



PACIFIC EDGE LTD

Annual Meeting of Shareholders

Thursday 16<sup>th</sup> August 2018

Addresses by Chairman & CEO

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## WELCOME

Good afternoon and welcome to the Pacific Edge 2018 Annual Meeting.

I am Chris Gallaher, Chairman of the Pacific Edge Board of Directors. And I thank you all for being with us here in Dunedin today; particularly those who have travelled to get here.

I also welcome those of you 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.

I do want to make special mention of David Band who is retiring from the Board today after 10 years of service, the last five years as Deputy Chairman.

I wish to formally thank David for his outstanding contribution to the Company and its development over a long period of time and his support for me as Deputy chair over the last two years.

We have a Director recruitment process in progress and will announce a replacement for David in due course.

I am also pleased to announce the appointment of Bryan Williams to the Deputy Chairman role.

Bryan, who originally hails from Dunedin, has been a Director of Pacific Edge since 2013, is an internationally recognised cancer researcher and an experienced company Director.

Anatole Masfen, who has been a Director of the Company since 2008, and who also chairs the audit and risk and the nominations sub-committees of the Board, retires by rotation and is standing for re-election by shareholders today. Your Board fully supports Anatole's re-election.

## MEETING AGENDA

We will start with presentations from myself followed by our CEO, Dave Darling.

Following these presentations, we will be happy to take questions from the floor and from those of you on-line on those presentations.

We will 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 to stay and share some light refreshments with the Pacific Edge team and the Board.

I declare that a quorum is present and that 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 31 March 2018 were released on 29 June and included in the annual report.

I would now like to take a few minutes to reflect on the past year and to outline the Board's priorities for the year ahead of us.

## CHAIR'S PRESENTATION

### CONSISTENCY OF PURPOSE AND STRATEGY

We have continued to hold firm to our purpose – why we do what we do.

Simply put; we are all about establishing 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.

The key market to deliver on this purpose is the USA healthcare market, the world's largest, and we continue to invest substantial sums in realising this opportunity.

The pace of our progress in this market is not where we would like it to be, we had planned to be able to bring the two key opportunities in this market, Kaiser Permanente and achieving our CMS local coverage determination, to conclusion in the last financial year and are working assiduously to do so.

Shareholders should be assured that we are doing everything within our control to close these transactions.

We took the opportunity during the year to conduct an external review of our go-to-market strategy for the USA market, by EY-Parthenon, a leading global consultancy practice. Pleasingly, this review confirmed both the scale of the opportunity and our market strategy and relative to our peer group, we continue to make good progress in the USA.

Dave Darling will go into more detail on the USA market in his presentation.

Very pleasingly we continue to make good progress in our New Zealand home market and we have signed our first commercial agreement in Singapore with the Raffles Group.

## FINANCIAL RESULTS

We took the opportunity to early adopt the new accounting standard for revenue recognition, NZ IFRS 15, which greatly simplifies the complex revenue recognition of sales in the USA market.

In short, sales from the USA, will be recognised on a cash received basis only, until we receive our LCD coverage and coverage contracts are concluded with commercial insurers. This gives transparency to our sales numbers, cash flows and debtors in the USA.

Our reported loss for the year was \$19.7m, a \$3m improvement over last year.

Had we continued to apply the old accounting standard and relative to the forecasts that were included in the November 2017 rights issue, total laboratory throughput was 91% of forecast, and revenue was 95 % of forecast.

Dave Darling will go into more detail on the financial results in his presentation.

## CAPITAL

We were encouraged by the support of shareholders in the November 2017 capital raising which generated \$21.3m of cash resources into the Company and the placement last month to Manchester Management Company of the USA which raised \$2.6m.

It was pleasing to attract this investment from an international investor in biotech and life sciences businesses at a price that supported the November rights issue price.

It adds depth to our share register and reflects a growing international investor interest in Pacific Edge.

The Company had \$16.2m cash on hand at 31 March, since then we have raised \$2.6 million from Manchester Management and our cash burn is on plan.

The Board and management have cash and cashflow management very front of mind as you would expect from a growth business in the cash burn phase.

The Company is focussed on getting to a cashflow break-even point this financial year and this very much depends on the successful closing out of the two USA transformational opportunities that I referred to earlier.

2019

The USA opportunity is the key to our success.

While it is the priority, we will also continue to complete our NZ rollout and build off our start in Singapore.

Our key metrics going forward will be billable tests and cashflow and we will be reporting against these in our formal reporting cycle.

Our Company is uniquely placed to capitalise on the demand for better, more accurate, less invasive and more cost-effective diagnostics.

Before handing over to Dave Darling, I want to finish with a sincere thanks to the Board for their commitment and wise counsel over the last year and to Dave and his team for their continuing passion and commitment to delivering on the potential of our Company.

While we are in a long game, and it has been a long journey for the team and our loyal shareholders, I appreciate the patience shown by all as we work to deliver our goals.

I'll now pass over to Dave to give his Chief Executive's review.

## MANAGEMENT PRESENTATION

### CXBLADDER: BETTER SOLUTIONS BETTER CARE

Our goals remain firm. They are to enable better patient care, better clinical decision making and better use of healthcare resources by providing faster, more accurate and less invasive diagnosis and management of bladder cancer. This is at the heart of our business and we judge our success on achieving these goals.

Our aim is to change long standing clinical practices and encourage adoption of Cxbladder. While it is taking longer than originally anticipated, as the hurdles continue to move in the USA healthcare and reimbursement market, we are making positive progress and have a well-considered strategy for realising the potential of your Company.

### FY18 MILESTONES

Again this year, we achieved a number of significant commercial milestones.

The US remains our primary focus – it is the world's biggest healthcare market and we are well down the commercial pathway and are now focused on building scale and growing test sales. The regulatory and reimbursement environment in the US has changed significantly since we first set our sights on this market. However, we have adapted our tactical plans to meet the needs of the changing environment and we are making good progress towards our goals.

There are three significant components of the US reimbursement process that diagnostic companies must attain; First, you need to have a dedicated code for your products; second, you need a national price; and last but not least you need to get included in the CMS insurance coverage (LCD).

Earlier this year, we were granted dedicated CPT codes for two of our tests, by the American Medical Association. This is a big milestone as CPT codes are only issued for tests that have entered the mainstream and where the volume of tests used by physicians has been shown to be indicative of significant adoption. It is the 'coming of age' for our tests.

The associated pricing for these codes will be publicly notified in November and this price will carry across to the test sales for patients that are covered by the CMS. So once we're included in the Local Coverage Determination, the product codes and pricing will all be in place. These are two of the key US reimbursement processes for us and will support any plans to enter into contract coverage with private insurers in the US.

We've seen great progress in New Zealand this year, with MidCentral and Canterbury added to the list of DHBs around New Zealand who have commercially adopted Cxbladder products and who are now using our tests at a growing volume.

Signing of our first commercial customer in South East Asia was also a real achievement in FY18. Raffles Medical Group is a fantastic new customer – they are one of the largest integrated healthcare providers in South East Asia, they operate across 4 countries in 13 cities and have more than 2 million customers under care. Our agreement is with Raffles Group Singapore, and it offers a stepping stone for us into the rest of the Raffles group. While this is a relatively small commercial proposition for Pacific Edge initially, the potential in South East Asia is huge and it could one day eclipse the USA.

We had a strong year on many fronts, however we didn't get all of our goals completed and closing the agreement with Kaiser Permanente and obtaining our Local Coverage Determination for the CMS patients, remain on our list of priorities for this year.

## FY18 RESULTS AT A GLANCE

Sales are growing strongly and in FY18, we saw good commercial growth with a 29% increase in laboratory throughput to 14,400 tests and 82% of those are billable. We also delivered a 26% growth in revenue measured on a like-for-like basis with last year, and 6% growth in our cash sales – there's not too many young companies growing at this rate. As we build our customer base, our sales will continue to scale up.

We are very conscious of the expenditure and investment we are making into our business, and while it's important for us to invest to build our business, we were pleased to have delivered a 10% reduction in our operating costs, with revenue outgrowing expenses by 13%.

The net operating cashflow deficit of \$(18.1)m was at a similar level to last year, with the cash receipts reflecting sales in the US that were completed over a period that may span over two

years earlier. So the revenue you see entering our books has taken some time to be recovered and booked.

This time taken to collect cash receipts will improve as commercial agreements with insurers, large institutions and the CMS are achieved. One of the key components for shortening this time to cash is gaining our product specific codes and the corresponding national price. So it was another great outcome for us in FY18 to be awarded specific products codes by the American Medical Association (AMA). We are now working to complete the award of our national product prices.

At 31 March 2018 cash in hand was \$16.2 million.

We are confident that cash sales will continue to grow over FY19. We appreciated the support of our shareholders for last year's Rights Issue and we are working hard to build sales across our target markets to get us to our cashflow breakeven position.

We are also conscious that there are expectations in the market of exponential sales growth. While these will occur, they will come as we build our customer base and lock in the repeatable sales, as we are now seeing in NZ.

#### NEW REVENUE REPORTING MODEL

As Chris mentioned, we have changed our revenue reporting model so that we now only recognise revenue for our US customers when the cash payment for the sale is received.

The lion's share of Pacific Edge's revenue is being generated from sales to individual patients in the US. Under this Business to Consumer relationship, the patients retain the liability of paying for the tests. Their insurer may pay some or all of the cost of the test, depending on their level of cover and then the patient remains responsible for paying any outstanding amount. As a result, receipt of cash can take anywhere from 1 to 24 months, with the bulk of cash receipts coming over 7 to 12 months from the time of sales.

Under the new standard, Pacific Edge's US revenue is only recognised for these customers when the cash payment is received. What this means is that a smaller revenue number, representing this cash-only element appeared in our FY18 financial accounts. However to be clear the remainder of the commercial tests completed in FY18, that would previously have been accounted for with the accrual revenue accounting, have not gone away and will appear on our revenue statement when the cash is received.

We believe this new reporting model, defined by the NZ IFRS accounting standard, provides a better picture of Pacific Edge's cash revenues, particularly from the US. We are still accruing some revenue for a small number of tests sold in other markets, where the reimbursement process is less complex and we have more certainty over payment.

## HAEMATURIA, BLADDER CANCER AND OUR US MARKET SIZE

The potential market for our tests remains enormous. In the US alone, approximately 7 million people present with blood in the urine, or haematuria, every year.

Haematuria is a key indicator of bladder cancer and the guidelines state that these patients, approximately 1.6 million of the 7 million, are worked up with expensive and invasive tests each year for bladder cancer. This gives rise to approximately 79,000 new cases of bladder cancer diagnosed in the US annually.

While it is a highly treatable disease it also has a 70% recurrence rate, meaning that patients live with a regime of regular testing for up to five years or more. The guideline driven requirement for ongoing monitoring sees approximately 800,000 patients, who have been treated, regularly returning to the clinic for on-going evaluation over a five year span.

Because of this, bladder cancer has the highest cost of any cancer – up to \$240,00 US dollars per patient.

EY-Parthenon completed a review of our addressable markets for Cxbladder in the US in 2017 and concluded that these markets are in excess of USD\$1.2 billion. We are progressively making inroads into this market and capturing key customers.

## CXBLADDER

Pacific Edge is the only Company in the world to offer a suite of molecular diagnostic tests in any one cancer that address different clinical needs of physicians across the detection and management pathway for urothelial cancer. This gives us a very unique and far reaching commercial proposition that we are now leveraging through our clinical publications and into our sales.

Our key advantages are multiple integrated products, ease of use, ability to transport across international borders and a fast laboratory turn-around time and most importantly the increase in clinical resolution. We are providing a unique 'one-stop-shop' that physicians and healthcare providers are looking for.

There is no longer any discussion about the clinical validity of our products. Cxbladder is progressively being added to the standard of care, is starting to replace the gold standard in treatment and management guidelines for large public healthcare in New Zealand and is being adopted strongly and widely offshore.

## PATIENTS SEEKING BETTER OPTIONS

There is growing recognition of Cxbladder's performance by clinicians and patients are becoming more aware of Cxbladder's non-invasive nature. Recently, in partnership with the Bladder Cancer Advocacy Network in the USA, we surveyed over 1,000 bladder cancer patients and caregivers in the USA. The results were astounding.

- 66% of patients say they suffer discomfort, pain, embarrassment or anxiety when having a cystoscopy,
- Of those, 71% say they would choose Cxbladder as part of their bladder cancer management plan.
- In addition, 68% would use Cxbladder to reduce the frequency of cystoscopies as part of their ongoing surveillance.

Patients and clinicians are clearly seeking a better option and Pacific Edge is providing it with Cxbladder.

### CANTERBURY DHB COMMERCIAL LOOKBACK

Medical products by their very nature have a high threshold for proof of performance before mainstream adoption. This burden of proof is extensive, time consuming and expensive. It provides a hurdle for strong adoption and drives reimbursement.

The commercial lookback by the Canterbury DHB on their use of Cxbladder for the evaluation of all haematuria patients, demonstrated the commercial benefits of our product and is a great endorsement for adoption by other large healthcare providers.

Canterbury had been using our tests with increasing volumes over the last 24 months and they completed an evaluation of this against their clinical and budgetary needs. What it found was that the use of Cxbladder delivers expected and published performance. As a result, Canterbury have rewritten their guidelines, removing the gold standard and replacing it with Cxbladder, so Cxbladder and imaging are now the new standard of care in the initial work-up of all haematuria patients.

The results, in abstract format, have been published in the British Journal of Urology International and a follow-up clinical paper is being drafted for submission for peer review and publication.

This clinical outcome saw Cxbladder added to the South Island wide, electronic Health Pathways guidelines. This means that primary care physicians get to use Cxbladder for the frontline management of all patients who present with blood in their urine. This outcome was more than we had expected and has led to a nationwide move by other DHBs to follow suit.

### NEW ZEALAND LEADING THE WAY IN THE ADOPTION AND USE OF CXBLADDER

As we expect to happen in other countries, New Zealand is now at tipping point with the majority of the large District Health Boards adopting Cxbladder and adding it into their standard of care. We have recently announced the addition of the Counties Manukau DHB to the growing list of New Zealand DHB's signing up and adding Cxbladder into their standard of care. Counties Manukau DHB provide healthcare services to approximately 12 % of New Zealand's population and they have a long queue of patients waiting for up to a year for a cystoscopy. Cxbladder will now fix that problem for them.

In New Zealand, there is no longer a question of clinical validity or utility – the outperformance of Cxbladder is accepted. It's now about the fit within the specific healthcare organisation, how they can best use our tests and allocating funds to pay for them.

- Mid-Central DHB led the world with the signing into commercial use of all four Cxbladder products.
- Bay of Plenty and Lakes DHBs continue to grow their use of Cxbladder.
- Canterbury DHB has integrated Cxbladder Triage into the Health Pathways – the recommended pathway of care for patients with haematuria
- Waitemata DHB has also added Cxbladder to their standard of care for all patients being managed for the recurrence of the disease.
- And most recently, Counties Manukau has joined the growing list of DHBs using our tests.

## SALES CHANNELS

New Zealand is a great example of what our tests can achieve in terms of better patient care, better outcomes and better use of limited healthcare resources.

Following the success we have seen in our home market, we are growing our focus internationally on the large healthcare institutions, which have similar characteristics to the DHBs in New Zealand. We have seen the impact our technology makes on these large healthcare providers who have burgeoning patient needs, few resources and need to show value changes for their clinical services.

The sales cycle may be longer, however once an agreement is in place, these larger customers provide significant volume with lower sales maintenance and more sustainable, longer term growth opportunities for our business.

In line with this, we have re-focussed our US sales team, added more resource for these institutions, while continuing to maintain relationships with existing large practice urologists.

User Programmes remain an essential part of our adoption strategy and a growing number of clinicians across the US, New Zealand, Australia and Singapore are engaged in User Programmes as part of their adoption cycle for Cxbladder. User Programmes enable the physicians to gain a first-hand experience in their specific clinical settings. This then leads to the selection of the Cxbladder product most suitable to their needs.

## US MARKET AND CUSTOMERS

The USA is the world's largest healthcare market, and with 5 million potential test opportunities for Cxbladder each year, it remains our primary focus.

We have been marketing our tests to urologists for the past three years and we are now seeing an increasing number transitioning from User Programmes to commercial customers.

The award of CPT codes and the associated pricing will allow us to start negotiating with insurers and funders and will carry across to the CMS. So once we're included in the Local Coverage Determination, the product codes and pricing will all be in place for reimbursement to commence.

We are now in contract with the VA and TRICARE which gives us access to a combined 20 million-plus military personnel in the US and their families. The VA has a large network of clinics across the US and each of these is autonomous, similar to the DHB network of large public health care providers in New Zealand.

Our Federal Supply Schedule agreement means we can sell our tests to VA physicians, at an agreed ceiling price, but each individual VA centre can still negotiate their own pricing. Gaining adoption in each centre is taking longer than we anticipated, however we are starting to see early sales from the initial centres we targeted. We are putting in place User Programmes for several of the larger sites and their success is expected to carry adoption across a large number of the VA sites.

**Kaiser Permanente** is one of the largest integrated healthcare organisations in the US, with its own network of clinics, hospitals and patient centres. It serves more than 11.8 million members and offers a significant opportunity for our Company.

To have a new healthcare product or service adopted into Kaiser requires a huge amount of clinical validation and sign off from a large team of clinical, budgeting and management personnel. The clinical validation requirements have been met by Pacific Edge, and demonstrate outstanding performance of our tests, but we have little control over the internal decision making process.

We are doing all that we can to conclude our process with Kaiser and move to a commercial relationship.

**CMS** – Good progress is also being made with the regulatory process to obtain a Local Coverage Determination, which will enable reimbursement for patients covered under the CMS. This is an iterative, unstructured and lengthy process that can take companies 3-5 years to complete and which everyone must follow.

Approximately 50% of our US patients are covered under the CMS and whilst we are obligated to carry out these tests and invoice the CMS, currently we are not yet able to receive payment. Once we receive our inclusion in the LCD, we will be able to receive reimbursement and we will seek payment for the many patients done to date.

The commercial process in these large organisations has been uncharted ground, and we have little control over their decision processes. However, our progress is in line with other similar companies operating in the US in the molecular diagnostic space with similar cancer focussed products.

## PERFORMANCE IN LINE WITH PEERS

If we look at our performance in comparison to other molecular diagnostic companies in the US, as outlined in our annual report and on the slide in front of you, you can see that we have a very similar sales trajectory from time of launch to that of our US Based, molecular diagnostic company, peers. Coverage and reimbursement decisions are key to driving volume. We expect to see an uplift in sales as we continue to sign commercial contracts and gain inclusion in the LCD.

## OTHER MARKETS

It has been satisfying to see the global firsts occurring with our large public healthcare providers in NZ. Test sales are growing and in FY18, NZ accounted for 14% of total laboratory through-put.

The uptake in Australia has been disappointing and we are taking over the sales process and will shift the focus to large healthcare institutions to replicate the success we are having in New Zealand.

Meanwhile, Singapore is turning into another early success story. We are only in the initial stages of entry into this market, but already we have multiple User Programmes underway with the large hospitals and have signed a commercial agreement with Raffles Medical Group who are represented in four countries and 13 cities across South East Asia.

## OUTLOOK

The commercial opportunity for our Company is becoming a reality and the market opportunity remains significant. There is growing awareness, support and adoption of our tests being reflected in sales in our key markets and also in the adoption to standards of care and inclusion in local guidelines. We expect to see continuing sales growth over the next year from new and existing customers.

The US remains our primary focus for growth and will be our main area of investment again in FY19 as we position Cxbladder as the preferred detection and management tests of choice for physicians, in a market that offers more than 5 million potential test opportunities each year.

Our priority remains to conclude the commercial process, as rapidly as possible, with Kaiser Permanente; and attain inclusion in the CMS Local Coverage Determination for reimbursement for the large and growing numbers of tests processed for patients covered under the CMS.

We have a growing list of large institutions in User Programmes in our key markets, many of which we expect will start their process of transition to a commercial dependence on Cxbladder products.

We will also be working closely with VA centres and TRICARE to build on initial sales and grow the penetration into the more than 300 VA clinics across the country.

With the adoption of the new accounting standard and the longer time than anticipated to finalise commercial agreements with Kaiser and attain inclusion in the Local Coverage Determination (LCD) for CMS patients, we expect to provide updated guidance in a cash revenue format for FY19 later in this calendar year.

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