



PACIFIC EDGE 

# INVESTOR UPDATE

JULY 2022



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FROM THE CEO

# EFFECTIVE ENGAGEMENT ACROSS THE CXBLADDER VALUE CHAIN



DEAR SHAREHOLDERS,

**Effective communication and engagement by Pacific Edge across the breadth of stakeholders in the healthcare value chain is crucial to driving the adoption of our suite of advanced genomic biomarker Cxbladder tests.**

As Pacific Edge seeks to establish Cxbladder as the standard of care for hematuria evaluation and surveillance for the recurrence of urothelial cancer, there are many organizations and individual stakeholders with whom we must communicate effectively and engage in market. Foremost among these stakeholders are the clinicians. They order the tests, collect samples, administer associated paperwork and interpret the results. Then there are the patients taking the tests, the organizations funding them, the guidelines committees adjudicating patient care protocols and our research collaborators building the evidence to support guideline inclusion.

In this shareholder update, we highlight our enhanced focus on medical communications and our in-market activities in a few key areas. Firstly, at the start of this month, we appointed David Sosa into the new role of Vice President Market Access and Reimbursement (see page 4). This role is primarily responsible for driving additional revenue from various market access activities with government payors and private payors, increasing payment percentages and total revenue and looking at international

opportunities for growth, leveraging our US laboratory.

This follows on the appointment of Dr Tamer Aboushwareb into the new role of Vice President Medical Affairs in June. This role is responsible for the inbound enrolment of patients in our clinical studies to enhance our evidence generation program. Tamer will also drive the communication of existing and future clinical evidence to clinicians, provider administrations and payors.

**“In this shareholder update, we highlight our enhanced focus on medical communications and our in-market activities in a few key areas.”**

Together, these positions elevate engagement and communication with key stakeholder groups. David and Tamer will also play pivotal roles in the evolution of our commercialization strategies.

Secondly, we have increased our visibility at marquee conferences like the American Urological Association (AUA) annual conference (see page 8) and the total number of conferences we attend. Crucially, these activities, which are synergistic, are just a few among the myriad of channels we are using to engage with clinical stakeholders.

The recognition of the value we are creating similarly depends

on effective communication of our strategy and progress we are making against it to shareholders. For this reason, we have included quarterly test volumes in this update for the first time, an important leading indicator of the continued progress we are making commercializing Cxbladder. We have also provided historic figures to illustrate our progress quarter on quarter (see page 3).

Our intention is to report these figures to the NZX and ASX as soon as practicable after the end of each quarter, while continuing to deliver a comprehensive data set with our full and half year results in May and November of each year.

Before closing I want to pay tribute to Jackie Walker, who at the end of August, is retiring so stepping down as Chief Executive of Pacific Edge Diagnostics USA after 10 years with the company. She has made an enormous contribution to the business, including playing a key role in some of the company's most significant commercial achievements.

I want to thank her again on behalf of shareholders and personally for the way she has welcomed me into the business.

I look forward to seeing you at Pacific Edge's Annual Shareholder Meeting later this month.

**Dr Peter Meintjes**  
Chief Executive

## TEST VOLUME PROGRESS

# BUILDING MOMENTUM FOR CXBLADDER IN THE US

### Cxbladder test volumes continue to increase, building momentum from the early results we signaled in May.

Total tests processed at our laboratories set a record in the three months to the end of June 2022, and showed a quarter-on-quarter increase of 13% to 7,055 tests from the 6,242 tests processed in the March 2022 quarter.

The result also represents an increase of 32% over the June 2021 quarter result of 5,356 tests and reflects increasing numbers of US based unique ordering clinicians using the test, an important measure of market penetration. This metric reached a record for the quarter of 894, up 36% from the same quarter a year ago.

Growth was weighted to the US where test volumes showed a quarter-on-quarter increase of 15% to 6,073 from the 5,290 in the three months to the end of March 2022 and a 42% increase on the 4,277 in the June 2021 quarter.

These numbers are encouraging and evidence of continued delivery against plan. The increase in volumes reflects growing awareness of the role Cxbladder can play in safely de-intensifying or intensifying the clinical workup for patients presenting with hematuria (blood in urine), resolving diagnostic dilemmas during hematuria evaluation (e.g., equivocal cystoscopy and atypical cytology), and monitoring for the recurrence of urothelial cancer in posttreatment patients. It also reflects the continued easing of COVID restrictions.

Despite a comprehensive program of virtual engagement, these restrictions had been limiting in person visits with clinicians and conference meetings. Importantly, COVID restrictions had also played a role in reducing patient visits creating significant disruption to the traditional care paradigm.

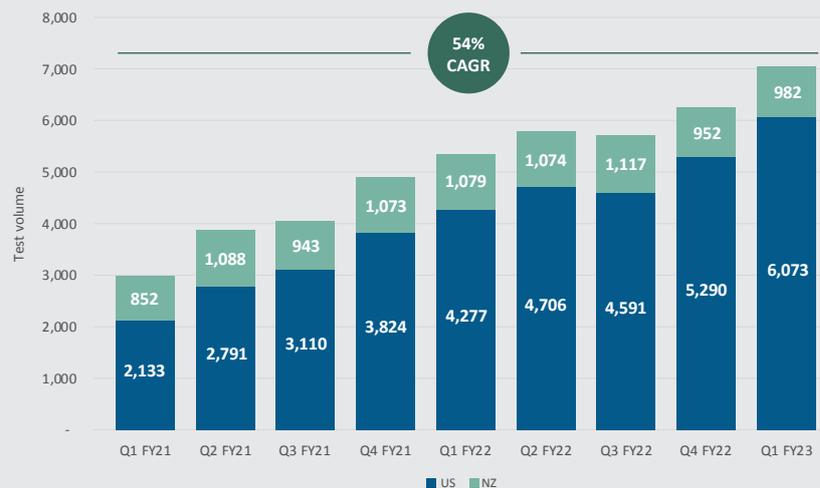
In the Asia Pacific, where test numbers are dominated by New Zealand, volumes have been more muted, reflecting the local market's maturity relative to the US. At present 14 of the 20 new Health New Zealand, Te Whatu Ora, regional divisions representing 70% of the New Zealand population, cover the tests.

Total test volumes in the three months to the end of June in the APAC region increased 3% on the March 2022 quarter to 982 tests

from 952 but fell 9% on the 1,079 tests in the June 2021 quarter.

Longer term we believe the consolidation of the New Zealand healthcare system will be positive for the adoption of Cxbladder as engagement with the national health authority may accelerate the adoption across the remainder of New Zealand's population, and the focus will shift towards increasing awareness and adoption at primary care following the example set by Canterbury and the Manawatu.

TOTAL TESTING VOLUME (PACIFIC EDGE GROUP)



UNIQUE ORDERING CLINICIANS (US)



## EXECUTIVE APPOINTMENTS IN THE US

# DRIVING GROWTH WITH GREAT TESTS AND GREAT SERVICE

Pacific Edge is working to drive both the understanding of the clinical evidence supporting our tests as well as their adoption. Clinicians, healthcare funders and providers, patients and the committees charged with setting standards of care need to be made aware of, and understand, the evidence. At the same time the ordering and paying for the tests and the results delivery needs to be seamless.

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Two appointments in June into new roles at Pacific Edge are aimed at delivering on these goals.

David Sosa has joined Pacific Edge as its new Vice President Market Access and Reimbursement. His position is focused on payor relations to increase payment rates from existing payors and contracting with new payors. He

will also develop an understanding of our economic value proposition among clinicians, hospital systems and payors and establish Cxbladder in markets where we do not yet operate. Finally he will also build the right relationships with strategic accounts like Kaiser Permanente and the US Veterans Health Administration. David comes to Pacific Edge with more than 25 years' experience working with diagnostic companies in the US.

Meanwhile, Dr Tamer Aboushwareb has been appointed Pacific Edge's Vice President of Medical Affairs and will lead a new team of five Medical Science Liaison Officers providing medical and scientific leadership for the company. The role is focused on engagement with key opinion leaders in urology and uro-oncology, the education of clinicians in the utility of our products, the enrolment of patients into our clinical studies and the communication of our evidence generation program in conferences across the USA and internationally.

Dr Aboushwareb is a urologist who comes to Pacific Edge with

a depth of experience in clinical, medical research, and commercial roles in urological medicine in Egypt and the US. He and his team will also be supporting market access and reimbursement efforts from a scientific and medical perspective.



David Sosa



Dr Tamer Aboushwareb

## CLINICAL STUDY PROGRESS

# MARKING THE STEPS TO GUIDELINE INCLUSION

Two important clinical studies to help Pacific Edge advance its case for inclusion in global standards of urothelial cancer care passed important milestones.

First, the Safe Testing of Risk for Asymptomatic Microhematuria (STRATA) clinical study has enrolled more than 50% of its subjects. The aims to further

demonstrate how Cxbladder can safely risk stratify patients presenting with hematuria into those that may receive a less-intense evaluation for the presence of bladder cancer and those that should continue with a standard evaluation.

The results from STRATA will strengthen the case for Cxbladder

tests to be inserted into the current American Urological Association (AUA) standard, and other global care standards, as part of the normal care management for those patients.

Meanwhile, the Longitudinal Bladder Cancer Study for Tumor Recurrence (LOBSTER), which is seeking to benchmark the utility

*continued on page 5*

## GUIDELINE STEPS CONTINUED FROM PAGE 4

of Cxbladder against the AUA protocols for the surveillance of recurrent urothelial cancer, has enrolled its first patient.

Both studies are key components of Pacific Edge’s clinical evidence generation program. Current AUA risk stratification protocols based on clinical risk factors alone are insufficient to reliably de-intensify urological evaluation for low-risk patients. We expect the STRATA study to demonstrate how Cxbladder can satisfy this unmet need.

At present the AUA microhematuria guideline recommends a shared patient-physician decision whether to proceed with cystoscopy for patients classified as low-risk, a cohort that currently represents only 5% of referred patients presenting with hematuria. We expect the STRATA study to demonstrate how Cxbladder can safely de-intensify evaluation for

a significantly higher proportion of patients than the current AUA guidelines, translating to greater focus on patients with disease.

**“... the studies are aimed at further reinforcing the potential for Cxbladder to reduce the burden of invasive cystoscopic evaluations”**

The LOBSTER study is aimed at reinforcing the potential of Cxbladder to assist clinicians in reducing the frequency of cystoscopies for patients under surveillance for the recurrence of urothelial cancer.

In both cases the studies are aimed at further reinforcing the potential for Cxbladder to reduce the burden of invasive and expensive cystoscopic evaluations, spare patients the potential

risks, discomfort, and anxiety from cystoscopy and potentially overcome entrenched patient non-compliance with management and surveillance regimes.

Finally, a third study the company is conducting with the US Veterans Health Administration – the Detection and Risk Stratification in Veterans Presenting with Hematuria (DRIVE) study – has expanded the number of actively enrolled sites by three to ten. The VA covers over 9 million patients and includes 171 Medical Centers and 1,113 outpatient sites, representing a significant opportunity for Cxbladder.

The DRIVE clinical study is an important engagement with VA urologists to determine utility in a cohort of VA patients, but it also has relevance to the AUA. As the study nears completion, Pacific Edge expects to slowly migrate the study sites and other VA sites to commercial adoption as part of a site-by-site rollout.

Study	Locations	Enrolled sites*	Progress and targets
STRATA	USA, Canada	10/11	- 50% enrolled - Full data targeted Q4 2023
DRIVE	USA	7/11	- Full data collected mid 2025
LOBSTER	USA, Australia	2/10	- First patient enrolled - Full data targeted 2025



<sup>1</sup> AUA Guideline and Woldu SL, Ng CK, Loo RK, Slezak JM, Jacobsen SJ, Tan WS, et al. (2021a). “Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria.” J Urol 205(5): 1387-1393

\*Initiated and enrolled



## GREENLIGHT AT KAISER

# PATIENTS WILL BE ABLE TO PROVIDE SAMPLES AT KAISER CLINICS, AND USE PACIFIC EDGE'S IN-HOME SAMPLING SYSTEM

The adoption of Cxbladder by Kaiser Permanente, one of the largest healthcare providers in the US, received a significant boost in May when it gave the greenlight to incorporate our tests within its electronic medical records (EMR) system.

While the project will take some months, once complete it will enable clinicians across the Kaiser Permanente Group to order Cxbladder tests and view results directly within their clinical workflow system rather than relying on a manual ordering system. Additionally, patients will be able to provide urine samples for Cxbladder tests at Kaiser Clinics and laboratories in addition to the current protocol of relying on the Cxbladder Patient in Home Sampling System (PIHSS) initiated during COVID.

The seamless availability of the tests and delivery of results through Kaiser's EMR is an important step to driving adoption of our tests. However, building understanding of the role Cxbladder can play in helping the diagnosis and management of the tests among Kaiser's clinicians will also be crucial to success.

While we work hand-in-hand with numerous Kaiser teams on IT integration, we will continue our clinic-by-clinic, clinician-by-clinician engagement to educate clinicians and grow adoption ahead of the deployment. We continue to see throughput volume increasing and two Kaiser hospitals are now in the Top 20 accounts by throughput.

### **PACIFIC EDGE & KAISER PERMANENTE**

**Customer:** Kaiser Health Plan – the payor arm of Kaiser Permanente

**Tests:** Cxbladder Triage and Cxbladder Monitor

### **About Kaiser Permanente:**

- Founded: 1945
- HQ: Oakland California
- 12.6 million members (85% in California)
- 39 hospitals, 734 offices
- US\$93.1bn<sup>2</sup> operating revenue

<sup>2</sup> 2021

## WRITING THE NEXT CHAPTER

**Pacific Edge Diagnostics USA Chief Executive Jackie Walker is stepping aside at the end of August after ten years leading the organization.**

In that role she has overseen some of Pacific Edge's most significant commercial achievements, including CMS coverage of Cxbladder and the Kaiser Permanente commercial agreement.

### Why did you take the role to lead PEDUSA?

I was really impressed by the company, the people, the vision, and all the work that had been done to develop its new cancer diagnostics technology. I was also very interested in getting into the molecular diagnostics field, which was changing the healthcare industry, and this was a great opportunity to do so.

### What have been the standout points over your ten years with the company?

There are many. Establishing the laboratory and headquarters in Hershey, Pennsylvania; building a great PEDUSA team and culture and bringing new non-invasive genomic tests to urologists that improve their clinical practice and quality of life for their bladder cancer patients were great achievements. Of course, gaining CMS coverage and the commercial agreement for Cxbladder with Kaiser Permanente, one of the country's leading healthcare providers, were very rewarding as well.

I've also really enjoyed the trips I have made to New Zealand and working with the team there. (Former CEO) Dave Darling and I were great partners.

Along with Jack Atchason and the PEDUSA team, we worked long hours together to overcome the challenges of the US healthcare market to steadily grow the business. It has been a great experience.

### What are you most proud of during your period of leadership?

In addition to all the milestone achievements above, I'm most proud of our PEDUSA team and the culture we've built. They are all passionate, hardworking, results-oriented, innovative, team players, who also like to have some fun, which has been at the core of our success.

### Why are you leaving and how do you feel about it?

It was a hard decision. I've had a wonderful and rewarding career and have truly enjoyed my role at Pacific Edge, but it's time for me to spend more time with my husband and family, who have been waiting patiently for me to retire and do the many things we love and have plans to do.

I am going to miss the people. We have an amazing team both in the US and New Zealand. I'm also going to miss our urology community and commercializing new innovative products. I want to thank my PEDUSA executive team for their hard work and leadership and the PEDUSA team for all they do as well as the PENZ team, the Board, and our shareholders for their continued support of our vision and mission.

Pacific Edge is at a great inflection point, and I know the team will continue to successfully build the business. I look forward to continuing to support the company after I retire and wish Pete, David and the rest of the team every success.

### What's next?

I am on several boards and work with community organizations and look forward to continuing my work with them. My husband, Roy, and I are building a beach house and plan to spend a lot more time there. We also love to travel, bike, hike, golf, fly fish, and do just about anything outdoors. We have lots of great plans, and it's time to write the next chapter.



### JACKIE WALKER

- Pacific Edge Diagnostics USA Chief Executive Officer
- Flinchbaugh Engineering, Director
- RETTEW Associates, Director

### Education:

- Duke University BSE (Engineering and French)
- University of North Carolina-Chapel Hill MBA

### Prior roles:

- OSspray President (biomaterials), President and CEO
- Ondine Biopharma (biotech), COO
- Dentsply International (medical equipment), Vice President & General Manager
- Ohmeda/BOC Healthcare (medical equipment), Director of Marketing

*Following Ms Walker's departure, PEDUSA Executive Chairman David Levison will assume the new role of PEDUSA President, reporting directly to Chief Executive Dr Peter Meintjes.*



## GAINING TRACTION AT US EVENTS

# INTEREST IN CXBLADDER STRONG AMONG US CLINICIANS

Pacific Edge saw strong interest in Cxbladder at the American Urological Association (AUA) annual conference in New Orleans in May. The AUA meeting, which this year returned after a two-year COVID impacted hiatus, is the biggest event on the US and global urological conference calendar,

attracting thousands of urologists, oncologists, researchers, educators, and healthcare professionals and companies.

Pacific Edge has been a long time and significant sponsor of the AUA and significantly increased its presence in the main exhibition hall (pictured), while also sponsoring

key sessions for Veterans Affairs and the newly created “Bladder Cancer Forum” where clinicians discussed bladder cancer management, as well as treatment strategies in challenging disease states.

### ABOUT US

Pacific Edge Limited (NZX/ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease.

Headquartered in Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

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