

INVESTOR UPDATE

MAY 2020



PACIFIC EDGE LTD

DEAR SHAREHOLDER

The last few months have been a time of significant challenge for people and businesses around the world. As we all navigate the restrictions created by COVID-19, I hope you and your loved ones are staying well and safe. Our thoughts are with those who have been affected by this pandemic.

We have continued to operate as an essential business

Pacific Edge has been operating as an essential business during this period, playing an important role in supporting medical practitioners by providing timely evaluation and diagnosis of bladder cancer.

Ensuring our people remain safe while continuing to work is a priority. Our laboratories in New Zealand and the USA already operate under very high standards of hygiene and safety, and we have also established separate teams, safe distancing and extra cleaning and sanitisation. I would like to acknowledge and thank all our people who are continuing to provide important diagnostic services to our communities during this time.

Growing recognition of the benefits of Cxbladder's in-home sampling solution

The COVID-19 global pandemic and the stay-at-home restrictions that have been subsequently introduced, have resulted in many healthcare providers and urologists around the world grappling with how to provide the best quality care for their patients. As a result, urologists have been increasing their use of telehealth and video consultations where possible, with procedures and consultations continuing for high risk patients or being delayed for those considered lower risk. However, patient concern is also something that urologists are taking into account with many patients saying they don't want to wait a long period of time to get the reassurance they require.

Cxbladder's in-home sampling programme is proving itself to be a unique solution, allowing for in-home testing for patients, with a minimum of face to face contact. Based on their test results, many patients are able to defer having further assessment and invasive procedures to a later date. This allows patients to stay safe in their 'bubbles' at home and also frees up essential healthcare capacity.

To highlight this growing interest, at the end of this newsletter, we have included some recent examples of how the Cxbladder in-home sampling programme is currently being referenced to great effect in the USA.

The clinical utility provided by in-home testing for haematuria and for patients being evaluated for the recurrence of bladder cancer is also being recognised in New Zealand, with two large public healthcare providers having recently commenced in-home sample collection using Cxbladder (see further details below).

New Zealand's public healthcare providers add further Cxbladder tests to their commercial use

Cxbladder is already being commercially used by 11 of the 20 District Health Boards (DHBs) in New Zealand, covering approximately 62% of New Zealand's population and we are working hard to get the remaining DHBs up and running.

Extended Use of Cxbladder Tests

In April, two of New Zealand's largest public healthcare providers (Counties Manukau Health and Waitematā District Health Board), increased their commercial use of Cxbladder by adding a second Cxbladder test to mainstream use. Counties Manukau Health has added Cxbladder Monitor to its existing use of Cxbladder Triage and Waitematā District Health Board has added Cxbladder Triage to its existing use of Cxbladder Monitor. Together, these two DHBs cover a population of more than 1.1 million people (approximately 23% of New Zealand's population).

In-Home Sampling

In addition, three public healthcare providers in New Zealand have also commenced their use of Cxbladder for in-home sample collection. Counties Manukau Health, Waitemata and MidCentral DHB's, (who combined serve a population of approximately 1.4 million people), are having Pacific Edge dispatch the Cxbladder test sample systems directly to patients at home, for in-home collection of their urine sample and return to the Pacific Edge laboratory by courier. Based on their Cxbladder results, many patients can have a cystoscopy procedure avoided completely or deferred to a later date. This means that many urologist appointments and procedures will be avoided at a time when public healthcare resources are being prioritised and people are being asked to 'stay at home'.

Review of clinical evidence by Novitas for inclusion in the Local Coverage Determination (LCD)

In February, a peer-reviewed paper was published in BMC Urology that provided further real world evidence of significant gains in clinical utility from the commercial adoption of Cxbladder Monitor (CxbM). Three public healthcare providers in New Zealand measured the performance of CxbM on a population of 309 bladder cancer patients monitored over a 35-month period. The paper concluded that CxbM accurately ruled out 78% of all patients and reduced the average number of annual cystoscopies by approximately 39%. During 35 months of follow-up, no patients progressed to invasive disease or metastases and there was no cancer-specific mortality.

Based on these published data, several of New Zealand's public healthcare providers have integrated CxbM into their routine clinical surveillance of patients for recurrence of bladder cancer.

This type of real world clinical utility evidence is also required for positive coverage decisions by reimbursement agencies in the US. Significantly, we were able to add this latest piece of peer-reviewed evidence into the clinical evidence dossier that is currently being reviewed by our Medicare Administrative Contractor (Novitas) as part of their ongoing consideration of our Local Coverage Determination application.

Annual results to be released by end-May 2020

We are now underway with the preparation of our year-end accounts, for the twelve months ended 31 March 2020. We expect to announce our results to the market by end-May 2020, followed by an investor conference call. Details of this will be provided to the NZX.

In the meantime, we hope you all stay safe.

Kind regards



Chris Gallaher
Chairman



David Darling
Chief Executive Officer

- (1) [Bladder Cancer Advocacy Network \(BCAN\) WEBINAR](#): BCAN in the USA provides thousands of patients, caregivers and the medical community with the educational resources and support services they need to navigate their bladder cancer journey. In a recent BCAN webinar for patients and families, leading US urologist, Dr Sia Daneshmand, specifically talks about in-home testing using “Cxbladder as an option for patients who are not considered to be high or low risk, but want to do something to get reassurance. In-home testing is also being investigated as a feasible solution for urology care beyond COVID-19”.
- (2) [UroToday video](#): [Urotoday](#) has added a video to their website with two leading US urologists (Dr Neal Shore and Dr Sima Porten) discussing alternative strategies to deliver bladder cancer investigation during COVID-19 and beyond.

Dr Shore and Dr Porten comment on how they are currently using Cxbladder’s in home sampling programme for the benefit of both their patients and their respective clinics. The video also includes a brief summary of Cxbladder and our in-home sampling programme from Dr Thomas Nifong – the VP of Lab Operations and Medical Director of Pacific Edge Diagnostics USA Ltd.

The discussion provides a timely overview of the benefits of using Cxbladder to identify at-risk patients for non-muscle invasive bladder cancer (NMIBC) in the at-home setting.

- (3) [LUGPA Website](#): Reference to Cxbladder’s in-home sampling programme has also been added to the COVID-19 information hub as a cancer resource on the Large Urology Group Practice Association website in the USA. LUGPA is the only nonprofit urology trade association in the US and represents approximately 2,400 urologists.

STAY IN TOUCH

ENEWS

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KEY DATES

FY20 Financial Year End: 31 March 2020

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CONTACT US

87 St David Street
P O Box 56, Dunedin, New Zealand
T +64 3 479 5800
E enquiries@pelnz.com
www.pacifiedgedx.com