PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

INVESTOR UPDATE

OCTOBER 2024

INSIDE

LETTER FROM THE CEO

A PATH TO MEDICARE COVERAGE CERTAINTY

Dear Shareholders,
I was pleased to see so many of you at our annual meeting last month.

The Auckland venue was packed with nearly 80 attending in person. A further 230 people joined online, making it one of the busiest meetings our registrar, MUFG Corporate Markets, has hosted this year.

The strong attendance and insightful questions received highlighted the value of this forum in helping shareholders better understand our strategy and the progress we're making. It also reaffirmed the strong support and interest we enjoy from shareholders for our vision and the potential of our technology even in the face of the continued uncertainty over Medicare coverage of our tests.

Despite the tremendous progress that we are making, the test volumes we report today are a reminder of the challenge the draft 'Genetic testing for oncology' local coverage determination (LCD) from Novitas, our Medicare Administrative Contractor (MAC), has presented to the company.

Total laboratory throughput was lower on the prior quarter again reflecting the challenges we have seen over the last few periods. The reduction in our sales team following the reorganization in the prior financial year and our decision to limit backfilling positions has reduced the reach of our sales force. Against this we have continued to benefit from sales force efficency improvements, a lift in volume from New Zealand and sustained demand from Kaiser Permanente.

During the meeting I was asked about my outlook for the remainder of the year and I noted there were more catalysts for positive progress than headwinds that could negatively affect the business.

> **"...we have charted a path to greater certainty regarding the Medicare coverage for our future products."**

Firstly, we see the potential for the American Urological Association to use language supportive of Cxbladder in the new microhematuria guideline following the review process that is now underway (see page 5).

We remain confident that Cxbladder Detect+ will achieve a price that will deliver a greater margin and marginal percentage than the current generation of products, underpinning our drive towards long term financial sustainability. As we detail on page 5, just after our annual meeting, the Centers for Medicare and Medicaid Services (CMS) published their provisional pricing recommendations and agreed with the Pricing Panel that gapfilling Detect+ was more appropriate due in its view to the absence of suitable crosswalk candidates in CMS Clinical Lab Fee Schedule.

With the review and comment period on the decision now open, we will continue our dialogue with CMS to better understand its rationale, as we maintain that suitable crosswalk candidates exist. Nevertheless, to keep our Detect+ launch plans on track, we will take the necessary steps with Novitas to determine a provisional price while we follow the alternative gapfill process.

Finally, while Novitas continues to review the draft LCD we believe the environment is now more favorable for Pacific Edge given the publication of the STRATA[1] study on the clinical utility of Triage and its reception within the broader urology community (see page 5). Furthermore, we have informed Novitas of our latest publication in the journal 'Diagnostics' on the Analytical Validation of Triage, Detect and Monitor that was developed after a recent update to our protocols[2].

These catalysts need to be balanced against the possibility of a non-coverage determination and - in the event of such 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. The Journal of Urology Vol 212 1-8 Jul 2024.
[2] Harvey et al (2024) Analytical Validation of Cxbladder Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.

determination - possible negative physician or patient response to our enhanced patient responsibility reimbursement initiatives.

However, as I noted at the meeting, we have weathered this uncertainty for over two years and irrespective of the immediate Novitas decision we have charted a path to greater certainty regarding Medicare coverage for our future products.

Following the annual meeting, the Board and the senior management team met for two days to discuss the long-term strategy for the company. Even prior to that session it was clear to us that the choices we make in the short term are contingent on the Novitas decision on whether to finalize, retire or start over on the LCD, but the long term objectives to transform the standard of care in urology for hematuria evaluation and the surveillance for bladder cancer recurrence remains unchanged.

We believe that we are on the right path of evidence generation which should deliver the coverage certainty from Medicare and other healthcare payers for both our existing and our next generation tests that is needed to appropriately support sustained future growth. We have therefore agreed to develop a plan for growth subject to key milestones and advance key elements of that plan even in the event of a negative determination. We will update shareholders when the path is clear.

Before closing I want to echo the tributes Directors made to Chris Gallaher as he presided over what we expect to be his last annual meeting. He has provided strong leadership for the company through a period of considerable change. I also want to thank Independent Director Mark Green who stepped down from the Board at the conclusion of the meeting. Mark has provided consistent insight that has challenged management to get the best outcomes for the company.

I look forward to updating you on our progress over the coming months on what I expect to be an important period for the company.

Best regards,

Dr Peter Meintjes
Chief Executive

TEST VOLUMES

SALES SLIGHTLY DOWN FOR Q2 25

Tests processed through our laboratories in the three months to the end of September 2024 (Q2 25) were slightly lower on the prior quarter (Q1 25).

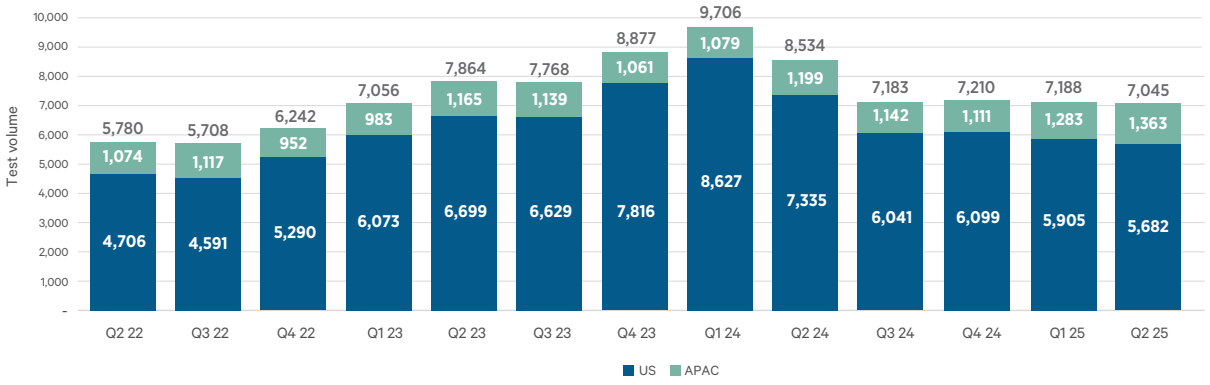
CMS' July 2024 decision to grant an extension to Novitas on its deliberations over Medicare coverage of our tests and the uncertainty associated with the extension added to the challenges faced by the sales team. However, continuing strong demand from our US customer Kaiser Permanente, the sustained benefits of our sales force efficiency gains and a lift in volume in the APAC region diluted the impact of these factors.

Total laboratory throughput (TLT) in Q2 25 fell 2.0% to 7,045 tests, a figure slightly down on the 7,188 tests in Q1 25. US TLT was 5,682 tests down 3.8% on the 5,905 in Q1 25. The average US sales force was steady at 15 FTE against Q1 25. The sales force efficiency metric fell to 379 tests per sales FTE down from 403 in the prior quarter consistent with the lower US volumes. Tests per unique ordering clinician (our preferred metric for measuring customer commitment to Cxbladder) was down slightly to 6.4 in Q2 25 from 6.8 in Q1 25 reflecting the lower volume (ordering clinicians were slightly higher at 890).

Asia Pacific volumes were up 6.2% to 1,363 tests from 1,283 in Q1 25 reflecting a lift in volume in New Zealand and growing, albeit still small volumes, from Australia and our distributors in Asia.

Group total test volumes for the half year (1H 25) were down 22% to 14,233 from 18,240 in 1H 24, the period just ahead of Pacific Edge undertaking a reorganization to reduce the size of the sales team to preserve cash to weather the Medicare uncertainty.

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

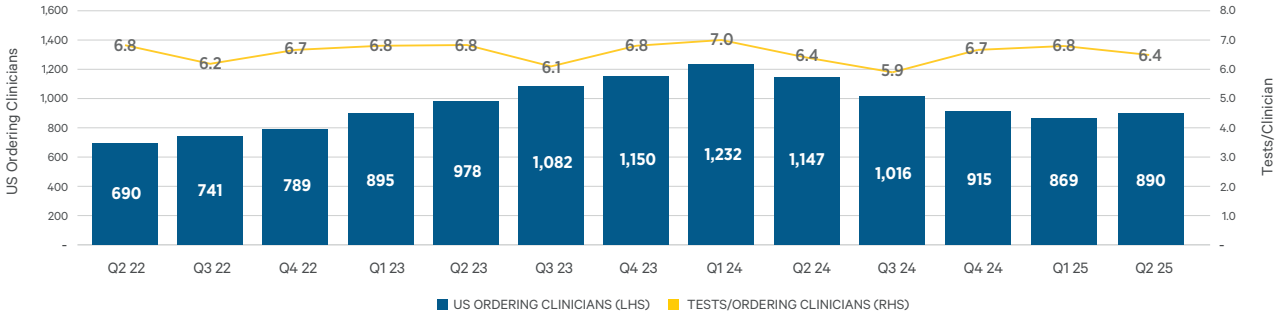
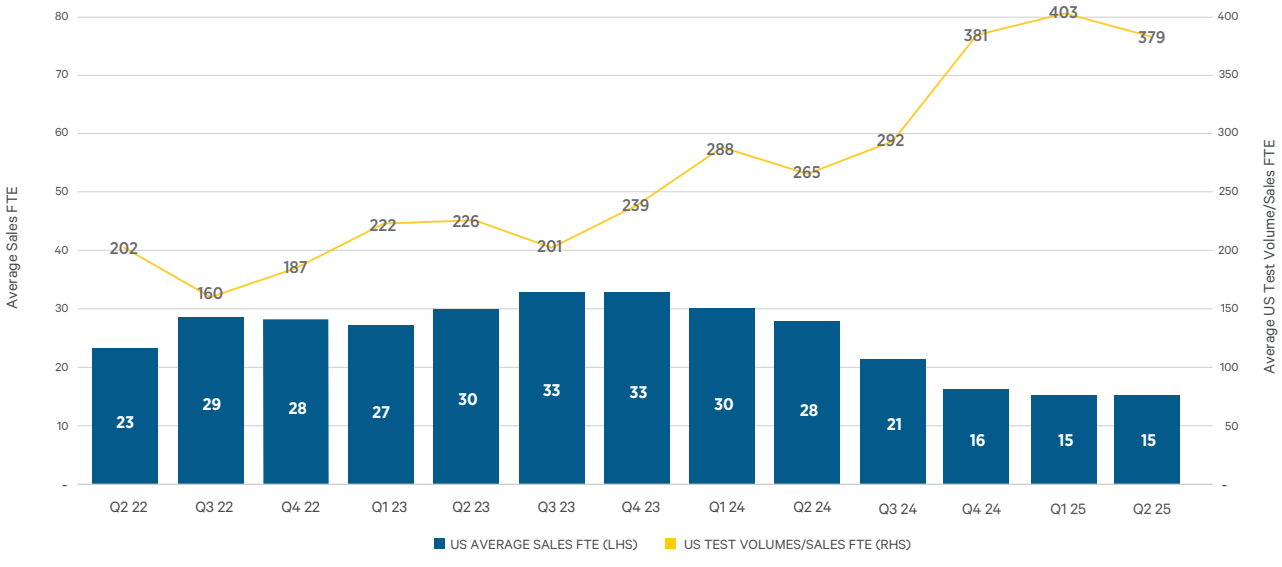


FIGURE 3: US SALES FORCE EFFICIENCY



AUA GUIDELINES INCLUSION

AUA SEEKS HEMATURIA GUIDELINE PEER REVIEW

Pacific Edge is awaiting the outcome of the American Urological Association (AUA) review of its microhematuria guidelines now underway. The outcome of the review, the first since 2020, has the potential to exert considerable influence over the adoption of Cxbladder in the US.

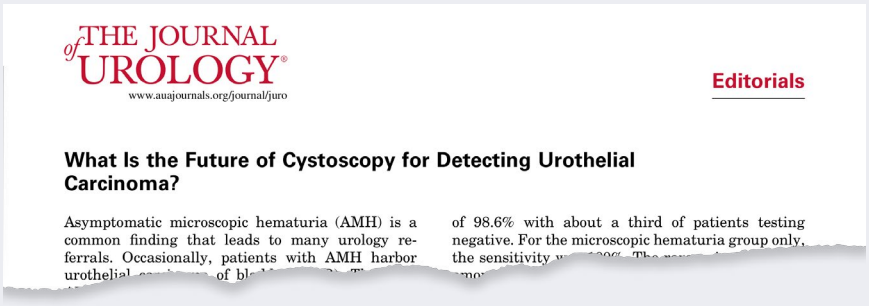
A draft of the revised guideline was made available to AUA members last month under strict conditions of confidentiality for peer review. Finalization of the standard and publication is expected in the coming months.

Positive language endorsing the use of Cxbladder would further validate the clinical value of our tests in the evaluation of patients with microhematuria. It could also drive changes in the medical and reimbursement policies of healthcare payers, change clinical practice and drive the adoption of our tests.

Notably, favorable product-specific language would have the effect of driving medical policy, including Medicare coverage of Cxbladder, or be used as the basis for a reconsideration request to Novitas, in the event of a non-coverage determination.

Pacific Edge Chief Medical Officer Dr Tamer Aboushwareb is contributing to the AUA's peer-review consultation on the guideline under the terms of a strict and personal AUA confidentiality agreement that prohibits the disclosure of the draft to Pacific Edge.

The review follows the publication of our STRATA[1] study in the Journal of Urology. As a randomized controlled trial of the test - the first study of this kind for a urine biomarker for hematuria evaluation - STRATA has delivered the evidence that meets the standard typically required for guideline committees to consider a change to standards of care. The guidelines review also follows the publication of an editorial in the Journal of Urology in September[2] supporting the use of Cxbladder to reduce unnecessary cystoscopies and clinicians to evaluate patients both presenting with hematuria and those under surveillance for bladder cancer recurrence.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Editorials

What Is the Future of Cystoscopy for Detecting Urothelial Carcinoma?

Asymptomatic microscopic hematuria (AMH) is a common finding that leads to many urology referrals. Occasionally, patients with AMH harbor urothelial

of 98.6% with about a third of patients testing negative. For the microscopic hematuria group only, the sensitivity

[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. The Journal of Urology Vol 212 1-8 Jul 2024
[2] Anderson (2024). The Future of Cystoscopy for Detecting Urothelial Carcinoma Vol. 212, 399-400, September 2024.

DETECT+ COMMERCIALIZATION

CMS PROPOSES 'GAPFILL' PRICING FOR DETECT+

With the Centers for Medicare & Medicaid Services (CMS) preliminary determination last month to pursue the gapfill process to establish a price for the test, Pacific Edge is focused on launching Detect+ in 2025 subject to key reimbursement and pricing milestones.

In its draft pricing document CMS stated: "there are no existing codes on the CLFS[1] with similar methods or resources. By gapfilling this code, the resources used in this code can be better estimated by a Medicare Administrative Contractor (MAC)".

The proposal to gapfill emphasizes the novelty of Detect+, as the process is most appropriate for novel technologies, novel combinations of technologies or novel clinical applications. The gapfill process will see all MACs providing a price to CMS, which then sets a price based on those submissions.

Pacific Edge will use the Notice and Comment period that now runs until the end of October to connect with CMS to understand its reasoning, prepare for gapfill in 2025, and work with Novitas on provisional pricing options to ensure no disruption to our Detect+ launch plans.

Our goal will be to ensure Detect+ comes to market with a price that recognizes its clinical and economic value in both safely sparing patients at a low risk of bladder cancer from invasive examinations and identifying those patients with an elevated risk of bladder cancer and requiring a more thorough clinical workup. Pacific Edge will use the existing crosswalk logic as the starting point for establishing a provisional price with Novitas and gapfill discussions with all MACs.

The provisional price we achieve with Novitas and the final gapfill price set the amount Pacific Edge will be reimbursed for all patients with Medicare and Medicare Advantage insurance (subject to coverage). It also sets a benchmark for non-contracted reimbursement and contracting negotiations to determine the price that other US health insurance companies will reimburse for tests.

[1] CMS Clinical Lab Fee Schedule

CXBLADDER ADOPTION IN FOCUS AT OUR ANNUAL MEETING

"We are giving people a better quality of life," Pacific Edge Chair Chris Gallaher told the company's Annual Shareholders Meeting in Auckland last month as he reflected on his near nine years at the helm of the company and his confidence in its future.

Mr Gallaher, who agreed in August to remain as Chairman during a transition to a successor in the coming year, made the comment as he recounted the journey of a friend in Melbourne who had endured fifty-two cystoscopies in his battle with recurrent bladder cancer. However, his friend could not use Cxbladder to reduce the burden of the examinations because the test – despite the wealth of evidence – was not yet included in Australian standards of care.

"It is not enough to have a very good test, we must also have the test that urologists will adopt and use," Mr Gallaher told the meeting.

This call to action framed the meeting's central theme—driving adoption of Pacific Edge's bladder cancer diagnostic tests.

Chief Executive Dr Peter Meintjes reviewed FY24 full-year performance and set out the steps the company was taking to secure coverage of the company's tests by Medicare, the single largest contract globally for Cxbladder. These steps included prudent management of cash reserves, engagement with industry and clinical key opinion leaders and the company's clinical evidence generation program.

Pacific Edge Diagnostics USA President David Levison detailed the path to commercialization of Cxbladder Detect+ and Monitor+, the next-generation tests. He also highlighted how digital tools – like the customer portal and IT system integrations with Kaiser Permanente and Lumea – enhance user experience and drive loyalty and market share.

Dr Meintjes, standing in for Chief Medical Officer Dr Tamer Aboushwareb, gave an overview of how our clinical evidence program drives changes in clinical practice, payer reimbursement policies, and care guidelines. He also outlined how our ongoing studies – DRIVE, microDRIVE, AUSSIE, LOBSTER, and CREDIBLE – would provide the necessary evidence to embed Cxbladder in clinical guidelines, secure payer coverage, and support new test commercialization.

FOR FULL MEETING DETAILS, INCLUDING MR. GALLAHER'S SPEECH, VISIT:

https://www.pacificedgedx.com/investors/investor-center/

KAISER REPORTS ON REAL WORLD UTILITY OF CXBLADDER IN NEW ABSTRACT

Southern California Permanente Medical Group (KP SoCal) is experiencing the benefits from deploying Cxbladder Triage in a consistent clinical pathway.

In an abstract covering the results of a large clinical study that will be presented to the Western Section of the American Urological Association (WSAUA) later this month, KP SoCal has detailed how it is using Cxbladder Triage to improve the evaluation of patients presenting with hematuria.

The authors of the abstract said: "Incorporating a highly reliable urine biomarker into clinical workflows for hematuria reduced the burden of cystoscopy substantially, improving patient satisfaction, urology access, and lowering overall cost of care."

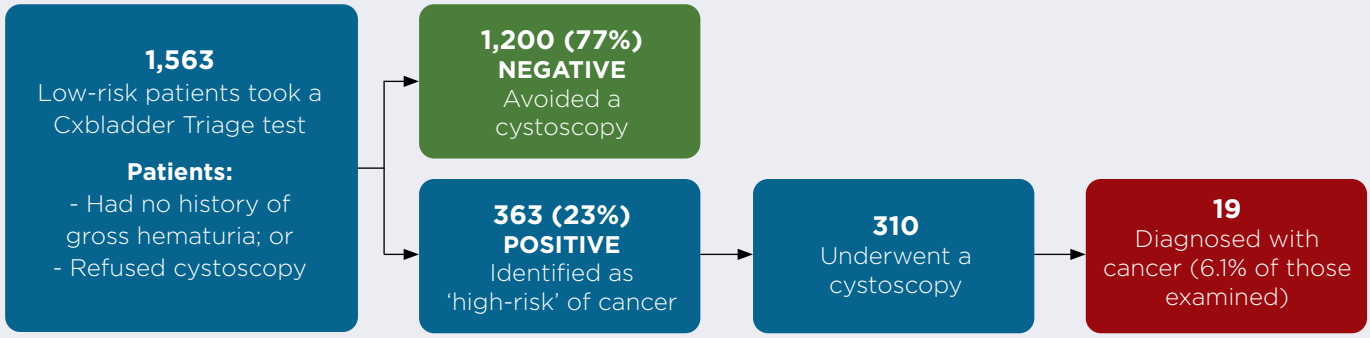
Real world evidence such as the Kaiser Permanente study and those underway in Australia (see page 8) supports the adoption of Cxbladder into clinical practice. The findings demonstrate how healthcare providers like Kaiser Permanente are using it to improve patient care, streamline workflows, and reduce costs.

Real world evidence is the ideal complement to the clinical utility evidence generated from our core evidence generation program and this is particularly the case with the Kaiser Permanente study as it independently demonstrates the clinical utility of Cxbladder in a US population, our largest market.

Kaiser Permanente is working toward a peer reviewed publication based on the complete data to be published in time for the AUA conference next year and, in the event of a Medicare non-coverage determination, the study will be used as a basis for a coverage reconsideration request.

The study involved 1,563 low-risk patients with no history of gross hematuria or those who declined cystoscopy. It showed that 1200 or 77% of the patients tested, were able to avoid an invasive cystoscopy. This not only boosted patient satisfaction but also improved access to urological care by freeing up resources and time for other patients. Of the 363 patients flagged as high-risk, 310 underwent cystoscopy, leading to 19 confirmed cancer diagnoses (6.1%).

CLINICAL UTILITY: PRELIMINARY RESULTS OF THE KAISER STUDY



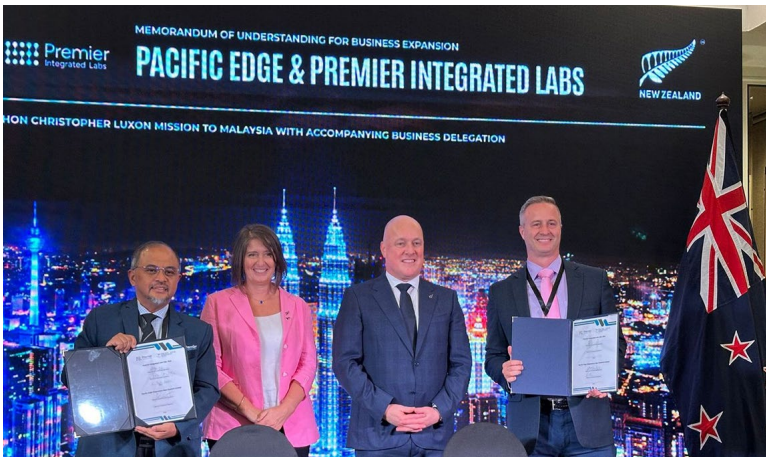
PACIFIC EDGE ON THE PODIUM AT UAA IN BALI

New evidence of Cxbladder's clinical utility was presented to the Urological Association of Asia (UAA) in early September.

Dr Prasanth Anton Sagayanathan from the Sunshine Coast University Hospital presented preliminary results from his study demonstrating the clinical utility of Cxbladder detecting bladder cancer in a Far North Queensland population. Meanwhile, Dr Arjun Guduguntla of Northern Health in Melbourne presented preliminary data on a proposed novel surveillance schedule using Cxbladder Monitor for patients on annual bladder surveillance.

Finally, Pacific Edge Chief Executive Dr Peter Meintjes presented data from the groundbreaking STRATA study[1], the first time clinical utility evidence from the randomized controlled trial has been presented to an APAC audience.

Prior to the activities at the UAA Congress Dr Meintjes visited Malaysia for a ceremonial signing of a lab partnering agreement with Premier Integrated Labs. The event was supported by New Zealand Trade and Enterprise and attended by the Prime Minister, the Right Honourable Christopher Luxon. Premier Integrated Labs is the sole supplier of laboratory services to Malaysia's IHH Healthcare, which operates the three largest individual hospitals in Malaysia. This partnership represents a further advance of Pacific Edge's strategy to expand the availability of Cxbladder across key international markets.



Ceremonial signing of partnership agreement with Malaysia's Premier Integrated Labs in Kuala Lumpur

PACIFIC EDGE'S GLOBAL OPERATIONS

[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. The Journal of Urology Vol 212 1-8 Jul 2024.

CLINICAL EVIDENCE PROGRAM

EVIDENCE TO DRIVE CLINICAL PRACTICE CHANGE

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 (MH) • Risk stratification	- Recruitment closed with 555 patients including 223 low risk patients (test and control) and interim analysis results published in Journal of Urology - Data cleaning for the final analysis was completed mid-Aug. The database lock is scheduled mid-Dec 2024 and the final Clinical Study Report (CSR) June 2025.
DRIVE (**D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria)	• CV for Detect⁺ • CV for Triage for a Veterans' cohort • Data for pooled analysis	• MH and gross hematuria (GH) • Risk stratification	- Enrolment closed with 710 patients enrolled including 46 tumour confirmed patients (target was 45) from across 10 US VA sites - Projections are for database lock mid-Nov 24 and publication submitted Q1 25
microDRIVE (**D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria)	• CV of Detect⁺ • Data for pooled analysis	• MH • Detection	- This is a network study across all VAMCs coordinated from a single US VA - 358 patients have consented for the study with 152 samples received to date - The target is 1000 patients with 35-50 tumour confirmed patients - Last patient in is now projected to be Q2 25
AUSSIE (**A**ustralian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia)	• CV of Detect⁺ (Australian cohort) • Data for pooled analysis	• MH and GH • Risk stratification	- Target enrolment: 600 patients across at least three Australian sites - 264 subjects are enrolled to date, including 15 UC confirmed (target is 35) - Last patient in is projected for Q2 25
POOLED ANALYSIS	• CV of Detect⁺	• MH and GH • Risk stratification	- MH and separately GH patient data from DRIVE, AUSSIE, and microDRIVE will be pooled and performance determined - Paper submissionis one quarter after publication of DRIVE, microDRIVE and AUSSIE
LOBSTER (**LO**ngitudinal **B**ladder cancer **S**tudy for **T**umor **R**ecurrence)	• CV of Monitor/ Monitor⁺	• Surveillance • Risk stratification	- Enrolment will complete once 75 UC recurrences have been observed across 8-10 sites - Enrolment is now 364 subjects providing 654 samples with 38 UC recurrences observed to date - Expected completion is mid 2025
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⁺	• MH • Risk stratification	- Protocol approved by Specialty Networks central IRB and 4 of 15 sites contracted - An interim analysis will be conducted at 600 subjects to determine if incidence is <5% tumours and if so, will continue to 1000 are enrolled - Enrolment due to commence Dec-2024

*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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