

# PACIFIC EDGE 2020 ANNUAL SHAREHOLDERS' MEETING

# CHAIR AND CEO SPEECHES

# CHAIRMAN'S PRESENTATION: CHRIS GALLAHER

# OUR COMMERCIAL JOURNEY

Staying the course over a long period of time and in the face of adversity, and continuing to believe that what you are doing will make a difference, is a testament to the commitment and resilience of Dave Darling and his team over a 15 year period.

We have been delighted in the last two months to have successfully achieved two of our most significant commercial milestones – agreement with Kaiser Permanente, one of the USA's largest and best regarded healthcare providers, to use our tests; and receiving inclusion in a Local Coverage Determination which was the final step needed to gain national reimbursement in the USA.

# LCD

Coverage under the LCD enables reimbursement from the Centres for Medicare and Medicaid ...the CMS... for two of our Cxbladder products. CMS patients represent approximately 40% of our Cxbladder commercial sales in the US and we expect this to increase steadily as we progress over the next 12 months.

In addition, we will be negotiating for payment on the historical 22,000 invoices we have submitted to the CMS prior to receiving the LCD, for which we have not been paid. Securing a significant proportion of these funds is important to Pacific Edge and our shareholders as it will provide us with additional capital to support the execution of our US commercial plans, and develop the next horizons of growth for your company.

The LCD inclusion is also expected to positively impact on demand and reimbursement decisions from other healthcare organisations and payers as well.

#### **ANZ Investment**

The achievement of the Kaiser Permanente and LCD milestones were the triggers for ANZ Investments to approach the company and offer to invest \$22m at a 14% premium to the prevailing share price.

This is a real financial vote of confidence in the company and its prospects by a substantial and reputable NZ Institution and has enabled us to broaden our institutional shareholding base and raise growth capital for the company in a very cost effective manner.

The market's response to these three recent events has been very encouraging for the Board and management and will, I hope, have given all shareholders confidence in our future outlook.



# **Other Highlights**

There were several other successes during the year.

Entering into a commercial agreement with Kaiser Permanente provides the company with a significant opportunity to develop short, medium and longer term value through multiple products with a single large institutional customer.

Another important achievement for us was inclusion in the USA's National Comprehensive Cancer Network bladder cancer guidelines. These guidelines are widely recognised and used as the standard for clinical policy and practice in oncology by clinicians and payers in the USA.

In addition, our commercial growth has continued and we have an increasing number of urologists and customers using our tests, particularly in the USA and in New Zealand.

Achieving these latest milestones is a testament to the hard work and perseverance of our Pacific Edge team, and the result of years of clinical research, sales and marketing activity, user programmes and relationship building with key organisations and influencers.

To attain this point in the company's growth has been both challenging and rewarding. On behalf of the Board, I would like to acknowledge and thank shareholders who have patiently supported us over this time.

# RESPONDING TO COVID-19

As a Board, our focus is on overseeing the successful implementation of our strategy, ensuring robust governance processes and supporting management. We are also heavily involved in the capital management and funding of our company and oversight of our commercial progress.

However, this year was the first time for any of us that we have had to deal with a global pandemic that closed down medical practices and affected patients around the world.

We felt the impact of COVID-19 in the first two weeks of April with urologists struggling with the conflicting demands of COVID-19 restrictions and managing bladder cancer patients, all of whom are deemed at-risk patients. However, our New Zealand business has been quick to return to normal trading and the USA, whilst still largely under the influence of COVID-19, has been making good progress.

Across this challenging time, we were able to reduce costs to offset expected income reductions and we also received financial support in the form of COVID-19 relief packages from Governments in New Zealand, Australia and the US.

#### OUR GROWTH STRATEGY

Our strategy remains consistent – to attain global reach with our comprehensive suite of Cxbladder products and to maximise the value of our technology for the benefit of our shareholders.



We will do this by:

- Commercialising all four of our Cxbladder tests in our targeted markets around the world;
- Sustaining our first mover advantage and positioning Cxbladder as the preferred detection and management test for urothelial cancer; and
- Growing the adoption of Cxbladder by large scale institutional healthcare customers, for multiple clinical needs.

Underpinning all this is the commitment to building a profitable business and delivering superior value to patients, physicians and our shareholders.

# OUTLOOK

We now have all the fundamentals in place and, on the back of this, we will be moving to scale up the adoption of our tests by large healthcare organisations in our targeted markets. This won't happen instantly but we do expect to see commercial use and revenues ramping up over the next 12 months and into the future.

Cash and cashflow management remain very front of mind as you would expect from a growth business. Including the recent growth capital from ANZ, Pacific Edge had total cash and cash equivalents of \$31.3 million as at 4 August 2020. We also expect the increase of commercial test sales to have a positive impact on our earnings and operating cashflows.

The US market remains our primary focus with an annual addressable market of \$1.2 billion US dollars<sup>1</sup>. To maximise our opportunity will require investment to ensure we are adequately resourced to deal with anticipated demand and to make sure our growth is executed seamlessly and positively.

Our company is uniquely placed to capitalise on the demand for better, more accurate, less invasive and more cost-effective diagnostics. As we progress with our key objectives, we expect demand and commercial use of our tests to gather pace.

Before handing over to Dave Darling, I would like to say a few thank yous.

First to your Board for their contribution and wise counsel over the last year. We are a small Board with a diverse range of skills and experience and everyone has enthusiastically gotten very involved in both the Board and Committee work. In a company such as ours, the workload on Directors is substantial and I am very grateful for the support of my colleagues over the year.

Next, to Dave Darling and his team ... the patience and perseverance to develop and commercialise a breakthrough medical device in the biggest and most challenging medical market in the world is an outstanding achievement for a company based out of Dunedin.

<sup>&</sup>lt;sup>1</sup> E Y Parthenon 2018



The job is not done yet and the challenge now in front of us is to grow the volume of our tests as rapidly as possible and convert our platform now established into value for our shareholders.

Last but not least, a sincere thank you to you, our owners, who have continued to support the company over our long journey and also shown great patience and perseverance.

## **CEO'S PRESENTATION: DAVE DARLING**

#### PROGRESS AGAINST STRATEGIC GOALS

Thank you to everyone for joining us today. I'd like to start today by looking at our progress against our key strategic goals.

#### LAUNCH AND COMMERCIALISE OUR TESTS

Urothelial cancer is a major global health problem and creates significant healthcare challenges. This disease is prevalent, has high recurrence rates, is persistent and is expensive to diagnose, treat and monitor.

Our proprietary suite of Cxbladder tests has been built to meet the multiple needs of physicians, healthcare providers, patients and healthcare payors. Our tests can be used across the full clinical pathway, from evaluation through to ongoing monitoring for recurrence of cancer, to address the many clinical challenges that physicians have identified for us. We know of no other company which has created a suite of commercial molecular diagnostic products that positively impact clinical decision making across the entire pathway.

We are commercialising our suite of tests in four targeted markets. These are markets of scale and markets that have a clear path to reimbursement with a high propensity to pay strong reimbursement rates for our tests.

Apart from Cxbladder, there have been no new bladder cancer molecular diagnostic tests commercially available the market in the last 18 years. In fact, we compete against standard technology and tools that have been in use in urology for some time.

The market offering us the largest and most accessible opportunity right now is the USA and it remains our primary commercial focus. The total market size for bladder cancer is estimated to be more than US\$5.0 billion with an estimated annual addressable market opportunity for our Cxbladder products of approximately US\$1.2b<sup>1</sup>.

New Zealand is our home market and is leading the way with the adoption of Cxbladder and inclusion in guidelines. There have been significant changes in the way most New Zealand urologists practice urology, with Cxbladder added into the standard of care for the majority of public healthcare providers. This major transformation in physician behaviour foretells the changes that we are now starting to see in the USA, with the recent announcement of Kaiser Permanente's commercial use of Cxbladder.



Australia and South East Asia also offer exciting opportunities for us, although we are at an earlier stage in the commercial pathway in these two markets. We are currently running clinical trials in Singapore and these are nearing completion. The published results will form the basis for a proposed Singapore-wide Cxbladder commercial programme.

In Australia, we are replicating our New Zealand-proven sales and marketing model, to drive sales and, in 2019, our experienced New Zealand Sales Manager relocated to Australia to implement our sales plan.

# SUSTAIN THE GLOBAL FIRST MOVER ADVANTAGE

Our second pathway to achieve commercial success is by sustaining our first mover advantage and positioning Cxbladder as the preferred detection and management tests for urothelial cancer.

Pacific Edge owns world leading technology and intellectual property and we have a significant time based competitive advantage. The ability for our tests to be used across the entire clinical pathway, the multiple tests, the consistent performance and the ease of transfer of urine samples from the patient to the lab, all enhance our competitive advantage.

# GROWING PORTFOLIO OF PEER REVIEWED, PUBLISHED PAPERS

To convince urologists, healthcare organisations and payers to adopt and grow their commercial use of Cxbladder, we need to have published, peer-reviewed clinical evidence. This is the trading currency for positive reimbursement decisions and recognition by industry guidelines.

We have generated in excess of 10 years of accumulated evidence on thousands of patients all published in leading, peer reviewed, urology and clinical journals, showing the outperformance of Cxbladder. This has been a significant and time consuming investment for the company and we are now seeing the fruits of this in the reimbursement milestones in the USA, increasing adoption in all our markets, and early stage inclusion in NZ and USA guidelines.

#### INCLUSION IN CLINICAL GUIDELINES

Inclusion in guidelines follows significant adoption by healthcare providers, and further empowers urologists and organisations to adopt and use our products. It's early days for us in our commercial leverage of the recent guidelines inclusion and this is a process that will continue over the next few years.

A highlight achievement this year was inclusion in the NCCN guidelines for patients being monitored for recurrence of urothelial cancer. This is a pivotal commercial outcome as these guidelines are widely recognised and used as the standard for clinical policy and practice in oncology by clinicians and payers in the USA.

Several of New Zealand's public healthcare providers have also integrated Cxbladder into clinical guidelines, replacing the gold standard cystoscopy in both the evaluation of haematuria and in the monitoring for recurrence of urothelial cancer.

Most recently, we have seen biomarker technology referenced in the American Urology Association guidelines for hematuria. In particular, it was satisfying to see the strong recognition of the performance



of Cxbladder, in the 2020 AUA guideline update, which specifically references a study, targeting Cxbladder guideline inclusion, that is currently being undertaken by leading US urologists and institutions that are utilising Cxbladder.

A second recent announcement has also been made by the AUA for Non-Muscle Invasive Bladder Cancer, which again, specifically refers to Cxbladder and highlighted the outperformance of Cxbladder in comparison to some of the already approved diagnostic tests in common use today.

For Pacific Edge, this highlights that the strategy and approach we have taken over the last decade is starting to resonate within the urology community.

We are now actively working with our growing user-base to continue the data capture and evidence development so that the guideline panels can confidently support stronger inclusion language for Cxbladder in the near future.

The important thing to remember here is that our efforts have created a mind shift among the urology decision makers and we now see changes in their clinical behaviour. We have a technology that is on track to positively disrupt the traditional approach taken in the detection and management of bladder cancer and we now have the 'ear' of the growing number of physicians who use our technology.

INCLUSION IN CMS'S REIMBURSEMENT COVERAGE IN USA

Inclusion in the Local Coverage Determination, or the LCD, is one of our biggest achievements to date and enables our ability to receive reimbursement for the many CMS patients that utilise Cxbladder. This completes the USA's CMS reimbursement milestones and is expected to result in significant commercial growth.

Inclusion in the LCD also supports our negotiations with the many private insurance payers in the US who provide insurance coverage for the approximately 60% of our current commercial tests performed in the US. The impact of these negotiations will be to increase our coverage and therefore reimbursement, as well as shortening the cycle time for claims payment, our receipt of the cash.

Now that we have inclusion in the LCD, we will also be seeking to negotiate with the CMS for reimbursement of the more than 22,000 tests, previously completed and invoiced for CMS patients. There is precedence for this with other companies which have been reimbursed for the products or services supplied prior to being covered under an LCD, however, the negotiation is product and company specific, which limits our ability to pre-determine the monetary size of any outcome.

GROW THE ADOPTION OF CXBLADDER BY LARGE SCALE HEALTHCARE ORGANISATIONS

Our third strategic pathway is scale adoption by large healthcare institutions in all our targeted markets, particularly the US.

While these large scale customers can take longer to bring to completion, once commercial agreement is reached, they can provide significant volume, require lower sales maintenance and deliver more sustainable, longer term growth opportunities.



# COMMERCIAL AGREEMENT WITH KAISER PERMANENTE

Most recently, we were very pleased to be approved for commercial use by Kaiser Permanente, one of the largest healthcare providers in the US. Kaiser has over 12 million members, operates 39 hospitals and employs approximately 23,000 physicians. This is a fantastic outcome after a long period of consultation and working closely with Kaiser Permanente, their due diligence and to ascertain the best use of Cxbladder in their healthcare settings.

The opportunity with Kaiser will see Cxbladder being used to the full extent of its commercial opportunity, where the Cxbladder sample collection kit will be sent to the home of patients who are scheduled for their 3-monthly clinic evaluation for monitoring for recurrence of bladder cancer. This will allow the patient to provide a non-invasive urine sample in the safety of their own home, which is of particular relevance and importance during this global pandemic.

The use of Cxbladder in this home setting breaks up the traditional patient care model which would previously require patients to visit Kaiser Permanente's clinics, hospitals or the physician's surgery for their evaluation. The eyes of the urology world are on us right now as we challenge traditional norms through our leading edge technology.

So, in the near term we are underway with our training programme for the many urology professionals at Kaiser. We must ensure that our supply chain operates effectively and provides accurate and timely results back to both Kaiser Permanente and their patients, 100% of the time, and retain our gold-standard service levels even as volumes ramp up. It is our intention to have all of the training requirements completed to meet their timelines, within a few months of the start of commercial services.

If executed well, the Kaiser Permanente programme will create multiple product use opportunities, with strong revenue and improved cash flow for our business.

GROWING USE/EVALUATION OF CXBLADDER BY LARGE SCALE HEALTHCARE ORGANISATIONS

Multiple institutions in both the USA and our other markets are currently using or evaluating Cxbladder, including some of the most highly recognised healthcare organisations in the world, such as Johns Hopkins Medicine and the Cleveland Clinic, to name a couple on our list.

Momentum is growing and the new contracts that will result from these will have a significant positive impact on our financial position when concluded.

Being covered by an LCD and having reached agreement with Kaiser Permanente will definitely assist in our negotiations with other targeted large scale customers and payers.

ADAPTING TO COVID-19: THE GLOBAL TELEHEALTH REVOLUTION

The COVID-19 pandemic has had a transformational effect on traditional healthcare.

The number of physicians using telehealth has grown significantly, with some organisations reporting up to 90% of their consultations being tele-consultations, up from around 30%.



Cxbladder now plays an important, enabling role in this new telehealth environment, allowing patient evaluation and assessment to be managed remotely. Our Cxbladder in-home urine sample process incorporates the delivery and of sample kits direct to patient's homes, oversight of the sample collection with one of our customer liaison managers, then collection and delivery to Pacific Edge laboratories for analysis, encryption and return of the result.

Given that many urology patients are in the +65 years age bracket and therefore at higher risk from COVID-19, it also helps to maintain social distancing, removing the need to visit busy medical centres or collection points.

The clinical utility provided by the Cxbladder in-home sampling programme has been recognised in both the USA and New Zealand. In New Zealand during the COVID lock-down, three large public healthcare providers have been actively using Cxbladder for in-home sample collection and two public healthcare providers have moved to mainstream commercial use from one and now on to two Cxbladder products. This has obvious benefits for patients and frees up essential healthcare capacity.

# QUOTE FROM DR NANCY GIN, KAISER PERMANENTE

In a MEDPAGE TODAY article, published in July, Dr Nancy Gin, the Executive Vice-President of Quality and, Chief Clinical Quality Officer for the Kaiser Federation, said..."that they [KP] had seen dramatic shifts in telemedicine, with remote healthcare visits increasing from about one in five visits before the pandemic to more than four in five. The speed with which this shift took place -- days and weeks rather than months and years -- stands as a collective accomplishment in the rapid evolution of care.

She also specifically mentioned Cxbladder, saying: "...similarly, patients can self-administer diagnostic tests to detect and monitor other conditions from home. For example, a simple urine test can be mailed directly to the homes of bladder cancer patients to monitor for the presence of cancer biomarker genes."

The global precedent has now been locked in place by the COVID pandemic, and we expect that teleconsultations will become more common practise going forward. In line with this, in-home sampling is also expected to become an accepted option for patients and physicians, even once the COVID-19 restrictions are eased. This provides yet another strong point of difference for our Cxbladder tests that is now being utlised by customers, such as Kaiser Permanente in the US and our NZ based public healthcare providers.

#### FY20 PERFORMANCE

We have already provided a lot of detail on our FY20 performance, in our results announcement and presentation and our annual report. I'll provide a short summary today.



# FY20 FINANCIAL SUMMARY

Our stated goal for the FY20 financial year was to continue the progression to achieving our pivotal commercial outcomes of Pacific Edge.... albeit with a similar net investment to the prior year..... We achieved this goal.

The key metrics we use to measure our progress are operating revenue, laboratory throughput and commercial test volumes. These all increased year on year.

Our financial results for the year ended 31 March 2020 include:

A 7% increase in Laboratory Throughput to more than 16,000 tests; a 14% increase in Operating revenue from test sales which was \$4.4m and we reported a Net Loss After Tax of \$(18.9)m.

#### NEAR TERM GOALS AND GROWTH CATALYSTS

Many of the foundations for commercial success have now been completed and adoption of Cxbladder and commercial sales are increasing.

We have identified opportunities for growth in all our targeted markets and are progressing in a number of key areas which will help us achieve our goals of growing our global reach, building and strengthening our customer base and increasing sales and adoption. All of which will drive greater cash revenue.

# USA - CATALYSTS

The USA remains our primary commercial focus and there are a number of catalysts which will drive our commercial growth:

The agreement with Kaiser and the coverage under the LCD will not only drive direct sales with those organisations but will also help us capture other large healthcare institutions and convert them to commercial customers.

We increased the number of US sales reps over the last quarter of FY20 to help drive growth in this market, and despite the impact of COVID-19, we are seeing an increasing number of healthcare organisations and urologists evaluating or commercially using Cxbladder. However, all-in-all we have seen a tougher than usual time in the USA over this COVID window, where many of the states are still in some form of lockdown and so access by our sales executives is limited.

We have a targeted list of institutions that have large scale commercial urology programmes in the US, that are currently using or evaluating Cxbladder and we will focus on getting these to emulate the Kaiser commercial outcome. We will also be working to add further large institutions to the list and to grow their commercial use. Concurrent with all of this, we will be putting a team of skilled negotiators to work on gaining in-contract status with the many private payers that are currently reimbursing us for Cxbladder.

We are planning to expand our specialist sales and customer service teams to take full advantage of the expected increase in adoption that comes from attainment of the LCD, the great endorsement from our agreement with Kaiser Permanente and to maximise the growth opportunity in the USA.



We will continue to invest in clinical evidence to support our adoption and are planning to launch our fourth product, Cxbladder Resolve, into the USA market following publication of the validation study late in the 2021 calendar year.

#### **REST OF WORLD**

In New Zealand, we are looking to bring the remaining public healthcare providers into contract and expand the use of Cxbladder tests by existing customers.

The focus for Australia and South East Asia is to transition the public health care providers from their clinical studies to a commercial customer model, as well as progress discussions with potential strategic partners in South East Asia. Right now these countries are still struggling with the COVID-19 pandemic and may take some time to return to normality.

#### NEAR-TERM OUTLOOK IS TO GROW OUR BUSINESS REVENUE

So in summary, our short to medium term focus is all about generating more revenue and improving cashflow.

Primarily it involves executing on the two recent commercial catalysts, the LCD for CMS patients and the commercial agreement with Kaiser Permanente. Both will require investment into additional resources to ensure we are able to leverage the opportunity and the anticipated increase in demand in a seamless and positive manner.

As well as future CMS tests, we will also be negotiating with Novitas for reimbursement for the 22,000+ tests done to date.

Inclusion in the LCD by the CMS also opens the doors for us to start contract negotiations with the more than 300 private payers who provide insurance to the 60% of our current commercial customer-base, to-date.

For Kaiser Permanente, our immediate next steps are further training for their healthcare professionals, and ensuring that our supply chain is in place and working at 100% effectiveness to provide Kaiser's urologists and their patients with our gold-standard of service and care.

The opportunity is then for further products to be adopted into use by Kaiser Permanente with the resulting revenue and cashflow benefits for our business.

Thank you.

ENDS