

# INVESTOR UPDATE

MAY 2019



PACIFIC EDGE LTD



## EXECUTIVE UPDATE

**David Darling, Chief Executive Officer**

We have now commenced our new financial year and we continue to work hard to progress our commercial journey to becoming a profitable company. We remain confident in the opportunities for our company, with millions of people around the world being tested for bladder cancer and those testing positive then requiring ongoing monitoring for recurrence.

As we have said previously, launching a new commercial diagnostic test is a massive challenge, particularly for a small company building a foothold in the global healthcare market. It involves years of research and development, generation of an extensive array of clinical evidence through multiple peer-reviewed studies, extensive processes and compliance to gain reimbursement, establishing commercial operations and gaining adoption.

We are making good progress – adoption is growing, we are in negotiation with some very large healthcare providers, we are well down the track with reimbursement processes and we have a growing library of clinical validation and evidence for our Cxbladder tests.

Whilst a small market, New Zealand is an example of what we can achieve. Our coverage is growing at a very encouraging rate with more than 3 million New Zealanders (over 60% of New Zealand's population) currently having access to Cxbladder through Pacific Edge's contracts with public healthcare providers.

Following the success with Cxbladder in New Zealand, we have increased our focus on institutional healthcare organisations in the USA and other markets.

The impact our technology makes for these large healthcare providers, who have burgeoning patient needs, finite resources and need to show value changes for their clinical

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services, is becoming clear to all and there is growing interest in our products. As we have successfully shown in New Zealand, while these larger institutional customers can take longer to bring to completion, once commercial agreement is reached they can provide significant volume, lower sales maintenance and more sustainable, longer term growth opportunities for our business.

In the US, along with Kaiser Permanente and Johns Hopkins, we are in discussions with a number of other large, institutional healthcare organisations. While we are just one of hundreds of suppliers they negotiate with every year, and with multiple decision makers and challenging product roll-out requirements, we are working hard to achieve all we can to conclude formal commercial agreements.

We also remain focused on attaining the Local Coverage Determination (LCD), which will allow for reimbursement from the Centers for Medicare and Medicaid (CMS). You can read more about the US reimbursement process and our progress in this newsletter.

We would like to thank shareholders for their continued support with the successful capital raise which was successfully completed earlier this year. This saw a number of new local and international investors join Pacific Edge's register and reflects the growing interest in our company from institutional investors and fund managers. Approximately \$12 million was raised, at the top end of our indicative range. The funds will provide additional capital resource as we progress our commercial objectives with the goal to become cash flow positive as soon as possible.

We have the right people, fantastic products and sales of our tests continue to grow, and we are working hard to achieve our goals.

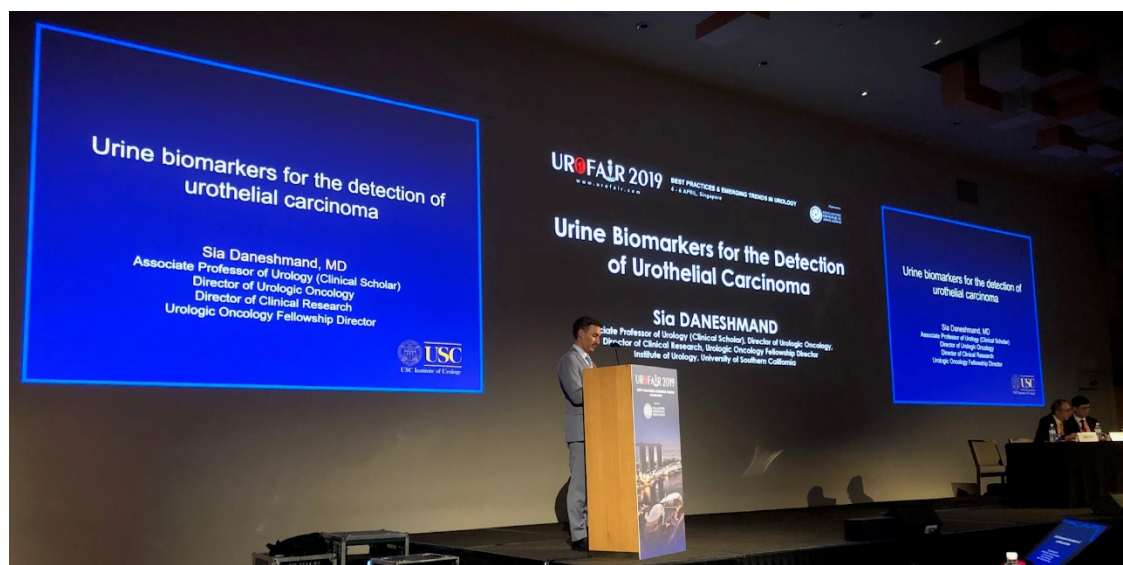
David Darling  
Chief Executive Officer

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## FY19 HIGHLIGHTS

- Continuing growth in sales and adoption of Cxbladder by leading healthcare organisations and urologists, in Pacific Edge's targeted markets of New Zealand, Australia, Singapore and the USA.
- Increased focus on institutional healthcare organisations in all markets is providing commercial traction.
- High levels of commercial adoption of Cxbladder in Pacific Edge's home market of New Zealand. Total contract coverage of New Zealand's population now more than 60% (more than 3 million people).
- Continuing commercial negotiations and start-up processes with targeted institutional customers in the USA, including Kaiser Permanente.
- Completion of two of the three milestones required for US CMS reimbursement, being receipt of national, product specific codes (issued by the American Medical Association (AMA)) and notification of a national price (US\$760 per test). Progress continues to be made with the third of these cornerstones, which is to have Cxbladder included in the LCD.
- Commencement of commercial evaluation with Johns Hopkins Medicine, a US\$8 billion integrated global health enterprise and one of the leading health care systems in the USA.
- User Programmes underway with five targeted hospitals in Singapore and some of these are expected to progress on to a commercial relationship in FY20.
- Taken over the sales and distribution of Cxbladder in Australia, building on the successful practices in the New Zealand market.
- Investment of \$2.6m by US private investment fund, Manchester Management Company, which specialises in biotech and life sciences investments.
- Successful capital raise of approximately \$12 million providing the capital to grow the business and deliver on our objective of becoming a profitable company

## UROFAIR SINGAPORE 2019



**Cxbladder performance was reviewed by more than 500 urological attendees at the prestigious South East Asian Urofair conference ([www.urofair.com](http://www.urofair.com))**

Held in Singapore on 4 to 6 April 2019, this is the premier annual scientific conference organised by the Singapore Urological Association. The conference was attended by 500+ Urologists and medical practitioners from across Asia and further afield and presented a unique opportunity to further raise the profile of Cxbladder with this key audience.

The theme for the conference was *'Best Practices and Emerging Trends in Urology'* and featured presentations on Cxbladder from two internationally recognised Urologists:

1. **Urine biomarkers for the detection of urothelial carcinoma:** Dr Sia Daneshmand (Associate Professor of Urology and Director of Urologic Oncology, Keck Medical Center of the University of Southern California).
2. **An evaluation of the real world use of Cxbladder and clinical utility in New Zealand:** Dr Madhusudan Koya (Clinical Director of Urology at the Waitemata DHB and President of the New Zealand Section of the Urological Society of Australia and New Zealand).

These presentations at the Urofair conference were another successful step in further raising the profile of both Pacific Edge and Cxbladder in Southeast Asia.

As previously highlighted, our growth strategy in Southeast Asia is currently focused on firstly, transitioning customers completing User Programmes on Cxbladder in Singapore into commercial customers and, secondly, progressing our ongoing discussions with potential strategic partners in this region.

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## NOTABLE COMMERCIAL EVALUATION IN USA

### Johns Hopkins Medicine Commercial Evaluation of Cxbladder

Johns Hopkins Medicine is an \$8 billion integrated global health enterprise and one of the leading health care systems in the United States. It operates six academic and community hospitals (including John Hopkins Hospital which is ranked in the top 3 in the US for 22 years), four suburban healthcare and surgery centers, and 40 primary and specialty care outpatient sites.

An initial group of Johns Hopkins urologists are using Cxbladder for patients requiring investigation of haematuria (blood in the urine) for the presence of bladder cancer. Payment will be received by Pacific Edge for these tests. The commercial evaluation allows Johns Hopkins' urologists to evaluate and determine the best fit for Cxbladder within their clinical practice and provide data specific to their organisation and patients.

This is a significant achievement to have Cxbladder considered for use by one of the most respected medical organisations in the USA. It is extremely difficult for small companies to gain access to organisations such as Johns Hopkins Medicine and this commercial evaluation is a major accomplishment for our company.

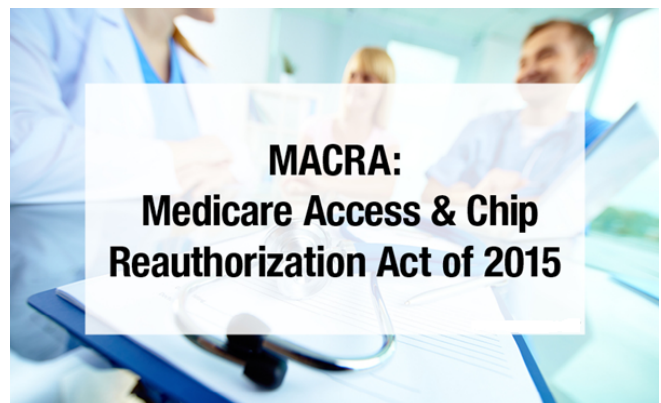


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## THE USA HEALTHCARE MARKET: MACRA ACT

The Medicare Access and CHIP Reauthorization Act (MACRA 2015) aims to shift those physicians who provide services to the CMS from fee-for-service billing to value based service provisions.

2019 marks the introduction of the Merit-Based Incentive Payment (MIPS) whereby physicians are paid based on the quality and effectiveness of care they provide. High value care will be defined by measures of quality and efficiency and providers earn more or less depending on their performance against those measures.



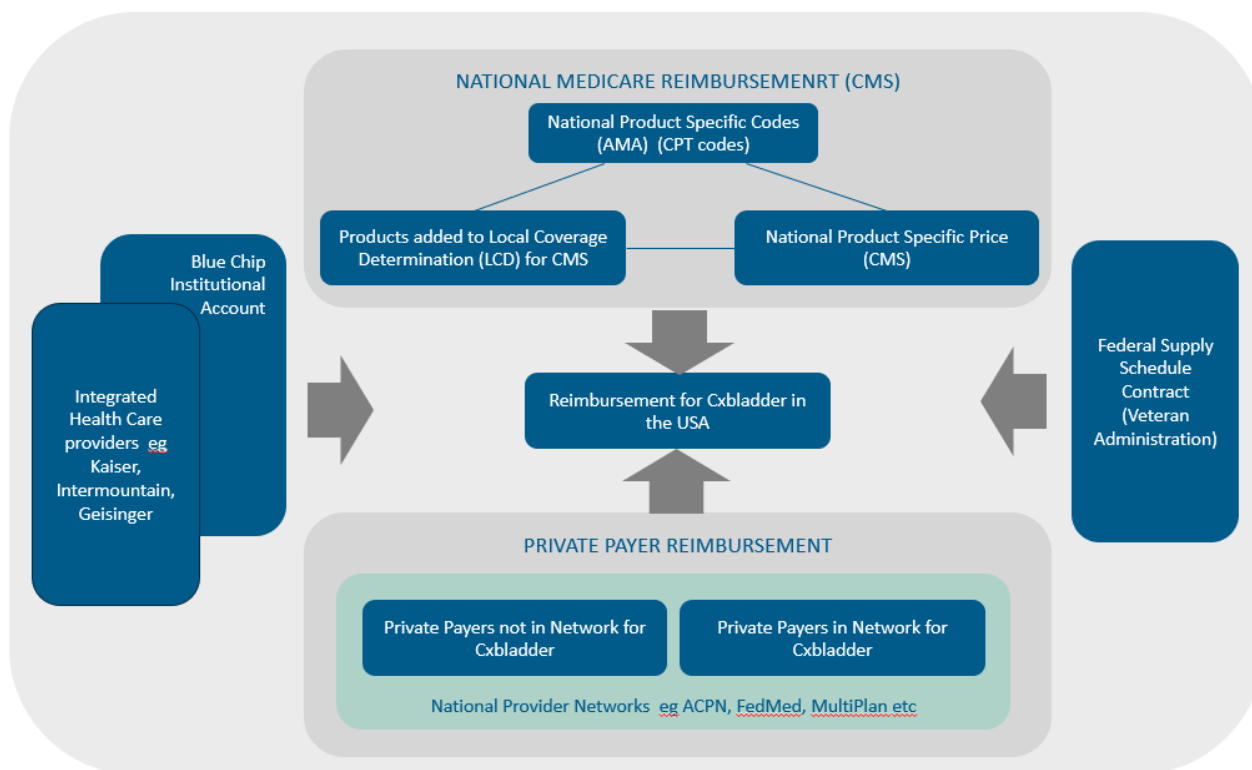
### What does this mean for Pacific Edge?

The MACRA Act 2015 is expected to be good news for Pacific Edge. Under the outcomes-based payment model, physicians are looking for products and services that demonstrate additional value. This value based healthcare approach is more closely aligned to the public healthcare framework in New Zealand where New Zealand physicians are required to replace an existing technology with a new technology to add value. This was seen in the recent adoption of Cxbladder by the Canterbury public healthcare provider, where Cxbladder and imaging have become the new guidelines for evaluation of all patients who present with haematuria for evaluation of urothelial carcinoma, and all other procedures have been removed from the guidelines.

Cxbladder provides additional value through its non-invasive nature and its ability to outperform most of the existing procedures. Clinical studies have shown that the use of Cxbladder significantly changes physician behaviour and decision making, with fewer total tests and invasive procedures for patients, leading to reduced costs and less potential for treatment related harm.

Compliance with treatment regimes and monitoring for recurrence of disease is also an important part of demonstrating value. Cxbladder's non-invasive format makes it easier for patients to comply with the monitoring programme required for bladder cancer where patients currently only have 40% compliance with physician and guidelines recommendations.

## THE USA REIMBURSEMENT PROCESS



The reimbursement system in the USA is lengthy and complex. Healthcare is provided by many organisations, both private and public. Healthcare insurance coverage is essential to successful commercial outcomes and is provided to people through private and public insurers. For example, public insurance providers include Medicare and Medicaid and the Veterans Health Administration, and private providers are insurance companies such as United Healthcare and AETNA. Many insurers also have their own networks of facilities and providers, such as Kaiser Permanente.

To enable consistent reimbursement, Pacific Edge must negotiate with individual private insurance providers to gain contracted reimbursement for its Cxbladder products. In addition, Pacific Edge must follow the regulated processes to be accepted for coverage by public insurance providers, such as the Veterans Administration and the CMS. While physicians can use Cxbladder if it is not specifically covered by contract, the reimbursement level and process is more challenging.

There are three critical factors which aid in the national public reimbursement process in the USA and also help facilitate a more rapid reimbursement from private payers (insurance):

1. Having product specific CPT Codes - which are issued by the American Medical Association for tests that have entered the mainstream with strong clinical evidence and where the volume of tests used by physicians has been shown to be indicative of significant adoption;
2. Receiving CPT Code pricing - which sets the price for test sales to the CMS once the LCD inclusion is received and also provides a basis for Pacific Edge to negotiate with private payers and funders in the USA. Pacific Edge received CPT Code pricing of US\$760 per test in October 2018, which was effective from 1 January 2019.
3. The third step is inclusion in the Local Coverage Decision (LCD) which allows for reimbursement by the CMS. This takes five years on average and requires a significant amount of published clinical and product validation. Inclusion in the LCD remains a priority focus for Pacific Edge and we continue to make steady progress in meeting the evidence needs of the CMS.

## INTRODUCING OUR TEAM

### **Tony Lough: Vice President of Clinical Science and Product Performance**

Evidence based decision making in the medical world drives adoption and uptake of novel and often very disruptive medical products such as Cxbladder. My job is to identify, plan and capture the evidence we need for successful representation of our products, either with clinicians, regulators or insurers.

We look to answer questions such as how useful the Cxbladder products are in the clinic, in what specific clinical applications and how might Cxbladder be improved for other applications. Mostly it's about generating the product performance evidence for the commercial adoption of Cxbladder. Day to day activities include designing the studies to collect the data, running effective in-country processes to generate high quality patient data and then curating and managing the data so that we can analyse it and publish it in peer reviewed scientific and clinical journals.



Designing and implementing international studies can be very challenging, for instance working with very busy physicians, obtaining consent from medical ethics boards, finding and training the medical support staff who consent patients and ensuring collection of high quality raw data.

Pacific Edge has a data library, collected from custom designed, international studies on more than 5,000 patients. This data is used to draft the many publications that form the basis of the peer reviewed published evidence, that is the currency in the medical world for adoption of new products.

I find it very satisfying to have my work wrapped up into an end product, such as peer-reviewed publications, performance data for a new product or a new research site. Above all, high quality data and evidence is ultimately reflected directly in revenue for the company. Part of my role is working out the nature of what is required for strategic objectives, such as providing a sufficient body of evidence supporting reimbursement from payers. To accommodate this, we've published three new peer reviewed scientific and clinical papers over the last 18 months, with more to come!

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## STAY IN TOUCH

### **ENEWS**

We encourage our shareholders to sign up to receive email notification of news and announcements from Pacific Edge.

[Sign up here](#) or visit the Investor Centre on our website [www.pacificgedx.com](http://www.pacificgedx.com).

### **KEY DATES**

FY19 Financial Year End: 31 March 2019  
2019 Results Announcement: 29 May 2019  
2019 Annual Report: By end-June 2019  
2019 Annual Shareholders' Meeting: 31 July 2019

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