14 JULY 2026

# PACIFIC EDGE APAC OPERATIONS ADVANCE TOWARDS PROFIT

**DUNEDIN, New Zealand** – Cancer diagnostics company Pacific Edge (NZX/ASX: PEB) today announces its APAC business is advancing towards profitability on a direct-cost basis supported by an increase in commercial test volumes and the increasing adoption of the company's next generation test Cxbladder Triage Plus.

The strong improvement in the regional operation is detailed in the company's Q1 27 update released today that showed APAC commercial tests rising 12.9% in Q1 27 to 1,158 tests from 1,026 tests in Q4 26[1].

APAC (unaudited) cash burn reduced to $0.17 million for the quarter, representing an improvement of approximately 9% on Q4 FY26 and approximately 15% on Q1 FY26, reflecting disciplined cost management, improved pricing, and a growing contribution from commercial testing[2].

APAC revenue of $2.0m contributed 19% of operating revenue in the second half of FY26, up from 8% in FY25. Cxbladder Triage Plus is a better performing test that is also priced higher, improving revenue, margin and margin percentage per test. The combination of volume growth and increasing percentage of Triage Plus tests in the product mix is expected to further improve revenue expectations.

Total laboratory throughput (TLT) was 5,116 for Q1 27 down 8.3% on the 5,582 recorded for Q4 26, with the extent of the fall largely due to an 82% reduction in clinical trials and investigator-initiated trial volumes to 115 in Q1 27 from 642 in Q4 26.

US commercial tests in Q1 27 were down a modest 2.4% to 3,295 from 3,375 in Q4 26 with the fall reflecting continuing attrition in the sales team to 5.0 from 7.7 FTEs in Q4 26 in line with the company's cash preservation initiatives in place ahead of the release of the draft Medicare policy. The company is now focused on selective investments to drive commercial execution in the US.

Pacific Edge Chief Executive Officer Dr Peter Meintjes said: "The quarterly performance of the Asia Pacific operations has demonstrated key results that we aim to replicate in the USA. Transition to Triage Plus and a focus on the strategic selling of clinical pathways to institutions has led to several quarters of consistent growth in commercial testing volume, revenue, margin and margin percentage. We are delighted with this progress and are seeking to maintain this momentum for multiple forward-looking quarters.

[1] Pacific Edge is today, for the first time, releasing quarterly commercial volumes to provide greater transparency to investors on the performance of the business. It intends to provide these figures in future quarterly updates.
[2] Pacific Edge is reporting APAC financial performance in this update as a one-off statement only to demonstrate the commercial momentum.

"In the US, Novitas's draft Local Coverage Determination published on May 14 *'Urine-based Biomarkers in Patients with Microhematuria'*, has created the opportunity for similar success. With selective investments in our commercial and digital teams, we are seeking to target integrated delivery networks (IDNs) such as academic centers and hospital systems with clinical pathways for Triage Plus, and re-focus our account executives on intermediate risk microhematuria patients where our value proposition is clearer, and our commercial strategy can be rebuilt around reimbursable use."

In addition to the improving performance of the APAC region, test volumes, and the change to the US sales strategy, the Q1 27 investor update also details:

- Pacific Edge's request that Novitas expand coverage to a broader range of patients presenting with hematuria. Pacific Edge spoke to the request at an Open Meeting on 18 June 2026 to hear public submissions on the draft LCD
- Updates on the company's clinical evidence programme to entrench the company's tests in guidelines and medical policy

Pacific Edge has updated its non-confidential Investor Presentation to ensure consistency with the points highlighted in this release and the Quarterly Shareholder Update.

The company looks forward to providing a further update to investors at its Annual Shareholder Meeting in Auckland on Thursday 20 August 2026 at 2pm.

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

For more information:

**Investors:**
Dr Peter Meintjes
Chief Executive
Pacific Edge
P: +64 22 032 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 suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with hematuria and those being monitored for recurrent

disease. The tests help improve the overall patient experience, while prioritizing time and clinical resources to optimize practice workflow and improve efficiency.

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

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

PacificEdge

# INVESTOR UPDATE



**JULY 2026**

**INSIDE**

LETTER FROM THE CEO

# Resetting for growth with Medicare coverage in sight

Dear Shareholders,

**Pacific Edge enters the second quarter of FY27 with a materially stronger strategic position than it held only a few months ago.**

The draft Novitas Local Coverage Determination for urine-based biomarkers in microhematuria, published in May, has established a clear pathway back to Medicare coverage for Cxbladder Triage and Triage Plus. While that progress has not yet translated into greater clinical adoption in the US, it has changed the foundation on which we can now build: one where our evidence is increasingly recognized, our value proposition is clearer, and our commercial strategy can be rebuilt around reimbursable use.

The quarter also reinforced the importance of our Asia Pacific business. APAC commercial tests rose 12.9%[1] further advancing the region towards profitability on a direct-cost basis. That momentum reflects disciplined commercial execution, improved pricing, and the growing contribution of Triage Plus, whose higher performance strengthens customer adoption and higher margin strengthens Pacific Edge's economics.

**"We are now focused on proving a sharper go-to-market model before committing capital to broader expansion."**

In the US, commercial volumes were broadly stable, but we continue to operate through the consequences of Medicare uncertainty and the capital-preservation decisions we made ahead of the draft policy. Despite our sales force decreasing for the quarter as we have prioritized the most productive and profitable territories, the number of ordering clinicians has increased to 814 for the quarter, up 7% on the 764 for Q4 26. With the smaller sales team our sales force efficiency metric has improved, driven by Kaiser Permanente and we are now focused on proving a sharper go-to-market model before committing capital to broader expansion.

Our go-to-market model is being built around the patient population now recognized in both the draft LCD and the AUA Microhematuria Guideline: intermediate-risk microhematuria patients. There are an estimated 1.14m intermediate-risk microhematuria patients referred to urology each year, but these patients are not concentrated solely in traditional urology practices because the population has a higher concentration of female patients, frequently treated by obstetrician-gynecologists (OBGYNs), urogynecologists (urogyns) and specialists in female pelvic medicine and reconstructive surgery (FPMRS). This requires a more targeted strategy, split between Integrated Delivery Networks (IDNs) and private practice settings.

At Novitas' public consultation meeting in June, we thanked the Medicare Administrative Contractor for recognizing urine-based biomarkers as a Medicare benefit, while making a specific request to expand beyond intermediate-risk microhematuria patients to include high-risk microhematuria patients. Our request was grounded in new peer-reviewed evidence that was not available to the AUA when they established the guidelines that shows consistent performance of Cxbladder Triage and Triage Plus across all risk categories of microhematuria patients.

We also asked Novitas to make several practical changes to the draft LCD that would reduce barriers to appropriate physician ordering (see page 7). We continue to expect a final LCD before the end of calendar 2026. By rule, Novitas must either finalize or withdraw the draft by 14 May 2027.

Commercial payer interest provides another important bridge to growth. Payers representing more than 10.5 million covered lives in the US are now ready to reimburse Cxbladder Triage and Triage Plus, and we expect that number to grow as Medicare coverage is finalized.

Our clinical evidence program remains central to this strategy. It is the reason Cxbladder Triage is recognized in the AUA guideline, the reason Triage Plus is included in the draft LCD, and the reason we continue to have confidence in the durability of our market position. During the quarter we reached the

targeted number of patients for the microDRIVE study. Clinical site monitoring and data cleaning are now underway, with database lock, analysis and publication processes to follow. We continue to expect publication in Q1 27.

microDRIVE is strategically important because it will add prospective validation evidence for Triage Plus in microhematuria patients and will also enable pooled analyses with DRIVE and AUSSIE. Those pooled analyses are expected to provide one of the strongest clinical validation datasets available for Triage Plus in microhematuria and gross hematuria, supporting our efforts with physicians, payers, guideline committees and Medicare policymakers.

The timing of this evidence program is also important. The AUA microhematuria guideline committee is not expected to reopen its literature review until mid to late 2027, with June 2027 the earliest planning assumption we are using. Our objective is to ensure that the next wave of clinical validation publications – including AUSSIE, microDRIVE and the pooled analyses from DRIVE, AUSSIE and microDRIVE – is available ahead of, or during, that review window. If the pooled analyses confirm the expected performance of Triage Plus across all microhematuria patients, we believe they can support both the addition of Triage Plus to the guideline-defined list of validated urine-based biomarkers and an expanded and more evidence-based definition of intermediate-risk microhematuria that better identifies the patients most likely to benefit from non-invasive risk stratification.

The path ahead still requires discipline. We are not yet through the Medicare process, and we will continue to manage capital carefully. However, the company now has a clearer reimbursement pathway, encouraging APAC momentum, a targeted US commercial strategy, growing payer support, and a clinical evidence program that continues to deliver. We are focused on translating those advantages into growth, reimbursement and a path to profitability and we are making a series of selective investments to capitalize on the opportunities we now enjoy.

I want to thank the Pacific Edge team for their perseverance and our shareholders for their continued support through a challenging but important period for the company. We look forward to updating you as the final LCD process advances and as our commercial and clinical evidence milestones are delivered.

With my warm regards,

**Dr Peter Meintjes**
Chief Executive

TEST VOLUMES

## Commercial momentum builds in APAC

**Pacific Edge's APAC operations are showing strong momentum in commercial test adoption. APAC commercial tests rose 12.9% in Q1 27 to 1,158 tests from 1,026 tests[1] in Q4 26, further advancing the region's march towards profitability on a direct cost basis (see below). This momentum is being assisted by a meaningful shift in test mix in the APAC region to Triage Plus with superior performance and higher margins.**

US commercial tests in Q1 27 were down a modest 2.4% to 3,295 from 3,375 in Q4 26 with the fall reflecting continuing attrition in the sales team to 5.0 FTEs from 7.7 FTE's in Q4 26 in line with the company's cash preservation initiatives ahead of the release of the draft Medicare policy. As noted in our Q4 26 investor update the company had adopted a policy of limiting the backfilling of not-yet-profitable territories ahead of the Medicare policy decision. As we set out below, we are now putting in place a sales strategy to reverse this decline.

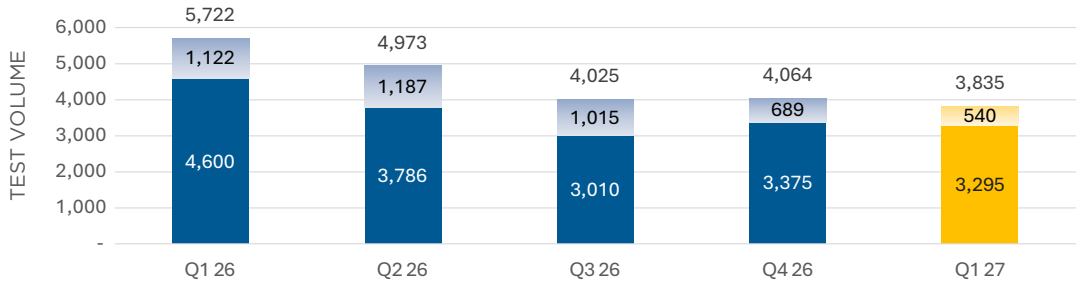
Total laboratory throughput (TLT) was 5,116 for Q1 27 down 8.3% on the 5,582 recorded for Q4 26, with the extent of the fall largely due to an 82% reduction in clinical trials and investigator-initiated trial volumes to 115 in Q1 27 from 642 in Q4 26. US test mix was stable.

Our US sales force efficiency metric of commercial tests per sales FTE rose to 659 from 440 in Q4 26 reflecting fewer sales FTE's, a focus on profitable territories and growing adoption of our tests in the Kaiser Permanente Southern California system. The number of ordering clinicians was 814, compared with 764 in Q4 26. Commercial tests per unique ordering clinician was 4.0, compared with 4.4 in Q4 26.

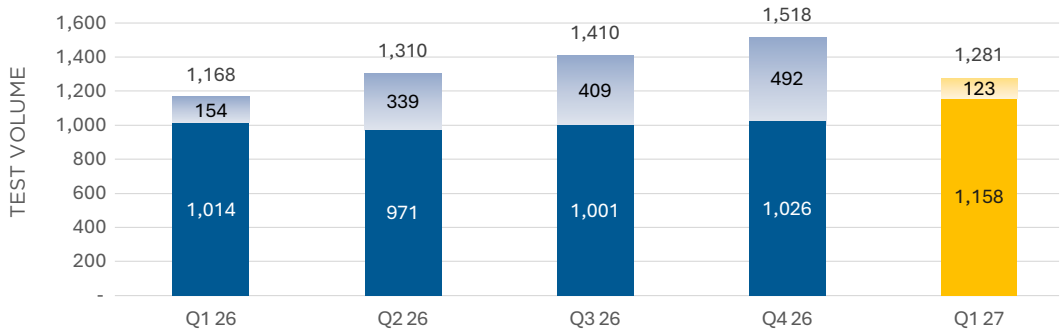
[1] Pacific Edge is today, for the first time, releasing quarterly commercial volumes to provide greater transparency to investors on the performance of the business. It intends to provide these figures in future quarterly updates.

## TEST VOLUMES CONTINUED

### US TOTAL THROUGHPUT

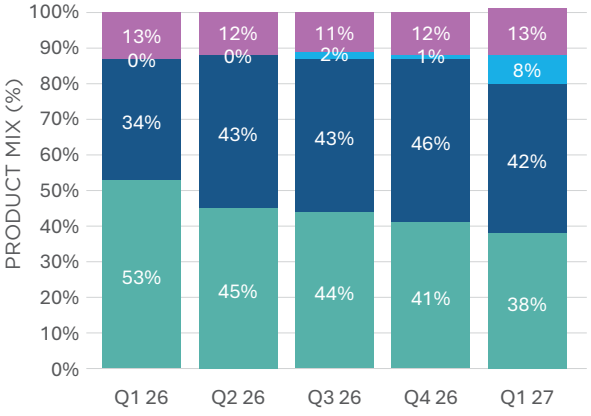



### APAC TOTAL THROUGHPUT

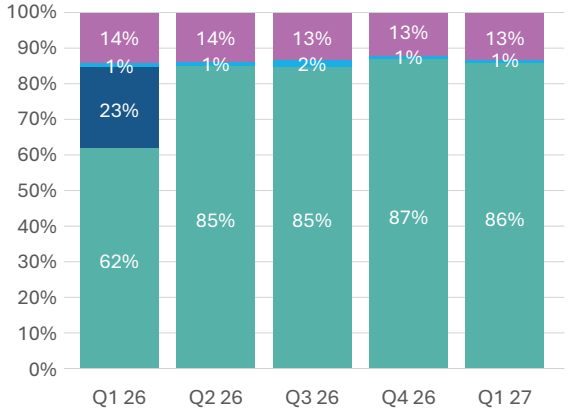



**Light shade:** Clinical study and evaluation tests **Dark Shade:** Commercial tests

### APAC COMMERCIAL PRODUCT MIX

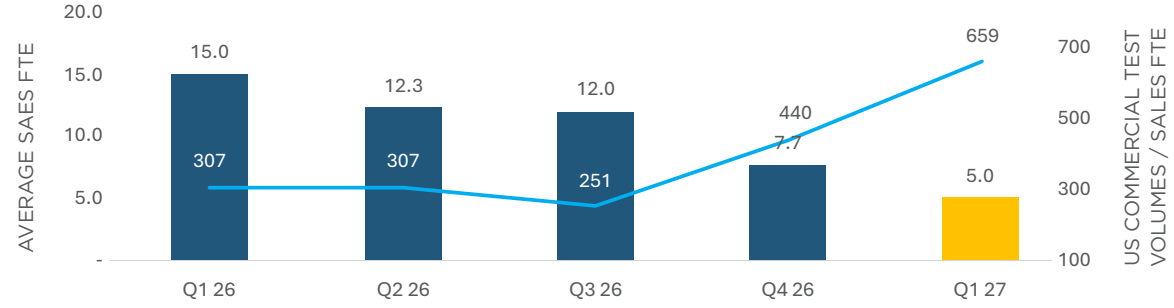



### US COMMERCIAL PRODUCT MIX




Triage Detect Triage Plus Monitor

### US SALES FORCE EFFICIENCY




**Bar graph:** US Average Sales FTE (LHS) **Line graph:** US Commercial Test Volume / Sales FTE (RHS)

APAC

# Momentum builds towards profitability

**Pacific Edge's APAC business is advancing towards profitability on a direct-cost basis, with cash burn reduced to $0.17 million for the quarter[1]. This represents an improvement of approximately 9% on Q4 26 and approximately 15% on Q1 26, reflecting disciplined cost management, improved pricing, and a growing contribution from commercial testing.**

Revenue momentum is also improving. APAC contributed 19% of operating revenue in the second half of FY26, up from 8% in FY25. The 2025 repricing program increased revenue per test by an average of 25%, while wider adoption of Cxbladder Triage Plus over legacy products delivered a further 20% uplift in revenue from the same testing volume. This mix benefit is expected to be amplified as testing volumes grow across the region.

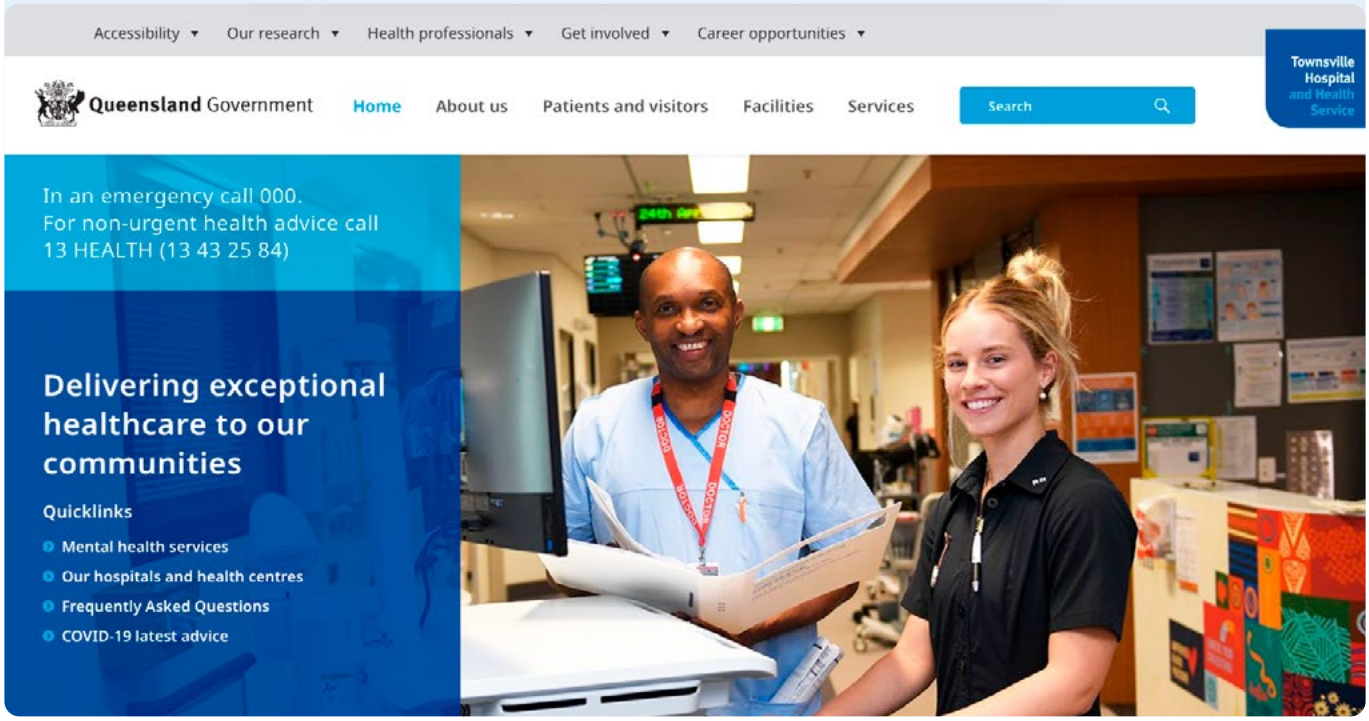
In New Zealand, Pacific Edge remains focused on establishing a national pathway for hematuria evaluation in partnership with Te Whatu Ora. Approximately 70% of New Zealanders already have access to Cxbladder testing, and the company is working to extend access more equitably across the country.

Across Asia, the company is building a network of laboratory and distribution partners to support in-market promotion of its testing services. Pacific Edge has now processed commercial samples from seven markets, either directly or through a distributor or laboratory partner. A key early win was Singapore General Hospital's implementation of the first clinical pathway for Cxbladder products in March 2026, providing an important reference point for adoption across other regional healthcare systems.


In Australia, Pacific Edge is pursuing hospital-by-hospital contracting with institutions that have evaluated Cxbladder. Northern Hospital and Townsville have established clinical pathways for Cxbladder products, supporting broader engagement with hospital systems in that country.

We see the development of a kit-based IVD as a further catalyst to accelerate of adoption across both Australia and Asia as the development will support a more scalable operating model.

[1] Pacific Edge is reporting APAC financial performance in this update as a one-off statement only to demonstrate the commercial momentum.



# Proving our US sales strategy with selective investments

**Our efforts are focused on the health care providers where intermediate risk hematuria patients are managed.**

Pacific Edge is sharpening its US commercial strategy to ensure it is tightly focussed on the intermediate-risk microhematuria (IRMH) patients indicated for its tests by both the draft *'Urine-based Biomarkers in Patients with Microhematuria'* Local Coverage Determination and the American Urological Association (AUA) Microhematuria guideline.

Pacific Edge's review of AUA data published by Woldu et al (2021)[1] estimates that ~1.14 million IRMH patients are referred from primary care to urology for the evaluation of their intermediate risk microhematuria. This is approximately half of the total intermediate-risk diagnoses and a substantial population of patients, many of whom remain at primary care – a practice that leads to delays in diagnosis, and a leading driver of muscle invasive bladder cancer at first diagnosis. Moreover, many of those that are referred to specialist secondary care, are often first seen by Advanced Practice Providers (APPs), Nurse Practitioners (NPs), or Physician Assistants (PAs). Meanwhile, an estimated 75% of IRMH patients are women and are treated by obstetrician-gynaecologists, urogynaecologists and specialists in female pelvic medicine and reconstructive surgery.

These population statistics require commercial efforts to be focused on where these patients are managed – split between Integrated Delivery Networks (IDNs) which care for an estimated 60% of the IRMH patients and private service providers that care for the remainder. IDNs offer a higher volume sales opportunity covering around 1,000 strategic accounts including 130 academic hospitals, 170 VA medical centers. The focus in these institutions is selling clinical pathways for Cxbladder (and the health system benefits the tests offer) to embed the tests in an IDN's clinical practice for the management of IRMH patients. The benefit is reliable reimbursement (lower denials), but the sales cycle is often longer and for the larger IDNs may require electronic medical record integrations. For these providers we are standing up an initial modest Strategic Sales team focused on Academic Institutions, Hospital Systems and VA Medical Centers.

Private practice providers represent a more diverse channel, spanning community urology clinics and large urology group practices. While the sales cycle in these settings is typically shorter than in large health systems, success requires a more tailored approach that speaks directly to practice economics, workflow efficiency, and the patient benefits of Cxbladder. This will be the focus of our existing Account Executives in the Specialty Sales team.

The Medicare uncertainty of the past year, and our decision to preserve capital while that uncertainty remained unresolved, have constrained our near-term commercial capacity. Our US sales force now stands at five. We are making selective investments in the team, and are focused on rebuilding our commercial model with discipline, testing the effectiveness of the revised approach in priority territories, covering rural areas with our customer service and proving the return on investment before committing capital to broader expansion.

Our initial focus will be on the growing number of regions and networks that have established medical policy for Cxbladder and those where there is already strong understanding of the clinical utility of our tests and the benefits they offer patients and health systems. In these markets, we are developing the sales tools, customer outreach and account strategies required to deliver the fastest path to profitable growth.

**GENDER OF HEMATURIA PATIENTS**
**Pacific Edge Estimates**

| PATIENT | FEMALE | MALE |
|---|---|---|
| Low Risk | 80% | 20% |
| Intermediate risk | 75% | 25% |
| High risk | 34% | 66% |

[1] Woldu SL, Ng CK, Loo RK, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria. J Urol. 2021;205(5):1387-1393. doi:10.1097/JU.0000000000001550.

HEALTHCARE PAYERS

## Commercial payers ready to reimburse Cxbladder

**US Commercial payers representing a total of 10.5 million lives are ready to reimburse Pacific Edge for the use of Cxbladder Triage and Triage Plus and we expect this to grow rapidly when Novitas finalizes the *'Urine-based Biomarkers in Patients with Microhematuria'* Local Coverage Determination.**

These payers include Kaiser Permanente, Blue Cross Blue Shield plans in North Carolina and South Carolina, Sentara and the BCBS plan in Kansas City Missouri. They represent just a fraction of the 223 million private insured lives covered by commercial payers. Finalized Medicare coverage – expected before the end of the year – will bring a further 66 million insured lives eligible for reimbursement. It is also expected to improve adoption by commercial payers, because it removes a key objection from commercial payers, while giving providers stronger evidence and policy language to overturn denials on appeal. We are advancing our case both directly with payers and indirectly through groups such as Avalon, EviCore, Carelon, Concert Genetics and ECRI that commercial payers use to inform coverage decisions. With a finalized LCD we will also leverage state biomarker laws, which mandate payers to reimburse a Medicare covered test.

NOVITAS OPEN MEETING

## Novitas asked to expand coverage

**Pacific Edge has asked Novitas to consider an expansion of the patients eligible for Medicare coverage under its draft *'Urine-based Biomarkers in Patients with Microhematuria'* LCD from intermediate risk to all risk categories.**

At Novitas' public consultation meeting on the draft LCD held in mid-June Pacific Edge took the opportunity to thank Novitas for its ground-breaking recognition of urine-based biomarkers as a Medicare benefit. However, we noted that there was additional peer-reviewed clinical evidence available to Novitas that was not cited in the draft LCD, nor considered by the American Urological Association in its 2025 revision to its microhematuria guideline that supports the use of Cxbladder Triage and Triage Plus in all microhematuria patients. We made a specific request that the LCD include high-risk microhematuria patients that are either unable to undergo cystoscopy due to other comorbidities or medical reasons while noting that this change would particularly benefit Medicare-aged men who are categorized as 'high-risk' based on their age alone.

Our arguments rely on a series of papers showing no statistical difference in the performance of Cxbladder Triage and Triage Plus between low, intermediate, and high-risk patients[1]. We also highlighted several documented cases where a high-risk patient would be unable to undergo a cystoscopy, due to mental, or physical limitations such as dementia or compromised anatomy. In these cases, urine-based biomarker testing would help physicians to decide whether an invasive procedure was truly needed, reducing unnecessary cystoscopy and imaging without compromising cancer detection.

We also sought a number of other practical changes to the LCD that could affect physician ordering. Firstly, we asked that the LCD's 6-month cystoscopy restriction should be removed or clarified to apply only to microhematuria evaluation, as patients may undergo cystoscopy for unrelated reasons. Secondly, we noted the LCD's requirement that "all potential causes" of hematuria be ruled out was overly broad and clinically impractical. The AUA Microhematuria Guideline supports a risk-based framework, excluding only apparent benign causes with further testing guided by physician judgment.

Thirdly, we asked the LCD language should be revised to focus on excluding clinically apparent causes, while explicitly recognizing physician discretion and finally we asked that the LCD's repeat testing restriction should be reduced from 6 to 3 months.

The final LCD and Novitas' response to comments can now be published in the Medicare Coverage Database with the approval from Medicare at any time from now. Pacific Edge continues to estimate that while Novitas controls the timeline, this may occur by the end of calendar 2026. Novitas is required to either finalize or withdraw the draft LCD by the middle of May 2027.

A transcript of the Open Public Meeting is available on the Novitas Solutions website.

[1] Based on the data from the Lotan et al (2023), Lotan et al (2024), Harvey et al (2025), Savage et al (2026), and Filson et al (2026). For detailed citations please see: https://www.cxbladder.com/nz/clinical-resources/clinical-publications/

# Evidence to drive clinical practice change

Our clinical study program is a key pillar of how Pacific Edge drives value. We are focused on generating the compelling clinical evidence required to drive behavior change in physicians. Specifically, we seek to produce evidence that is founded on the frameworks of Analytical Validity (AV), Clinical Validity (CV), and Clinical Utility (CU), with the endpoints and sample sizes required for coverage decisions and guideline inclusion.

| STUDY | GOAL | POPULATION AND USE | STATUS |
|---|---|---|---|
| **STRATA**<br>**S**afe **T**esting of **R**isk for **A**symptoma**T**ic Microhematuri**A** | • CU Triage (lower risk MH) and CU Triage Plus (retrospective) | • MH<br>• Risk stratification | • Recruitment closed with 555 patients including 223 low risk patients (test and control)<br>• Interim analysis results published leading to AUA Guidelines inclusion in 2025 update<br>• Final analysis publication is being developed and will confirm published findings |
| **DRIVE**<br>**D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria | • CV of Triage Plus (MH or GH)<br>• Data for MH & GH pooled analyses | • MH and GH<br>• Risk stratification | • Enrolment closed with 710 patients including 48 tumour confirmed patients from 10 US VA sites<br>• Database lock completed and manuscript published |
| **microDRIVE**<br>**D**etection and **R**isk stratification **I**n **VE**terans presenting with microhematuria | • CV of Triage Plus (MH or GH)<br>• Data for MH & GH pooled analyses | • MH<br>• Risk stratification | • Last patient enrolled is achieved with 35 UC confirmed subjects, final subject data to be collected is expected in Jul-26, final monitoring by Aug-26, database lock in Sep-26 and publication early 2027<br>• Publication provides opportunity to publish a pooled analysis validating Triage Plus with MH patients from microDRIVE, DRIVE and AUSSIE studies |
| **AUSSIE**<br>**A**ustralian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia | • CV Triage Plus (MH or GH)<br>• Data for MH & GH pooled analyses | • MH and GH<br>• Risk stratification | • There are 691 evaluable subjects enrolled including 54 confirmed bladder tumor patients (10 MH UC; 43 GH UC; 1 adenocarcinoma)<br>• Publication is projected for Q3 2026 |
| **POOLED ANALYSES** | • CV Triage Plus (MH & GH) pooled analysis | • MH and GH<br>• Risk stratification | • MH patient data from DRIVE, AUSSIE & microDRIVE will be analysed with publication expected Q1-2027<br>• Separately GH patient data and demographic data will be analysed with publication expected in early 2027 |
| **CREDIBLE**<br>**C**ystoscopic **RED**uction **I**n **BL**adder **E**valuations for microhematuria | • CU Triage Plus | • MH<br>• Risk stratification | • Currently 247 patients are enrolled of 1000 targeted<br>• Enrolment is lower than expected and we will close unproductive sites and open new sites to the study<br>• Enrolment phase expected to continue until Q2 to Q3 2027 |
| **LOBSTER**<br>**LO**ngitudinal **B**ladder cancer **S**tudy for **T**umor **R**ecurrence | • CV Cxbladder Surveillance (low-, int.- and high-risk) | • Surveillance<br>• Risk stratification | • Enrolment completed (Q4-25) having achieved our target of 75 confirmed recurrences<br>• Data monitoring is expected to continue providing for an interim analysis Dec-26<br>• Currently there are 448 subjects enrolled with 1314 samples<br>• Sample collection at scheduled surveillance visits will continue through to Oct-27 |
| **OCTOPUS**<br>**O**ngoing **C**xbladder **T**esting for **O**ptimized **P**atient Experience in **U**rothelial **S**urveillance | • CU Cxbladder Surveillance (low-, int.- and high-risk) | • Surveillance<br>• Risk stratification | • Currently at the planning stage. Advisory Board completed Dec-2025 and protocol synopsis developed. There will be no further progress until a business case is approved |

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



## ABOUT US

Pacific Edge Limited (NZX/ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease. Headquartered in Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

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**CONTACT US:**

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

# PACIFIC EDGE:

## INTRODUCTION & FY26 RESULTS

*Dr Peter Meintjes*
***Chief Executive Officer***

*Grant Gibson*
***Chief Financial Officer***

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# INTRODUCTION TO PACIFIC EDGE



PacificEdge®
CANCER DIAGNOSTICS

# SNAPSHOT: PACIFIC EDGE - THE FIRST MOVER IN BLADDER CANCER DIAGNOSTICS

## MAJOR GROWTH CATALYST: DRAFT MEDICARE COVERAGE PROPOSED IN MAY 2026


**US$10.2b[4]**

Global Market Opportunity

### SCIENCE, TECH AND IP

Cxbladder tests are patented **non-invasive** urine tests that deliver **proven clinical, economic and patient value**

### CLINICAL EVIDENCE

Cxbladder tests are supported by a **robust portfolio of clinical evidence**, and the AUA[1] has recognized Cxbladder Triage with a **'Grade A' evidence rating** – the only urine biomarker to achieve that rating

### SUBSTANTIAL MARKET OPPORTUNITY

The primary symptom of bladder cancer is hematuria with ~7m diagnoses each year in the US driving a **global market opportunity of US$10.2 billion**

### GROWTH CATALYST WITH MEDICARE COVERAGE

Draft LCD[2] for Triage & Triage Plus **released in May 2026.** Final LCD expected by Jan 2027[3]. Novitas confirms **claim-by-claim reimbursement for both tests**

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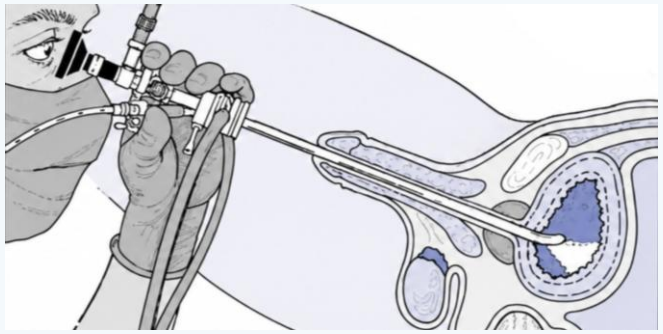
1. AUA = American Urological Association,
2. LCD = Local Coverage Determination.
3. Novitas must publish the final LCD or retire the draft LCD within 365 days after publishing a draft LCD
4. See slides 37-39 for assumptions

# BLADDER CANCER – A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE

## AN INVASIVE STATUS QUO – A NON-INVASIVE OPPORTUNITY

### CYSTOSCOPY



Source: Nursing Skills

### CXBLADDER TEST


- Cystoscopy – an invasive, uncomfortable and costly procedure to visually inspect the bladder by inserting a camera into the urethra
  - The standard hematuria workup, where the majority of patients are found to have no cancer
  - In a survey[4] of US NMIBC patients under surveillance, 78% said they experienced some pain, with 25% saying it was moderate to "worst imaginable"
- The result is systemic over-proceduralization: millions of avoidable cystoscopies every year, adding cost, patient discomfort, infection risk and urology backlog
- Non-invasive genomic urine testing like Cxbladder can rule out cancer and prioritize patients who truly need cystoscopy – a large unmet clinical need
  - women are an under-served market, with hematuria frequently dismissed as urinary tract infections (UTI)

**1st**
Costliest cancer to treat on a per-patient basis[1]

**6th**
Most common cancer in men[2]

**9th**
Most common cancer world-wide[2]

**~614K**
Annual cases and growing[2]

**>220K**
Annual Deaths[2]

**>50%**
Recurrence[3]

**4.9m[5]**
Annual cystoscopies avoided globally if **Cxbladder** tests were used to evaluate intermediate risk patients presenting with hematuria[5]

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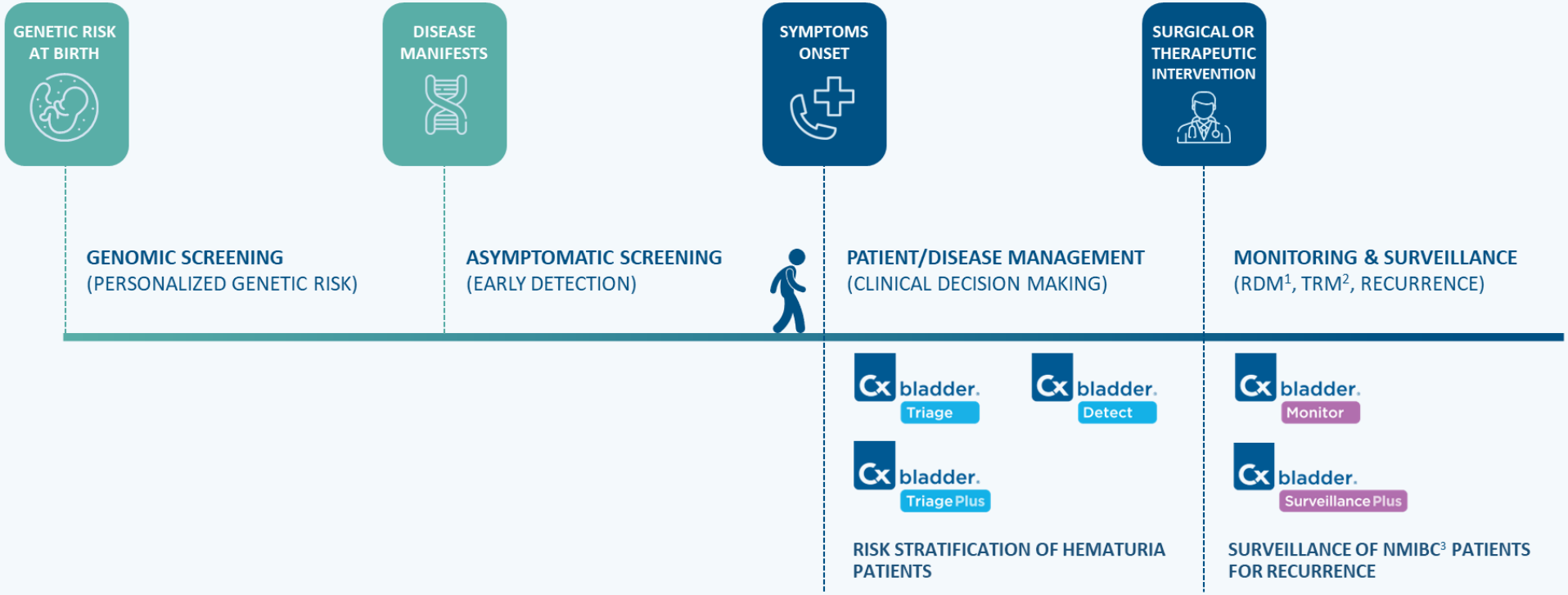
1. Sievert et al (2009) Economic aspects of bladder cancer: what are the benefits and costs? World J Urol. 2009 Mar 7;27(3):295–300. doi: 10.1007/s00345-009-0395-z
2. World Cancer Research Fund. Statistics are from 2022.
3. Average recurrence for low grade non-muscle invasive bladder cancer as published in Palou J et al (2012): Eur Urol 2012; 62: 118.
4. The Survey was conducted by the Bladder Cancer Advocacy Network (BCAN)
5. Company estimate

# CXBLADDER: TESTS TO RULE OUT CANCER OR PRIORITIZE PATIENTS

## THE PATIENT CARE PATHWAY






**>130,000**
Patients that have used Cxbladder

**>5,000**
Urologists that have ordered Cxbladder

**>30**
Publications demonstrating AV, CV or CU evidence[5]

**Grade A**
Evidence rating by the AUA[4] in its 2025 Microhematuria Guideline

1. RDM: Residual Disease Monitoring
2. TRM: Therapeutic Response Monitoring
3. NMIBC: non-muscle invasive bladder cancer
4. AUA: American Urological Association
5. AV, CV, CU are Analytical Validity, Clinical Validity, and Clinical Utility which are required for medical policy and guidelines

# DRIVING ECONOMIC VALUE FOR PATIENTS, HOSPITALS AND PAYERS

## CXBLADDER DELIVERS CLINICAL UTILITY, PATIENT SATISFACTION AND ECONOMIC VALUE



### CANCER INCIDENCE IN MICROHEMATURIA PATIENTS

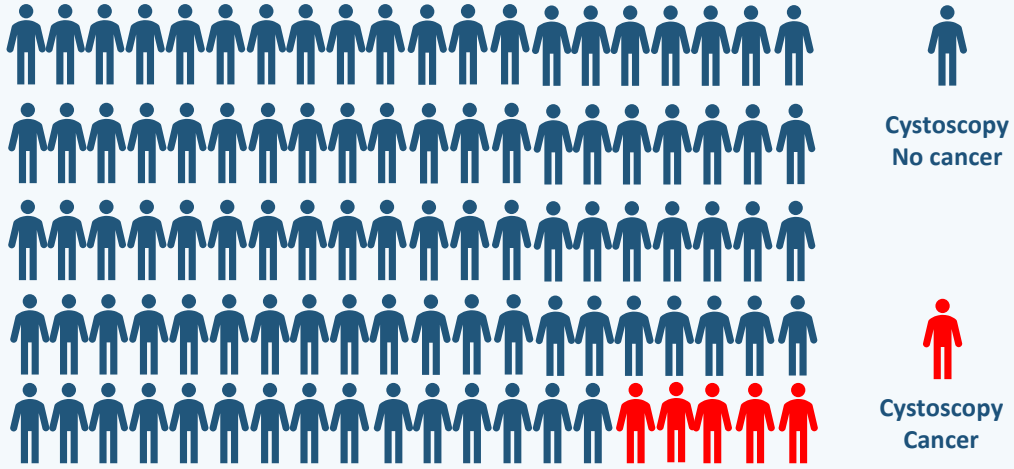
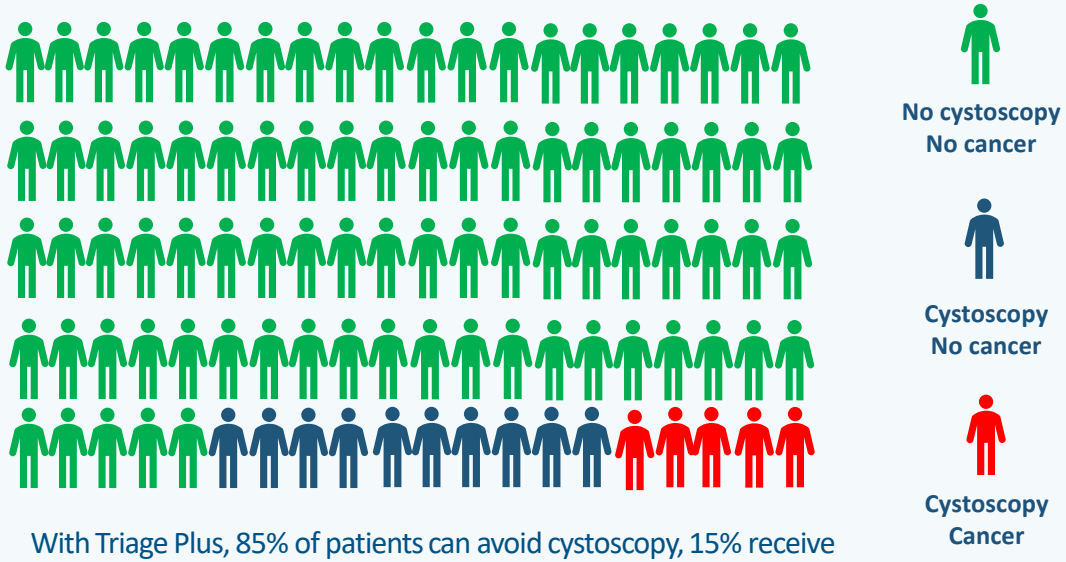



Illustration shows incidence of bladder cancer in microhematuria populations at 5%[1]

### CYSTOSCOPIES SAFELY AVOIDED USING CXBLADDER




With Triage Plus, 85% of patients can avoid cystoscopy, 15% receive cystoscopy to find the same 5 cancer patients

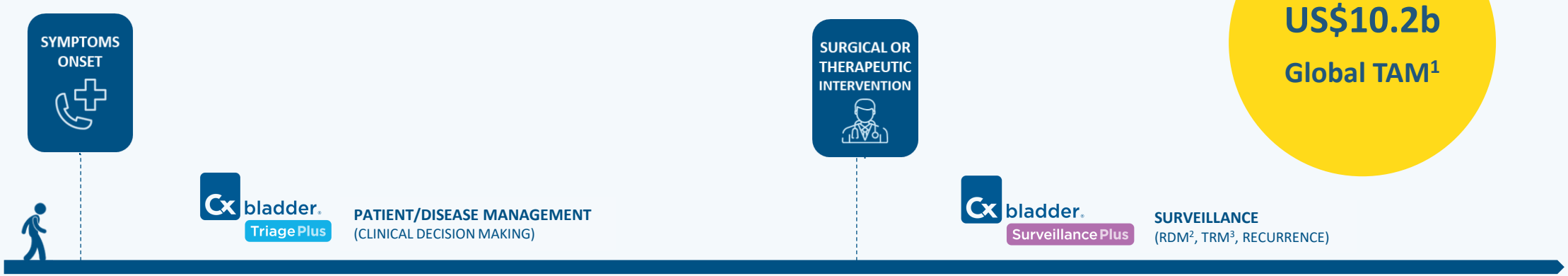
- Cxbladder avoids invasive, unnecessary procedures saving >US$500/patient driving down costs for health systems and payers[2]
- Only 63% of counties in the US have a registered urologist[3] and only 13% of high-risk microhematuria patients receiving a cystoscopy[4]
- The US population is ageing and the urologists per person over 65 is falling (from 23.8/100k to 15.8/100k in 2035[5]) potentially delaying diagnosis
- Medicare reimbursement for cystoscopy has declined from US$204.80 in 2023 to US$172.80 in 2026[6]


1. AUA Guidelines cite incidence of bladder cancer in microhematuria risk categories from 0.4-6%. 5% is an example
2. Tyson et al (2024) Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)
3. https://www.auanet.org/research-and-data/aua-census/census-results
4. https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncr.25048
5. Nam et al. (2021) Projected US Urology Workforce per Capita, 2020-2060 JAMA Network Open Published Online: November 16, 2021
6. https://www.cms.gov/medicare/physician-fee-schedule/search

# CXBLADDER MARKET OPPORTUNITY

## CXBLADDER OFFERS A SIGNIFICANT ADDRESSABLE GLOBAL MARKET ANNUALLY

**US$10.2b**
**Global TAM[1]**




| Population | All hematuria | Microhematuria[4] Low \| Intermediate \| High | Gross[4] Hematuria | Annual cases of bladder cancer | Living with bladder cancer | TAM | |
|---|---|---|---|---|---|---|---|
| 340m | ~7m | 0.20m \| 1.14m \| 1.46m | 700k | ~90k | ~750k | US$6.4b | *Primary growth focus due to higher CMS pricing* |
| 830m | ~17m | 0.47m \| 2.71m \| 3.46m | 1.7m | ~58k | ~300k | US$1.9b | *NZ market mature. Australia and SEA in business development* |
| 600m | ~12m | 0.34m \| 1.96m \| 2.5m | 1.7m | ~180k | ~1m | US$1.9b | *New market accessed via IVD / kitted tests* |

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 37-39 for details.
2. RDM: Residual Disease Monitoring
3. TRM: Therapeutic Response Monitoring
4. Management estimates derived from referred hematuria data in Woldu et al (2021). MH estimated at 80% and GH at 20%. MH Risk categories: Low 7%, Intermediate 41%, High 52%. See Slide 37-39 for details.

# FY26 FINANCIAL AND OPERATIONAL RESULTS



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# FY26: ADVANCED MEDICARE COVERAGE WITH PRUDENT CAPITAL MANAGEMENT



**24,190**
GLOBAL TESTS[1]
-16.3%
on FY25

US Total Tests[1] 18,784, -21.4% on FY25; APAC Total Tests[1] 5,406 +7.9% on FY25

**18,783**
COMMERCIAL TESTS -23.8% on FY25

US Commercial Tests 14,771, -26.5% on FY25; APAC Commercial Tests 4,012, -11.9% on FY25

**$11.5M**
OPERATING REVENUE -47.4% on FY25

2H 26 Operating Revenue $5.6m –6.4% on 1H 26; Total Revenue of $13.6M -44.8% on FY25

**-$35.8M**
NET LOSS AFTER TAX UP 19.5% on FY25

2H 26 Net Loss After Tax ($16.7m) down 12.8% on 1H 26 amid capital preservation initiatives

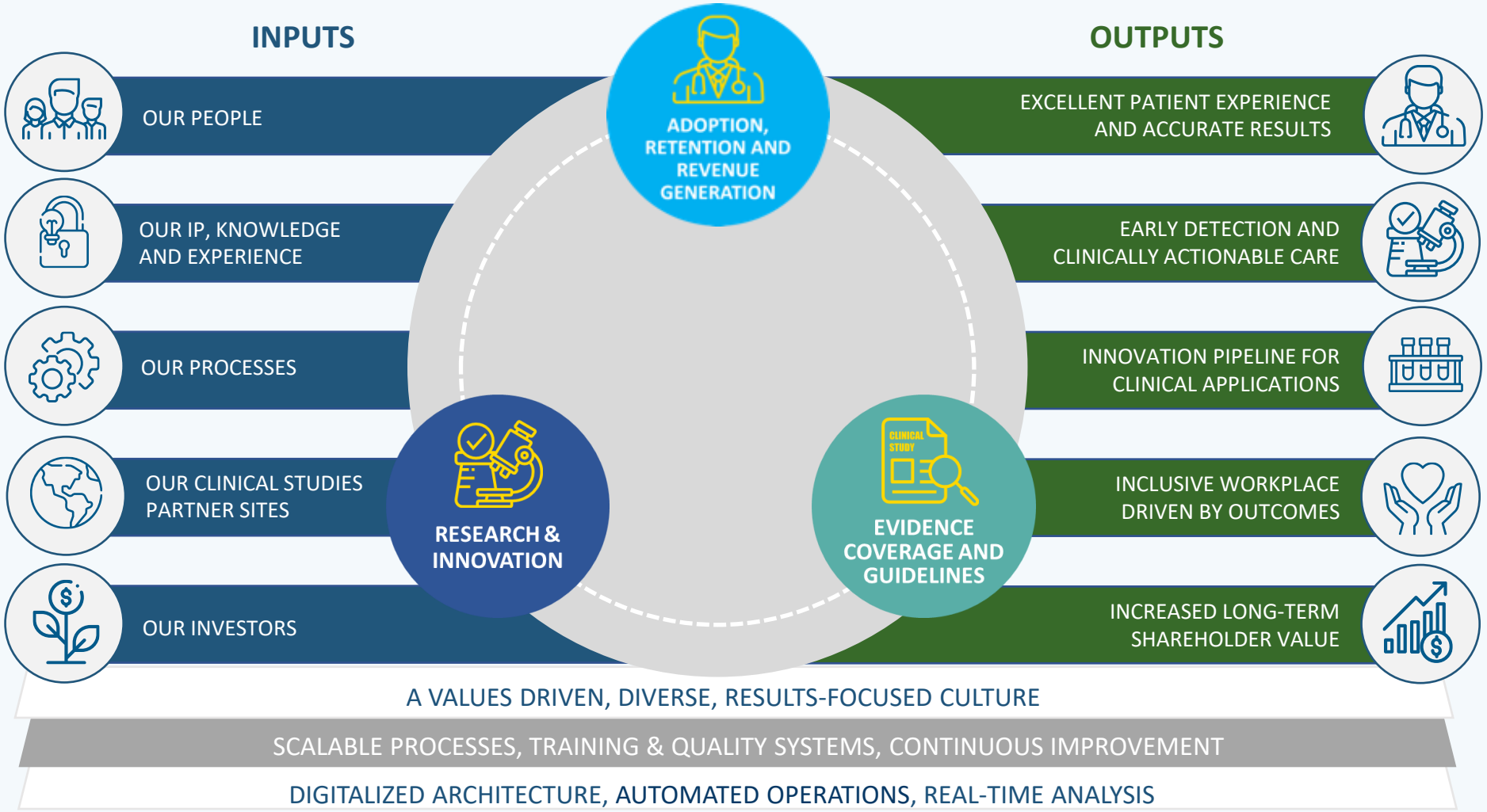
**$2.4M**
2H 26 CASH BURN/MONTH DOWN 27.7% ON 1H 26

31 March 2026 $7.8M Cash and cash equivalents[2] down 64.8% on $22.1M at Sept 2025

- Draft LCD[3] published 14 May 2026 proposes Triage and Triage Plus as the only tests appropriate for Medicare reimbursement; final LCD is estimated to be effective by Jan 2027; Pacific Edge has been advised that claim-by-claim reimbursement is appropriate for intermediate risk microhematuria patients
- FY26 operating revenue fell due to Medicare non-coverage determination; APAC shows steady growth on smaller volumes
- 2H 26 cash burn reduced through careful expense management; targeting a monthly average cash burn for FY27 of NZ$2.5m vs NZ$2.85m for FY26.
- $36.1 million capital raising closed to strengthen our balance sheet and drive revenue growth from claim-by-claim reimbursement

1. Total Laboratory Throughput (TLT) including commercial, pre-commercial and clinical studies testing
2. Cash, short-term deposits and term deposits
3. The draft LCD is titled 'Urine-based Biomarkers in Patients with Microhematuria'

# VALUE CREATION THROUGH THREE PILLARS



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# DRAFT LCD PROPOSES MEDICARE COVERAGE FOR TRIAGE AND TRIAGE PLUS

## NOVITAS[1] CONFIRMS PACIFIC EDGE CAN SUBMIT HEMATURIA TEST CLAIMS AS THEY ARE OUTSIDE PRIOR LCD[2]

EVIDENCE COVERAGE AND GUIDELINES



### FINALIZED LCD EXPECTED TO ACCLERATE PACIFIC EDGE'S PATH TO PROFITABILITY

- Novitas has issued a draft LCD *'Urine-based Biomarkers in Patients with Microhematuria'* (DL40378) supporting Medicare coverage of Cxbladder Triage and Triage Plus
- No other urine-based biomarkers are included in the draft coding article (DA60424) associated with the LCD, creating a moat around our microhematuria business
- US Customers can be shifted over to Triage Plus for:
  - Improved performance characteristics and clinical utility on a broader range of patient types
  - Greater reduction in unnecessary procedures further reducing costs to healthcare systems and payers
  - Greater revenue, margin and margin percentage per test
    - US$1,328 is a 75% revenue improvement over the US$760 for legacy products
- The clear language in the draft LCD increases likely reimbursement success from Medicare Advantage payers, Commercial payers and positive assessments from Data Curators/Assessors
- Triage and Triage Plus are eligible for claim-by-claim reimbursement with publication of the draft

*"Use of validated multi-analyte UBBs may be reasonable and necessary to support risk-stratification in appropriately counseled, intermediate-risk patients with MH who are considering deferral of cystoscopy."*

*- DRAFT LCD: 'Urine-based Biomarkers in Patients with Microhematuria' (DL40378)*

Medicare

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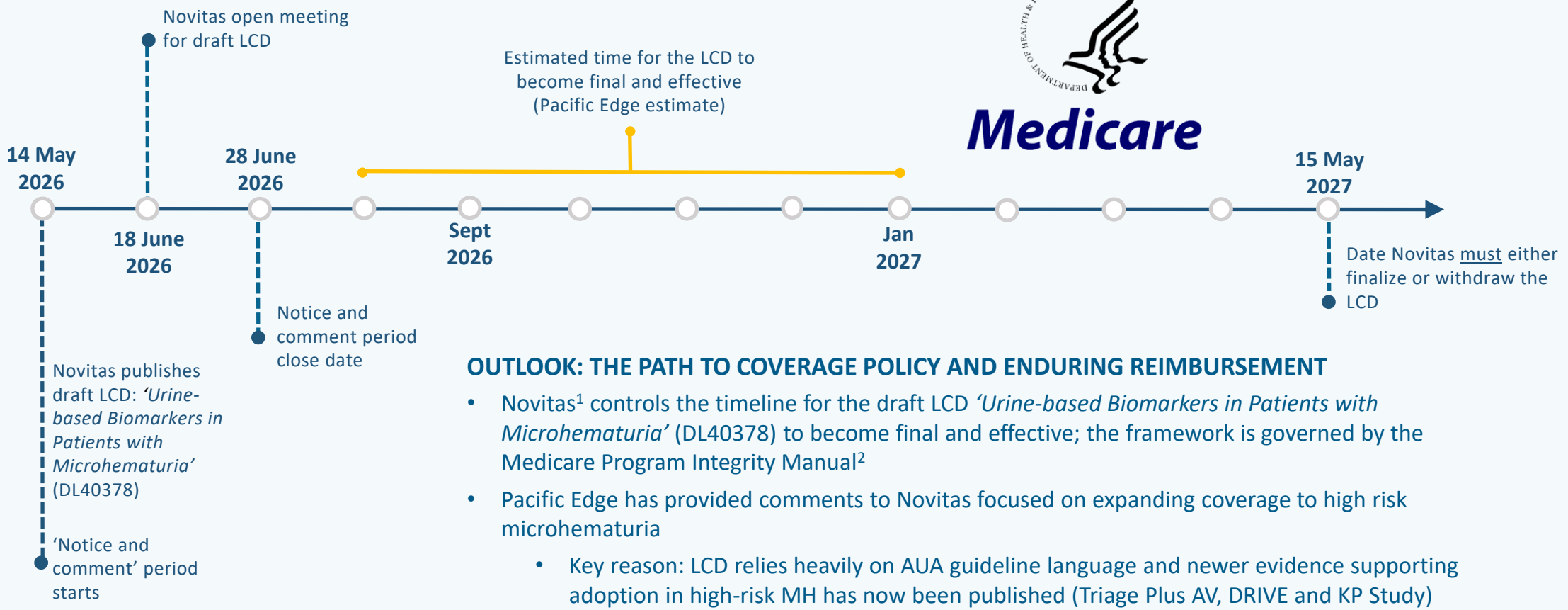
1. Novitas is the Medicare Administrative Contractor with responsibility for Pacific Edge's US laboratory
2. L39365 is the LCD "Genetic Testing in Oncology: Specific Tests' that contains a non-coverage determination for Cxbladder tests

# MEDICARE RE-COVERAGE TIMELINES

## DRAFT LCD RELEASED, FINAL COVERAGE ESTIMATED BY END OF 2026

EVIDENCE COVERAGE AND GUIDELINES






### OUTLOOK: THE PATH TO COVERAGE POLICY AND ENDURING REIMBURSEMENT

- Novitas[1] controls the timeline for the draft LCD *'Urine-based Biomarkers in Patients with Microhematuria'* (DL40378) to become final and effective; the framework is governed by the Medicare Program Integrity Manual[2]
- Pacific Edge has provided comments to Novitas focused on expanding coverage to high risk microhematuria
  - Key reason: LCD relies heavily on AUA guideline language and newer evidence supporting adoption in high-risk MH has now been published (Triage Plus AV, DRIVE and KP Study)
- Novitas must respond to all comments on the draft LCD and may take a maximum of 365 days from publishing of the draft to finalize, or withdraw, the LCD (15 May 2027)
- The finalized LCD becomes effective 45 days after being published

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1. Novitas is the Medicare Administrative Contractor with jurisdiction of Pacific Edge's lab in Pennsylvania, USA
2. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf

# DRIVING CLINICAL VALUE FOR PHYSICIANS, HOSPITALS AND PAYERS

## COMPELLING CLINICAL EVIDENCE CHANGES CLINICAL PRACTICE, MEDICAL POLICY 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 |
| **5. STRATA second publication** | - CU of Triage Plus (concordance[2]) | Q4 2026 |
| **6. AUSSIE Clinical Validation** | - CV of Triage Plus | Q3 2026 |
| **7. microDRIVE Clinical Validation** | - CV of Triage Plus | Q1 2027 |
| **8. Surveillance Plus Analytical Validation** | - AV of Surveillance Plus | Q2 2027 |
| **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 | Q3 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 clinical evidence required to drive behavior change in physicians
- Clinical evidence is generated within a framework of Analytical Validity (AV), Clinical Validity (CV) and Clinical Utility (CU)[1]
- AV, CV and CU are required to change physician behavior, payer policy and guideline recommendations
- The AV, CV and CU studies have clinically relevant patient populations with the endpoints and sample sizes required for coverage decisions and guideline inclusion
- On May 14, 2026, draft Medicare coverage for Triage & Triage Plus has been established on the strength of our AV, CV and CU evidence

Already published evidence

1. Clinical Utility (CU) - Evidence a test that can usefully change patient management within the context of care for the defined population and indication Clinical Validity (CV) - Evidence a test works in the same way on an independent eligible population for a given indication. Analytical validity (AV) - Evidence a test is repeatable in the lab for a given indication and population

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# INDEPENDENT STUDIES SUPPLEMENT OUR EVIDENCE PORTFOLIO

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




| INDEPENDENT STUDY FOCUS | INSTITUTION | TEST AND EVIDENCE TYPE | PUBLICATION DATE[1] |
|---|---|---|---|
| Real World Utility of Triage in MH: A Matched Cohort Study | Kaiser Permanente, US | CU Triage (RWE) | Q1 2026[2] |
| Patient preference and satisfaction of "biomarkers vs cystoscopy" | Mayo Clinic, US | CU Monitor | Q3 2026 |
| NZ Hematuria Pathway comparing T/D with Triage Plus on AUSSIE samples | Canterbury DHB | CU of Triage Plus | Q3 2026 |
| Retrospective concordance of Triage and Triage Plus in the Kaiser System | Kaiser Permanente, US | CU Triage Plus | 2027 |
| 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<br>CU Surveillance Plus | 2027 |
| Test utility in assessing response to BCG[3] in high-grade bladder cancer patients | University of Miami, US | CU Monitor<br>CU Surveillance Plus | 2027 |
| Test utility for the surveillance of MIBC[4] treated with bladder sparing methods (PRESERVE Trial) | Cleveland Clinic, US | CU Monitor<br>CU Surveillance Plus | 2028 |
| A Randomized Trial of Apalutamide in Non-Muscle Invasive Bladder Cancer | National Institutes of Health, US | CU Monitor<br>CU Surveillance Plus | 2029 |

Already published evidence

- Investigator initiated trials (IITs) are independent studies in which Pacific Edge typically provides free testing, so provide significant value at low cost
- IITs extend the evidence portfolio for new indications of existing tests and may inform new 'core' clinical trials
- IITs are an important part of Key Opinion Leader (KOL) engagement and generate publications or podium presentations that give profile to Cxbladder and Pacific Edge

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1. All dates are calendar year and our best current estimates
2. Filson et al (2026); Real-World Utility of Cxbladder Triage for Patients with Microhematuria: A Matched Cohort Study, Urology Practice® (2026), doi: 10.1097/UPJ.0000000000000972.
3. BCG: Bacillus Calmette–Guérin is a bacterium instilled into the bladder that triggers an immune response that targets and destroys cancer cells.
4. MIBC: Muscle Invasive Bladder Cancer

# MOUNTING POLICY MOMENTUM YET TO LIFT US VOLUMES

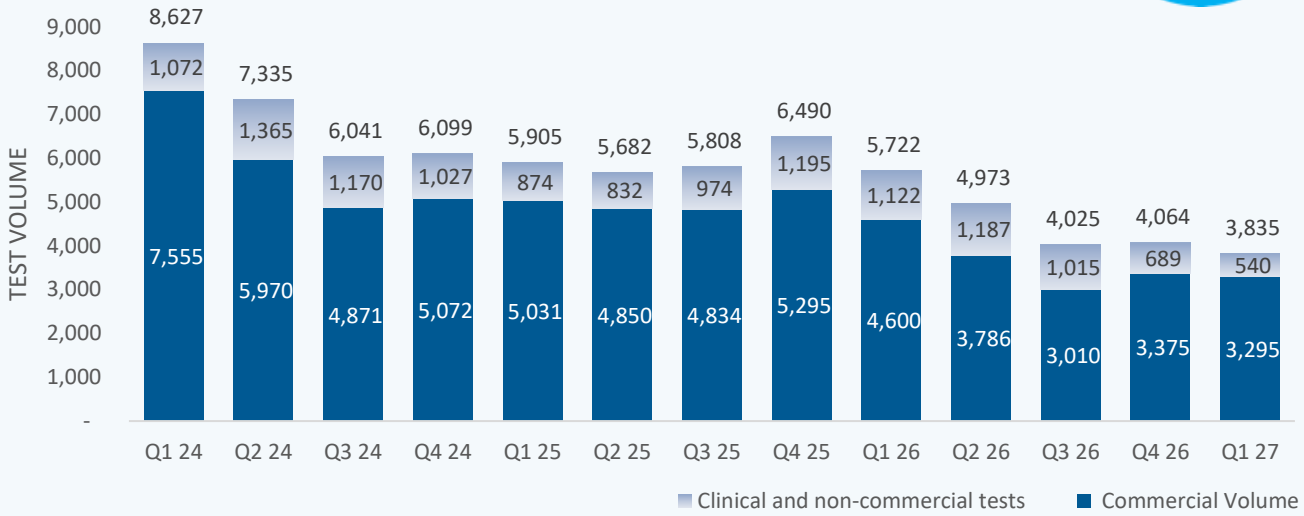
ADOPTION, RETENTION AND REVENUE GENERATION



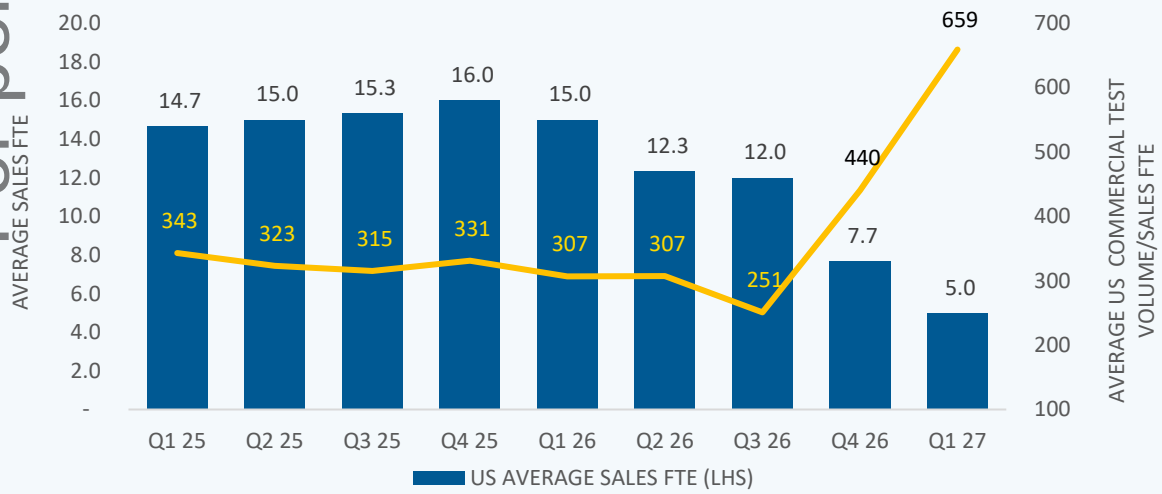
## TOTAL THROUGHPUT DOWN, SALES EFFICIENCY UP

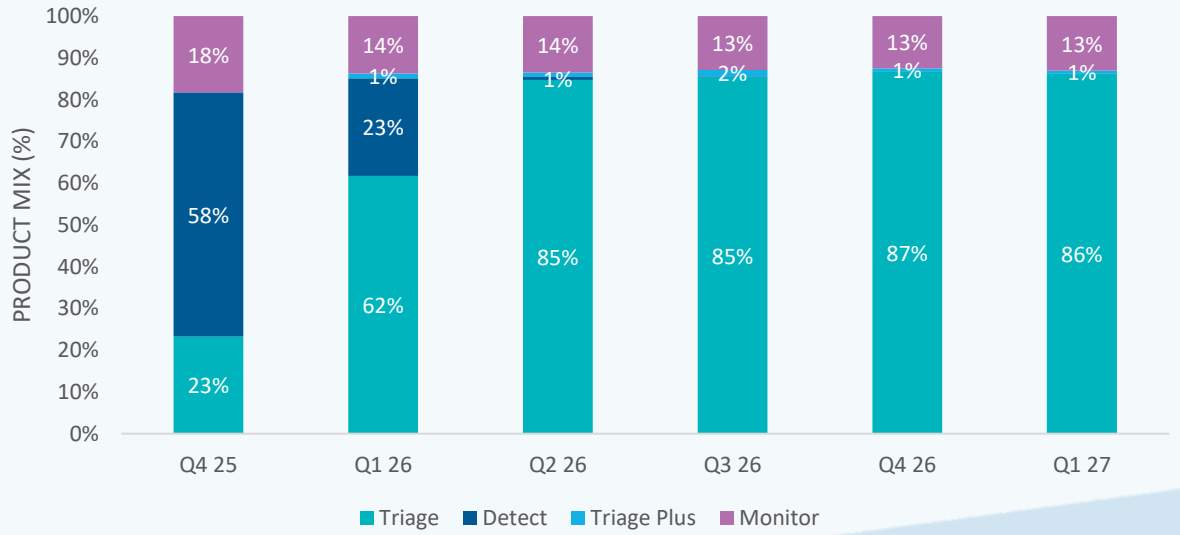
- US commercial operations challenged by Medicare non-coverage headwinds throughout FY26 and continued into Q1 27
- Commercial throughput holding steady for three consecutive quarters despite drop in Sales FTE in line with capital preservation goals ahead of Medicare policy
- Sales force efficiency metric (commercial test/FTE) increased from 440 in Q4 26 to 659 in Q1 27, principally due to head count reductions and increased Kaiser Permanente volumes
- Commercial product mix rapidly shifted from Detect to Triage in Q1 26

## US TOTAL TEST VOLUME[1] AND COMMERCIAL PRODUCT MIX




## US SALES FORCE EFFICENCY[2]




1. Total Laboratory Throughput in Asia and Pacific including commercial, pre-commercial and clinical studies testing
2. Pacific Edge has previously used Total Lab Throughput, but has changed its reporting to focus on Commercial throughput, which accounts for the differences in reported figures compared to previous quarterly and half yearly reporting

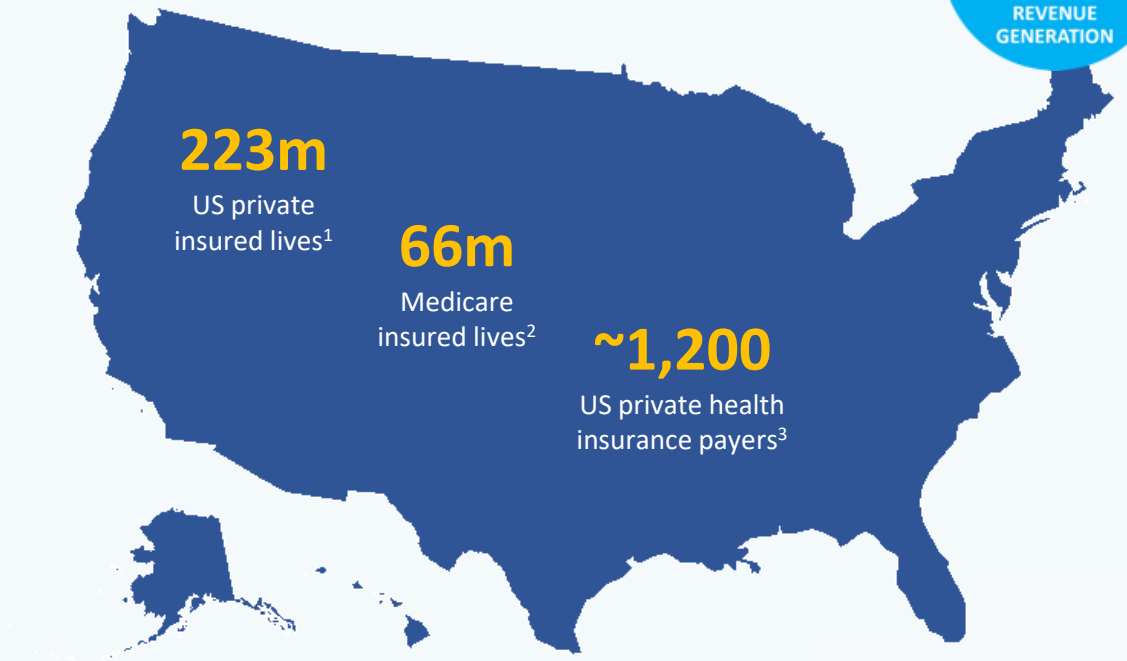
# US COMMERCIAL PAYERS: MEDICARE POLICY EXPECTED TO UNLOCK VOLUMES



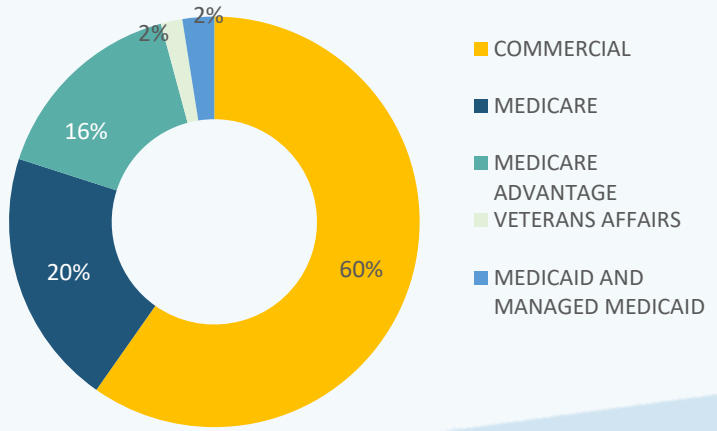
ADOPTION, RETENTION AND REVENUE GENERATION

## THE US PRIVATE HEALTH INSURANCE MARKET IS A LARGE OPPORTUNITY

- Commercial payers are a significant opportunity covering almost four times more lives than Medicare
- Microhematuria patients skew younger with commercial health insurance, thus represent most of the total serviceable market for hematuria evaluation
- Final coverage policy from Medicare is expected to unlock revenue from Commercial Payers by:
  - Removing a key reason to deny reimbursement
  - Providing additional evidence to overturn denials on appeal
  - Providing language that commercial payers can adopt in their own policies
  - Leveraging State Biomarker Laws to mandate payment from commercial payers
- We focus on establishing medical policy directly with payers or through third parties like Avalon, EviCore, Carelon, Concert Genetics and ECRI[4]




## PACIFIC EDGE PAYER MIX (2H 26)

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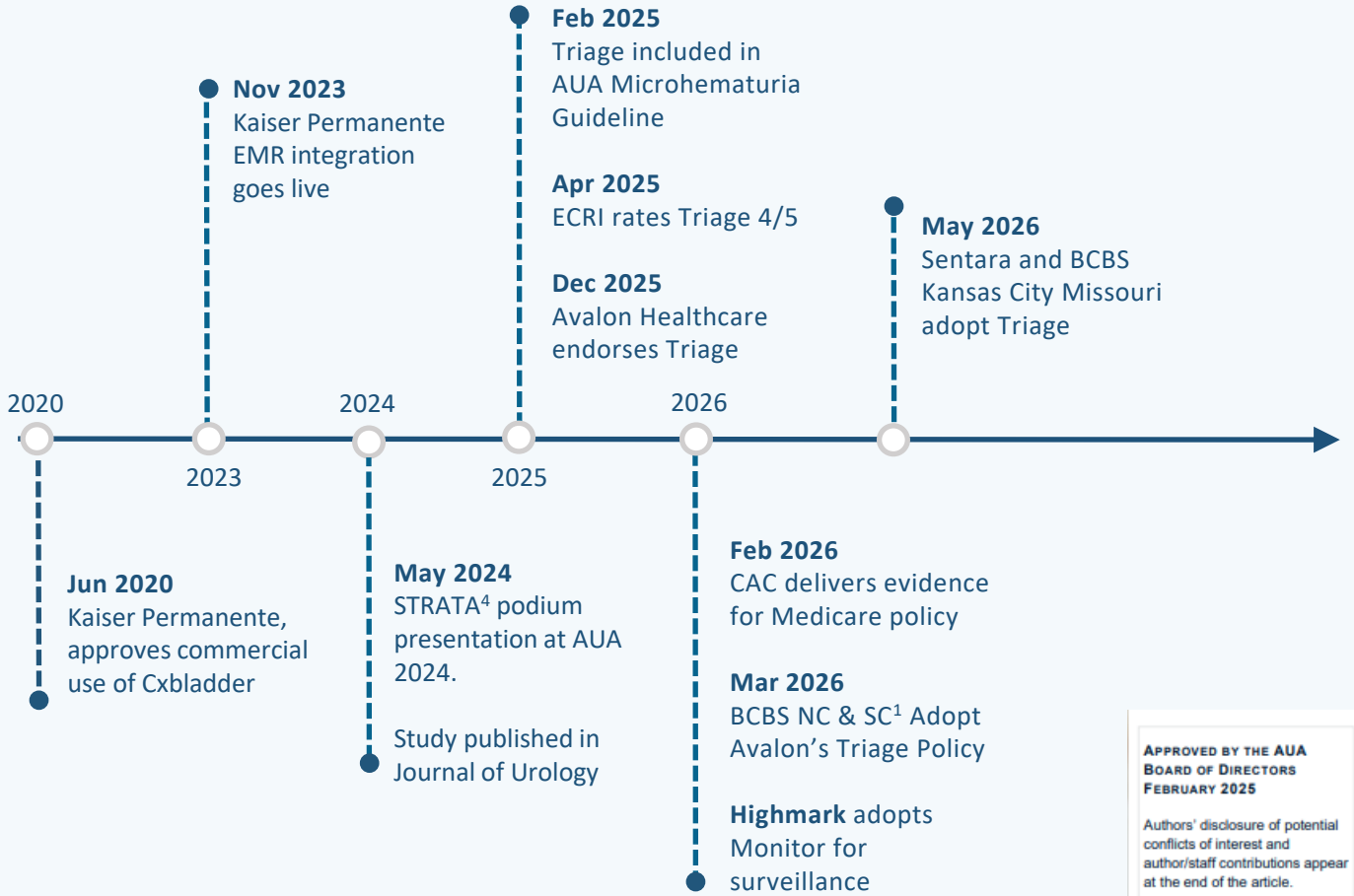
1. https://www.census.gov/library/publications/2025/demo/p60-288.html
2. https://www.medicare.gov/about-us
3. https://content.naic.org/sites/default/files/2024-annual-health-industry-commentary.pdf
4. ECRI is the Emergency Care Research Institute

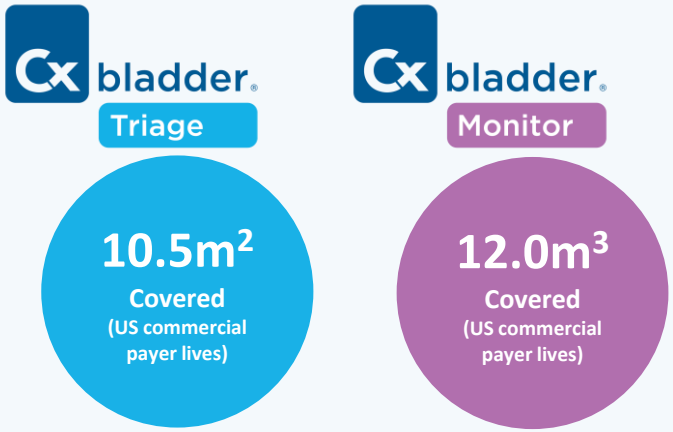
# BUILDING U.S. COMMERCIAL PAYER MOMEMTUM

## MEDICARE COVERAGE UNLOCKS FURTHER COMMERCIAL PAYER POLICY

ADOPTION, RETENTION AND REVENUE GENERATION






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.



**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*

1. BCBS NC & SC are the Blue Cross Blue Shield plans of North Carolina and South Carolina
2. Includes Kaiser SoCal, BCBS NC, SC & Kansas City and Sentara
3. Includes Kaiser SoCal, Highmark
4. Lotan Y, Daneshmand S, Shore N, Black P, Scarpato KP, Patel A, Lough T, Shoskes DA, Raman JD. A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. J Urol 2024. doi: 10.1097/JU.0000000000003991

PacificEdge® CANCER DIAGNOSTICS

# TARGETING INTERMEDIATE RISK MICROHEMATURIA PATIENTS

## LARGE INTERMEDIATE RISK POPULATION IS NUANCED TO ACCESS

ADOPTION, RETENTION AND REVENUE GENERATION



### SEX ASSIGNED AT BIRTH FOR HEMATURIA PATIENTS[3]

| PATIENT | FEMALE | MALE |
|---|---|---|
| Low risk | 80% | 20% |
| Intermediate risk | 75% | 25% |
| High risk | 34% | 66% |

### TARGETING INTERMEDIATE RISK MICROHEMATURIA PATIENTS

- Intermediate risk hematuria (IRMH) patients are predominantly female
- IRMH patients often stay at primary care, or are triaged at secondary care before seeing a general urologist by APPs, NPs or PAs[1]
- In addition to general urology, IRMH patients are commonly seen by URPS, urogyns, OBGYN and FPMRS[2]
- Consequently, Pacific Edge intends to focus on:
  - Integrated Delivery Networks – health systems that are integrated between primary and secondary care
    - Hospital Systems
    - Academic Institutions
    - Veterans Association
  - APPs, NPs and PAs at general urology practices
  - Female-specific specialties like uro-gyns, OBGYNs, URPS & FPMRS

PacificEdge® CANCER DIAGNOSTICS

1. APPs are Advanced Practice Providers, NPs are Nurse Practitioners and PAs are Physicians Assistants
2. URPS is Urogynaecology and Reconstructive Pelvic Surgery, urogyn is urogynaecologist, OBGYN is Obstetrician-Gynaecologist and FPMRS is Female Pelvic Medicine and Reconstructive Surgery
3. Management estimates derived from referred hematuria data in Woldu et al (2021). See Slide 37-39 for details

# INTERMEDIATE RISK MICROHEMATURIA SALES APPROACH

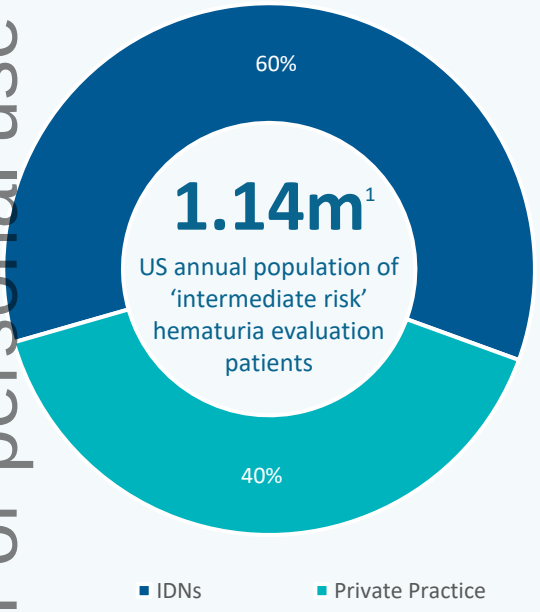
## INTEGRATED DELIVERY NETWORKS ARE THE TOP TARGET FOR INTERMEDIATE RISK MICROHEMATURIA

ADOPTION, RETENTION AND REVENUE GENERATION



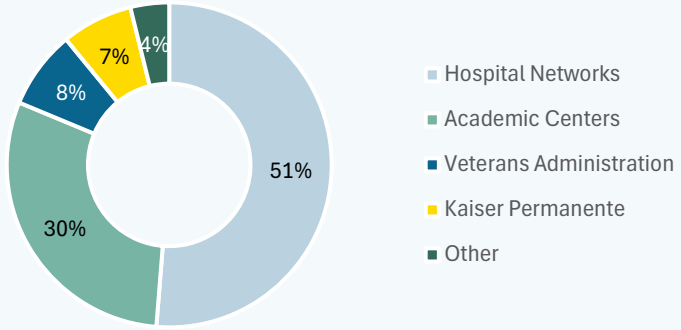
### HEALTHCARE PROVIDER TYPE

(SHARE OF PATIENT VOLUME)[3]



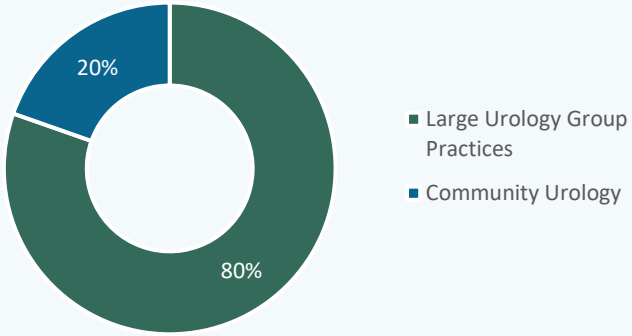

### INTEGRATED DELIVERY NETWORKS

(SHARE OF PATIENT VOLUME)[3]




### PRIVATE PRACTICE

(SHARE OF PATIENT VOLUME)[3]




### US COMMERCIAL SALES OPERATIONS

- **Strategic Accounts** focused on IDNs
  - Up to 1,000 strategic accounts including 130 Academic Hospitals, 170 VA medical centers and 18 VISNs[2]
  - Integrated primary and secondary care, capitated with centralized decision making on adoption of clinical pathways
  - Focused on selling clinical pathways to deliver Cxbladder clinical utility, health economics and minimize reimbursement denials
  - Generally, will require/desire EMR integrations
  - Longer sales cycle with stickier revenue once pathways are implemented
- **Specialty Sales** focused on Community Practice and LUGPAs
  - 35-45% of the urology patients are seen in community practice or LUGPA clinics across the US
  - **Community Urology:** Practice-level decision making; short sales cycle; procedure driven; limited opportunity for pathways, but may benefit from Customer Portal aligned with pathways
  - **LUGPA Clinics:** Practice-level decision making within LUGPAs; short sales cycle; procedure driven; limited opportunity for pathways
  - **LUGPAs:** May offer some centralized decision making across multiple LUGPA Clinics; longer sales cycle; procedure driven; potential opportunity for pathways with EMR and/or pathology lab integrations

PacificEdge® CANCER DIAGNOSTICS

1. Management estimates derived from referred hematuria data in Woldu et al (2021). MH estimated at 80% and GH at 20%. MH Risk categories: Low 7%, Intermediate 41%, High 52%. See slides 37-39 for details.
2. VISN stands for Veterans Integrated Service Network
3. Share of patient volume figures are management estimates

# IMPLEMENTING CLINICAL PATHWAYS AT INTEGRATED DELIVERY NETWORKS

## HELPING IDNs TO SAFELY REDUCE PATIENTS SEEN BY UROLOGISTS AND UNNECESSARY PROCEDURES

ADOPTION, RETENTION AND REVENUE GENERATION



**PATIENT PRESENTS WITH HEMATURIA**

Exclude benign reasons for hematuria

- UTI[1]
- Kidney stones
- Kidney disease
- BPH[2]
- Prostatitis

**HIGH RISK EXCLUSIONS**

Must answer **'No'** to all:

- Male Aged ≥ 60 yrs
- History of gross hematuria in the past 12 months
- Heavy smokers (> 30 pack/yrs)
- ≥ 25 RBC/HPF3
- Surgically altered bladder or neobladder

If **'Yes'** to any question, refer to cystoscopy

**DEFERRAL CRITERIA**

Must answer **'No'** to all:

**Two-week** deferral:

- Active UTI
- Cystoscopy
- Catheterization
- Urethral lesion

**Six-week** deferral:

- Pelvic radiation therapy

cxbladder Triage Plus

**PATIENT MANAGEMENT**

**Low risk**
- Defer cystoscopy
- Repeat UA in 12 months

**Intermediate risk**
- Cystoscopy
- Renal ultrasound

**High risk**
- Cystoscopy
- CT Urogram

### CXBLADDER TRIAGE OR TRIAGE PLUS MICROHEMATURIA CLINICAL PATHWAY – A WIN FOR IDNs AND PACIFIC EDGE

- AUA guidelines, Medicare coverage and commercial payer coverage provide the foundation for selling clinical pathways to IDNs
- Safely reduce urology specialist engagement and unnecessary procedures (cystoscopy, ultrasound, CT urogram)
- Aligned with clinician financial incentives (RVUs[4]) within IDN incentive structures
- Improve the patient experience - reduced wait times, fewer invasive procedures and improves overall service quality
- Revenue from clinical pathway implementation is more reliable and predictable based on the inclusion criteria of the clinical pathway

PacificEdge® CANCER DIAGNOSTICS

1. UTI is a urinary tract infection
2. BPH is Benign Prostate Hyperplasia, an enlarged prostate
3. RBC/HPF is a measure of the red blood cell count under a high-power field microscope
4. RVU is a relative value unit, and how IDNs structure incentives for physicians

# KAISER PERMANENTE: A PARTNERSHIP WITH ONE OF THE LARGEST US PRIVATE PAYERS

PILOT STUDY WITH KAISER PERMANENTE MID-ATLANTIC POINTS TO THE LARGER OPPORTUNITY

ADOPTION, RETENTION AND REVENUE GENERATION



## KAISER PERMANENTE – REAL WORLD CLINICAL AND ECONOMIC VALUE

- KP SoCal[1] has 4.9 million members. The broader Kaiser system has 12.6 million members
- KP SoCal is contracted for Triage and Monitor and implemented electronic ordering through their HealthConnect EMR in 2023; all 15 sites ordering
- Pacific Edge is working with KP to drive volume growth within KP SoCal
- Pacific Edge has recently entered into an agreement with KP Mid-Atlantic[2] (~800,000 members) for a pilot study with a Triage protocol that mirrors KP SoCal
- The partnership with KP has delivered unique compelling real-world evidence for Triage; new studies are expected to deliver similar value for Triage Plus


KAISER PERMANENTE

### LARGEST EVER CLINICAL STUDY OF URINE-BASED BIOMARKERS FOR HEMATURIA EVALUATION

| | |
|---|---|
| **3,353** | risk-matched patients for indisputable statistical power |
| **~80%** | of patients identified as low probability by Cxbladder Triage |
| **952** | cystoscopies avoided (284 per 1,000 referrals for hematuria) & 70 CTs avoided (21 per 1,000 referrals) |

**No difference** in overall cancer detection rates between those who received the Triage test (0.33%) and their matched cohort (0.6%) (p=0.105)

1. KP SoCal refers to the Southern California Permanente Medical Group
2. KP Mid-Atlantic refers to the Mid-Atlantic Permanente Medical Group

PacificEdge® CANCER DIAGNOSTICS

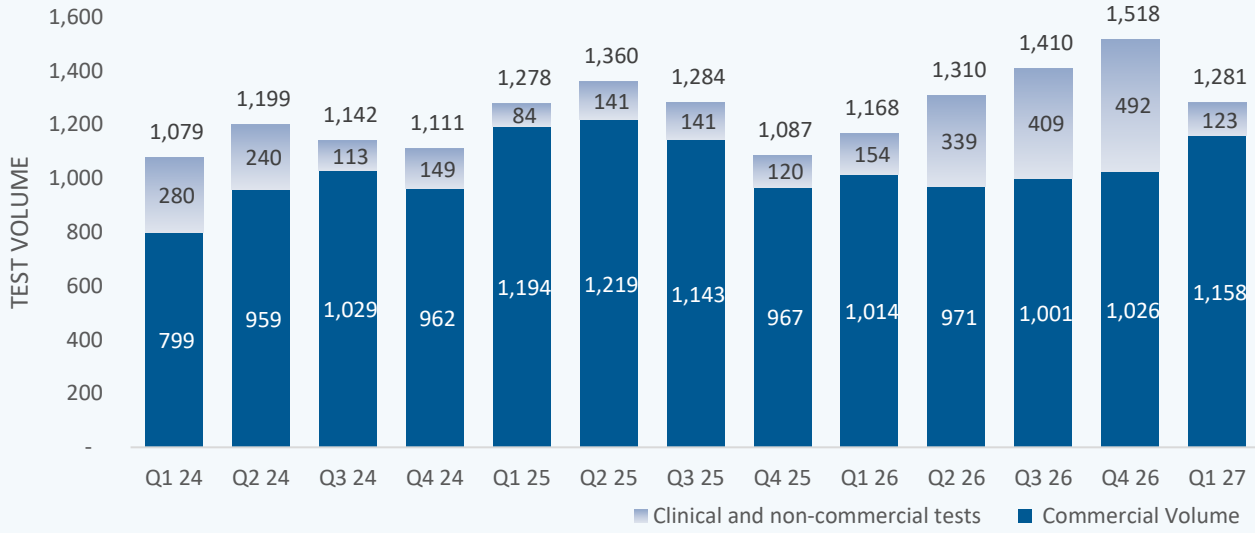
# APAC CHARTING A PATH TO PROFITABILITY

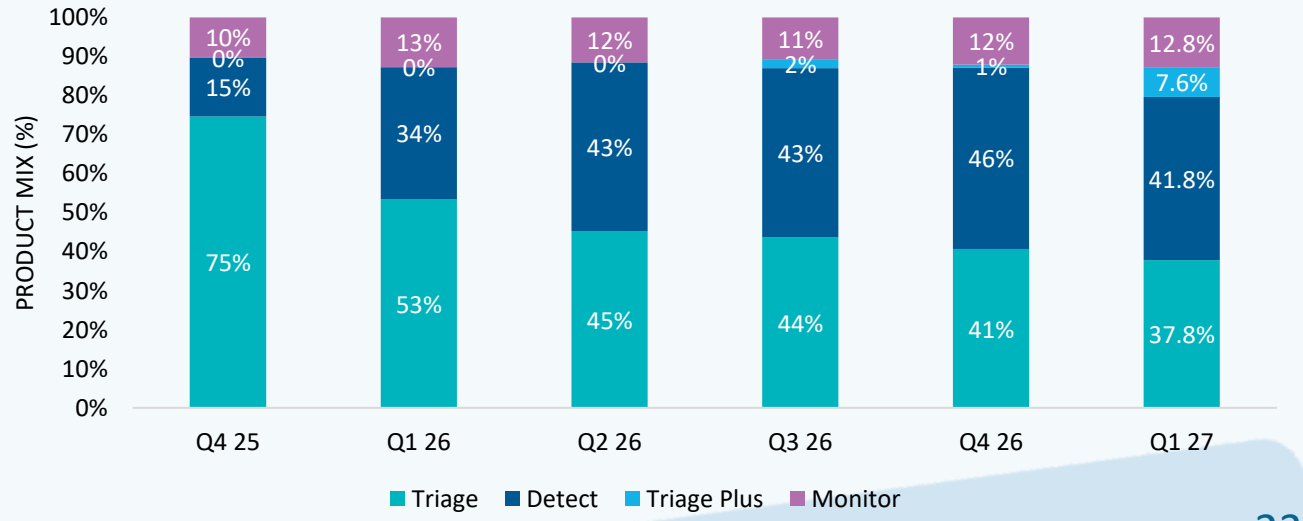
ADOPTION, RETENTION AND REVENUE GENERATION

## APAC COMMERCIAL

- APAC revenue was $2.0m in FY26 and contributed 19% of operating revenue in 2H 26, an increase from 8% in FY25
- APAC Commercial and Clinical Operations (excluding R&D costs) is trending towards profitability (on a direct cost basis) with a cash burn rate of $0.17m for Q1 of FY27, which is a:
  - ~9% improvement on the cash burn rate vs Q4 FY26
  - ~15% improvement on the cash burn rate vs Q1 FY26
- Repricing in 2025 created on average 25% more revenue per test
- Triage Plus increased to 8% of product mix in Q1 27
  - Triage Plus has the potential for ~20% more revenue per test


## APAC TOTAL TEST VOLUME[1] AND COMMERCIAL PRODUCT MIX




1. Total Laboratory Throughput in Asia and Pacific including commercial, pre-commercial and clinical studies testing
2. MSAC: Medical Services Advisory Committee: advises on public funding for health services for Australian Medicare reimbursement

# CONSOLIDATING NEW ZEALAND AND DEVELOPING AUSTRALIA AND ASIA

ADOPTION, RETENTION AND REVENUE GENERATION

## NEW ZEALAND: SEEKING A NATIONAL HEMATURIA EVALUATION PATHWAY

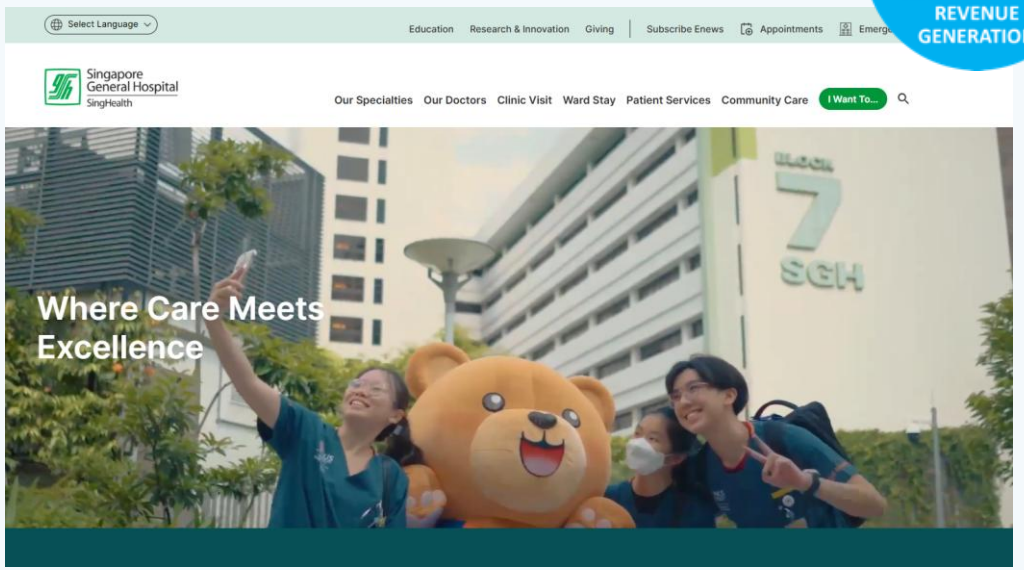
- ~70% of New Zealanders have access to Cxbladder testing
- Cxbladder is under consideration for nationally funded clinical pathway for hematuria evaluation with *Te Whatu Ora.* Funding has yet to be approved

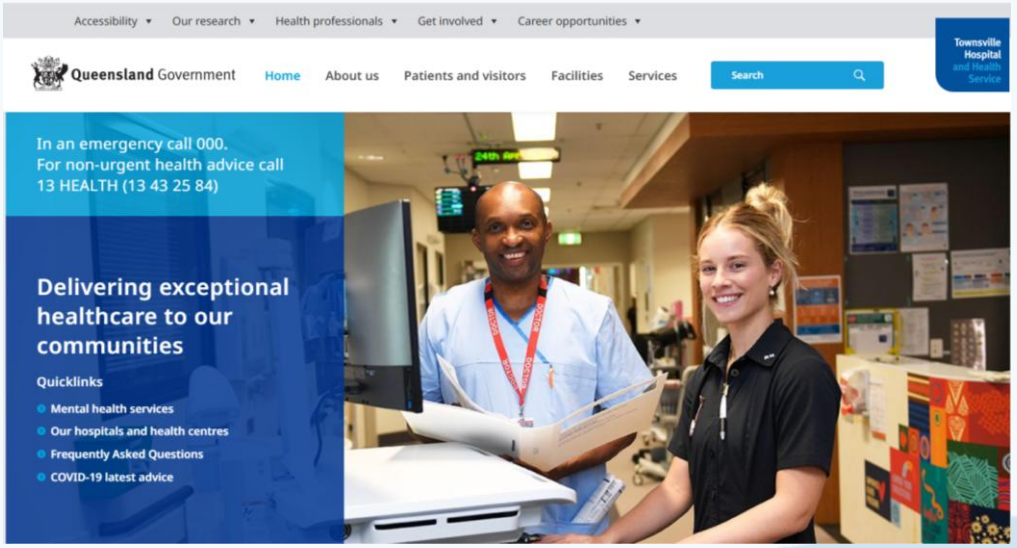
## ASIA: BUSINESS DEVELOPMENT WITH EARLY WINS

- In Asia we are establishing a network of lab partners for in-market promotion of our testing services
- We have processed commercial samples from seven[1] markets, selling either directly or through a distributor/lab partner
- Singapore General Hospital implemented the first clinical pathway for Cxbladder products in March 2026
- Longer-term strategy involves deploying kit-based IVDs through the lab partner network

## AUSTRALIA: BUSINESS DEVELOPMENT WITH HOSPITAL CONTRACTING

- In Australia we are focused on contracting with individual hospitals that have evaluated Cxbladder
- Northern Hospital and Townsville have established clinical pathways for Cxbladder products
- MSAC[2] reimbursement requires Cxbladder tests to be run in Australia
  - When developed, kit-based IVDs for Cxbladder can be run by partner labs in Australia




1. The seven countries are: Singapore, Hong Kong, Philippines, Brunei, Malaysia, Taiwan and Thailand
2. MSAC: Medical Services Advisory Committee: advises on public funding for health services for Australian Medicare reimbursement

# RESEARCH, DEVELOPMENT AND INNOVATION

## IDENTIFYING MARKETS WHERE WE HAVE A CREDIBLE RIGHT TO WIN

RESEARCH & INNOVATION



RESEARCH & INNOVATION

INTELLECTUAL PROPERTY

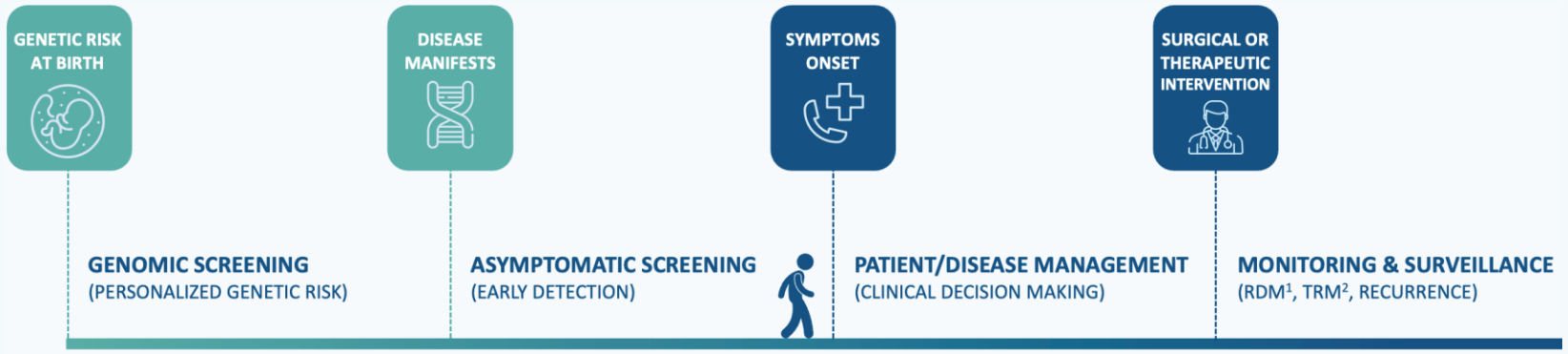
TECHNOLOGY

PRODUCT

COMMERCIALIZATION

**THE MOLECULAR DIAGNOSTICS VALUE CHAIN LEADS OUR SEARCH FOR UNMET NEEDS**

- **Identify and develop substantial market opportunities** where an **unmet clinical need** can be addressed through non-invasive molecular biomarker tests where we have a **credible right to win**
- **Generate compelling clinical evidence** that turns IP/Technology/Products into clinically validated molecular tests for guideline inclusion and payer coverage
- **Commercialize clinically validated products** to institutional, community and primary healthcare providers that require physician "behavior change" supported by ancillary innovations in digital connectivity, 'big data', CRM, 3PL and PIHSS[3]




PacificEdge® CANCER DIAGNOSTICS

1. RDM: Residual Disease Monitoring
2. TRM: Therapeutic Response Monitoring
3. CRM: Customer Relationship Management Systems; 3PL: Third Party Logistics; PIHSS: Patient in Home Sampling System

# NEXT GENERATION PRODUCTS ALREADY DELIVERING STRATEGIC VALUE

## TRIAGE PLUS AND SURVEILLANCE PLUS OFFER SUPERIOR PERFORMANCE, PRICING AND MARGIN

RESEARCH & INNOVATION



- **Cxbladder Triage Plus has been analytically validated and clinically validated for all hematuria patients (MH and GH)**
  - Triage Plus has provisional patents filed, AV published, CV published, priced at US$1,328/ test by Medicare, and draft coverage has been proposed by Novitas
  - The US$1,328 price strengthens the economics of operating an Account Executive and the future profitability profile of the company
  - We are seeking to have Triage Plus added to the AUA microhematuria guideline alongside Triage at the next update (not expected to start until mid-2027)
- **Cxbladder Surveillance Plus tests for recurrent disease in NMIBC[1] patients**
  - Surveillance Plus is in development focused on multiple types of DNA markers using ddPCR[2]; AV and CV are expected to be published in early FY28
  - Surveillance Plus has completed a 'Freedom to Operate' analysis, and provisional patenting is in progress
  - Pacific Edge is targeting to submit Surveillance Plus for a CPT-PLA code by 9 December 2026. If that date is achieved, Pacific Edge currently expects claim-by-claim reimbursement from July 2027 once Novitas adds the code to A58917 at local provisional pricing
  - This may lead to additional US revenue during FY28 while seeking a pricing crosswalk for Surveillance Plus to a US$1,800 ddPCR test and LCD coverage from Novitas

Cx bladder® Triage Plus

Cx bladder® Surveillance Plus

PacificEdge® CANCER DIAGNOSTICS

1. NMIBC is non-muscle invasive bladder cancer
2. ddPCR is droplet digital Polymerase Chain Reaction

# 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)
  - Prototype development plan is in place and ready to be implemented subject to budget approval

*Clinical Lab Scientist Jolene Mok (left) Chief Scientific Officer Parry Guilford (center) and Chief Technology Officer Justin Harvey (right)*

Pacific Edge® 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

# FY26 FINANCIAL PERFORMANCE



PacificEdge®
CANCER DIAGNOSTICS

# POSITIONING PACIFIC EDGE FOR MEDICARE RE-COVERAGE

## COST SAVINGS MINIMIZE CASH BURN



| Financial Period ($000) | 2H 26 (Unaudited) | 1H 26 (Unaudited) | FY26 (Audited) | FY25 (Audited) | 2H 26 vs 1H 26 | FY26 vs FY25 |
|---|---|---|---|---|---|---|
| Operating Revenue | $5,560 | $5,939 | $11,499 | $21,846 | (6.4%) | (47.4%) |
| Total Revenue | $6,457 | $7,123 | $13,580 | $24,616 | (9.3%) | (44.8%) |
| Operating Expenses | $23,119 | $26,239 | $49,358 | $54,552 | (11.9%) | (9.5%) |
| **Net Loss After Tax** | **($16,662)** | **($19,116)** | **($35,778)** | **($29,936)** | **(12.8%)** | **19.5%** |
| Cash Receipts from Customers | $5,245 | $7,985 | $13,230 | $21,572 | (34.3%) | (38.7%) |
| Net Cash Flows to Operating Activities | ($12,912) | ($19,026) | ($31,938) | ($24,740) | (32.1%) | 29.1% |
| **Net Cash[1]** | **$7,776** | **$22,121** | **$7,776** | **$22,568** | **(64.8%)** | **(65.5%)** |
| Monthly Cash Burn (NZ$m) | $2.4 | $3.3 | $2.9 | $2.3 | (27.7%) | 23.4% |

- Operating revenue fell after loss of Medicare and Medicare Advantage coverage and reduced test volumes
- We have not accrued revenue from Medicare tests during FY26 while we pursue the appeals strategy
- We continue to maintain a US market presence that positions the company for regaining Medicare coverage, while focusing on reducing operating expenses, which fell 11.9% in 2H 26 against 1H 26
- Sales force reductions and other capital saving measures have cycled through from 1H 26 into 2H 26, with 2H 26 monthly cash burn 27.7% lower than 1H 26
- Secured $20.7 million in new equity in August 2025
- Secured $36.1 million in new equity in May 2026 ($25.4 in placement, $10.7 million Retail Offer)

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

# OPERATING EXPENSES

## ALL COSTS REDUCED WITH LARGEST REDUCTION IN SALES AND MARKETING

| Financial Period ($000)[1] | 2H 26 (Unaudited) | 1H 26 (Unaudited) | FY26 (Audited) | FY25 (Audited) | 2H 26 vs. 1H 26 | FY26 vs. FY25 |
|---|---|---|---|---|---|---|
| Laboratory Operations | $5,722 | $5,884 | $11,606 | $12,490 | (2.8%) | (7.1%) |
| Research | $6,366 | $7,065 | $13,431 | $14,631 | (9.9%) | (8.2%) |
| Sales and Marketing | $6,765 | $8,453 | $15,218 | $17,530 | (20.0%) | (13.2%) |
| General Administration | $4,266 | $4,837 | $9,103 | $9,901 | (11.8%) | (8.1%) |
| **Total operating expenses** | **$23,119** | **$26,239** | **$49,358** | **$54,552** | **(11.9%)** | **(9.5%)** |

Operating expenses have reduced by 9.5% on FY25 through careful expense management targeting capital preservation

- Laboratory Operations expense decrease of 7.1% on FY25 driven by decreased testing volumes.
- Research expenses reduced by 8.2% on FY25 with reduced clinical studies costs incurred as studies reach conclusion during FY26
- Sales and Marketing expenses down 13.2% on FY25 as the focus shifts to profitable sales, reducing US sales FTE
- General and Administration expenses down 8.1% in line with capital preservation initiatives across the business

# OUTLOOK



PacificEdge®
CANCER DIAGNOSTICS

# OUTLOOK

## POSITIONED TO UNLOCK VALUE THROUGH UPCOMING COMMERCIAL, CLINICAL AND INNOVATION MILESTONES



### COMMERCIAL CATALYSTS FOR NEAR-TERM VALUE CREATION

- Draft LCD (DL40378) proposes coverage for Triage and Triage Plus for intermediate risk microhematuria patients
- Claim-by-claim reimbursement for Triage and Triage Plus for intermediate risk microhematuria in alignment with DL40378
- Progressively phasing in Triage Plus at US$1,328 to US customers accelerates path to profitability while saving costs for healthcare systems
- Advancing medical policy for Triage with commercial payers, leveraging the draft LCD, AUA Guideline, ECRI[1] review and Avalon policy
- Cxbladder is under consideration by Health New Zealand for a National Pathway in FY27

### CLINICAL EVIDENCE DRIVES MEDIUM-TERM VALUE CREATION

- DRIVE publication[2] supports Triage Plus validity; awaiting "updated literature review" by AUA for subsequent guideline inclusion
- Kaiser Permanente study shows real world evidence for Cxbladder Triage in largest urine-based biomarker study of hematuria patients
- Evidence generation program delivers stepwise milestones for sustained shareholder value
- Draft LCD, AUA (Grade A Evidence), ECRI[2] (4/5 Evidence) and Avalon (Covered) have created the precedent for turning Cxbladder evidence into robust medical policy
- BCBS[3] NC, BCBS SC, BCBS Kansas City and Sentara have adopted commercial payer policy for Triage

### INNOVATION DRIVES LONG-TERM VALUE CREATION

- Next generation products demonstrate superior performance that underpins greater clinical indications, improved patient experience, healthcare system cost savings and is expected to substantially improve unit economics
- Targeting CPT-PLA coding submission for Surveillance Plus in December 2026 seeking claim-by-claim revenue after July 1, 2027
- Seeking US$1,800 for Surveillance Plus with provisional local pricing from Novitas and final pricing via crosswalk during FY28
- Ongoing investment in product simplification and kitted IVD products to enable de-centralized international deployment

PacificEdge® CANCER DIAGNOSTICS

1. ECRI is the Emergency Care Research Institute
2. 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.
3. BCBS is Blue Cross Blue Shield

# APPENDIX



PacificEdge®
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# THE CXBLADDER SUITE

| | Hematuria Evaluation | | | NMIBC[1] Surveillance | |
|---|---|---|---|---|---|
| **Cxbladder Product** | **Triage** | **Detect** | **Triage Plus** | **Monitor** | **Surveillance Plus** |
| **Product Summary** | Risk stratification of microhematuria patients to rule out the majority of those patients from further workup for bladder cancer | Adjunctive use with cystoscopy on hematuria patients to resolve diagnostic dilemmas (e.g. equivocal cystoscopy and atypical cytology) | Risk stratification and adjunctive use on any hematuria patient with improved performance over Triage and Detect | Alternative to cystoscopy for NMIBC patients undergoing surveillance for recurrence | Alternative to cystoscopy for NMIBC patients undergoing surveillance for recurrence. Currently in development, showing improved performance |
| **Analytical composition** | 5 RNA biomarkers + patient clinical factors | 5 RNA biomarkers | 5 RNA biomarkers + 6 DNA SNVs from 2 genes (FGFR3/ TERT) | 5 RNA biomarkers + patient tumor history | 13 SNVs across 5 genes<br>2 fusions associated with 1 gene<br>1 methylation marker<br>2 control markers |
| **Test Performance** | Hematuria[2]<br>Sn: 95%<br>Sp: 45%<br>NPV: 99%<br>PPV: N/A | Hematuria[3]<br>Sn: 82%**<br>Sp: 94%*<br>NPV: 97%**<br>PPV: 68%* | Hematuria[4]<br>Sn: 93.6%****<br>Sp: 98.2%***<br>NPV: 99.4%****<br>PPV: 74.6%*** | All risk groups[5,6]<br>Sn: 93%<br>Sp: N/A<br>NPV: 97%<br>PPV: N/A | All Risk Groups<br>Sn: Not yet published<br>Sp: Not yet published<br>NPV: Not yet published<br>PPV: Not yet published |
| **When is it used?** | Prior to cystoscopy | Prior to cystoscopy / as an adjunct / 3 weeks post cystoscopy | | As a non-invasive surveillance alternative | |
| **Commercially available?** | ✓ | ✓ | Commercially available in APAC and under “early access” in US, pending coverage | ✓ | CPT-PLA code targeted for Dec 2026<br>Reimbursed on A58917 in Jul 2027 |
| **Medicare Pricing (USD)** | **$760** | **$760** | **$1,328** | **$760** | **$1,800 (seeking by crosswalk)** |

* When higher 0.23 cut point on test report is used
** When lower 0.12 cut point on test report is used
*** When higher 0.54 cut point on test report is used
**** When lower 0.15 cut point on test report is used

1. NMIBC: non-muscle invasive bladder cancer
2. Kavalieris et al. (2015) A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to triage out patients presenting with hematuria who have a low probability of urothelial carcinoma. BMC Urol 2015;15:23.
3. O’Sullivan et al. (2012) A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. J Urol 2012; 188:741–7.
4. Harvey et al. (2025) Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Hematuria Patients for Urothelial Carcinoma. Diagnostics. 2025; 15(14):1739. https://doi.org/10.3390/diagnostics15141739
5. Kavalieris et al. (2017) Performance Characteristics of a Multigene Urine Biomarker Test for Monitoring for Recurrent Urothelial Carcinoma in a Multicenter Study. J Urol 2017;197:6,1419-1426.
6. Lotan et al. (2017) Clinical comparison of noninvasive urine tests for ruling out recurrent urothelial carcinoma. Urologic Oncology: Seminars and Original Investigations. Elsevier; 2017; 1–8.

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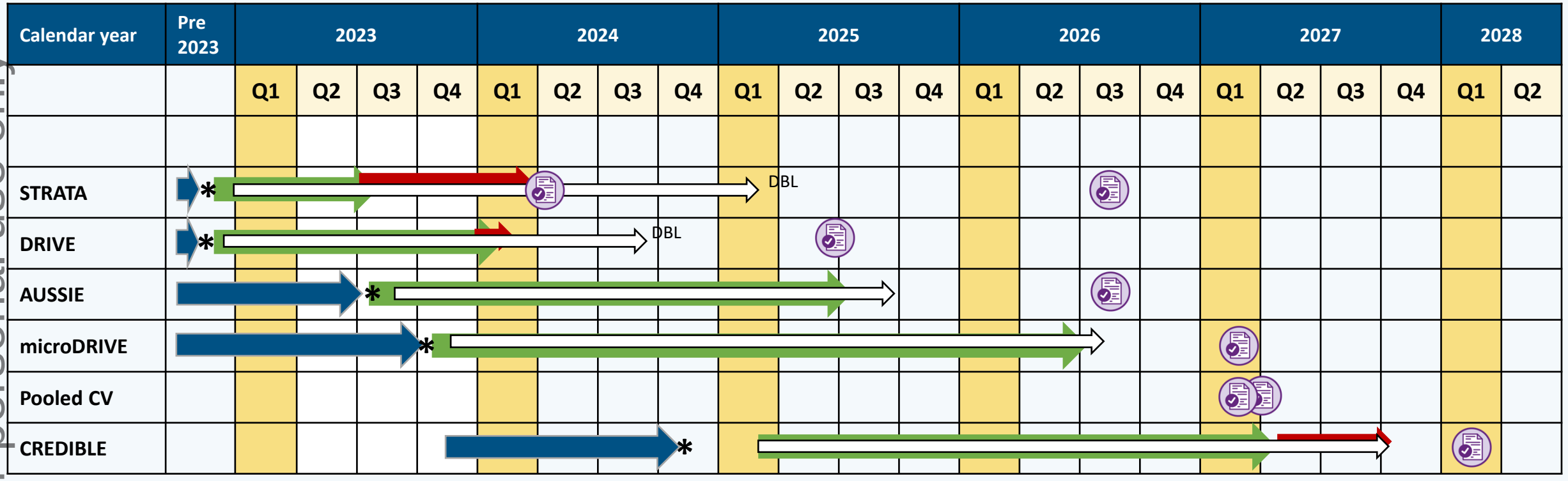
# HEMATURIA EVALUATION FIVE YEAR CLINICAL STUDIES ROADMAP




**Legend:**

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



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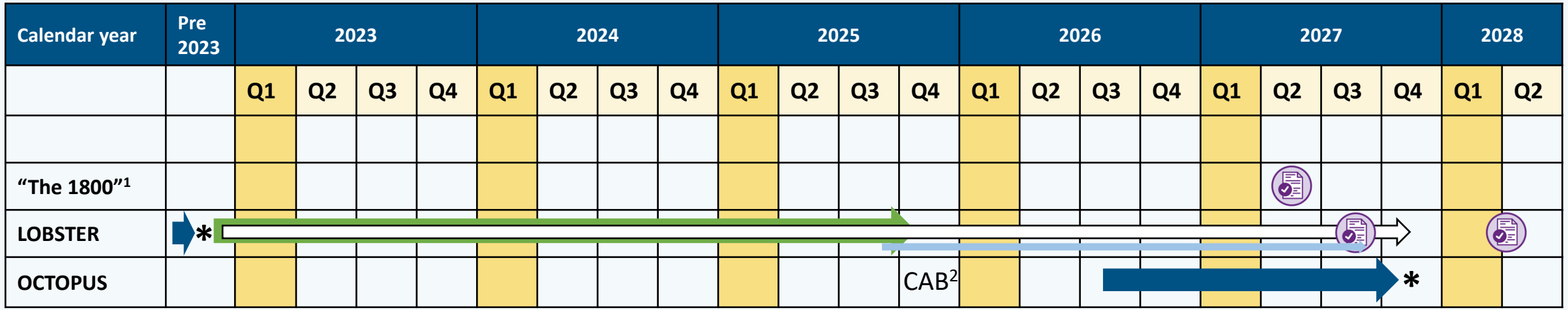
# SURVEILLANCE FIVE YEAR CLINICAL STUDIES ROADMAP




**Legend:**

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



1. "The 1800" is the Surveillance Plus development dataset
2. CAB is the Pacific Edge Clinical Advisory Board. It was convened at SUO in Arizona to review and confirm the clinical study trial design for OCTOPUS

# SOURCES AND ASSUMPTIONS - TOTAL ADDRESSABLE MARKET (US)



| REGION | STATISTIC | | SOURCE |
|---|---|---|---|
| UNITED STATES | 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 |
| | Proportion of gross hematuria amongst those referred for clinical workup | 700,000 | Pacific Edge estimate |
| | Proportion of microhematuria amongst those referred for clinical workup | 2,800,000 | Pacific Edge estimate |
| | Proportion of low-risk microhematuria | 200,000 | Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines |
| | Proportion of intermediate-risk microhematuria | 1,140,000 | Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines |
| | Proportion of high-risk microhematuria | 1,460,000 | Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines |
| | Annual cases of bladder cancer | 84,870 | National Cancer Institute |
| | Patients living with bladder cancer | 744,044 | National Cancer Institute |
| | Test opportunities | 4,416,066 | Pacific Edge estimate |
| | Price of Cxbladder (US$) | $1,328 for Cxbladder Triage Plus, $1,800 for Cxbladder Monitor | |
| | TAM (US$billion) | $6.4 | |

# SOURCES AND ASSUMPTIONS - TOTAL ADDRESSABLE MARKET (EUROPE)



| REGION | STATISTIC | | SOURCE |
|---|---|---|---|
| **EUROPE (EXCLUDING RUSSIA)** | Population | 600,000,000 | World-population - Europe<br>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 |
| | Proportion of gross hematuria amongst those referred for clinical workup | 1,200,000 | Pacific Edge estimate |
| | Proportion of microhematuria amongst those referred for clinical workup | 4,800,000 | Pacific Edge estimate |
| | Proportion of low-risk microhematuria | 340,000 | Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines |
| | Proportion of intermediate-risk microhematuria | 1,960,000 | Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines |
| | Proportion of high-risk microhematuria | 2,500,000 | Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines |
| | 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 | 7,010,000 | Pacific Edge estimate |
| | Price of Cxbladder EURO | €245 | Pacific Edge estimate |
| | TAM (US$billion) | $1.9 | |

# SOURCES AND ASSUMPTIONS - TOTAL ADDRESSABLE MARKET (APAC)



| REGION | STATISTIC | | SOURCE |
|---|---|---|---|
| APAC (EXCLUDING INDIA AND CHINA) | Population | 830,000,000 | World population - Southeast Asia<br>Population Pyramid - Japan<br>Population Pyramid - Hong Kong |
| | 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 |
| | Proportion of gross hematuria amongst those referred for clinical workup | 1,660,000 | Pacific Edge estimate |
| | Proportion of microhematuria amongst those referred for clinical workup | 6,640,000 | Pacific Edge estimate |
| | Proportion of low-risk microhematuria | 470,000 | Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; AUA 2025 guidelines |
| | Proportion of intermediate-risk microhematuria | 2,710,000 | Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; AUA 2025 guidelines |
| | Proportion of high-risk microhematuria | 3,460,000 | Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; AUA 2025 guidelines |
| | Annual cases of bladder cancer | 58,000 | WHO<br>Hong Kong |
| | Patients living with bladder cancer | 290,000 | Pacific Edge estimate - 5 years of annual cases |
| | Test opportunities | 3,531,000 | Pacific Edge estimate |
| | Price of Cxbladder (US$) | $550 | Pacific Edge estimate |
| | TAM (US$billion) | $1.9 | |



**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

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