PACIFIC EDGE LTD

INVESTOR UPDATE

APRIL 2021

Pictured: Tessy George, Clinical Laboratory Scientist

IN THIS EDITION

WELCOME **FROM THE CHAIRMAN**

Over the last year we have seen the global community come together to tackle the COVID-19 pandemic. It has been very pleasing to see how Pacific Edge's people have responded so strongly in these challenging times.

We remain committed to delivering on our strategy to build a profitable business that will also ensure that more patients globally will have access to the best bladder cancer diagnostics now and into the future.

We are seeing the benefits of the significant effort and resources that have gone into building the business foundations and commercialising our suite of Cxbladder products, which addresses large unmet needs in the detection and management of bladder cancer. Despite having to work in a very challenging business environment, the Pacific Edge teams have adapted to a world of virtual selling and have concluded some major reimbursement milestones that have enabled a shortening in our time from test performance to cash receipt and a lift in our revenue.

After more than 18 years leading Pacific Edge from a research concept to a fully fledged commercial entity well positioned to deliver the global growth potential of its technology, CEO David Darling has announced his intention to retire from his role in April next year. This will be a carefully planned process, allowing plenty of time for a handover and seamless transition. Following this, Pacific Edge will continue to benefit from Dave's expertise and knowledge as he will take on a consulting role with the company.

The Board wishes to acknowledge the outstanding contribution Dave has made to Pacific Edge and the passion and sustained energy he has bought to the role over a very long period of time. Dave's expertise, persistence and perseverance in the face of challenges have marked him as an outstanding CEO. He has driven the development and execution of Pacific Edge's global strategy and the successful achievement of major commercial milestones in a highly competitive global market. The company is in a strong position, with world class products, a long term strategy and a vision which is now being realised and an outstanding team of New Zealand and international based people.

A formal process will be undertaken by the Board to appoint a new CEO to lead Pacific Edge as we take the next steps in our commercial journey.

Additionally, we have been pleased to add new skills to the Board with the recent appointment of Anna Stove as a Director. Anna has extensive international experience after a successful career with global pharmaceutical leader Glaxo Smith Kline and will contribute strongly to the governance of Pacific Edge as we continue with our global growth strategy. The appointment of Anna to the Board of Directors is another step in the process of Board rejuvenation that we have in process.

Thank you to our shareholders for your continued support.

CHRIS GALLAHER
CHAIRMAN PACIFIC EDGE

"David Darling has contributed hugely to the development and execution of Pacific Edge's global strategy and driven its commercial growth in a highly competitive market. His expertise, persistence and perseverance in the face of challenges have marked him as an outstanding CEO."

UPDATE **FROM THE CEO**

OUR TEAM HAS BEEN BUSY over recent months as we build on the commercial milestones achieved last year - firstly, reaching a commercial agreement with Kaiser Permanente; and secondly, inclusion in the Centers for Medicare and Medicaid Services (CMS) Local Coverage Determination (LCD) in the US from 1 July 2020, which enabled Cxbladder to be fully reimbursed for CMS patients going forward. These milestones paved the way for other service contracts as well as insurance coverage by United Healthcare.

Scaling up our commercial operations

We are now scaling up our business in the US to leverage these achievements and drive further commercial growth. Over the last six months, we have added six additional sales representatives in new territories with a further three to be recruited in early FY22. We have also recruited a Medical Science Liaison to provide more clinical input to urologist customers and further develop our Key Opinion Leader network; and additional in-house customer service representatives to help with the increased demand for our Patient In-Home Sample System (PIHSS). Finally, our senior leadership in the US has been strengthened with the addition of David Levison, who has stepped across from the Board of Directors to join the US executive team. David has been the founder and CEO of a high growth medical technology business in the US and has significant molecular diagnostics commercial experience.

Ongoing impact of COVID-19

The global COVID-19 pandemic has had a profound impact on the delivery of healthcare in the US, and around the world in general, and is likely to continue to impact through 2H21 and beyond. Many of the conventional detection, treatment and management paradigms have changed and of particular notice has been the rise of telemedicine and virtual selling, both providing positive opportunities and outcomes for Cxbladder.

Despite the negative impact of COVID-19, we are experiencing continued growth in test volumes and revenue, albeit at a rate that may be slower than could otherwise be expected in a COVID-19 free operating environment.

Our New Zealand business has recovered from the initial COVID-19 impact early in 2020 and, despite the continued disruption, continues to grow following the easing of ongoing lockdowns. The US business has largely recovered and continues to steadily improve. This is despite patients in the US continuing to struggle to get appointments with urologists due to restrictions on access to hospitals as well as reduced availability as many urologists have had added responsibilities in assisting with COVID-related care. In this environment, we have seen a pleasing uptake in the use of our home sample collection system. In addition, the US commercial and sales teams have adapted well to the challenges of virtual selling.

Centers for Medicare and Medicaid Services (CMS)

We are seeing pleasing progress in other areas too. Since we achieved LCD coverage for Cxbladder Detect and Cxbladder Monitor from 1 July 2020, we have received close to 100% payment for CMS patient claims, within 35 to 40 days. This has resulted in strong revenue growth and a significant improvement in our cash payment terms, noting that CMS related tests (Medicare and Medicare Advantage) accounted for 67% of our US commercial test volume in the first half of FY21. The LCD coverage also plays an important role by providing further in-market validation and is providing leverage for Cxbladder adoption and insurance coverage by other customers that we have been actively targeting.

Negotiations continue with the CMS for the reimbursement of the previously invoiced but unpaid Cxbladder tests done for CMS patients up to 30 June 2020. This is a long process and there is no certainty as to whether these tests will be reimbursed or at what price.

Kaiser Permanente

Following the commercial agreement with Kaiser Permanente (KP) last year, we have spent a significant amount of time working to integrate Cxbladder into their systems to ensure all Pacific Edge's supply chain logistics and the back end of the Cxbladder in-home sampling system are in place to provide our gold standard service for urologists and patients. This has gone well and commercial testing is

underway for patients who are scheduled for monitoring for recurrence.

COVID-19 has impacted the speed of the rollout across the KP network as California has been swamped with successive waves of new COVID-19 outbreaks. However, we expect test volumes to accelerate with the easing of COVID-19 related restrictions.

While KP has initially started with Cxbladder Monitor for monitoring the recurrence of disease in their patients, they remain positive about the commercial start-up of other Cxbladder products in the near future.

Growing commercial adoption of Cxbladder

In line with our growth strategy, we have targeted a number of large US healthcare organisations and institutions and are working with them to emulate the successful commercial outcome that we have achieved with KP. As a result of our efforts, a number are currently using or evaluating Cxbladder. The validation that comes from the CMS coverage and a commercial relationship with a renowned scale organisation such as KP, has made it significantly easier to gain traction as we approach other large institutions to expand adoption and commercial use of Cxbladder.

Physician owned organisations are another important customer group and we were pleased to recently announce the conclusion of a commercial agreement with Facey Medical Group in California. They are of a similar size to Mid-Central District Health Board in New Zealand and will be utilising Cxbladder Detect and Cxbladder Monitor for their patients. Whilst test volumes are not expected to be large compared to a healthcare organisation such as KP, it does demonstrate the ongoing commercial adoption of Cxbladder in the US as we continue to position Cxbladder as the preferred diagnostic test for urologists evaluating patients for bladder cancer.

We are also strengthening our team of skilled negotiators in the US who work on gaining in-network and, in some cases, in-contract status with private payers that are currently reimbursing us for Cxbladder tests and others that we have targeted to provide reimbursement coverage. Recently, we were pleased to advise that our Cxbladder tests are now covered by United Healthcare, the largest healthcare group in the US, for holders of their Medicare Advantage Medical Policy. This is a significant achievement and will be of benefit to millions of Americans seeking better clinical solutions and health outcomes for bladder cancer diagnosis. You can read more on this coverage announcement in this newsletter.

Growth catalysts and outlook

Our key objectives remain as follows:

- publish additional clinical evidence supporting the clinical utility of Cxbladder, to drive further reimbursement, coverage and guideline inclusion;
- achieve commercial contracts with other large institutional healthcare customers;
- grow the number of Cxbladder tests ordered and products used by our existing customers;
- gain stronger inclusion in clinical guidelines for the diagnosis and management of bladder cancer;
- expand reimbursement coverage with private payers in the US;
- continue to scale-up the business to meet the expected increase in demand for Cxbladder in all our target markets; and
- publication of the clinical evidence developed with large institutional healthcare providers in Singapore to drive the commercial adoption of Cxbladder in Southeast Asia.

I have recently advised the Board of my intention to retire as CEO in April 2022, though I will continue to support the company in a consulting role. It has been a great privilege to have worked with such an outstanding team over the past 18 years, all of whom share the same passion for delivering better ways to diagnose and monitor cancer.

Pacific Edge has a fantastic team, with proven performance and is well positioned to deliver the significant growth opportunities ahead of it. With the achievement of several major commercial milestones, the company is now in a new stage in its evolution. I believe that it is the right time for me to begin the process of succession to ensure a seamless transition over the next 12 months.

I look forward to seeing the company's continued growth and development in the ensuing years.

DAVID DARLING
CHIEF EXECUTIVE OFFICER

FOCUS ON GROWTH IN **THE US COVID ENVIRONMENT**

The COVID-19 environment has raised a number of challenges for our US sales team. In particular, access to urology offices has been extremely limited with restrictions on all non-essential visitors including Pacific Edge's sales professionals. This limits our ability to remind, educate and update urologists about our products, Medicare coverage, new published Cxbladder performance evidence and key sales messaging such as the ability to support urologists with the convenience and utility of the Cxbladder in-home sampling system.

The frequency of patient visits to medical centres and doctors' offices has also declined significantly.

This has led to the rapid and wide adoption of telemedicine over the past year, which is one of the few positive outcomes of COVID-19. Our Patient In-Home Sampling System (PIHSS) is ideally suited to be used in conjunction with telemedicine during this time when patients are restricted from travelling to medical centres.

Our PIHSS has been viewed as a real advance in urologic care by those who have utilised it, providing a valuable service to our clinicians and patients, while helping to maintain the sales of Cxbladder during the pandemic despite lower patient volumes. It is widely accepted that the future healthcare operating environment will include telemedicine as a key component of its delivery mechanism, which plays to Cxbladder's strength.

Another challenge which has directly impacted our ability to build and nurture relationships has been a lack of in-person urology conferences globally because of the pandemic. These have historically been a major source of selling opportunities to current customers and prospecting for new urologist customers. While they have been replaced by virtual exhibit halls, these have not been as effective as face-to-face sales opportunities.

To mitigate and overcome these COVID-related restrictions and challenges, Pacific Edge has transformed its sales strategy, with a focus on maximizing virtual sales contact and programs as well as significant marketing efforts to reach customers (urologists, staff, and patients) through both traditional and alternative digital channels. We have redesigned our messaging to be simple, of high value and relevant to the COVID-19 operating environment. The focus has been our CMS coverage and the PIHSS.

We have deep and long standing relationships with many urologists and, as a result, our follow-up calls are more likely to be heard, giving us greater access than others. Our direct-to-patient marketing efforts have resulted in more patient inquiries and creating awareness with new clinicians who are adopting Cxbladder. These tactics have delivered positive growth results for the company.

The molecular diagnostics selling environment in the US continues to be very challenging and is ever changing. Some parts of the country are seeing some easing of restrictions, while others are not. Our sales and marketing team are constantly assessing the various geographic challenges and altering strategies to seize the opportunities and mitigate the challenges to successfully grow the Cxbladder business.

JACKIE WALKER
CHIEF EXECUTIVE OFFICER PEDUSA

PORTFOLIO OF POSITIVE CLINICAL EVIDENCE **CONTINUES TO GROW AND DRIVE ADOPTION**

Significant Clinical Utility Gained from Cxbladder Triage

Published clinical evidence is the trading currency for positive reimbursement decisions, inclusion in guidelines and wide adoption by physicians.

Our most recent publication of peer-reviewed clinical evidence was in December 2020. This independent real-world study highlighted the sustained outperformance of a new clinical standard of care adopted by the Canterbury District Health Board (CDHB) in New Zealand. This new standard of care utilises Cxbladder Triage as the sole urine diagnostic test to be used in combination with imaging for the investigation of all patients who present with blood in their urine (haematuria), a key symptom of bladder cancer.

The results from this publication provided significant evidence supporting the use of Cxbladder Triage in everyday commercial practice as a rule-out test for both low and high-risk patients undergoing investigation for haematuria.

The study concluded that Cxbladder is consistently able to correctly identify those patients who can be assessed in primary care without the need for secondary care referral.

This outcome significantly reduces the burden of invasive and expensive cystoscopic evaluations and spares patients the potential risks, discomfort and anxiety from having a cystoscopy, without compromising detection rates for bladder cancer. It also allows healthcare resources to be better focused on patients most in need.

READ THE FULL ANNOUNCEMENT HERE

UNITED HEALTHCARE ISSUES POSITIVE COVERAGE DECISION FOR CXBLADDER

United Healthcare is the largest healthcare group in the US, with over 50 million members including more than 5.7 million Medicare Advantage members.

Effective from 1 April 2021, Cxbladder is now being covered as a 'medically necessary bladder tumor marker test', under United Healthcare's Molecular Pathology/Molecular Diagnostics/Genetic Testing (Medicare Advantage) - Medical Policy.

This follows from the positive coverage decision issued by the Centres for Medicare and Medicaid Services (CMS) in 2020, with millions of Americans now covered for use of Cxbladder non-invasive, highly accurate tests for the detection and management of urothelial and bladder cancer.

Over the last six months, we have been expanding our US sales team to deliver on the growth opportunities available to Cxbladder.

These specialist sales people will continue to work closely with urologists whose patients are covered by the CMS and United Healthcare, to encourage and support them in their use of our Cxbladder products.

In 2019, UnitedHealth Group had a 14.1 percent share of the U.S. health insurance market, with direct premiums written amounting to approximately US$107 billion. The organisation partners with 6,500 hospitals and care facilities nationwide, and more than 1.3 million physicians and other providers.

DAVID LEVISON

EXECUTIVE CHAIR, PEDUSA

"The positive coverage decisions by the CMS and United Healthcare reflect the validation that comes from independent published clinical evidence. These successful coverage decisions add further validation of Cxbladder and a point of inflexion for other healthcare insurers."

David Levison

UNDERSTANDING OUR BUSINESS:
US ACADEMIC MEDICAL CENTRES

The US healthcare system is made up of a large number of very different healthcare providers, from sole practice clinicians, to large community practices and large urology group practices through to separately funded federal institutions like the Veterans Administration and the CMS, as well as large integrated healthcare organisations such as Kaiser Permanente.

Academic Medical Centres are another type of large scale provider. These are educational institutions, usually Universities with their own large healthcare provider businesses. They often integrate a medical school with a teaching hospital and healthcare system. They are built on the concept of unifying medical education, research and care.

These Centres provide teaching and real-world experience, as well as being the epicentres for leading edge clinical research, and are influential in driving innovations in medicine and healthcare that benefit their patients. While such institutions account for just 5% of hospitals in the US, they account for nearly 25% of clinical care based on total hospital revenue. Approximately 27% of all US urologists practice in an Academic Medical Centre[1]. Accordingly these are key commercial targets for Cxbladder adoption and use.

There are more than 120 of these types of organisations in the US and they include well known names such as The Johns Hopkins Hospital and the Mayo Clinic. Another example is the Keck School of Medicine of the University of Southern California, which is ranked in the top 10 in urology in the US. Their urology team includes more than 65 board-certified urologists, radiologists, oncologic surgeons and specialised pathologists who are proficient in the most advanced diagnostic, surgical and recovery approaches.

These Academic Medical Centres are an important customer group for Pacific Edge and a number of them, including Johns Hopkins, the Keck School of Medicine and the Cleveland Clinic, are either actively using Cxbladder or are currently involved in User Programmes to validate the effectiveness of Cxbladder in their particular clinical setting. Our focus is on converting these influential healthcare providers into large scale Cxbladder commercial customers in the future.

[1] 2019 The State of the Urology Workforce Census Book

WELCOME TO ANNA STOVE, **NEW INDEPENDENT DIRECTOR**

From 15 March this year, we were pleased to welcome Anna Stove to the Pacific Edge Board of Directors, as an Independent Director. This brings our Board to a total of six Directors with a corresponding increase in the diversity of skills and thinking.

Anna has global executive experience and a successful 25+ year track record in leading and driving transformational change within the healthcare sector. She has held a number of governance roles with private and listed organisations and is currently Chair of Global Women New Zealand and a Director of Rua Bioscience and TAB NZ. Anna was the General Manager of GlaxoSmithKline New Zealand for seven years and prior to that, held a number of senior roles with multinational science-led healthcare companies across Europe and Asia.

Anna will hold office until Pacific Edge's 2021 Annual Meeting at which time she will offer herself for election by shareholders.

Listen to Anna Stove talk about her role on the Pacific Edge Board here: https://youtu.be/LbRzSGOG_4w.

"I am excited to be joining the Pacific Edge Board. I've been impressed with Pacific Edge's patient centric approach with their Cxbladder tests, which is positively disrupting the urology landscape globally." **Anna Stove**

INTRODUCING TONY LOUGH, **VP CLINICAL SCIENCE AND PRODUCT PERFORMANCE**

Tony joined Pacific Edge in 2016, bringing extensive research management experience to the team. He was previously CEO of a government-university funded enterprise that was built to provide a national genomics infrastructure to the research sector. Prior to that he was a genomic team leader at the Auckland-based biotechnology company, Genesis Research and Development Corporation, leading projects in the commercialisation of macromolecular signalling.

In his role at Pacific Edge, Tony is responsible for building the data that drives the evidence generation that is used by the company to gain traction with the physicians. This includes designing, implementing and analysing the outcomes of clinical trials using Cxbladder in different settings around the world. This also includes looking back at the full clinical trials database and working out how well the tests performed. We asked Tony for his feedback on the importance of clinical evidence and the impact COVID-19 has had on his role.

> "Cxbladder is cutting edge diagnostic technology and if myself or someone I knew had haematuria, I would definitely advise them to use Cxbladder." **Tony Lough**

Why are clinical trials important?

Credibility of Cxbladder rests on peer reviewed evidence provided by publication within international journals. The potential of molecular diagnostics technology (such as Cxbladder), like that of any diagnostics technology, depends on clinically validated performance and on the increase in clinical utility when the new technology is adopted. Coverage by the CMS, United Healthcare and other payers for a molecular diagnostics product or test can be obtained through the demonstration of its clinical utility, particularly in terms of how a new test can improve patient outcome.

Proving the utility of a test involves clinical data generation often in a real-world setting and can be likened to a technical lookback on the overall performance of the new product.

It is also necessary to evaluate analytical validity (the

accuracy, precision, and reproducibility of test results) and clinical validity (how well a test can determine the presence, absence, or risk of disease). Definitive increase in clinical utility, without harm to the patient, is becoming an increasingly important criterion for the market success of new molecular diagnostics.

Successful clinical trials are an ongoing significant investment for the company and have been the catalyst for many of our achievements to date. In particular, coverage with CMS and United Healthcare Medicare Advantage, commercial agreement with Kaiser Permanente and the high level of adoption amongst New Zealand's public health providers are all examples of how our clinical evidence generates a commercial outcome.

We are continuing our investment into clinical evidence to drive further niche clinical applications, stronger customer adoption, positive decisions on inclusion into guidelines and broader guideline inclusion language.

How does molecular diagnostics compare to traditional diagnostic tests?

Cxbladder, a non-invasive, high performance and easy-to-use urine test, is built on molecular diagnostics which offers a number of benefits above other traditional testing, including greater precision and high sensitivity. Molecular-based diagnostics now account for around one-eighth of the global market – a real opportunity for growth – while showing great promise for improved outcomes in so many diseases.

How has the COVID environment impacted on your role?

The pandemic has had a notable negative impact on our ability to recruit patients into the studies that we have running around the world. Pacific Edge is currently running the world's first randomised control trial using Cxbladder as a detection and management tool for bladder cancer. This study requires recruitment of low risk patients in order to provide evidence that it is possible to safely not undertake cystoscopy for low risk patients. Initially, the pandemic restrictions meant that patients were declining to go to clinic or were deliberately managed by clinics using a telemedicine approach. This has had a negative flow-on effect on our recruitment numbers into the trial. Pleasingly however, as time has passed in the new COVID-19 world, the number of patients returning to the clinic and recruited to studies has improved.

STAY IN TOUCH

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KEY DATES

27 May: FY21 Financial Results Announcement

End-June: Annual Report Released

29 July: Shareholder Meeting

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