PACIFIC EDGE LTD

INVESTOR UPDATE

OCTOBER 2022

INSIDE

FROM THE CEO

BUILDING MOMENTUM IN OUR MARKETS

Dear Shareholders,

In this second quarter shareholder update, I am pleased to report the investments we are making to drive the adoption of Cxbladder tests globally are delivering early results.

As we detail on page 3, the volume of Cxbladder tests processed at our US and New Zealand laboratories has risen strongly against the first quarter and the prior year, with the increase in throughput being mirrored by an increase in the number of US clinicians ordering our tests.

We have on-boarded 14 new people since the end of March, bringing our global team to 100 at the end of September. Most of the new hires are charged with advancing our revenue growth objectives and increasing awareness of the peer-reviewed clinical evidence that underpins the clinical value of Cxbladder.

We have hired effectively against plan with the recruitment of new Account Executives (AEs) and marketing hires, while establishing our new Medical Affairs Team and new Virtual Sales Team. The Virtual Sales team, responsible for growing our sales pipeline through prospecting activities, while enhancing the Cxbladder customer experience with streamlined service, ordering, and delivery of test results, is the first among these new hires to have a clear impact. We expect all commercial hires to build further momentum in the quarters ahead.

Our US National Sales Meeting (see page 5), held in September under the banner of 'Unlocking Our Potential', was a key step towards this goal. We assembled all staff across the broader commercial team and focused our training on a standardized selling process, maturing our new AEs, and upskilling our tenured AEs, while creating opportunities to share successes, and reinforcing a culture that celebrates excellence at Pacific Edge.

> **"The increase in throughput is being mirrored by an increase in the number of US clinicians ordering our tests"**

In the New Zealand market, we continue to make progress in encouraging healthcare providers to use Cxbladder earlier in the patient care pathway (see page 4). We have also made further steps into new markets such as Australia and Singapore, including the recruitment of a new business development manager for Southeast Asia, based in Singapore.

We continue to advance our clinical evidence generation program to strengthen the case for Cxbladder to be included in global standards of care and gain coverage by healthcare payors. Patient recruitment is steadily rising for studies already underway, while the more-recently initiated studies are navigating key administrative milestones (see page 6).

This important progress continues despite the release for public comment in July of a proposed new Local Coverage Determination (LCD) from Novitas, the Medicare Administrative Contractor with jurisdiction for our US laboratory. If accepted without change, this proposed LCD would result in a loss of coverage for Cxbladder tests by the US Centers for Medicare & Medicaid Services (CMS).

As demonstrated by the continued increase in Cxbladder testing volume, the proposal has had little to no impact on demand for our tests. Cxbladder remains a covered test while submissions on the proposed LCD are being considered, and feedback from our sales force is that it is not on the radar of our key US customers and physicians.

Pacific Edge maintains that in the absence of any adverse reporting event about the performance of Cxbladder, it would be unprecedented to lose coverage. To this end, we have offered comments on the proposal (see page 4). We maintain our position that the proposed LCD is unlikely to survive in its current form and continue to responsibly plan for all eventualities.

We look forward to providing a further update when we release our half year financial results on 24 November 2022.

Dr Peter Meintjes
Chief Executive

TEST VOLUMES

INVESTMENTS IN US SALES AND MARKETING DRIVING RESULTS

Cxbladder tests processed at Pacific Edge's laboratories in the US and New Zealand have set another record in an early demonstration that our investments to drive adoption are delivering results.

In the three months to the end of September 2022, the team processed 7,861 tests, a 36% improvement on the 5,780 tests processed in the same quarter in the prior financial year and an 11% increase on the 7,055 tests processed in the three months to the end of June 2022. For the six-month period, test volumes reached 14,916, a 34% increase on the 11,136 tests processed in the same period in the prior financial year.

US test volumes for the latest three-month period increased to 6,696, a 42% improvement on the 4,706 in the same period a year ago and up 10% on the 6,073 processed in the three months to the end of June. For the six-month period, US test volumes were also up 42% on the same period a year ago to 12,769.

We have also seen an increase in US clinicians ordering our tests to 979, a 42% increase on the 689 ordering clinicians at the same time a year ago and 10% ahead of the 894 ordering clinicians at the end of June 2022.

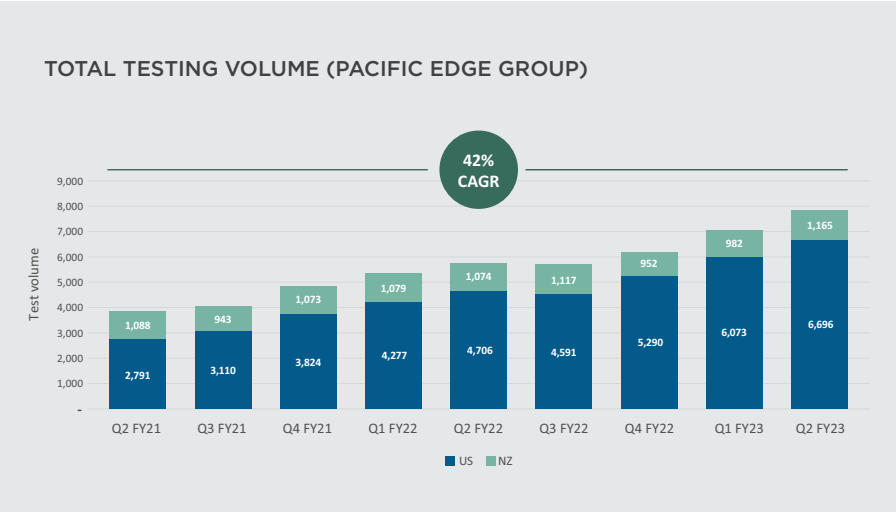
Our internal metrics show that this increase in ordering clinicians reflects an important contribution from the new Virtual Sales Team, a key element of the investment program to drive growth we set out in May 2022. This team has had an immediate impact through prospecting activities, and by assisting on-the-ground teams with the on-boarding of new clinicians and urology practices, while ensuring the streamlined ordering of tests and results delivery.

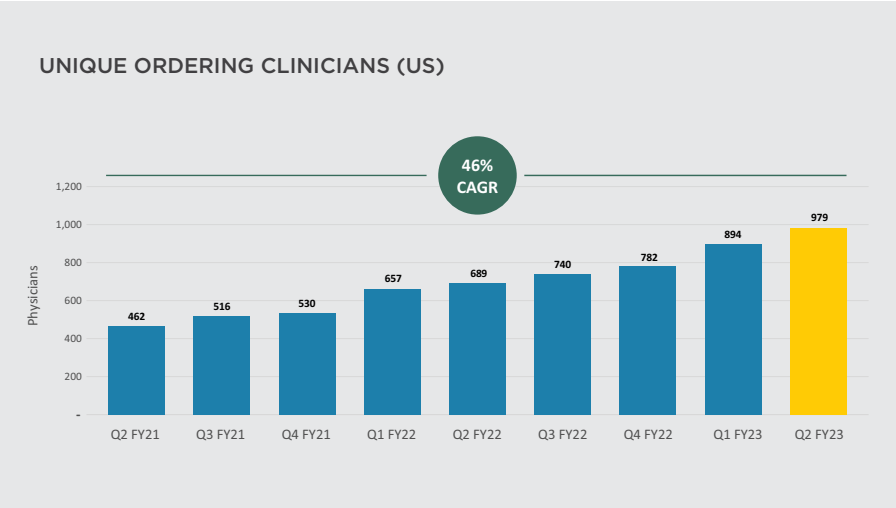
We continue to prudently invest in line with the investment program, which as we mentioned in May is linked to the achievement of certain revenue milestones. In addition to the hiring of a new Virtual Sales team, our recruitment program has included hiring of account and marketing executives and the establishment of a new Medical Affairs team.

We are confident that these investments will continue to build sales momentum. The Account Executives we hired last year are beginning to hit their stride, while new hires are learning the ropes and bringing fresh insights and energy to the team.

We are seeing early results with opportunities emerging in previously uncovered territories. Similarly, our Medical Science Liaison team is quickly upskilling, developing strategies to drive enrolment in our clinical studies and support our sales efforts.

In the Asia Pacific, where test numbers are dominated by the relatively mature New Zealand market, volumes in the three-month period were 1,165, an 8% increase on the same period a year ago and a 19% increase on the June 2022 quarter. For the six-month period, New Zealand test volumes were largely flat on the same period a year ago at 2,147 tests.





PRIMARY CARE

CXBLADDER BUILDS MOMENTUM IN THE COMMUNITY

Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral and *Te Whatu Ora* Whanganui have become the latest New Zealand regional public healthcare providers to adopt Cxbladder in the primary care setting.

From the end of September General Practitioners in Palmerston North, the Horowhenua, Manawatu, Otaki and the Whanganui districts have been able to use Cxbladder Triage (CxbT), together with imaging to assist them to safely rule out bladder cancer in patients presenting with hematuria.

By identifying these patients in primary care, CxbT reduces the need for urology referral and further invasive testing, such as a cystoscopy. This new primary care pathway offers a streamlined standard of care and is receiving increasing attention from patient advocacy groups, as it provides patients with greater comfort and peace of mind.

The approach was pioneered in Canterbury and was supported by a clinical review published in the New Zealand Medical Journal in 2020[1]. The review showed fewer patients were referred to secondary care and required invasive procedures. When cancer was diagnosed the time to treatment was also reduced. Meanwhile those who received a negative CxbT test gained early reassurance (within a couple of weeks) that they did not have bladder cancer.

More than 70% of New Zealand's population now has access to Cxbladder through the public health system and we are actively engaging with the national system, *Te Whatu Ora* – Health New Zealand and *Te Aka Whai Ora*, the new Māori Health Authority, to expand access for the remainder of the population.

[1] Davidson P, McGeoch G, Shand B. Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. NZ Med J 2020. 133:1527

NOVITAS PROPOSAL

SEEKING US REIMBURSEMENT CERTAINTY

Pacific Edge has seen no disruption to demand for Cxbladder and it remains a covered and reimbursed test by the Centers for Medicare & Medicaid Services (CMS), despite the proposed Local Coverage Determination (LCD) that would see Cxbladder Detect and Cxbladder Monitor lose coverage if implemented without any changes.

Novitas, the Medicare Administrative Contractor with jurisdiction for Pacific Edge's laboratory in Hershey Pennsylvania, issued and sought public comment on the LCD in July. Pacific Edge submitted written comments for consideration supported by multiple Key Opinion Leading customers, the patient advocacy group BCAN (Bladder Cancer Advocacy Network) and our industry partner the Coalition for 21st Century Medicine (C21), which also coordinated with other affected companies in its response.

Subsequent to the comment period closing on 6 September 2022, Pacific Edge has requested meetings with Novitas directly and with the CEOs of Guidewell (Novitas' parent company) and CMS with assistance and coordination from C21.

Our view remains that the proposed LCD contains inconsistencies, unintended consequences and a methodology that may violate Medicare's rules.

Most notably, the proposed LCD appears focused on tests for guiding therapeutic decisions after a confirmed diagnosis (PGx or Pharmacogenomics testing), apparently excluding diagnostic biomarker tests from clinical tool kits. The LCD also takes the highly unusual step of 'outsourcing' coverage determinations to third party databases.

We have yet to hear how our submissions have been received and do not know when we will get a response. However, we will get 45 days' notice of the adoption of a new LCD.

Meanwhile, a proposed LCD must be withdrawn or adopted within a year of the closure of public comment. So, if Novitas issues a new draft LCD the clock starts again. We are looking forward to gaining certainty from Novitas.

NATIONAL SALES MEETING

UNLOCKING OUR POTENTIAL

"Unlocking Our Potential" was the theme of the Pacific Edge Diagnostics USA (PEDUSA) national sales meeting held in Hershey, PA in mid-September. Traditionally an annual event, COVID restrictions forced us to cancel two previous meetings, so this was the first in-person gathering of the entire sales force in over three years.

The meeting was a key initiative of our strategy to build capability and capacity within Pacific Edge to drive the adoption of Cxbladder and accelerate revenue growth. It helped to build relationships within the commercial team and was a significant step towards standardizing process and training new hires, ensuring new account executives benefit from the insights of tenured executives and they in turn benefit from the energy and insights new team members bring to the company.

Over the course of three productive days, the US sales, and executive teams, with some customer service, and laboratory team involvement as well, were able to interact and discuss ways that we can better help clinicians and patients in the diagnosis of bladder cancer. The focus on unlocking our potential reflected our understanding that impactful insights delivered at the right moment can help solidify the value that Cxbladder offers to clinicians and patients.

> **"The meeting was a key initiative to build capacity and capability"**

To that end, the team heard from a practicing urologist that uses Cxbladder, a bladder cancer patient, and a broad array of Pacific Edge experts on how to lead sales conversations with impactful insights. We also discussed the existing high-quality peer reviewed evidence for Cxbladder that answers the range of questions that patients and our customers regularly face and how to present this information in a meaningful way that leads to increased Cxbladder utilization at the earliest point in patient care.

The sessions – along with a team scavenger hunt around Hershey and an evening event to celebrate our retiring PEDUSA Chief Executive Jackie Walker – renewed and re-energized relationships across the entire US based Pacific Edge team. It was also a great opportunity for staff to meet the new team members who have joined PEDUSA since our last meeting three years ago. Of course, all good sales reps know that what matters from here is the follow up – we will be tracking their progress and continuing to reinforce the new enhanced selling model until a review of the implementation in early 2023.

CLINICAL EVIDENCE PROGRAM ADVANCES

Clinical evidence fundamentally underpins commercial success in healthcare and consequently is one of the key pillars of our investment program. High-quality clinical evidence is needed by clinicians to make the decision to adopt Cxbladder in clinical practice and by healthcare payors to make decisions to cover and reimburse a Cxbladder test. The guidelines committees of professional medical societies, including the American Urological Association (AUA), the National Comprehensive Cancer Network (NCCN) and the European Association of Urology (EAU), also need the evidence to support embedding Cxbladder as a standard of care. All our studies made progress during the last quarter.

STUDY	ENROLLED SITES AND LOCATIONS	Q2* FY23 PROGRESS AND TARGETS
US and Singapore studies	Complete	- Enrolment and analysis complete, under peer review and pending publication
STRATA (Safe Testing of Risk for Asymptomatic Microhematuria)	11 USA and Canada	- Enrolment total is 412, including 100 'low risk' subjects that are the focus of the study - Target (Q4 2023) 600 subjects, including 120 low risk subjects randomized to test arm
DRIVE (Detection and Risk Stratification in Veterans Presenting with Hematuria)	10 USA	- Enrolment total is 491 - Target (Q2 2025) ~600 patients
LOBSTER (Longitudinal Bladder Cancer Study for Tumor Recurrence)	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
DEDUCT (Detection of Disease in the Upper Tract)	1/3	- One site is open for this pilot study and the first patient in is expected by Dec 2022
MONSTER (Monitoring Study of Post-Treatment Effectiveness for Residual 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*

THE STRATEGIC RATIONALE OF OUR STUDIES

Our clinical studies are principally aimed at delivering two types of evidence: clinical validity evidence (evidence that Cxbladder accurately identifies a patient's clinical status in an independent patient cohort) and clinical utility evidence (evidence that Cxbladder is clinically useful for physicians for a defined population and indication). We are also undertaking studies to deliver analytical validity evidence (evidence that a test is repeatable in laboratory conditions).

US and Singapore Studies – studies to further develop the clinical validity of Cxbladder tests in facilitating the early detection, intensifying or de-intensify hematuria evaluation and assistance in adjudicating equivocal cystoscopy.

STRATA – a study to further demonstrate the clinical utility of Cxbladder in safely risk-stratifying patients presenting with hematuria into those that may receive a less intense evaluation for the presence of urothelial cancer and those that should continue with a standard evaluation. The aim is to show how Cxbladder can safely de-intensify evaluation for a significantly higher proportion of low risk patients than the current AUA guidelines.

DRIVE – a study underway in partnership with the US Veterans Health Administration (VA). It seeks to demonstrate to VA urologists the clinical validity of Cxbladder in a cohort of VA patients, but it is also relevant to Pacific Edge's drive for the inclusion of Cxbladder in the AUA guidelines for the evaluation of patients with gross hematuria and micro hematuria.

LOBSTER – a study aimed at further demonstrating the clinical validity of Cxbladder in assisting clinicians to reduce the frequency of cystoscopies for patients under surveillance for the recurrence of urothelial cancer. Like the STRATA study, LOBSTER aims to further demonstrate Cxbladder can reduce the burden of invasive and expensive cystoscopy evaluations, spare patients the potential risks, discomfort, and anxiety from cystoscopy and potentially overcome entrenched patient noncompliance with management and surveillance regimes.

DEDUCT – a study to demonstrate the clinical validity of Cxbladder for the detection of urothelial carcinoma in the urinary upper tract (UTUC) where the ureters connect the bladder to the kidney. It is aimed at evaluating Cxbladder's potential to safely avoid ureteroscopy, risk-stratify patients suspected to have UTUC and avoid unnecessary ureteroscopy and radiation exposure through imaging. It is foundational evidence necessary for the inclusion of Cxbladder in AUA guidelines for the treatment of UTUC.

MONSTER – a pilot study to analytically validate the performance characteristics of Cxbladder against white light cystoscopy during the surveillance of urothelial cancer. This is a study to determine the presence of a tumor and safely risk-stratify patients for residual disease prior to the 6-week re-resection for high grade patients or the 3-month flexible cystoscopy check for all patients. The study could be expanded to the US depending on the outcome of the pilot.

US LEADERSHIP

NAVIGATING KNOWN CHALLENGES

David Levison assumed the new role of Pacific Edge Diagnostics USA (PEDUSA) President from the start of September, taking direct strategic and operational control of our largest and fastest growing operations.

David brings to the business more than 25 years in the healthcare industry, working across a range of sectors from pharmaceuticals to services and diagnostics. He has been the founder and CEO of several high growth medical and medical technology businesses and for the four years until November 2020 was a Non-Executive Director on the Pacific Edge Board.

You have moved from being Executive Chairman of PEDUSA to President Americas; why have you taken on the role?
The investments that we have made in Pacific Edge recently and have planned for the future will allow the global organization to attain new levels of clinical acceptance and financial progress. In the US, the addition of Medical Affairs, Market Access and Reimbursement teams, and local clinical evidence development capabilities are solidifying the foundation for our future growth. I am excited by the opportunity to make the Cxbladder products a more important tool for all US based urologists.

What gives you confidence that you can drive the adoption of Pacific Edge's technologies in the world's largest healthcare market?
The current standard of care for both hematuria evaluation and bladder cancer surveillance has not been optimized for the advances in molecular diagnostic signatures like Cxbladder. Established procedures and tests, like cystoscopy and cytology, were introduced many years ago as stand-alone products before the development of molecular medicine. When integrated into clinical pathways, Cxbladder can help clinicians target the specific patients that are likely to benefit from a full urology work-up as well as those patients that can be spared the time, expense, and discomfort. Our customer Kaiser Permanente, known for its innovative approach to healthcare, is adopting Cxbladder in this integrated way and we believe will serve as a model for further clinical adoption.

What do you see as the biggest challenges?
The good news is that our challenges are known, and we have plans in place for overcoming them. Our products have historically not had the level of published clinical evidence that is required to drive adoption and be included in standard of care guidelines. The pipeline of clinical evidence that is in development will allow us to show urologists the full range of benefits they can derive from the use of Cxbladder products.

What is the professional experience that has been most helpful to you in this role?
There have been multiple. Having been the founding CEO of molecular diagnostics companies, from start-up to full commercialization, helps me understand the road that Pacific Edge is traveling and anticipate the next twist and turn of our journey. Having worked with the Centers for Medicare & Medicaid Services, commercial insurance companies, and the US Food and Drug Administration has provided me with insights into the transition from scientific insights to commercial success. And lastly, having been on the Board of Directors of both Pacific Edge as well as other firms, I understand the importance of effective communication with investors, Directors, and the wide variety of parties interested in the success of Pacific Edge.

Where are you most likely to be found on a Saturday afternoon?
I am likely to be doing some combination of the following: working in our fruit and vegetable garden, cooking a meal for family and friends, visiting with one of our five children, or trying to fit in a run or walk for some exercise.

DAVID LEVISON

- Pacific Edge Diagnostics USA – President Americas

Former roles:
- Pacific Edge - Non-Executive Director
- Qlarity Imaging - Chief Executive Officer
- CardioDx – Director Chief Executive Officer and Chief Strategic Officer
- CareDx - Board member
- Texas Pacific Ventures - Venture Partner
- iScribe - Founder, President, and Director

Education:
- B.A. (Williams)
- MBA (Stanford)

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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