

## 2019 ANNUAL MEETING CHAIR AND CEO'S PRESENTATIONS

### **CHAIRMAN'S PRESENTATION: CHRIS GALLAHER**

#### **SLIDE 5: PACIFIC EDGE: CANCER DIAGNOSTICS COMPANY**

Our consistency of purpose and strategy has not changed and we continue to make progress in our commercial journey. We are very conscious that our pace in some areas is not as fast as we, or our shareholders, would like it to be.

As we have continued to learn, everything outside of our control in our space takes much longer than planned or hoped for.

Our goal remains to establish Cxbladder as the world's leading molecular diagnostic technology for the detection and management of urothelial cancer and to maximise the value of our technology for the benefit of our shareholders.

Pacific Edge owns world leading technology and intellectual property and we have a significant time based competitive advantage over the competition.

Urothelial cancer is primarily bladder cancer but also includes cancers of the upper urinary tract. It is the sixth most common cancer in the USA and the fourth most common in men. It has the highest recurrence rate of any cancer and the highest costs per patient. Traditional methods of diagnosis and monitoring are invasive, expensive and their performance falls short of physician's expectations.

Cxbladder provides a non-invasive, accurate and simple solution and our suite of tests is meeting the needs of physicians, patients and healthcare payors.

The US market remains our primary focus with a potential market opportunity of more than a billion US dollars.

In all our markets, we have increased our focus on large healthcare organisations, which can take longer to bring into contract but offer significantly higher, long term value and reimbursement.

We have a first mover advantage in urothelial cancer with 17 years of R&D behind us, and a growing portfolio of clinical evidence supporting the performance and clinical utility of our tests. We are now seeing growing adoption and commercial use of our tests by key opinion leaders and urologists.

#### **SLIDE 6: BOARD REPORT FY19**

As a Board, our focus is on overseeing the successful implementation of our strategy .... gaining commercial adoption of Cxbladder by large healthcare organisations in our targeted markets, and particularly the USA.

Our commercial approach was validated through an independent review by EY-Parthenon last year, which confirmed both the scale of the opportunity and our market strategy.

Key milestones are being achieved, both in the US and in our other markets of Southeast Asia, Australia and NZ.

Of particular note, we now have two of the three national reimbursement milestones required in the USA, which enables us to progress commercial discussions with healthcare payors and institutional organisations.

Gaining inclusion in the Local Coverage Determination for the Centres for Medicare and Medicaid is the third reimbursement milestone and it remains a critical focus for our team. This is an unprescribed process, based on published clinical evidence. Our library of peer reviewed clinical papers continues to grow with several new, very positive papers in recent months which we expect to be of benefit in the LCD review process.

In New Zealand, we have seen an escalation in uptake by the District Health Boards. Contract coverage is now over 60% of the population and we expect the other DHBs to follow their lead. Commercial test sales are increasing and we expect the NZ business to reach a cashflow breakeven position this year, which will be a major highlight for our company and will further support the validity of our commercial strategy.

Southeast Asia is a longer term opportunity but could one day be bigger even than the States. We are in the very early stages still, and have started with user programmes in Singapore. We hope to see these to start transitioning to commercial customers in the near future.

As I noted earlier, the timeline to broad commercial success has taken longer than originally anticipated but we are confident we are doing the right things and making progress in the areas that we can control.

Our reported loss for the year was \$17.9m, a \$2m reduction on last year and was in line with our internal expectations.

Pacific Edge has always been run on a tight budget, with funding support sought from shareholders in smaller increments and on a more regular basis, rather than large capital raisings.

We have constrained our expenditure on the US sales force last year and this has cost us some growth. This is always a difficult balancing act between conserving scarce capital resources and continuing to drive growth.

I would like to thank shareholders for their support for last year's \$12m capital raising, which saw a number of new investors also join our register. There is also growing interest from overseas investors in our company, which was reflected in last year's placement from Manchester Management Company in the USA, which raised \$2.6m.

Cash and cashflow management is very front of mind as you would expect from a growth business. The company had cash of \$12.8m as at 31 March 2019, and our cash burn remains in line with our expectations at about \$1.1m per month. We expect the escalation of commercial test sales, particularly in NZ, to have a positive impact on our operating cashflows.

Our focus for FY19 remains on completing commercial arrangements with large healthcare institutions in all our targeted markets. Obtaining the LCD for CMS reimbursement is also a priority. We will be working to bring on board the remaining DHBs in NZ and to expand our presence in Southeast Asia, and in Australia where we have now taken over the sales process.

I would like to sincerely thank the Board for their enthusiasm, skills, knowledge and support they have given me as Chair over the last year. Without singling any of my colleagues out, I will do so! Both John and Sarah have come onto the Board as part of our Board renewal process and have enthusiastically taken the Chair roles in our two most important Board Committees. We conducted an external review of your Board's effectiveness during the year and our benchmark outcomes were very pleasing. I believe that shareholders are well served by your Board.

Our company is uniquely placed to capitalise on the demand for better, more accurate, less invasive and more cost-effective diagnostics. We appreciate and thank shareholders for your patience and support and are working hard to deliver value for your investment in Pacific Edge.

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

### **SLIDE 8: FY19 HIGHLIGHTS AND MILESTONES**

Despite not achieving all of the goals we set for ourselves, FY19 was a year of strong progress with a number of achievements:

- Commercial sales and billable test volumes grew, with accelerated momentum in Q4, primarily driven from the growing adoption by NZ's public healthcare providers.
- We achieved two of the three milestones for US reimbursement.
- Our portfolio of clinical evidence has evolved and grown and we were added to the local guidelines for some of the large public healthcare providers in New Zealand giving us a strong Q4 revenue for our NZ based business.
- And financially, we reported an improvement in Net Operating Cash Outflow and Net Loss.
- We also completed a successful \$12m capital raise, providing us with the resources to continue on our strategic pathway.

### **SLIDE 9: FY19 FINANCIAL SNAPSHOT**

Under our financial reporting model, we only recognise revenue for US customers when cash payment is received. Revenue therefore excludes tests done for the CMS, which comprised approximately 50 percent of our tests in FY19. Once we receive the LCD, we will be able to negotiate with the CMS for reimbursement of our large back-log of more than 17,000 test invoiced to the CMS to-date.

In FY19, revenue was up 12%, total operating expenses reduced by 7% and a net loss of \$17.9m was a 9% improvement on the prior year.

Our focus on disciplined cash management saw net operating cash outflow reduce from \$18.1m to \$17.5m for the year, a 3% decrease on FY18.

US payment terms currently average between 7 to 12 months from completion of test to payment by relevant US payer (insurer). However, the introduction of national product specific CPT codes for Cxbladder Detect and Cxbladder Monitor in the USA, effective from 1 January 2019, has had a positive impact on cash collection rates in Q419 and this positive trend is expected to continue over FY20.

#### **SLIDE 10: FY19 KEY METRICS – LABORATORY THROUGHPUT**

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

The growing commercial adoption of Cxbladder can be seen in the percentage of billable tests, up to 81% of total laboratory tests compared to 74% two years ago.

Momentum is growing and we have seen accelerated growth in lab throughput, particularly in the last quarter of FY19.

Test volumes are well up on the same quarter last year, and the positive trends seen in Q3 to Q4 have continued into this financial year. This increase in commercial test demand is mainly being driven by the public health care providers in New Zealand, as more of them adopt Cxbladder at scale.

The US remains our biggest market with 80% of throughput, compared to 20% in 'Rest of World' markets which themselves have grown 83% year on year.

#### **SLIDE 11: COMMERCIAL PROGRESS BY REGION IN FY19**

In the last year, we made progress on many fronts that move our business forward. We are now growing our commercial base in all our target markets and building scale in our business.

#### **SLIDE 12: GROWING COMMERCIAL ADOPTION IN NEW ZEALAND**

Our home market of 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.

The majority of New Zealand's public healthcare providers are using Cxbladder commercially in their regions with a combined coverage of more than 3 million people, or over 60% of New Zealand's population. In some of these public healthcare providers, Cxbladder has also been added into clinical guidelines, replacing the gold standard cystoscopy in both the evaluation of haematuria and in the monitoring for recurrence of urothelial cancer.

Demand and commercial sales in NZ are exceeding our expectations and are expected to continue to grow as the remaining DHBs come on board and test usage grows.

While small in terms of test numbers relative to the US, this adoption by the majority of the New Zealand's national healthcare providers and the compelling look-back studies they have completed, are significant steps in terms of global credibility.

The actions being taken here lead the world and their demonstrable benefits have been transformational for urology healthcare here in New Zealand. This progress is being watched carefully by large healthcare institutions and leading urologists around the world, and are another step towards gaining wider adoption for Cxbladder.

#### SLIDE 13: **CONTINUED REIMBURSEMENT PROGRESS IN THE US**

The USA remains our primary commercial focus with an estimated addressable annual market opportunity for Cxbladder of around US\$1.2b, this was ratified by EY Parthenon in 2018.

Our tests can be used for the 7 million people who present annually with haematuria, the 3.4 million who require further workup for bladder cancer annually, and the 800,000 who need monitoring for recurrence of the disease more than 3 times per year. So you can see that this is a sizeable market where there has been no new commercial tests launched in 17 years.

There are three key reimbursement milestones required to fully enable reimbursement from both private and public payers in the US – receipt of CPT Codes; a national price; and inclusion in the Local Coverage Determination for the CMS. We have achieved two of these milestones and are working hard to achieve the third.

In March 2018, we received national product specific codes for Cxbladder Detect and Cxbladder Monitor. This is a big achievement as these 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. The panel of experts at the American Medical Association looks at the clinical evidence, the volume of tests used annually and, on the basis of their review, CPT Codes were issued in 2018 for two of our Cxbladder products. Currently Cxbladder Detect accounts for the majority of US sales, with Monitor following. A CPT code for Cxbladder Triage is expected to follow as adoption of Cxbladder Triage grows in the US.

In October 2018, we received notification of a national price for all Cxbladder tests of US\$760 per test.

The successful achievement of these two reimbursement milestones has allowed us to initiate negotiations for contract terms with private payers. On successful completion, these will enable a shortening of the overall administration of the payer transaction... that will help the urologist and provide an improvement in the time to receipt of cash for Pacific Edge.

Progress continues to be made with the process to obtain inclusion in the Local Coverage Determination, which will enable reimbursement for patients covered under the CMS.

The publication of peer reviewed clinical papers is a critical part of the LCD process and the recent publications in the prestigious European Urology journal and the real-world evidence on clinical utility

published in the NZ Medical Journal, will be expected to help drive positive reimbursement decisions with both private payers and the CMS.

**SLIDE 14: FOCUS ON INSTITUTIONAL HEALTHCARE ORGANISATIONS**

Across all of our target markets, we continue our focus on large institutional healthcare organisations. We have seen the impact our technology makes on these large healthcare providers who have burgeoning patient needs, few resources, aging populations and need to show value changes for their clinical services.

While these institutional customers can take longer to bring to completion, once commercial agreement is reached, they provide significant volume, require lower sales maintenance and deliver more sustainable, longer term growth opportunities with shorter cash conversion cycles. This is what we have seen over the last two years with the Canterbury public healthcare providers.

In line with this, we have transferred our NZ Sales Manager to replicate the successful New Zealand commercialisation model into Australia.

**SLIDE 15: KEY INSTITUTIONAL CUSTOMERS**

We have a growing list of large healthcare organisations using our tests.

In South East Asia, we have User Programmes underway with the five largest hospitals in Singapore. These are nearing completion and our focus will be on transitioning these hospitals to commercial customers and growing the adoption of Cxbladder by other large healthcare organisations in the region. We have started our commercial sales with the Raffles Medical Group and are building acceptance and experience with the use of Cxbladder in the Asian population.

In the US we have re-focussed our US sales team and added more resource for these institutions. We are in ongoing commercial negotiations and start up processes with multiple targeted institutional customers in the USA, including John Hopkins Medicine, which commenced a commercial evaluation of Cxbladder during the year.

**SLIDE 16: GROWING CLINICAL EVIDENCE FOR CXBLADDER**

We have generated in excess of 10 years of accumulated evidence 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 investment in the reimbursement milestones in the USA, increasing adoption in all our markets, and inclusion in NZ and USA guidelines.

**SLIDE 17: COMMERCIAL PROGRESS IN LINE WITH PEERS**

Published evidence is the key ingredient in driving positive reimbursement decisions and widespread adoption of Cxbladder with customers globally. With growing adoption will come inclusion into more international clinical guidelines, underpinning the expected acceleration in revenue for the company, as has been seen in other companies in the US who have traversed this path.

Just this month, we were advised that Cxbladder has been included in the latest version of the National Comprehensive Cancer Network (NCCN) Guidelines for Bladder Cancer in the USA.... as an approved clinical intervention for high-risk patients being monitored for the recurrence of urothelial cancer.

This is a pivotal commercial outcome for the company with the NCCN Guidelines widely recognised and used as the standard for clinical policy and practice in oncology by clinicians and payors in the USA. To be considered for review and inclusion in the NCCN guidelines requires an extensive portfolio of clinical evidence, a track record of clinical use, and broad adoption by physicians.

#### SLIDE 18: EUROPEAN UROLOGY PUBLICATION

The clinical evidence behind our Cxbladder tests is extensive and has shown to be commercially actionable. New publications, commercial look-backs and clinical utility studies consistently and repeatedly define the outperformance of Cxbladder compared to other tests used every day in the clinic, including the gold standard cystoscopy. This evidence supports Cxbladder's additional clinical utility; its patient benefits; and its ability to reduce healthcare costs. These are the features driving the successes that we have announced over the last 12 months and foretell the path forward in the other markets.

The most recent clinical publication has been in European Urology, the world's number one ranked urology journal with a reading audience in excess of 20,000 medical professionals globally.

This paper further extends Cxbladder's clinical utility for physicians and patients through its ability to remove the well-recognised diagnostic dilemma faced by physicians and patients alike - when the existing gold standard tests and procedures are not able to determine a clear diagnostic outcome.

In simple terms, Cxbladder delivered 100% accuracy in adjudicating all patients with urothelial cancer from amongst those with atypical and equivocal diagnostic results. This enabled physicians to resolve this diagnostic dilemma without the inconvenience and added cost of re-evaluating the patient.

Cxbladder also significantly outperformed cytology for accurately identifying patients who do not have urothelial cancer.

This real world outcome positions Cxbladder for consideration for inclusion in international guidelines which in turn will fuel broader acceptance and adoption by physicians.

Over the preceding years, many of our customers in the USA have been hampered in their commercial use of Cxbladder as the Cxbladder technology has not been specifically included in the guideline recommendations. So, inclusion in the NCCN Bladder Cancer guidelines is a major commercial inflexion point for us and will be of significant value as we progress our commercial discussions with our many urologist customers including the large healthcare organisations we are targeting.

**SLIDE 19: CLINICAL LOOK BACK STUDY**

Providing evidence of clinical utility is now a requirement for the issue of positive reimbursement and coverage decisions around the world. Physicians and payers need to be able to clearly identify the change in clinical behaviour that will come about when the technology has been adopted.

During the year Canterbury DHB published their commercial lookback following adoption and integration of Cxbladder into their standard of care, showing a significant increase in clinical utility from a reduction by more than 30% of cystoscopies they would otherwise have used.

**SLIDE 20: THE OPPORTUNITY FOR CXBLADDER**

I'd now like to take a few minutes to review what we are seeking to achieve with Cxbladder globally and the scale of the opportunity for our company....

**SLIDE 21: DETECTING AND MANAGING UC**

So why urothelial cancer? Well it's a horrible disease. It's largely a man's disease with 80% of patients being men and 20% being women. It's about blood in your urine and if you have urothelial cancer, it's about being monitored for most of your life with expensive and invasive procedures.

Urothelial cancer is a major global health problem and creates a significant healthcare challenge. It is prevalent, has high recurrence rates and is expensive to diagnose and monitor.

In the US alone, 3.4 million people are evaluated for UC every year, and over 81,000 new cases are diagnosed annually. Including those being monitored for recurrence of the disease, more than 800,000 patients are being managed for urothelial cancer at any one time, multiple times per year and all of these patients will benefit from the use of Cxbladder.

**SLIDE 22: CLINICAL PATHWAY FOR UC IN THE USA**

Haematuria is blood in the urine and is a key indicator of urothelial cancer. Up to 20% of all urologic visits are for haematuria, and up to 20% of Medicare patients present with haematuria annually. There are various causes for blood in the urine and the priority for the physician is to determine if the patient has cancer.

Every year in the USA, approximately 7 million patients with haematuria present to their primary care physician and are evaluated. 3.4 million of these are referred to a specialist for further work up. Historically, evaluation and workups involved an arduous regime of invasive and expensive tests, including cystoscopy which is a tube with a scope inserted into the urethra used to scan the bladder.

EY Parthenon has estimated in 2018 that the annual addressable market for Cxbladder tests is US\$ 1.2 billion. There have been no new diagnostic tests commercially available in urothelial cancer over the last 17 years. Cxbladder has global first mover advantage and has built all of the necessary evidence to enable a transformation in the detection and management of urothelial cancer. You have been witnessing it all happening first, here in NZ.

So why is Cxbladder so effective? Cxbladder allows for non-invasive testing using urine based, liquid-biopsy tests.

Patients who do not have cancer can now be removed from having a referral to urologists for a full work-up, very accurately.

Only those identified as 'at-risk' now require a further work up. Further evaluation by a urologist allows for the identification of high risk patients and allows treatment plans to be tailored to their needs.

The monitoring for recurrence of the disease is now easier and simpler for patients, using Cxbladder's unique sample container allowing them to complete the test at home and send it in for analysis, rather than having to visit their specialist.

Overall, using Cxbladder in the evaluation of haematuria in patients has been shown to repeatedly, reduce the need for cystoscopy by up to 60%. The test provides better and more detailed information for physicians, the non-invasive nature increases patient compliance with the monitoring regimen and it is providing significant cost savings for healthcare payers.

#### **SLIDE 23: PATIENTS DON'T LIKE INVASIVE TESTS**

The recent study by the Bladder Cancer Advocacy Network, on the regular use of cystoscopy, showed that the majority of patients receiving a cystoscopy reported moderate to severe discomfort, anxiety and pain.

Compliance by patients with the physician's recommendations is a major issue. A large 2011 study showed that physicians and patients are not following current recommendations, with only 1 out of every 4,545 patients receiving all the recommended measures for surveillance. The authors noted that the invasive nature and treatment strategies may play a part in non-adherence to clinical practice guidelines.

In a recent clinical paper, the use of Cxbladder on the evaluation of haematuria patients in NZ has been shown to lead to a 35% reduction in the use of cystoscopy and, for patients who are being regularly monitored for recurrence of the disease, more than 70% do not receive a cystoscopy, whilst providing highly accurate results for physicians.

#### **SLIDE 24: CXBLADDER: MEETING AN UNMET CLINICAL NEED**

Cxbladder's multiple products have been developed to meet the specific defined needs of urologist physicians and they represent a transformational shift in the way that bladder cancer is detected and managed. It's been tremendously exciting to see our products now being recognised in guidelines.....now to turn this into cash revenue.

#### **SLIDE 25: FY20 OUTLOOK**

This has been a journey of building foundations in a healthcare environment where the burden of proof is very high. Today we see that most of the foundations for commercial success have now been completed with

increasing recognition in local and national guidelines. The adoption of Cxbladder and commercial sales are increasing and we remain focused on completing the Local Coverage Determination as the key to our national reimbursement and a scale ramp in our revenue. Guidelines inclusion and the LCD will accelerate the adoption of Cxbladder as has been seen in other comparator molecular diagnostic companies.

**SLIDE 26: KEY OBJECTIVES FOR FY20**

We have a number of key objectives over the near term 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.

We have identified the key opportunities for growth in all our targeted markets and will continue to direct our time and resources to achieve these.

**SLIDE 27: PRIMARY FOCUS REMAINS THE USA**

The USA remains our primary commercial focus with an estimated annual market opportunity for our Cxbladder products of approximately US\$1.2b. Our test can be used for the 7 million people who present with haematuria, the 3.4 million who require further workup for bladder cancer, and the 800,000 who need monitoring, multiple times per year, for recurrence of the disease.

**SLIDE 28: POSITIVE GROWTH OUTLOOK**

Pacific Edge has been constantly treading new ground. Our tests are disruptive to conventional clinical pathways and as we have learnt, the adoption process in the US can be time consuming and requires substantial resource.

We are seeing accelerating momentum in commercial sales from new and existing customers and we expect this to continue.

Demand from public healthcare providers in New Zealand is expected to grow strongly and positively impact on laboratory throughput volumes and cash revenue.

Cash investment in our company is always one of our key focal points while we are still losing more cash than we make. We have held the US sales force at a lower level than planned to conserve our cash while we complete the CMS and LCD. FY20 total operating expenses are expected to remain in line with FY19.

Cxbladder test demand by US physicians is expected to be positively impacted in FY20 from having national product specific CPT codes for Cxbladder and a national CMS reimbursement price in place.

Our compelling dossier of clinical evidence, which is being published in top tier international journals, is expected to facilitate positive reimbursement decisions by both private and public payers over the near term.

The benefits and value our Cxbladder tests offer and the opportunities for our company are huge.

31 July 2019



We are making positive commercial progress and we thank you for your continued support as we work hard to attain our goals to make a step change in our revenue growth and realise our full potential.

ENDS