

# INVESTOR UPDATE

OCTOBER 2016



PACIFIC EDGE LTD



## EXECUTIVE UPDATE

David Darling, Managing Director and CEO

We have now completed the first six months of FY17 and Cxbladder continues to gain momentum. We have multiple products in our markets of choice and are gaining increasing recognition as a cost efficient, accurate and easy to use family of tests. Our revenue and the number of tests run in our laboratories continue to grow as we build the foundations for strong adoption.

### Growing adoption of Cxbladder

We are pleased with the growing adoption of Cxbladder and have seen a groundswell of uptake by both private and public health funders, particularly in New Zealand.

Recently, two major private health insurance providers – nib and Sovereign – have confirmed specialist coverage. We have sent a communication to all urologists in New Zealand to notify them of the new private insurance cover arrangements. This complements the recognition Cxbladder is receiving in the public healthcare sector, as seen with the commercial agreement with the Canterbury District Health Board (DHB) and most recently, with the Waitemata DHB [as announced this week](#).

This will see Cxbladder Monitor used to evaluate low risk patients for a recurrence of the disease. Many patients will have between 12 and 24 visits to their urologist during their five year monitoring period, and coupled with a high rate of recurrence, may be on a regular monitoring programme for the rest of their lives. Cxbladder provides a simple, accurate and non-invasive test for these patients.

Our goal in New Zealand is to provide all New Zealanders with access to Cxbladder, whether it be through the private or public health system. We are looking to bring on other private insurance providers and expand the access already available through some DHBs.

### Good progress with transformational customers

We remain focused on achieving our financial milestone of \$100 million in revenue. Our progress towards this will be determined by acceptance and uptake of our Cxbladder products with the large US organisations that we have identified as transformational customers – the Veterans Administration (VA), TRICARE, Kaiser Permanente, and the Centers for Medicare and Medicaid (CMS).

## CONTENTS

Executive Update

Approved Provider as part of the TRICARE Health Plan Network

MTANZ Award for Cxbladder

Explaining our Key Performance Indicators: Laboratory Throughput

Pacific Edge in TIN100 Top Ten

Cxbladder In The News

Introducing Chris Gallaher

Upcoming Dates

CHECK OUT OUR NEW-LOOK CXBLADDER WEBSITE

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



PACIFIC EDGE LTD

In the USA, we have identified five large VA centres and our sales force is now actively marketing Cxbladder to these targeted clinics. Pleasingly, we have also agreed a list price with the VA which meets our expectations.

We have also recently been confirmed as an approved provider as part of the TRICARE Health Plan Network, which provides healthcare coverage to approximately 9.4 million beneficiaries around the world under the USA Military Health System.

Being in-contract and having a contracted price is a significant step in the commercial sales process for both the VA and TRICARE.

We are well through the joint analysis of data from the Kaiser Permanente (Kaiser) User Programme, and expect to present this to Kaiser for them to consider shortly. They will then make a decision regarding where in their clinical pathway they will deploy Cxbladder to enhance their healthcare offering to their 9.5 million customers.

The size and scale of Kaiser is alluring. However, the final commercial decision process has yet to be negotiated and Kaiser's specific application in their clinical pathway will dictate just how many tests will be used annually.

As one of our key goals, we are working hard to complete the CMS process to gain our Local Coverage Decision as soon as possible. This is an iterative process, common to all, and we need to follow this regulatory process, which can take time. Pleasingly, we are well down the track on this process.

Together, these large organisations could offer access to millions of potential test opportunities and we are already underway with the VA and TRICARE.

#### **More products in targeted markets**

Our strategy is to deliver high growth over the medium term by creating more products and building scale in an increasing number of targeted markets.

The US launch of the much awaited Cxbladder Monitor test is underway with selected urologists. It will then be commercially

available in all of our targeted markets, and joins Cxbladder Detect and Cxbladder Triage in our family of tests. We are also on track to launch our fourth product, Cxbladder Predict, in New Zealand at the end of this year, followed by a rollout into other markets in line with our usual launch processes.

User Programmes remain an important part of our strategy and we will continue to encourage clinicians to trial our Cxbladder products in their own clinical settings. We are starting to see good traction with more urologists completing User Programmes and transitioning to commercial relationships.

The USA remains our primary focus, but we are also continuing to build sales in New Zealand and Australia. South East Asia also offers exciting potential and we now have an established base in Singapore which will allow us to support current activity and investigate other opportunities in the region.

#### **Annual Shareholders Meeting**

Our annual meeting was held in August in Dunedin and for the first time, we also offered shareholders the opportunity to participate in the meeting online. All resolutions were passed at the meeting, including the election of new Director and Chairman, Chris Gallaher. You can read more about Chris in this newsletter.

#### **Looking forward**

We have a well-considered plan of action for the year and are making good progress against our objectives. While we are still in the early stages of our journey, we are working hard to ensure our suite of products are the preferred choice for urologists and large healthcare organisations.

We look forward to providing shareholders with an update on our laboratory test throughput growth, including the total test numbers, and our financial performance, in November when we release our interim financial results for the first half of FY17.

I hope you find this update of interest. As always, we welcome your feedback and questions. Our contact details are on the back of this newsletter.

## PACIFIC EDGE CONFIRMED AS APPROVED PROVIDER TO TRICARE IN USA

Pacific Edge's USA subsidiary, PEDUSA, is now an approved provider as part of the TRICARE Health Plan Network, which provides healthcare coverage to approximately 9.4 million beneficiaries around the world under the USA Military Health System, including active military and veterans.



This follows on from the signing of a Federal Supply Schedule agreement in February 2016, which provided Pacific Edge with access to the 10.2 million veterans enrolled in the Veterans Administration. Provider approval with TRICARE will add significant scope to Pacific Edge's USA military customer base, with an additional 4 million lives not covered by the VA.

Like the VA, it is anticipated that User Programmes will be required in some situations. An opportunity exists for the company to add a dedicated Sales Executive to the team to service the VA and active Military.

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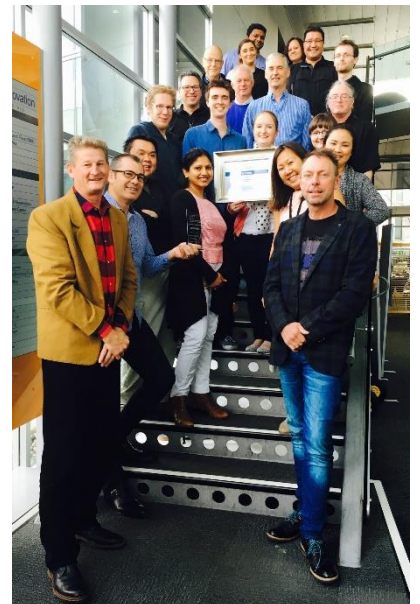
## MTANZ AWARD FOR CXBLADDER

This year, the Medical Technology Association of New Zealand (MTANZ) Innovation Award was won by Pacific Edge for its Cxbladder technology. The Award recognises the innovative and extraordinary contribution of medical technology in improving health outcomes of New Zealand patients.

The MTANZ award judging panel said Cxbladder was an "excellent disruptive technology that was personalised to the patient... and will contribute to the precision medicine wave coming at us."

"Our organisation believes these awards, which are open to both imported and locally developed medical technology, highlight the tremendous innovation in the NZ health technology market. Such innovation delivers better outcomes for patients, better value for our health system and opportunities for export income for NZ," explains MTANZ chief executive Faye Sumner.

Watch our new video on innovation and what it means to us.



*The Pacific Edge team celebrating the MTANZ Innovation Award*



## EXPLAINING OUR KEY PERFORMANCE INDICATORS:

### LABORATORY THROUGHPUT

Pacific Edge has a number of Key Performance Indicators (KPIs) which help management and the Board track and measure the performance and progress of the company. An important KPI is Laboratory Throughput which is the total number of tests processed through Pacific Edge's laboratories in a six-month period. This total includes both tests as part of User Programmes and commercial sales.

Pacific Edge is in an early stage of its commercialisation, and User Programmes are important to encourage clinicians to trial Cxbladder in their own clinical settings and determine the best clinical fit. Our sales people then work with these clinicians to progress them into commercial customers. Every User Programme is different, and the scale and duration of each Programme depends on the characteristics of the healthcare provider. Pacific Edge's largest User Programme to date has been the recently completed recruitment of patients for the User Programme with Kaiser Permanente.

Seasonality also impacts on the number of tests flowing through Pacific Edge's laboratories, particularly in the USA. In the USA summer months (July to September), we see an annual downward trend with patients and clinicians alike being on holiday. Similarly, we see a steady upward trend later in the calendar year as Americans with private healthcare insurance reach their annual fixed deductible level (the amount a patient must pay before their insurance kicks in) and then start to undertake the medically recommended actions and treatments for which they will be reimbursed by their insurance company. It has been recently cited that 60% of USA employees have deductible levels greater than \$1,000<sup>1</sup>.

Furthermore, large User Programmes that have finished but not yet converted to commercial sales, also create a lag in the number of tests used. Together, these factors create an annual pattern of variation in total Laboratory Throughput numbers. Eventually, as Cxbladder becomes more widely recognised, the User Programmes will become less frequent and create less impact on our annual variance.



<sup>1</sup> <http://www.healthsystemtracker.org/insight/payments-for-cost-sharing-increasing-rapidly-over-time/>

# TIN100 TOP 10 HOT EMERGING COMPANIES



Pacific Edge's growing success has been recognised with the company named in the TIN100 Top Ten list of Hot Emerging Companies for the second year in a row.

TIN Managing Director, Greg Shanahan, said: "This year's Ten Hot Emerging Companies in the TIN100 Report are an exceptionally high-performing group. All ten companies are exciting examples of how technology is disrupting the way we do business, from the development of wireless power systems to new remote methods for diagnosing cancer,"

Pacific Edge now has three products in market and a fourth product to be launched in New Zealand later this year, followed by a global rollout in targeted markets in 2017. The company's strategy to offer a 'one stop shop' of bladder cancer detection and management tests to meet different clinical needs is reaping returns, as urologists and patients realise the benefits of the simple, accurate and non-invasive Cxbladder tests.

David Darling commented: "We were pleased to see our positive progress recognised in the TIN100 Top Ten list. The list includes some heavy hitters in ICT and software-as-a-service companies and we are delighted to be recognised alongside them in the Top Ten. We are a small company and our team continues to punch well above its weight in the global market."

## CXBLADDER IN THE NEWS

Pacific Edge and Cxbladder recently featured in a publication titled "The Fight Against Cancer", which was included in over 450,000 issues of USA Today in selected states, reaching some 1.3 million readers.

The campaign saw us uniting with likeminded industry leaders and advocates to provide the most recent information and resources available to inform, prevent and treat cancer in the 21st century.

We are proud to be featured amongst this leading group of experts and luminaries, who have shared their personal experiences, innovative technologies, research and cancer awareness efforts.

Included in the publication was an article by Dr Neal Shore, talking about how new urine based genomic markers can assist physicians and patients; improving outcomes while minimising unnecessary procedures and lowering health care costs. While unable to mention specific brands, the Cxbladder test results were cited by Dr Shore.

A full page Cxbladder advertisement featured next to Dr Shore's article, along with information about online patient community, bladdercancer.me.

[Dr Shore's article can be read here.](#)



**TRIAGE - DETECT - MONITOR**  
The genomic test for the detection and management of bladder cancer

Cxbladder is a family of non-invasive laboratory tests optimized to help assess the probability that a patient has bladder cancer, giving actionable results that can make a meaningful difference in their treatment.

**ACTIONABLE RESULTS:**

- More reliable and objective than other urine-based cancer detection tests, making it an effective adjunct to cystoscopy
- Overall high sensitivity and specificity with a Negative Predictive Value = 97%
- Detected 100% of T1-T3, Tis and upper tract tumors and 93% of all high grade tumors\*
- Superior performance in detecting bladder cancer, outperforming cytology in clinical studies\*\*

\*O'Sullivan et al (2015), J Urol, 193, 741-747

**How Cxbladder CAN BE USED IN YOUR PRACTICE:**

- Triage patients presenting with hematuria that may not require a full workup by helping to rule out the presence of bladder cancer
- Complement cystoscopy for bladder cancer detection, including detection of ureteral tumors not visible by cystoscopy
- Replace the need for other urine-based tests in primary workup
- Replace the need for CT/MRI in primary workup in some instances
- Use triage/urine surveillance to Monitor for recurrent bladder cancer as the preferred adjunct to cystoscopy
- Improve patient compliance with accurate, non-invasive testing

For more information please visit [www.cxbladder.com](http://www.cxbladder.com)

## INTRODUCING CHRIS GALLAHER

Chris Gallaher was appointed as Pacific Edge's new Chairman in August this year. He was most recently Group Chief Financial Officer for Fulton Hogan and has held senior executive and CEO roles with Vector, Village Roadshow and Carter Holt Harvey.

Chris says the appeal of Pacific Edge is that, at its core, it is a business that improves people's lives, by providing better, more effective and less invasive cancer diagnosis.

He says he has always been attracted to new challenges and sees Pacific Edge as being in an exciting stage in its growth.

"The biggest challenge is convincing the urological community of the benefits and value of our products and services. Medical communities are conservative by nature; and for very good reason, given that they are dealing with people's lives and, particularly in the USA, in a litigious environment. It takes time, effort, patience and investment to succeed in this challenge; however, Pacific Edge is well advanced on that journey and if we can succeed in the USA, the opportunity is enormous."



Born in Dunedin and now living in Melbourne with his wife and two daughters, Chris is still a regular visitor back to his hometown and a strong supporter of the All Blacks, the Highlanders and the Dunedin RFC Sharks.

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## STAY IN TOUCH

We welcome contact from our shareholders and have provided a number of ways that you can follow our company and 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.pacificedgedx.com](http://www.pacificedgedx.com)

### FOLLOW US

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

### UPCOMING DATES

**Balance Date: First Half FY17:**  
30 September 2016  
**2016 Interim Results Announcement:**  
24 November 2016  
**2016 Interim Report:**  
By end-December 2016

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This Investor Update has been provided to keep our shareholders informed on our progress, and complements our formal communications such as our shareholder reports, results announcements and annual meeting.