PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

INVESTOR UPDATE

JULY 2024

INSIDE

LETTER FROM THE CEO

LOOKING TO THE CATALYSTS OF THE FIRST QUARTER

Dear Shareholders,
The first quarter of the 2025 financial year will be the last quarter before we learn how Novitas, our Medicare Administrative Contractor, has responded to our comments and finalizes DL39365.

Once again, I'm tremendously proud of the team at Pacific Edge; one that has delivered on key strategic milestones and sustained commercial performance despite the uncertainty regarding Medicare reimbursement for Cxbladder.

Test volumes processed through our laboratories were steady over Q4 24, down 0.3% to 7,188 (see pages 3 and 4). Laboratory throughput was supported by a strong performance from our APAC operation, led primarily by growth in the New Zealand market and a sustained growth trajectory from our US customer Kaiser Permanente. These gains were diluted by attrition in the sales force as we have continued to limit the backfilling of commercial staff while Medicare reimbursement uncertainty continues.

As I highlighted in our Annual Report released at the end of June, Q2 25 is likely to feature three significant developments that will be highly determinative of our results for the current financial year and our strategy at least for the short to medium term.

Novitas is expected to finalize the draft LCD 'Genetic Testing for Oncology' (DL39365) by the end of July including a response to all submitted comments. This final LCD directly affects the Medicare reimbursement of our Cxbladder tests and the rate of adoption.

By September we are also expecting the Centers for Medicare and Medicaid Services to have reviewed our proposal for a Cxbladder Detect+ price of approximately $1,590 (see page 5). Detect+ delivers significant performance improvements over our existing tests thanks to its incorporation of DNA biomarkers of bladder cancer. A favorable outcome for Detect+ pricing is expected to significantly increase the value of our total addressable market, improve the economics of promoting our tests, and if supported by positive language in the microhematuria guidelines, accelerate the rate of adoption by clinicians and healthcare payers.

Finally, we will also soon learn if our recently released STRATA[1] study, which demonstrated the clinical utility of Cxbladder Triage to risk stratify microhematuria patients, is sufficient to convince the American Urological Association to make an amendment to the 2020 guidelines for the evaluation and management of hematuria. A favorable outcome (coupled with a positive Medicare coverage determination) would entrench Medicare coverage of Cxbladder, drive demand with physicians and patients and improve our ability to influence coverage by private healthcare payers. In the event of a Medicare non-coverage determination, guidelines inclusion would significantly increase the probability of regaining coverage.

> **"A favorable outcome for Detect+ pricing is expected to significantly increase the value of our total addressable market, improve the economics of promoting our tests, and if supported by positive language in the microhematuria guidelines, accelerate the rate of adoption by clinicians and healthcare payers."**

We expect all these matters to be settled before our Annual Shareholder Meeting to be held on 24 September 2024 in Auckland. Consequently, in keeping with the approach we took last year, we intend at this meeting to offer a

[1] Lotan et al. (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. (In Press) The Journal of Urology Vol 212 1-8 Jul 2024.

'deeper dive' into the business with presentations from our Chair, Chris Gallaher, myself as well as other senior management. It will also be the last time Chris and Mark Green attend the meeting as Directors of the company and we look forward to the opportunity to acknowledge and celebrate their contribution.

While the last 12 months have been unsettling for investors, I remain steadfast in the view that even in the event of short-term adversity, the long-term view for Pacific Edge remains one of rapid, sustained growth once we gain certainty over Medicare's continued coverage of our tests. The key question is – in the face of these immediate developments – how we execute on the opportunities before us to achieve that goal.

We will update Shareholders ahead of the ASM with the agenda, and with these key events resolved, I am confident that we can provide transparent insight into our strategy and answer any questions you may have.

I look forward to seeing you there.

Best regards,

Dr Peter Meintjes
Chief Executive

TEST VOLUMES

US SALES TEAM SUSTAINS PERFORMANCE IMPROVEMENTS

Tests processed through our laboratories in the three months to the end of June 2024 were steady on the prior quarter (Q4 24) as we continued to benefit from improved performance from a lean sales force in the US, an acceleration of demand in New Zealand and sustained growth from Kaiser Permanente.

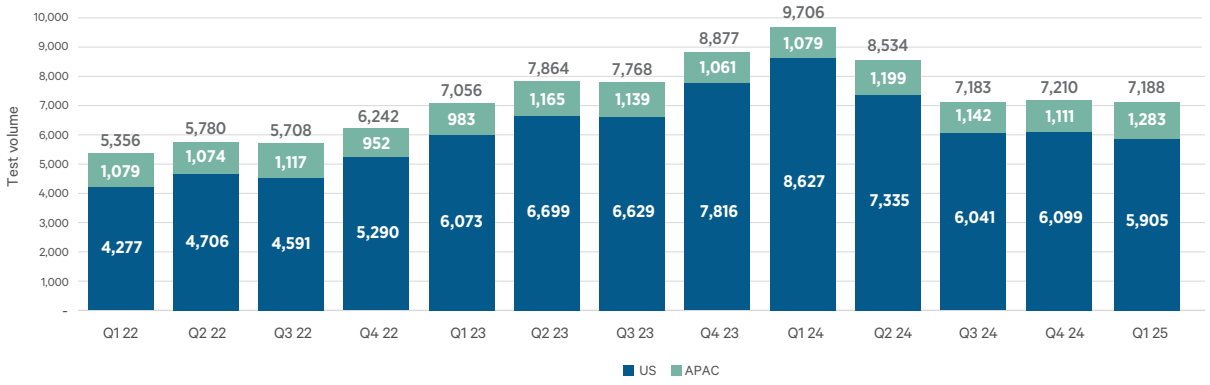
Volumes in Q1 25 flattened to 7,188 tests, a figure down 0.3% on the 7,210 tests in Q4 24. US volumes were 5,905 tests down 3.2% on the 6,099 in Q4 24. The result follows from a further reduction in our direct sales team and previously reported improvements in sales force efficiency alongside a growing contribution from Kaiser Permanente following the incorporation of Cxbladder into its electronic medical records system.

Q1 25 saw another reduction in US account executives, down to an average of 15 FTEs across the quarter from 16 FTEs in Q4 24. This drop follows a decision to limit backfilling of commercial staff while Medicare reimbursement uncertainty continues. The combination of fewer FTEs and the increased Kaiser Permanente volumes has lifted our sales force efficiency metric (403 tests per average sales FTE in Q1 25 vs 381 in Q4 24 and 288 in the same period a year ago).

In the US, tests per ordering clinician (our preferred metric for measuring customer commitment to Cxbladder) increased to 6.8 in Q1 25, from 6.7 in Q4 24 reflecting ongoing efficiency improvements, our enhanced sales messaging, which focuses on the clinical value of Cxbladder in the evaluation of hematuria, and again the impact of the increased Kaiser Permanente volumes.

Asia Pacific volumes were up 15.5% on Q4 24 to 1,283 tests. The region benefited from an increase in demand from New Zealand for surveillance evaluations in particular (Cxbladder Monitor volumes were up 17%). The result also benefited from demand from new regions in the South Island delivering samples. Volumes from Australia and Asia reached a new quarterly record although totals remain small.

FIGURE 1: TOTAL TEST VOLUMES[1]



[1] Volumes in some prior quarters of FY24 are marginally different from those reported in earlier investor updates reflecting post period adjustments.

FIGURE 2: CXBLADDER CLINICAL ADOPTION

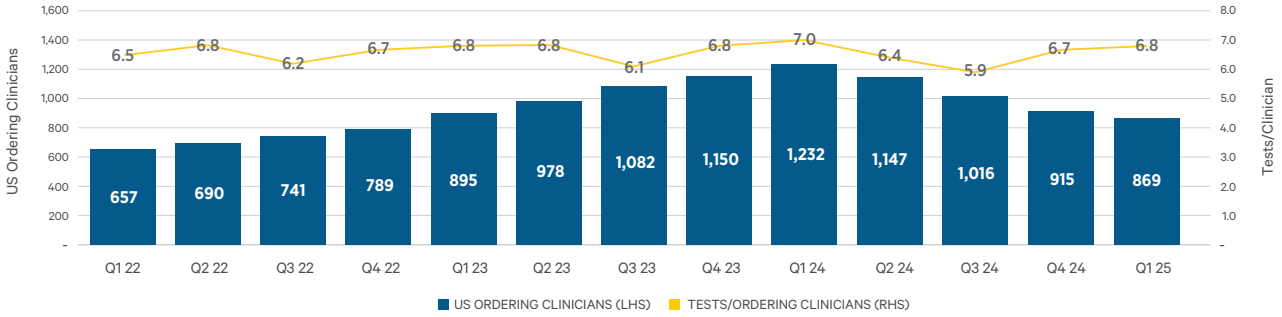
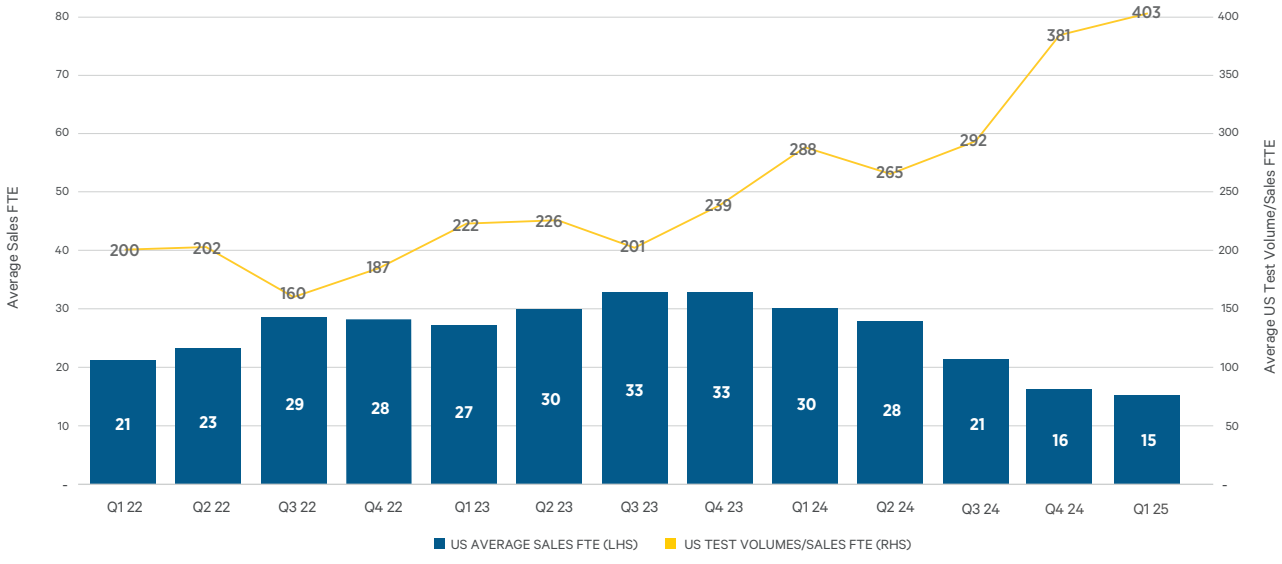


FIGURE 3: US SALES FORCE EFFICIENCY



ACKNOWLEDGING OUR TECHNOLOGICAL ADVANCES

Pacific Edge has made what we believe is a compelling case for the Centers for Medicare and Medicaid Services (CMS) to price Cxbladder Detect+ via 'Crosswalk', a process that acknowledges the advancement of incorporating both RNA and DNA markers for the detection of bladder cancer in patient samples.

If CMS shares our view and agrees that Detect+ should attract a price of US$1,590, Pacific Edge would gain significant upside to our existing market opportunity for hematuria evaluation. The value of the total addressable market would grow, our margin per test would increase, the profitability profile of operating a sales resource would increase and the risk associated with scaling our sales force would decrease.

Coupled with the known published improvements for Detect+ and any future guidelines inclusion, the rate of adoption by clinicians and healthcare payers would also be expected to increase, significantly changing the outlook for Pacific Edge.

The CMS price for Detect+ sets the amount Pacific Edge will be reimbursed for all patients with Medicare and Medicare Advantage insurance (assuming a positive coverage decision). While private health insurance companies make separate coverage decisions based on their own medical policy for a test, the CMS price typically sets a benchmark for non-contracted reimbursement and contracting negotiations.

Pacific Edge publicly set out its arguments at the CMS Clinical Lab Fee Schedule (CLFS) annual meeting held at the end of June. Our team led by David Sosa, Vice President of Market Access, argued CMS should Crosswalk the price for Detect+ to a combination of Cxbladder Detect (with a price of US$760) and an HPV[1] cancer test called NavDx (with a price of US$827.69) developed by US precision cancer company Naveris. NavDx is the only dd-PCR based MAAA (multi-analyte with algorithmic analysis) test with a price in the CLFS, and consequently, we believe this is the most appropriate Crosswalk candidate based on the technology and resource usage involved in performing a Detect+ test.

If CMS agrees with our Crosswalk proposal, we expect to be notified by the time we gather for our annual meeting in September. The price will then be subject to a 'Notice and Comment' period of 60 days before finalization and becoming effective on 1 January 2025.

However, if CMS does not agree with our Crosswalk proposal, it may choose an alternative technology match from their database with a different price or direct Pacific Edge to a 'Gap Fill' process, potentially delaying pricing by another year. We remain optimistic about CMS' assessment and its potential impact on Pacific Edge's financial performance.

[1] HPV Human papillomavirus

SURVEY: PATIENTS SHOW STRONG INTEREST IN NON-INVASIVE ALTERNATIVES TO CYSTOSCOPY

Patients being monitored for recurrent bladder cancer are interested in non-invasive test alternatives to minimize the discomfort and anxiety associated with cystoscopy.

That is the finding of a new survey of 1,507 US patients conducted by Pacific Edge working with the Bladder Cancer Advocacy Network (BCAN).

Asked about their experience with cystoscopy, 42% of patients indicated that they felt 'moderate' to 'extreme' discomfort during the procedure. Meanwhile, 78% of patients indicated that they experienced some pain, and 25% indicated that the pain was 'moderate' to 'the worst imaginable'. Furthermore, 56% of patients indicated that they experienced 'moderate' to 'extreme' anxiety.

All patients in the survey were registered with BCAN's Patient Survey Network and were being monitored for recurrent non-muscle invasive bladder cancer (NMIBC).

When presented with introductory information on Cxbladder Monitor, a non-invasive urine test with the option of in-home sampling that can help reduce the frequency of surveillance cystoscopy, 38% of patients were willing to incorporate the test into their monitoring schedule while a further 51% were interested and wanted to learn more.

Of significant note, 80% of patients rated the availability of urine-based test options as moderately to extremely important. Despite this, 82% were unaware of leading test options such as Cxbladder Monitor and 80% reported they had not discussed non-invasive test alternatives with their doctor.

The results of the survey also suggest non-invasive diagnostic tools such as Cxbladder Monitor may help to address an ongoing issue with patient compliance. Recent American Urological Association (AUA) data[2] suggests that the average length of follow-up monitoring among NMIBC patients is just 1.8 years[2]. This is in sharp contrast to the AUA guidelines which recommend regular cystoscopies for all risk categories until at least 5 years after the most-recent removal of a tumor. For high and intermediate risk patients, the expectation is that scheduled checks continue indefinitely.

Pacific Edge Chief Medical Officer Tamer Aboushwareb said: "If applied to the right patient population, clinicians have an opportunity to dramatically reduce the burden of surveillance for recurrence in their NMIBC patients with Cxbladder Monitor, simultaneously maximizing patient comfort and improving compliance with long-term monitoring. Reducing the frequency of cystoscopy required and the travel burden linked to in-clinic visits also has a societal benefit that is often unrealized."

Andrea Maddox-Smith, CEO of the Bladder Cancer Advocacy Network said: "As the leading bladder cancer advocacy organization in the United States, we know that patients are interested in having less invasive ways to diagnose and monitor NMIBC. Safe, reliable and effective non-invasive surveillance options are good news for patients."

SURVEILLANCE PATIENTS EXPERIENCE WITH CYSTOSCOPY[1]

42%
INDICATED 'MODERATE' TO 'EXTREME' DISCOMFORT

78%
OF PATIENTS INDICATED THAT THEY EXPERIENCED SOME PAIN

56%
INDICATED THAT THEY EXPERIENCED 'MODERATE' TO 'EXTREME' ANXIETY

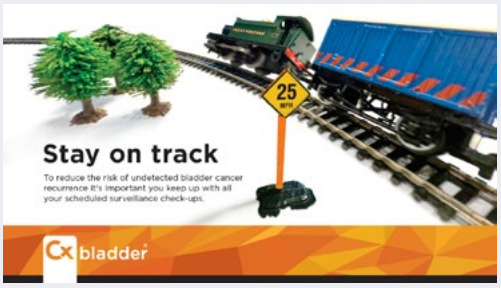
[1] Survey: Surveillance Patients Show Strong Interest in Non-Invasive Test Options (cxbladder.com)
[2] American Urological Association AQUA Registry Data

BLADDER CANCER AWARENESS MONTH

GLOBAL TEAMS RALLY BEHIND OUR MISSION

In May Pacific Edge joined with organizations around the world including the Bladder Cancer Advocacy Network (BCAN) to support Bladder Cancer Awareness Month.

Bladder Cancer Awareness Month is a time for those affected by bladder cancer to stand together and raise awareness of the disease while working to better support its care. Every year, over 610,000 people are diagnosed with bladder cancer around the world, and more than 1.9 million people are living with the disease. Globally, bladder cancer is the ninth most diagnosed cancer, and the sixth most common among men[1].



This year, in response to recent patient survey findings and AUA data suggesting surveillance compliance remains an ongoing challenge (see page 6 for more detail), we led with the campaign message 'Stay on track'. This message encouraged patients being monitored for recurrent NMIBC to keep up with scheduled surveillance check-ups. To help ease the burden of invasive testing, the campaign promoted Cxbladder Monitor as a non-invasive alternative to surveillance patients that can reduce the frequency of cystoscopy.

We anchored the 'Stay on track' campaign activity with the placement of collateral in urology clinics across the US and communication of patient survey findings. Our teams around the world then worked to raise the profile of Bladder Cancer Awareness Month with an orange themed dress up. This initiative was promoted across our digital channels alongside social media posts designed to increase awareness of bladder cancer symptoms and risk factors. 'Stay on track' social media posts reinforced the importance of regular surveillance checks to ensure early detection of any recurrent disease.

[1] https://worldbladdercancer.org/news_events/bladder-cancer-awareness-month-in-may-and-why-it-is-important/

OUR CLINICAL STUDY PROGRAM

BUILDING LONG TERM VALUE

Our clinical study program is at the foundation of Pacific Edge's value. We are focused on generating the compelling clinical evidence required to drive behavior change in physicians that is founded on the frameworks of Analytical Validity, Clinical Validity, and Clinical Utility, with the end points and sample sizes required for coverage decisions and guideline inclusion.

STUDY	GOAL	POPULATION AND USE	STATUS
STRATA (**S**afe **T**esting of **R**isk for **A**symptoma**T**ic Microhematuri**A**)	• CU for Triage • CU for Detect⁺ (retrospective)	• Microhematuria • Risk stratification	- First paper published in the Journal of Urology in May 2024 and presented at the AUA annual conference - Study sites will close late 2024 and final study reports completed early 2025
DRIVE (**D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria)	• CV for Detect⁺, Detect & Triage within a Veterans' cohort • Data for pooled analysis	• Micro and gross hematuria • Risk stratification	- Enrolment closed with 710 patients across 10 Veterans Affairs sites - Data cleanup underway and Detect⁺ runs expected Q3 2024 - Publication targeted for Q2 2025
microDRIVE (**D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria)	• CV of Detect⁺ • Data for pooled analysis	• Microhematuria • Detection	- Recruitment commenced November 2023 as a network study across all US Veterans Affairs Medical Centers coordinated from a single Veterans Affairs site - 208 patients have been consented for the study with 102 samples received to date - The target is up to 1000 patients including 35 tumor confirmed patients - Enrollment end is targeted for early 2025 and publication Q3 2025
AUSSIE (**A**ustralian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia)	• CV of Detect⁺ with an Australian cohort • Data for pooled analysis	• Micro and gross hematuria • Risk stratification	- Target enrolment: 600 patients across three Australian sites - Enrolment commenced September 2023 - 98 subjects are consented to the study and 93 samples have been received - 2 sites enrolling and 1 further site expected to commence within a month - Target publication Q4 2025
POOLED ANALYSIS	• CV of Detect⁺	• Microhematuria • Gross hematuria • Risk stratification	- Microhematuria and separately Gross Hematuria patients from DRIVE, AUSSIE and microDRIVE will be pooled and performance determined - Target publication Q1 2026
LOBSTER (**LO**ngitudinal **B**ladder cancer **S**tudy for **T**umor **R**ecurrence)	• CV of Monitor/ Monitor⁺	• Surveillance • Risk stratification	- Target enrollment is 400-500 subjects across 10 sites (US, Australia) - A total of 321 subjects have consented to the study with 532 samples received - The enrolment phase is expected to end early 2025 - Target publication Q1 2026
CREDIBLE (**C**ystoscopic **RED**uction **I**n **BL**adder **E**valuations for microhematuria) - A randomized, controlled, clinical utility study for hematuria evaluation	• CU of Detect⁺	• Microhematuria • Risk stratification	- Target enrolment is 1,000 subjects with an interim analysis at 600 to determine if the primary objective has been addressed - First patient in targeted for Dec 2024 - 15 US sites anticipated - Target publication Q1 2028

*Dates are calendar year not financial years

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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