

# INVESTOR UPDATE

OCTOBER 2020



PACIFIC EDGE LTD

## DEAR SHAREHOLDER

The last few months have been an exciting and transformational time for our company and our shareholders, as we have successfully achieved two of our most significant commercial milestones in the US whilst the world has been grappling with a pandemic.

Firstly, we reached agreement with Kaiser Permanente, one of the US's largest and best regarded healthcare providers, to commercially use our all of our Cxbladder products in the US.

Secondly, after a long and protracted period of clinical evidence development, Cxbladder has now been covered by the Centers for Medicare and Medicaid Services (CMS). Coverage by the CMS's LCD was the final of the three elements needed to gain national reimbursement for the approximately 62 million<sup>1</sup> people receiving insurance coverage by the CMS in the USA. We have now had two full months of revenue from the CMS, with all of our eligible claims being paid to date. This is the key driver enabling our US business to post monthly record revenues in August and September.

To conclude these outcomes during the COVID-19 pandemic is testimony to the relationships that we have built over time with these organisations and the proven, outstanding performance of our Cxbladder technology.

It has also been a time of significant challenge as we have navigated the world of urology during the global COVID-19 pandemic. Our focus remains on keeping our people safe and keeping our operations team functioning to provide the essential service that makes such a big impact on the patients with or who are suspected of having bladder cancer.

### Turning up the gas on growth

For our company, these two outcomes have triggered a scale-up of our commercial operations and our teams to deliver on the growth opportunities that are now available to us in the US and our other targeted markets.

There are three separate initiatives underway. First; we are underway with the expansion of our direct sales force in new sales



## IN THIS EDITION:

- Turning up the Gas on Growth
- Getting in close to Kaiser Permanente
- Medicare and Inclusion in the LCD
- Ongoing Impact of COVID-19
- Our Short and Near Term Focus
- 2020 Annual Shareholders' Meeting
- Cxbladder In-Home Sampling Program
- Growing our US Reimbursement
- A Day In The Life Of.....Jim DeMarco

<sup>1</sup> <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts>

territories in the US, who will focus on large urology and community practices and encourage them to use our Cxbladder products.

Second; our specialist sales executives are focussed on converting other large institutional customers in the US and leveraging the great validation milestones from Cxbladder's coverage in the CMS's LCD and our commercial relationship with Kaiser Permanente.

Third; we are expanding our customer services liaison team as we work with Kaiser Permanente and others who are using the Cxbladder patient in home sampling program.

Our laboratories in both New Zealand and the US have plenty of existing testing capacity to cope with the expected increase in demand for Cxbladder.

#### **Getting in close to Kaiser Permanente**

Since reaching commercial agreement with Kaiser, the Kaiser and Pacific Edge teams have been focussed on the integration and inclusion of Pacific Edge's Cxbladder logistics and supply chain Cxbladder into Kaiser's ordering systems and Health Connect, their Electronic Medical Records system. Health Connect provides the final test results back to the urologist in the format and on the standard system that Kaiser use to manage their patients, and will facilitate easy access for review of patient results by the physician.

It is critical to a successful outcome in this relationship that the urologist user-experience is first class. We have been integrating and testing our services and our supply-chain logistics with Kaiser's electronic ordering process so that Kaiser urologists and their patients, experience our gold-standard of service and care. We expect to have the majority of this work completed shortly, enabling Kaiser to start ordering commercial tests.

#### **Medicare and CMS Coverage**

Attaining CMS coverage in the Local Coverage Determination, or the LCD, is one of our biggest achievements to date and enables Pacific Edge to receive reimbursement for the many CMS patients that utilise Cxbladder. With more than 43% of our US commercial tests being for CMS patients, we are now seeing a significant increase in our recognised revenue and cash receipts.

Although tempered by the continued COVID-19 impact in the US, with many patients still unable to visit a clinic, we are nevertheless continuing to see growth in the numbers of tests we are processing each month for patients covered under Medicare and Medicare Advantage.

The first payments for claims submitted under the LCD have now been successfully processed and the cash received. As more hospitals and clinics re-open, we expect to see test numbers and revenue continue to increase.

#### **Impact of COVID-19 will be felt for some time**

While we are on a very positive growth trajectory, our outlook has been somewhat tempered by the ongoing impact of COVID-19 for businesses, healthcare organisations, people and patients around the world.

The escalation of COVID-19 in March through to July 2020, in the US and around the world, saw our test numbers and revenue drop as urologists scrambled to work out how best to manage their patients, many of whom are over 60 years of age and are considered 'at-risk'.

As more healthcare providers transitioned to telehealth, urologists saw the opportunity to use

the Cxbladder urine sample collection system as a means of keeping people at home while also being able to keep on top of clinical needs for evaluation for disease. More urologists started to utilise our Cxbladder patient in-home sampling programme (PIHSP) and test numbers and revenue have begun recovering and trending upwards to our expected performance numbers.

In New Zealand, monthly test volumes have recovered strongly from their April lows with total lab throughput for the month of September recording a 55% year on year increase. In the US, monthly test volumes have largely recovered from their April lows. However, we expect COVID-19 restrictions will continue to have a negative

impact on US lab throughput numbers until those restrictions are eased.

It has been a tribute to our team that we have been able to lift and grow the business despite the many challenges presented by COVID-19.

Whilst the PIHSP helps our growth, it is not necessarily a panacea for all people in all situations to deal with the challenges presented by COVID-19 and we have yet to see how dominant it will become in our commercial programme post-COVID-19.

### **Our short to medium term focus**

As we outlined at our recent annual shareholders' meeting, our short to medium term focus is all about generating significant growth in the number of commercial tests processed in our two laboratories, contributing revenue growth and improving cashflow.

Specifically for the US this involves executing on the two recent and positive commercial catalysts, Cxbladder's coverage in the LCD for CMS patients and the commercial rollout within Kaiser Permanente. Both will require investment in additional resources to ensure we are fully leveraging these commercial opportunities and the anticipated increase in demand in a seamless and positive manner.

Cxbladder's coverage in the LCD by the CMS is now opening the doors for Cxbladder to be further recognised by some commercial insurance providers and insurance networks. Of the more than 500 private payers in the US we are focusing on the top 100 private payers who account for approximately 80% of all commercial payer transactions. Of these top 100, approximately 30 cover the majority of our current patient private insurance coverage. We intend to use a new dedicated contracted team of specialists to carry out negotiations for coverage by the remaining commercial payers.

With Kaiser Permanente, our future growth opportunity is to follow the successful integration of Cxbladder Monitor with our other Cxbladder products, thereby delivering further growth in revenue and cashflow for our business.

In New Zealand, we are continuing the work to bring the remaining public healthcare providers into contract and to expand the number of Cxbladder products in mainstream commercial use by our existing customers. Our goal is to get the New Zealand business to a break-even position as soon as possible.

The focus for Australia and Southeast Asia is to transition the public health care providers from their clinical studies to commercial customer relationships and to consequently grow commercial test volumes for these new markets. We have now concluded the recruitment of patients into the Singapore User Programmes at the five public hospitals and are underway with the analysis of the data. We will continue to progress discussions with potential strategic partners in Southeast Asia in conjunction with the large public healthcare providers.

At a time when many companies have been crippled by COVID-19 and are reporting significant losses on a prior comparative period basis, we have been successfully able to weather the global pandemic, significantly de-risk the company through the achievement of two major commercial milestones, further strengthen our balance sheet and continue to grow our business. We look forward to keeping you updated on our progress, when we release our FY21 half year results in November 2020.

Thank you for your continued support.

**David Darling**  
**Chief Executive Officer**

## 2020 ANNUAL SHAREHOLDERS' MEETING

This year, given the COVID-19 environment, we made the decision to hold our Annual Meeting virtually. We had great participation online, with more than 100 shareholders joining the meeting and a record number of questions.

The meeting provided an opportunity to talk in more detail about our recent achievements and the progress our company is making. If you are interested, we encourage you to view the presentation and speeches on our website at: [www.pacifiedgedx.com/investors/shareholder-meetings/](http://www.pacifiedgedx.com/investors/shareholder-meetings/).

All resolutions were passed by shareholders, comprising the following:

- Re-election of Bryan Williams as a Director of the Company.
- Re-election of David Darling as a Director of the Company.
- Authorised the Directors to fix the auditors' remuneration for the ensuing year.

---

## GROWING VALUE FROM CXBLADDER PATIENT IN-HOME SAMPLING PROGRAM

While New Zealand was quick to react to control the spread of COVID-19, the USA, our largest market for our Cxbladder tests, is still facing significant challenges with new waves of re-emergence COVID-19. This has seen the closure of hospitals and clinics and at-risk patients remain hesitant to leave their homes to visit busy medical centres, hospitals and collection points unless absolutely necessary.

This is where the value offered by the Cxbladder patient in-home sampling programme is really coming to the fore. In New Zealand, we have seen several DHBs actively using Cxbladder for in-home sampling for many of their patient referrals and, in the US, uptake is also increasing.

Kaiser Permanente will also be using the Cxbladder in-home sampling programme with their patients. The Cxbladder sample collection system will be sent to patients who are scheduled for their next clinical evaluation for monitoring for recurrence of bladder cancer. This will allow them to provide a non-invasive urine sample in the privacy and safety of their own home and for the physician to maintain an active clinical surveillance of their patients.

The use of Cxbladder in this home setting resets the traditional face to face patient care model and is of particular relevance and importance during this global pandemic. We would like to see this become the 'normal' for managing patients over these challenging times where it is not possible to bring them into clinic. Telehealth has become a more mainstream component of patient health management and we expect to see Cxbladder continue to benefit as in-home sampling becomes a more integrated and valued alternative for many patients and physicians around the world.



## BUILDING OUR REIMBURSEMENT IN THE US

The US healthcare reimbursement system consists of a mix of public and private third-party insurance coverage with approximately 18% of the US population covered by Medicare public insurance and 67% covered by private insurance<sup>2</sup>.

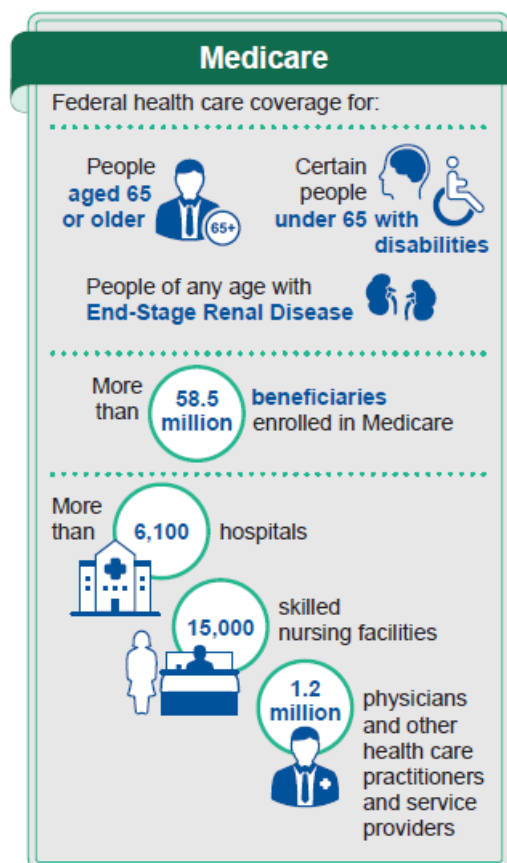
Medicare is the public health insurance scheme for all US adults aged 65 years and over, and provided through the CMS. The recent coverage of Cxbladder by the CMS's LCD has now enabled Pacific Edge to receive reimbursement for Cxbladder tests ordered by the physicians for their Medicare patients. Right now, approximately 43% of all of our commercial Cxbladder tests in the US are carried out for patients who have Medicare coverage and another 28% are for patients with Medicare Advantage plans. As a result, approximately 71% of our commercial tests in the US are currently for Medicare and Medicare Advantage patients.

The remaining 29% of our current commercial tests are for patients covered by private commercial insurance companies, making these commercial payers a significant contributor to our reimbursement and one of the focal points for our future growth.

The US market consists of approximately 500 regional and national commercial payers. The top 100 commercial payers account for approximately 80% of the private pay covered lives in the US and include companies such as United Healthcare, Blue Cross Blue Shield, Aetna and Humana. Of these top 100 there are approximately 30 commercial payers who currently provide the majority of our reimbursement for patients with private healthcare insurance in the US.

In addition there are also other large healthcare systems in the US, such as Kaiser Permanente which offer their own healthcare insurance plans. Reaching commercial agreement with Kaiser Permanente for all of our Cxbladder products in the US, is a significant vote of confidence in our Cxbladder technology. It also provides external validation for Cxbladder with other large commercial payers that we are seeking coverage and reimbursement from in the US.

Our focus over the next 12 to 24 months is to work with the top 100 private payers to gain coverage and inclusion in their reimbursement networks, thereby ensuring rapid and repeated reimbursement payments for the Cxbladder tests processed for their patients. As our test volumes grow and the mix of customers changes we expect the proportion of tests contributing to our revenue to change.



<sup>2</sup> <https://www.census.gov/library/publications/2019/demo/p60-267.html>



## A DAY IN THE LIFE OF.....

### JIM DEMARCO VICE PRESIDENT OF INSTITUTIONAL ACCOUNTS AND PAYER RELATIONS

Institutional and Payer Accounts are two market sectors that have a major impact on our business in the US and currently make up approximately 29% of Pacific Edge's commercial tests sales. These types of accounts typically demand their own specialised strategy and commercial execution due to their increased bureaucracy and cross functional key stakeholders involved in diagnostic testing decision making.

Jim DeMarco is responsible for leveraging into the US market the recent commercial successes with Medicare and Kaiser Permanente. The key components that we leverage to grow our US sales include building and sustaining relationships with key opinion leaders in urology, dissemination of Pacific Edge's pivotal clinical evidence dossier to build urologist awareness, and recognition and inclusion in the national bladder cancer guidelines. Iteration of these key components on a daily basis help us to refine our commercial plans and deploy our sales resources in an optimal way resulting in further awareness and broader use of Cxbladder products.



#### **Payer Accounts**

Our recent announced Medicare coverage is a game changer for our commercial business in the US and will allow us to be more aggressive in pursuing commercial payer access and potential contracting where appropriate. The key is to tailor our clinical evidence to meet the specific perspective. Over the short to medium term we will continue building and shaping our US sales team by adding additional National Account Managers to our team who have strong commercial payer relationships. This will further strengthen our sales reach in the US and will assist us in executing on our goal of entering into new commercial agreements with the other commercial payers we are targeting in the US.

#### **Institutional Accounts**

These are large academic and institutional accounts, such as John Hopkins, Intermountain, Geisinger and the University of Southern California to name a few of our targeted institutional customers. Our US sales strategy continues to focus on converting more of these high volume institutional accounts into commercial customers to broaden the commercial reach of Cxbladder and to increase commercial usage.

As you can imagine, time is valuable for our targeted commercial payer and institutional account customers. We spend a lot of our time each day collaborating across our team to ensure the most effective messaging and presentation is made for each target customer. This includes ensuring we have the market research and analytics to inform our messaging and Cxbladder's value proposition for each target customer. We work with several in-market commercial specialists to gain insights for these customer meetings. Making sure we are regularly contacting the right person in each organisation is also an important part of our sales process.

Another great way to meet with key Institutional Account customers has been through Bladder Cancer conferences. Of course, these have been dramatically affected by COVID-19 so we've had to adapt our sales strategy to the current environment. As a result, we are now doing a lot more "virtual selling" by reaching our target customers through digital marketing, phone calls, emails, Zoom meetings, webinars, and various conventional marketing initiatives such as product mailers, print advertising and other promotional efforts. We've also adapted our product offering to have an increased focus on the benefits of our patient in-home sampling program.

Scale adoption of Cxbladder by select healthcare institutions remains a key commercial focus for Pacific Edge in all markets, but particularly in the US. Commercialising healthcare technologies such as Cxbladder which disrupts common urology practice, comes with many challenges. However, Pacific Edge is now in a unique

global position, with a first mover advantage, a large addressable market, high profile validation customers and proven products that deliver better care for patients, better utility for urologists and savings for the payers.

## STAY IN TOUCH

### ENEWS

We encourage our shareholders to sign up to receive email notification of news and announcements from Pacific Edge.

[Sign up here](#) or visit the Investor Centre on our website [www.pacifiedgedx.com](http://www.pacifiedgedx.com).

### KEY DATES

FY21 1H Financial Results Announcement: 26<sup>th</sup> November 2020

FY21 Financial Year End: 31<sup>st</sup> March 2021

### FOLLOW US

[www.facebook.com/PacificEdgeLtd/](https://www.facebook.com/PacificEdgeLtd/)

[www.facebook.com/Cxbladder/](https://www.facebook.com/Cxbladder/)

[www.twitter.com/PacificEdgeLtd](https://www.twitter.com/PacificEdgeLtd)

[www.twitter.com/Cxbladder](https://www.twitter.com/Cxbladder)

[www.linkedin.com/company/pacific-edge-ltd](https://www.linkedin.com/company/pacific-edge-ltd)

[www.bladdercancer.me](http://www.bladdercancer.me)

### CONTACT US

87 St David Street

P O Box 56, Dunedin, New Zealand

T +64 3 479 5800

E [enquiries@pelnz.com](mailto:enquiries@pelnz.com)

[www.pacifiedgedx.com](http://www.pacifiedgedx.com)