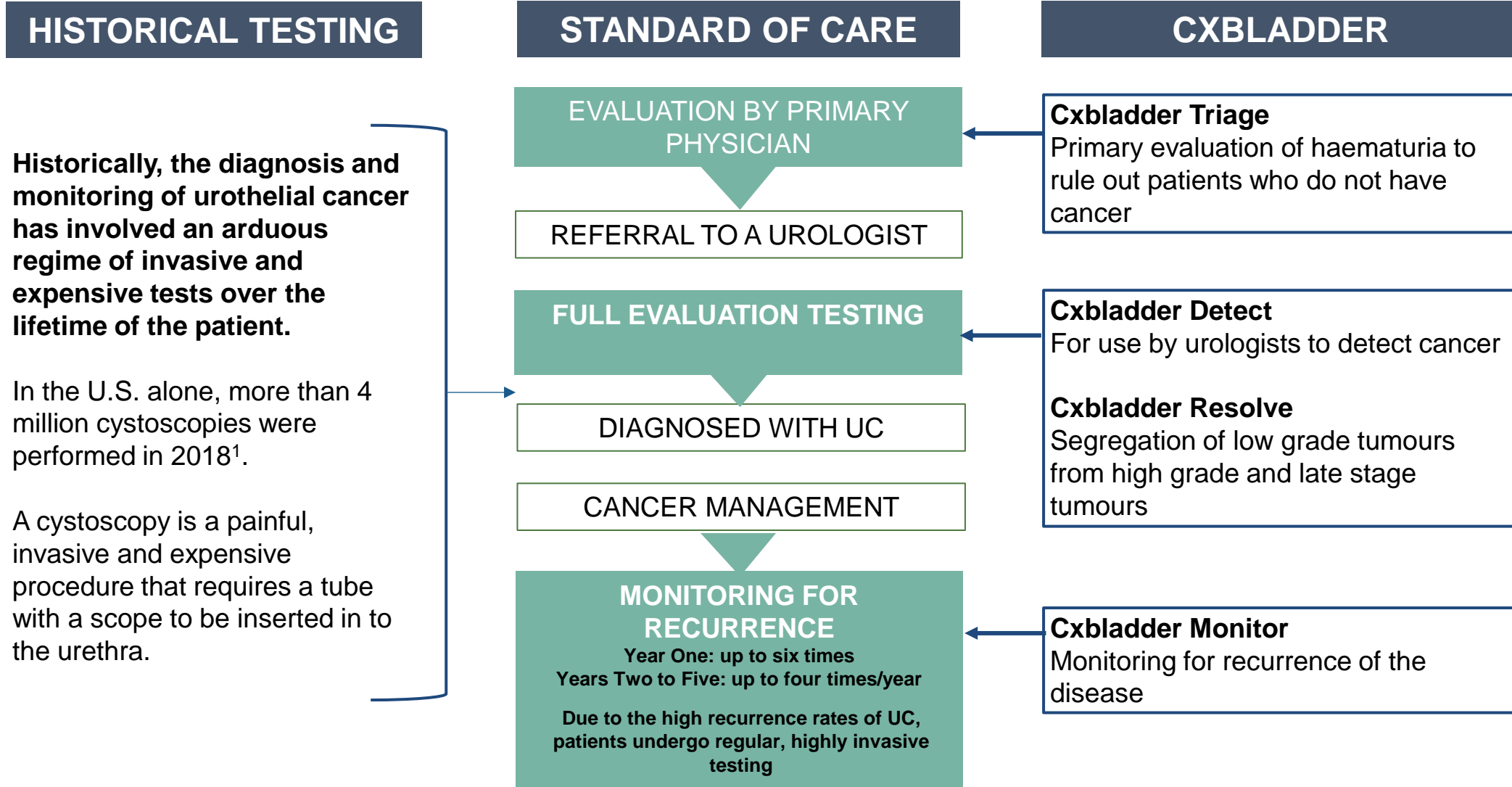


- Four class leading, accurate, non-invasive, urine based diagnostic tests for UC addressing multiple unmet needs across the clinical pathway.
  - **Cxbladder Triage (CxbT)**: Front line test for use in the primary evaluation of haematuria to rule out patients who do not have cancer
  - **Cxbladder Detect (CxbD)**: For use by urologists for patients who have been referred for a full urothelial cancer workup to detect cancers
  - **Cxbladder Resolve<sup>1</sup> (CxbR)**: Segregates low grade tumours from high grade and late stage tumours
  - **Cxbladder Monitor (CxbM)**: Provides front line identification for patients returning to the clinic who do not have UC
- Globally Cxbladder are the first new diagnostic tests for UC to be made commercially available in 17 years.
- Non-invasive, accurate, clinically validated, high clinical utility.
- Integrated into standards of care and guidelines for a number of providers in New Zealand and the U.S.

**Cxbladder provides better care for patients, better utility for urologists and savings for the payers**

1. Cxbladder Resolve has not yet launched in the USA

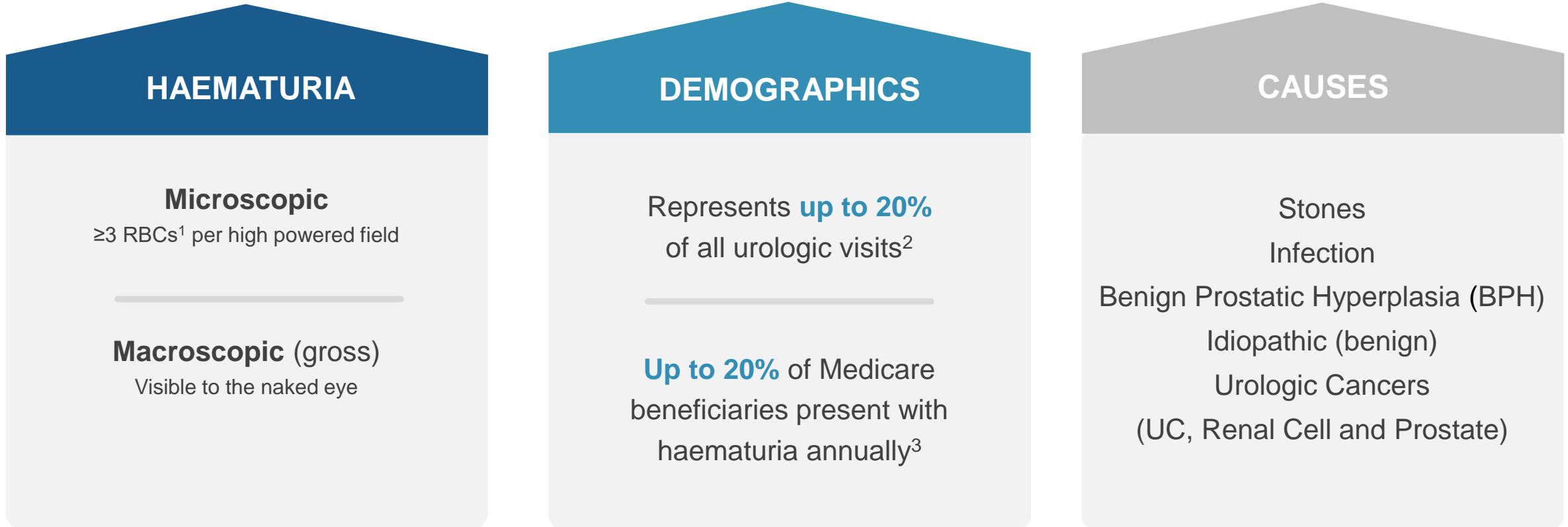
# Cxbladder is Used at Multiple Decision Points across the Clinical Pathway



1. Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC), July 2019

# The Evaluation of Haematuria: Large Global Market Opportunity for Cxbladder

Cxbladder accurately rules-out patients who do not have UC



**Approximately 80% of macrohaematuria patients and 98% of microhaematuria patients who have a workup for UC do not have cancer – the new guidelines in New Zealand now enable all of these patients to be tested by Cxbladder**

1. RBC: Red Blood Cells

2. American Urological Association, 2016.





3. Haematuria is the most common symptom of bladder cancer

# Cxbladder Provides Actionable Results for Multiple, Physician-Defined, Clinical Needs

## Clinical Gaps

- 1. Patients unable to undergo standard work-up:**
  - Renal insufficiency
  - Dye allergies
  - Pregnancy
- 2. Current AUA Haematuria Guidelines over prescribe<sup>1</sup>:**
  - High marginal costs > US\$1 million to find an additional cancer
  - Extensive radiation creates more cancers than it finds
- 3. Chronic unresolved haematuria:**
  - Need to confirm no presence of UC after initial work-up
  - Inconclusive results (i.e. atypical cytology and equivocal cystoscopy) create diagnostic dilemmas for Urologists
- 4. Performance of existing tests and procedures falls short of physicians expectations:**
  - Current guidelines require multiple expensive and invasive tests
  - Gold standard cystoscopy has relatively poor sensitivity (73%) and specificity (67%-81%)<sup>2</sup>

## Clinical Utility of Cxbladder

-  **Confirms**  
The absence of UC with high sensitivity AND high NPV<sup>3</sup> – “Power of the Negative”
-  **Replaces**  
The old regime of expensive and invasive tests
-  **Triages**  
Patients who have a low risk of disease removing them from having a full clinical work-up, lowering healthcare costs and patient fatigue
-  **Clarifies**  
Provides accurate adjudication of atypical or equivocal results from existing gold standard tests and procedures, thereby lowering the need for patients to have further invasive tests and procedures

1. Georgiera et al JAMA Internal Medicine 2019.

2. Mowatt et al 2011 Jochem et al 2007.

3. Negative Predictive Value (NPV); used in conjunction with high sensitivity, provides rule-out capability for the high proportion of patients who do not have disease

# Cxbladder has Multiple Layers of Intellectual Property

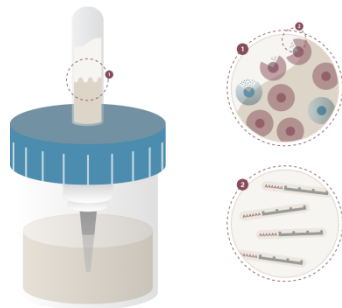
Sample Collection

RT-qPCR<sup>1</sup>

Biomarker Measurement

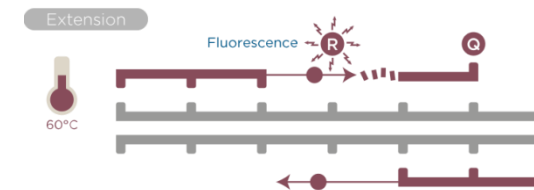
## 1 Unique proprietary buffer in the sample system

Midstream urine is collected in a Cxbladder urine collection cup. RNA in the cells is preserved in a proprietary buffer enabling global transport to Pacific Edge's CAP accredited, CLIA-approved laboratories in New Zealand and the U.S.



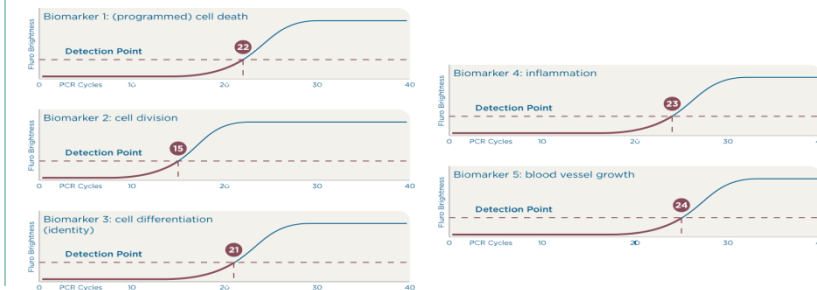
## 2 Specific proprietary genomic biomarkers for urothelial cancer

Genomic biomarkers, specific to urothelial cancer, identified by Pacific Edge's intellectual property are amplified from RNA and quantified in Pacific Edge's high-throughput laboratories



## 3 Proprietary trade secret algorithms in central repository

Cxbladder score is calculated from the quantity of each genomic biomarker in relation to each other and additional data from phenotypic biomarkers and clinical variables using a proprietary algorithm



1. RT-qPCR: Reverse Transcription Quantitative Polymerase Chain Reaction: Industry recognised standards, well validated molecular process used to estimate the concentrations of specific oligonucleotides

# Patient Compliance with Current Surveillance Guidelines is Poor

**Onerous, invasive and expensive tests and procedures drive a low level of patient compliance with urologists recommendations – resulting in poorer patient outcomes**

A 2011 study of patients with bladder cancer between 1992 and 2002 found only **1/4545 received all the recommended measures**; much of the variation is unexplained but the authors noted that “Due to the invasive nature of the surveillance and treatment strategies, non-adherence with clinical-practice guidelines may be attributed to patient factors such as advanced age or the pre-existing comorbid conditions”<sup>1</sup>



Of 2017 patients included, **651 (32%) received cystoscopy less frequently than every 4 months**. One third of veterans with high-risk non-muscle invasive bladder cancer (NMIBC) do not receive the recommended high intensity surveillance<sup>2</sup>



“Only **40% of patients adhere to the recommended schedule** of bladder cancer surveillance”<sup>3</sup>

1. Chamie K, Saigal CS, Lai J et al. Cancer. 2011;117(23):5392-5401.

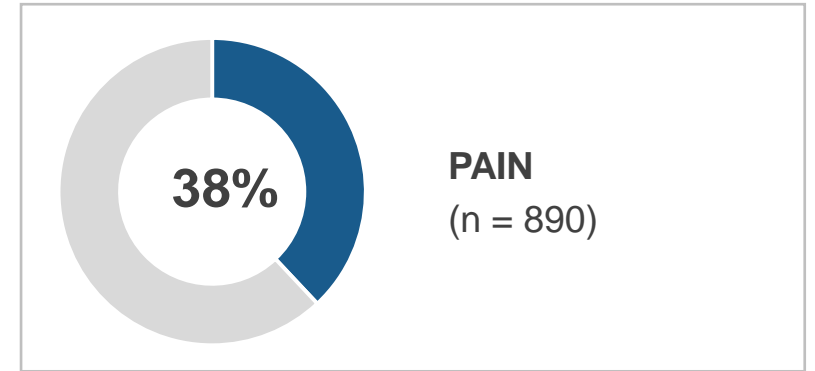
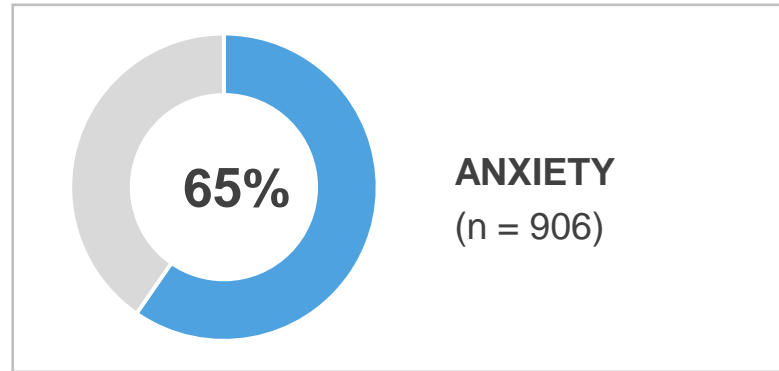
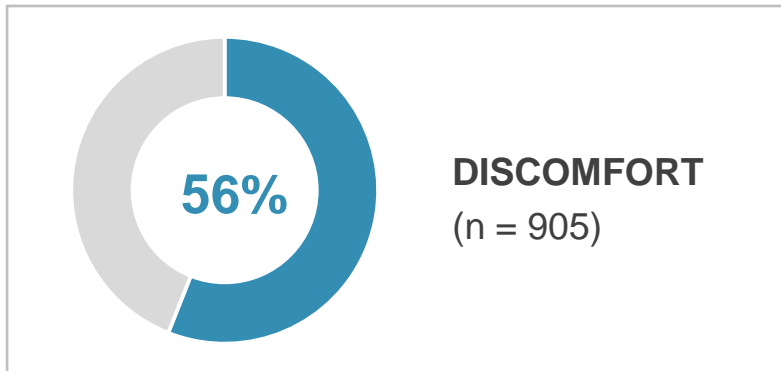
2. Han et al. Patient, Provider, and Facility Factors Associated with Underuse of Guideline Recommended Surveillance for High-Risk Non-Muscle Invasive Bladder Cancer – A National Study. Veteran Affairs Urological Forum. AUA Poster Presentation May 2018.

3. Schrag D, Hsieh LJ, Rabbani F et al. J Natl Cancer Inst. 2003;95(8):588-597.

# Patients Dislike Invasive Tests

## Patient Feedback Regarding Cystoscopy: A BCAN<sup>1</sup> Survey in > 900 U.S. Patients with UC

### PATIENTS REPORTED MODERATE TO SEVERE:




### PATIENT COMMENTS:

- “I recommend being put to sleep. Dealing with these while awake was horrible.”
- “Asked doc for valium to relax, as anxiety is rampant and pain is terrible.”
- “Avoid office cystoscopy and insist on procedure being done in the operating room under general anesthesia.”
- “Cystoscopy has to be done under general anesthesia because it is so painful. Urination is extremely painful for two to three days afterwards.”
- “How clean is the tool? I get a lot of infections post cystoscopy and TURBT.”
- “Usually ends with an infection.”
- “Barbaric. Needs to be a better and more comfortable process.”
- “There has to be a better, non-invasive procedure. My urothelial passage has been destroyed, now have a suprapubic catheter.”

1. Bladder Cancer Advocacy Network patient survey, 2018, Urology Times.





# Clinical Evidence

# Major Peer-Reviewed Publications Highlight the Clinical Validation of Cxbladder

Cxbladder has class leading performance metrics: Sensitivity, Specificity and Negative Predictive Value

Publication	N		Cxbladder Results			
	Patients	Samples	Sensitivity	Specificity	NPV	Outperformed All Comparator Covered Tests
O'Sullivan P, Sharples K, Dalphin M et al. <i>Journal of Urology</i> , 2012.	485		81.8%	85.1%		✓
Breen V, Kasabov N, Kamat AM et al. <i>BMC Medical Research Methodology</i> , 2015.	939		81.8%	85.1%		✓ (including FISH)
Kavalieris L, O'Sullivan PJ, Suttie JM et al. <i>BMC Urology</i> , 2015.	587		<b>95.1%</b>		<b>98.5%</b>	
Kavalieris L, O'Sullivan P, Frampton C et al. <i>Journal of Urology</i> , 2017.	763	1036	<b>93%</b>		<b>97%</b>	
Lotan Y, O'Sullivan P, Raman JD et al. <i>Urologic Oncology</i> , 2017.	803	1016	<b>91%</b>		<b>96%</b>	✓ (including FISH)

# Major Peer-Reviewed Publications Highlight the Clinical Utility of Cxbladder

## Cxbladder significantly reduces the need for expensive, invasive tests

Publication	Setting	N		Impact of Cxbladder Results	
		Patients	Samples	On Diagnostic Tests	On Invasive Tests
Darling D, Luxmanan C, O'Sullivan P et al. Advances in Therapy, 2017.	Haematuria Evaluation	33	396	Decrease (5%; 25%)	Decrease (11%; 31%)
Lough T, Luo Q, Luxmanan C et al. BMC Urology, 2018.	Haematuria Evaluation	33	396	Decrease (41% per patient)	Decrease (51% per patient)
Lough T, Luo Q, O'Sullivan P et al. Oncology and Therapy, 2018.	UC Surveillance	30	828	Decrease (38.7%)	Decrease (37.2%)
Davidson P, McGeogh G, Shand B NZ Medical Journal, 2019	Haematuria Evaluation	570	570	Decrease (32.7%)	Decrease (32.7%)
Konety et al, European Urology 2019	Atypical cytology and equivocal cystoscopy	852	852	Correctly adjudicated 100% of Atypical cytology	Correctly adjudicated 100% of equivocal cystoscopy

# Diagnostic Out-Performance Published in the World's #1 Urology Journal

## Demonstrates the significant clinical utility of Cxbladder

- Diagnostic outperformance published in global number one<sup>1</sup> 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.
  - **“Significant utility is gained from the inclusion of Cxbladder in the evaluation of patients for UC in both haematuria and monitoring settings, with 35% of patients avoiding cystoscopies”**
  - **“Cxbladder correctly adjudicated 100% of atypical cytologies and equivocal cystoscopies”**



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

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

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**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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**Abstract**

**Background:** 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).

**Objective:** To evaluate the performance of Cxbladder and urine cytology, and Cxbladder's adjudication of atypical cytology and equivocal cystoscopy.

**Design, setting, and participants:** 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.

**Outcome measurements and statistical analysis:** 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.

**Results and limitations:** 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.

**Conclusions:** Cxbladder correctly adjudicated all patients diagnosed with UC among



# Commercial Progress

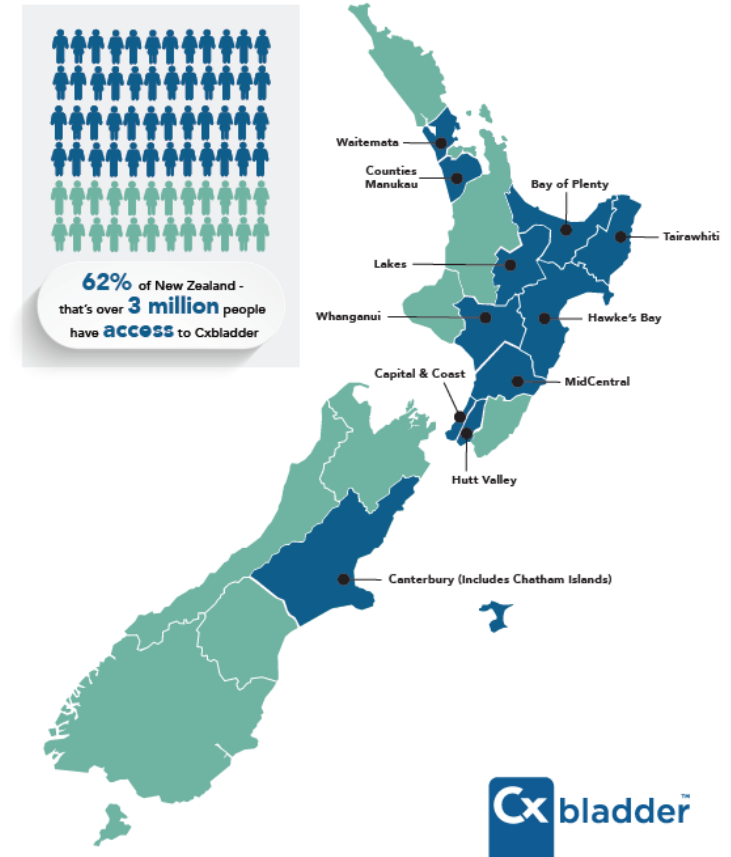
# Growing Commercial Adoption in New Zealand Leads the World

- 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 cystoscopy.
- Demand exceeding expectations with strong growth from new and existing customers.
- Demand expected to continue to grow in FY20.

**Total contract coverage of more than 60% of New Zealand's population through public healthcare providers**

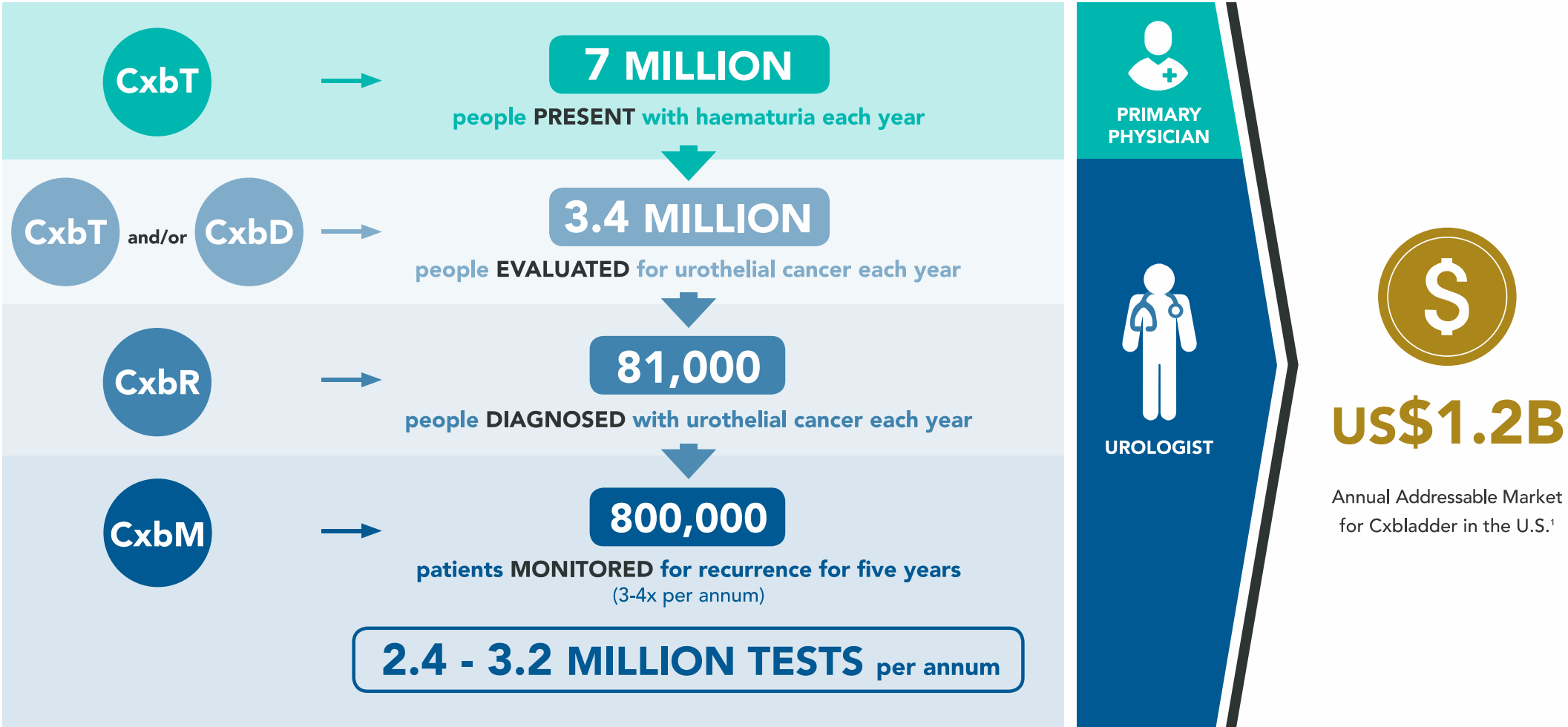
## Contract Coverage of New Zealand's Population Using Cxbladder

April 2019



# Our Primary Focus: The U.S. Market

A scale opportunity in both the evaluation of haematuria and monitoring for UC recurrence






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




# One More Milestone Needed to Obtain National Public Reimbursement in the U.S.

**CMS** - The Centers for Medicare & Medicaid Services (CMS) is the U.S. federal agency that administers the Medicare program and works in partnership with state governments to administer Medicaid and other health programmes. Medicare is the federal health insurance program for (1) people who are 65 or older, (2) certain younger people with disabilities and (3) people with End-Stage Renal Disease. This is the scheme that covers most of the CMS patients for whom Pacific Edge provides tests. **These patients account for approximately 47% of Pacific Edge's total U.S. laboratory throughput. As at 30 September 2019, PEB had completed and invoiced a total of 19,361 tests for CMS patients in the U.S., for which they are yet to be reimbursed. PEB will seek reimbursement for these tests when they receive a Local Coverage Determination (LCD) for Cxbladder.**

## 2 of the 3 milestones required for national public reimbursement in the U.S were successfully achieved in FY19

-  **1** Receipt of Product Specific CPT codes for Cxbladder Detect and Cxbladder Monitor (March 2018) – which improves cash conversion.
-  **2** Notification of a National Price for all Cxbladder tests of US\$760 per test for the CMS (announced October 2018, effective 1 January 2019) – which facilitates private payer negotiations.
-  **3** Progress is being made with the third and final milestone, to have Cxbladder included in a Local Coverage Determination (LCD) - which would allow for reimbursement from the CMS for approximately 47% of Pacific Edge's total U.S. laboratory throughput.

## Clinical evidence milestones required for Cxbladder's inclusion in a LCD

-  **1** Analytical Validity
-  **2** Clinical Validity
-  **3** Clinical Utility – Pacific Edge will continue its submission of clinical evidence in support of Cxbladder's inclusion in a LCD. An updated dossier of evidence focused on clinical utility was submitted for review in August 2019.

**Local Coverage Determination (LCD)** - A Local Coverage Determination is a decision by a Medicare Administrative Contractor (MAC) which determines whether a particular service offered by a healthcare provider in their geographic jurisdiction is 'reasonable and necessary' and therefore covered for reimbursement by the CMS. These coverage decisions are issued in a document called a Local Coverage Determination (LCD). An LCD provides specific conditions of the coverage, including price, and guidance on reimbursement including coverage guidance and coding information. This information is useful to the many other private payers (insurance companies) for their contracting of the same product or service. PEB, which has a centralised laboratory service business with a Laboratory Developed Test, need a LCD from their local MAC to gain U.S.-wide reimbursement coverage.



# Estimated Timeframes for Completion of LCD Review

## New CMS review process estimated to take ~6 months from evidence submission

- Inclusion in a LCD for reimbursement for CMS patients requires iterative review and sign-off of the clinical evidence for Cxbladder by our MAC (Novitas)
- Legislation changed in early 2019 targeted to provide applicants with greater transparency to the LCD process
- In the expert opinion of PEB's LCD consultant, the process between valid submission of Cxbladder's new evidence and the conclusion of the formal review process is expected to take ~6 months

## PEB reasonably expects to know the outcome of the LCD review process in Q1 2020

- The LCD process requires submission of new Cxbladder clinical utility evidence
- Cxbladder's evidence dossier has recently been updated with new evidence<sup>1</sup> from two additional publications, and Cxbladder's recent inclusion in the NCCN guidelines. This additional new evidence is expected to meet Novitas's requirements for clinical utility<sup>2</sup>
- An updated dossier of evidence was submitted to PEB's MAC for formal review in August 2019
- Expert opinion estimates the completion of the LCD review and outcome could reasonably be expected in the Q1 of FY21<sup>2</sup>

<sup>1</sup> Evidence must be peer reviewed published scientific and clinical evidence

<sup>2</sup> Expert opinion from PEB's LCD consultant

# Successful Inclusion in a LCD is Expected to Result in Significant Commercial Growth

## ✓ Test adoption and revenue growth:

U.S. adoption and demand for Cxbladder is expected to be positively impacted on inclusion in a LCD – which is expected to result in accelerated revenue growth (as evidenced by the growth profiles of other listed peer group diagnostic companies in the U.S.).

An LCD provides insurance coverage for all U.S. patients who are covered by the CMS in the urologist's clinical pathway for the detection and management of urothelial cancer. An LCD will also support Pacific Edge's commercial negotiations with private insurance payers in the U.S.

Recent inclusion in the NCCN guidelines combined with a successful LCD inclusion would be transformational to test adoption and revenue growth.

## ✓ Balance Sheet:

Following inclusion, Pacific Edge will enter into negotiations with the CMS for reimbursement of the large number of Cxbladder tests that have been invoiced to the CMS:

- As at 30 September 2019, PEB had completed and invoiced a total of 19,361 tests for CMS patients in the U.S., which are yet to be reimbursed.
- This negotiation with the CMS is expected to result in a one-off backlog payment to Pacific Edge.

## ✓ Cashflow:

On inclusion in a LCD, Pacific Edge will receive regular payment for all future covered tests conducted on CMS patients. At forecast test volumes, this is expected to improve operating cashflow by approximately NZ\$800k per month.

Payments for tests conducted on CMS patients (who currently account for approximately 47% of total U.S. laboratory throughput) are expected to be paid within 45 days of receipt (versus a current cash conversion period of 7 to 12 months), resulting in a significant positive impact on the operating cashflow of the company.

Timing for cash receipts will improve significantly with the award of a LCD as PEB will also be in a better position to enter into more contracts with other individual payers (such as insurance companies). Once in contract with private payers, their normal payment terms apply.

# Institutional Users and Payers in the U.S. Validate Cxbladder

## Healthcare Institutions Commercially Using Cxbladder

- Johns Hopkins Medicine
- Carolina Urologic Research Center
- Cleveland Clinic
- Fox Chase Cancer Center
- Penn State Milton S. Hershey Medical Center
- UCLA
- University of Minnesota
- Mount Sinai Hospital (NY)
- University of Pennsylvania
- University of Southern California
- University of Rochester
- University of Oklahoma
- City of Hope
- Thomas Jefferson University
- University of California-San Diego
- University of California-San Francisco

## Major Insurance Companies Paying for Cxbladder

- Aetna
- Blue Cross Blue Shield
- Cigna
- Humana
- Medicare Advantage
- United Healthcare
- Veterans Health Association
- MediNcrease Health Plans

- An additional 15 Healthcare Institutions in the U.S. are currently evaluating Cxbladder for commercial use
- Academic centres are healthcare centres of excellence that have high volume healthcare businesses

# 1H20 Financial Result Summary

(NZ\$'000)	1H20 <sup>1</sup>	1H19 <sup>1</sup>	% Change
Operating Revenue <sup>2</sup> (test sales)	2,285	2,033	12%
Total Revenue	2,701	2,639	2%
Operating Expenses	12,090	11,358	6%
Total Comprehensive Loss	9,406	8,718	8%
Cash Receipts from Customers	2,350	2,026	16%
Net Operating Cash Outflow	7,405	8,612	(14%)
Cash on hand as at 30 September	4,737	10,060	(53%)

1. Half year ended 30 September

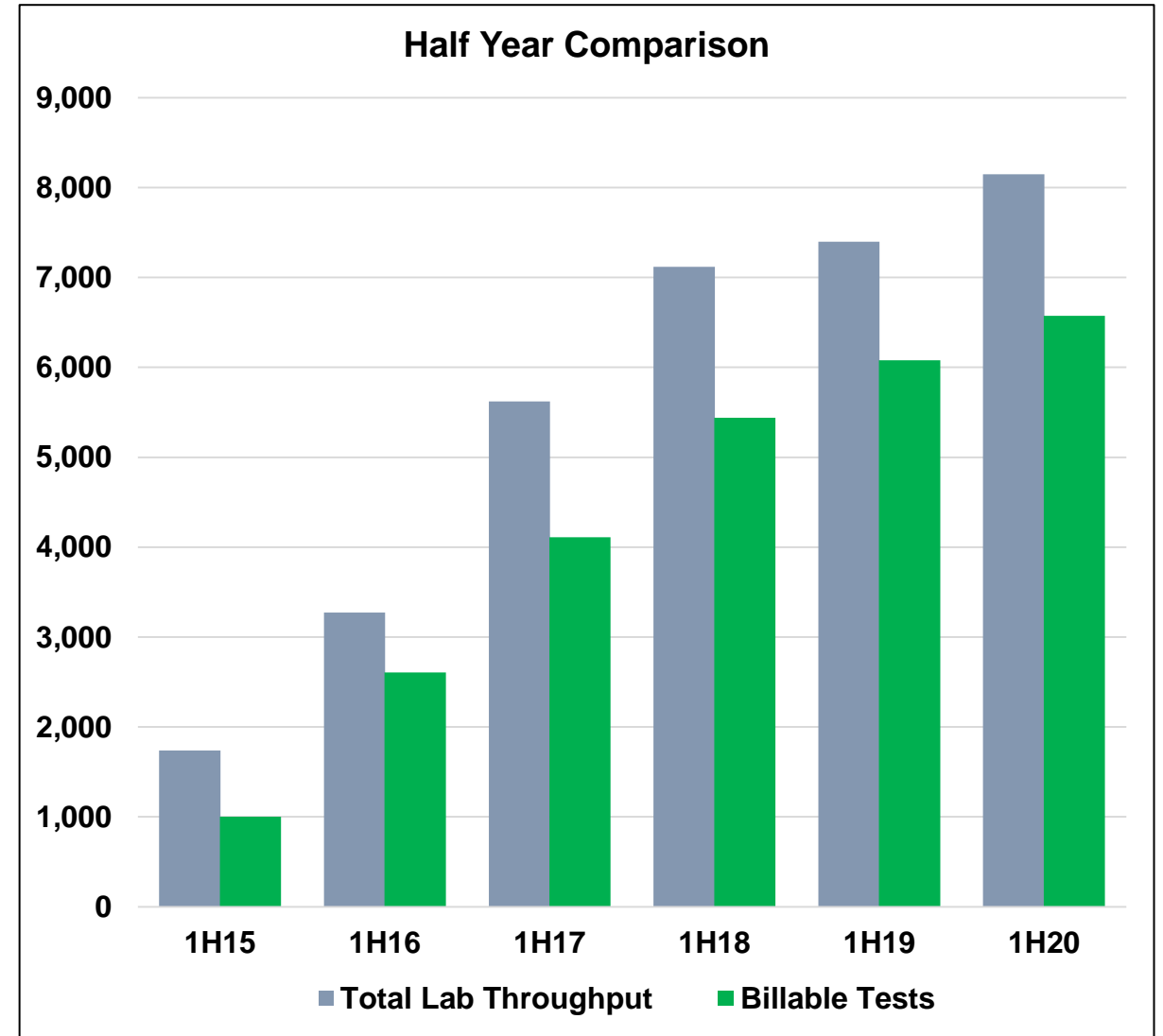
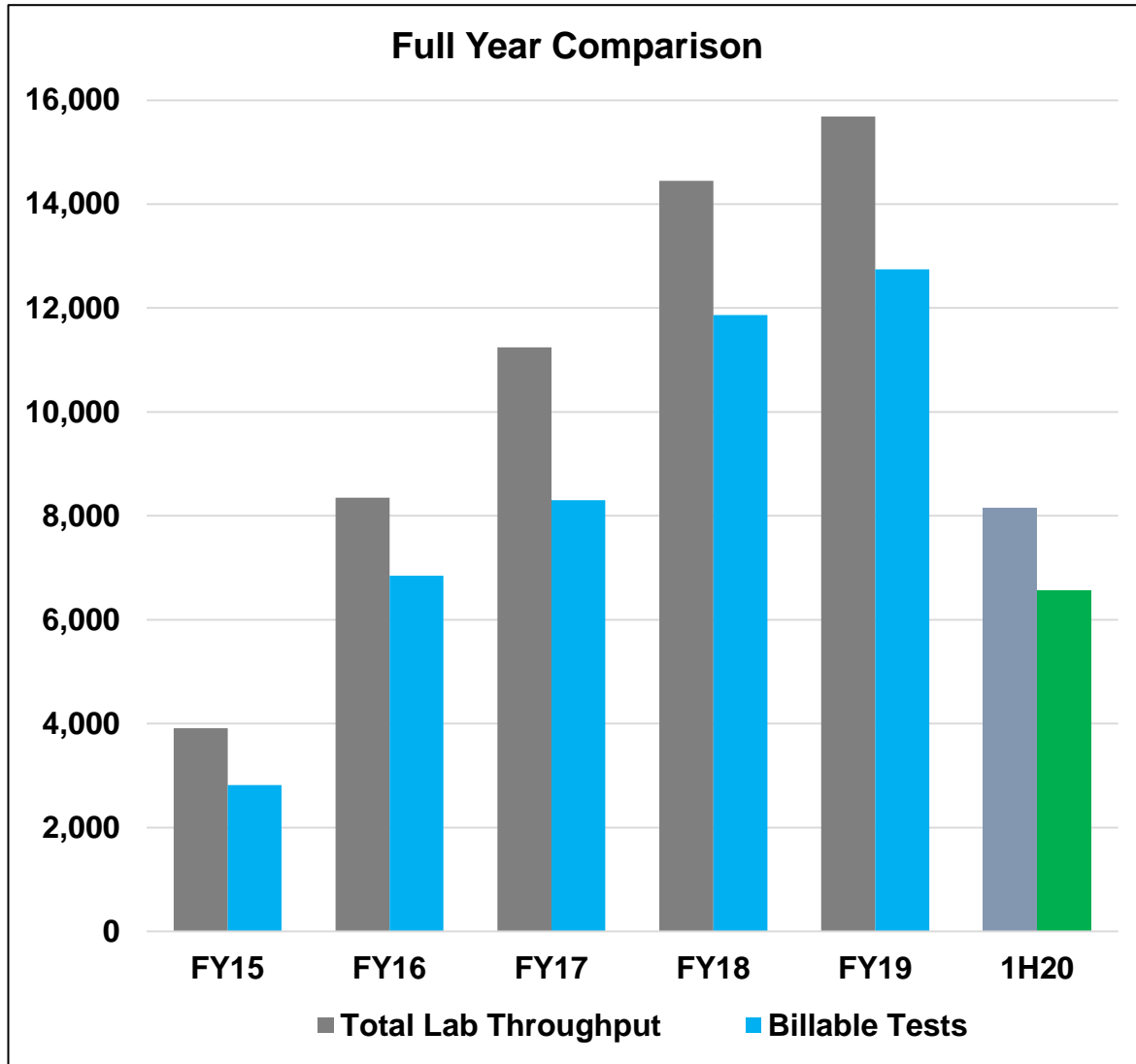
2. Operating revenue excludes tests sold in the U.S. for which cash payment has yet to be received, as well as tests covered by the CMS. CMS tests account for approximately 47% of total U.S. laboratory throughput and PEB will seek reimbursement for these invoiced tests on a successful inclusion in the CMS's LCD. As at 30 September 2019, Pacific Edge has completed and invoiced a total of 19,361 tests for CMS patients in the U.S, which are yet to be reimbursed.

# 1H20 Financial Result Highlights and Commercial Milestones

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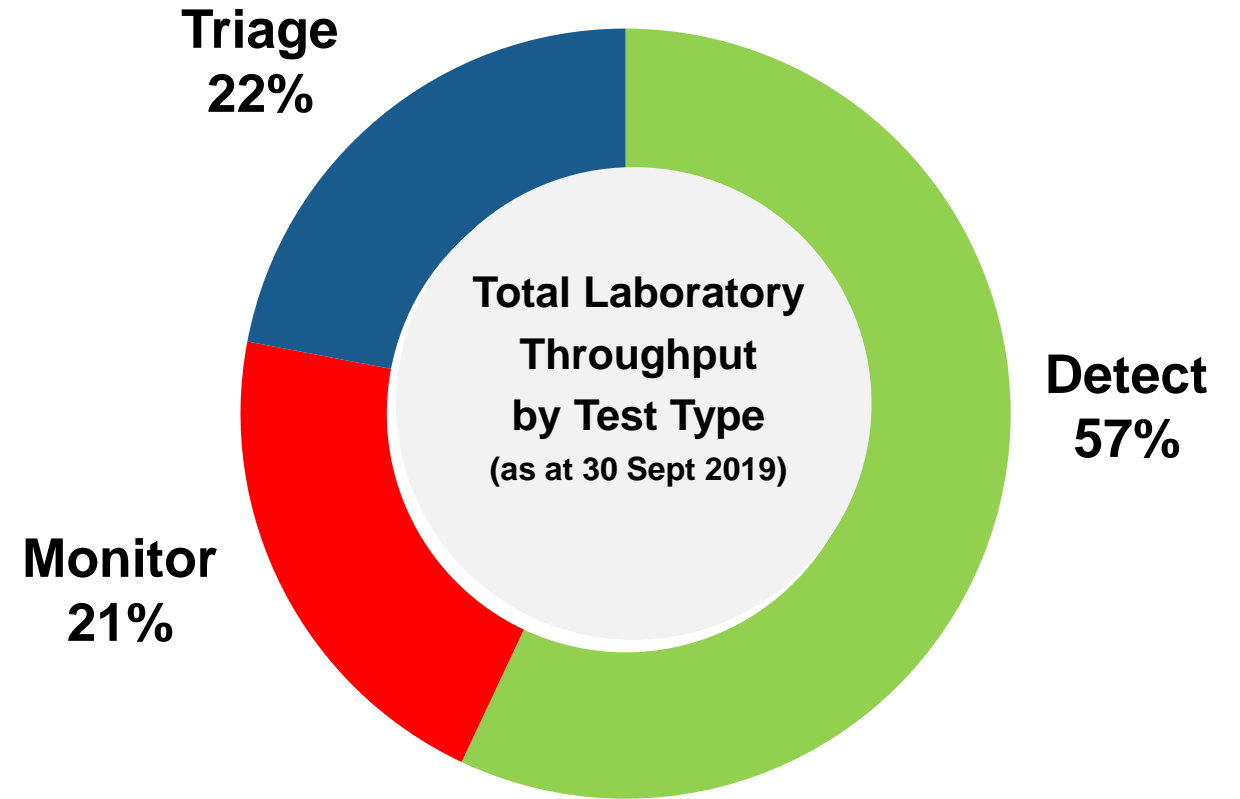
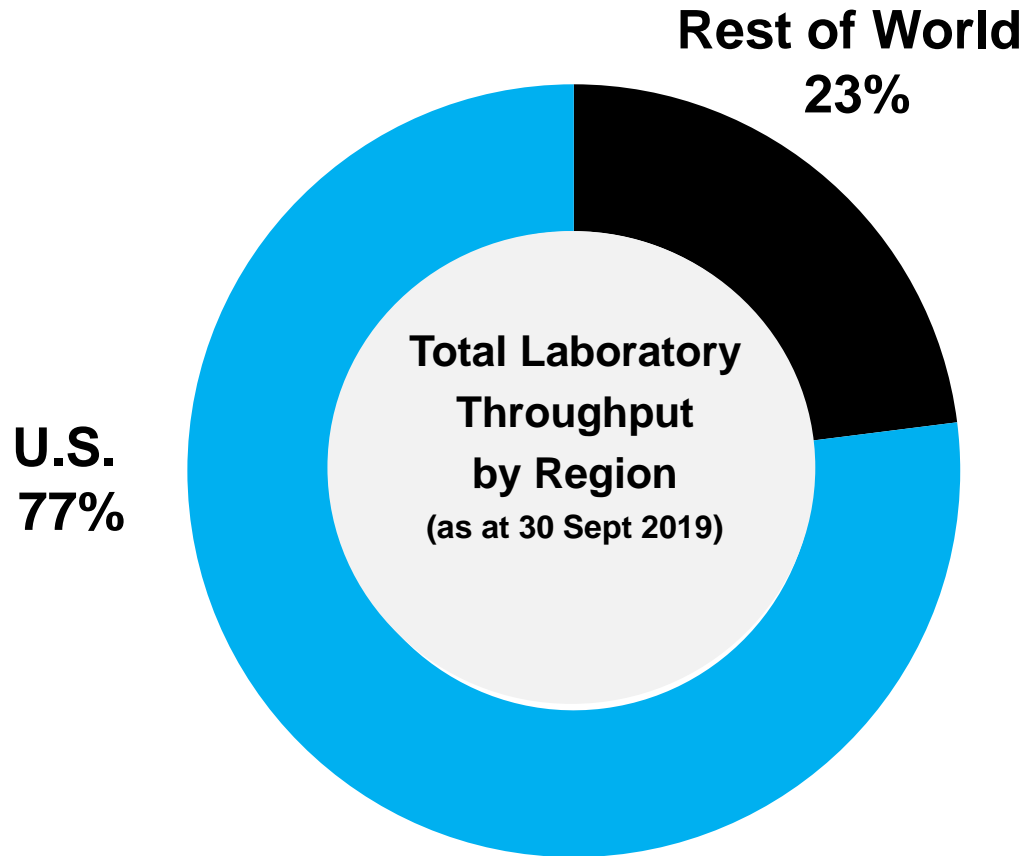
- Cash receipts from customers increased 16% on pcp and 37% on 2H19.
- Operating revenue from Cxbladder test sales increased 12% on pcp.
- Total laboratory throughput increased 10% on pcp to 8,147 tests.
- Total laboratory throughput for New Zealand, Australia and Singapore increased 50% on pcp to 1,896 tests
- Total billable tests increased 8% on pcp to 6,573 tests.
- Net operating cash outflow reduced 14% on pcp.
- Cxbladder included in the NCCN guidelines as an approved intervention for patients being monitored for the recurrence of UC.
- Publication of a further two peer reviewed papers highlighting Cxbladder's outperformance adding significant additional clinical utility evidence in support of Cxbladder.

# Total Laboratory Throughput Comparison



# Unique Multi-Market and Multi-Product Opportunity for Cxbladder

Progressive adoption of the suite of tests provides a unique, global competitive advantage



# Successful Execution of Key Objectives is Driving Growth

Execution of commercial objectives over the short to medium term is expected to result in a step change in growth

## U.S.:

- Achieve the third and final milestone (LCD) for national reimbursement.
- Increase the focus on closing institutional customers.
- Launch 4<sup>th</sup> Cxbladder product (Cxbladder Resolve) and upsell additional Cxbladder tests.
- Build on initial sales to the Veterans Administration and other Federal, Military and institutional scale customers.

## New Zealand:

- Further accelerate the roll out of Cxbladder with public health care providers (DHBs).
- Bring New Zealand subsidiary to a cashflow positive position.

## Australia:

- Replicate the successful New Zealand sales and marketing model to drive sales growth.

## South East Asia:

- Transition our User Programmes in Singapore into commercial customers.
- Progress discussions with potential strategic partners.

## Clinical Evidence:

- Continue to expand the evidence portfolio to drive further reimbursement, coverage and guideline inclusion.



# Positive Growth Outlook

Continued growth in commercial sales is expected from new and existing customers.

Demand from public healthcare providers in New Zealand is expected to grow strongly and positively impact laboratory throughput volumes.

Inclusion in the NCCN guidelines recommendations for surveillance of high risk patients is expected to positively impact commercial growth in the U.S.

Compelling clinical validation and clinical utility evidence is expected to facilitate significantly stronger test adoption, reimbursement and further guideline inclusion.

U.S. demand is expected to be positively impacted from having national product specific CPT codes and a national CMS reimbursement price in place.

Total operating expenses in FY20 are expected to remain in line with FY19.



# Capital Raising

# Pacific Edge is seeking to raise NZ\$20m through a fully underwritten placement and rights issue

## Purpose:

The offer is to provide capital resources to assist the company to progress commercial objectives in the targeted markets and become cash flow positive as soon as possible. In the absence of LCD inclusion or other material commercial development, this capital is expected to provide funding until January 2021.

## Summary of Offer Terms:

Placement	
Offer Size	\$7.0m (46,666,667m shares) fully underwritten
Offer Price	\$0.15 per new share, representing a 11.8% discount to five day VWAP prior to announcement of \$0.170 per share
Ranking	New Shares issued on completion of the Placement will rank equally with existing shares and will be quoted on NZX and be eligible to participate in the Rights Offer
Eligibility	Institutional Investors and New Zealand resident clients of retail brokers

1 for 4.25 Rights Offer	
Offer Size	\$13.1m (131,362,852m shares) fully underwritten
Offer Price	\$0.10 per new share, representing a 41.2% discount to five day VWAP prior to announcement of \$0.170 per share and a 34.0% discount to the Theoretical-Ex-Rights and Placement Adjusted Price of \$0.152 per share
Ranking	New Shares issued on completion of the Rights Offer will rank equally with Pacific Edge's existing quoted ordinary shares
Eligibility	Any person who is recorded in Pacific Edge's share register as a Shareholder at 5.00pm (NZ time) on the Record Date: (a) whose address is shown in Pacific Edge's share register as being in New Zealand, Australia or Singapore; or (b) whose address is shown in Pacific Edge's share register as being in Hong Kong who Pacific Edge considers is a professional investor as defined in the Securities and Futures Ordinance (Cap.571) of the Laws of Hong Kong; and, in each case, to whom Pacific Edge, in its sole discretion, is satisfied that the Offer may lawfully be made under all applicable laws without the need for any registration, lodgment or other formality and who is not in the United States and is not acting for the account or benefit of a person in the United States
Rights Trading	PEB intends that the Rights will be quoted on the NZX Main Board

# Capital Raising Timetable

Offer announced	21 November 2019
<b>Placement</b>	
Placement conducted under trading halt	21 November 2019
Trading expected to resume	22 November 2019
Settlement and allotment of placement shares	26 November 2019
<b>Rights Offer</b>	
Shares quoted "ex-rights" and Rights trading commence	28 November 2019
Record date for rights issue Offer Document	29 November 2019
Offer Document and Acceptance Forms sent to Eligible Shareholders	2 December 2019
Rights Trading cease	5 December 2019
Rights Offer closes	11 December 2019
Settlement and allotment of rights issue shares	18 December 2019

# FY20 Interim Result and Capital Raising Presentation

21 November 2019



**PACIFIC EDGE**  
CANCER DIAGNOSTICS COMPANY