PACIFIC EDGE LTD

Annual Meeting of Shareholders

Thursday 24th August 2017

Addresses by Chairman & CEO

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## WELCOME

Good afternoon and welcome to the Pacific Edge 2017 Annual Meeting and I thank you all for being here today.

For those who don't know me, I am Chris Gallaher, Chairman of the Pacific Edge Board of Directors.

Welcome to all of you who are with us here in Dunedin and also to those who are joining the meeting online.

## BOARD OF DIRECTORS

I would like to start by introducing my fellow Directors.

David Band, Bryan Williams, David Levison, Anatole Masfen and David Darling who is also our Chief Executive Officer.

Both David Darling and Bryan Williams have retired by rotation and are standing for re-election by Shareholders today. Your Board fully supports their re-election.

## MEETING AGENDA

We'll start today with presentations from myself and from Dave Darling.

Following these we will be happy to take questions from Shareholders on the presentations.

We'll then move to the formal business of the meeting and the resolutions contained in the Notice of Meeting. There will be an opportunity for you to ask questions on each resolution before it is put to the vote.

Following the voting on resolutions, we will be happy to take any general questions you may have in relation to our Company and its operations.

Following the close of the meeting, I invite you all to stay and share some light refreshments with the Pacific Edge team and your Board.

A copy of the speeches and slide presentation from today's meeting will be available on our website.

I declare that a quorum is present and the meeting has been duly convened.

The Notice of Meeting, which includes the explanatory notes, has been circulated to all Shareholders and I intend to take it as read.

The audited financial statements for the year ended 31st March 2017 were released on the 24th May and are set out in the Company's Annual Report which was made available to Shareholders on the 30th June.

The minutes of the 2016 Annual Shareholders Meeting have been approved by Directors and are available for inspection.

## CHAIRMAN'S SPEECH

It has now been a year since I joined the Pacific Edge Board and I would like to take a few minutes to reflect on the last year.

The first reflection that I have is to note the real and genuine passion that our stakeholders have for the Company, its products and its future.

From our employees through to the Board and our Shareholders, this passion to create and be a part of something special is what will get us to where we aspire to be.

The second matter I want to reflect on is that of our key objective - why we exist and why we do what we do.

Right from the beginning of our journey, the Company has sought to establish Cxbladder as the world's leading molecular diagnostic technology for the detection and management of bladder cancer and to maximise the value of our technology for the benefit of our Shareholders.

Nothing has changed; this remains our key objective.

## TARGETING LARGE SCALE MARKETS

The key market to deliver this objective is the US; the world's largest healthcare market, and since listing, substantial investment has been made in establishing our presence and facilities in this market.

Our activities in the US have been well supported by our business in New Zealand and we are also developing businesses in Australia and Singapore.

But to be very clear, the Company's primary strategic objective is to win in the US market.

We do get a number of questions on the US healthcare market - how it works and how we are progressing with our targeted customers.

It is a unique market; very different from the markets that we are most familiar with, and we are now using our twice yearly Investor Updates and our annual and half year reports to provide more information and knowledge for our Shareholders.

We hope you're finding these updates informative and of benefit.

Dave Darling will provide more detail in his presentation but in overview;

The US is the largest and most significant healthcare market in the world and is one of the most challenging.

We believe that there is in the order of 3 million test opportunities potentially available for us, in the US market across the different stages of the clinical pathways that we now cover with our tests. As a comparable, there are 11,700 urologists in the US compared to 300 in Australasia.

That is the scale of the opportunity for us and why our key focus and investment has been targeted at this market.

Bringing new medical products to market, which seek to disrupt decades of standard clinical pathways, takes time, investment, and you must have the correct building blocks in place.

We have built a strong foundation in the US with all of the necessary pieces in place to succeed in this market. We are making good progress and have a big first mover advantage.

After our announcement of a very successful user study with Kaiser Permanente late last year, I know many of you will be interested in our progress. Dave Darling will go into more detail but from my perspective, we are making very good progress in achieving a commercial outcome with this very important customer.

We hope to be in a position to announce a commercial outcome in the near future, the timing of which depends on Kaiser Permanente's contractual processes which we don't control.

Dave Darling will speak further on progress with the other key US transformational customers in his presentation.

A significant milestone was reached late last year when Pacific Edge became the only company in the world to offer a suite of four products comprehensively addressing the multiple clinical needs of Urologists.

It is our goal and challenge now to convert this opportunity into revenue.

You will have seen the recent announcement with another of New Zealand's large public healthcare providers signing up to use the full suite of Cxbladder products in their standard of care; we have signed our first major hospital in South Australia; and User Programmes have commenced in Singapore.

## US REVENUE RECOGNITION

The Board is very aware of the rate of revenue generation, cash flow and the capital needs of the Company and continues to monitor them closely.

Our spend will be increasingly offset and eventually surpassed by new revenue, as we gain access and traction with the large scale customers we are targeting.

The rate at which this occurs will depend on the rate at which we are able to scale up these organisations and is something that is very difficult to forecast.

The Board and management are doing all in their control to bring these opportunities to conclusion, however, we are in the hands of the internal processes of these large customers.

Our financial result this year was a reported loss of $21.04 million.

This was below our plan and although an improvement on last year in operating terms, was impacted by the decision by the Board working with our Auditors to take a conservative position to write off some long standing receivables.

These arose from revenues we have invoiced for tests that we conducted but had not yet been reimbursed for by the Centres for Medicare and Medicaid in the US.

For a company to be reimbursed by the CMS, it must have a Local Coverage Determination or an LCD for short.

Gaining our LCD has been a long and protracted process and pleasingly, we are well progressed in this. We are fortunate to have David Levison on our Board who has achieved LCD status in his US healthcare business and he is pleased with the pace of our progress in achieving our LCD.

While we are waiting for our LCD, we are still obligated to provide and invoice for tests used by patients covered by CMS and it is worthy of noting that we will continue to seek recovery of those debts that we have written off in our accounts in FY17.

## COMMERCIAL TRACTION

Our Company is in a long game, the opportunity before us is very significant and we are still in the early stages of our life cycle.

We are on the cusp of realising this potential for the benefit of our Shareholders.

We sincerely appreciate your support, particularly those who have been with us since the early days. We have been talking about our strategy and our focus on these large scale customers for a while and I know many of you are waiting eagerly for our revenue to scale up. While this has taken us longer than we anticipated, we are achieving important strategic milestones and these are taking us closer and closer towards achieving our immediate goal to become a cash flow positive company.

Before handing over to Dave Darling; I would like to sincerely thank the Board for their commitment and wise counsel over the last year and to Dave and his management team for their passion and commitment to delivering on the potential of our Company.

I'll now pass you over to Dave Darling to talk more about the Company's performance and our near term goals.

# CEO's PRESENTATION

Hello everyone and thank you for joining us this afternoon.

## OUR PURPOSE AND STRATEGIC PROGRESS

Our aspirations have not changed and our goal remains the same – to establish Pacific Edge and Cxbladder as the world's leading molecular diagnostic technology for the detection and management of urothelial cancer, and maximise the value of our technology for the benefit of our Shareholders.

We're making good progress and gaining traction in all our markets, with increasing adoption and coverage from healthcare organisations and insurers.

The United States remains our largest opportunity and our main focus and we are targeting a number of large scale healthcare providers. These are very large organisations with many people and processes that we need to interact with, none of which we can control, and getting our products into commercial use can be a long and protracted process. However, we are working as hard as we can on the things we can control, to sign up these large customers as quickly as possible. We are now on the

cusp of a step change, with a number of highly respected, healthcare organisations, who we signed up in 2016, starting to adopt our products.

We are also continuing to build our presence in New Zealand, Australia and Singapore.

You will have seen our most recent announcements concerning the large public healthcare providers in New Zealand who have adopted Cxbladder and written it into their standard of care, a huge outcome and one that we are now leveraging into our other markets.

We are investing in our future and the creation and growth of a strong global company, and I would like to thank all of our Shareholders and other stakeholders for your continued support.

## HAEMATURIA AND UROTHELIAL CANCER

There are three major components to the commercial opportunity for our Company.

Firstly; haematuria, blood in the urine, is a major symptom of bladder cancer and these patients who present to the clinic for evaluation are the key targets for some of our products. The incidence of haematuria is very high - up to 7 million people present to a clinic with haematuria each year in the US alone and 1.5 million of these have an extensive work-up, each costing several thousand dollars, identifying approximately 79,000 patients with disease. Most of this very large investment in those patients who don't have cancer is unnecessary, is wasted and generates poor compliance by the patient with their treatment and management regime.

Secondly; bladder cancer is the most common form of urothelial cancer. It's the ninth most common cancer in the world and the fifth most common in the US. Due to its high recurrence rate, it has the highest total medical costs of any cancer, approaching US$240 thousand dollars over a patient's lifetime; and third but not least; the clinical guidelines require bladder cancer patients to adhere to a regime of continual monitoring and checks, sometimes up to five times per year for five years where they are also required to undergo an expensive and invasive regime of tests. With a 70% recurrence rate for bladder cancer, some patients will be monitored for the rest of their life. In the US alone this can give rise to approx. 820,000 patients returning to the clinic several times per year, giving rise to approximately 2.4 million test opportunities.

## CXBLADDER SPANS THE CLINICAL PATHWAY

We are the only company in the world to have four molecular diagnostic tests that span the clinical pathway for urothelial cancer. This is a huge achievement for our Company.

Each of our products has a specific role in the clinical pathway, and all of them offer a more effective, accurate and non-invasive diagnostic option for patients and clinicians.

## FY17 MILESTONES

We are gaining momentum in the execution of our commercial strategy as can be measured by the many achievements during the FY17 year.

We strengthened our foundations further with new product offerings, new product launches and peer reviewed scientific publications, all of which underpin our sales and revenue going forward.

Our commercial focus remains on building adoption and sales of our Cxbladder products, particularly in the United States. In particular, we have made significant progress with the large scale organisations we are targeting, which have the potential to be transformational for our Company.

We have seen increasing adoption by healthcare providers and insurers, helped in part by multiple clinical and utility studies produced and published during the year, all of which validate the superior performance of our products.

## CLINICAL DECISION MAKING USING CXBLADDER

Published, peer reviewed clinical papers are a key element of our market entry and product adoption. They are the trading-currency needed for reimbursement and are essential for validating the performance and clinical utility of our products with major healthcare providers and funders, particularly in the US, as well as encouraging adoption and changes to the Standard of Care.

So what do we mean when we refer to clinical utility? It's the reference to the change in behaviour that Urologists undergo when they adopt our Cxbladder technology.

In a study published during the last year, the use of Cxbladder Triage and Cxbladder Detect led to compelling changes in Urologists' decision making, leading to fewer total tests and less invasive procedures. This implies a reduction in healthcare costs and an improved experience and outcome for patients.

As you can see on the next slide, it's a compelling outcome.

## FY17 FINANCIALS

Our positive traction is reflected in our growing sales, with FY17 operating revenue up 62% on the prior year to $8.1 million. This excludes any contribution from transformational customers which have yet to impact significantly on our revenue line.

Laboratory throughput, which includes product sales and User Programmes, increased by 35% to more than 11,000 tests.

We continue to invest in the foundations of our business: new products; clinical studies that lead to peer reviewed publications which as we have said are the trading-currency of the US healthcare system; people, particularly our sales team in the US; Intellectual Property and Market Expansion.

Our operating costs were comparable to the previous year and, overall, we reported a $14.9 million operating loss, down 4% on last year. This excludes two non-cash, one-off costs totalling $6.2 million - the first relating to the windup of the Employee Incentive Scheme; and the second due to the conservative position taken to write off bad debts and a provision for doubtful debt; revenue that is invoiced to the CMS but not yet recovered, for their patients that we have been testing.

Our sales activity is gaining momentum and our revenue is beginning to off-set a growing proportion of our costs. Our aim is to become a cash flow positive company as quickly as possible.

## TRANSFORMATIONAL CUSTOMERS

In the US, over 90% of people have health insurance and they are sometimes covered by more than one type of insurance. Approx. 67% of people have private insurance, and 37% are covered by Government insurance, with around 5% of that being military cover through the Veterans Administration and TRICARE, with the balance of the 37% being through the Centres for Medicare and Medicaid Services or (CMS) in short.

We have targeted four large scale customers and we have already started commercial activity with two of them.

For the Veterans Administration; two of the initial five VA centres we were targeting are now sending in tests and we have expanded our focus to 14 centres. Our sales force are working hard to grow adoption and we expect several more clinics to incorporate Cxbladder into their clinical practice in the near future.

We were also approved as a provider to TRICARE in October 2016, opening the gate to 9.4 million lives including active military personnel and some veterans.

The large scale User Programme last year with Kaiser Permanente was very successful. It has been a comprehensive process over the last two years, working with Kaiser to ensure that our Cxbladder tests work well in their clinical setting. In November last year, we successfully completed the last evaluation hurdle and are now nearing the end of the negotiations on a commercial agreement. However nothing is certain until we have completed negotiations and signed the agreement. Having said that it is all looking very positive. We are contemporaneously working with Kaiser's staff on the necessary business elements to ensure that the start-up of commercial tests can occur shortly after we have both have signed the agreement.

It's important to understand how significant this is – Kaiser is one of the largest integrated healthcare providers in the US. What we mean when we say this is, that they provide a 'one-stop-shop' for patients, they have their own guidelines, their own hospitals, laboratories, clinics and their own insurance cover. They are regarded, as arguably, the single most important, non-federally funded, validation organisation in the US and when Kaiser adopts a new technology, it's watched very closely by the rest of the healthcare industry.

So when we sign up with them and they use our tests in their clinical pathway, it is the ultimate measure of clinical utility and a huge credibility boost for us when we are commercialising with other organisations, including government funders like the CMS.

We see an organisation such as Kaiser as being very similar in commercial complexity to the large public healthcare providers that we have here in New Zealand. What we have seen in New Zealand is that these large public providers can take some time to sign up, however, once they have committed and are underway, they are able to move at pace with little input from Pacific Edge.

Our fourth targeted organisation is the Centres for Medicare and Medicaid otherwise referred to as the CMS. The CMS is the federally funded healthcare provider to all people over the age of 65 years. It has high hurdles to climb over. This includes validated performance and testimony from leading Urologists on their reasoning for adoption and changes in their clinical decisions as a result of using Cxbladder; and requires Pacific Edge to have been providing its tests in market for some time, often years, in order to meet their needs. We have been working with the CMS for some time now and we

are well progressed in the process to gain a Local Coverage Determination (LCD) which will allow us to get reimbursement from Medicare for our tests.

In addition to these identified transformational customers, we are continuing to leverage User Programmes and target large urology groups, with sales now moving at pace and growing our revenues with these and other larger organisations, User Programmes remain an important part of our strategy.

## OTHER MARKETS

While the US is our largest scale opportunity, we have been making great strides in New Zealand and are gaining traction in Australia and Singapore.

We announced a new partnership with Tolmar in Australia early last year and their urology sales team are leveraging their existing relationships to market and sell our Cxbladder products. Recently, Tolmar has started commercial activity with a large hospital in South Australia.

We have established a base in Singapore and are currently running User Programmes with two large hospitals. We are in the process of signing up more User Programmes as we build awareness of our tests with Urologists and healthcare providers, to be used on patients presenting with haematuria and medical tourists coming for regular check-ups.

New Zealand is a smaller commercial opportunity for us but very important and it serves as a good trial for similar executions in other markets. We have approved cover by two large private healthcare insurers and our products are in use by a majority of the DHBs with three of these large public healthcare providers adopting at scale and writing Cxbladder into their standard of care. This is the 'Holy Grail' for any commercial healthcare products.

In the last few weeks, MidCentral DHB signed an agreement which extends its use to the full suite of Cxbladder products. They were the first DHB in NZ to sign a commercial agreement and commence using our products in 2013, and it is a wonderful endorsement that they have grown their use and understanding of the Cxbladder performance and are now incorporating our products in the standard of care across the bladder cancer pathway from initial diagnosis to post-treatment surveillance.

There is now a critical mass of public health care providers who have signed Cxbladder into their standard of care.

## REVENUE OUTLOOK AND DRIVERS

Our revenue will continue its strong growth and will be driven by our continuing focus on four main areas.

**Markets**
We will continue to focus on our existing targeted markets, particularly the significant opportunity in the US as this dominates our revenue and offers the fastest revenue growth. New Zealand has made great strides in the scale adoption of Cxbladder by the large public providers and, whilst the revenue is small, it will continue to grow.

South East Asia could potentially be even bigger than the US one day, and we now have an established base in Singapore and hope to initiate our first commercial customer there this year.

**Products**
Our products have been developed, validated and are being rolled out across our markets. We are already seeing the benefits of having a suite of products that cover the clinical pathway, with some of our customers now utilising two or more of our tests in their clinical practices.

In line with our usual launch timeline, our more recent products are still being rolled out across our international markets. We will look to launch Cxbladder Resolve into the US and Australia this year to coincide with the publication of the product performance in a peer reviewed scientific paper.

2016 saw us commercially launch Cxbladder Triage and Cxbladder Monitor into the US. It's still early for these products, however, the market has reacted strongly, particularly with regard to the use of Cxbladder Monitor, in both New Zealand and the US, for monitoring patients returning to the clinic for evaluation for recurrence of their cancer.

**Customers**
We are making good progress in our sales strategy and converting an increasing number of User Programmes into commercial customers. Our primary focus is on establishing commercial agreements and traction with the large scale organisations we are targeting in the US – the VA, TRICARE, Kaiser Permanente and the CMS.

In particular, we anticipate being underway with the supply of Cxbladder tests to Kaiser Permanente shortly after signing off the agreement, although, as always, we are dependent on their internal processes. We are continuing our drive on building commercial relationships with the targeted VA centres and are focused on gaining our Local Coverage Determination enabling us to recover revenue for tests for patients covered by the CMS.

**Sales Channels**
We have identified a number of channels which will help build the commercial use of our products, ranging from increased marketing, relationship building with DHBs, the use of specialist and experienced sales executives and the targeting of specific large scale organisations. A key focus for us in FY18 will be to get more recognition in the standards of care.

**In Conclusion**
We have maintained a consistent growth strategy and are delivering on our planned outcomes.

Moving forward, you can expect to see more of the same as we continue to focus on gaining traction in the US and our other targeted markets and we are expecting a step-up in the number of tests processed and revenue, once we get underway with Kaiser Permanente.

We are making strong commercial progress and expect to see sales continue to grow in FY18 as these large scale organisations transition into commercial customers and build significant sales volume.