

Annual Meeting of Shareholders
Thursday 13<sup>th</sup> August 2015

Addresses by Chairman & CEO

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**WELCOME** 

Good afternoon and welcome to the Pacific Edge 2015 Annual Meeting. Thank you all for being

here today.

I am Chris Swann, the chairman of the Pacific Edge Board.

Today, we are broadcasting this meeting live.

Welcome to all of you joining the meeting online.

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 31 March 2015 were released on the 28 May and are set out in the Company's Annual Report which was made available to shareholders

on the 29 June.

The minutes of the 2014 Annual Shareholders Meeting have been approved by Directors and are

available for inspection.

**BOARD OF DIRECTORS** 

I would like to introduce you to my fellow directors.

David Band, Anatole Masfen, Charles Sitch, Bryan Williams and David Darling.

Standing for re-election today are Anatole Masfen and Bryan Williams.

The Board unanimously supports the election of these directors.

**MANAGEMENT** 

Pacific Edge has a lean management structure with knowledge and experienced executives

leading our businesses.

With us today are David Darling, CEO; Jimmy Suttie, COO; Kate Rankin, CFO; Jackie Walker, CEO of Pacific Edge Diagnostics USA and Brent Pownall, Commercial Director, Pacific Edge

Diagnostics NZ.

MEETING AGENDA

The agenda for today is as follows. First there will be a presentation from David Darling, our CEO. Pacific Edge has made great progress over the last year and David will share with you some

of the highlights as he reviews FY15 and looks at our progress in the current year so far.

Pacific Edge Limited : Annual Meeting of Shareholders Thursday 13<sup>th</sup> August 2015 Following this, we are happy to take questions from shareholders, relating to the presentations.

Please note that the only persons entitled to speak at the meeting are shareholders, proxy holders or corporate representatives of a shareholder.

We will then move to the formal part 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. Voting today will be by way of a poll and includes postal votes and proxies received by 4pm on Tuesday 11 August 2015.

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

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

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

# **OUR STRATEGY**

Our high growth strategy is firmly in place and we are now starting to see some good traction from our long term investment.

We are building the scale of our business by creating more products and building sales in an increasing number of markets. This is resulting in growing revenue from the sale of our novel Cxbladder tests.

The USA is our primary market and offers a massive opportunity for our company, with millions of potential test opportunities. We are making good inroads in the US and although it is still early days, we have some exciting initiatives now in place which could be transformational. We also have operations in New Zealand and Australia and are currently assessing the opportunity in South East Asia.

#### SHAREHOLDER COMPENSATION UPDATE

As you will be aware, in May this year, we settled a case with the FMA with regard to what they considered to be breaches of continuous disclosure obligations in 2013.

The delay of the announcements in question was not made with an intent to breach continuous disclosure but rather to meet the specific needs of the US contractual counterparties.

Compensation has now closed with a total of NZ\$365,000 being paid out to valid claims, less than the provision of \$500,000 included in the FY15 financial statements.

**FUNDING FOR GROWTH** 

The Board remains confident the company is on track to achieve our goal of \$100 million of

gross revenue by our fifth full year of trading.

We completed a successful capital raising in July this year, raising \$35.3 million through a fully underwritten rights offer. Sixty-seven percent of the rights were taken up by existing

shareholders and the balance was taken up by the underwriters.

We believe this additional capital, along with funding from technology grants and growing

cashflow from sales, is sufficient to support our current growth plans.

I would like to thank our shareholders who participated in the capital raising and who continue

to support our strategy. The Board is focused on driving shareholder value and we look forward

to another year of improving performance and growing returns.

I would now like to hand you over to our CEO, David Darling.

CEO'S ADDRESS: DAVID DARLING

At Pacific Edge, we believe in setting goals that challenge and stretch us, being forthright about

what we want to achieve and delivering on what we've promised.

Each year, we identify our goals for the upcoming 12 months and share these in our annual

report and at our annual meeting.

Today, I'd like to review our objectives and performance for FY15, as well as talk in more detail

about our goals for the current year and our progress to date.

FY15 Highlights

FY15 was another strong year of growth for our company and our momentum is building,

particularly in the USA and New Zealand.

Highlights included a strong uplift in our commercial revenue which reflected the rollout of our

US sales and marketing strategy following our initial launch into that market in mid-2013.

We also developed our second product, Cxbladder Triage, and launched in New Zealand in December 2014, on time and to specification. This product has been well received by urologists

and doctors alike and we have just received CLIA approval for commercial processing in our New

Zealand laboratory.

In early July we commenced the launch programme in the US. We have started with our key urology leaders and will culminate with the laboratory being approved for commercial scale use

of Cxbladder Triage by November this year.

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There is a growing awareness and acceptance of our products in the market, and our User Programmes continue to be a critical element in encouraging urologists to trial our products in their clinical settings prior to commercial use.

The announcement of the Kaiser Permanente User Programme was very significant as they are one of the United States largest not-for-profit health insurers and providers, serving more than 10 million members. If our product is accepted by their urologists, it will provide access to a significantly large number of test opportunities annually.

We also continued to invest into our growth strategy, in four key areas – People; including an expanded US sales team; protecting our intellectual property; expanding our market presence, identifying new market opportunities; and putting new products into the market.

In 2014, we set out our objectives for the 2015 financial year. We have made excellent progress against all of these and I would like to thank our team for all of their hard work and effort to make this happen. This is particularly impressive for such a small team operating globally. We are punching well above our weight.

# Our Goals and Progress in FY15

## Expand Our USA Sales Presence and Drive Global Revenue

Our primary goal for FY15 was to expand our in-market and sales presence to drive our revenue growth, both in the US and in our other markets.

As advised, we invested into recruiting new specialist sales people and expanded our US sales team from four to twelve. Their primary role is to build relationships with targeted urologists and encourage them to use our products.

Our revenue comes from reimbursement by private insurance companies for the sale of our diagnostic test Cxbladder Detect and we reported our first significant revenue result in FY15, with \$1.9 million in sales and a total income and revenue of \$4.1 million, in line with expectations ..... A great outcome.

Our progress is reflected in our increasing laboratory throughput, which includes commercial sales as well as the tests processed for the User Programmes. We reported a 278% increase in lab throughput in the first half of FY15 and a further 140% increase in the second half.

## Continue To Build Our Market Presence and Customer Base, Rollout User Programmes

User Programmes are an essential element in our strategy. They allow urologists to test drive our Cxbladder tests in their own clinical environment. Our mission is to then transition them through into commercial customers. We have found that once they have trialled our products, they are quick to see the positive clinical benefits. It has been our learning that some take significant time to complete this transition, while others move through more quickly.

During the year, we significantly increased the number of User Programmes in New Zealand, Australia and the US.

Of particular note, was the announcement of the large scale User Programme with Kaiser Permanente, one of the largest not for profit health insurers in the US. They have their own networks of medical providers, and we are running the User Programme with the Southern California Permanente Medical Group.

## Continue To Negotiate Agreements With Payers And NPNs

Payers and National Provider Networks are important parts of the US healthcare system and they help facilitate access to our products by physicians. We now have agreements with the four largest NPNs in America, including FedMed, ACPN, Stratose and Multiplan, the last of which we signed in FY15.

We are also progressing discussions with the Centre for Medicare and Medicaid Services. Medicare is a key government healthcare programme that provides medical and health-related services to tens of millions of elderly and low income people in the USA. It represents approximately 40% of our potential market.

The Veteran's Administration is also an important organisation, which provides patient care and other services to the 8.8 million US veterans and their families from 1700 care centres with an annual budget of US\$152 billion. To gain access to the VA and to reach these patients, we need to be approved and added to the Federal Supply Schedule and we are in the last phase of that process.

## Continue To Invest Into R&D and Protection of IP

R&D is an important part of our strategy and we are continuing to invest into new products, as well clinical studies and protecting our IP.

We have launched two products and are currently developing two new Cxbladder products to add to our suite of bladder cancer tests.

We completed two large validation studies for Cxbladder and have had four peer-reviewed clinical and science papers published to date, with further papers pending. A great outcome! These all help to build the credibility of our products amongst the medical community.

We also completed a large study which demonstrated the outperformance of Cxbladder compared to other widely used non-invasive tests, including the UroVysion™ FISH assay which is widely used in the USA. The FISH test is reimbursed by most major payers and the findings of this study are expected to be highly relevant for both physicians and payer organisations.

Protecting our intellectual property is important as it underpins any commercial opportunity, not just for Cxbladder but also for our other cancer diagnostic technologies. We were granted multiple patents in FY15 which protects our IP in a number of different markets.

Further research has shown that Cxbladder has detection capability for tumours that occur in the urinary tract above the bladder and our claims are now broader than just the bladder and include urinary cancers. Another great outcome.

# Successfully Launch Second Cxbladder Product, Cxbladder Triage

We also set out to launch a second Cxbladder product in FY15, and completed the launch of Cxbladder Triage in New Zealand in December last year, on plan and to schedule.

This takes us one step closer to our goal of creating a one stop shop of proprietary tests for detection and management of bladder cancer.

Clinical support for this second test was provided in a peer reviewed science paper in the respected BMC Urology Journal in April this year.

It is a real testimony to our scientists, contributing clinicians and product development team to be able to build and clinically test another high performance product. Pacific Edge is now one of only a handful of companies globally who have multiple, bespoke, molecular diagnostic tests in the market.

#### Build Presence In Targeted Markets

Our final objective for FY15 was to grow our presence in our targeted markets. We made solid progress in the US as we have discussed, as well as in our other markets.

In New Zealand, we launched our ecommerce site, making Cxbladder easily accessible by New Zealand urologists, physicians and patients. We also signed agreements with urologists servicing the Bay of Plenty and Lakes District Health Boards.

We continue to work with the National Health Committee to put Cxbladder into the Standard of Care in New Zealand. The aim is to have Cxbladder formally assessed at a national level, which will facilitate mainstream use by health providers and create an evidence platform which can be used to leverage access and reimbursement in New Zealand and international markets.

Australia is performing below our expectations and we are now taking a more active role in sales and marketing and expect to be making changes in our distribution channels over the next year to help grow our sales. This is a reasonable size market and remains a good opportunity for our company.

We also identified an opportunity in South East Asia and have begun preliminary investigations into this market.

# Investing in our People

The success of our company is founded on the expertise, experience and dedication of all our staff. We are committed to recruiting and retaining the best possible talent and as our company grows and evolves, we will continue to build our teams to ensure we have the expertise and capability in place to achieve our goals. In the past two years, we have refreshed our Board with three new directors, strengthened the executive team with the appointment of Kate Rankin our CFO in FY15, expanded our US sales team and expanded our product development team.

# FY15 Summary Financial Performance

# Result Reflects Ongoing Investment into Growth Strategy

FY15 really confirmed to us our transformation and progression from the original R&D company we started in 2002 into a commercial organisation generating revenue in several markets around the world.

Our financial results reflect our investment into our growth strategy and our progress over the year on our stated objectives.

Revenue grew as a result of increasing commercial sales. Expenses reflect our investment into People, Intellectual Property, Market Expansion and Product Development and also include the provision for shareholder compensation.

Our bottom line result was a Net Loss After Tax of \$11.2 million.

# Our Goals for FY16 and Progress to Date

So looking forward, what are our goals for FY16 and how are we progressing against them in the vear to date?

#### Usa Healthcare Market

The USA remains our primary focus. It is the world's largest healthcare market with over 10,000 urologists and millions of potential clinical opportunities for our Cxbladder products.

We have grown our understanding and knowledge of the US market over the past two years and now have a proven plan in place to expand our market share.

We will also continue to build our sales in New Zealand and Australia, where we have established commercial partnerships.

We have identified South East Asia as offering exciting potential and will continue to assess other markets and the opportunities they may offer.

We will look to build on the power of the patient to take control of their health and well-being through our e-commerce site and the Patient Community bladdercancer.me, developed specifically for bladder cancer patients, families and helthcare providers. This is expected to add significantly to our customer base over time through providing direct access to Cxbladder products.

#### Usa Healthcare Market: Infrastructure

To build our presence in the US, we are further expanding our specialist sales team from 12 to 18 people and we have 19 targeted sales regions.

We have recruited two of these sales people already and they are now going through training and are expected to start in their sales territories in September.

A further four sales executives are expected to be recruited and in place by November.

Their primary focus will be to build awareness of Cxbladder with targeted urologists and encourage them to trial our product through a User Programme.

#### Usa Healthcare Market: Customers

We are continuing to progress our discussions with the Centre for Medicare and Medicaid Services and are now one step further along in our progress with the VA, having submitted our dossier to gain access to the Federal Supply Schedule.

We are also focused on completing the Kaiser Permanente User Programme this financial year and then transitioning them into a commercial relationship in 2016. This could be a transformational customer for our business if our product is accepted for use by their physicians.

# User Programmes: Continued Rollout

Recruitment of patients for the Kaiser Permanente trial has now begun, although it has been a bit slower at the start than anticipated. There are a significant number of consents in process with patient samples being analysed in our Hershey laboratory.

## South East Asia: Market Entry

Our second area of focus is growing our international presence. We have identified an opportunity in South East Asia and we are now looking to finalise our business case for entry into this market.

There are two distinct segments of interest: Firstly, patients requiring testing and management for bladder cancer, in the same way as our other markets.

Secondly and more unique to South East Asia, is the rapidly growing number of medical tourists who come to the region for regular wellness and medical checkups, where our Cxbladder tests could be a part of a variety of tests offered to patients seeking an annual wellness regime.

Logistically and commercially, Singapore is a great gateway to the markets of South East Asia. It offers a number of benefits, including the widespread use of English, internationally certified hospitals and a significant and growing population of medical tourists supported by a strong commercial drive in these countries to build businesses of scale to meet their needs.

We have now launched a User Programme with the prestigious Tan Tock Seng hospital in Singapore and the first tests have arrived in Dunedin, enabling us to trial the supply chain logistics. We are targeting a further three sites for User Programmes this year in Singapore.

Other potential market opportunities in the region include Bangkok and Taipei, which are also popular destinations for medical tourists.

# Deliver A One Stop Shop Of Cxbladder Products

Our aim is to provide urologists with a 'one stop shop' by offering a suite of Cxbladder products designed to meet the specific clinical needs of the different patient groups.

# Cxbladder Triage: Usa Launch

Our second product, Cxbladder Triage, was launched in New Zealand at the end of last year and we went live with the launch programme in the US in July, with commercial laboratory processing expected in November.

We have received CLIA approval for the commercial processing of US based patient samples for this new test for our Dunedin laboratory and expect to have approval for our Hershey based laboratory by November.

#### **Cxbladder Pipeline: Product Development**

We have a further two products in the pipeline and will follow the same launch plan, firstly in New Zealand with a fast follow up in the USA. We are on track to deliver our third product to the market later this year.

## **Engagement: Patient Community**

Our final objective for this year is to engage with the people that matter – those suffering from bladder cancer and their families.

We are proud to be the leading sponsor of an online patient community, which has been developed by Melon Health.

#### **BLADDERCANCER.ME**

This community site provides online, relevant resources for bladder cancer patients including peer support, access to appropriate healthcare providers and symptom tracking.

We are very proud to sponsor this site and provide support for the large number of people globally who are diagnosed with bladder cancer.

# Looking forward

We remain firmly focused on high growth. We have a well considered plan of action for the year and are already making excellent progress against our objectives.

# Strategic Opportunities For Growth

We will achieve our high growth ambitions by:

- Creating more products;
- Expanding our presence in both existing and new international markets;
- Creating more sales channels such as our ecommerce site;
- Building out our customer base through our proven User Programme strategy and
- Recruiting and empowering high calibre people.

# An Exciting Future For Our Company

We are at an exciting stage of our journey, as we continue the transition into a successful global business.

We expect our growth to pick up pace over the next year as we expand our efforts in the USA and build towards our goal of generating \$100 million of gross revenue.

Thank you all for listening and for your support. We are excited about where our company is heading and what we are now achieving.