14 JULY 2025

CXBLADDER DEMAND RESILIENT DESPITE COVERAGE LOSS

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today reports resilient demand for its tests in the three months to the end of June 2025 (Q1 26) despite to loss of Medicare coverage in April 2025 and the disruption caused from the transition of US customers from Detect to Triage.

The company also reports positive discussions with Medicare Administrative Contractor Novitas following Pacific Edge lodging a Medicare reconsideration request based on evidence not considered in the review that led to the non-coverage decision. The new evidence includes the ground-breaking STRATA[1] randomized control study demonstrating the clinical utility of Cxbladder Triage and the new AUA microhematuria guideline.

US TLT in Q1 26 was down 11.9% to 5,717 tests from 6,490 in Q4 25 with the drop in volumes largely due to the disruption of asking physicians to switch from Cxbladder Detect to Triage for hematuria evaluation. Pacific Edge accelerated the decision to discontinue Detect in the US market following the inclusion of Triage in the new American Urological Association Microhematuria guideline and the non-coverage determination.

Cxbladder Triage represented around 77% of US TLT in June 2025 up from 22% in Q4 25, the quarter prior to the decision to discontinue Detect. Meanwhile, Detect tests received for processing (which our customer service attempts to transition to Triage tests with clinician approval) made up only 6% of all tests received for the month of June 2025, down from the 59% received in Q4 25 the last quarter before the determination became effective.

Total laboratory throughput (TLT) in Q1 26 fell 8.9% to 6,900 from the 7,577 tests in Q4 25.

Our sales force efficiency metric in Q1 26 was 381 compared to 406 tests per sales FTE in Q4 25 reflecting the disruptions caused by switching customers from Detect to Triage, which requires additional patient information.

The requirement to provide an advanced beneficiary notice (ABN) with a Cxbladder Monitor test has also impacted volumes, but insulates the company from running unpaid tests, because the ABN informs the patient they may be held financially responsible for the test if Medicare denies payment. Tests per unique US ordering clinician (our preferred metric for measuring customer commitment to Cxbladder) were 6.3, down from the 7.1 tests in Q4 25.

Meanwhile, the volumes from our key contracted US customers such as Kaiser Permanente are unaffected by the determination.

Asia Pacific volumes were up 8.8% to 1,183 from 1,087 in Q4 25, a move that reflected volume growth in all markets; Australia Southeast Asia and New Zealand.

The Q1 26 investor update also covers:

- The publication of data demonstrating the Analytical Validation of Triage Plus in *Diagnostics*[2]. This publication is one of two pieces of clinical evidence Pacific Edge requires to support a reconsideration request from Novitas regarding the Medicare coverage of Triage Plus
- A preview of the company's annual meeting on 6 August 2025 in Auckland and the detail of the company's ~$21 million capital raising.

Released for and on behalf of Pacific Edge by Grant Gibson Chief Financial Officer.

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OVERVIEW

Pacific Edge: www.pacificedgedx.com

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.

Cxbladder: www.cxbladder.com

Cxbladder is a suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with microhematuria and those being monitored for recurrent disease. The tests help improve the overall patient experience, while prioritizing time and clinical resources to optimize practice workflow and improve efficiency.

Supported by over 20 years of research, Cxbladder's evidence portfolio extends to more than 25 peer reviewed publications, and Cxbladder Triage is now included in the American Urological Association's Microhematuria Guideline. To drive increased adoption and improved patient health outcomes, Cxbladder is the focal point of numerous ongoing and planned studies designed to generate further clinical utility evidence.

Cxbladder is available in the US, Australasia, and Israel and in markets throughout Asia and South America. In the US, the test has been used by over 5,000 urologists who have ordered more than 130,000 tests. In New Zealand, Cxbladder is accessible to around 70% of the population via public healthcare and all residents have the option of buying the test online.

PacificEdge

INVESTOR UPDATE

JULY 2025

INSIDE

LETTER FROM THE CEO

Maintaining the momentum established through guideline inclusion

Dear Shareholders,

Pacific Edge enters FY 26 leaning into the opportunities created with the company-defining milestone of Cxbladder's inclusion in the American Urological Association's microhematuria guideline in February 2025. The guideline has cemented our position as the best-in-class provider of tests for hematuria evaluation and surveillance of non-muscle invasive bladder cancer patients both in the US and further afield.

The guideline, when combined with the new publications from our evidence generation program, is shifting clinical sentiment towards the adoption of our tests. As the only product with a 'Grade A'[1] evidence rating in the guideline, we have expanded the moat around our business, strengthening our first mover advantage as we seek to regain Medicare coverage for our tests.

The clearest evidence of this sentiment shift, as detailed on page 6, is the way US customers have transitioned to Cxbladder Triage for hematuria evaluation — with Triage accounting for 77% of US tests in June, up from 22% in Q4 FY 25. We accelerated the transition of US customers to Triage after the non-coverage on the *'Genetic Testing for Oncology: Specific Tests'* Local Coverage Determination (LCD) (L39365) ended Medicare coverage of our tests. Moving to Triage better prepares our customers for the future update to Triage Plus when we receive coverage for that test at a higher price.

> **"...now we must focus on scalable and profitable growth in sales to increase shareholder value."**

We are in the midst of a capital raise, in which $16.1 million has already been pledged to the company from the placement offer in May 2025. We are intending to seek $5 million (with over subscriptions possible with Board approval) through the associated share purchase plan (SPP[2]). These funds will extend the cash runway for over 12 months without Medicare coverage and without reductions in our cost base that would undermine our core priorities. The placement, which is subject to shareholder approval at the Annual Shareholders' Meeting (ASM) in August, and funds raised through the SPP will also support our goal to regain coverage and grow in non-Medicare channels.

The AUA guideline has allowed us to view the non-coverage determination differently, not least because it offers a clinically validated and authoritative reason for clinicians to continue to order our tests, for healthcare providers to integrate Cxbladder into clinical pathways and for payers to pay for medically reasonable and necessary testing.

As we navigated the negative market messaging from loss of Medicare coverage, and the operational logistics of converting all customers over to Triage, the test volumes in this quarter are yet to show the effect of the AUA guideline inclusion (see page 3-4), but we are advancing a range of initiatives to achieve this goal.

We continue to leverage the AUA guideline to appeal all Medicare denials for Triage and anticipate payment on these tests through that process[3].

Similarly, we continue to appeal all commercial payer denials for Triage, moving quickly to "external review" to drive payment and create opportunities for contracting. We have also initiated a pilot program to establish 'Client Billing' as a practice, leveraging the 'in-network' status many of our larger customers enjoy with commercial payers.

These initiatives — enabled by the AUA guideline inclusion — are still in the early stages but represent a significant potential pathway to expand adoption and drive revenue as part of our broader commercial payer strategy. We have already had contracting wins with the Blue Cross Blue Shield Group Purchasing Organization, gained a favorable recommendation from ECRI[4] – a data curator to which many commercial payers subscribe, and we are in numerous conversations for positive medical policy with the larger commercial payers. We ended the quarter with a win by securing 'in-network' status with Optum Veterans' Affairs Community Care Network (VACCN). The Optum VACCN covers healthcare costs for the VA for veterans across the eastern and central US who are unable to get a timely appointment within a VA facility and will pay Pacific Edge for Cxbladder at the Medicare rate.

Our efforts to regain Medicare coverage continue. In March 2025 we lodged a reconsideration request based on evidence not considered in the review that led to the non-coverage LCD. The new evidence includes the ground-breaking STRATA[5] randomized control study demonstrating the clinical utility of Cxbladder Triage and the new AUA microhematuria guideline.

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[1] The AUA defines 'Grade A' evidence as evidence with a high certainty rating and notes evidence of this grade makes it "very confident that the true effect lies close to that of the estimate of the effect.

[2] No offer of new shares is made under the SPP unless and until Pacific Edge sends the SPP offer document to shareholders. No money is currently being sought, and new shares cannot currently be applied for or acquired under the SPP.

[3] For a description of the Medicare appeals process please refer to our Annual Report published on 30 June 2025.

[4] ECRI is the Emergency Care Research Institute https://home.ecri.org/

[5] 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.

On June 26, 2025 (US time) we met with Novitas[6] Medical Affairs to discuss the reconsideration request we had made for Triage in March. The conversations were thorough and engaging, with the Novitas team noting that they had familiarized themselves with the AUA microhematuria guideline ahead of our call. The Novitas team made it clear that they understood how our test could deliver clinical utility to physicians and economic utility to insurers and expressed their commitment to provide medically reasonable and necessary testing to the Medicare population. They discussed with us the precise indications for coverage, focused on how physicians select patients for Triage testing. The 2020 and 2025 AUA Guidelines, the Kaiser Abstract from the AUA, and our STRATA publication clearly identify those patient types, and Novitas gave a non-binding verbal indication that our evidence was compelling for the purposes of re-opening the LCD.

We have a second meeting with Novitas on July 17 to discuss the reconsideration request for Cxbladder Monitor that we submitted in May, and we look forward to submitting a request later this year for Medicare coverage of Triage Plus, when the Analytical Validation (published 8 July 2025 online in Diagnostics[7]) and Clinical Validation (DRIVE study, in peer review) are published. We note that the Medicare Program Integrity Manual allows Novitas to combine reconsideration requests together when opening an LCD and overlapping submissions may affect the previously estimated timelines.

Pacific Edge's success with these strategies substantially depends on the shareholder approval of the placement and support for the $5 million SPP. Shareholders will shortly receive the receive the SPP documentation, and the Notice of our ASM (NOM) to be held in Auckland on 6 August 2025. The NOM will detail the approvals Pacific Edge requires and rationale for each of them.

I encourage you to consider these documents carefully and to support the company through what stands to be a key period in its development.

While the loss of Medicare coverage in April was disappointing, inclusion in the AUA Guideline and the positive attitude of payers including Novitas to that milestone gives me the confidence that we have already achieved what's necessary for enduring coverage of Cxbladder Triage and that now we must focus on scalable and profitable growth in sales to increase shareholder value.

I look forward to seeing you all at our meeting in August.

With my warm regards,

Dr Peter Meintjes
Chief Executive

TEST VOLUMES

Test demand resilient despite Medicare coverage loss

Tests processed through Pacific Edge's laboratories in the three months to the end of June 2025 (Q1 26) and test demand have been resilient in the face of the Medicare non-coverage determination and the disruption caused from the transition from Detect to Triage.

US TLT was down 11.9% to 5,717 tests from 6,490 in Q4 25 with the drop in volumes largely due to the disruption of asking physicians to switch from Cxbladder Detect to Triage for hematuria evaluation. Pacific Edge accelerated the decision to discontinue Detect in the US market following the inclusion of Triage in the new American Urological Association Microhematuria guideline and the non-coverage determination became effective.

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Asia Pacific volumes were up 8.8% to 1,183 from 1,087 in Q4 25, a move that reflected volume growth in all markets; Australia Southeast Asia and New Zealand.

[6] Novitas is the Medicare administrative contractor with responsibility for our US laboratory.
[6] Harvey, J.C. et al. (2025) Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Hematuria Patients for Urothelial Carcinoma. Diagnostics 2025, 15, 1739.

FIGURE 1: TOTAL TEST VOLUMES

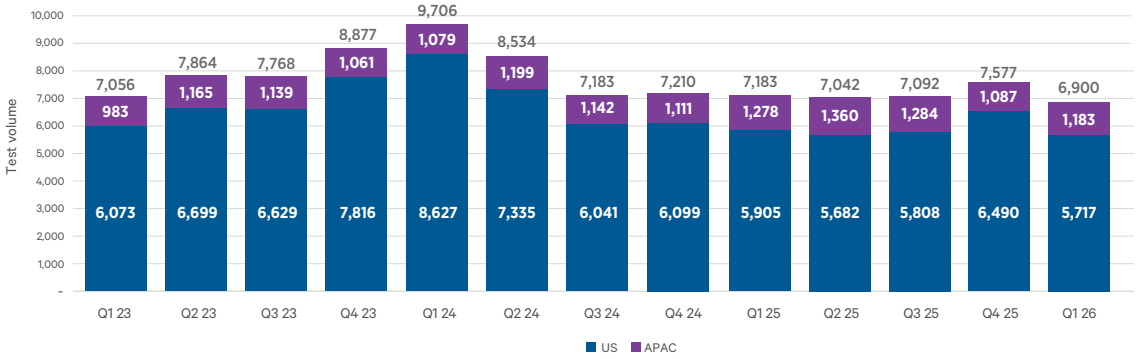


FIGURE 2: CXBLADDER CLINICAL ADOPTION

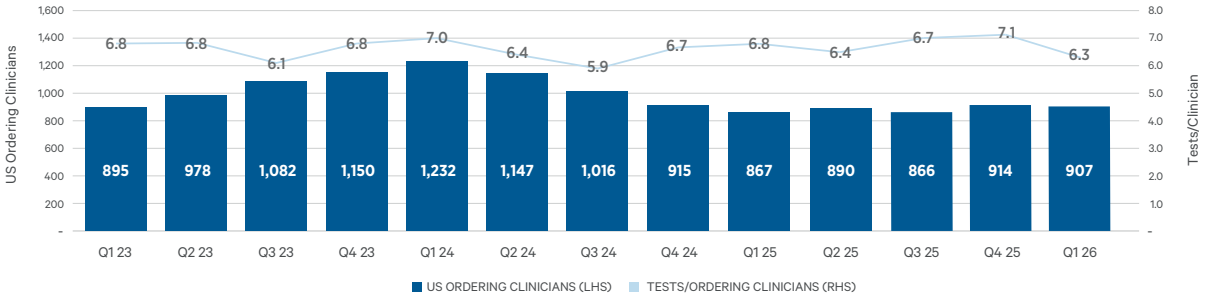


FIGURE 3: US SALES FORCE EFFICIENCY

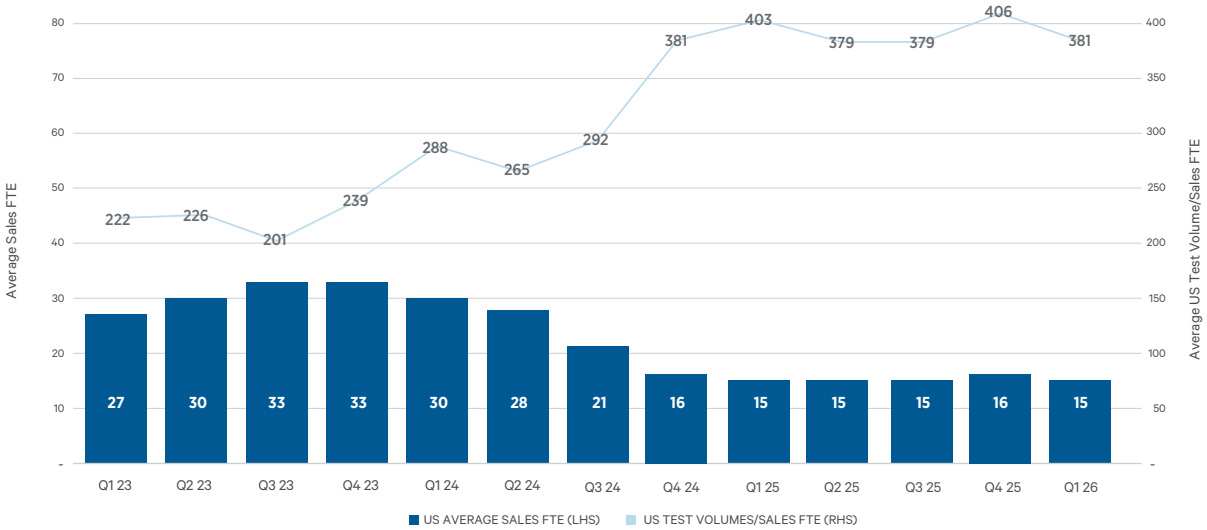
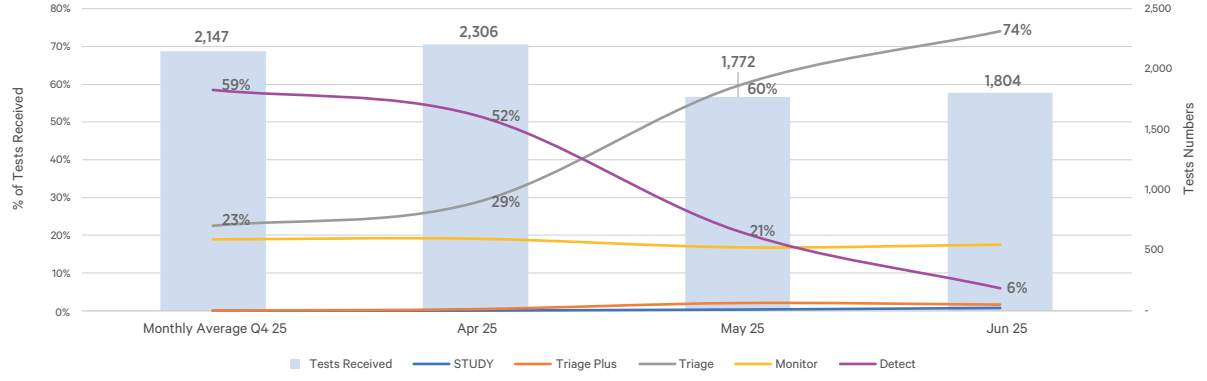


FIGURE 4: US TESTS RECEIVED AND TEST MIX



Major shareholders back capital raise

Pacific Edge has received strong support from institutional investors in the first phase of its capital raise that is targeted at sustaining the company's commercial momentum, advancing its next-generation product pipeline, and regaining Medicare coverage for its Cxbladder tests.

The $16 million raised through a placement of new shares to institutional and other selected investors, exceeded the initial $15 million target after the Board accepted oversubscriptions.

The placement, which is subject to shareholder approval at the company's annual meeting in August, is priced at $0.10 per share — an 18% premium to the 20-day volume weighted average price (VWAP) up to and including 29 May 2025 (the day prior to the public announcement of the capital raising through the NZX and ASX).

The second phase of the capital raising — a $5 million Share Purchase Plan (SPP) to be offered to eligible retail shareholders at the same price — is expected to open in mid-July and is contingent on the placement becoming unconditional.[1]

We are encouraged by the strong support we have received from our institutional shareholders, which reflects recognition of the value we have created in the face of the significant challenges of the last year. The capital will help us maintain our momentum and ensure we are well-positioned to respond strategically to both challenges and opportunities. We are looking forward to giving all eligible shareholders the opportunity to participate at the same offer price as the placement.

A full agenda for Annual Shareholders' Meeting

Pacific Edge is holding its Annual Shareholders' Meeting in Auckland on **Wednesday 6 August beginning at 3:00pm** and we are looking forward to seeing all our shareholders there. Chairman Chris Gallaher and Chief Executive Dr Peter Meintjes will provide a strategic update at the meeting covering the opportunities that have emerged for the business since Cxbladder Triage was included in the AUA microhematuria guideline and the path to regaining Medicare coverage of the company's tests.

The meeting also has a full agenda of matters for shareholders to consider. These include the re-election of Directors including Chris Gallaher, Sarah Park and Tony Barclay.

The meeting will also seek shareholder approval for the $16.1 million placement of shares to selected shareholders and resolutions to approve an increase in the Directors fees pool. A key element of this second proposal is that the first year of this increase is paid in shares rather than cash to support the company's ongoing need to preserve capital as it seeks to regain Medicare coverage. This share issue will also be put to shareholders for approval.

Further details can be found in the Notice of Meeting to be mailed to shareholders imminently and on the investor section of the website at: www.pacificedgedx.com/investors/investor-center/

Meanwhile we would appreciate shareholders signaling their attention to attending via the follow Eventbrite link https://bit.ly/PacificEdgeASM2025

[1] No offer of new shares is made under the SPP unless and until Pacific Edge sends the SPP offer document to shareholders. No money is currently being sought and new shares cannot be applied for or acquired under the SPP.

Triage Plus analytical validation published

Triage Plus has moved a step closer towards commercial launch with the publication of its analytical validation in *Diagnostics*[1].

This publication is one of two pieces of clinical evidence Pacific Edge requires to support a reconsideration request from Novitas[2] regarding the Medicare coverage of Triage Plus. The second element, the DRIVE study, was submitted for peer review in June. If the reconsideration request is successful, that is the final hurdle before commercialization of the test in the US.

In the AV publication Triage Plus demonstrated a sensitivity of 93.6%, specificity of 90.8%, positive predictive value (PPV) of 46.5%, negative predictive value of 99.4%, and a test-negative rate of 84.1%[3]. The study concluded: *"Cxbladder Triage Plus... provides a non-invasive, highly sensitive, and reproducible tool that aids in risk stratification of patients with hematuria."*

In addition to providing superior performance characteristics that will benefit patients, clinicians, and healthcare payers, the test, once commercialized, is expected to boost the economics of Pacific Edge's US commercial operations. The Centers for Medicare and Medicaid Services has set a draft price for the test at US$1,018 — a substantial premium over the current US$760 price for Triage. At this price, which is due to be finalised in January 2026, the margin per test is higher and the profitability threshold lower than Triage, enabling faster scaling and a quicker path to profitability.

"Triage Plus... [is] a non-invasive, highly sensitive, and reproducible tool that aids in risk stratification."

[1] Harvey, J.C. et al. (2025) Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Hematuria Patients for Urothelial Carcinoma. Diagnostics 2025, 15, 1739. Also available at the following link: https://www.mdpi.com/2075-4418/15/14/1739
[2] Novitas is the Medicare Administative Contractor with responsibility for Pacific Edge's US laboratory.
[3] For definitions Sensitivity, Specificity, Negative Predictive Value, and Positive Predictive Value please refer to glossary in the Capital raising presentation released to the NZX and ASX on 29 May 2025. All values quoted are at a score threshold of 0.15.

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. Specifically, we seek to produce evidence that is founded on the frameworks of Analytical Validity (AV), Clinical Validity (CV) and Clinical Utility (CU), with the endpoints 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 Triage • CV/CU Triage Plus (retrospective)	• Microhematuria (MH) • Risk stratification	• Recruitment closed with 555 patients including 223 low risk patients (test and control). • Interim analysis results published leading to AUA Guidelines inclusion in 2025 update. • Database lock expected July 2025 and Clinical Study Report (CSR) expected Oct 2025.
DRIVE **D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria	• CV Triage Plus for a Veterans' cohort • Data MH pooled analysis	• MH and gross hematuria (GH) • Risk stratification	• Enrolment closed with 710 patients including 48 tumour confirmed patients from 10 US VA sites. • Database lock completed and publication submitted June 2025.
microDRIVE **D**etection and **R**isk stratification **I**n **VE**terans presenting with microhematuria	• CV Triage Plus • Data MH pooled analysis	• MH • Risk stratification	• Currently 254[1] samples received to date with 6 Urothelial Cancer (UC) cases confirmed including matched samples. • Study expanded to 4 active sites with 1-2 more sites at feasibility assessment. • The target is 1000 patients with 35 tumour confirmed patients with LPI projected to be delayed beyond Q4 2025 and more likely Q2 2026.
AUSSIE **A**ustralian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia	• CV Triage Plus (Australian cohort) • Data MH pooled analysis	• MH and GH • Risk stratification	• The target is 35 UC confirmed patients including a minimum of 10 MH UC confirmed. • Currently 704 subjects enrolled with 47 UC confirmed (GH+MH) including 7 MH UC patients. • Last patient in projected to be Q3 2025.
POOLED ANALYSIS	• CV Triage Plus	• MH and GH • Risk stratification	• MH (and separately GH) patient data from DRIVE, AUSSIE and microDRIVE will be pooled and analyzed. • GH paper submission is expected in 2026, and MH pooled analysis is delayed due to microDRIVE until at least Q2 2025.
LOBSTER **LO**ngitudinal **B**ladder cancer **S**tudy for **T**umor **R**ecurrence	• CV Monitor and Monitor Plus	• Surveillance • Risk stratification	• Enrolment will be complete when 75 UC recurrences are observed. • Currently 454 subjects enrolled with 1,044 samples and 70 confirmed UC recurrences. • We project last patient Q4-2025 and cleanup of data to follow.
CREDIBLE **C**ystoscopic **RED**uction **I**n **BL**adder **E**valuations for microhematuria	• CU Triage Plus	• MH • Risk stratification	• Contracts completed (15/15), study level Institutional Review Board (IRB) approvals and site level IRB approvals (14/15). • Site authorized to enroll (11/15), remainder due by end of July. • 8 sites are actively enrolling with 26 subjects enrolled.

Quarterly dates are calendar year not financial years

[1] This figure is smaller than the figure provided in the company's 2025 annual report due to a revision subsequent to its publication on 30 June 2025.

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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