

# INVESTOR UPDATE

DECEMBER 2019



PACIFIC EDGE LTD



## EXECUTIVE UPDATE

David Darling, Chief Executive Officer

We were pleased to announce our FY20 half year results on 21 November 2019, reporting increased cash receipts, revenue and laboratory throughput as our Cxbladder diagnostic tests are adopted into guidelines in the USA and New Zealand and clinical evidence publications continue to mount in favour of Cxbladder.

At the same time, we announced a fully underwritten capital raise to assist Pacific Edge to progress its commercial objectives to become cash flow positive as soon as possible. The \$7 million Placement has been completed and we were delighted with the support we received from new and existing shareholders, both in New Zealand and internationally. Many of these are experienced investors in the global medtech sector and their support reflects their confidence in our strategy and Pacific Edge's future prospects.

All shareholders have the opportunity to participate in the second component of the capital raise, a fully underwritten, pro rata, renounceable, 1 for 4.25 Rights Offer at 10 cents per share. The Offer Document and Entitlement and Acceptance Form have been sent to shareholders. To aid shareholders in understanding our capital raising process, we have provided further commentary on the Placement and Rights Issue on page 6 of this newsletter.

We are making good progress in our target markets of the USA, New Zealand, Australia and South East Asia and we achieved a number of important commercial achievements in the six-month period. A summary of key milestones is on the next page, and further detail can be read in the half year results announcement on our website <https://www.pacifiedgedx.com/news-and-events/news/2019/>.

Our focus in the USA remains on gaining inclusion in the Local Coverage Determination (LCD) for patients of the Centers for Medicare and Medicaid Services (CMS) and accelerating the commercial adoption of our suite of Cxbladder tests in all our target markets.

A successful LCD decision, in combination with the recent inclusion in guidelines in the USA and New Zealand, is expected to result in strong increases in test adoption, revenue growth and operating cash flow.

**Pacific Edge  
pro-rata 1 for 4.25  
Renounceable Rights  
Offer**

**REMINDER:  
YOU HAVE UNTIL  
5.00PM ON  
WEDNESDAY  
11 DECEMBER 2019  
TO SUBSCRIBE FOR  
NEW SHARES**

Further details about the Rights Issue and the terms and conditions of the issue are set out in the Offer Document and associated application form.

The annual addressable market for our suite of Cxbladder products was estimated by EY Parthenon as being US\$1.2 billion<sup>1</sup>. We are focused on completing agreements for the adoption and commercial use of Cxbladder and building sales from the large institutional accounts and payers we are targeting in the USA, including Kaiser Permanente, Johns Hopkins Medicine, the Veterans Administration, Tricare, the CMS and other blue-chip institutions.

Demand from public healthcare providers in New Zealand is expected to continue to grow strongly and positively impact commercial test throughput volumes in the future, as remaining public healthcare providers start commercial use at scale, and those that have commenced, progress on to using more than one of the Cxbladder suite of products.

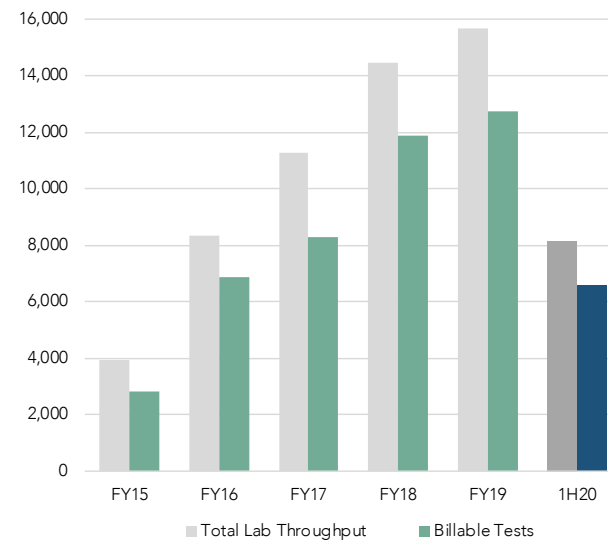
Further peer reviewed clinical papers of Cxbladder's performance are expected to be published in key urology journals over the second half of FY20, providing additional compelling evidence supporting the clinical utility of Cxbladder. The publication of these papers is also expected to support Pacific Edge's LCD application with the CMS.

We continue to move ever closer to achieving our commercial goals, particularly in the USA, and steady progress is being made. Adoption of Cxbladder is growing and commercial sales are increasing.

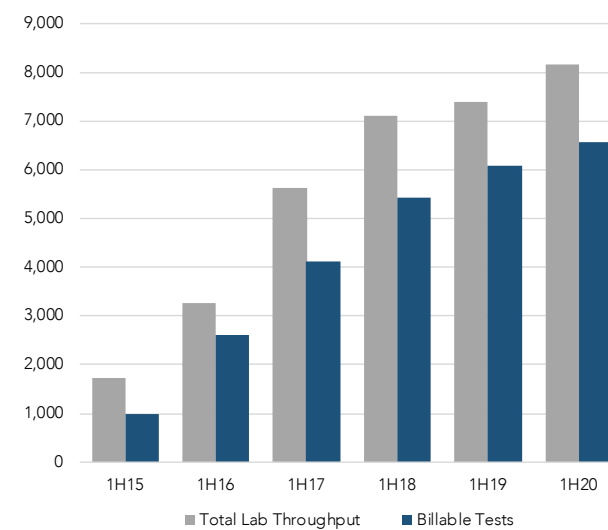
We remain focused on further accelerating the adoption of Cxbladder by large healthcare organisations, both in New Zealand and internationally, and growing our revenue. Gaining inclusion in the LCD for CMS patients in the USA remains our priority and we are working hard on the successful execution of this next phase of our global growth plan as we continue to progress our objective of taking Cxbladder to the world.

## Total Laboratory Throughput Comparison

### Full Year Comparison



### Half Year Comparison



## HALF YEAR SNAPSHOT

For the six months to 30 September 2019 (compared to prior comparable period (pcp))

- Cash receipts from customers grew to \$2.4m, a 16% increase on pcp and a 37% increase on 2H19
- Operating revenue from test sales increased 12% to \$2.3m, with total revenue for the period of \$2.7m
- Total laboratory throughput (which includes commercial sales as well as tests from User Programmes) grew 10%
- Total laboratory throughput for the PEDNZ business (New Zealand, Australia and Singapore), grew by 50%, driven by continued strong demand from public healthcare providers in New Zealand and User Programmes in South East Asia
- Total billable tests grew to 6,573 tests, an 8% increase
- Total operating expenses were \$(12.1m), a 6% increase
- Net operating cash outflow reduced to \$(7.4m), a 14% decrease
- Overall, the Company reported a net loss of \$9.4m for the half year period, an 8% increase on pcp
- Pacific Edge had cash, cash equivalents and short term deposits of \$4.7m as at 30 September 2019

### Summary of Key Commercial Milestones in the Half Year Period

- Cxbladder inclusion in USA's National Comprehensive Cancer Network (NCCN)<sup>2</sup> guidelines as an approved intervention for high risk patients being monitored for recurrence of urothelial cancer (UC), further validating Cxbladder and enabling increased use by clinicians
- Continuing adoption and increasing test use by New Zealand public healthcare providers (DHBs), with increasing commercial use expected to continue to positively impact commercial test throughput growth in 2H20
- Publication of two further papers in peer-reviewed journals, including the world's number one ranked urology journal<sup>3</sup>, adding significant additional clinical utility evidence in support of Cxbladder
- Updated dossier of clinical evidence accepted for formal review by the CMS in the USA, as part of process for inclusion in the LCD for the USA market. A successful inclusion in the LCD, combined with the recently announced inclusion in the NCCN guidelines, is expected to result in strong increases in test adoption, revenue growth and operating cashflow
- Growing recognition and adoption by large healthcare institutions in the USA, with a growing number of very large and reputable healthcare providers and academic centres growing their commercial use of Cxbladder or currently evaluating Cxbladder for commercial use
- Continuing progress in South East Asia with clinical trials with the five largest public hospitals in Singapore nearing completion. Published results from these will form the basis for a proposed Singapore-wide commercial programme

Further details on key milestones can be viewed in the half year results announcement on our website.

<sup>1</sup> EY-Parthenon business review of the annual addressable market opportunity for Cxbladder in the U.S. completed February 2018.

<sup>2</sup> National Comprehensive Cancer Network (NCCN) guidelines provide urology guidelines for physicians treating and managing patients with cancer and are reviewed annually. Cxbladder received inclusion in the July 2019 update to the NCCN guidelines.

<sup>3</sup> European Urology is ranked world no. 1 in urology and is read by more than 20,000 physicians. Its Impact Factor is 17.581

## GROWING MOMENTUM IN NEW ZEALAND

### CXBLADDER ADOPTED BY NEW ZEALAND'S PUBLIC HEALTHCARE PROVIDERS

Validation from the New Zealand market continues to grow, with more than 60% of New Zealand's population now covered by contracts with national public healthcare providers (District Health Boards, DHBs). This is expected to increase as we work closely with the remaining public healthcare providers to increase coverage.

The contribution from these providers is expected to continue to positively impact commercial test throughput in the second half of FY20.

The majority of the public healthcare providers in New Zealand have now adopted Cxbladder into their standard of care and in some instances, replaced the gold standard cystoscopy in both the evaluation of haematuria and in the monitoring for recurrence of UC.

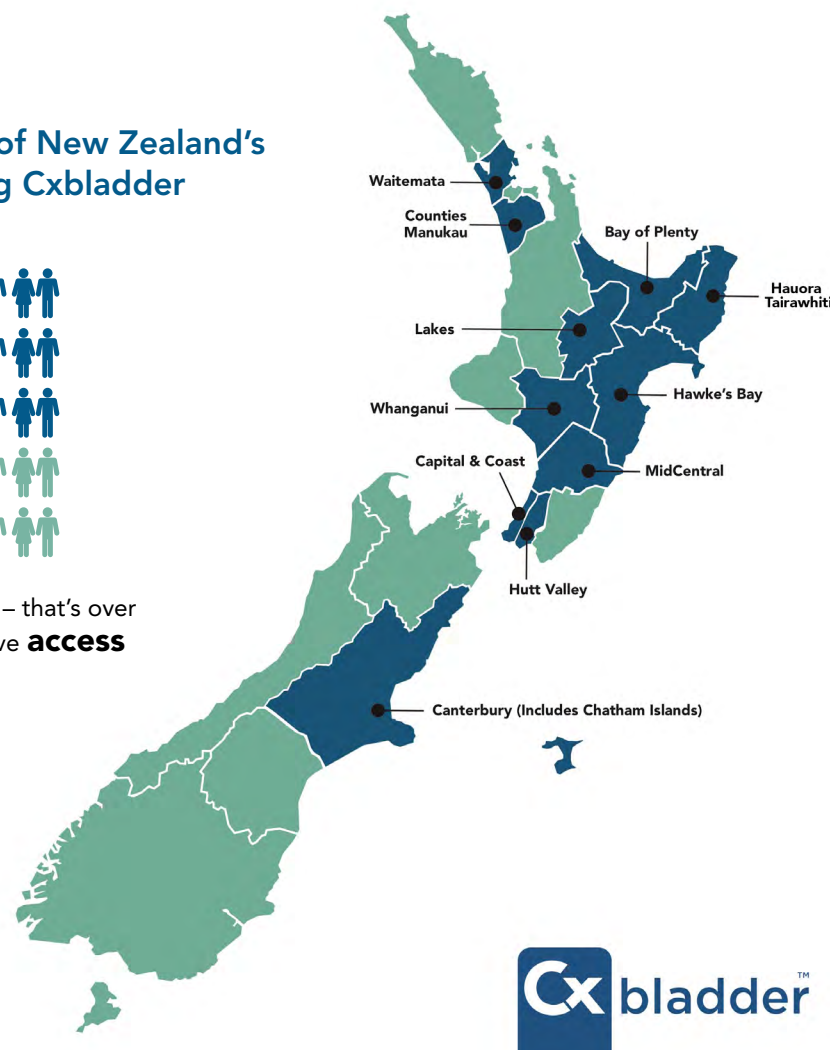
Many of the healthcare providers in Pacific Edge's other target markets of Australia, Singapore and the USA have similar challenges to New Zealand's public healthcare providers, with increasing demand for services, capacity limitations and constraints on servicing time, all of which may impact negatively on the patient.

Accordingly, healthcare providers in New Zealand and internationally are continually looking for ways to deliver better care, more efficiently and cost effectively. The successful look-back audits that have been published on Cxbladder by public healthcare providers in New Zealand have been of particular interest to other potential customers in our target markets.

### Contract Cover of New Zealand's Population Using Cxbladder



**62%** of New Zealand – that's over **3 million** people have access to Cxbladder



## COMPELLING EVIDENCE SUPPORTS CXBLADDER

### UROTODAY VIDEO PRESENTATION

In May 2019, a paper published in the world number one ranked urology journal, European Urology, validated the use of Cxbladder to remove the global diagnostic dilemma faced by physicians in treating and managing patients with urothelial cancer.

This dilemma occurs on a surprisingly high number of patients, when the existing gold standard tests and procedures are not able to determine a clear diagnostic outcome for the assessment of urothelial cancer. This diagnostic dilemma leads to many patients having to have further tests and procedures many of which are invasive. Cxbladder solves this dilemma.

In a video released on UroToday, two of the authors of the paper, Dr Badrinath Konety and Dr Neal Shore, provide an overview of the compelling evidence and findings of this study and their conclusions and recommendations.



or view on the UroToday website  
[www.urotoday.com](http://www.urotoday.com) under Bladder Cancer videos

*Dr. Badrinath Konety MD, MBA serves as CEO of the University of Minnesota Physicians as well as Vice Dean for Clinical Affairs at the University of Minnesota Medical School. He is also a professor in the Department of Urology and Director of the Institute for Prostate and Urologic Cancers.*

*Dr Neal Shore, MD, is the Medical Director of the Carolina Urologic Research Center. He practices with Atlantic Urology Clinics in Myrtle Beach, South Carolina. Both Dr Konety and Dr Shore regularly use Cxbladder in their medical practices.*

### Concluding statements from Dr Badrinath Konety:

- "Cxbladder is a, I would say, a next generation of bladder markers, and we've been trying to develop bladder markers to better identify bladder cancer using urine specimens for the better part of three or four decades now and each decade or two we come up with the next generation."
- "[Cxbladder] has "been a brilliant technology that we are going to be able to use, I use it quite a bit in my practice based on specific indications."
- "So the idea is, can we somehow figure out a way to reduce all these unnecessary workup in patients who are going to turn out to be negative on that kind of a workup anyways. So this marker Cxbladder in a nutshell, we think can really help..."
- "So in conclusion, Cxbladder clearly appears to outperform urine cytology for identifying patients with Urothelial Carcinoma overall, it missed fewer cancers, only about 8% of cancers as opposed to a much larger percentage with urine cytology. It clearly adjudicated all the atypical cytology patients and helps in patients with atypical cytology, and equivocal cystoscopy."
- "This really provides a strong argument for using Cxbladder instead of cytology as the accompanying test to a cystoscopy. This will avoid the atypical cytology results and potentially minimize the unnecessary workup in some of these patients, particularly those undergoing hematuria workup."
- "I think there's significant utility in using Cxbladder in evaluation of patients both in the context of hematuria, but also for surveillance of those who have a prior history of urothelial carcinoma. This would allow us to avoid unnecessary cystoscopies potentially in about 35% of patients."
- "The AUA guidelines on non-muscle invasive bladder cancer do indicate that urinary markers could potentially be of value in interpreting the likelihood of cancer in patients with atypical urine cytology, or in those who are undergoing intravascular BCG therapy to assess response. So that may be one potential setting in which something like Cxbladder could be used in adjudicating atypical reads on cytology or it could also be used in place of cytology as a companion to cystoscopy, to really help identify more of the tumors and also decrease the false-negative rate."



## WHY A PLACEMENT AND A RIGHTS ISSUE TO RAISE \$20 MILLION IN NEW CAPITAL?

By undertaking the capital raising in two components - a Placement of new shares and a Rights Issue for existing shareholders - Pacific Edge has been able to raise significant new capital to enable the company to achieve its core objective to break-even as soon as possible.

The Placement of new shares was structured so as to introduce new investors to the register and was at a price that was close to the market price of the day. Despite the strong demand, the Placement was limited to \$7 million, ensuring capacity for existing shareholders wanting to participate in the Rights Issue and minimising dilution. The Placement was successfully completed and strongly supported, with a number of new NZ and international investors joining the company's share register.

The issue of a 'Right', is a right to buy a share at a certain price at a future date. It grants shareholders the right, but not the obligation, to buy new shares. With the Rights, a shareholder can purchase new shares at a discount to the market price. Shareholders may also trade their Rights on the market the same way that they would trade ordinary shares, enabling them to gain some value if they decide not to take up their Rights and participate in the capital raise.

Pacific Edge is offering existing shareholders the 'right' to acquire new Pacific Edge shares at 10 cents per share. This is a discount to the Placement (which was at 15 cents per share).

If you decide to trade your rights, their value is dependent on what another party (buyer) is willing to pay for them. Assuming a market share price of 15 cents per Pacific Edge share, and a Rights price of 10 cents, it suggests that trading of the Right could be expected to be in the range up to 5 cents per Right.

In any capital raising where there is an increase in the total number of the shares in the market, then there could be a dilution on existing shareholders. By taking up their Rights, existing shareholders are able to avoid unnecessary dilution. The Rights on offer to each shareholder are proportional to each shareholder's current shareholding. If you do not wish to participate in the capital raising and take up your Rights, your shareholding will be diluted due to the new shares being issued to existing and new shareholders. Pacific Edge has arranged for a broker to sell the rights for ineligible shareholders on a best efforts basis and return any proceeds to those investors.

In conclusion, this capital raising process gives existing shareholders the opportunity to participate in the capital raising on more favourable terms than those purchasing new shares in the Placement. With the Rights issue being 'fully-underwritten', it guarantees that the company will achieve the full \$20 million in funds to enable it to achieve its core objective to break-even as soon as possible.

## INTRODUCING OUR TEAM

### WELCOME TO GRANT GIBSON, CHIEF FINANCIAL OFFICER

Grant Gibson has been appointed as Pacific Edge's new Chief Financial Officer. Grant is an experienced financial executive and chartered accountant, who brings significant financial experience to the role.

Grant was most recently Chief Financial and Operating Officer for Dunedin-based company, TracMap, where he was responsible for leading the financial management and operations across the company with commercial subsidiaries in three international markets. Prior to that, he worked in executive finance roles at Westpac, including as Head of Finance for Westpac New Zealand. He was the head of the finance team for New Zealand's largest financial transaction, the local incorporation of Westpac New Zealand, a complex and heavily regulated transaction involving billions of dollars.

Grant replaces Kate Rankin who has been Chief Financial Officer over the past five years and has made a significant contribution to our company.

### 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.pacificedgedx.com](http://www.pacificedgedx.com).

#### UPCOMING KEY DATES

FY20 Financial Year End: 31 March 2020

FY20 Results Announcement: By end-May 2020

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PACIFIC EDGE IS HONOURED  
TO HAVE BEEN ANNOUNCED  
AS THE WINNER OF THE  
**EXCELLENCE IN INNOVATION  
AWARD 2019**

OTAGO EXPORT  
AWARDS



**PACIFIC EDGE**   
CANCER DIAGNOSTICS COMPANY