For personal use only

25 November 2025

UNAUDITED FINANCIAL RESULTS FOR THE SIX MONTHS TO 30 SEPTEMBER 2025

POSITIONING FOR MEDICARE-LED RECOVERY

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today announces its results for the six months to the end of September 2025 (1H 26) showing the company positioning itself for a recovery led by Medicare reinstating reimbursement of Cxbladder.

The company enters the second half of FY 26 in its strongest position yet for a positive update to Medicare policy and a subsequent resumption in growth. The next catalyzing event in the re-coverage process is the Contractor Advisory Committee (CAC) that Novitas[1] has proposed to convene on 19 February 2026. Such expert committees are generally convened ahead of developing new or substantially revised medical policy.

1H 26 FINANCIAL AND PERFORMANCE PROGRESS[2]

- Operating revenue was down to $5.9 million from $10.9 million in 2H 25 following Medicare coverage loss. Total revenue was down to $7.1 million from $12.5 million in 2H 25.
- With the loss of Medicare Coverage, Medicare revenue cannot be recognized until successfully appealed, a process expected to delay revenue recognition by 6-9 months.
- Total laboratory throughput[3] (TLT) of Cxbladder tests of 13,191; down 10.1% on 2H 25; commercial tests down 15.9% on 2H 25 to 10,371 tests
- US test sales/FTE of 403 for Q2 26, up 5.8% on 1Q 26 following sales force reduction and a focus on the most profitable territories
- Net loss after tax of $19.1 million, higher than the $15.4 million net loss in 2H 25 following lower revenue and strategy to position the company for a Medicare-led recovery; net operating costs decreased 5.9% on 2H 25.
- Net cash flow to operating activities at $19.0 million is more than the $12.3 million in 2H 25, following lower revenue, and the costs associated with the strategic positioning of the company for a Medicare led recovery
- Cash and cash equivalents and short-term deposits at $22.1 million; supported by successful $20.7 million capital raise in August 2025; canvasing strategic options given an extended Medicare re-coverage timeline and appeals delays

1H 26 STRATEGIC HIGHLIGHTS

- Strongest position yet for a Medicare policy change, after AUA[4] support for Cxbladder Triage prompts Novitas to convene a CAC on 19 February 2026
- Cxbladder evidence portfolio continues to grow with key publications: Analytical Validation of Triage Plus (Harvey et al. 2025[5]) and Clinical Validation of Triage Plus (Savage et al.

[1] Novitas is the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge's lab in the USA
[2] All comparisons are to the second half of the prior financial year unless otherwise stated.
[3] Total Laboratory Throughput (TLT) includes commercial, pre-commercial and clinical studies testing.
[4] AUA: American Urological Association
[5] Harvey et al. (2025) Analytical Validation of Cxbladder® Triage Plus Assay for risk stratification of hematuria patients for urothelial carcinoma Diagnostics 2025, 15, 1739.

2025; the DRIVE Study[6]); a new Kaiser Permanente study covering real-world evidence of Cxbladder Triage's Clinical Utility is also expected to be published ahead of the CAC

- Pacific Edge's longer-term economics reinforced after Centers for Medicare and Medicaid Services (CMS) sets draft Triage Plus test price of US$1,328, a 75% increase over the US$760 price of the existing products; our global addressable market expands to US$10.8 billion[7]
- Commercial operations positioned for Medicare policy change; focus retained on profitable territories, non-Medicare revenue streams and selling the clinical and economic value of Cxbladder

Chairman Chris Gallaher said: "Pacific Edge has made significant progress over the half year of entrenching its first-mover advantage in urine-based biomarkers for hematuria evaluation, with a continued focus on strengthening the clinical evidence for Cxbladder Triage and Triage Plus and driving recognition of that evidence in clinical practice.

"These achievements represent a further validation of the company's strategic direction and the long-term opportunity ahead. The Board recognizes that maintaining our US market presence through the delay in Medicare coverage places pressure on capital, but this is a deliberate decision to preserve the value created and position Pacific Edge to capitalize swiftly when coverage is achieved."

Chief Executive Dr Peter Meintjes said: "During the half year, we strengthened our clinical foundation for Cxbladder with AV and CV publications and reinforced our long-term economics gaining a favorable CMS pricing decision for Triage Plus. This latter outcome highlights how we continue to create value through the development of next-generation products and the clinical evidence that supports them. While the timing of Medicare coverage remains outside our control, we are now in our strongest position yet to drive a change in Medicare policy and to accelerate growth should recognition be achieved."

FINANCIAL RESULTS

Operating revenue is down to $5.9 million from $10.9 million in 2H 25, with the fall largely reflecting the loss of Medicare coverage at the start of the period and the reduction in commercial test volumes.

Pacific Edge expects revenue to lift for 2H 26 after taking claims through the Medicare Appeals Process, but that revenue recognition can only come after success in front of an Administrative Law Judge (ALJ). Normal timeframes associated with appeals to the ALJ are 6-9 months, delaying recognition of any success until, at best, in 2H 26 and there could be unknown delays to the scheduling of ALJs on account of the 43-day government shutdown in the US.

---

[6] Savage et al. (2025). Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study. Urol Oncol. Oct 31 2025; doi:10.1016/j.urolonc.2025.10.008

[7] See page 38 of the investor presentation released to the NZX and ASX today for the assumptions underlying this estimate.

For personal use only

For personal use only

Total laboratory throughput (TLT) of Cxbladder tests fell to 13,191, down 10.1% on 2H 25, while commercial test volumes fell to 10,371, down 15.9% on 2H 25. The fall is primarily due to the operating conditions in an environment of Medicare non-coverage but is compounded by the transition of Detect customers to Triage that gives Pacific Edge the chance of successful reimbursement on appeal to Medicare, given the AUA guideline inclusion for Triage.

Importantly, non-Medicare volumes, largely buoyed by Kaiser Permanente remain relatively steady, and early indicators are that payment is increasing from non-Kaiser Permanente commercial payers.

Despite the fall in commercial volumes, US test sales/FTE of 403 for Q2 26, improved 5.8% on Q1 26 following a sales force reduction and a focus on the most profitable territories; Pacific Edge is not reporting US ASP[8] in this period as it has recognized no revenue of Medicare tests since the loss of coverage as it appeals non-payment through the Medicare appeals process. Asia Pacific (APAC) TLT increased 5.4% on 2H 25 with the increase largely reflecting an increase in non-billable tests including evaluation tests and tests for clinical studies.

Total operating expenses were down 5.9% on 2H 25 as we focused on managing costs.

Pacific Edge's operating cost base continues to reflect our determination to maintain our market presence, positioning the company for a faster recovery following an expected affirmation of Medicare coverage in calendar year 2026. Because of this decision the net loss after tax increased to $19.1 million, from the $15.4 million net loss in 2H 25.

STRATEGIC PROGRESS

The financial performance should not detract from Pacific Edge's significant strategic achievements of the first half of the financial year.

The company-defining recognition of Cxbladder Triage's Clinical Utility in the AUA's February 2025 revision to its Microhematuria Guideline — and our ground-breaking STRATA[9] study that precipitated that recognition — are delivering early signs of shift in both Medicare and non-Medicare medical policy.

The most tangible evidence of this was Novitas' September 2025 decision to convene a CAC to discuss evidence for the use of urine-based biomarkers in patients with microhematuria. Such panels are typically convened by MACs ahead of establishing new or substantially revised medical policy, i.e. a local coverage determination (LCD).

Novitas — which can change Medicare policy based on published evidence and evidence-based clinical opinion — will use the panel to systematically capture clinical opinion (in addition to the AUA guideline) and is expected to subsequently develop its LCD policy. The panel can comprise healthcare professionals, beneficiary representatives, and representatives of medical organizations. Pacific Edge is nominating panel members with a deep understanding of the

[8] US ASP: US Average Sales Price (US Operating Revenue in USD / US Commercial Test Volumes)
[9] 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

For personal use only

latest clinical evidence for Cxbladder Triage and Triage Plus, other urine-based biomarkers and the AUA Guideline.

Novitas expects any CAC member to be able to discuss “the quality and strength of the available evidence and any compelling clinical data to assist in defining meaningful and measurable patient outcomes”. Consequently, we expect any CAC member to be familiar with the STRATA Study, the recently published Analytical Validation studies of our existing Triage, Detect and Monitor tests, our Analytical Validation of Triage Plus and our DRIVE Study for the Clinical Validation of Triage Plus, which was published in the Journal of Urologic Oncology. We also expect Kaiser Permanente’s study demonstrating the Clinical Utility of Cxbladder Triage in a real-world setting to be presented to the CAC.

Since learning about the CAC meeting scheduled for 19 February 2026, and as signaled in Q2 26 investor update in October 2025, it has become apparent that regaining Medicare coverage of our tests will take longer than we anticipated. Further detail on our new anticipated timelines is covered in the presentation released to NZX and ASX today.

The second significant strategic milestone was CMS’s decision to provide a draft price of US$1,328 per test, a significant premium to the US$760 price of our existing tests. The price, assuming no change, will become effective on 1 January 2026 and promises to significantly strengthen our long-term economics.

The DRIVE publication on Triage Plus is a tangible demonstration of the value we are generating from our Research Development & Innovation and Clinical Evidence activities. While in an earlier phase of development, we see similar promise for our next generation test for the surveillance of bladder cancer recurrence, Cxbladder Surveillance Plus.

Finally, we have continued to advance our process to appeal all Cxbladder Triage tests not reimbursed by Medicare supported by the AUA Guideline and the STRATA study. The guideline in particular supports our argument that the tests are "medically reasonable and necessary," a key criterion under the US Social Security Act for Medicare coverage. To date we have appealed every denied Triage and Triage Plus claim on behalf of the Medicare beneficiary

We have yet to receive notification from the Office of Medicare Hearings and Appeals of a date for a substantive hearing before an Administrative Law Judge on any of our claims. We are confident of our case and expect to see many of the tests reimbursed.

BALANCE SHEET AND FUNDING

Supported by the successful $20.7 million capital raise in August 2025, Pacific Edge ended the period with cash and cash equivalents and short-term deposits of $22.1 million, steady on the $22.6 million at the end of March 2025.

However, given the expected delay to the reopening of the LCD and the long-time frames associated with the Medicare appeals process, the company now expects it will either need to complete capital initiatives and/or reduce its cash burn to see the company through to the point

of Medicare coverage. The company is considering a range of options and will update shareholders as it gains more certainty on the best path forward.

OUTLOOK

Dr Meintjes said non-coverage determinations for Triage, Detect, Monitor and Triage Plus continue to create a challenging sales and marketing environment, and additional challenges for reimbursement. However, the company continues to see significant near-term catalysts for value creation.

“These catalysts include medical policy change, increased sales momentum from non-Medicare payers supported by the AUA Guideline and our growing body of clinical evidence; reimbursement through the Medicare Appeals process and eventually a change to Medicare policy through the multiple reconsideration requests already submitted and additional publications we will submit in support of those requests when they are published,” Dr Meintjes said.

“The response of the CAC to our evidence and the weight of clinical opinion will be highly indicative of success across these initiatives and we look forward to updating shareholders on the outcome of that meeting early in the New Year.”

For more information:

Investors:
Dr Peter Meintjes
Chief Executive
Pacific Edge
P: 022 032 1263

Media:
Richard Inder
The Project
P: +64 21 645 643

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 urine-based genomic biomarker test optimized for the detection and surveillance of bladder cancer. The Cxbladder evidence portfolio developed over the past 14 years includes more than 20 peer reviewed publications for primary detection, surveillance, adjudication of atypical urine cytology and equivocal cystoscopy. Cxbladder is the focal point of numerous ongoing and planned clinical studies to generate an ever-increasing body of clinical utility evidence supporting adoption and use in the clinic to improve patient health outcomes. Cxbladder has been trusted by over 4,400 US urologists in the diagnosis and management of more than 100,000 patients, including the option for in-home sample collection. In New

For personal use only

Zealand, Cxbladder is accessible to 75% of the population via public healthcare and all residents have the option of buying the test online.

For personal use only

For personal use only

Pacific Edge

1H 2026 Investor Presentation

Dr Peter Meintjes
Chief Executive Officer

Grant Gibson
Chief Financial Officer

25 November 2025

IMPORTANT NOTICE AND DISCLAIMER

This presentation has been prepared by Pacific Edge Limited (PEL) solely to provide interested parties with further information about PEL and its activities at the date of this presentation.

Information of a general nature
The information in this presentation is of a general nature and does not purport to be complete nor does it contain all the information which a prospective investor may require in evaluating a possible investment in PEL or that would be required in a product disclosure statement, prospectus or other disclosure document for the purposes of the New Zealand Financial Markets Conduct Act 2013 (FMCA) or the Australian Corporations Act 2001. PEL is subject to a disclosure obligation that requires it to notify certain material information to NZX Limited (NZX) and ASX Limited (ASX) for the purpose of that information being made available to participants in the market and that information can be found by visiting www.nzx.com/companies/PEB and www2.asx.com.au/markets/company/PEB. This presentation should be read in conjunction with PEL's other periodic and continuous disclosure announcements released to NZX and ASX.

Not an offer
This presentation is for information purposes only and is not an invitation or offer of securities for subscription, purchase or sale in any jurisdiction.

Not financial product advice
This presentation does not constitute legal, financial, tax, financial product advice or investment advice or a recommendation to acquire PEL securities and has been prepared without taking into account the objectives, financial situation or needs of investors.

Forward-looking statements
This presentation may contain forward-looking statements that reflect PEL's current views with respect to future events. Forward-looking statements, by their very nature, are not guarantees of future outcomes and involve inherent risks and uncertainties. Many of those risks and uncertainties are matters which are beyond PEL's control and could cause actual results to differ from those predicted. Variations could either be materially positive or materially negative. The information is stated only as at the date of this presentation. Except as required by law or regulation (including the NZX Listing Rules and ASX Listing Rules), PEL undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. To the maximum extent permitted by law, the directors of PEL, PEL and any of its related bodies corporate and affiliates, and their respective officers, partners, employees, agents, associates and advisers do not make any representation or warranty, express or implied, as to the accuracy, reliability or completeness of such information, or the likelihood of fulfilment of any forward-looking statement or any event or results expressed or implied in any forward-looking statement, and disclaim all responsibility and liability for these forward-looking statements (including, without limitation, liability for negligence).

Financial data
All dollar values are in New Zealand dollars unless otherwise stated. This presentation should be read in conjunction with, and subject to, the explanations and views of future outlook on market conditions, earnings and activities given recent announcements to the NZX and ASX.

Non-GAAP financial information
This presentation contains certain financial measures that are "non-GAAP financial information" under the New Zealand Financial Markets Authority Guidance Note on disclosing non-GAAP financial information, "non-IFRS financial information" (and potentially under other regulatory guidelines or rules). Such financial information and financial measures (including EBITDA, Cash Burn and Capex) do not have standardised meanings prescribed under NZ IFRS or IFRS and therefore, may not be comparable to similarly titled measures presented by other entities, and should not be construed as an alternative to other financial measures determined in accordance with NZ IFRS, or IFRS.)

Effect of rounding
A number of figures, amounts, percentages, estimates, calculations of value and fractions in this presentation are subject to the effect of rounding. Accordingly, the actual calculation of these figures may differ from the figures set out in this presentation.

Past performance
Investors should note that past performance, including past share price performance, cannot be relied upon as an indicator of (and provides no guidance as to) future PEL performance, including future financial position or share price performance.

Disclaimer
To the maximum extent permitted by law, none of PEL and its advisers, affiliates, related bodies corporate, nor their respective directors, officers, partners, employees and agents makes any representation or warranty, express or implied, as to the materiality, currency, accuracy, reliability or completeness of information in this presentation; and none of them shall have any liability (including for negligence) for:

- any errors or omissions in this presentation; or
- any failure to correct or update this presentation, or any other written or oral communications provided in relation to this presentation; or
- any claim, loss or damage (whether foreseeable or not) arising from the use of any information in this presentation or otherwise arising in connection with this presentation or the information contained in it.

ersonal use only

POSITIONING FOR MEDICARE-LED RECOVERY AFTER EVIDENCE AND PRICING WINS

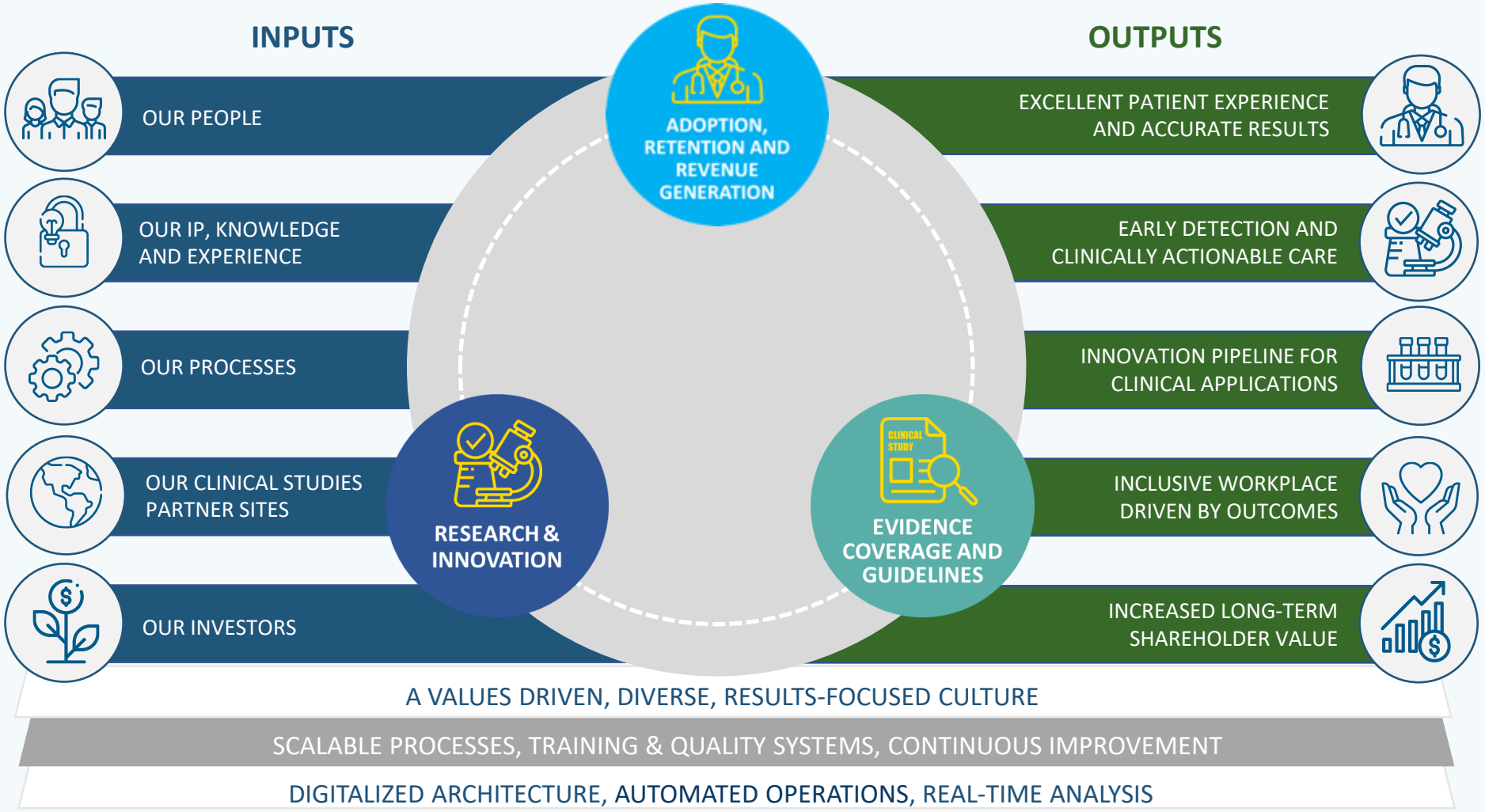
US Total Tests[1] 10,693, -13.1% on 2H 25; APAC Total Tests[1] 2,498 +5.4% on 2H 25	US Commercial Tests 8,386 -17.6% on 2H 25; APAC Commercial Tests 1,985 -7.2% on 2H 25	Total Revenue of $7.1M -42.8% on 2H 25	Operating Expenses of $26.2M 5.9% less on 2H 25 of $27.9M	1H 26 cash flow to Operating Activities of ($19.0M) 55.1% higher on ($12.3M) in 2H 25

- Maintaining US market presence to position Pacific Edge for Medicare appeals and re-coverage progress; operating revenue falls resulting in a rise in net losses and cash burn after coverage loss, partially offset by operating efficiencies
- Test volumes reflect loss of coverage and disruptions of migration to Triage from Detect; US test sales/FTE rise for Q2 26 +5.8% on Q1 26 following sales force reductions
- Expert Contractor Advisory Committee convened by Novitas acknowledges the weight of evidence supporting Cxbladder's clinical value
- Longer term economics reinforced by draft CMS pricing of Triage Plus at US$1,328 per test vs. US$760 per test for the current generation of tests
- Considering capital initiatives to meet longer than expected Medicare re-coverage timeline

1. Total Laboratory Throughput (TLT) including commercial, pre-commercial and clinical studies testing
2. Cash, short-term deposits and term deposits

ersonal use only

VALUE CREATION THROUGH THREE PILLARS



ersonal use only

PacificEdge®
CANCER DIAGNOSTICS

THE STRONGEST POSITION YET TO DRIVE MEDICARE POLICY CHANGE

POLICY DRIVERS – EVIDENCE AND CLINICAL OPINION – NOW IN CXBLADDER'S FAVOR

EVIDENCE COVERAGE AND GUIDELINES

NOVITAS CONVENES A CONTRACTOR ADVISORY COMMITTEE

- In September 2025, Novitas[1] called for an expert Contractor Advisory Committee (CAC)
  - CACs are generally convened ahead of developing new or substantially revised medical policy (LCD[2])
  - Precipitated by the company-defining February 2025 revision to the AUA Microhematuria Guideline (last revised in 2020), which allowed the use of biomarkers for the first time
  - Designed to systematically capture clinical opinion from practicing physicians in addition to published evidence and the AUA guidelines
- **CAC purpose:** **"**to discuss evidence for the use of urine-based biomarkers in patients with microhematuria."
  - Given the recent published evidence of Triage Plus (including the recently published Drive Study)[4] Pacific Edge expects the next generation test to be included in the discussion
- **Membership:** healthcare professionals, beneficiary representatives, and representatives of medical organizations
  - Pacific Edge has nominated urologists who are familiar with the latest evidence, the new AUA guideline and regularly use Cxbladder tests
- **Meeting date:** 19 February 2026 at 6pm (ET)[3]; open to the public and tone will be indicative of re-coverage success.

American Urological Association

"… [for] intermediate-risk patients who want to avoid cystoscopy and accept the risk of forgoing direct visual inspection of the bladder urothelium, ***clinicians may offer urine cytology or validated urine-based tumor markers to facilitate the decision regarding utility of cystoscopy****."*

– 2025 AUA Microhematuria Guideline Amendment

ersonal use only

Pacific Edge® CANCER DIAGNOSTICS

1. Novitas is Pacific Edge's Medicare Administrative Contractor (MAC)
2. LCD: Local Coverage Determination
3. 12.00pm Friday 20 February 2026 (NZT)
4. Savage et al (2025) Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study

THE STRONGEST POSITION YET TO DRIVE MEDICARE POLICY CHANGE

A COMPELLING AND GROWING PORTFOLIO OF EVIDENCE TO ENTRENCH CXBLADDER IN CLINICAL PRACTICE

EVIDENCE COVERAGE AND GUIDELINES

STUDY	TEST AND EVIDENCE	PUBLICATION DATE [1]
1. STRATA Clinical Utility	- CU of Triage	Published May 2024
2. Automated RNA & DNA extraction	- AV of Triage, Detect and Monitor	Published September 2024
3. Triage Plus Analytical Validation	- AV of Triage Plus	Published July 2025
4. DRIVE Clinical Validation	- CV of Triage Plus	Published October 2025[7]
5. STRATA second publication	- CU of Triage Plus (concordance[2])	Q2 2026
6. AUSSIE Clinical Validation	- CV of Triage Plus	Q2 2026
7. microDRIVE Clinical Validation	- CV of Triage Plus	Q4 2026
8. Surveillance Plus Analytical Validation	- AV of Surveillance Plus	Q3 2026
9. Pooled Analysis MH Clinical Validation[3]	- CV of Triage Plus	Q1 2027
10. Pooled Analysis GH Clinical Validation[3]	- CV of Triage Plus	Q1 2027
11. LOBSTER Clinical Validation	- CV of Monitor/Surveillance Plus	Q1 2027
12. CREDIBLE Clinical Utility	- CU of Triage Plus	Q1 2028
13. OCTOPUS Clinical Utility	- CU Surveillance Plus	Not started

[1] All dates are calendar year and our best current estimates
[2] Concordance will be demonstrated by comparing Triage and Triage Plus on identical samples
[3] The MH and GH pooled analysis brings together data from DRIVE, AUSSIE and microDRIVE

- Pacific Edge generates the compelling clinical evidence required to drive behavior change in physicians
- Clinical evidence is generated in a rigid framework of Analytical Validity (AV), Clinical Validity (CV) and Clinical Utility (CU)
- Clinical Studies have clearly defined patient populations with the endpoints and sample sizes required for coverage decisions and guideline inclusion
- We are seeking Medicare coverage for Triage, Monitor and Triage Plus through reconsideration requests to Novitas based on new evidence

New evidence to be presented to the CAC in February 2026 to support Medicare coverage reconsideration

Personal Use Only

MEDICARE RE-COVERAGE: ESTIMATED TIMELINES

COVERAGE DECISIONS, PRIOTIZATION AND TIMELINES ARE AT THE DISCRETION OF NOVITAS[1]

EVIDENCE COVERAGE AND GUIDELINES

MEDICARE COVERAGE REQUEST	CATALYST	2026*				2027*			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
L39365 Reconsideration request (Triage) March 2025	STRATA Study (May 2024) AUA Microhematuria Guideline (Feb 2025)								
L39365 Reconsideration request (Monitor) May 2025	AV of Triage, Detect & Monitor (Sept 2024) 2x RWE of Monitor (March 2025)								
New LCD request (Triage/Triage Plus) November 2025	AV of Triage Plus (Q2 25) CV of Triage Plus – DRIVE Study[2] (Q4 25)								

*Calendar year

Contractor Advisory Meeting (CAC) Meeting – February 19, 2026

Estimated opening of Novitas draft LCD

Estimated Novitas determination

12-months after opening (worst case, assuming opening)

- Medicare non-coverage of Cxbladder Triage, Monitor, Detect & Triage Plus was effective on 24 April 2025
- The review was limited to evidence submitted prior to 9 September 2023
- Pacific Edge has submitted Reconsideration Requests of L39365 for Triage and Monitor
- Pacific Edge has submitted a new LCD request for hematuria evaluation for Triage/Triage Plus
- Novitas controls the timing of the LCD opening, but must finalize the LCD within 12 months of opening
- Novitas announced a CAC to meet on 19 February 2026 (ET), increasing re-coverage expectations, but extending timelines
- Evidence published after the CAC can be submitted during the comment period of the LCD

Medicare

ersonal use only

PacificEdge® CANCER DIAGNOSTICS

1. Novitas is the Medicare Administrative Contractor (MAC) charged with making the Medicare local coverage determination for Pacific Edge's US laboratory
2. Savage et al. (2025). Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study. Urol Oncol. Oct 31 2025;doi:10.1016/j.urolonc.2025.10.008

INDEPENDENT STUDIES SUPPLEMENT OUR EVIDENCE PORTFOLIO

INVESTIGATOR INITIATED TRIALS AND INDEPENDENT STUDIES DELIVER CLINICAL UTILITY AT MODEST SCALE

EVIDENCE COVERAGE AND GUIDELINES

INDEPENDENT STUDY FOCUS	INSTITUTION/ LOCATION	TEST AND EVIDENCE	PUBLICATION DATE
Real World Utility of Triage in MH: A Matched Cohort Study	Kaiser Permanente, US	CU Triage (RWE)	Q4 2025
Patient preference and satisfaction of "biomarkers vs cystoscopy"	Mayo Clinic, US	CU Monitor	Q1 2026
Test utility in screening patients at risk for bladder cancer	UT Southwestern, US	CU Triage Plus	2027
Test utility in assessing therapy success in a reduced chemotherapy protocol for upper tract tumors	Israel Institute of Technology, Israel	CU Monitor CU Surveillance Plus	2027
Test utility in assessing response to BCG[2] in high-grade bladder cancer patients	University of Miami, US	CU Monitor CU Surveillance Plus	2027
Test utility for the surveillance of MIBC[3] treated with bladder sparing methods (PRESERVE Trial)	Cleveland Clinic, US	CU Monitor CU Surveillance Plus	2028
A Randomized Trial of Apalutamide in Non-Muscle Invasive Bladder Cancer	National Institutes of Health, US	CU Monitor CU Surveillance Plus	2029

New evidence to be presented to the CAC in February 2026 to support Medicare coverage reconsideration

LATEST INVESTIGATOR INITIATED TRIAL (IIT) SHOWS PATIENT PREFERENCE FOR CXB MONITOR

- New study ready for publication led by Mark Tyson at the Mayo Clinic, comparing Cxbladder Monitor to cystoscopy in bladder cancer surveillance[1]
  - 74.2% preferred Monitor vs Cystoscopy
  - Comparable diagnostic performance
  - Abstract to be submitted to AUA 2026

PacificEdge® CANCER DIAGNOSTICS

1. Mestas et al (2025) A Randomized Multicenter Crossover Study to Evaluate Patient Preference and Satisfaction with Urine-Based Molecular Testing versus Cystoscopy for Surveillance of Non-Muscle-Invasive Bladder Cancer (NMIBC). Unpublished Manuscript.
2. BCG: Bacillus Calmette–Guérin is a bacterium instilled into the bladder that triggers an immune response that targets and destroys cancer cells.
3. MIBC: Muscle Invasive Bladder Cancer

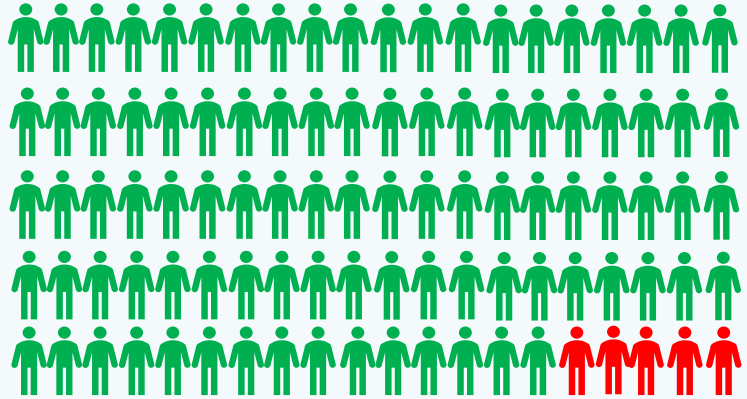
ersonal use only

BUDGET IMPACT MODELS DEMONSTRATE ECONOMIC VALUE FOR CXBLADDER

BIMS[1] DEMONSTRATE CLINICAL UTILITY AND ECONOMIC SAVINGS FOR HEALTHCARE SYSTEMS

EVIDENCE COVERAGE AND GUIDELINES

CANCER INCIDENCE IN MICROHEMATURIA PATIENTS

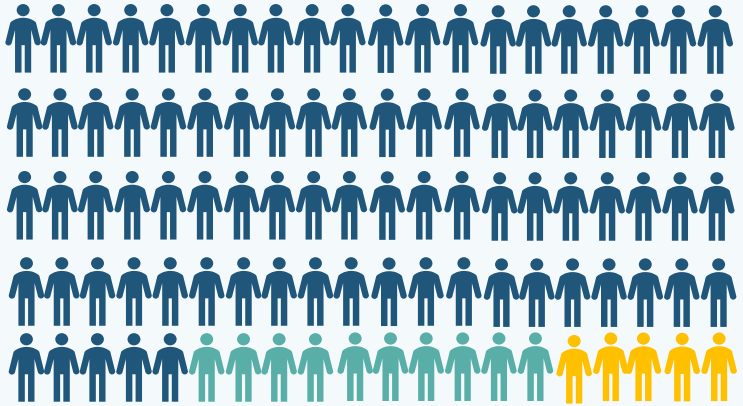


Microhematuria patient with no cancer

Microhematuria patient with cancer

Incidence of bladder cancer in microhematuria populations is 5%

CYSTOSCOPIES SAFELY AVOIDED USING CXBLADDER[2]



Cystoscopy avoided

Normal Cystoscopy

Cystoscopy undertaken and cancer found

With Cxbladder, 85% of patients can avoid cystoscopy, 15% receive cystoscopy, 5 cancers found

REDUCTIONS IN CYSTOSCOPY DRIVE SAVINGS FOR HEALTHCARE PAYERS

- Published BIMs help shift payer policy and can be tailored to specific payer needs; our models already show meaningful savings
  - In the U.S., Cxbladder at scale could spare ~1.5 million hematuria patients from cystoscopy and save >US$500 per patient[3]
  - In bladder-cancer surveillance protocols, Cxbladder can save payers ~US$680 per patient over five years[4]
- Economic and Sustainability Publications in progress:
  - Triage Plus BIM — targeting publication FY27
  - Surveillance Plus BIM — work commencing FY28
  - Carbon Footprint impact of implementing Cxbladder at primary care for hematuria evaluation — targeting FY27

ersonal use only

PacificEdge® CANCER DIAGNOSTICS

1. BIM is a Budget Impact Model
2. Harvey et al (2025) Analytical Validation of Cxbladder® Triage Plus Assay for risk stratification of hematuria patients for urothelial carcinoma Diagnostics 2025, 15, 1739.
3. Tyson et al (2024) Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)
4. Tyson et al (2025) Economic Impact Model of Incorporating Cxbladder Monitor in the Surveillance of Non-muscle Invasive Bladder Cancer JU Open Plus 3(4):e00028, April 2025.

VOLUMES REFLECT REDUCED SALES REACH AND MEDICARE UNCERTAINTY

ADOPTION, RETENTION AND REVENUE GENERATION

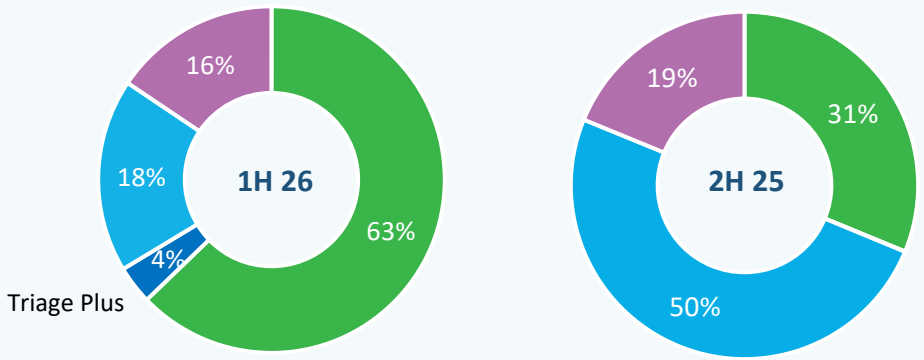
FY 25 TOTAL LAB THROUGHPUT (TLT*)

- Global Commercial test volumes of 13,191 for 1H 26 down 10.1% on 2H 25 amid US challenges of selling a test not covered by Medicare, the reduced reach sales force, offset by 5.4% uplift in APAC

MEDICARE NON-COVERAGE RESPONSE

- Cxbladder Detect migrated to Triage, accelerating a plan previously intended to coincide with the commercial launch of Triage Plus
- Seeking reimbursement through the Medicare Appeals Process
- The sales force is focused on patients suitable for Triage, which are younger patients with microhematuria and commercial insurance

TEST VOLUMES BY TYPE (TLT*)



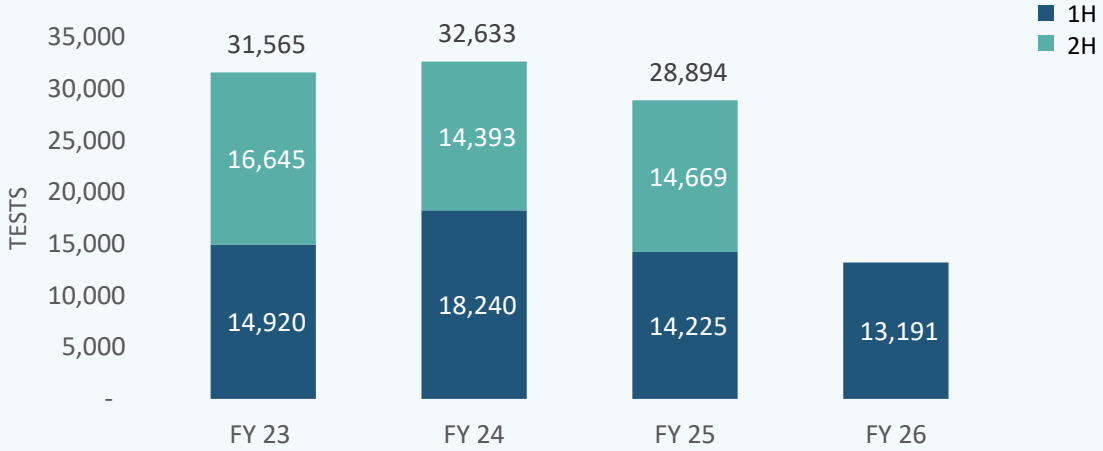
Cxbladder Triage

Cxbladder Detect

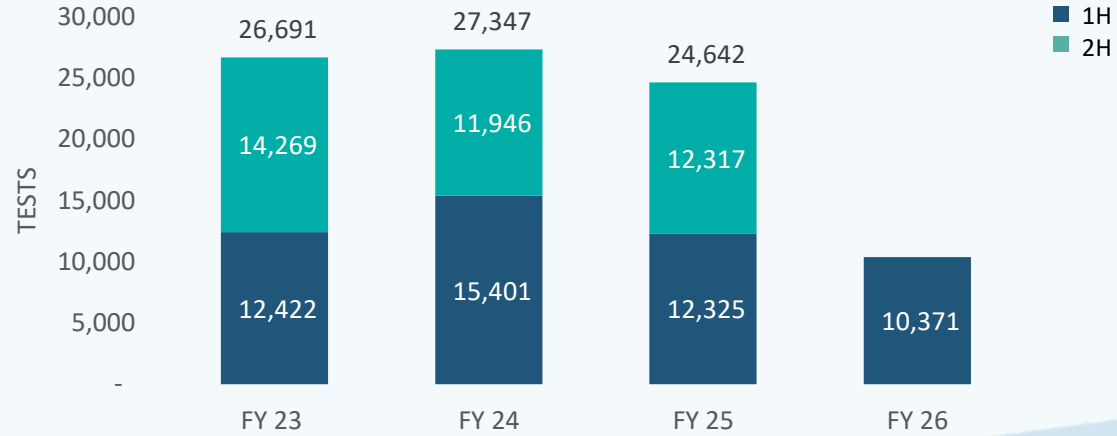
Cxbladder Monitor

Cxbladder Triage Plus

GLOBAL TOTAL TEST VOLUMES (TLT[1])



GLOBAL COMMERCIAL TEST VOLUMES*



PacificEdge® CANCER DIAGNOSTICS

1. TLT is the Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing. Commercial volumes, and test type are only updated at the half and full year results of each financial year.

ersonal use only

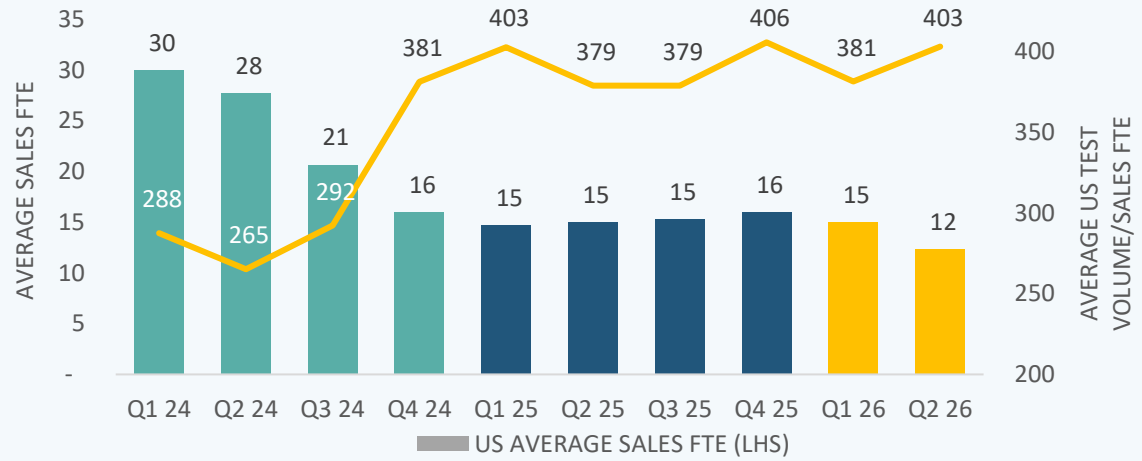
SALES PERFORMANCE IMPROVEMENTS SUSTAINED IN 1H 26

WE REGULARLY SEE OPPORTUNITIES TO EDUCATE ON THE AUA GUIDELINE

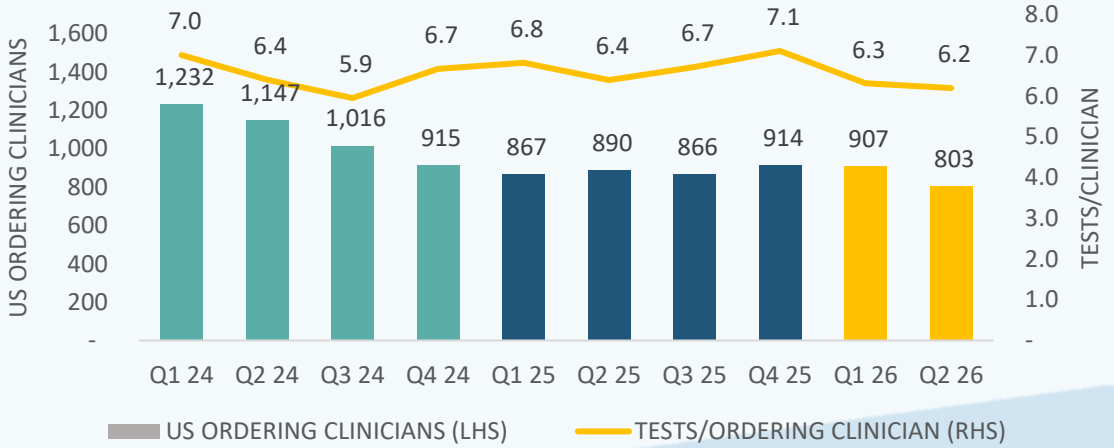
ADOPTION, RETENTION AND REVENUE GENERATION

- Clinical commitment (tests/ordering clinician) fall in Q2 26 reflecting the disruptions of transition to Triage from Detect and challenges of selling a test not covered by Medicare
- Sales force efficiency (tests volume / sales FTE) at 403 in Q2 26 is well ahead of the low point of 160 in Q3 22
- Sales FTE down to an average of 12 in Q2 26 from >30 in Q1 24 before restructure to focus on cash conservation

US SALES FORCE EFFICIENCY



US CLINICAL COMMITMENT



PacificEdge® CANCER DIAGNOSTICS

1. ASP: US Operating Revenue in USD / US Commercial Test Volumes. Commercial volumes, and ASP are only updated at the half and full year results of each financial year.

ersonal use only

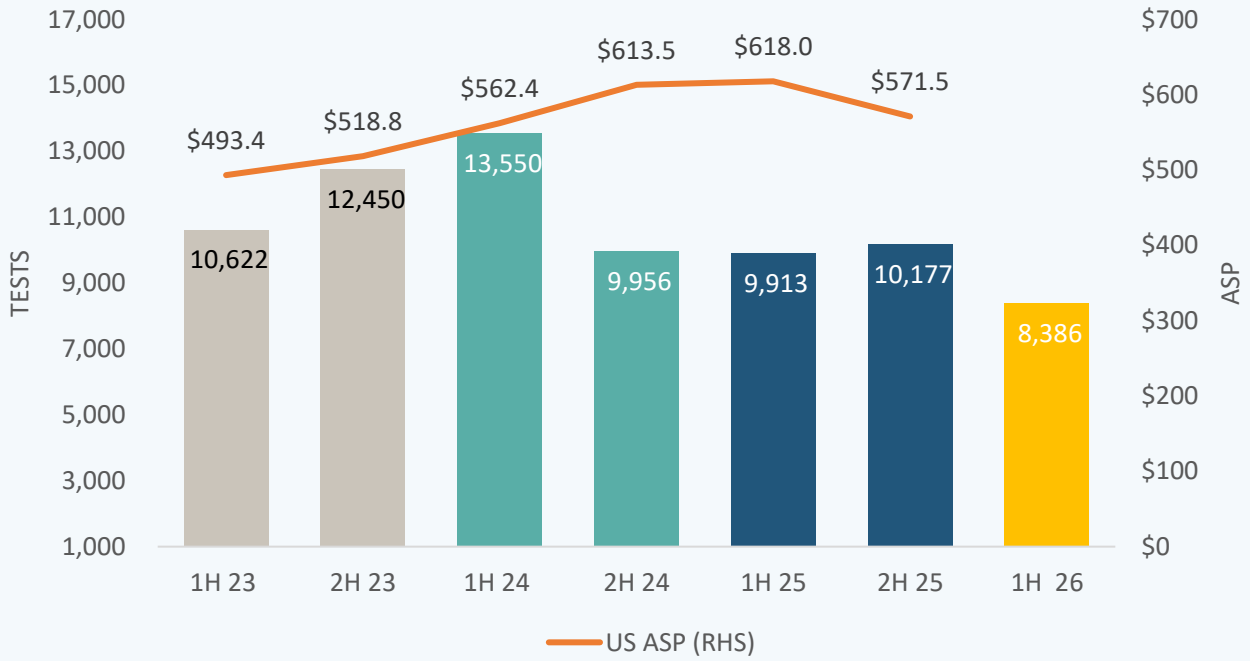
FOUNDATIONS FOR GROWTH – US CASH COLLECTIONS PROCESSES IMPROVE

ADOPTION, RETENTION AND REVENUE GENERATION

REIMBURSEMENT & CASH COLLECTIONS

- Loss of Medicare Coverage impacts US test volumes
  - Denied Triage Medicare tests will be appealed to an Administrative Law Judge (ALJ) given its guideline inclusion, making the case that it is medically reasonable and necessary
  - Appealing to the ALJ typically takes 6-9 months
  - Medicare tests completed in 1H 26 that have been denied for payment have had no revenue recognized in the half, with revenue to be added if tests are successfully appealed
- Measures in place to mitigate the loss of Medicare coverage are delivering
  - Enhanced Patient Responsibility - patients with non-contracted private insurance (i.e. non-Kaiser) pay a fixed dollar amount "maximum out of pocket"
  - Increased utilization of appropriate patient types from Kaiser Permanente after EMR integration
  - Improved medical necessity documentation to improve billing and appeals processes for Commercial payers
- Improved cash collections are typically permanent improvements that we expect to maintain as we scale

US COMMERCIAL TEST VOLUMES[1] AND AVERAGE SELLING PRICE[2]



1. Total Laboratory Throughput in the US including commercial, pre-commercial and clinical studies testing
2. ASP: US Operating Revenue in USD / US Commercial Test Volumes; ASP not reported in 1H 26 due to accounting changes in revenue accrual while Medicare tests are being appealed.

ersonal use only

CONSOLIDATING NEW ZEALAND AND DEVELOPING AUSTRALIA AND APAC

ADOPTION, RETENTION AND REVENUE GENERATION

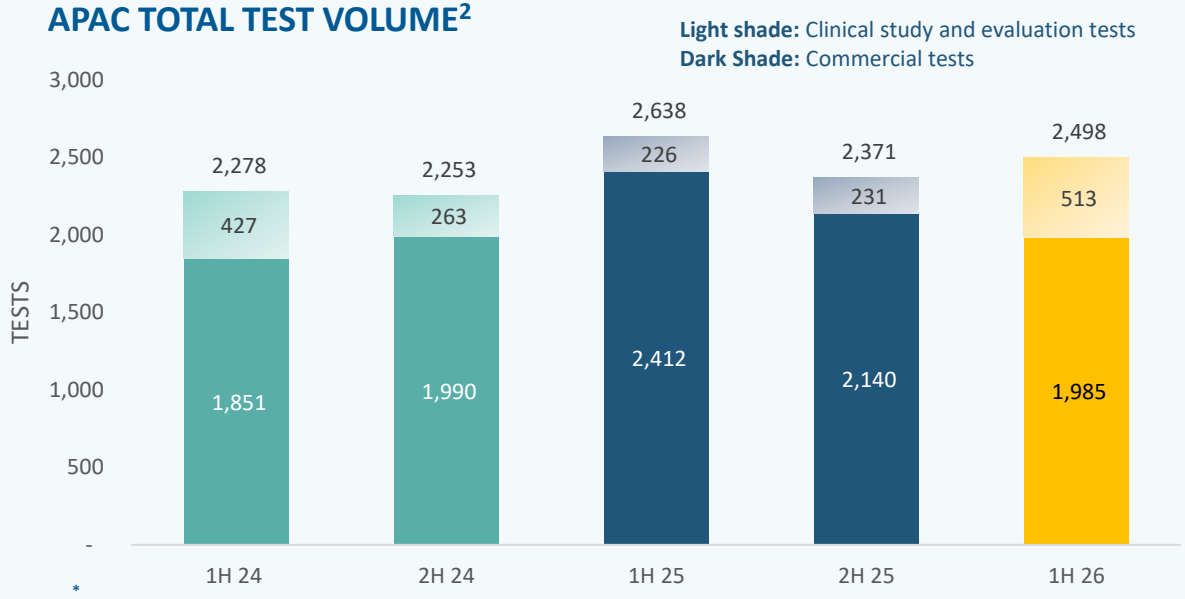
SEEKING A NATIONAL HEMATURIA EVALUATION PATHWAY IN NZ

- Quarterly total test volumes rise lifted by an increase in clinical studies and non-billable tests
- STRATA[1] and AUA Microhematuria Guideline are well understood in *Te Whatu Ora*/Health New Zealand; Pacific Edge is focused on a national pathway for hematuria evaluation

AUSTRALIA & ASIA PACIFIC

- Southeast Asia is still in business development, and we are extending our reach into the market through a distributor network which has seen testing volumes grow
- While our primary near-term focus remains on the US, Southeast Asia has large population centers, private healthcare systems, and favorable cultural and demographic considerations to be a high-volume market for an IVD-kitted product

APAC TOTAL TEST VOLUME[2]



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. Total Laboratory Throughput in Asia and Pacific including commercial, pre-commercial and clinical studies testing

ersonal use only

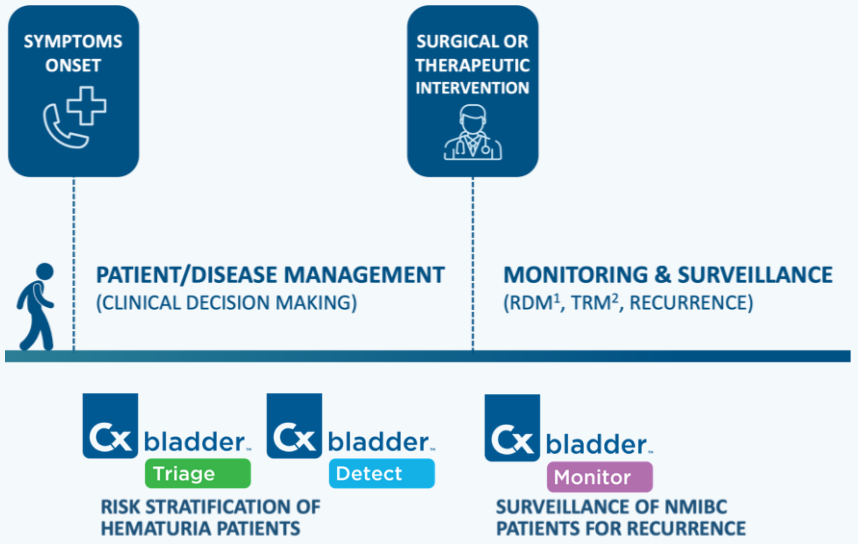
DRIVING VALUE THROUGH PRODUCT INNOVATION

NEXT GENERATION TESTS HAVE SUPERIOR PERFORMANCE AND PRICING

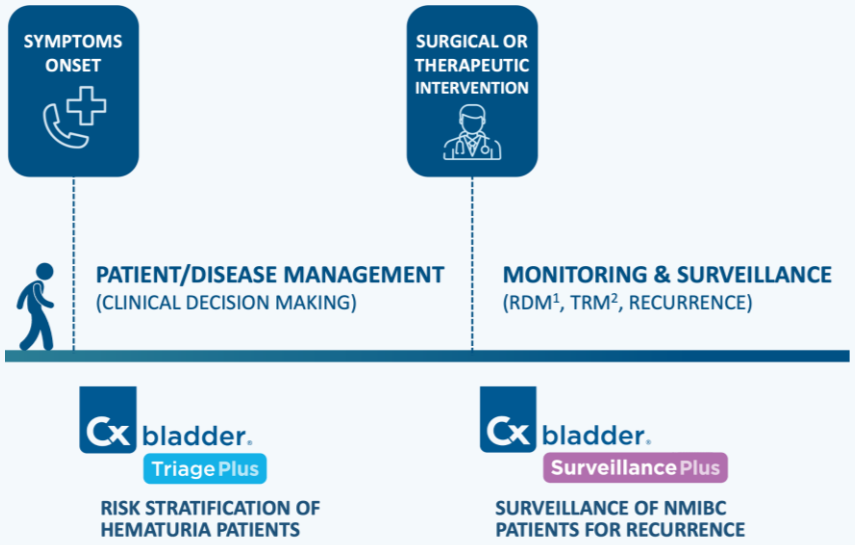
RESEARCH & INNOVATION

- Cxbladder Triage Plus has been analytically validated and clinically validated for all hematuria patients (micro and gross)
  - Triage Plus has provisional patents filed, AV published, CV published, priced at $1,328/ test, and coverage has been requested from Novitas.
  - The draft price is significant premium to the US$760 CMS price for our existing tests, promising to strengthen the economics of the company
  - Triage Plus is being trialed in 'early access' and we are seeking to be added to the AUA microhematuria guideline alongside Triage in FY27
- Cxbladder Surveillance Plus tests for recurrent disease in NMIBC[1] patients.
  - Surveillance Plus is in development and is expected to be analytically validated and clinically validated during FY27
  - Surveillance Plus uses ddPCR[4] technology, has 'Freedom to Operate' review completed, and has provisional patenting in progress
  - We are seeking a technology crosswalk for Surveillance Plus to an US$1800 ddPCR[4] test, and claim-by-claim reimbursement until a local coverage determination incorporating Surveillance Plus is developed

CURRENT STATE



FUTURE STATE



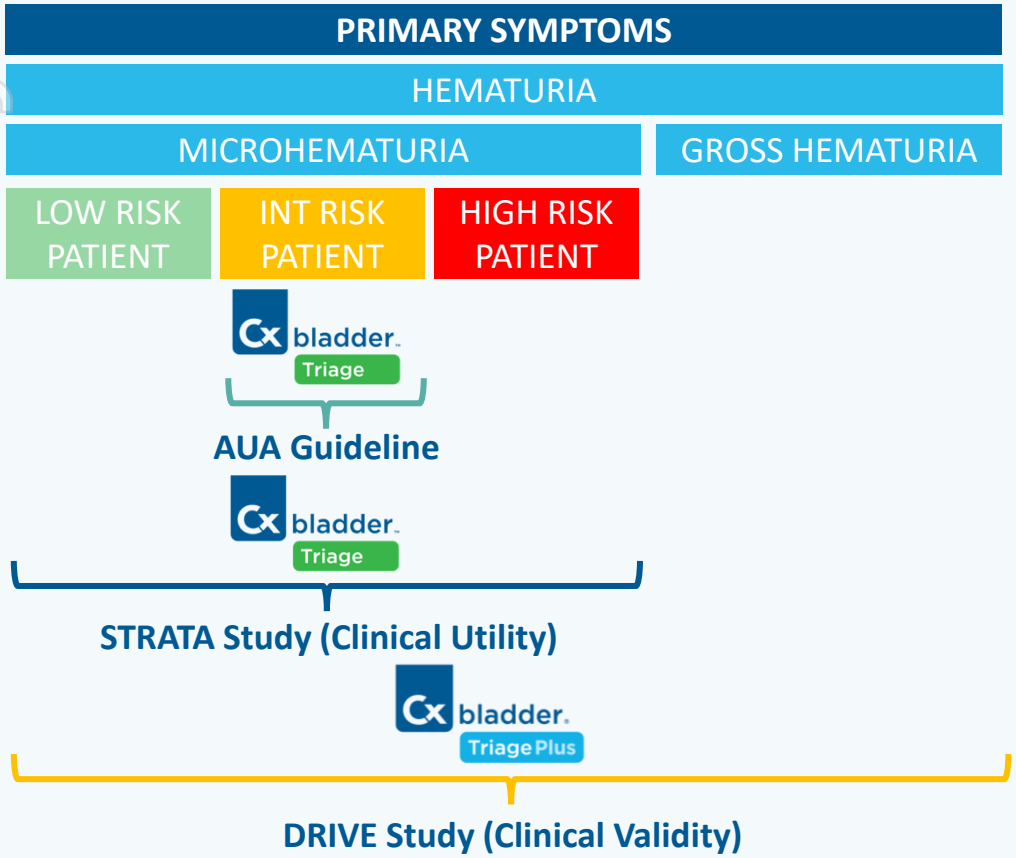
PacificEdge® CANCER DIAGNOSTICS

1. NMIBC is non-muscle invasive bladder cancer
2. RDM: Residual Disease Monitoring
3. TRM: Therapeutic Response Monitoring
4. ddPCR is droplet digital Polymerase Chain Reaction

Personal use only

DRIVE STUDY VALIDATES CXBLADDER TRIAGE PLUS IN A BROAD POPULATION

RESEARCH & INNOVATION



THE DRIVE STUDY – CLINICAL VALIDATION OF TRIAGE PLUS

- The DRIVE Study — the Diagnostic Performance of Cxbladder Triage Plus for the Identification and Priority Evaluation of Veterans at Risk for Urothelial Carcinoma — was published in the Journal of Urologic Oncology in October 2025[1]
- The study confirmed the superior performance characteristics in both gross and microhematuria patients, validating the proof-of-concept study[2] and the analytical validation study[3]
- Supports:
  - Medicare coverage request for patients with microhematuria and gross hematuria
  - An amendment to the AUA Microhematuria Guideline

"These findings indicate that Cxbladder Triage Plus may be safely used to rule out or detect [urothelial cancer] in patients with hematuria."

- DRIVE Study Authors

For personal use only

PacificEdge® CANCER DIAGNOSTICS

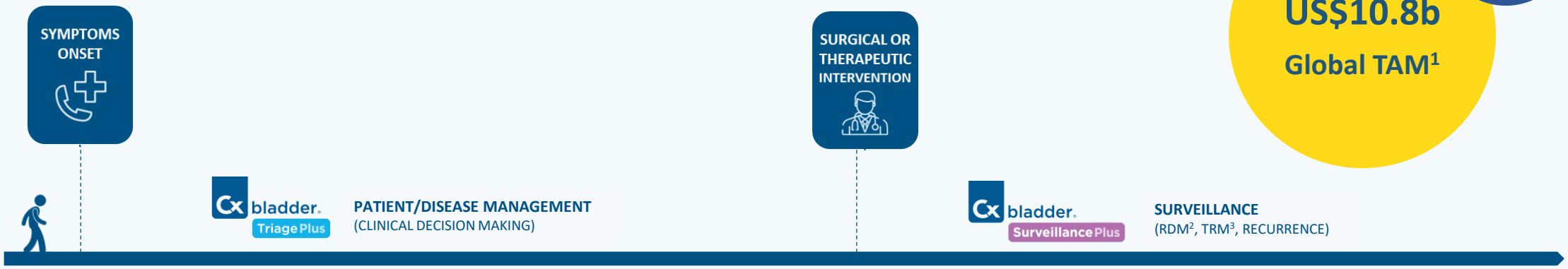
1. Savage et al (2025) Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study
2. Lotan et al (2024) Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-109
3. Harvey et al (2025) Analytical Validation of Cxbladder® Triage Plus Assay for risk stratification of hematuria patients for urothelial carcinoma Diagnostics 2025, 15, 1739.

CMS TRIAGE PLUS PRICING HAS EXPANDED THE GLOBAL OPPORTUNITY

DRAFT PRICE OF US$1,328/TEST IS A 75% PREMIUM TO CURRENT TESTS

US$10.8b
Global TAM[1]

RESEARCH & INNOVATION



	Population	Present with hematuria	Referred for clinical workup	Receive cystoscopy	Annual cases of bladder cancer	Living with bladder cancer	TAM	
US	340m	~7m	~3.5m	~1.1m	~90k	~750k	US$6.7b	*Primary growth focus due to higher CMS pricing*
APAC	830m	~17m	~8.5m	~3.3m	~58k	~300k	US$2.1b	*NZ market mature. Australia and SEA in business development*
EU	600m	~12m	~6m	>4.0m	~180k	~1m	US$2.0b	*New market accessed via IVD / kitted tests*

For personal use only

PacificEdge® CANCER DIAGNOSTICS

1. Pacific Edge estimate using US$1,328 price for hematuria testing (priced by Medicare) in the US and US$1,800 for NMIBC surveillance (seeking crosswalk price – not yet priced by Medicare) with next generation products Triage Plus and Surveillance Plus. Other market assumptions for APAC and Europe. See slide 38 for details.
2. RDM: Residual Disease Monitoring
3. TRM: Therapeutic Response Monitoring

EXPANDING MARKET OPPORTUNITIES WITH INNOVATION

DEVELOPING AN IVD[1] IS THE PRIMARY AVENUE FOR INTERNATIONAL OPPORTUNITIES

RESEARCH & INNOVATION

ADVANCING IVD DEVELOPMENT FOR INTERNATIONAL MARKETS

- Pacific Edge is following a well-worn model of development and execution in the US with a CAP/CLIA-approved LDT[2] providing service to the entire USA
- International markets require a different approach in which Pacific Edge seeks to create a 'kitted' IVD medical device
- Benefits of this approach:
  - IVDs can be run by any accredited lab partner in any geography
  - Customer-side logistics are easier, faster and customer service is local
  - Partner labs make a margin by running the IVD test – increases sales opportunities and motivation to increase volumes
  - Decentralized deployment allows faster scalability
  - Research Use Only versions of the product can be used to develop business, select partners and run evaluation programs in preparation for IVD launch
- Pacific Edge is simplifying its tests and accelerating the development of an IVD called Triage Plus IVD, for decentralized lab deployment and international market expansion. Key objectives:
  - Establishing IVD regulatory framework for our next generation tests that includes IVD-R (Europe), FDA (USA) and ISO-13485[3] (Rest of World)
  - Targeting prototypes by the end of FY26; manufacture and commencement of clinical and analytical validation commencing in FY27

Chief Scientific Officer Parry Guilford (center) and Chief Technology Officer Justin Harvey (right)

ersonal use only

PacificEdge® CANCER DIAGNOSTICS

1. IVD stands for *in vitro* diagnostic – a type of medical device for regulatory purposes
2. CAP is the College of American Pathologists, CLIA is the Clinical Laboratory Improvement Amendments and LDT is a laboratory developed test
3. IVD-R European In Vitro Diagnostic Regulation; FDA, US Food and Drug Administration; ISO International Organization for Standardization

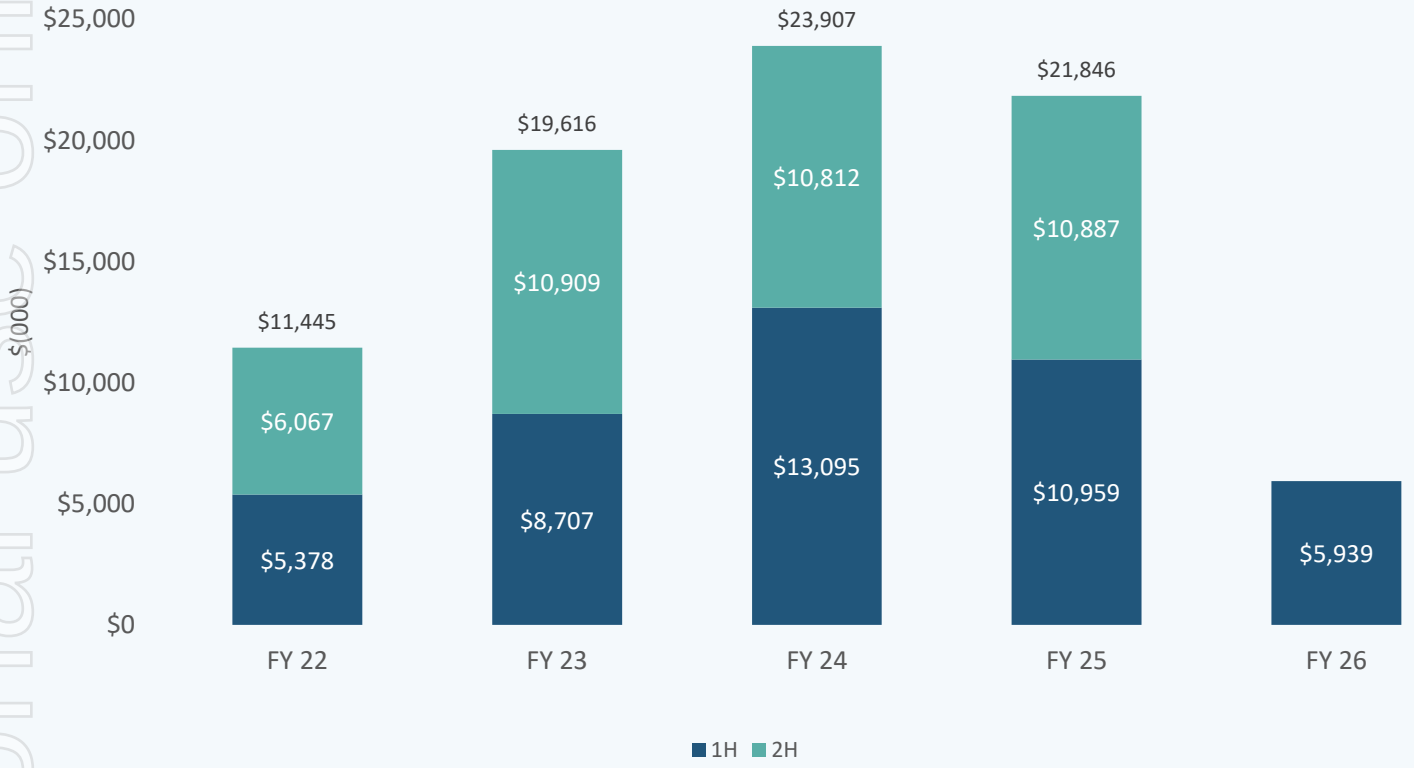
FINANCIAL PERFORMANCE

For personal use only

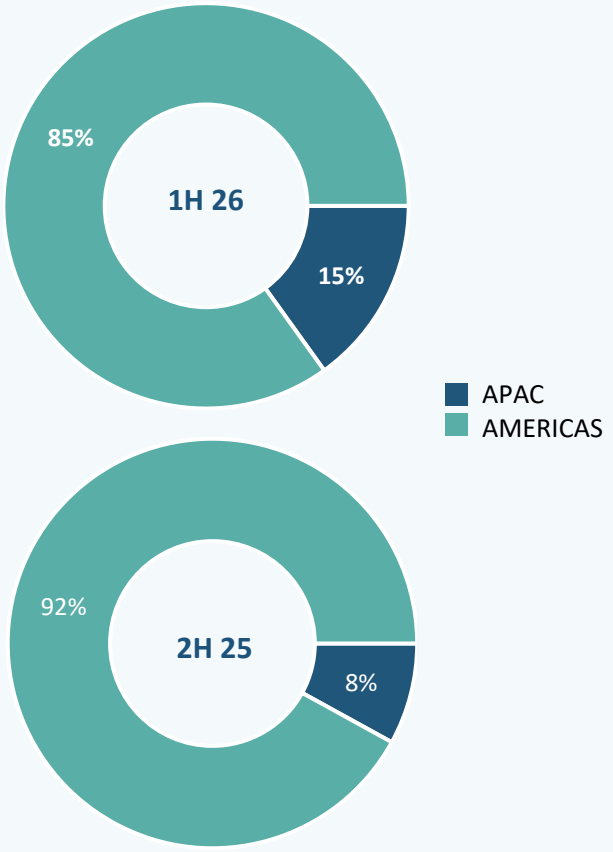
PacificEdge®
CANCER DIAGNOSTICS

LOOKING TO US CATALYSTS TO DRIVE A RECOVERY IN REVENUE

PACIFIC EDGE OPERATING REVENUE[1]



REGIONAL REVENUE CONTRIBUTION



ersonal use only

PacificEdge® CANCER DIAGNOSTICS

1. No accrual accounting for revenue for tests performed for Medicare patients, even though a substantial number of tests have been undertaken. This revenue will be recognized in 2H 26 if the appeals against non-reimbursement are successful.

POSITIONING PACIFIC EDGE FOR A MEDICARE APPEALS SUCCESS AND COVERAGE

COST SAVINGS MINIMIZE CASH BURN; ANY MEDICARE APPEALS SUCCESS LIKELY RECOGNISED AS REVENUE IN 2H 26

FINANCIAL PERIOD	1H 26	2H 25	1H 25	FY 25	1H 26 vs. 1H 25	1H 26 vs. 2H 25
	$000	$000	$000	$000	△ %	△ %
Operating revenue	$5,939	$10,887	$10,959	$21,846	-45.8%	-45.4%
Total revenue	$7,123	$12,461	$12,155	$24,616	-41.4%	-42.8%
Operating expenses	$26,239	$27,894	$26,658	$54,552	-1.6%	-5.9%
Net Loss After Tax	**-$19,116**	**-$15,433**	**-$14,503**	**-$29,936**	**31.8%**	**23.9%**
Cash receipts from customers	$7,985	$10,447	$11,125	$21,572	-28.2%	-23.6%
Net cash flows to operating activities	$19,026	$12,266	$12,474	$24,740	52.5%	55.1%
Net cash, cash equivalents and short term deposits[1]	**$22,121**	**$22,568**	**$35,931**	**$22,568**	**-38.4%**	**-2.0%**

- Operating revenue falls after loss of Medicare and Medicare Advantage coverage and reduced test volumes
- We have not accrued any revenue from Medicare tests while we determine the success of the appeals strategy
  - Success will result in revenue for 1H 26 tests being recognised in 2H 26
- We continue to maintain a US market presence that positions the company for an affirmation of Medicare coverage, while focusing on reducing operating expenses, which fell 5.9% against 2H 25
- Operating Cash Flows of (19.0M), higher than the ($12.3M) in 2H 25 due to the revenue fall. Cash outflow in the first half of each financial year is generally higher than the second half of the financial year with payments that cover a 12-month period weighted towards the first half of the year
- Secured $20.7 million in new equity in August 2025, but with delay to re-coverage we expect we will need to complete capital initiatives and/or reduce cash burn; we are considering our options

1. Net cash, cash equivalents and short-term deposits at the end of the period

ersonal use only

OPERATING EXPENSES CONTAINED AMID CAPTIAL PRESERVATION DRIVE

INVESTMENT FOCUSSED ON LONG-TERM STRATEGIC INITIATIVES

FINANCIAL PERIOD	1H 26 $000	2H 25 $000	1H 25 $000	FY 25 $000	1H 26 vs. 1H 25 △ %	1H 26 vs. 2H 25 △ %
Laboratory operations	$5,884	$6,532	$5,958	$12,490	-1.2%	-9.9%
Research	$7,065	$7,401	$7,230	$14,631	-2.3%	-4.5%
Sales and marketing	$8,453	$9,285	$8,245	$17,530	2.5%	-9.0%
General and administration	$4,837	$4,676	$5,225	$9,901	-7.4%	3.4%
Total operating expenses	**$26,239**	**$27,894**	**$26,658**	**$54,552**	**-1.6%**	**-5.9%**

- Operating expenses down 5.9% on 2H 25 as cost management initiatives implemented.
- Laboratory operations down 9.9% driven by lower test volumes.
- Research costs down 4.5% on 2H 25 as some clinical study costs decrease for those near completion
- Sales and marketing costs down 9.0% on 2H 25 impacted by the reduction in sales FTE.
- General and administration expenses up 3.4% on 2H 25 reflecting higher legal costs from the proceedings undertaken at the end of FY25 attempting to prevent the loss of Medicare coverage

ersonal use only

ersonal use only

OUTLOOK 1/2

INNOVATION DRIVES LONG-TERM VALUE CREATION

- Triage Plus has a US$1,328 price, is being tested in ‘early access’ and needs only Medicare coverage for wider commercial adoption
- Surveillance Plus remains in development, but we are seeking a direct technology crosswalk price to US$1,800 based on its final product configuration
- Investing in innovation and product development for IVD kits to support entry into international markets in a de-centralized deployment model

CLINICAL EVIDENCE DRIVES MEDIUM-TERM VALUE CREATION

- The DRIVE publication[1] provides the clinical validation of Triage Plus and has been submitted to Novitas and the AUA for coverage consideration and guidelines inclusion
- The clinical evidence generation program is scheduled out for over four years to deliver strategic milestones that driven sustained value creation for shareholders
- AUA guideline inclusion demonstrates the success of this strategy that can be repeated to expand the indications for exist products and establish new indications for new products

1. Savage et al., Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.

ersonal use only

OUTLOOK 2/2

COMMERCIAL HEADWINDS FOR NEAR-TERM VALUE CREATION

- Non-coverage determinations for Triage, Detect, Monitor and Triage Plus continue to create a challenging sales and marketing environment, and additional challenges for reimbursement
- The convening of the Contractor Advisory Committee is a positive move towards the reinstatement of coverage, but delays our expected timeline for re-coverage necessitating the Board to consider capital initiatives and/or reduce cash burn.

COMMERCIAL CATALYSTS FOR NEAR-TERM VALUE CREATION

- AUA microhematuria guideline enables sales, marketing and reimbursement activities. We are determined to maximize this milestone through existing and new initiatives
- Seek payment from Medicare for all Triage tests performed on Medicare patients through the Medicare Appeals process, relying on the AUA Guideline
- Advance medical policy with commercial payers as the market for Triage on microhematuria patients shifts the payer mix towards commercial payers
- Increase the percentage of electronically ordered tests and patients with commercial insurance
- Cxbladder is under consideration by *Te Whatu Ora* for a National Pathway in New Zealand in FY27

APPENDIX

For personal use only

PacificEdge®
CANCER DIAGNOSTICS

PACIFIC EDGE IS FOUNDED ON DELIVERING POSITIVE OUTCOMES FOR SOCIETY

WE CREATE VALUE BY PRIORITISING OUR PATIENTS, OUR PHYSICIANS AND OUR PEOPLE

Our Mission

To help improve people's lives and patient outcomes by providing leading solutions for the early detection and management of cancer

Our Vision

A world where the early diagnosis and better treatment of cancer is within reach of everyone

WE PUT PATIENTS FIRST IN EVERYTHING WE DO

- **WE are committed to customer success**
- **WE are guided by data and evidence**
- **WE are trusting and transparent**
- **WE support our teammates**
- **WE celebrate successes, large and small**

ersonal use only

PACIFIC EDGE IS A GLOBAL COMPANY WITH A GLOBAL OPPORTUNITY

US$10.8b[1]

Global Opportunity

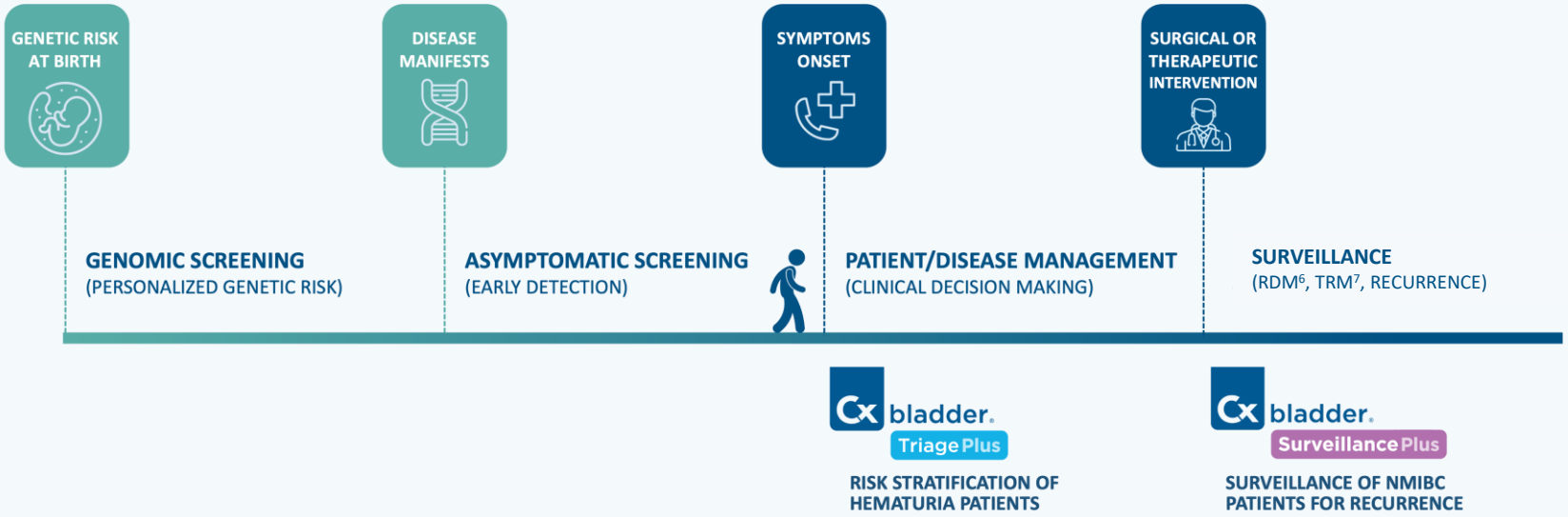
1. Pacific Edge estimate using US$1,328 price for hematuria testing (priced by Medicare) and US$1800 for NMIBC surveillance (seeking crosswalk price – not yet priced by Medicare) with next generation products Triage Plus and Surveillance Plus. Other market assumptions for APAC and Europe. See slide 38 for details

ersonal use only

MOLECULAR DIAGNOSTICS VALUE CHAIN: PATIENT JOURNEY

CXBLADDER – FIRST MOVER AND MARKET LEADER IN BLADDER CANCER DIAGNOSTICS

- **Technology**: RNA/DNA patent-protected urine biomarker tests for hematuria evaluation and NMIBC[1] surveillance
- **Clinical Evidence**: AV/CV/CU[2] evidence generated in a structured framework compliant with GCP[3] and IVD[4] standards
- **Clinical Guidelines**: Recognized by the American Urological Association (AUA) Guideline as 'Grade A' evidence
- **Economic Utility**: offering improved patient care and significant health system cost savings, estimated at >US$500 per US patient[5]
- **Commercial**: 'first-mover' advantage, national sales coverage in the USA, market dominant in NZ, business development in APAC
- **Pricing:** Triage Plus priced by CMS at $1,328, Surveillance Plus pricing sought at $1,800 by crosswalk



1. NMIBC is non-muscle invasive bladder cancer
2. AV/CV/CU is analytical validation, clinical validation and clinical utility evidence
3. GCP is 'Good Clinical Practice' needed for FDA or other medical device certification
4. IVD is an *in vitro* diagnostic medical device
5. Tyson et al (2024) Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)
6. RDM: Residual Disease Monitoring
7. TRM: Therapeutic Response Monitoring

ersonal use only

DRIVING ECONOMIC VALUE FOR PATIENTS, HOSPITALS AND PAYERS

CXBLADDER DELIVERS CLINICAL UTILITY, PATIENT SATISFACTION AND ECONOMIC VALUE

- The number of urologists is falling in the USA – forecast to drop from 23.8/100k to as low as 15.8/100k in 2035[1]
- The population in the USA is ageing, with an increasing number of patients requiring urology care
- Cxbladder avoids invasive, unnecessary procedures for patients driving down costs for health systems and payers[2]
- At scale, Cxbladder can spare up to 1.5m patients in the US from cystoscopy and save >US$500/US patient[2]

CANCER INCIDENCE IN MICROHEMATURIA PATIENTS

Incidence of bladder cancer in microhematuria populations is 5%

CYSTOSCOPIES SAFELY AVOIDED USING CXBLADDER

With Cxbladder, 85% of patients can avoid cystoscopy, 15% receive cystoscopy, 5 cancers found

For personal use only

1. Nam et al. (2021) Projected US Urology Workforce per Capita, 2020-2060 JAMA Network Open Published Online: November 16, 2021
2. Tyson et al (2024) Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)

BACKGROUND ON BLADDER CANCER AND HEMATURIA EVALUATION

- Bladder Cancer
  - Bladder Cancer is the 10th most commonly occurring cancer, but is more common in men (6th most commonly occurring cancer in Men)
  - An estimated 83,190 patients were diagnosed with bladder cancer in the USA in 2024 at an average age of 73[1]
- Hematuria Evaluation
  - Hematuria (Blood in the urine) is the most common sign of bladder cancer with ~7m patients diagnosed each year in the US
    - Microhematuria (MH) visible with microscopy or gross hematuria (GH) visible with the naked eye
  - Hematuria can be caused by bladder cancer or other causes, including BPH, infection, stones, idiopathic, etc.
  - NMIBC[2] is easily treated by tumor resection, but requires surveillance due to >70% chance of recurrence
- Standard of Care
  - Current standard of care requires that every patient presenting with MH receives a cystoscopy to determine if the cause is bladder cancer
- Cystoscopy
  - Cystoscopy is an invasive and costly procedure that involves a visual inspection of the lining of the bladder by inserting a camera into the urethra
  - 78% of patients reported experiencing pain during cystoscopy and 25% rated as moderate to severe[3]

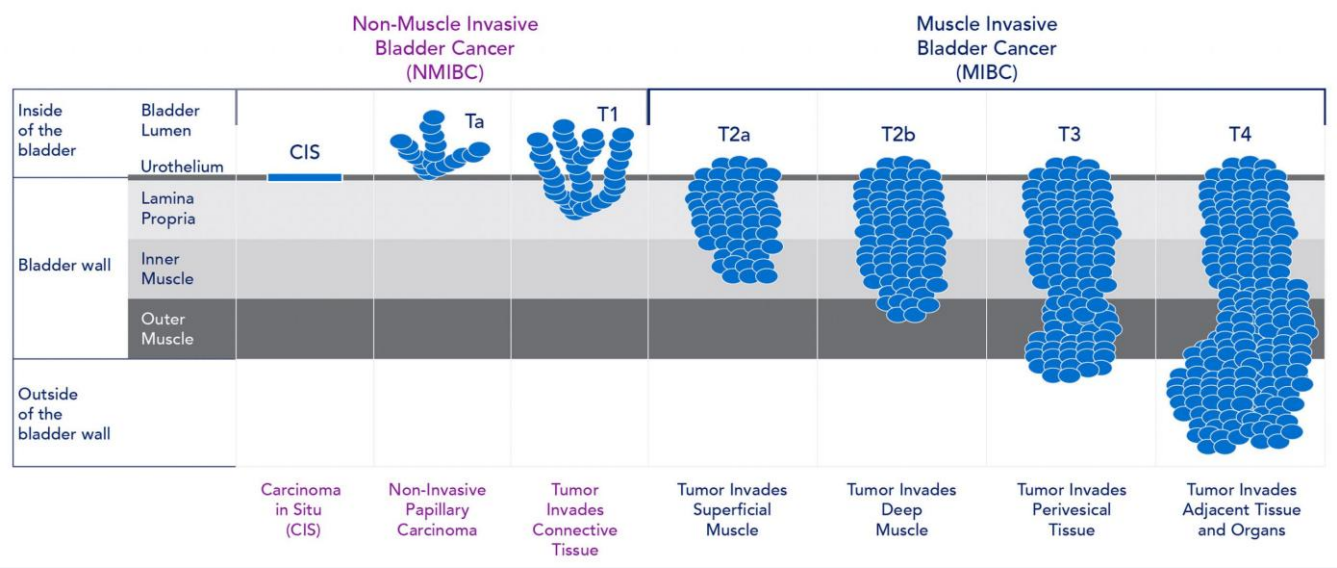
Personal use only

PacificEdge® CANCER DIAGNOSTICS

1. American Cancer Society (https://www.cancer.org/cancer/types/bladder-cancer/about/key-statistics.html)
2. NMIBC is non-muscle invasive bladder cancer (~70% of all diagnoses)
3. Survey conducted by the Bladder Cancer Advocacy Network (patient advocacy group) and published at WSAUA Meeting 2024

BACKGROUND ON NMIBC AND MIBC

- Bladder Cancer
  - An estimated 83,190 patients were diagnosed with bladder cancer in the USA in 2024 at an average age of 73[1]
- Non-muscle invasive Bladder Cancer (NMIBC)
  - NMIBC tumors represent approximately 75% of the bladder cancer diagnoses each year (CIS, Ta and T1)
  - NMIBC tumors *are localized* and present on the lining of the bladder wall and shed cancer cells and cell-free DNA/RNA into the urine in the bladder
  - NMIBC tumors are highly treatable with surgery/resection and deemed *cancer free* after surgery/resection
  - NMIBC patients are placed on a *surveillance protocol* after surgery/resection, because *recurrence can be 50-70% within the first two years*[2]
  - **NMIBC → TURBT → Surveillance**
- Muscle-invasive Bladder Cancer (MIBC)
  - MIBC tumors represent approximately 25% of the bladder cancer diagnoses each year (T2-4)
  - MIBC tumors differ from NMIBC tumors, because they shed cells/nucleotides to the blood
  - MIBC patients have advanced/serious disease, require high-levels of intervention (radical cystectomy followed by multiple therapies)
  - MIBC patients are *not deemed cancer free* after cystectomy and *frequently monitored for residual and metastatic disease*
  - **MIBC → Cystectomy → Monitoring**



1. American Cancer Society. *Cancer Facts & Figures* 2024
2. Holzbeierlein J, Bixler BR, Buckley DI, et al. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline: 2024 amendment. J Urol. 2024;10.1097/JU.0000000000003846.

PacificEdge® CANCER DIAGNOSTICS

personal use only

NMIBC STANDARD OF CARE: INTERVENTION AND SURVEILLANCE

- NMIBC Standard of Care – Intervention
  - After NMIBC diagnosis, the standard intervention is a Trans-Urethral Resection of a Bladder Tumor (TURBT)
    - TURBT involves inserting a camera into the urethra and the use of small instruments like a wire loop or laser to cut or burn away the tumor tissue
    - Patients are deemed *cancer free post TURBT when muscles and tumor margins are confirmed free of disease by pathology*
  - A resection biopsy taken during surgery is used to stage the tumor (T0, Ta, CIS, T1-4) and determine the grade (low or high grade) which also provides the risk of recurrence.
  - All NMIBC patients are then classified into risk categories based on this information (low, intermediate and high risk).
- NMIBC Standard of Care - Surveillance
  - BCG (bacillus calmette guérin) is administered for several weeks after TURBT to initiate an immune response towards the tumor. Some patients are 'non-responders'
  - A cystoscopy at 3 months is recommended for every patient
  - Following the 3-month cystoscopy, patients are recommended for routine surveillance protocols involving cystoscopy and imaging among others based on their risk category
  - Due to the high burden of these protocols, the average patient only stays on surveillance for 1.8 years not 5[1] as recommended by most guidelines

1. AUA AQUA Registry

ersonal use only

PacificEdge® CANCER DIAGNOSTICS

PACIFIC EDGE – TAKING NEW ZEALAND INNOVATION GLOBAL

2011
2011 Pacific Edge Diagnostics New Zealand (PEDNZ) established

2012
Dec 2012 Launch of Pacific Edge Diagnostics USA and Cxb Detect

2013
Mar 2013 First commercial sale (Cxb Detect) for PEDUSA

May 2013 First commercial sale (Cxb Detect) for PEDNZ

2014
Dec 2014 Launch of Cxbladder Triage

2015
Dec 2015 Launch of Cxbladder Monitor

2016

2018
Feb 2018 Cxb Triage adopted into Canterbury Community Health Pathways with primary care referral

2019

2020
Jun 2020 Kaiser Permanente, approves commercial use of Cxbladder

Jul 2020 Medicare reimbursement of Cxbladder at US$760/test

2021
Aug 2021 Cxbladder reaches 70% public healthcare coverage in NZ

Oct 2021 PEB raises $103.5m (~US$72.5m)

2022
Dec 2022 Lotan et al: Enhanced Cxbladder Tests Deliver Improved Performance. Journal of Urology

2023
Nov 2023 Kaiser Permanente EMR integration goes live

2024
May 2024 STRATA podium presentation at AUA 2024. Study published in Journal of Urology

2025
Feb 2025 Triage included in AUA Microhematuria Guideline

Apr 2025 Medicare non-coverage Effective

Oct 2025 Triage Plus gets CMS draft price of US$1328


Approved by the AUA Board of Directors February 2025

Authors' disclosure of potential conflicts of interest and author/staff contributions appear at the end of the article.

© 2025 by the American Urological Association

MICROHEMATURIA: AUA/SUFU GUIDELINE (2020, AMENDED 2025)

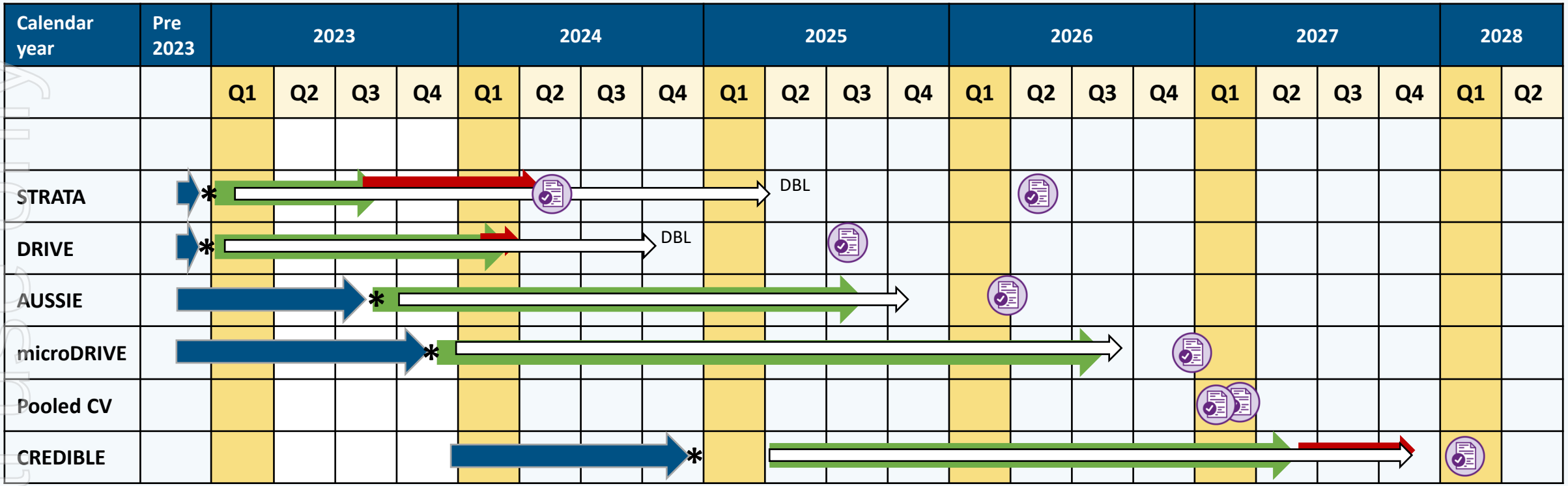
Guideline Panel

Daniel A. Barocas, MD, MPH; Stephen Boorjian, MD;* Ronald Alvarez, MD, MBA; Tracy M. Downs, MD; Cary P. Gross, MD; Blake Hamilton, MD; Kathleen Kobashi, MD; Robert Lipman; Yair Lotan, MD; Casey Ng, MD; Matthew Nielsen, MD, MS; Andrew Peterson, MD; Jay Raman, MD; Rebecca Smith-Bindman, MD*

PacificEdge® CANCER DIAGNOSTICS

personal use only

HEMATURIA EVALUATION FIVE YEAR CLINICAL STUDIES ROADMAP



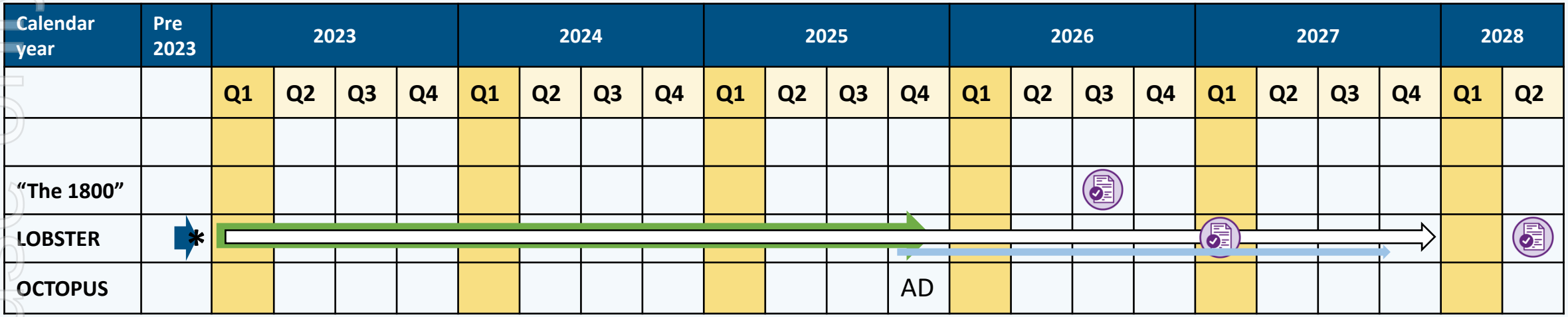
Legend:

- Pre-activation (docs, CTA etc)
- SIV
- Enrollment
- Data Cleaning
- Publication Submitted
- Records review / follow-up
- DBL — Database lock

Personal use only

PacificEdge® CANCER DIAGNOSTICS

SURVEILLANCE FIVE YEAR CLINICAL STUDIES ROADMAP



Note – "The 1800" is the Surveillance Plus development dataset
Note AD; Advisory Board at SUO to confirm OCTOPUS design

Legend:

- Pre-activation (docs, CTA etc)
- SIV
- Enrollment
- Data Cleaning
- Publication Submitted
- Records review / follow-up
- DBL Database lock
- Scheduled surveillance visits

Personal use only

PacificEdge® CANCER DIAGNOSTICS

PERFORMANCE CHARACTERISTICS OF CXBLADDER PRODUCTS

	Sensitivity (Sn)	Specificity (Sp)	NPV	PPV	ROR	Comment
Triage Plus	94%	77%	99.3%	26%	71%	Clinical Validation of Triage Plus in a veterans cohort[1]
Triage	89-96%	34-63%	98-99%	11-15%	35-63%	Range determined by 5 publications[2,3,4,5,6] that meet specific criteria[7]
Monitor	92%	-	96%	-	32%	Clinical Validation of Monitor in development dataset (n=543 from 424 patients, non-bootstrapped)[8]

1. Savage et al (2025)
2. Kavaliers et al (2015)
3. Davidson et al (2019)
4. Lotan et al (2023)
5. Davidson et al (2020)
6. Lotan et al 2024)
7. The specific criteria are:
8. Kavalieris et al (2017)

NOTE #1: Full references provided on later slide

Abbreviations - MH: Microhematuria, GH: Gross Hematuria, Sn: Sensitivity, Sp: Specificity, NPV: Negative Predictive Value, PPV: Positive Predictive Value, ROR: Rule Out Rate

ersonal use only

SUMMARY OF CXBLADDER CLINICAL EVIDENCE

		Publication or Study	Population	Sn	NPV	Sp	PPV	ROR	Comment
Triage Plus	AV	Harvey et al., (2025)	Synthetic Analytes MH (382) + GH (605)	93.6%	99.4%	90.8%	46.4%	84.1%	Development dataset includes MH (38.7%) & GH (61.3%) to establish AV performance characteristics
	CV	DRIVE (Savage et al., 2025)	MH (254) + GH (267)	94%	99.3%	77%	26%	71%	Publication accepted; Note: at upper 0.54 threshold, PPV = 51% & Sp = 95%
		AUSSIE	MH + GH						Study in progress on MH + GH patients
		microDRIVE	MH						Study in progress on MH + GH patients
	CU	CREDIBLE	MH						Study in progress on MH patients
Triage	AV	Harvey et al., 2024	Synthetic Analytes	N/A	N/A	N/A	N/A	N/A	Multi-product analytical validation of Cxbladder Triage, Detect and Monitor
	CV	Kavalieris et al., 2015	GH (587)	95%	98.5%	45%	-	40%	Sn, Sp, NPV values when TNR is 40%
		Davidson et al., 2019	MH (185) + GH (366)	95.5%	98.6%	34.3%	-		Cxb Triage & imaging combined performance had a Sn of 97.7% & NPV of 99.8%
			MH (185)	100%	100%	42.6%	-		
			GH (366)	95.1%	98%	32.8%	-		
		Lotan et al., 2023	MH (320) + GH (484)	89%	99%	63%	16%	59%	Pooled data from US (GH) and Singapore (MH+GH) cohorts (n=804)
		DRIVE (Savage et al., 2025)	MH (254) + GH (267)	93%	98.5%	38%	11%	35%	Publication accepted
	CU	Davidson et al., 2020	MH (318) + GH (566)	89.4%	98.9%	59%	-	53%	Study wide CV: Cxb Triage & imaging combined performance: Sn 98.1%, NPV 99.9%, Sp 98.4%
		Lotan et al., 2024	LR MH (135) + NLR GH (255)	90%	99%	56%	15%	63%	Low risk MH patients (n=135) randomised; 59% relative cystoscopy reduction; 22 UC cases (270 overall)
Monitor	AV	Harvey et al., 2024	Synthetic Analytes	N/A	N/A	N/A	N/A	N/A	Multi-product analytical validation of all Cxbladder products
	CV	Kavalieris et al., 2017	NMIBC (1036) (all risk categories)	93%	97%	-	-	34%	Internally validated "bootstrap corrected estimates" from development dataset (n=1036), Sn of CxbM was 97% (N = 70/72) for HG tumors and 85% (N = 66/78) for LG tumors
		LOBSTER	NMIBC (all risk categories)						Study in progress on NMIBC patients. 1183 patients estimated
	CU	Koya et al., 2020	NMIBC (257) (low risk only)	N/A	N/A	N/A	N/A	77.4%	Modest real world evidence study with no comparison to cystoscopies that safely reduced cystoscopies by 39% as the primary endpoint
		Li et al., 2023	NMIBC (92)	100%	100%	78%	33%	72%	Small (n=92), real world study, at-home Monitor testing safely reduced cystoscopy by ~72%, with no missed recurrences & high patient satisfaction
		Guduguntla et al., 2025	NMIBC (98)	N/A	N/A	N/A			Small real world evidence study with no comparison cystoscopy that safely reduced cystoscopies by 59% as the primary endpoint

NOTE #1: Full references provided on following slide
NOTE #2: Development, feasibility and/or proof of concept studies are detailed within the references on the following slide
Abbreviations - MH: Microhematuria, GH: Gross Hematuria, Sn: Sensitivity, Sp: Specificity, NPV: Negative Predictive Value, PPV: Positive Predictive Value, ROR: Rule Out Rate

Personal use only

REFERENCES SUMMARY OF CLINICAL EVIDENCE

	References	Comment
Proof of Concept	Holyoake et al., (2008). Development of a Multiplex RNA Urine Test for the Detection and Stratification of Transitional Cell Carcinoma of the Bladder. Clin Cancer Res 14(3): 742-749	Feasibility of urine-based assay including biomarker discovery for urothelial cancer detection initial algorithm development
	O'Sullivan et al., (2012). A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. The Journal of urology, 188(3), 741-747.	Development/feasibility of Cxbladder Detect assay and algorithm based on RNA expression biomarkers
	Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.	Pooled data from MH and GH cohorts (*n*=804) for 'multi-modal' (RNA+DNA) assay and algorithm development for next generation Cxbladder product including TERT and FGFR3 SNPs. Called Detect+ in publication.
	Tyson et al., (2024). Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients. Urol Prac 11(1):54-60	Budget impact model for hematuria pathway, incorporating Cxbladder Detect into patient management
Triage Plus	Harvey et al., submitted. Analytical Validation of Cxbladder® Triage Plus Assay for risk stratification of hematuria patients for urothelial carcinoma Diagnostics 2025, 15, 1739.	Analytical validation of Triage Plus
	Savage et al., Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.	Clinical validation of Triage Plus (DRIVE Study)
Triage	Kavalieris et al., (2015). A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to triage outpatients presenting with hematuria who have a low probability of urothelial carcinoma. BMC urology, 15(1), 1-12.	Algorithm development and clinical validation of Cxbladder Triage
	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.	Analytical validation of all Cxbladder products Triage, Detect and Monitor
	Davidson et al., (2019). Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of haematuria may reduce the need for cystoscopy. NZ Med J, 132(1497), 55-64.	Clinical validation of Cxbladder Triage
	Davidson et al., (2020). Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. The New Zealand Medical Journal (Online), 133(1527), 71-82.	Clinical utility of Cxbladder Triage
	Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.	Clinical validation of Cxbladder Triage from pooled data (USPrimary and Singapore pooled analysis; n=804)
	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 utility of Cxbladder Triage from STRATA study showing a 59% relative reduction in cystoscopy when comparing test and control arms
Monitor	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.	Analytical validation of all Cxbladder products Triage, Detect and Monitor
	Kavalieris et al., (2017). Performance characteristics of a multigene urine biomarker test for monitoring for recurrent urothelial carcinoma in a multicenter study. The Journal of Urology, 197(6), 1419-1426.	Algorithm development and clinical validation of Cxbladder Monitor
	Koya et al., (2020). An evaluation of the real-world use and clinical utility of the Cxbladder Monitor assay in the follow-up of patients previously treated for bladder cancer. BMC urology, 20(1), 1-9.	Clinical utility of Cxbladder Monitor with low risk NMIBC patients
	Li et al., (2023). Cxbladder Monitor testing to reduce cystoscopy frequency in patients with bladder cancer. Urologic Oncology: Seminars and Original Investigations, 41 (7), 326.e1 – 326.38.	Clinical utility of Cxbladder Monitor with NMIBC patients
	Tyson et al., accepted. Economic Impact Model of Incorporating Cxbladder Monitor in the Surveillance of Non-Muscle Invasive Bladder Cancer. JU Open Plus, accepted	Budgetary impact model when Cxbladder Monitor was incorporated into patient management

ersonal use only

SOURCES AND ASSUMPTIONS - TOTAL ADRESSABLE MARKET

REGION	STATISTIC		SOURCE
US	Population	341,762,685	https://www.census.gov/popclock/
	Incidence of hematuria	7,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Referred for clinical workup	3,500,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Receive a cystoscopy	>1,000,000	Kenigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29–34, 2021
	Annual cases of bladder cancer	84,870	National Cancer Institute
	Patients living with bladder cancer	744,044	National Cancer Institute
	Test opportunities	4,616,066	Pacific Edge estimate using 1 test per hematuria patient and 1.5 tests/year per NMIBC patient
	Price of Cxbladder (US$)	US$1,328 (Triage Plus) US$1800 (Surveillance Plus)	Triage Plus has been priced by Medicare. Surveillance Plus has not yet been priced – we are seeking a crosswalk
	TAM (US$b)	US$6.7	

Europe (excluding Russia)	Population	600,000,000	World-population - Europe; World-population – Russia
	Incidence of hematuria	12,000,000	Science Direct
	Referred for clinical workup	6,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Receive a cystoscopy	4,000,000	Rindorf, D, et al. The extent of experiencing availability issues and deteriorating performance associated with reusable cystoscopies, a multicentre study.
	Annual cases of bladder cancer	180,000	Uroweb
	Patients living with bladder cancer	900,000	Pacific Edge estimate - 5 years of annual cases
	Test opportunities	7,350,000	Pacific Edge estimate
	Price of Cxbladder EURO	€ 245	Pacific Edge estimate
	TAM (US$b)	US$2.0	

APAC (excluding India and China)	Population	830,000,000	World population - Southeast Asia; Population Pyramid - Japan;
	Incidence of hematuria	16,600,000	Science Direct
	Referred for clinical workup	8,300,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Receive a cystoscopy	3,320,000	Pacific Edge estimate
	Annual cases of bladder cancer	58,000	WHO; Hong Kong
	Patients living with bladder cancer	290,000	Pacific Edge estimate - 5 years of annual cases
	Test opportunities	3,755,000	Pacific Edge estimate
	Price of Cxbladder (US$)	$550	Pacific Edge estimate
	TAM (US$b)	US$2.1	

ersonal use only

KEY CLINICAL ADVISORS AND CONSULTANTS

Professor Yair Lotan, MD
Institution: UT Southwestern Medical Center
Relationship: Consultant, CAB member, IIT PI, CT PI
Brief Bio: Published >500 articles. Contributor to AUA/ASCO/ASTRO MIBC and Hematuria Guidelines. Chair of AUA Core Curriculum. BCAN Adboard

Professor Sam Chang, MD, MBA
Institution: Vanderbilt Cancer Center
Relationship: Consultant, CAB member
Brief Bio: Published >200 articles. Chair of AUA NMIBC Guidelines, SUO Executive Board, ABU/AUA Examination Committee, BCAN Adboard, AUA representative to the AJCC

Assistant Professor John Sfakianos
Institution: Icahn School of Medicine at Mount Sinai
Relationship: Consultant, CAB member
Brief Bio: Published >20 articles. Reviewer for J Urol and Urologic Oncology

Professor Dan Barocas, MD, MPH, FACS
Institution: Vanderbilt University Medical Center
Relationship: Consultant, CAB member
Brief Bio: Published >100 articles. AUA Guidelines panel for microscopic hematuria. Reviewer for AUA educational materials

Associate Professor, Siamak Daneshmand, MD
Institution: Keck School of Medicine at USC
Relationship: Consultant, CAB member, CT PI
Brief Bio: Published >200 articles. Editorial board of the J Urol, Bladder Cancer Journal, Current Opinions in Urology, BCAN Adboard, AUA/SUO Guideline Committee on NMIBC

Associate Professor Katie Murray, DOMS, FACS
Institution: NYU Langone
Relationship: Consultant, CAB member,
Brief Bio: Published >80 articles. Deputy Editor for J Urol. Leadership roles for SUO Young Urologic Oncology Clinical Trials

Professor Jonathan Wright, MD, MS, FACS
Institution: Fred Hutchinson Cancer Center at UW
Relationship: Consultant, CAB member, CT PI
Brief Bio: Member of ACS, SUO, AUA

Professor Wade Sexton, MD
Institution: University of South Florida & Moffitt Cancer Center
Relationship: Consultant, CAB member
Brief Bio: Published >100 articles. NCCN Bladder Cancer Guidelines, AUA Annual Board Review Course

Professor Jay Raman, MD
Institution: Penn State and Hershey Medical Center
Relationship: Consultant, CAB member, CT PI
Brief Bio: Published >350 articles. Chair of AUA Office of Education and Past-President of the Mid-Atlantic AUA section. Urology Advisory Council for ACS, Hematuria Guidelines member

Associate Professor Kristen Scarpato, MD, MPH, FACS
Institution: Vanderbilt University Medical Center
Relationship: Consultant, CAB member, CT PI
Brief Bio: SUO Education Committee, AUA Core Curriculum, Urology Practice Editorial Committee

ASCO: American Society of Clinical Oncology
ASTRO: American Society of Radiation Oncology
AUA: American Urological Association
BCAN: Bladder Cancer Advocacy Network
CAB: Clinical Advisory Board
CT PI: Clinical Trials Principal Investigator
FACS: Fellow of the American College of Surgeons
IIT PI: Investigator Initiated Trial Principal Investigator
J Urol: Journal of Urology
KOL: Key Opinion Leader
MPH: Master of Public Health
SUO: Society of Urologic Oncology

For personal use only

PacificEdge® CANCER DIAGNOSTICS

FOR MORE INFORMATION:

Dr. Peter Meintjes
Chief Executive Officer
email: peter.meintjes@pelnz.com

Grant Gibson
Chief Financial Officer
email: grant.gibson@pelnz.com

Pacific Edge
87 St David Street, PO Box 56, Dunedin, New Zealand
P +64 3 577 6733 Within NZ 0800 555 563
email: investors@pacificedge.co.nz
www.pacificedgedx.com

ersonal use only

personal use only

CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

PacificEdge
CANCER DIAGNOSTICS

For personal use only

Consolidated Interim Financial Statements

Notes to the Financial Statements

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

	NOTES	UNAUDITED SEPT 2025 6 MONTHS ($000)	UNAUDITED SEPT 2024 6 MONTHS ($000)	AUDITED MARCH 2025 12 MONTHS ($000)
REVENUE				
Operating Revenue	4	5,939	10,959	21,846
Total Operating Revenue		**5,939**	**10,959**	**21,846**
Other Income	4	897	385	903
Interest Income		299	1,193	1,925
Foreign Exchange (Loss)		(12)	(382)	(58)
Total Revenue and Other Income		**7,123**	**12,155**	**24,616**
OPERATING EXPENSES				
Laboratory Operations		5,884	5,958	12,490
Research		7,065	7,230	14,631
Sales and Marketing		8,453	8,245	17,530
General and Administration		4,837	5,225	9,901
Total Operating Expenses	5	**26,239**	**26,658**	**54,552**
NET LOSS BEFORE TAX		**(19,116)**	**(14,503)**	**(29,936)**
Income Tax Expense		-	-	-
LOSS FOR THE YEAR AFTER TAX		**(19,116)**	**(14,503)**	**(29,936)**
Items that may be reclassified to profit or loss:				
Translation of Foreign Operations		(82)	(155)	25
TOTAL COMPREHENSIVE LOSS atttributable to equity holders of the Company		**(19,198)**	**(14,658)**	**(29,911)**
Earnings per share for loss attributable to the equity holders of the Company during the year				
Basic and Diluted Earnings per share		(0.022)	(0.018)	(0.037)

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements.

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2025

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

	NOTES	SHARE CAPITAL ($000)	ACCUMULATED LOSSES ($000)	SHARE BASED PAYMENTS RESERVE ($000)	FOREIGN CURRENCY TRANSLATION RESERVE ($000)	TOTAL EQUITY ($000)
UNAUDITED 6 MONTHS TO 30 SEPT 2024						
Balance as at 31 March 2024		**294,400**	**(246,349)**	**5,607**	**964**	**54,622**
(Loss) After Tax		-	(14,503)	-	-	(14,503)
Other Comprehensive Income		-	-	-	(155)	(155)
Total Comprehensive Loss atttributable to equity holders of the Company		-	(14,503)	-	(155)	(14,658)
Transactions with owners in their capacity as owners:						
Share Based Payments - Employee Remuneration	7	58	-	-	-	58
Share Based Payment - Employee Share Options	7	-	63	571	-	634
Balance as at 30 September 2024		**294,458**	**(260,789)**	**6,178**	**809**	**40,656**
AUDITED 12 MONTHS TO 31 MARCH 2025						
Balance as at 31 March 2024		**294,400**	**(246,349)**	**5,607**	**964**	**54,622**
(Loss) After Tax		-	(29,936)	-	-	(29,936)
Other Comprehensive Income		-	-	-	25	25
Total Comprehensive Loss atttributable to equity holders of the Company		-	(29,936)	-	25	(29,911)
Transactions with owners in their capacity as owners:						
Share Based Payments - Employee Remuneration	7	58	-	-	-	58
Share Based Payment - Employee Share Options	7	-	63	1,253	-	1,316
Balance as at 31 March 2025		**294,458**	**(276,222)**	**6,860**	**989**	**26,085**
UNAUDITED 6 MONTHS TO 30 SEPT 2025						
Balance as at 31 March 2025		**294,458**	**(276,222)**	**6,860**	**989**	**26,085**
(Loss) After Tax		-	(19,116)	-	-	(19,116)
Other Comprehensive Income		-	-	-	(82)	(82)
Total Comprehensive Loss atttributable to equity holders of the Company		-	(19,116)	-	(82)	(19,198)
Transactions with owners in their capacity as owners:						
Issue of Share Capital (net of issue costs)	7	19,548	-	-	-	19,548
Share Based Payments - Employee Remuneration	7	77	-	-	-	77
Share Based Payment - Employee Share Options	7	-	63	321	-	384
Balance as at 30 September 2025		**314,083**	**(295,275)**	**7,181**	**907**	**26,896**

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements.

personal use only

CONSOLIDATED BALANCE SHEET

AS AT 30 SEPTEMBER 2025

	NOTES	UNAUDITED SEPT 2025 6 MONTHS ($000)	UNAUDITED SEPT 2024 6 MONTHS ($000)	AUDITED MARCH 2025 12 MONTHS ($000)
CURRENT ASSETS				
Cash and Cash Equivalents		15,121	21,931	9,482
Short Term Deposits		7,000	14,000	13,086
Receivables		3,753	5,143	4,970
Inventory		1,933	1,335	1,607
Other Assets		1,773	1,905	1,679
Total Current Assets		**29,580**	**44,314**	**30,824**
NON-CURRENT ASSETS				
Property, Plant and Equipment		2,583	2,728	2,980
Right of Use Assets		1,893	2,902	2,445
Intangible Assets		608	907	781
Total Non-Current Assets		**5,084**	**6,537**	**6,206**
TOTAL ASSETS		**34,664**	**50,851**	**37,030**
CURRENT LIABILITIES				
Payables and Accruals		5,446	6,869	8,044
Borrowings		300	300	300
Lease Liabilities		1,471	1,260	1,413
Total Current Liabilities		**7,217**	**8,429**	**9,757**
NON-CURRENT LIABILITIES				
Lease Liabilities		551	1,766	1,188
Total Non-Current Liabilities		**551**	**1,766**	**1,188**
TOTAL LIABILITIES		**7,768**	**10,195**	**10,945**
NET ASSETS		**26,896**	**40,656**	**26,085**
Represented by:				
EQUITY				
Share Capital	7	314,083	294,458	294,458
Accumulated Losses		(295,275)	(260,789)	(276,222)
Share Based Payments Reserve		7,181	6,178	6,860
Foreign Translation Reserve		907	809	989
TOTAL EQUITY		**26,896**	**40,656**	**26,085**
FURTHER INFORMATION:				
Net Tangible Assets Per Share ($)	9	0.026	0.049	0.031

For and on behalf of the Board of Directors:

Director **Director**

Dated 24th day of November 2025

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements.

personal use only

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2025

CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

	NOTES	UNAUDITED SEPT 2025 6 MONTHS ($000)	UNAUDITED SEPT 2024 6 MONTHS ($000)	AUDITED MARCH 2025 12 MONTHS ($000)
CASH FLOWS TO OPERATING ACTIVITIES				
Cash was provided from:				
Receipts from Customers		7,985	11,125	21,572
Receipts from Research Tax Incentives and Grant Providers		-	16	677
Interest Received		427	995	2,121
		8,412	12,136	24,370
Cash was disbursed to:				
Payments to Suppliers and Employees		27,393	24,567	49,097
Net GST inflow		45	43	13
		27,438	24,610	49,110
Net Cash Flows To Operating Activities	8	**(19,026)**	**(12,474)**	**(24,740)**
CASH FLOWS FROM INVESTING ACTIVITIES:				
Cash was provided from:				
Proceeds from Sale of Plant and Equipment		-	-	54
Proceeds from Short Term Deposits		15,086	34,000	48,000
		15,086	34,000	48,054
Cash was disbursed to:				
Purchase of Short Term Deposits		9,000	27,145	40,086
Capital Expenditure on Plant and Equipment		51	278	867
Capital Expenditure on Intangible Assets		14	252	406
		9,065	27,675	41,359
Net Cash Flows From Investing Activities		**6,021**	**6,325**	**6,695**
CASH FLOWS FROM (TO) FINANCING ACTIVITIES:				
Cash was received from:				
Ordinary Shares Issued		20,825	-	-
		20,825	-	-
Cash was disbursed to:				
Security deposited for Credit Cards		-	-	146
Repayment of Leases - Principal		686	614	1,266
Repayment of Leases - Interest		76	118	230
Issue Expenses		1,338		
		2,100	732	1,642
Net Cash Flows From (To) Financing Activities		**18,725**	**(732)**	**(1,642)**
Net Increase (Decrease) in Cash Held		**5,720**	**(6,881)**	**(19,687)**
Add Opening Cash Brought Forward		9,482	29,261	29,261
Effect of Exchange Rate Changes on Net Cash		(81)	(449)	(92)
Ending Cash Carried Forward		**15,121**	**21,931**	**9,482**

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements.

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

1 . SUMMARY OF ACCOUNTING POLICIES

The unaudited consolidated interim financial statements ("Interim Financial Statements") presented are those of Pacific Edge Limited ("Company") and its subsidiaries ("Group"). The Company is registered and domiciled in New Zealand. The Group's purpose is to research, develop and commercialise diagnostic and prognostic tools for the early detection and management of cancers. Pacific Edge Diagnostics New Zealand Limited and Pacific Edge Diagnostics USA Limited manage and operate the laboratories used for the detection of bladder cancer. Pacific Edge (Australia) Pty Limited's purpose is the sales and marketing of bladder cancer products research in the Australian market and develop the Cxbladder products and other prognostic tools. Pacific Edge Analytical Services Limited is a dormant entity.

The Company is a for profit entity, registered in New Zealand under the Companies Act 1993 and is a reporting entity for the purposes of the Financial Markets Conduct Act 2013. The Company is dual listed, with its primary listing of ordinary shares quoted in New Zealand on the NZX Main Board, and a secondary listing in Australia as a Foreign Exempt Entity on the ASX.

a) Basis of Preparation of Financial Statements

The Interim Financial Statements for the six months ended 30 September 2025 have been prepared in accordance with New Zealand Generally Accepted Accounting Practice (GAAP) and the Financial Markets Conduct Act 2013. They comply with the New Zealand Equivalents to International Financial Reporting Standards (NZ IFRS) and other guidance as issued by the External Reporting Board, as appropriate for entities, and with International Financial Reporting Standards.

The Interim Financial Statements have been prepared in accordance with NZ IAS 34 - Interim Financial Reporting. In complying with NZ IAS 34, these consolidated Interim Financial Statements also comply with IAS 34 - Interim Financial Reporting and should be read in conjunction with the Company's 2025 Annual Report.

The Interim Financial Statements are prepared on the basis of historical cost, except where otherwise identified. The presentational currency used in the preparation of the financial statements is New Zealand dollars and all values are rounded to the nearest thousand dollars ($000).

b) Accounting Policies and Accounting Estimates

All material accounting policies have been applied on a basis consistent with those used in the audited financial statements of Pacific Edge Limited for the year ended 31 March 2025.

personal use only

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2025

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

c) Going Concern

The Interim Financial Statements have been prepared on the going concern basis which assumes that the Company and Group will have sufficient cash to pay its debts as they fall due for a minimum of 12 months from the signing of the Interim Financial Statements.

As at 30 September 2025, the Company and Group had $22.121m of cash, cash equivalents and short term deposits on hand (Sept 2024: $35.931m) and net assets of 26.896m (Sept 2024: 40.656m). Net cash out flows from operating activities for the six month period to 30 September 2025 were $19.026m (Sept 2024: $12.474m). While the Company and Group continues to incur operating losses, the Company and Group remains solvent and continues to pay its debts as they fall due.

The loss of Medicare Coverage on 24 April 2025 has reduced Group revenue and US test volumes for the six months to 30 September 2025. The Company and Group continues to focus on the paths available for re-coverage. This includes appealing all claims denied by Medicare for Cxbladder Triage to derive payment from those tests, while the company has made reconsideration requests for L39365 with Novitas (the Medicare Administrative Contractor "MAC") for Cxbladder Triage and Monitor. Novitas is expected to convene an expert panel in February 2026 to consider coverage for urinary biomarker tests for microhematuria evaluation given the 2025 update to the American Urological Association (AUA) microhematuria guideline. Pacific Edge notes that under the Medicare Program Integrity Manual, these meetings are initiated by the MAC and generally precede the draft issuance of a new or substantially revised Local Coverage Determination (LCD). Re-coverage would be expected to provide an uplift in revenue generation and the financial performance of the Company and Group.

In assessing going concern, the Company and Group's management have prepared cash flow forecasts which indicate that, in the absence of a reduction in cash burn and/or capital initiatives, the Company and Group may not have sufficient cash to meet its existing minimum expenditure commitments and support its planned levels of activity for the full 12 month period from the date of signing these financial statements.

This indicates that there is a material uncertainty as at 30 September 2025 that may cast significant doubt on the Company's and Group's ability to continue as a going concern and, therefore, that it may be unable to realise its assets and discharge its liabilities in the normal course of business. The Company and Group has a history of successful capital initiatives and is actively pursuing a number of options. The Directors are confident that they will be able to achieve additional funding and/or reductions in cash burn to enable the Company and Group to meet its minimum expenditure requirements and support its planned ambitions.

d) Authorisation

The Interim Financial Statements were authorised by the Board of Directors on 24 November 2025. The Annual Financial Statements for the year ended 31 March 2025 were authorised by the Board of Directors on 29 May 2025.

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

e) Audit

The Interim Financial Statements for the six months ended 30 September 2025 are unaudited. Comparative balances for 30 September 2024 are unaudited, whilst the comparative balances for 31 March 2025 are audited.

f) Basis of Consolidation

The following entities and the basis of their inclusion for consolidation in these Interim Financial Statements are as follows:

			Ownership Interests & Voting Rights	
Name of Subsidiary	**Place of Incorporation (or registration) and Operation**	**Principal Activity**	**30 Sept 2025 (%)**	**30 Sept 2024 (%)**
Pacific Edge Diagnostics New Zealand Limited	New Zealand	Commercial Sales and Diagnostic Laboratory	100	100
Pacific Edge (Australia) Pty Limited	Australia	Commercial Sales and Biotechnology Research & Development	100	100
Pacific Edge Diagnostics USA Limited	USA	Commercial Sales and Diagnostic Laboratory	100	100
Pacific Edge Singapore Pte Limited	Singapore	Commercial Sales and Biotechnology Research & Development. Disolved and struck off 20 February 2025	NA	100
Pacific Edge Analytical Services Limited	New Zealand	Dormant Company	100	100

2. INVESTMENT AND ADVANCES IN SUBSIDIARIES

The consolidated Interim Financial Statements incorporate the assets and liabilities and results of Pacific Edge Diagnostics New Zealand Limited, Pacific Edge (Australia) Pty Limited, Pacific Edge Diagnostics USA Limited, Pacific Edge Diagnostics Singapore Pte Limited (30 September 2024 only) and Pacific Edge Analytical Services Limited, all of which are 100% owned by the Company. Subsidiaries have a 31 March balance date. The investments in and advances to subsidiaries are eliminated on consolidation in the Group financial statements.

3. DIVIDENDS

The Company does not propose to pay dividends to shareholders similar to previous years. This policy continues.

personal use only

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2025

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

4. REVENUE AND OTHER INCOME

	Unaudited Sept 2025 6 Months ($000)	**Unaudited Sept 2024 6 Months ($000)**	**Audited March 2025 12 Months ($000)**
Cxbladder Sales			
- US - Accrual Accounting	4,115	8,889	17,517
- US - Cash Accounting	928	1,178	2,565
- Total US Sales	5,043	10,067	20,082
- Rest of World	896	892	1,764
Total Operating Revenue	**5,939**	**10,959**	**21,846**
Other Income			
Grant Revenue	-	-	22
Research Rebates and Tax Incentives	897	385	881
Total Other Income	**897**	**385**	**903**

On 24 April 2025*, Local Coverage Determination (L39365) 'Genetic Testing in Oncology: Specific Tests' became effective in the US, halting Medicare coverage of Cxbladder tests.

Pacific Edge had previously generated approximately 60% of its US revenue from Medicare and approximately 56% of total Operating Revenue.

Pacific Edge is focusing on the paths available to recoverage, which include Medicare appeals for Cxbladder Triage to get paid based on its inclusion in the AUA microhematuria guideline despite the non-coverage determination and reconsideration requests for Triage, Triage Plus and Monitor which have been submitted to the Medicare Approved Contractor Novitas.

Due to the non-coverage, Medicare tests performed during the six months to 30 September 2025 have not been accrued in the six months to 30 September 2025 given the uncertainity in determining the level of success of appeals. This accounting treatment has changed from the treatment in the twelve months to 31 March 2025 when revenue for tests performed for Medicare were accrued based on the anticipated funds that would be received from Medicare.

Pacific Edge is in the process of appealing for Cxbladder Triage Medicare tests that have been completed since the date the Local Coverage Determination became effective and remain unpaid up to 30 September 2025. If these appeals are successful, revenue will be recognised for tests when the proceeds are received from the appeal process.

If sufficient appeals are successful and revenue is expected to be reliably calculated, the company may be able to recommence accounting for Medicare tests on an accrual basis for the 31 March 2026 accounts.

*All dates with an asterisk refer to US dates

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

5. OPERATING EXPENSES

The note below highlights total expenses shown within total operating expenses. These items are then split across functions laboratory, research, sales and marketing and general and administration as reported in the annual report.

	Unaudited Sept 2025 6 Months ($000)	Unaudited Sept 2024 6 Months ($000)	Audited March 2025 12 Months ($000)
Operating Expenses			
Amortisation	187	295	571
Auditors Remuneration			
- Group year end financial statements	102	99	198
- Half year review of financial statements	35	35	35
- Travel Costs	6	-	10
Other services provided by PricewaterhouseCoopers New Zealand			
- Assurance on Carbon Emissions - Scope 1 and 2	-	-	30
- Financial Training Workshops	-	1	1
Total Auditors Remuneration	**143**	**135**	**274**
Consultant Costs	1,121	1,149	2,257
Depreciation	418	390	842
Depreciation on Right of Use Assets	682	661	1,344
Directors Fees	314	247	470
Employee Benefits	12,383	12,784	26,268
Employee Share Scheme Expenses	77	58	58
Employee Share Options	384	635	1,317
Interest on Lease Liabilities	76	118	230
Legal Expenses	732	256	611
NZX / ASX / Registry Fees	108	124	230
Rental and Lease Expense	28	75	143
Site Fees - Clinical Studies	1,730	2,062	4,052
Other Operating Expenses	7,856	7,669	15,885
Total Operating Expenses	**26,239**	**26,658**	**54,552**

personal use only

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2025

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

Employee Share Scheme

Employee Share Scheme Expenses are a non-cash expense. These relate to shares issued to employees in lieu of cash bonuses.

Employee Share Options

Employee Share Options are a non-cash expense. Refer to Note 8 of the Annual Report for details of the accounting policy for Employee Share Schemes.

Other Operating Expenses

The major categories of expenditure which make up operating expenses, but are not disclosed separately above: Laboratory costs, Information Technology costs, Compliance and Regulatory costs, Investor Relations costs.

6. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer who makes strategic decisions.

There are two operating segments at balance date:

1. **Commercial**: The sales, marketing, laboratory and support operations to run the commercial businesses worldwide; and
2. **Research**: The research and development of diagnostic and prognostic products for human cancer.

The reportable operating segment Commercial derives its revenue primarily from sales of Cxbladder tests and the reportable operating segment Research derives its revenue primarily from grant income. The Chief Executive Officer assesses the performance of the operating segments based on net loss for the period.

Segment income, expenses and profitability are presented on a gross basis excluding inter-segment eliminations to best represent the performance of each segment operating as independent business units. The segment information provided to the Chief Executive Officer for the reportable segments described above, for the six months ended 30 September 2025 is shown on the following page.

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

Unaudited 6 Months to 30 September 2025	Commercial ($000)	Research ($000)	Less: Eliminations ($000)	Total External Income ($000)
Income				
Operating Revenue - External	5,939	-	-	5,939
Other Income	606	1,251	(960)	897
Interest Income	5	294	-	299
Foreign Exchange Gain	(5)	(7)	-	(12)
Total Income	**6,545**	**1,538**	**(960)**	**7,123**
Expenses				
Other Expenses	8,499	4,579	(960)	12,118
Employee Benefits	7,710	5,124	-	12,834
Depreciation & Amortisation	953	334	-	1,287
Total Operating Expenses	**17,162**	**10,037**	**(960)**	**26,239**
Loss Before Tax	**(10,617)**	**(8,499)**	**-**	**(19,116)**
Income Tax Expense	-	-	-	-
Loss After Tax	**(10,617)**	**(8,499)**	**-**	**(19,116)**
Net Cash Flow to Operating Activities	**(8,948)**	**(10,078)**	**-**	**(19,026)**

Unaudited 6 Months to 30 September 2024	Commercial ($000)	Research ($000)	Less: Eliminations ($000)	Total External Income ($000)
Income				
Operating Revenue - External	10,959	-	-	10,959
Other Income	617	785	(1,017)	385
Interest Income	7	1,186	-	1,193
Foreign Exchange Gain	-	(382)	-	(382)
Total Income	**11,583**	**1,589**	**(1,017)**	**12,155**
Expenses				
Other Expenses	15,814	10,516	(1,017)	25,313
Depreciation & Amortisation	890	455	-	1,345
Total Operating Expenses	**16,704**	**10,971**	**(1,017)**	**26,658**
Loss Before Tax	**(5,121)**	**(9,382)**	**-**	**(14,503)**
Income Tax Expense	-	-	-	-
Loss After Tax	**(5,121)**	**(9,382)**	**-**	**(14,503)**
Net Cash Flow to Operating Activities	**(4,109)**	**(8,365)**	**-**	**(12,474)**

pwc

personal use only

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

Audited 12 Months to 31 March 2025	Commercial ($000)	Research ($000)	Less: Eliminations ($000)	Total External Income ($000)
Income				
Operating Revenue - External	21,852	-	(6)	21,846
Other Income	1,237	4,757	(5,091)	903
Interest Income	12	1,913	-	1,925
Foreign Exchange Gain	(2)	(56)	-	(58)
Total Income	**23,099**	**6,614**	**(5,097)**	**24,616**
Expenses				
Other Expenses	19,636	9,612	(5,097)	24,151
Employee Benefits	16,532	11,111	-	27,643
Depreciation & Amortisation	1,864	894	-	2,758
Total Operating Expenses	**38,032**	**21,617**	**(5,097)**	**54,552**
Loss Before Tax	**(14,933)**	**(15,003)**	**-**	**(29,936)**
Income Tax Expense	-	-	-	-
Loss After Tax	**(14,933)**	**(15,003)**	**-**	**(29,936)**
Net Cash Flow to Operating Activities	**(13,031)**	**(11,709)**	**-**	**(24,740)**

Eliminations

These are the intercompany transactions between the subsidiaries and the Parent. These are eliminated on consolidation of Group results. The Research segment of the business utilise consumables and other components that are purchased by the Commercial segments of the business, with the costs of these components allocated to Research segment, and the Commercial segment recognising revenue from the sale.

Total Laboratory Throughput:

Unaudited	Commercial # Tests	Research # Tests	Total # Tests
6 months ended 30 September 2025	10,371	2,820	13,191
6 months ended 30 September 2024	12,323	1,910	14,233
12 months ended 31 March 2025	24,642	4,252	28,894

Laboratory Throughput is a key metric for the Group. Laboratory Throughput provides evidence of the usage of Cxbladder products globally and the rates of adoption between different customer segments. Total Laboratory Throughput includes commercial tests, which are invoiced to customers, and research tests which are not considered to be billable as these tests relate to user programs or other non-chargeable activities.

pwc

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

Commercial test numbers are also a key metric for the Group: Commercial Tests are those tests for which the Company is actively seeking reimbursement and cash receipts, and tests performed at no charge in order to gain new customers.

Segment Assets and Liabilities Information:

Unaudited as at 30 September 2025	Commercial ($000)	Research ($000)	Total ($000)
Total Assets	7,542	27,122	34,664
Total Liabilities	4,151	3,617	7,768

Unaudited as at 30 September 2024	Commercial ($000)	Research ($000)	Total ($000)
Total Assets	10,359	40,492	50,851
Total Liabilities	6,106	4,089	10,195

Audited as at 31 March 2025	Commercial ($000)	Research ($000)	Total ($000)
Total Assets	11,257	25,773	37,030
Total Liabilities	6,449	4,496	10,945

Additions to non current assets for the period include:

	Commercial ($000)	Research ($000)	Total ($000)
Property, Plant & Equipment	48	3	51
Right of Use Assets	396	-	396
Intangible Assets	14	-	14
Total Additions to Non Current Assets	**458**	**3**	**461**

The amounts provided to the Chief Executive Officer with respect to total assets and total liabilities are measured in a manner consistent with that of the financial statements. These assets and liabilities are allocated based on the operation of the segment and the physical location of the asset.

There are no unallocated assets or liabilities.

pwc

personal use only

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2025

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

Geographic Split of Revenue and Non-Current Assets

The Group generates most of the operating revenue from Commercial tests from the US and New Zealand and also receives Grant revenue from New Zealand. Rest of World consists of Revenue from Australia and Southeast Asia.

	Unaudited Sept 2025 6 Months ($000)	Unaudited Sept 2024 6 Months ($000)	Audited March 2025 12 Months ($000)
Operating and Grant Revenue			
US	5,043	10,067	20,143
New Zealand	1,375	1,228	2,499
Rest of World	418	49	107
Total Operating and Grant Revenue	**6,836**	**11,344**	**22,749**

	Unaudited Sept 2025 6 Months ($000)	Unaudited Sept 2024 6 Months ($000)	Audited March 2025 12 Months ($000)
Non-Current Assets			
US	2,624	3,469	3,455
New Zealand	2,459	3,066	2,750
Rest of World	1	2	1
Total Non-Current Assets	**5,084**	**6,537**	**6,206**

7. SHARE CAPITAL

	Unaudited Sept 2025 6 Months Shares (000)	Unaudited Sept 2025 6 Months ($000)	Unaudited Sept 2024 6 Months ($000)	Audited March 2025 12 Months ($000)
Opening Balance	**811,916**	**294,458**	**294,400**	**294,400**
Issue of Ordinary Shares				
- Issue of Ordinary Shares - Placement[1]	160,728	16,073	-	-
- Issue of Ordinary Shares - Retail Offer[2]	46,622	4,662	-	-
- Issue of Ordinary Shares - Employee Remuneration[3]	736	77	58	58
- Issue of Ordinary Shares - Directors Fees[4]	1,508	151	-	-
- Issue of Ordinary Shares - Share Issue Expense[5]	625	63	-	-
Less Share Issue Expense	-	(1,401)	-	-
Movement	**210,219**	**19,625**	**58**	**58**
Closing Balance	**1,022,135**	**314,083**	**294,458**	**294,458**

pwc

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

[1] During the period 160,728,498 shares were issued resulting from a Share Placement at an average price of $0.100 per share. (September 2024: Nil, March 2025: Nil)

[2] During the period 46,621,913 shares were issued resulting from a Share Retail Offer at an average price of $0.100 per share. (September 2024: Nil, March 2025: Nil)

[3] During the period 736,475 shares were issued as part of employees remuneration in lieu of cash payments at an average price of $0.105 per share. (September 2024: 644,630 at $0.090 and March 2025: 644,630 at $0.090).

[4] During the period 1,507,600 shares were issued to Directors in lieu of Directors Fees at an average price of $0.100 per share. (September 2024: Nil, March 2025: Nil)

[5] During the period 625,000 shares were issued as Non-cash consideration, being in recognition of providing legal advice during the capital raise an average price of $0.100 per share. (September 2024: Nil, March 2025: Nil)

There are 1,022,135,460 (September 2024: 811,915,974 and March 2025: 811,915,974) ordinary shares on issue. All fully paid shares in the Company have equal voting rights and equal rights to dividends. All Ordinary Shares are fully paid and have no par value.

8. RECONCILIATION OF CASH FLOWS TO OPERATING ACTIVITIES WITH OPERATING NET LOSS

	Unaudited Sept 2025 6 Months ($000)	Unaudited Sept 2024 6 Months ($000)	Audited March 2025 12 Months ($000)
Net Loss for the Period	(19,116)	(14,503)	(29,936)
Add Non Cash Items:			
Depreciation	418	390	842
(Profit) on disposal of Property, Plant and Equipment	(23)	-	(19)
Amortisation	187	295	571
Employee Share options	382	635	1,317
Employee bonuses paid in shares in lieu of cash	140	58	58
Depreciation on right of use assets	682	661	1,344
Interest on finance leases shown in lease repayments	76	118	230
Total Non Cash Items	**1,862**	**2,157**	**4,343**
Add Movements in Other Working Capital items:			
(Increase) Decrease in Receivables and Other Assets	1,123	(978)	(576)
(Increase) Decrease in Inventory	(326)	353	81
Increase (Decrease) in Payables and Accruals	(2,595)	116	1,289
Effect of exchange rates on net cash	26	381	59
Total Movement in Other Working Capital	**(1,772)**	**(128)**	**853**
Net Cash Flows to Operating Activities	**(19,026)**	**(12,474)**	**(24,740)**

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2025

9. NET TANGIBLE ASSETS

Net Tangible Assets per share is a non-GAAP measure that is required to be disclosed by the NZX Listing Rules. The calculation of the Group's Net Tangible Assets per share and its reconciliation to the consolidated balance sheet is presented below.

	Unaudited Sept 2025 6 Months ($000)	Unaudited Sept 2024 6 Months ($000)	Audited March 2025 12 Months ($000)
Total Assets	34,664	50,851	37,030
Less Intangible Assets	608	907	781
Less Total Liabilities	7,768	10,195	10,945
Net Tangible Assets	**26,288**	**39,749**	**25,304**
Number of Shares Issued (000's)	1,022,135	811,916	811,916
Net Tangible Assets Per Share	**$0.026**	**$0.049**	**$0.031**

10. CONTINGENT LIABILITIES

There were no known contingent liabilities at 30 September 2025 (September 2024: Nil and March 2025 : Nil). The Company and Group have not granted any securities in respect of liabilities payable by any other party whatsoever.

11. CONTINGENT ASSETS

Pacific Edge is in the process of appealing for Cxbladder Triage Medicare tests that have been completed since the date the Local Coverage Determination became effective and remain unpaid up to 30 September 2025. If these appeals are successful, revenue will be recognised for tests when the proceeds are received from the appeal process.

12. CAPITAL COMMITMENTS

There are no capital commitments at 30 September 2025 (September 2024: Nil and March 2025: Nil).

13. RELATED PARTIES

Details of all related party relationships have been disclosed in the annual report for the year ended 31 March 2025.

In addition to these disclosures, during the six months to 30 September 2025, shareholders resolved to increase the Director Remuneration Pool, with the increase in pool to be issued as shares in lieu of cash.

personal use only

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2025

13. RELATED PARTIES (continued)

Shareholders resolved to issue up to 1,930,000 shares to Directors at a price of $0.100 per share. Directors could elect to receive a reduced number of shares to offset the tax obligation via a net settlement option, which some Directors elected to do. There were 1,507,600 Shares issued to Directors for directors fees in lieu of Cash. Shareholders received an Independent Report which considered the terms and conditions of the issue of shares to Directors was fair to Shareholders who were not associated with the Directors prior to the vote agreeing to the issue.

14. LOCAL COVERAGE DETERMINATION (LCD) CHANGES

On 24 April 2025*, Local Coverage Determination (L39365) 'Genetic Testing in Oncology: Specific Tests' became effective in the US, halting Medicare coverage of Cxbladder tests.

Pacific Edge had previously generated approximately 60% of its US revenue from Medicare and approximately 56% of total Operating Revenue.

Further details on the impact of this loss of Medicare coverage is detailed on Note 4 - Revenue.

*All dates with an asterisk refer to US dates

15. SUBSEQUENT EVENTS

There are no subsequent events.

personal use only

For personal use only

Independent auditor's review report

To the shareholders of Pacific Edge Limited

Report on the consolidated interim financial statements

Our conclusion

We have reviewed the consolidated interim financial statements of Pacific Edge Limited (the Company) and its subsidiaries (the Group), which comprise the consolidated balance sheet as at 30 September 2025, and the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the six months ended on that date, and notes, comprising material accounting policy information and other explanatory information.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying consolidated interim financial statements of the Group do not present fairly, in all material respects, the financial position of the Group as at 30 September 2025, and its financial performance and cash flows for the six months then ended, in accordance with International Accounting Standard 34 *Interim Financial Reporting* (IAS 34) and New Zealand Equivalent to International Accounting Standard 34 *Interim Financial Reporting* (NZ IAS 34).

Basis for conclusion

We conducted our review in accordance with the New Zealand Standard on Review Engagements 2410 (Revised) *Review of Financial Statements Performed by the Independent Auditor of the Entity* (NZ SRE 2410 (Revised)). Our responsibilities are further described in the *Auditor's responsibilities for the review of the consolidated interim financial statements* section of our report.

We are independent of the Group in accordance with the relevant ethical requirements in New Zealand relating to the audit of the annual financial statements, and we have fulfilled our other ethical responsibilities in accordance with these ethical requirements.

Other than in our capacity as auditor and assurance practitioner, we have no other relationships with, or interests in, the Group.

Material uncertainty related to going concern

We draw attention to the disclosures in Note 1 to the consolidated interim financial statements, which indicates that the Company, as at 30 September 2025, had $22.121m of cash, cash equivalents and short term deposits on hand (Sept 2024: $35.931m), net assets of $26.896m (Sept 2024: $40.656m), and net cash outflows from operating activities for the six month period to 30 September 2025 were of $19.026m (Sept 2024: $12.474m).

As stated in Note 1, if the Company is unable to achieve additional funding and/or achieve appropriate cash burn reduction measures it may not have sufficient funds to meet its obligations and be unable to realise its assets and discharge its liabilities in the normal course of business. These events or conditions, along with other matters set forth in Note 1, indicate that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

PricewaterhouseCoopers, PwC Centre, 60 Cashel Street,
PO Box 13-244, Christchurch 8141, New Zealand
T: +64 3 374 3000

Responsibilities of Directors for the consolidated interim financial statements

The Directors of the Company are responsible on behalf of the Company for the preparation and fair presentation of these consolidated interim financial statements in accordance with IAS 34 and NZ IAS 34 and for such internal control as the Directors determine is necessary to enable the preparation and fair presentation of the consolidated interim financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's responsibilities for the review of the consolidated interim financial statements

Our responsibility is to express a conclusion on the consolidated interim financial statements based on our review. NZ SRE 2410 (Revised) requires us to conclude whether anything has come to our attention that causes us to believe that the consolidated interim financial statements, taken as a whole, are not prepared in all material respects, in accordance with IAS 34 and NZ IAS 34.

A review of consolidated interim financial statements in accordance with NZ SRE 2410 (Revised) is a limited assurance engagement. We perform procedures, primarily consisting of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. The procedures performed in a review are substantially less than those performed in an audit conducted in accordance with International Standards on Auditing (New Zealand) and consequently does not enable us to obtain assurance that we might identify in an audit. Accordingly, we do not express an audit opinion on these consolidated interim financial statements.

Who we report to

This report is made solely to the Company's Shareholders, as a body. Our review work has been undertaken so that we might state those matters which we are required to state to them in our review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's Shareholders, as a body, for our review procedures, for this report or for the conclusion we have formed.

The engagement partner on the review resulting in this independent auditor's review report is Nathan Wylie.

For and on behalf of:

PricewaterhouseCoopers Christchurch
24 November 2025

For personal use only

personal use only

PacificEdge
CANCER DIAGNOSTICS

87 St David Street, PO Box 56, Dunedin, New Zealand
P 0800 555 563 (NZ) | +64 3 577 6733 (Outside NZ)
F +64 3 974 9393
www.pacificedgedx.com

For personal use only

NZX
NEW ZEALAND'S EXCHANGE
TE PAEHOKO O AOTEAROA

Template
Results announcement
(for Equity Security issuer/Equity and Debt Security issuer)

Updated as at March 2025

Please do not amend or delete individual rows. As this template relates to prescribed content, changes to content should only be made where it is clearly indicated that this is permitted, otherwise, if an Issuer considers a particular element does not apply, mark the row as N/A, Any other changes to this prescribed form must first be approved by NZX as required under NZX Listing Rule 3.26.1.

Results for announcement to the market		
Name of issuer	Pacific Edge Limited	
Reporting Period	6 months to 30 September 2025	
Previous Reporting Period	6 months to 30 September 2024	
Currency	NZD (New Zealand Dollar)	
	Amount (000s)	**Percentage change**
Revenue from continuing operations	$5,939	46% Decrease
Total Revenue	$7,123	41% Decrease
Net profit/(loss) from continuing operations	($19,116)	32% Larger Loss
Total net profit/(loss)	($19,116)	32% Larger Loss
Interim/Final Dividend		
Amount per Quoted Equity Security	The Company does not propose to pay dividends to shareholders	
Imputed amount per Quoted Equity Security	Not Applicable	
Record Date	Not Applicable	
Dividend Payment Date	Not Applicable	
	Current period	**Prior comparable period**
Net tangible assets per Quoted Equity Security (in dollars and cents per security)	$0.026	$0.049
A brief explanation of any of the figures above necessary to enable the figures to be understood	For commentary on the results, please refer to the commentary in the accompanying NZX release. Further information is also set out in the unaudited financial statements of the Company for the 6 months to 30 September 2025 which accompany this Results Announcement.	
Authority for this announcement		
Name of person authorised to make this announcement	Grant Gibson	
Contact person for this announcement	Grant Gibson	
Contact phone number	0800 555 563	
Contact email address	grant.gibson@pelnz.com	

Date of release through MAP	25/11/2025

Unaudited financial statements accompany this announcement.

For personal use only