PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

INVESTOR UPDATE

JANUARY 23

INSIDE

LETTER FROM THE CEO

DELIVERING ON OUR GROWTH OBJECTIVES

Dear Investors,

In this third quarter update, I am pleased to advise that we are continuing to deliver on our growth objectives. Pacific Edge closed out 2022 confident the new approach we are taking to drive increased adoption and use of Cxbladder is delivering on its goals.

Test volumes for the third quarter of the 2023 financial year are up 36% on the same period in the prior financial year to 7,768. Consistent with prior years, we observed a seasonal slowdown that comes with the Thanksgiving, Christmas, and New Year holiday season (see page 3).

Throughput remained flat on the 7,864 achieved in the second quarter of the current financial year, though notably the number of unique ordering clinicians increased.

In the previous quarter, we added two new sales roles with a focus on National Accounts (see page 4). With these appointments, we have now largely put in place the size and diversity of roles in the commercial team that we need for our next phase of growth. We are looking towards the 2024 financial year when we expect these initiatives to start to demonstrate a return by increasing the number of tests per ordering clinician, while continuing our upward momentum on the number of ordering clinicians and revenue.

As we highlighted at our 1H23 results in November, we are seeing similar encouraging signs across the initiatives we announced in May. Our new Direct Sales team members are gaining confidence and knowledge in their territories. To support the expected volume growth, we have added to our laboratory, scientific and customer support staff.

In the previous quarter, our Medical Affairs team have also begun to demonstrate the value they bring to the business. Communicating the portfolio of evidence supporting Cxbladder to clinical and commercial decision makers is no small task. Ultimately, it requires our people to be able to engage with them as equals, and to be able to answer nuanced questions of science or clinical practice confidently and with conviction.

> **"We have now largely put in place the size and diversity of roles ... for our next phase of growth."**

At the Society for Urologic Oncology (SUO) meeting in San Diego in December, and in meetings following the conference (see page 5), various key opinion leaders (KOLs) from the urology community regularly acknowledged that the Medical Affairs team was bringing a new sense of purpose by putting Pacific Edge and Cxbladder at the center of conversations around innovation in biomarkers – a key feature of international conferences.

Decision makers are not only talking to Pacific Edge about the evidence and the clinical utility of the products. More and more they are now talking to one another on the value of integrating Cxbladder into their practice. We are also seeing a new enthusiasm for clinicians to be involved in upcoming clinical trials.

Finally, we were excited to announce in December acceptance for publication in the Journal of Urology new research demonstrating that the addition of DNA biomarkers to Cxbladder can deliver significant improvements in test performance (see page 6). The study and the enhanced test that we are commercializing on the back of it, Cxbladder Detect⁺, positions the company to extend our leadership in best-in-class diagnostic tools for the detection and management of bladder cancer.

Cxbladder Detect⁺ represents an exciting evolution for the company. As a single product for hematuria evaluation with significantly enhanced performance characteristics, it allows us to offer new solutions to the clinicians, healthcare funders and providers and those who set global standards of care.

We continue to actively engage with our legal advisors, our industry coalition partners and with all appropriate formal channels with Novitas and CMS regarding the proposed LCD and remain confident that our feedback will be incorporated into revisions to the proposal that will benefit patients, payors and diagnostics companies, including continued reimbursement for Cxbladder.

On behalf of the entire Pacific Edge team, I wish you all a good start to the New Year.

Ngā mihi,

Dr Peter Meintjes

TEST VOLUMES

SUSTAINING STRONG THROUGHPUT

Cxbladder tests processed at Pacific Edge's laboratories in the US and New Zealand have sustained the strong performance of prior quarters despite the seasonal headwinds of holidays with reduced laboratory operating days and reduced physician schedules.

In the three months to the end of December 2022 (Q3 23), the team processed 7,768 tests, a 36% increase over Q3 22. This growth rate is in line with the year-on-year growth rates we achieved in Q2 23 and ahead of the year-on-year growth rate of 32% achieved in Q1 23.

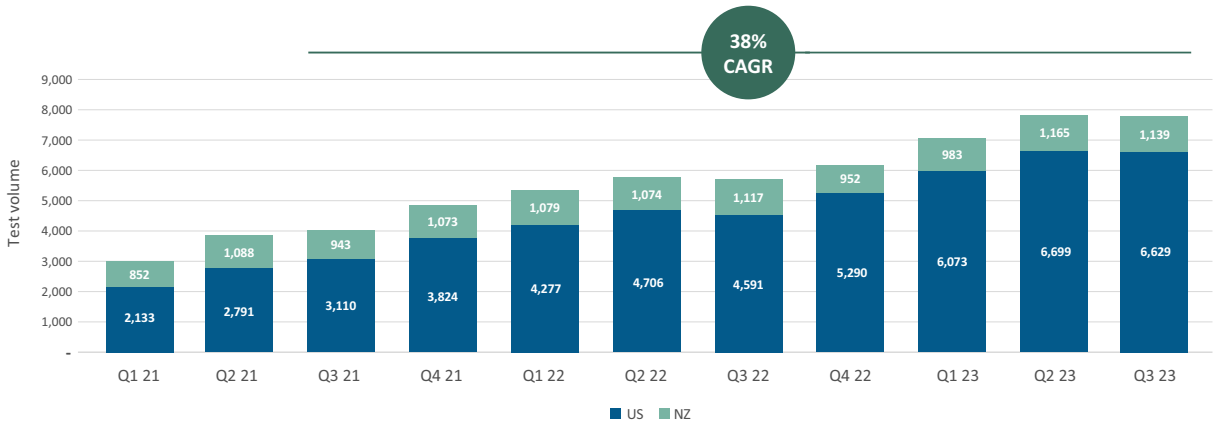
Volumes were flat on the Q2 23's 7,864[1] tests reflecting the seasonal slowdown we see from Thanksgiving through to the New Year and the start of the fourth quarter as urologists and patients take holidays. As we have seen in prior years, we expect a return to quarter-on-quarter growth in the last three months of the financial year.

US test volumes for Q3 23 were 6,629, a 44% improvement on the 4,591 in Q3 22, but flat on the 6,699 tests in the Q2 23. The number of unique US ordering clinicians has continued to grow to 1,076 at the end of the Q3 23, up 45% on Q3 22 and up 10% on Q2 23.

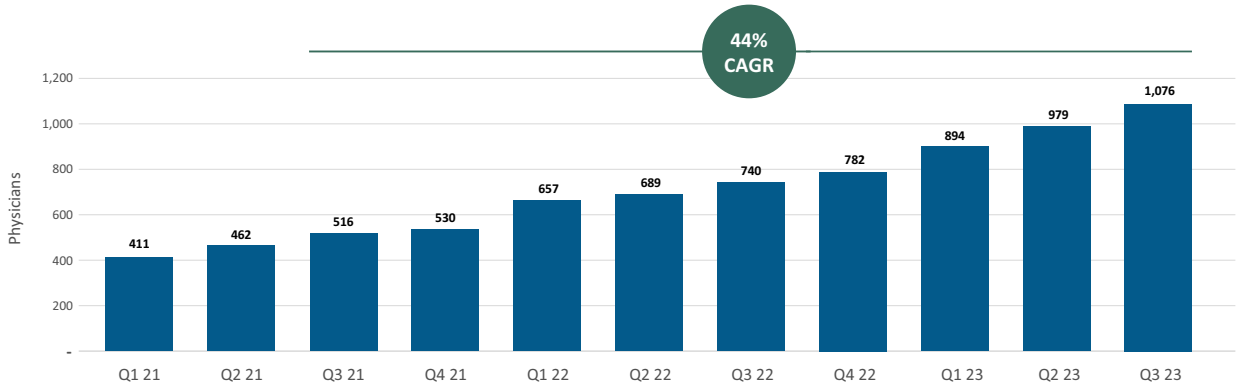
In line with the seasonal trends observed in the prior years, tests per physician in Q3 23 fell to 6.2 from 6.8 in Q2 23.

Q3 23 APAC volumes were up 2% on Q3 22 at 1,139 and flat on the 1,165 in Q2 23, with the relatively mature New Zealand market dominating throughput.

TOTAL TEST VOLUMES: GROUP



UNIQUE ORDERING CLINICIANS: US



[1] Test numbers in Q1 23 and Q2 23 are respectively one and three more than previously reported due to the reclassification of tests arising from the clarification of information required to support test results.

NATIONAL ACCOUNTS

TAPPING THE LARGEST POOLS OF CXBLADDER DEMAND

As a continued enhancement to Pacific Edge's sales strategy, the PEDUSA team now has a small and dedicated team to work with national accounts.

National Accounts are those institutions and practices that have larger influence on the practice of urology either through their ability to influence clinical standards and practice, or through their scope, size, and reputation.

Pacific Edge has always had strong relationships with these National Accounts, managed by the sales and executive teams, and believe this new focus will enhance these relationships.

These National Accounts will initially total approximately 50 institutions in the US, but this focus can be expanded as we prove our selling model.

National Accounts are expected to have longer sales cycles and complex decision-making processes. However, they are expected to standardize and systematize their technology adoption, which increases the

"stickiness" as they look to establish protocols for the appropriate use of Cxbladder in their patient population.

To help lead this initiative, we have appointed an experienced and award-winning sales leader, Melissa Garcia, as our new National Account Director. Joining her in the National Accounts Team is Joe Swanson – a top performer among our Account Executives. The new team will work closely with our Medical Affairs, Market Access, and field sales teams to establish our National Accounts strategy, and refine it in response to market dynamics.

We expect the new team to be a performance driver in the 2024 financial year.

STAFFED FOR THE NEXT PHASE OF GROWTH

Pacific Edge is now confident we have largely recruited the people we need to deliver on the next leg of our growth plan.

With the team set, our focus is now on execution to realize our throughput and revenue goals while assessing the effectiveness of our expansions and initiatives in FY23.

Since the end of September our global team has grown by 15 people to around 115 and we now expect it to stabilize at this level for our next phase of growth. We are targeting the 2024 financial year where this investment in people should be driving a meaningful contribution to Pacific Edge's financial and operational performance.

Key achievements in the US include the recruitment of a new Director of National Accounts (see above), stabilizing the number of territories for the Direct Sales Team and rounding out the Medical Affairs Team. In New Zealand we have built out the back-office, laboratory and research and development teams to ensure we are positioned to deliver seamless service to our global customers and our clinical research partners as we grow.

CONFERENCES

MONITOR'S DAY IN THE SUN

Cxbladder Monitor and our freshly minted Medical Affairs Team were front and center at the Society of Urologic Oncology (SUO) meeting in San Diego at the start of December.

The conference is a premier gathering for clinicians who manage patients already diagnosed with bladder cancer. For these clinicians, having treated the cancer, Cxbladder Monitor (CxbM) is of intense interest due to its potential to reduce the frequency of surveillance cystoscopy, and therefore improve compliance with surveillance for recurrent bladder cancer.

A highlight of the conference, attended by about 1000 clinicians and industry professionals was a Cxbladder Breakfast Symposium on the real-life impacts of Cxbladder tests for the diagnosis and surveillance of bladder cancer. The event featured three leading urologists – Dr Sia Daneshmand, Dr Sima Porten, and Dr John Sfakianos and was chaired by Pacific Edge's VP of Medical Affairs Dr Tamer Aboushwareb.

Key successes of the symposium, and the conference at large, included the endorsement by independent clinicians of CxbM's clinical utility, the evidence to support its use, and how - by offering options to reduce the number of cystoscopies – CxbM helped to overcome patient reticence towards surveillance regimes for cancer recurrence.

In a sign of the success of our new Medical Affairs team, Pacific Edge was roundly praised for its research and its commitment to a full clinical evidence generation program and has set a new template for engagement at similar events in the future.

Medical Affairs led podium presentations, side line conversations with clinicians, and formal sessions. A key initiative was the Principle Investigator Meeting for STRATA which was attended by all principle investigators and coordinators in the STRATA trial (see page 7) to discuss challenges and drive faster enrolment of appropriate patients for the trial. We plan to hold PI meetings for other clinical studies at similar conferences going forward.

Finally, the SUO conference also hosted the first meeting of Pacific Edge's Clinical Advisory Board (CAB). This body, a panel of our most trusted advisors from renowned academic centers, includes leading urologists from around the US, four of whom sit on the AUA guidelines committees. The CAB provided us with highly useful insights in how to drive our product development and clinical study program. It was also supportive of our test validation roadmap for Detect⁺ (see page 6).

STRENGTHENING KAISER CLINICIAN RELATIONSHIPS

Cxbladder remains on track to be integrated within the Kaiser Permanente electronic medical record (EMR) system with the rollout starting with Southern California (SoCal). As a partner in this project, Pacific Edge was invited to attend a Kaiser Permanente internal conference for urologists in October and had the opportunity to raise awareness of the rollout to a number of urologists not already familiar with the internal developments. In December, Pacific Edge Medical Affairs and Senior Management were invited to address the SoCal organization's 13 urology chiefs over dinner and received positive confirmation on the performance of Cxbladder and the desire to rollout systematically via EMR.

> **"We are confident of … the successful conclusion of this project before the end of March 2023."**

These opportunities reinforce Pacific Edge's position as an innovation partner for Kaiser Permanente, underpinned by a shared desire to reduce unnecessary cystoscopies during hematuria evaluation and surveillance, and to ultimately move towards proactive routine testing of "At Risk" populations defined by age, smoking history and other clinical factors in the EMR. We remain encouraged that we will be able to announce a successful conclusion to the integration project prior to the end of the financial year.

EXTENDING OUR DIAGNOSTIC LEAD

An enhanced version of Cxbladder Detect (CxbD) is set to extend Pacific Edge's first mover advantage in providing best-in-class diagnostic tools for the detection and management of bladder cancer.

In December we announced new peer-reviewed evidence that demonstrates the addition of DNA biomarkers to Cxbladder Triage (CxbT) and CxbD, Pacific Edge's products for hematuria evaluation, deliver significant performance improvements.

The study, to be published in the prestigious American Urological Association's Journal of Urology, showed the enhanced test Cxbladder Detect⁺ (CxbD⁺) delivered Sensitivity of 97% (+23% compared with CxbD), Specificity of 90% (+8%), Negative Predictive Value of 99.7% (+2.5%), Positive Predictive Value of 44% (+19%) and Rule-out Rate of 83% (+5%). The study is available for review on the Cxbladder website.

By adding DNA biomarkers, we have developed CxbD⁺, as a single product for hematuria evaluation that can assist clinicians to risk stratify patients to rule in and safely rule out the presence of bladder cancer for any hematuria patient at any point in the patient care pathway. CxbD⁺ is the first combined RNA and DNA biomarker test for detection of bladder cancer.

The study enrolled 804 patients from two cohorts (344 from the US and 460 from Singapore). The study validates the use of Cxbladder in a Southeast Asian patient population, further strengthening the evidence for genomic biomarker tests in genetically diverse populations.

CxbD⁺ will require its own coding, coverage, and pricing decisions to ultimately establish reimbursement. However, given the increased performance it could potentially receive a higher price.

We expect no negative impact to revenue from existing products - commercial Triage and Detect customers will only be transitioned to CxbD⁺ after reimbursement is established. The company will continue to explore whether DNA markers will have a similar impact on the performance of Cxbladder Monitor for surveillance of recurrence of disease.

DNA MARKERS LIFT CXBLADDER PERFORMANCE[2]

Test	Sensitivity	Specificity	NPV	PPV	ROR
Cxbladder tests enhanced with DNA biomarkers					
CxbT⁺	95%	78%	99.5%	26%	73%
CxbD⁺	97%	90%	99.7%	44%	83%
Existing Cxbladder tests					
CxbT	89%	63%	99%	16%	59%
CxbD	74%	82%	97%	25%	78%

A **CxbD⁺ negative** patient has a low probability of Urothelial Carcinoma because CxbD⁺ combines the characteristics of high Sensitivity (97%), NPV (99.7%) and Specificity (90%) with a Rule out rate (ROR) of 83%.

A **CxbD⁺ positive** patient conversely has a higher probability of urothelial cancer for the same reasons. A positive test therefore can be used to justify an intensification of urologic evaluation and assist the adjudication of diagnostic dilemmas such as equivocal cystoscopy or urine cytology.

Sensitivity - the frequency with which a test correctly identifies patients with a disease.
Specificity - the frequency with which a test correctly identifies patients without a disease.
Negative Predictive Value (NPV) - the percentage of negative tests being true negatives (by standard of care).
Positive Predictive Value (PPV) - the percentage of positive tests being true positives (by standard of care).
Rule-out Rate (ROR) - the percentage of tests that return a negative result.

[2] Lotan et al 'Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification' Journal of Urology 2022 Dec 30;101097JU0000000000003126. doi: 10.1097/JU.0000000000003126 online ahead of print.

DETECT⁺ DRIVES EVIDENCE PROGRAM CHANGE

With the delivery of new and exciting evidence showing the analytical validity of Cxbladder Detect⁺ (CxbD⁺), we have modified our existing clinical evidence generation program to optimize the path to coverage for Detect⁺. Specifically, the primary endpoint of the DRIVE study has been updated to Detect⁺ alongside Triage. Specifically, the DRIVE study will generate clinical validity evidence for CxbD⁺. The STRATA study will offer clinical utility evidence for CxbD⁺ as a secondary objective. Additionally, we will launch the AUSSIE study to develop clinical validity evidence for CxbD⁺ in an Australian healthcare system for accurate risk stratification to intensify or de-intensify hematuria evaluation. We will announce additional clinical studies as part of our medical communications program as those plans mature.

ONGOING STUDY PROGRAM	ENROLLED SITES AND LOCATIONS	PROGRESS AND TARGETS*
STRATA - Safe **T**esting of **R**isk for **A**symptoma**T**ic Microhematuri**A**	11/11 USA and Canada	- Enrolment total is 430, including 106 'low risk' subjects that are the focus of the study - Target ~600 subjects, including 120 low risk subjects randomized to test arm - Last patient in Q2 2023 - Follow up until Q2 2024
DRIVE - Detection and **RI**sk Stratification in **VE**terans Presenting with Hematuria	7/11 (VA) USA	- Enrolment total is 513 - Target (Q2 2025) ~600 patients - Last patient in: Q2 2023 - Follow up: until Q2 2025
AUSSIE - Australian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia	1/1 Australia	- Enrolment due to start in March 2023
DEDUCT - DEtection of **D**isease in the **U**pper tra**CT**	1/3	- One site is open for this pilot study and the first patient in is expected by Dec 2022
LOBSTER - LOngitudinal **B**ladder Cancer **S**tudy for **T**umor R**E**cur**R**ence	2/10	- Two sites are open and another 8 are at pre-activation. Enrolment is now 27 patients - Each site will enroll 100 patients within 12 months and follow up for another 12 months
MONSTER - MONitoring **S**tudy of post-**T**reatment **E**ffectiveness for **R**esidual Disease	0/1 New Zealand	- Finalizing protocol documentation and commenced engagement with ethics committee - Target (Q1 2023) first patient

**Dates are calendar year, not financial years*

Analytical validity: Develop a test that is repeatable in the lab for a given indication and population.

Clinical validity: Make sure the test works in the same way on an independent eligible population for the given indication.

Clinical utility: Put the test in the hands of a physician to establish that it can usefully change patient management within the context of care for the defined population and indication.

Visit the Pacific Edge website to learn more about the strategic rationale for our studies.

DRIVING PERFORMANCE EXCELLENCE

Darrell Morgan joined Pacific Edge in October as Chief Operating Officer. In this role he is overseeing the company's global laboratory operations, manufacturing, logistics and inventory management. Based in Dunedin, he is also charged with driving the quality and compliance functions and operationalizing people and culture initiatives.

Darrell has more than 37 years' experience in senior roles in the UK, Europe, and New Zealand. They have included pharmaceutical research and development, immunodiagnostics, and device development for drug delivery across human and animal health. He has also held technical operations and customer-facing roles.

What attracted you to working at Pacific Edge?

My career in human health has been driven by a passion to make a positive impact on patient health and wellbeing. At Pacific Edge I can help our patients through their bladder cancer diagnosis journey, providing world class clinical diagnostics with class leading customer service. I want patients to be confident that whatever their Cxbladder result, that the result is accurate, will be provided in a timely fashion and backed-up by Pacific Edge's experts in customer care.

You have now been in the role for three months – what do you see as your priorities for the year ahead?

The first three months has given me insights into where I need to focus. These are:

- Continuing to build a world class team of manufacturing scientists, supply chain experts, quality managers and molecular diagnostic specialists.
- Performance Excellence – developing a Lean 6-Sigma approach to reagent manufacture, clinical diagnostic assay work-streams, inventory management and customer service.
- Scale-Up and growth. Pacific Edge's growth strategy will be underpinned by right sized manufacturing, testing and clinical diagnostic capabilities. The next year will see increased capability in reagent manufacture, automated solutions for tube filling and labelling, and increased capacity to match forecast volume growth from new market opportunities and product updates.

> **"At Pacific Edge I can help patients through their bladder cancer journey."**

What is one of the biggest challenges you are now facing?

The war in Ukraine and COVID-19 in China continue to cause significant disruption to supply chains, especially with laboratory consumables or highly specialized equipment or molecular diagnostic grade chemicals/PCR enzymes. Our team has done a magnificent job over the last 3 years, but we still see daily issues with freight delays, long lead times for oligoprimers[3] and primary closures for our reagents.

Outside of your work at Pacific Edge describe to us your most memorable day of 2022?

My family and I are relocating from Auckland to Dunedin. We sold our house at auction in November which was both fascinating and terrifying! It was memorable in that we could see the result of the hard work in getting the house ready for auction, but also stressful - not knowing if the house would sell or not and what the price would be. The auction was successful and allows us to be in our new home in Dunedin in time for Christmas.

DARRELL MORGAN
October 2022 – present
Chief Operating Officer – Pacific Edge

Former roles:

Argenta (Animal Health Contract Research and Development)
2013 - October 2022 - Product Development Director with earlier senior roles in product and business development and research and development.

UCB (Pharmaceutical Manufacturing)
2004 - 2012 – Director, Head of Patient Solution Technologies, Life Cycle Management with earlier roles in sterile drug product/device development and industrialisation.

Oxford GlycoSciences (Biopharmaceutical Research and Development)
1999 - 2003 – Pharmaceutical Development Manager

Fisons/Rhone-Poulenc Rorer (Pharmaceutical Research, Development and Manufacture)
1990-1999

Amersham International (Immunodiagnostic Manufacture)
1985-1990

[3] Oligoprimers are synthesised chains of DNA and RNA that Pacific Edge uses to copy or amplify the gene signatures that are the focus of Cxbladder tests.

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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