



PacificEdge

INVESTOR UPDATE

JANUARY 2026

INSIDE

Letter from the CEO	2
Q3 26 test volumes	5
Medicare expert panel convened	5
Commercial payer gains	6
Pacific Edge's new Chair	7
Chris Gallaher retires	7
Clinical evidence	8

Looking toward Novitas expert panel deliberations



Dear Shareholders,

Pacific Edge enters 2026 in the strongest position to establish enduring Medicare coverage policy in a Local Coverage Determination (LCD) — the strategic focus for more than a decade. If successful this will establish a materially more certain environment for reimbursement for Cxbladder by Medicare and other providers in the US.

We committed to this goal — an LCD in favor of our tests — when we launched clinical laboratory operations in the US in 2013. We have worked diligently through various challenges, developing tremendous support along the way.

The next indication that positive LCD language could be drafted comes on 20 February 12.00pm (NZST)¹ when our Medicare Administrative Contractor (MAC) Novitas is scheduled to hold an expert Contractor Advisory Committee (CAC) to review coverage for urine-based biomarker tests for hematuria evaluation.

The meeting, precipitated by the February 2025 update to the American Urological Association's (AUA) Microhematuria Guideline, is significant. CACs are generally convened ahead of developing new or substantially revised medical policy as a draft LCD. They are designed to capture clinical opinion from practicing physicians in addition to published evidence and the AUA guidelines to *"ensure an unbiased and contemporary consideration of the state-of-the-art technology and science"*.

As a consequence of this and its scheduling during NZX and ASX trading hours (and after consulting with a range of parties) we expect the CAC to be accompanied by a trading halt of Pacific Edge's shares (see page 5).

The landmark inclusion of Cxbladder Triage in the February 2025 update to the AUA's Microhematuria Guideline has delivered a dramatic shift in our engagement with Novitas and sets the scene with

Medicare. It has also led to stronger engagement with the Centers for Medicare and Medicaid Services (CMS) and its Coverage and Analysis Group (CAG), the team that leads the evidence review and policy work behind Medicare decisions.

During meetings with Novitas in 2025 we worked hard to build professional goodwill between our two organizations, and we are encouraged by the results.

Notably, Novitas has asked us to provide the names of key opinion leaders (KOLs) that are familiar with the guidelines, with urine-based biomarkers and with our tests to ensure that they have the best clinical information on which to develop medical policy. This gives all stakeholders, Novitas, urologists, patients and Pacific Edge the best chance of an outcome that ensures an accurate assessment of the clinical and economic value of our tests.

We believe Novitas understands the anomaly of Medicare beneficiaries not receiving guideline-recommended testing and the fact that the evidence for Cxbladder has advanced past the current LCD (Genetic Testing for

Oncology: Specific Tests (L39365), which was finalized in early 2025 and only considered evidence published before September 2023). This LCD excluded the STRATA² study which formed the basis of establishing urine-based biomarkers in the AUA guideline, and several other more-recent published papers supporting the clinical value of Cxbladder products. It also excludes a Kaiser Permanente study that has recently been accepted by *Urology Practice* for publication. This is the largest study ever performed on urine-based biomarkers for hematuria evaluation, and provides compelling real-world evidence for the clinical utility of Cxbladder.

We also believe Novitas understands that this anomaly could persuade an Administrative Law Judge (ALJ), the determinative (Level 3) stage of the Medicare Appeals process we are now pursuing for all Cxbladder Triage tests denied reimbursement.

"Novitas has asked us to provide the names of key opinion leaders (KOLs) that are familiar with the guidelines, with urine-based biomarkers and with our tests..."

¹ 19 February 2026 at 6:00pm (US ET)

² 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.

We have lodged these appeals on the basis that Cxbladder Triage tests are medically reasonable and necessary — the statutory threshold for coverage under the US Social Security Act — substantiated by the test's inclusion in the AUA Guideline and that the published clinical evidence has advanced on the evidence reviewed in the non-coverage determination finalised last year. We have yet to make our first appeal before an ALJ, but we were pleased to hear in January that our first hearing of four cases has been set down for 24 February 2026 just after the CAC meeting (see page 6). After a December meeting with CMS and the CAG, they are aware that the clinical evidence has moved past the policy, that guideline-recommended testing is not being covered by Novitas, and the potential for medical policy to be set by an ALJ rather than through the normal coverage process.

Perhaps most significantly, we are entering into this important engagement at the CAC with the weight of clinical opinion in our favor. For instance, the AUA continues to be a key supporter of our efforts and through their public policy committees have used their weight to directly engage Novitas and Medicare regarding the importance of reviewing their guidelines to ensure Medicare patients have access to the latest medically reasonable and necessary testing. The proof of this shift in clinical sentiment will come in the language of the draft LCD that Novitas issues in the months after the meeting.

While we don't know the date on which that draft LCD will be published, we expect that Novitas will act expediently for all the reasons set out above.

An LCD, if written to cover Cxbladder, will represent an even greater defining moment for the company than the AUA Guideline of February 2025. The key element that distinguishes this milestone from our prior Medicare coverage status is that the LCD should create medical policy language clarifying the appropriate use of Cxbladder tests, beyond the prior coding policy that permitted our tests to be paid without establishing coverage language.³ Furthermore, positive coverage language should provide unequivocal guidance to Medicare Advantage payers to pay for our tests and create new avenues to appeal denied tests from commercial payers using "state biomarker laws" championed by the American Cancer Society (ACS)⁴.

We expect the cumulative effects to be observed by an increase to our Average Sales Price (ASP) on any covered test. This is a trend we have already

observed among commercial payers since guideline inclusion, despite the non-coverage determination from April 2025. Similarly, with reduced administrative challenges, we expect this to provide the opportunity for us to drive higher demand for our tests from the figures that we report today.

Thinking further ahead, the DRIVE publication in late October made available the clinical validation evidence that Triage Plus should also be covered alongside Triage that is already in the AUA Guideline. The US\$1,328 Medicare price established for Triage Plus — now effective since 1 January 2026 — is a substantial increase over the US\$760 Medicare price for our existing tests.

Despite the challenges with Medicare, we continue to make progress with commercial payers. Significantly, a large diagnostic intelligence provider, Avalon Healthcare Systems, which supports healthcare payers covering 44 million lives to determine reimbursement policies, has endorsed Cxbladder Triage. Both developments should support growth in non-Medicare payer volumes. The endorsement by Avalon, and the earlier endorsement by the Emergency Care Research Institute⁵ (ECRI), an organization that performs a similar role to Avalon, provide authoritative templates for Novitas as it deliberates on Medicare coverage in the coming months.

December 2025 meanwhile saw a major change to our leadership that we expect to substantially shape our future with the appointment of our new Chair Simon Flood. Simon took over from Chris Gallaher who had delayed his retirement until a successor was recruited. I know shareholders are as grateful as management and the broader Pacific Edge team for the support that Chris has provided the company over many years.

I look forward to providing you with an update on the outcome of the CAC meeting in February.

With my warm regards,



Dr Peter Meintjes
Chief Executive

³ Cxbladder had received positive coding guidance on LCA58529 in July 2020, but were non-covered on L39365 in April 2025.

⁴ American Cancer Society (ACS) State Biomarker Law summary page at <https://www.fightcancer.org/what-we-do/access-biomarker-testing>

⁵ <https://home.ecri.org/>

US challenges and the seasonal slowdown

Cxbladder tests processed through Pacific Edge's laboratories in the three months to the end of December 2026 (Q3 26) have remained subdued, even as strategic momentum mounts for a Medicare policy decision to reimburse Cxbladder Triage.

Total laboratory throughput (TLT) in Q3 26 fell 13.4% to 5,446 tests from 6,286 in Q2 26. US TLT was down 19.5% to 4,003 tests from 4,971 in Q2 26. APAC volumes rose 9.7% to 1,443 tests from 1,315 in Q2 26 lifted by an increase in commercial test volumes.

The challenges of the prior quarter — the continued fallout from the disruptions of transitioning US customers from Cxbladder Detect to Triage and the ongoing challenges associated of selling a product not covered by Medicare — continue to represent a considerable headwind to the company and were exacerbated by the seasonal holiday slowdown.

In the US, Pacific Edge accelerated the decision to discontinue Detect following the inclusion of Triage in the new American Urological Association (AUA) Microhematuria Guideline in February 2025 and the non-coverage determination. Reflecting the weaker volumes our sales force efficiency metric (tests per sales FTE) fell to 334 from 403 in Q2 26, with sales team numbers steady at 12 FTEs.

The number of ordering clinicians fell to 691 from 803 ordering clinicians in Q2 26. Tests per unique ordering clinician were 5.8 compared to 6.2 in Q2 26.

FIGURE 1: TOTAL TEST VOLUMES

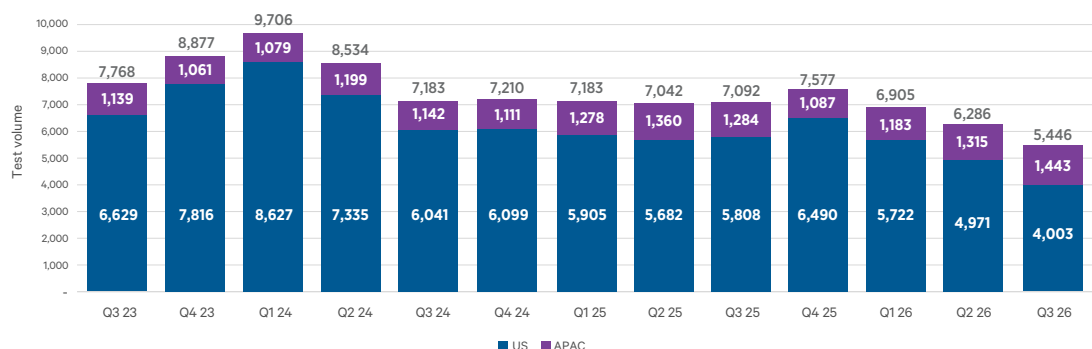


FIGURE 2: CXBLADDER CLINICAL ADOPTION

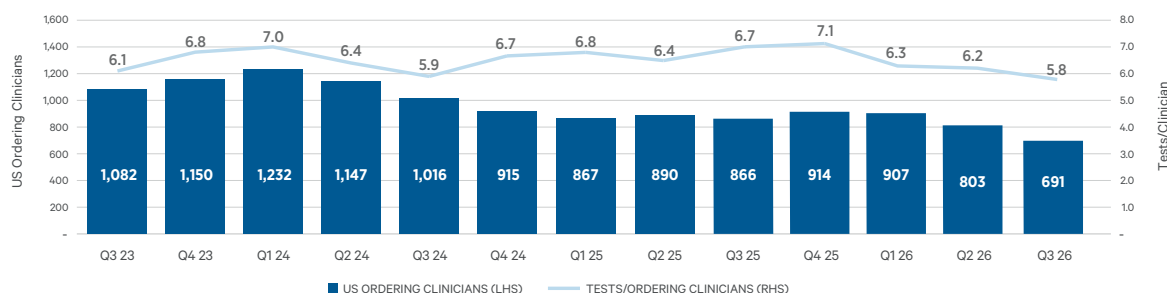
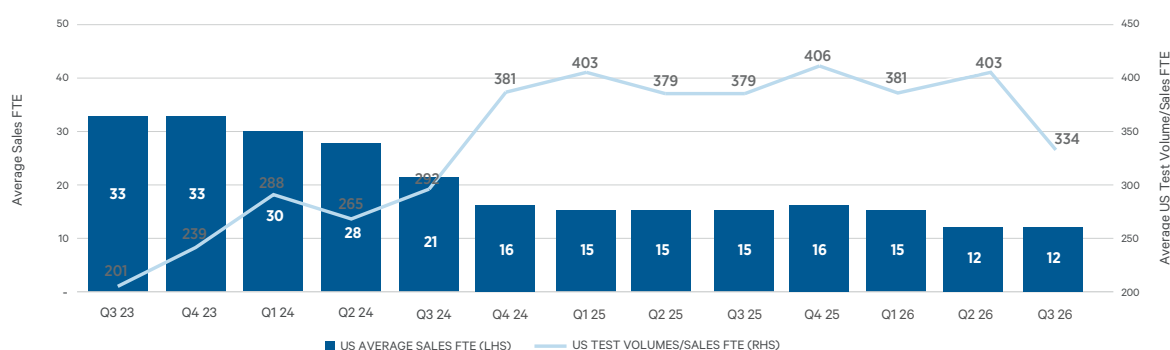


FIGURE 3: US SALES FORCE EFFICIENCY



Contractor Advisory Committee: what to look for

Novitas' Contractor Advisor Committee meeting scheduled for mid-February will be an important test of the progress Pacific Edge has made in convincing the Medicare Administrative Contractor to change medical policy on Cxbladder. Below is a guide to what shareholders should look for from this important meeting.

MEETING DATE	19 February 2026 6pm US ET (20 February 2026 12.00pm NZ ST)
FORMAL NOTICE OF MEETING	Novitas will publish registration details to its website two weeks prior to the CAC.
HOW TO WATCH	The meeting will be streamed live. Novitas' website is only accessible from US IP addresses, but Pacific Edge expects to be able to provide registration details of how to join the meeting in an announcement to shareholders ahead of the meeting.
PURPOSE	To discuss evidence for the use of urine-based biomarkers in patients with microhematuria.
WHY IS IT IMPORTANT	CACs are generally convened ahead of the development of new or substantially revised medical policy via a Local Coverage Determination. They are intended to supplement the MAC's internal expertise by systematically capturing clinical opinion from practicing physicians in addition to published evidence to ensure an unbiased and contemporary consideration of state-of-the-art technology and science.
TRADING HALT	We expect Pacific Edge's shares on the NZX and the ASX will enter a trading halt ahead of the meeting until we can provide an update on the proceedings of the meeting, expected before the commencement of trading on the NZX on Monday 23 February 2026.
PARTICIPANTS	<ul style="list-style-type: none"> • Novitas Medical Directors and other Medical Affairs staff • The Centers for Medicare & Medicaid Services (CMS) • Panelists: Clinicians selected by Novitas for their expertise, their familiarity with the guidelines, the merits of urine-based biomarkers and our tests. In a positive sign, Urologists familiar with our tests have been confirmed as panelists • Public (listen only)
WHAT TO LOOK FOR	<p>Signals that matter for coverage outcomes:</p> <ul style="list-style-type: none"> • Panelists: We will be noting who outside of our nominees have been accepted on the panel, their level of familiarity with the published clinical evidence and their level of influence within the AUA community • Medical Policy supporting the need for urine-based biomarkers in hematuria evaluation: We will be listening for comments regarding the general utility of biomarkers for hematuria evaluation. Specifically, the appropriate patient types, how to identify those patients and what physicians should do with a test result • Clinical evidence for Cxbladder: We will be listening for comments regarding the evidence portfolio for Triage and Triage Plus. Most important is the evidence not previously reviewed by Novitas for L39365 e.g. STRATA Study, Triage AV Publication, Triage Plus AV Publication, DRIVE Study and the Kaiser real world study accepted for publication by <i>Urology Practice</i> • Medical Necessity: We will be listening for panelists to specifically tell Novitas that Cxbladder products are medically reasonable and necessary for contemporary practice of urology care and that CMS should pay for these tests
WHAT TO EXPECT AFTER THE MEETING	<ul style="list-style-type: none"> • A formal transcript and recording of the meeting will be posted to the Novitas website after the meeting's conclusion. However, given that this often takes many weeks, Pacific Edge will make an informal transcript available prior to exiting the trading halt • We would expect Novitas to turn their attention to the development of a draft LCD, a potential catalyst that recognizes the value of our tests. Our expectations for the issue of this draft range from the middle of Q2 Calendar 2026 to early Q3 Calendar 2026

First Administrative Law Judge hearing set

In January, the Office of Medicare Hearings and Appeals (OMHA) notified us that our first reimbursement appeal has been scheduled for a hearing before an Administrative Law Judge (ALJ) on 24 February 2026.

This ALJ hearing is a determinative stage of the Medicare appeals pathway we are pursuing for all eligible Cxbladder Triage tests that have been denied Medicare reimbursement since the Cxbladder non-coverage determination took effect in April 2025. We have lodged these appeals on the basis that Cxbladder Triage tests are medically reasonable and necessary — the statutory threshold for coverage under the US Social Security Act — substantiated by the test's inclusion in the AUA Guideline and that the published clinical evidence has advanced the evidence reviewed in the non-coverage determination 'Genetic Testing for Oncology: Specific Tests' (L39365) finalized last year.

Consistent success in overturning denials could materially influence FY26 and FY27 revenue, by establishing a precedent for the more than 1,650 tests that have been denied reimbursement to date. ALJs sit at the third level of the Medicare appeals process and, while a judge is expected to give deference to Local Coverage Determinations (LCDs), they are not bound by them. They can also consider additional evidence, including:

- The updated AUA 2025 Microhematuria Guideline
- New clinical evidence, including the STRATA study that underpinned the Guideline change and the new Kaiser real world study
- Third-party assessments such as the Emergency Care Research Institute (ECRI), which recently gave Triage a positive 4/5 rating and the endorsement by Avalon Healthcare Systems (see below)

Following the hearing, the ALJ has 90 days to issue a decision, unless Pacific Edge agrees to waive the deadline and extend the timeframe.

COMMERCIAL PAYERS

Cxbladder endorsed by large diagnostic test intelligence provider

Avalon Healthcare Systems¹, a large diagnostic intelligence provider that is used by healthcare payers and providers supporting more than 44 million US lives², has declared Cxbladder Triage as 'meeting coverage' criteria.

Avalon's determination, which follows closely the wording used in the AUA Microhematuria Guideline for the use of urine biomarkers, will be highly influential for the more than 30 health plans that use its insights to determine reimbursement policies. These payers include Blue Cross Blue Shield of North and South Carolina, among others. It is a significant achievement of our strategy to leverage the Guideline to drive the adoption of our tests among non-Medicare payers and we expect it to assist our discussions to change reimbursement policies with these payers and drive adoption of our tests.

Avalon's policy states Triage meets coverage criteria when it is used to facilitate the decision regarding the utility of cystoscopy for individuals with microhematuria when: the patient has been classified as intermediate risk; the individual has acknowledged a desire to avoid cystoscopy; and has accepted the risk of forgoing direct visual inspection via a cystoscopy.



¹ <https://www.avalonhcs.com/solutions/>

² <https://www.avalonhcs.com/newsroom/avalon-2025-lab-trend-report-genetic-testing-soars-as-routine-testing-stabilizes/>

Simon Flood takes over as Chair



Pacific Edge has a new Chair.

Simon Flood was appointed as an Independent Director of the company in early December and at the conclusion of the December Board meeting was appointed Chair, replacing Chris Gallaher who retired after nine years at the helm.

Simon says he is excited to join Pacific Edge at a pivotal time, describing the company as a first mover and market leader in bladder cancer diagnostics. He is looking forward to working with the Board and Management Team as Pacific Edge continues to drive towards reimbursement certainty in the US.

“Pacific Edge’s tests offer clinical utility, patient satisfaction and economic value to healthcare payers around the world. It is differentiated from other companies as the first mover, for having the highest quality clinical evidence and an ongoing robust evidence generation program that will entrench its leadership. It is a significant opportunity, and I am delighted to lead the governance function,” Simon said.

Simon brings deep global capital markets and investment management experience, having held senior roles in London, Hong Kong and Singapore with Mercury Asset Management / Merrill Lynch Investment Managers, Axa Investment Managers, and Lion Global Investors.

He has also worked as an Executive Director at UK-based, technology-focused venture capital firm Imprimatur Capital, building additional expertise in scaling innovative businesses.

Since returning to New Zealand in 2015, Simon has taken on a range of governance roles, including Chairman of Queenstown Airport and a recent appointment to the Tertiary Education Commission, alongside several South Island organizations.

“Pacific Edge’s tests offer clinical utility, patient satisfaction and economic value to healthcare payers around the world...”

Mana and guardianship

A patu pounamu, a symbol of mana, guardianship and leadership, was gifted to retiring Chair Chris Gallaher by Deputy Chair Bryan Williams on behalf of the Directors and Management in acknowledgement of nine years of steadfast commitment to the company.

Following the December Board meeting, Pacific Edge Directors and guests marked Chris’ tenure as Chair with a dinner where he was presented with a ceremonial patu in recognition of his leadership. Over the past nine years, particularly through the more recent challenges over Medicare reimbursement in the US, he provided stability and confidence for shareholders and stakeholders alike, deferring his retirement at the request of the Board until a successor was appointed.

The Board and Management thanks Chris for his leadership and wishes him well in his long-delayed retirement.



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 Safe Testing of Risk for Asymptomatic Microhematuria	<ul style="list-style-type: none"> CU Triage (lower risk MH) and CU Triage Plus (retrospective) 	<ul style="list-style-type: none"> MH Risk stratification 	<ul style="list-style-type: none"> 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
DRIVE Detection and Risk stratification In VETERANS presenting with hematuria	<ul style="list-style-type: none"> CV of Triage Plus (MH or GH) Data for MH & GH pooled analyses 	<ul style="list-style-type: none"> MH and GH Risk stratification 	<ul style="list-style-type: none"> Enrolment closed with 710 patients including 48 tumour confirmed patients from 10 US VA sites Database lock completed and manuscript published
microDRIVE Detection and Risk stratification In VETERANS presenting with microhematuria	<ul style="list-style-type: none"> CV of Triage Plus (MH or GH) Data for MH & GH pooled analyses 	<ul style="list-style-type: none"> MH and GH Risk stratification 	<ul style="list-style-type: none"> Study expanded to 3 active sites, 421 samples, not including protocol deviations, received to date including 16 UC confirmed (35 targeted) Study design has been changed to include high risk patients presenting with GH The target is 35 or more UC confirmed subjects
AUSSIE Australian Urologic risk Stratification of patients with hematuria	<ul style="list-style-type: none"> CV Triage Plus (MH or GH) Data for MH & GH pooled analyses 	<ul style="list-style-type: none"> MH and GH Risk stratification 	<ul style="list-style-type: none"> There are 753 subjects enrolled including 55 UC confirmed (GH+MH) including 10 MH UC patients Recruitment target achieved Enrolment is closed, clinical database lock occurred Dec-2025, final Triage Plus data expected Jan-2026 and publication submission expected March-May 2026
POOLED ANALYSES	<ul style="list-style-type: none"> CV Triage Plus MH Patients CV Triage Plus GH Patients 	<ul style="list-style-type: none"> MH and GH Risk stratification 	<ul style="list-style-type: none"> Patient data from DRIVE, AUSSIE and microDRIVE will be pooled and analyzed in two studies for MH and GH MH pooled analysis is expected for submission in late 2026 GH pooled analysis is expected for submission in late 2026
CREDIBLE Cystoscopic REDuction In BLadder Evaluations for microhematuria	<ul style="list-style-type: none"> CU Triage Plus 	<ul style="list-style-type: none"> MH Risk stratification 	<ul style="list-style-type: none"> All sites have completed contracts and IRB approvals All fifteen sites now activated, 128 patients enrolled of 1000 targeted Enrollment lower than expected, we will add up to 6 more sites to the study Enrollment phase expected to continue until Q2 27
LOBSTER LONGitudinal Bladder cancer Study for Tumor Recurrence	<ul style="list-style-type: none"> CV Cxbladder Surveillance (low-, int.- and high-risk) 	<ul style="list-style-type: none"> Surveillance Risk stratification 	<ul style="list-style-type: none"> Enrolment completed Q3 25 for an interim analysis — 75 UC recurrences observed (78 UCs confirmed as of 01 Dec 2025, however, only the first 75 will form the basis of the interim analysis) Currently 481 subjects enrolled with 1,211 samples Protocol amendment provides for continued scheduled surveillance visits and urine collections into 2027
OCTOPUS Ongoing Cxbladder Testing for Optimized Patient Experience in Urothelial Surveillance	<ul style="list-style-type: none"> CU Cxbladder Surveillance (low-, int.- and high-risk) 	<ul style="list-style-type: none"> Surveillance Risk stratification 	<ul style="list-style-type: none"> Currently at the planning stage Advisory Board completed Dec-2025 Business case and protocol under development First patient anticipated for mid to late 2027

- Microhematuria (MH), Gross hematuria (GH)
- Cxbladder Triage Plus (Triage Plus)
- Cxbladder Monitor Plus is now called Cxladder Surveillance
- Quarterly dates are calendar year not financial year



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.

VISIT US ONLINE:

www.pacifiedgedx.com
www.cxbladder.com

FOLLOW US ON SOCIAL MEDIA:

www.facebook.com/PacificEdgeLtd
www.facebook.com/Cxbladder
www.twitter.com/PacificEdgeLtd
www.twitter.com/Cxbladder
www.linkedin.com/company/pacific-edge-ltd

CONTACT US:

Centre for Innovation
87 St David Street
PO Box 56
Dunedin 9016, New Zealand
T: 0800 555 563 (NZ)
+64 3 577 6733 (Overseas)
E: investors@pacifiedge.co.nz