



**PACIFIC EDGE**  
Cancer Diagnostic Company

# Pacific Edge Limited

## Business Overview

March 2015





## Pacific Edge | Gaining traction in key customers of scale in the US

Pacific Edge specialises in the discovery and commercialisation of diagnostic and prognostic technology for the early detection and management of cancer

Pacific Edge has fully developed commercialisation infrastructure in place and has two products currently “in market” in the US, Australasia and rolling out into Asia

Listed on the NZ stock exchange with a market capitalisation of ~NZ\$233m

### Regulatory approvals in place for the world’s largest healthcare market

- CLIA<sup>1</sup> certification received for both the US and NZ laboratory
- CAP<sup>2</sup> accreditation received for US laboratory
- CE<sup>3</sup> mark for Europe
- TGA<sup>4</sup> approval for Cxbladder kit in place for Australia

### Reimbursement structures in place and underway

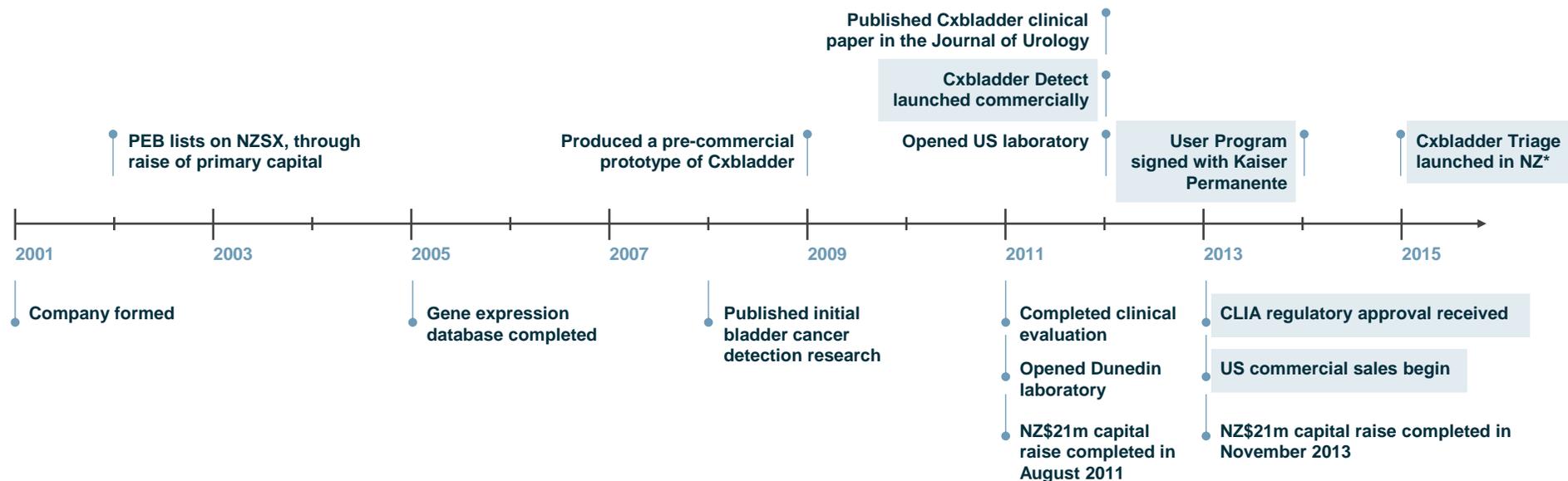
- Currently receiving private insurer revenue and have adoption evaluation underway with Kaiser Permanente
- Process underway with key customers Center for Medicare & Medicaid Services (“CMS”) and Veterans Association with conclusion expected in 2015

### Company announcements reflect rollout commercialisation infrastructure



1. Clinical Laboratory Improvement Amendments  
2. College of American Pathologists  
3. Conformité Européenne (mandatory conformity marking)  
4. Therapeutic Goods Administration

# Pacific Edge | Commercialisation infrastructure now in place for Australasia, US and SE Asia



1. Cxbladder Triage launched in New Zealand on 8 December 2014 and will launch in the US in June 2015

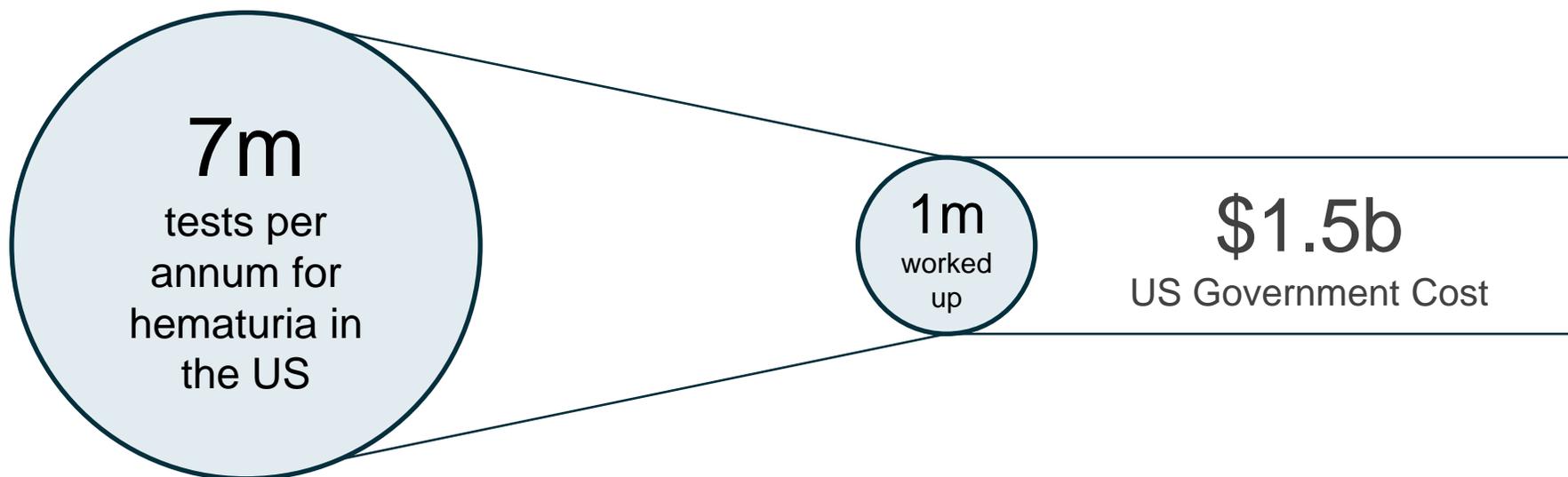


## Bladder cancer | Currently the highest total medical cost per patient of all cancers

Bladder cancer has high prevalence, is extremely costly to treat, and current treatments are invasive causing issues with patient compliance

- Worldwide, bladder cancer is the sixth most prevalent form of cancer (8% of male cancers and 2% of female)<sup>1</sup> with a high recurrence rate
- Bladder cancer has the highest medical cost per patient of all cancers, costing US\$240,000 diagnosis to death
- Cystoscopy procedure involves examining the inside of the bladder via the urethra and is expensive and invasive for patients
- US Market is the worlds largest healthcare market investing a large amount of money in evaluating patients that present with haematuria
- Cxbladder offers a step change in performance

### Target Market

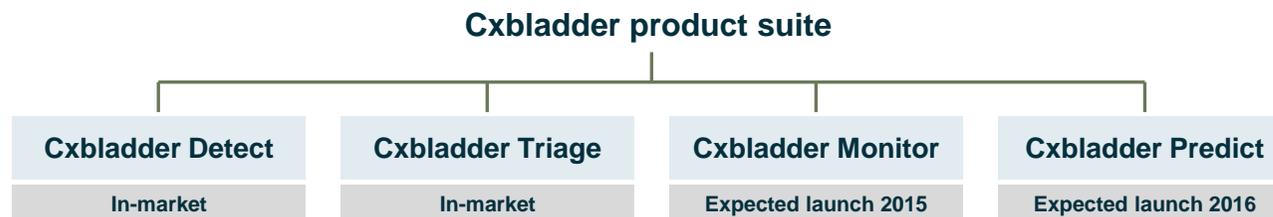


1. United States National Comprehensive Cancer Network

## Cxbladder | A new class of bladder cancer detection tests



Our suite of products enables us to provide a 'one-stop shop' for urologists



### Specific product benefits

- Enhanced clinical capability for Urologists
  - Early detection
  - Better characterisation
  - Greater accuracy
- Patient compliance
  - Non-invasive testing
  - Greater utility
- Production and healthcare costs
  - Most accurate and cost effective adjunct to cystoscopy
  - Fully replaces the need for cytology
  - Cost savings achieved provides a compelling value proposition to both clinicians and insurers

## Cxbladder is Highly Accurate | Detects 100% of tumours of concern to Urologists



	Pacific Edge Cxbladder Detect	Alere NMP22 BladderChek	Alere NPM22 ELISA	Cytology
<b>Stage Sensitivity</b>				
<b>Tis</b>	100%	0%	0%	100%
<b>Ta</b>	77%	39%	32%	29%
<b>T1</b>	100%	43%	71%	50%
<b>T2</b>	100%	13%	57%	100%
<b>Overall Sensitivity</b>	82%	35%	45%	46%
<b>Specificity</b>	85%	96%	88%	96%
<b>Negative predictive value</b>	97%	n/a	n/a	n/a



## Cxbladder Detect vs. Triage | Different strengths provide complimentary results

	Cxbladder Triage	Cxbladder Detect
Non-invasive, requires single urine sample sent to our lab	✓	✓
Test result output	Quantitative inputs, binary output	Quantitative inputs quantitative output score
Early evaluation of hematuria	✓	
Adjunct to cystoscopy in urological evaluation		✓
High test Sensitivity	✓✓	✓
High Negative Predictive Value	✓	✓
High test Specificity		✓
Rule out the presence of bladder cancer	✓✓	✓
Confirm/support diagnosis of bladder cancer		✓

- **Triage provides the strongest screening process to remove those without bladder cancer**
- **Detect provides the most information for those with bladder cancer**



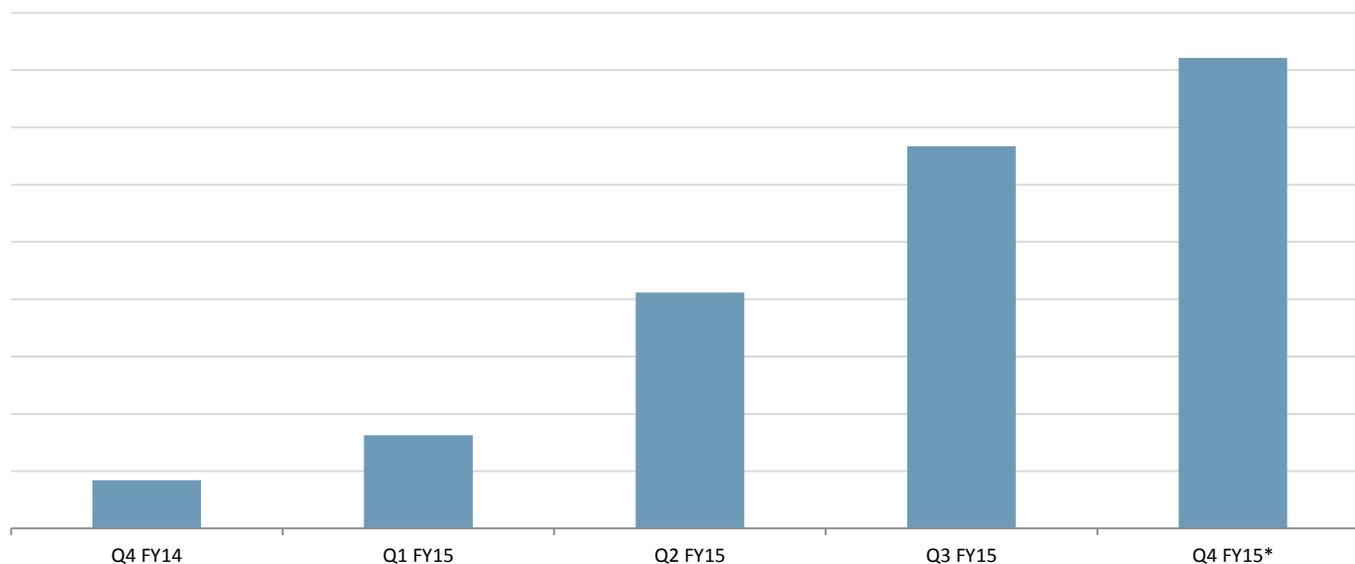
## Cxbladder | Lab throughput data is a measure of adoption

Lab throughput is the strongest tangible measure of adoption for Pacific Edge

Throughput has continued to improve substantially throughout the first full year of trading in the US

Q4 FY15 has also been subject to lower results due to the introduction of the Affordable Care Act in January 2015

Lab throughput showing significant improvements



\* Grossed up at current rate to reflect full period



## Kaiser Permanente User Program example | Saving a large payer significant cost

**Pacific Edge recently signed a User Program agreement with Kaiser Permanente**

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Kaiser Permanente is a fully Integrated Healthcare Provider (IHCP), from the time the patient enters the healthcare system to their post treatment management

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**Kaiser Permanente is a large payer with 9.5 million lives under coverage**

Kaiser Permanente has a strong corporate decision making model

- Kaiser covers 9.5 million people, approximately double the population of New Zealand
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**Kaiser Permanente will enrol 2,000 patients over the next six months to evaluate Cxbladder Triage in their clinical settings**

Adoption by Kaiser Permanente is a significant milestone

- Kaiser Permanente will recruit up to 2,000 patients in a User Programme (UP) to evaluate the effectiveness of Cxbladder in Kaiser Permanente's clinical settings
  - A decision to adopt commercially and a pricing decision are expected to follow a successful outcome
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If, as expected, Kaiser adopts commercially, the successful outcome will be viewed by the US healthcare community as a significant clinical endorsement

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Our technology is underwritten by a strong intellectual property base, progressive and on-going science publication listings, and a successful in-clinic track record

### Published clinical and science papers:

- Holyoake et al (2008). Development of a Multiplex RNA Urine Test for the Detection and Stratification of Transitional Cell Carcinoma of the Bladder. *Clinical Cancer Research*, 14(3), 742-749.
- O'Sullivan et al (2012). A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. *Journal of Urology*, 188, 741-747.

### Clinical and science papers submitted for publication pending editorial review:

- Kavalieris et al (2015) A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to triage out patients presenting with hematuria who have a low probability of urothelial carcinoma.
- Breen 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

#### A Multigene Urine Test for the Detection and Stratification of Bladder Cancer in Patients Presenting with Hematuria

Paul O'Sullivan,\* Katrina Sharples, Mark Dalphin,\* Peter Davidson,\* Peter Gilling,\* Lisa Cambridge,\* Justin Harvey,\* Tumi Toro,\* Nardia Giles,\* Carthika Luxmanan,\* Cris Felipe Alves, Han-Seung Yoon, Victoria Hinder, Jonathan Masters,\* Andrew Kennedy-Smith,\* Tony Beaven\* and Parry J. Guilford\*,†

*"There are ~360,000 new cases of bladder cancer worldwide annually and ~145,000 deaths from the disease"*

*Results suggest Cxbladder significantly outperforms competitors*

#### Development of a Multiplex RNA Urine Test for the Detection and Stratification of Transitional Cell Carcinoma of the Bladder

Andrew Holyoake,<sup>1</sup> Paul O'Sullivan,<sup>1</sup> Rob Pollock,<sup>1</sup> Terry Best,<sup>1</sup> Jun Watanabe,<sup>3</sup> Yoichiro Kajita,<sup>3</sup> Yoshiyuki Matsui,<sup>3</sup> Masaaki Ito,<sup>3</sup> Hiroyuki Nishiyama,<sup>3</sup> Natalie Kerr,<sup>1</sup> Fernanda da Silva Tatley,<sup>1</sup> Lisa Cambridge,<sup>1</sup> Tumi Toro,<sup>1</sup> Osamu Ogawa,<sup>3</sup> and Parry Guilford<sup>1,2</sup>

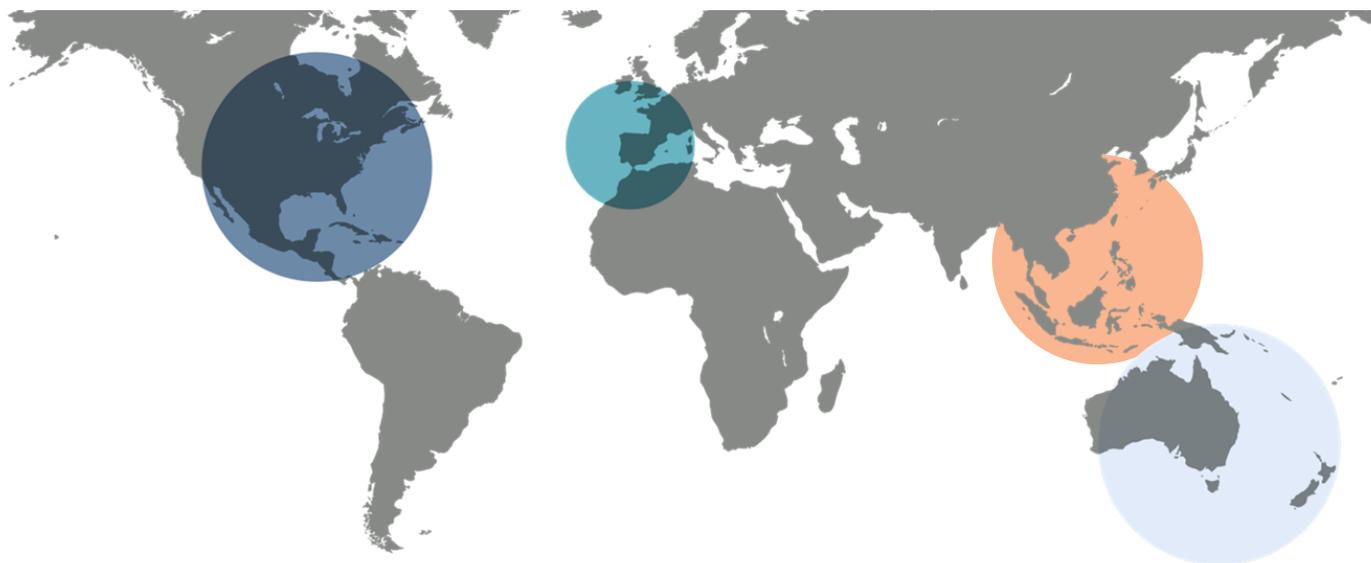
*"There were 54 patients with UC in whom the Cxbladder-D test was positive... At a specificity of 90% Cxbladder-S correctly classified 32 of 35 (91%) of the high risk UC cases."*



## Markets | Cxbladder products are currently in market in Australasia and the US

Pacific Edge started the evaluation of the South East Asian market during 2014 and are on track to initiate a commercial presence by April 2015

South East Asia represents a novel market opportunity based around medical tourism



	Population (millions)	Number of Urologists	Patients with Haematuria	Expected Steady-State (annual no. of tests sold)	Expected cost of evaluation of Haematuria on National Health Systems (US\$)
New Zealand / Australia	24	300	50,000	85,000	50 million
US	327	10,500	1 million	2 million	1.5 billion



## Pacific Edge | Experienced Board and senior executive team

### Key senior executive team members

<b>David Darling, CEO Pacific Edge and Group</b>	<b>Jackie Walker, CEO Pacific Edge Diagnostics USA</b>	<b>Parry Guilford, CSO Pacific Edge</b>	<b>Jimmy Suttie, COO Pacific Edge</b>
Dave has over 30 years' business experience in life sciences and biotechnology. He has led Pacific Edge from its early inception and has significant executive and leadership experience in the development and international commercialisation of biomedical and biotechnology business and products. During his career, Dave has held a number of positions in governance, executive and senior management.	Jackie brings to the company over 25 years of extensive leadership experience in commercialising medical technologies in the US and a strong general management background. Prior to joining Pacific Edge Diagnostics USA, Jackie held senior executive positions at Osspray Ltd, Ondine Biomedica, Dentsply International, a NASDAQ-100 company, and Ohmeda Medical.	Parry has led the science, research and development at Pacific Edge from its early days. As one of the founding scientists and a member of the Scientific Advisory Board of the Company, Parry is the architect of many of the Company's product prototypes. Parry's focus today and going forward is to being his world class skills and experience on the step change in biotechnology for the Company's next generation of products.	Jimmy leads the new product development and product improvement processes at Pacific Edge. As a highly published scientist with a strong record in leading product development teams in the primary sector, Jimmy is a seasoned professional. Jimmy's focus today and going forward is to ensure that the operational science of the franchise is delivered effectively into Pacific Edge's commercial laboratories and to ensure that the new products are brought on-line and to specification.

### Selected Board members

<b>David Band Independent Chairman</b>	<b>Bryan Williams Independent Director</b>	<b>Charles Sitch Independent Director</b>
David Band is an experienced international businessman. His career encompasses a period as Director of the Advanced Business Programme at the University of Otago and significant international experience in corporate consulting and management.	Bryan Williams has significant business and US governance experience. Bryan is also internationally recognised cancer researcher and research administrator. Bryan was chairman of MEI Pharma, a NASDAQ listed company for seven years, is presently chairman of the Board of Biograd Australia, and is a director of Cancer Trials Australia and the MIMR-PHI Institute of Medical Research.	Charles is a director of Spark (formerly Telecom New Zealand) and was previously a director of the global management consulting firm McKinsey and Co for 24 years. At McKinsey he was a leader of the retail, consumer and marketing practices and later a senior director, primarily working with CEOs and Boards on strategy and operations turnarounds. He led McKinsey industry practices in New York, Shanghai and Sydney.



## The opportunity | Objectives for 2015 / 2016

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### **Launch into SE Asia via Singapore**

Appoint supply chain logistics provider

Employ on the ground sales

Initiate four key user programmes with leading hospitals and clinics

Follow up in Bangkok and Taipei targeting medical tourists

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### **Escalation of growth in the US**

Current sales force = 12 executives

Roll out to 18 sales executives covering 19 targeted sales geographies

Capture the Veterans Association and CMS and initiate commercial relationship

Launch Cxbladder Triage

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### **Bring into commercialisation Cxbladder Monitor and Predict**

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**David Darling**

**CEO, Pacific Edge Limited**

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**[www.pacificedge.co.nz](http://www.pacificedge.co.nz)**

**[www.cxbladder.com](http://www.cxbladder.com)**

**[www.pacificedgedx.com](http://www.pacificedgedx.com)**

**[www.bladdercancer.me](http://www.bladdercancer.me)**



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## Safe Harbour Statement

Statements in this presentation about Pacific Edge's expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as believe, will, expect, anticipate, estimate, intend, plan and would. For example, statements concerning the development and commercialization of new products, regulatory approvals, customer adoption, and results of future clinical studies are all forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from those expressed or implied. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include but are not limited to the possibility that the market for the sale of our Cxbladder product in the targeted markets may not develop as expected. The foregoing describes some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements. For additional information about risks and uncertainties Pacific Edge face and a discussion of our financial statements and footnotes, see documents Pacific Edge file with the NZX, including our most recent annual report and all subsequent