PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

INVESTOR UPDATE

APRIL 2024

INSIDE

LETTER FROM THE CEO

DEMONSTRATING RESILIENCE

Dear Shareholders,
As I have reflected on our achievements of the fourth quarter and my second full financial year leading the company, I am left with a sense of gratitude for the extraordinary efforts of my team. I am also confident in our ability to address future challenges.

Our navigation of the Medicare coverage uncertainty alongside our diligent work ethic in overcoming the typical challenges that fast-growing companies face, have demonstrated a resilience that justifies investor confidence in our prospects.

We have been tested by a series of unpredictable events, but remain firmly focused on the actions that drive results:

- generating compelling clinical evidence for our existing urology products to ensure clinically validated molecular tests for guidelines inclusion and payer coverage; and
- commercializing those clinically validated molecular tests through defined clinical pathways at secondary care and community practice in urology.

This focus is also evident with the progress we report in today's investor update. We have delivered steady quarter-on-quarter test volumes (see page 4). We achieved this increase with a smaller, but more efficient sales force and one that is focused on selling the clinical utility of Cxbladder and the value it offers healthcare payers.

Certainly, a Medicare non-coverage determination would impact our volumes, but we expect it would be temporary, because we are confident that our clinical study program provides the foundations to regain coverage from any possible non-coverage determination.

Indeed, today we provide several key successes that further demonstrate our program will deliver the endpoints of analytical validity (AV), clinical validity (CV) and clinical utility (CU) needed for coverage and inclusion in clinical guidelines. And, with the support of a comprehensive medical communications program, that it will drive momentum in the adoption of our tests through defined clinical pathways.

> **"STRATA is... the strongest evidence yet for inclusion of a Cxbladder product in the AUA Guidelines."**

The first paper from our STRATA study (page 5), which successfully concluded enrolment in July 2023, has been accepted by the American Urological Association (AUA) for a podium presentation at its Annual Meeting in San Antonio, Texas, May 3-6. Furthermore, we were requested to submit a manuscript prepared from the same data for publication in the Journal of Urology edition that coincides with the AUA Annual Meeting, but are yet to be advised of its acceptance.

The paper for the AUA and the manuscript focuses on the CU of Cxbladder Triage in safely reducing the need for cystoscopies (established as a reduction of 59% in low-risk hematuria patients in this study). It will also confirm the previously published accuracy of the test for all patient types in the study design.

STRATA is the first ever randomized controlled trial of a urine biomarker for hematuria evaluation and provides the strongest evidence yet for inclusion of a Cxbladder product in the AUA Guidelines. Huge kudos goes to the Clinical and Medical teams under the leadership of Dr. Tamer Aboushwareb who challenged the team to bring forward this publication by more than nine months to meet the AUA publishing deadlines for inclusion in this year's annual meeting.

Further publications leveraging STRATA data will directly compare Detect$^+$ against Triage to demonstrate equivalent or better clinical utility, and superior performance characteristics in clinical validation. Data collected from the study has also been used to increase the size of the discovery dataset to further improve the Detect$^+$ algorithm.

As we set out on page 8, each publication of new AV, CV or CU evidence offers us an opportunity to either entrench coverage, or in the event of a Medicare non-coverage decision, an opportunity to regain it through a reconsideration request.

The steps we have taken over the last two years, many of which have been implemented on an accelerated timeline, give us the confidence that any loss of coverage can be regained with our current cash reserves.

Shifting focus to future products, we also report on our progress to commercialize Cxbladder Detect+, which over the longer term we expect to become our sole test for hematuria evaluation.

We previously noted for investors that we have received a CPT Code for Detect+ (0420), which was made effective on 1 January 2024. We now turn our attention to the pricing of the test, where we will pursue a 'Crosswalk' strategy that we outline on page 7.

Medicare's pricing process is typically a straight- forward mathematical calculation based on technological similarities to previously priced tests. In accordance with this, we are seeking a higher price and a higher margin that could meaningfully strengthen the underlying economics of our business, specifically the economics of operating the Account Executives in our Direct Sales team.

With the release of our FY 24 financial results in May, we expect to further demonstrate the progress we are making towards a more-efficient operation. As we signaled in the Q3 24 investor update, our sales team has made good progress towards operating at breakeven and cash outflow is now driven almost entirely by long-term strategic imperatives.

Finally, before closing I want to acknowledge the support and commitment of Chairman Chris Gallaher and Non-Executive Director Mark Green, who last month announced their intention to retire from the Pacific Edge Board (see page 6).

Both Directors have pulled out all the stops for Pacific Edge, supporting my transition into the Chief Executive role and assisted in driving the change that now gives us such confidence in the future.

Chris in particular deserves recognition for his leadership of the Board and putting Pacific Edge on a footing that positions us for success no matter the short-term coverage challenges we face.

I look forward to further updating you on our progress in May.

Dr Peter Meintjes
Chief Executive

TEST VOLUMES

VOLUMES STEADY AMID EFFICIENCY IMPROVEMENTS

Cxbladder tests processed at Pacific Edge's laboratories in the three months to the end of March 2024 were steady on the prior quarter.

The result, achieved with a smaller sales force, has benefited from previously reported improvements in sales force efficiency and a growing contribution of tests from Kaiser Permanente following the incorporation of Cxbladder tests into its electronic medical records system. In addition, throughput in Q4 24, has been supported by a traditional seasonal catch up in the US after the slow Thanksgiving-Christmas holiday period and sustained ordering from physicians.

Volumes in Q4 24[1] rose to 7,210 tests, a figure up 0.4% on the 7,183 tests in Q3 24. US volumes were 6,099 tests up 1.0% on the 6,041 tests of the prior quarter. Asia Pacific volumes were down 2.7% on the prior quarter to 1,111 tests, with the result impacted by the traditional slowdown in New Zealand post the Christmas period.

We entered Q4 24 with fewer sales reps, down to an average of 16 FTEs across the quarter from 21 FTEs in Q3 24. This drop reflects the lagged impact of the reorganization in Q2 24, and other initiatives aimed at preserving capital. The combination of fewer FTEs and efficiency gains has driven our sales force efficiency metric up 30.4% (381 tests per average FTE over the quarter in Q4 24 vs 292 in Q3 24).

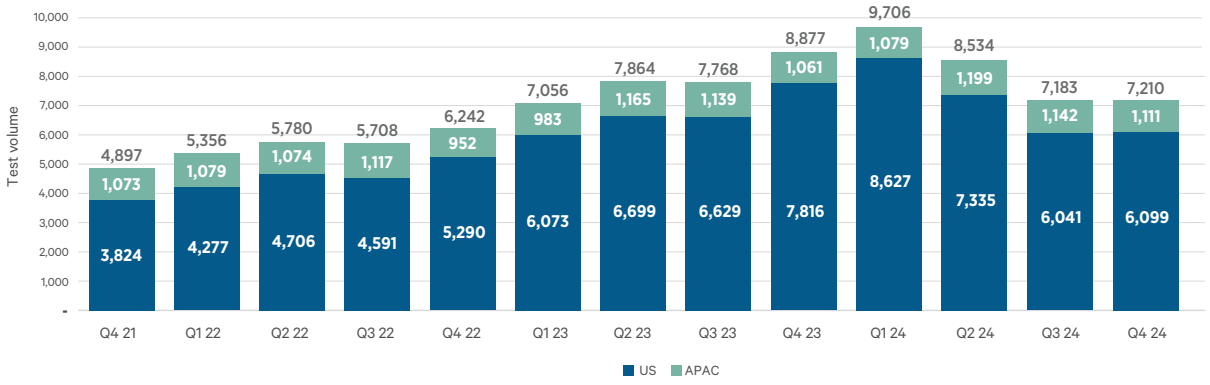
Tests per unique ordering clinician (our preferred metric for measuring customer commitment to Cxbladder) increased to 6.7 in Q4 24, from 5.9 in Q3 24 reflecting efficiency improvements and the company's determination for sales territories to operate profitably.

Test volumes for the 12 months to the end of March 2024 (FY 24) were up 3.4% to 32,633 from 31,565 in FY 23 with the easing of growth reflecting the ongoing uncertainty over Medicare coverage and the associated reorganization.

Test volumes processed through our US laboratory rose 3.3% in FY 24 over FY 23 to 28,102. Tests processed at our Dunedin Laboratory for the APAC region rose 4.2% over the same period to 4,531 tests.

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

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

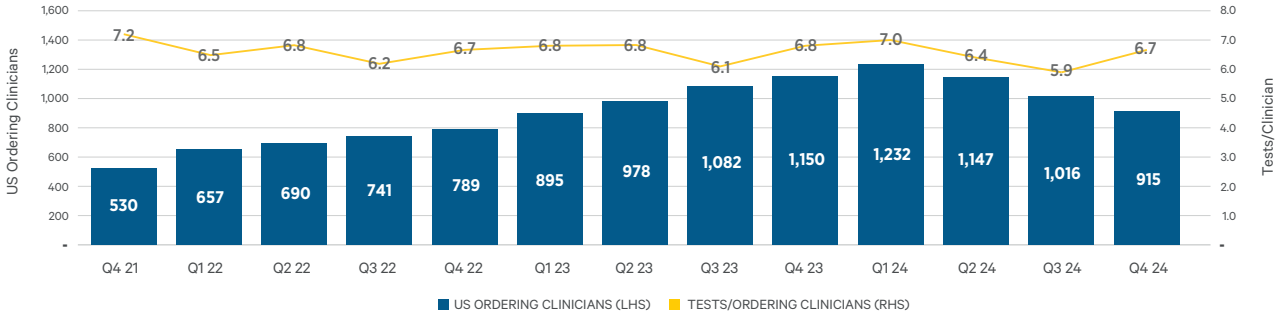
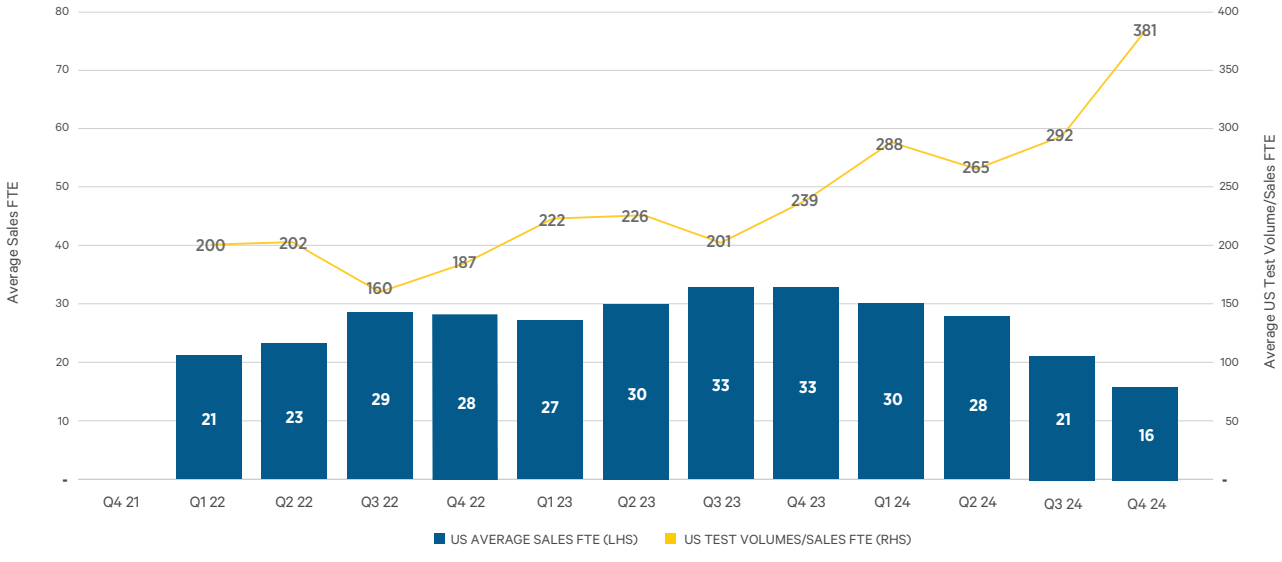


FIGURE 3: US SALES FORCE EFFICIENCY



CLINICAL UTILITY EVIDENCE FOR TRIAGE

The first paper from our STRATA[1] study – one showing conclusive evidence of Cxbladder Triage's clinical utility – will be presented in May to the American Urological Association (AUA) annual conference, the world's most important urology meeting.

The paper demonstrates Cxbladder Triage can help clinicians to safely and more effectively risk-stratify low-risk hematuria patients when compared to AUA guidelines. Specifically, clinicians undertook 59% fewer cystoscopies on patients in the test arm of the study, when they could use information generated by a Cxbladder Triage test to help them determine the intensity of a patient workup.

Referencing the clinical utility of the test, authors of the paper led by UT Southwestern Professor of Urology Dr Yair Lotan, said: "Cxbladder Triage can help reduce the burden of unnecessary cystoscopies... resulting in less patient morbidity and discomfort, improved access to care, and reduced environmental impact."

STRATA is the first ever randomized controlled trial of a urine biomarker for hematuria evaluation and this paper is the strongest clinical utility evidence yet for inclusion of a Cxbladder product in the AUA Guidelines. Similarly, Pacific Edge expects to use this publication in any Medicare coverage reconsideration or redetermination process.

Pacific Edge submitted an abstract summarizing the draft results from STRATA for consideration at the AUA Meeting. Recognizing the paradigm-shifting and practice-changing nature of STRATA's results during the review of the abstract, the AUA invited Pacific Edge to submit a full manuscript for peer-review. While, the manuscript is still in the process of peer review, it will form the basis of a podium presentation at the AUA Meeting during a session covering advances in bladder cancer.

The evidence accumulated during STRATA included a total of 449 patients of which 205 were assessed as low risk and were randomized to either the control arm (where the results of the test were not shared with the clinician) or test arm where clinicians were provided a Cxbladder Triage result. Of those in the control arm, 67% elected to have a cystoscopy, while 27% in the test arm elected to have a cystoscopy.

Importantly, no cancers have yet been found in any of the test arm patients who had a negative Triage test throughout the AUA-recommended follow up period of 3-24 months, thus further demonstrating that avoiding cystoscopies can be done safely with appropriately validated urine biomarkers.

The AUA Annual Meeting is expected to attract more than 10,000 delegates from around the world and is to be held in May 3-6 in San Antonio, Texas. https://www.auanet.org

The abstract of the paper is available on our website.

[1] Safe Testing of Risk for AsymptomaTic microhematuriA.

STRATA TO SUPPORT DETECT+

While the primary endpoints for STRATA have been met and will be published and presented at the AUA conference, the data generated in this study will be leveraged going forward to demonstrate the clinical utility of Detect+, which over the long-term is expected to become our sole test for hematuria evaluation.

Pacific Edge has already established the superior analytical performance of Detect+ and will undertake analyses to demonstrate equivalent clinical utility with superior clinical validation in a concordance study.

The studies necessary for the clinical validation of Detect+, DRIVE, microDRIVE and AUSSIE studies and the subsequent pooled analysis of all three, are continuing to enroll broadly as expected. They are expected to demonstrate clinical validation of Detect+ in microhematuria and gross hematuria patients.

GOVERNANCE

STABILITY THROUGH UNCERTAINTY

Chris Gallaher

Mark Green

Pacific Edge Chair Chris Gallaher and Non-Executive Director Mark Green have given advanced notice of their intention to step aside from the Board later this year, delivering stability as the company navigates the continued Medicare uncertainty.

Mr Gallaher, who joined the Pacific Edge Board in July 2016, has resolved to reduce his governance commitments, and has indicated his intention to retire from the Board following the appointment of a successor and a structured handover at the end of this year.

Meanwhile, with his family moving to New York later this year, Mr Green has notified the Board he does not intend to seek re-election at the company's next Annual Shareholders Meeting in September. Mr Green joined the Pacific Edge Board in May 2021.

Mr Gallaher said: "It has long been my declared intention to reduce my governance commitments when I turned seventy, which I will later this year. Pacific Edge is on the threshold of a new phase of development, with Medicare's upcoming determination, either way, having implications for the long-term future and strategy for the company.

"I have great confidence in the future of Pacific Edge. We have over the last two years established a dedicated and skilled management team under Chief Executive Dr Peter Meintjes to develop our world-leading technology with comprehensive clinical evidence generation and drive adoption in the US market.

"I want to thank my fellow directors for the support and council over my tenure. On behalf of shareholders, I also want to thank Mark for his support and service to the company. I am looking forward to working with the whole team during this period of transition."

The Board's Nomination Committee has commenced a process to appoint a new Chair and consider the recruitment of new Independent Directors.

AUTOMATION

NEW VALIDATION DATA

Pacific Edge, as part of our commitment to continuous improvement, is automating the extraction and processing of DNA and RNA in patient samples, a key step in the Cxbladder testing process.

The new approach enhances our ability to scale as demand for our tests grow while reducing the use of various chemicals in the extraction procedure.

Importantly, this gives the opportunity for Pacific Edge to publish new Analytical Validation data. This data, once published, will allow healthcare payers, including Novitas, the Medicare Administrative Contractor with authority for our US Laboratory, to more easily assess the analytical validity of our tests. It will also give Pacific Edge an opportunity to apply for coverage reconsideration should Novitas make a Medicare noncoverage determination.

We expect the required analytical validation to be completed in the next few weeks and are targeting the publication of the data in the second or third quarter of this calendar year.

Chief Technology Officer Dr Justin Harvey with a Hamilton liquid handling platform, one piece of equipment that helps to automate Cxbladder sample processing.

DETECT+ COMMERCIALIZATION

DETECT+ PRICING MAY LIFT BUSINESS ECONOMICS

Pacific Edge, having achieved coding of Detect+, has turned its attention to Medicare pricing – the next step towards commercial launch.

Successful execution on this process has the potential to strengthen the economics of Detect+ and, given our goal of making it the sole test for hematuria evaluation, the potential to significantly strengthen the underlying economics of the direct sales team and the company.

"The Medicare price sets a benchmark for all other US healthcare payers. Our goal therefore is to seek a price that recognizes the value of our new test to clinicians and healthcare payers," says Chief Executive Dr Peter Meintjes.

Pacific Edge is seeking pricing for Detect+ through the Centers for Medicare & Medicaid Services (CMS) 'Crosswalk' process. It benchmarks Detect+ against comparable tests that have a similar clinical and resource usage profile, typically based on the underlying technology.

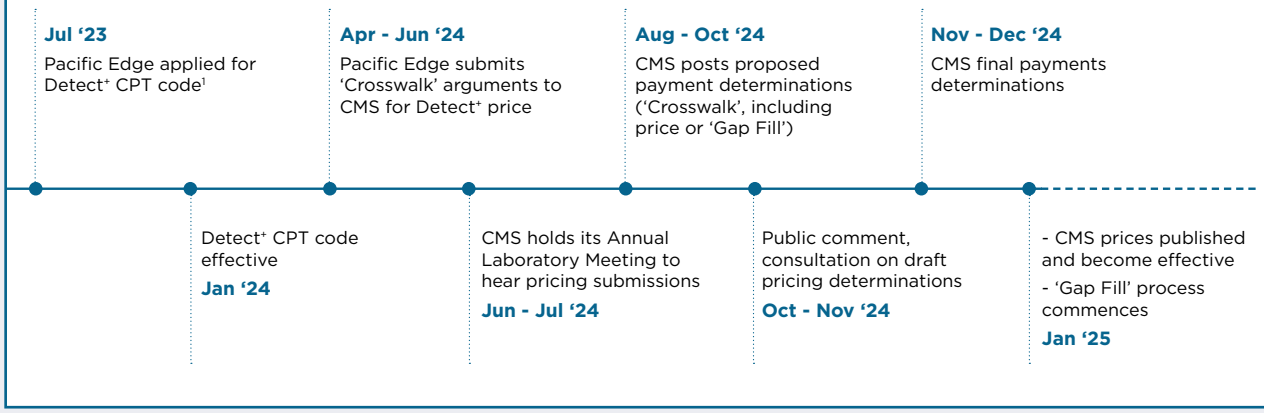
The price for our existing tests ($760) provides the best available reference for the RNA component of Detect+. To price the DNA component, we will identify for CMS an appropriate comparable test with the greatest technological similarity and resource usage to our workflow and seek to add the already established price of the two together to determine the price of the combined product.

If successful, we expect that Detect+ will have a higher price and higher gross margin than our current tests, changing the underlying economics of Cxbladder customer acquisition and the profitability profile for adding sales representatives.

We will submit our views to CMS in the middle of the year and expect a preliminary determination, potentially as soon as August.

If CMS determines there are no comparable technologies (and therefore the 'Crosswalk' process is not appropriate) Pacific Edge will be directed to the 'Gap Fill' process to determine the Detect+ price. The 'Gap Fill' approach involves CMS soliciting feedback from all Medicare Administrative Contractors on their estimate of the cost of the test, a process that is likely to delay the pricing of Detect+ by a year.

DETECT+ PRICING: THE PREREQUISITE FOR COMMERCIAL LAUNCH



[1] A CPT (Current Procedural Terminology) code is a medical code used to describe medical, surgical, and diagnostic services and procedures in the US healthcare system.

MEDICARE

CATALYSTS FOR MEDICARE COVERAGE CERTAINTY

Pacific Edge is well positioned, in the event of an unfavorable 'Genetic testing for oncology' (DL39365) local coverage determination, to regain coverage.

All our studies are configured with the analytical validity (AV), clinical validity (CV), and clinical utility (CU) endpoints sought by Novitas[1], the broader urological community, and the clinical guidelines committees.

With each release of new data offering us an opportunity to lodge a reconsideration request for Medicare coverage, we are confident we are steadily building what we believe will be an unassailable case. Meanwhile, should any of our tests be included in clinical guidelines, we would also lodge a reconsideration request based on the weight of clinical opinion.

Our efforts are also bolstered by a number of investigator-initiated trials. These trials are generally more limited in scope than those undertaken by Pacific Edge, but they still offer endpoints expected to be supportive of our existing portfolio of clinical evidence.

'Genetic testing for oncology' LCD (DL39365)

Novitas[1] must finalize or withdraw DL39365 before 26 July 2024. In the event of a favorable determination, Medicare coverage of any (or all) of Detect, Triage and Monitor (and potentially Detect⁺) will continue uninterrupted. In the event of an unfavorable determination, Pacific Edge has:

- recourse to legal outcomes (which are subject to significant uncertainties over timelines and success); and
- opportunities to seek a reconsideration of coverage with the publication of new evidence (see below) or the inclusion of tests in clinical guidelines based on the weight of clinical opinion.

Medicare reconsideration requests

(Reconsideration requests take Novitas[1] approximately 12 months to process from the lodging of a valid request)

Catalyst	Test and evidence standard[2]	Expected date of reconsideration request[3]
1. **STRATA** data published	- CU of Triage	May 2024
2. Analytical Validation of automated RNA and DNA extraction published	- AV of Triage, Detect, Detect⁺, Monitor and Monitor⁺	Q3 2024
3. **DRIVE** data published	- CV of Detect⁺ - CV of Triage	Q2 2025
4. **microDRIVE** published	- CV of Detect⁺	Q3 2025
5. **AUSSIE** data published	- CV of Detect⁺	Q4 2025
6. **Pooled CV** data published[4]	- CV of Detect⁺	Q1 2026
7. **LOBSTER** published	- CV of Monitor/Monitor⁺	Q1 2026
8. **CREDIBLE** data published	- CU of Detect⁺	Q1 2028

[1] Novitas is the Medicare Administrative Contractor with authority for Pacific Edge's US laboratory.
[2] AV, CV CU, respectively Analytical Validity, Clinical Validity, Clinical Utility.
[3] All dates are calendar year rather than financial year.
[4] The pooled analysis brings together data from DRIVE, AUSSIE and microDRIVE.

CLINICAL STUDY UPDATE

STRENGTHENING THE CLINICAL UTILITY CASE

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 to be published in May at the AUA conference
DRIVE (**D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria)	• CV for Detect⁺ • CV for Triage and within a Veterans' cohort • Data for pooled analysis	• Micro and gross hematuria • Risk stratification	- Enrolment closed with 684 patients across 10 VA sites - 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 VAMCs coordinated from a single US VA site - 106 patients have consented for the study with 84 samples received to date - The target is 1000 patients with 35-50 tumor confirmed patients - Target 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 and 56 subjects are enrolled to date - 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 426 subjects across 10 sites (US, Australia) - Enrolment is now 227 subjects with 395 samples received to date - The enrolment phase is expected to end late 2024 - 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 enrollment is 1000 subjects with an interim analysis at 600 to determine if the primary objective has been addressed - Due to commence late 2024 - Target publication Q1 2028

*Dates are calendar year not financial years

Clinical Utility (CU) - Evidence a test that can usefully change patient management within the context of care for the defined population and indication.

Clinical Validity (CV) - Evidence a test works in the same way on an independent eligible population for a given indication.

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

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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