



**PacificEdge<sup>®</sup>**  
CANCER DIAGNOSTICS

# Capital Raising Presentation

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**Chief Executive Officer**

*Grant Gibson*  
**Chief Financial Officer**

**8 May 2026**

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# 1. PACIFIC EDGE OVERVIEW



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CANCER DIAGNOSTICS

# EXECUTIVE SUMMARY

## SIGNIFICANT VALUE CREATION OPPORTUNITIES, SUPPORTED BY PRUDENT CAPITAL MANAGEMENT



### 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 has recognized Cxbladder Triage with a **'Grade A' evidence rating** – the only urine biomarker to achieve that rating



### KEY SHORT-TERM CATALYST

Draft LCD for Triage & potentially Triage Plus expected **anytime before September 2026**. Final LCD expected anytime before March 2027<sup>1</sup>. Intention to leverage the draft LCD to **seek claim-by-claim reimbursement** to drive revenue prior to final effective coverage



### 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\$10.8 billion**



### PRUDENT CAPITAL MANAGEMENT

**Cash burn actively reduced** in 2H 26 vs 1H 26. Further phased cash management activities have commenced. Balancing cash preservation with maintaining core capabilities for commercial scaling post-coverage



### FOCUSED PATH TO PROFITABILITY

**Triage Plus has confirmed Medicare pricing at US\$1,328/test** (increased from US\$760 for Triage). Post-coverage focus on sales force efficiency, implementing clinical pathways at institutional accounts and scaling throughput beyond historic levels

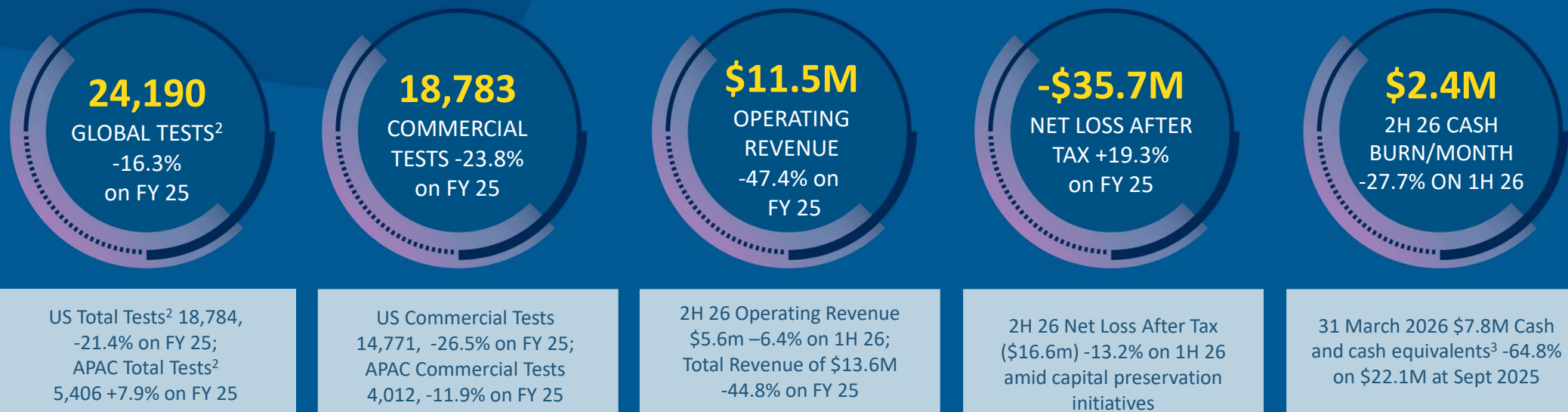
# CAPITAL RAISING OVERVIEW

<p><b>Pacific Edge Summary</b></p>	<ul style="list-style-type: none"> <li>▪ Pacific Edge Limited (NZX/ASX:PEB) (<b>Pacific Edge</b> or the <b>Company</b>) is a cancer diagnostics company that develops and commercializes non-invasive bladder cancer diagnostic and prognostic tests, sold primarily under the “Cxbladder” brand</li> <li>▪ The Company focuses on genomic urine biomarker tests that support both detection of new bladder cancer in patients presenting with hematuria and surveillance of patients with known or suspected recurrent disease</li> <li>▪ These tests help clinicians improve patient experience whilst optimizing workflow and efficiency</li> </ul>
<p><b>Medicare Coverage Update</b></p>	<ul style="list-style-type: none"> <li>▪ A Contractor Advisory Committee (CAC) meeting hosted by Novitas on 19 February 2026 provided an evidence-based mandate for the coverage of urine-based biomarkers, regularly citing Cxbladder publications (see Slide 14)</li> <li>▪ Pacific Edge currently expects Novitas to publish a draft Local Coverage Determination (LCD) for hematuria evaluation, that includes coverage for Triage, and potentially Triage Plus, anytime before September 2026. Publishing a draft is followed by ‘notice and comment’ (minimum of 45 days), before then addressing the comments and finalizing. Once finally published, the LCD takes a further 45 days for the final LCD<sup>1</sup> to become effective</li> <li>▪ Pacific Edge intends to seek claim-by-claim reimbursement for Triage, and potentially Triage Plus, supported by medical necessity documentation after the publication of the draft LCD, documenting these tests for hematuria patients (not only cancer patients). This is supported by the AUA microhematuria guideline. Reimbursement would assist with increasing revenue and reducing cash burn between the draft and final-effective LCD</li> </ul>
<p><b>Cash Preservation Measures</b></p>	<ul style="list-style-type: none"> <li>▪ Pacific Edge has taken several actions during FY 26 to reduce monthly average cash burn to NZ\$2.4m for 2H 26, down from NZ\$3.3m for 1H 26</li> <li>▪ Pacific Edge has made reductions through working capital optimization, phasing and prioritizing R&amp;D and clinical studies expenses, deferring CAPEX, reducing headcount and not backfilling departures in the commercial team</li> <li>▪ In FY 27, Pacific Edge has commenced further phased reductions towards a target monthly average cash burn of NZ\$2.5m vs NZ\$2.85m for FY 26 and further prioritization of R&amp;D and clinical studies expenses, travel reduction and shifting discretionary cash compensation to equity awards</li> <li>▪ Pacific Edge is balancing cash preservation measures with protecting core assets of the business to preserve our ability to scale commercially after Medicare re-coverage</li> </ul>

## CAPITAL RAISING OVERVIEW (CONTINUED)

<p><b>Key Upcoming Milestones / Catalysts</b></p>	<ul style="list-style-type: none"> <li>▪ Anticipated publication of the draft LCD with clear policy language that demonstrates medical necessity of Cxbladder Triage and potentially Triage Plus</li> <li>▪ Leveraging the draft LCD to seek claim-by-claim reimbursement from Novitas for hematuria testing that would assist with increasing revenue and reducing cash burn between the draft and final-effective LCD</li> <li>▪ Final coverage policy from Medicare expected to unlock revenue from Commercial Payers by 1) removing a key reason to deny, 2) providing language that commercial payers can adopt in their own policies and 3) leveraging State Biomarker Laws<sup>1</sup> to mandate payment from commercial payers</li> <li>▪ Pacific Edge is currently targeting to submit Cxbladder Surveillance Plus for a CPT-PLA<sup>2</sup> code by 9 December 2026. If that date is achieved, Pacific Edge currently expects claim-by-claim reimbursement from July 2027 by Novitas at provisional local pricing once the code is added to A58917, leading to additional US revenue during FY 28</li> <li>▪ Te Whatu Ora / Health New Zealand is considering Cxbladder for a National Clinical Pathway for hematuria evaluation in 2026</li> <li>▪ Mid-Atlantic Permanente Medical Group has begun a 150-sample Pilot Study for Cxbladder Triage mirroring the protocol from Southern California, which if successful, may lead to future expansion within the Kaiser Permanente Health System to the Mid-Atlantic region covering 800k lives</li> </ul>
<p><b>Unaudited FY 26 financial information<sup>3</sup> demonstrates capital discipline</b></p>	<ul style="list-style-type: none"> <li>▪ FY 26 operating revenue fell to \$11.5 million from \$21.8 million in FY 25 after non-coverage determination ended Medicare reimbursement and US total laboratory throughput (TLT) fell 21.4% to 18,784 tests from 23,885. APAC improved revenue with TLT rising 7.9% to 5,406</li> <li>▪ Total expenses fell to \$49.3 million from \$54.6 million in FY25 with capital conservation initiatives reducing average 2H 26 monthly cash burn 27.7% to \$2.4 million per month from \$3.3 million in 1H 26. Further capital preservation initiatives post financial year end are targeting a monthly average cash burn of NZ\$2.5m for FY 27</li> <li>▪ Cash and cash equivalents at 30 April 2026 of \$5.1m. Cash and cash equivalents at 31 March 2026 (FY) of \$7.8m and \$22.1m at 30 September 2025 (HY)</li> <li>▪ Net loss increased to \$35.7 million from \$29.9 million in FY 25</li> </ul>
<p><b>Capital Raising to Advance Commercialisation</b></p>	<ul style="list-style-type: none"> <li>▪ Pacific Edge is conducting a NZ\$24 million placement and retail offer of new Pacific Edge ordinary shares (the Offer) with funds used to strengthen its balance sheet to support ongoing operations and growth, support the company to achieve Medicare re-coverage, and continue evidence generation, product development and innovation</li> <li>▪ Offer price of NZ\$0.170 per share (Offer Price), which represents a 2.3% discount to the last traded price on NZX on 8 May 2026 of NZ\$0.174</li> <li>▪ Post successful completion of the Offer, Pacific Edge will have available funding of NZ\$29.1 million<sup>4</sup></li> </ul>

# UNAUDITED FY 26 FINANCIAL INFORMATION: CASH BURN REDUCED ON 1H 26<sup>1</sup>



- Operating revenue fell due to Medicare non-coverage determination and disruptions caused by the US shift from Detect to Triage, APAC volumes show steady growth amid growing albeit small volumes from Asian markets
- 2H 26 cash burn reduced through careful expense management; further phased reductions towards a target monthly average cash burn for FY 27 of NZ\$2.5m vs NZ\$2.85m for FY 26
- Net losses increased following revenue reductions and ongoing Medicare appeals not accrued
- \$24m capital raising launched to strengthen our balance sheet to support ongoing operations and growth, position the company for phased execution post re-coverage

1. FY 26 financial information is taken from management accounts and has not been audited by Pacific Edge's external auditors. Following the audit process, FY 26 financial information in this presentation may change. Pacific Edge expects to release its audited financial statements for FY 26 on 25 May 2026  
 2. Total Laboratory Throughput (TLT) including commercial, pre-commercial and clinical studies testing  
 3. Cash, short-term deposits and term deposits

# CORPORATE OVERVIEW

CORPORATE SNAPSHOT	
<b>NZX Code:</b>	PEB
<b>Share Price:</b> <i>As at 8 May 2026</i>	NZX - NZ\$0.174
<b>Shares on issue:</b>	1,023 million
<b>Market Capitalisation:</b> <i>At NZ\$0.174 per Share</i>	NZ\$178 million
<b>Top 20 Shareholders:</b>	~53%
<b>Cash at bank:</b> <i>As at 30 April 2026</i>	~NZ\$5.1 million
<b>Debt<sup>1</sup>:</b> <i>As at 30 April 2026</i>	~NZ\$0.5 million

## BOARD AND MANAGEMENT



**Simon Flood (Chairman)** is an investment and governance leader with global capital markets experience in London, Hong Kong and Singapore. He has held senior executive roles with Mercury Asset Management / Merrill Lynch Investment Managers, Lion Global Investors and AXA Investment Managers. He now holds governance roles with private and public institutions, including Chair of Queenstown Airport.

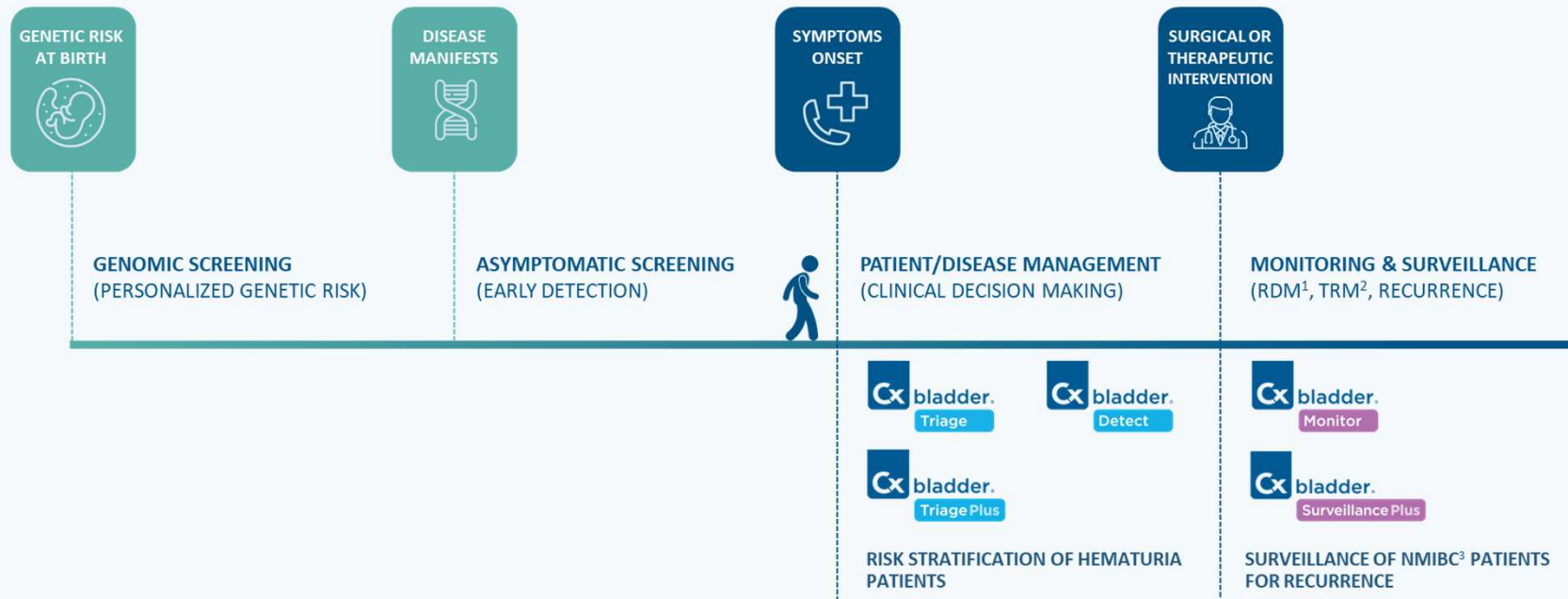


**Dr Peter Meintjes (CEO)** is an experienced commercial leader in molecular diagnostics and genomics focused on nascent market development of disruptive innovations. Prior to joining Pacific Edge, he was based in Boston in a succession of diagnostic leadership roles, including Chief Commercial Officer at Eurofins Transplant Genomics and the CEO at Omixon.

<b>Directors</b>	Sarah Park	Anna Stove
	Anatole Masfen*	Tony Barclay
<b>Senior Leadership Team</b>	Prof. Dr Bryan Williams	
	Grant Gibson – CFO	Dr Tamer Aboushwareb – CMO
	Darrell Morgan – COO	Zoe O'Donnell – Head of People
	Dr Justin Harvey – CTO	Glen Costin – President APAC
	Prof. Dr Parry Guilford – CSO	

# 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

**Grade A**

Evidence rating by the AUA<sup>4</sup> 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

# THE CXBLADDER SUITE

Cxbladder Product	Hematuria Evaluation			NMIBC <sup>1</sup> Surveillance	
	Triage	Detect	Triage Plus	Monitor	Surveillance Plus
<b>Product Summary</b>	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
<b>Analytical composition</b>	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 2 fusions associated with 1 gene 1 methylation marker 2 control markers
<b>Test Performance</b>	Hematuria <sup>2</sup> Sn: 95% Sp: 45% NPV: 99% PPV: N/A	Hematuria <sup>3</sup> Sn: 82%** Sp: 94%* NPV: 97%** PPV: 68%*	Hematuria <sup>4</sup> Sn: 93.6%*** Sp: 98.2%*** NPV: 99.4%*** PPV: 74.6%***	All risk groups <sup>5,6</sup> Sn: 93% Sp: N/A NPV: 97% PPV: N/A	All Risk Groups Sn: Not yet published Sp: Not yet published NPV: Not yet published PPV: Not yet published
<b>When is it used?</b>	Prior to cystoscopy	Prior to cystoscopy / as an adjunct / 3 weeks post cystoscopy		As a non-invasive surveillance alternative	
<b>Commercially available?</b>	✓	✓	Commercially available in APAC and under “early access” in US, pending coverage	✓	CPT-PLA code targeted for Dec 2026 Reimbursed on A58917 in Jul 2027
<b>Medicare Pricing (USD)</b>	<b>\$760</b>	<b>\$760</b>	<b>\$1,328</b>	<b>\$760</b>	<b>\$1,800 (seeking by crosswalk)</b>

\* 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.

# DRIVING ECONOMIC VALUE FOR PATIENTS, HOSPITALS AND PAYERS

CXBLADDER DELIVERS CLINICAL UTILITY, PATIENT SATISFACTION AND ECONOMIC VALUE

## CANCER INCIDENCE IN MICROHEMATURIA PATIENTS

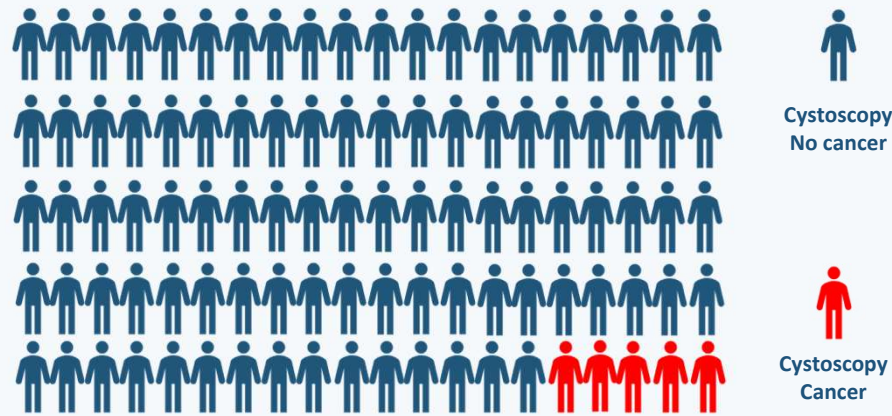
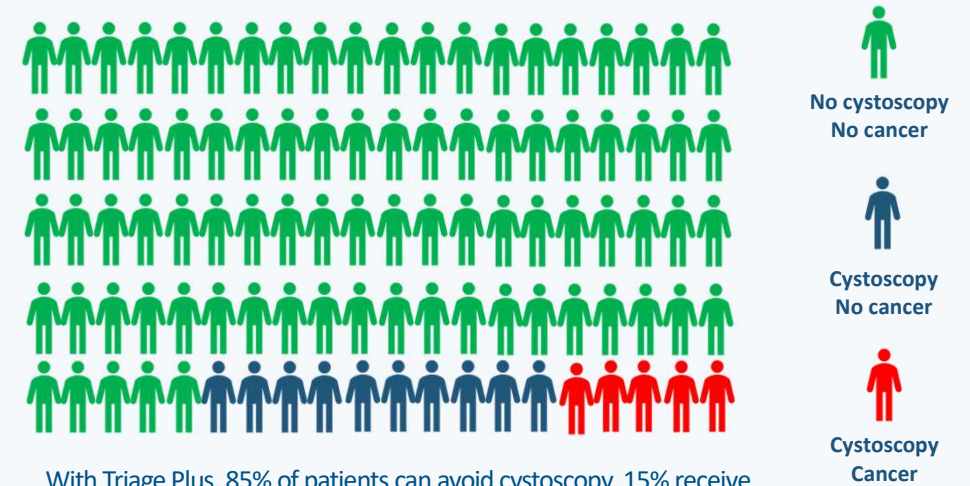


Illustration shows incidence of bladder cancer in microhematuria populations at 5%<sup>1</sup>

## CYSTOSCOPES SAFELY AVOIDED USING CXBLADDER



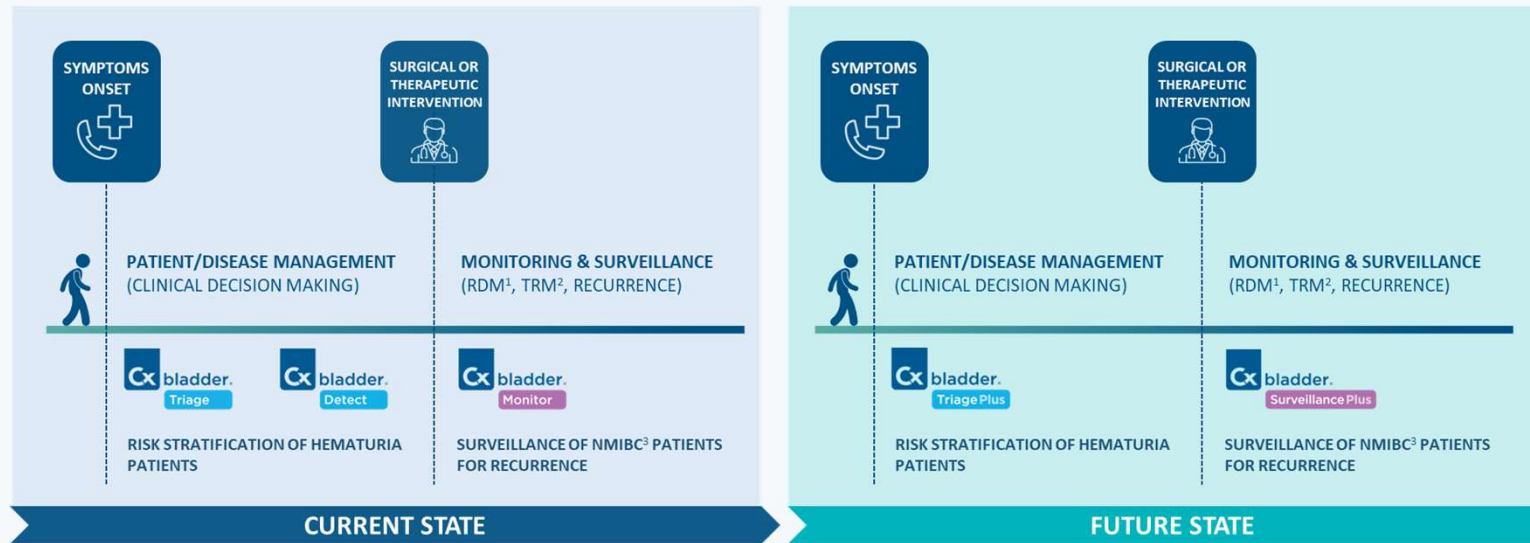
With Triage Plus, 85% of patients can avoid cystoscopy, 15% receive cystoscopy to find the same 5 cancer patients

- Cxbladder avoids invasive, unnecessary procedures for patients driving down costs for health systems and payers<sup>2</sup>
- At scale, Cxbladder can spare more than 1.5 million patients in the US from cystoscopy and save >US\$500/patient<sup>2</sup>
- The population in the USA is ageing, with an increasing number of patients requiring urology care
- The number of urologists per person over 65 is falling in the USA (from 23.8/100k to 15.8/100k in 2035<sup>3</sup>) potentially delaying diagnosis
- Medicare reimbursement for cystoscopy has declined from US\$204.80 in 2023 to US\$172.80 in 2026<sup>4</sup>

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. Nam et al. (2021) Projected US Urology Workforce per Capita, 2020-2060 JAMA Network Open Published Online: November 16, 2021  
4. <https://www.cms.gov/medicare/physician-fee-schedule/search>

# DRIVING STRATEGIC VALUE THROUGH PRODUCT INNOVATION

NEXT GENERATION TESTS HAVE SUPERIOR PERFORMANCE AND PRICING



- **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 US\$1,328/ test, and coverage has been requested from Novitas
  - The US\$1,328 price strengthens the economics of operating an Account Executive and the future profitability profile 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<sup>1</sup> patients**
  - Surveillance Plus is in development and is expected to be analytically validated and clinically validated during FY27
  - Surveillance Plus uses DNA markers and ddPCR<sup>4</sup> technology, 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, the code would be approved by CMS before 1 April 2027, effective in the CLFS on 1 July 2027 and added to Novitas’ Local Coverage Article A58917 during July 2027
  - Pacific Edge currently expects claim-by-claim reimbursement for Surveillance Plus from July 2027 by Novitas at provisional local pricing once the code is added to A58917, leading to additional US revenue during FY28, while seeking a pricing crosswalk for Surveillance Plus to a US\$1,800 ddPCR<sup>4</sup> test.








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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

## 2. COMMERCIAL PATHWAY AND ANTICIPATED MEDICARE RE- COVERAGE

# SUMMARY OF NOVITAS CONTRACTOR ADVISORY COMMITTEE – FEBRUARY 2026

EXPERT PANELISTS HIGHLIGHT NEED FOR REVISIONS TO MEDICARE POLICY  
CXBLADDER EVIDENCE AS A DRIVER FOR CHANGE

 <p><b>Strong clinical evidence</b></p>	<p>The committee regularly noted the strong clinical evidence supporting Cxbladder Triage and Triage Plus throughout the call (most notably STRATA and the Kaiser Study)</p>
 <p><b>Use across all risk categories</b></p>	<p>Panel supported use of validated biomarkers across all hematuria risk groups and multiple settings: initial evaluation, reflex after inconclusive tests, adjunct to difficult cystoscopies, repeat use in recurrent cases, and as a non-invasive option</p>
 <p><b>Logistical benefits</b></p>	<p>Logistical and economic benefits from primary care use were emphasized, including better access for rural patients, prioritization of high-risk referrals, earlier detection to avoid more invasive disease, and advancing care for women where hematuria is often dismissed as a UTI</p>
 <p><b>Improved standard of care</b></p>	<p>Strong alignment that Cxbladder tests have robust evidence and clinical utility, with several experts explicitly appealing for Medicare reimbursement and broad access to improve standards of care</p>
 <p><b>Pathway to re-coverage</b></p>	<p>Novitas will use panel feedback, evidence and AUA guideline updates to decide on a new coverage policy, with a draft LCD expected anytime before September 2026, and a final-effective LCD expected anytime before March 2027</p>

*“The vast majority of patients with microhematuria in the US are not getting referred to urologists or any evaluation whatsoever... the consequence is that **many patients are getting delayed in diagnosis**”*

- Prof Yair Lotan, UTSW

*“only 13% of patients with high-risk microhematuria actually underwent cystoscopy... so that is why a **biomarker could be so appealing**”*

- Dr Jason Hafron, Michigan Institute of Urology

Pacific Edge considers that the panel provided a clear endorsement of urine-based biomarkers as medically reasonable and necessary and **IMPORTANTLY, appropriate for Medicare recoverage**<sup>1</sup>

# ANTICIPATED MEDICARE RE-COVERAGE: ESTIMATED TIMELINES

DRAFT LCD RELEASE AND FINAL COVERAGE TIMELINES ARE AT THE DISCRETION OF NOVITAS

MEDICARE COVERAGE REQUEST	CATALYST	CY2026				CY2027			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
L39365 Reconsideration request (Triage) March 2025	STRATA Study (May 2024) AUA Microhematuria Guideline (Feb 2025)	★	■		■			■	
New LCD request (Triage/Triage Plus) November 2025	AV of Triage Plus (Q2 25) CV of Triage Plus – DRIVE Study (Q4 25)	★	■		■			■	

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

- Novitas controls the timeline for publishing an LCD; the framework is governed by the Medicare Program Integrity Manual
- A draft LCD is subject to ‘notice and comment’ for a minimum of 45 days, including an open public meeting
- After the draft LCD is published, we will seek reimbursement for products covered by the draft LCD, noting positive language for hematuria patients can be differentiated from negative language for cancer patients on L39365
- Novitas must respond to all comments when finalizing the draft LCD and may take a maximum of 365 days from draft publishing to final publishing<sup>1</sup>
- The finalized LCD becomes effective 45 days after being published

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

Novitas publishes draft LCD (estimate) ■

LCD finalized (estimate) ■

12-months after estimated draft (assumed worst case) ■



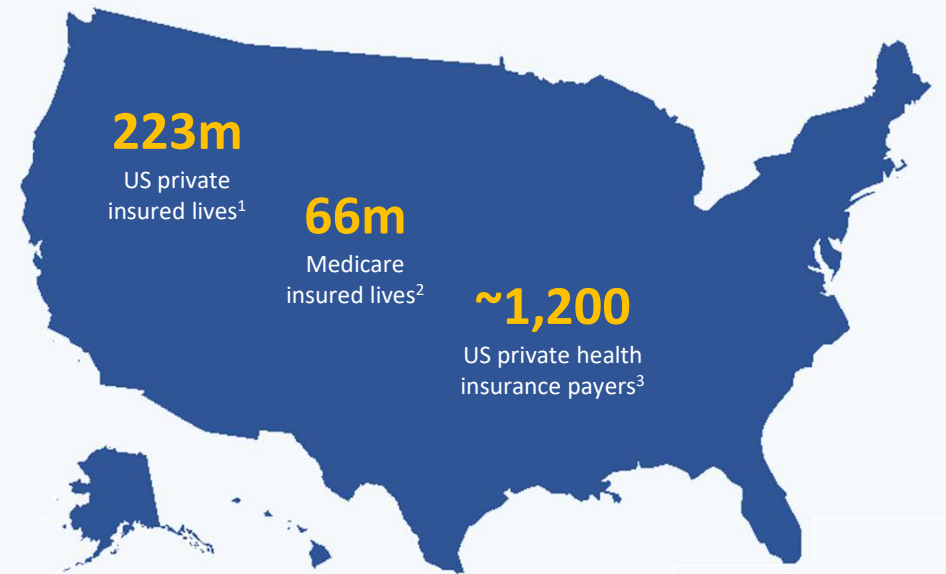
**Medicare**

1. It is also open to Novitas to retire, rather than finalize, the draft LCD. Novitas must publish the final LCD or retire the draft LCD within 365 days after publishing a draft LCD

# US COMMERCIAL PAYERS: MEDICARE POLICY EXPECTED TO UNLOCK VOLUMES

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

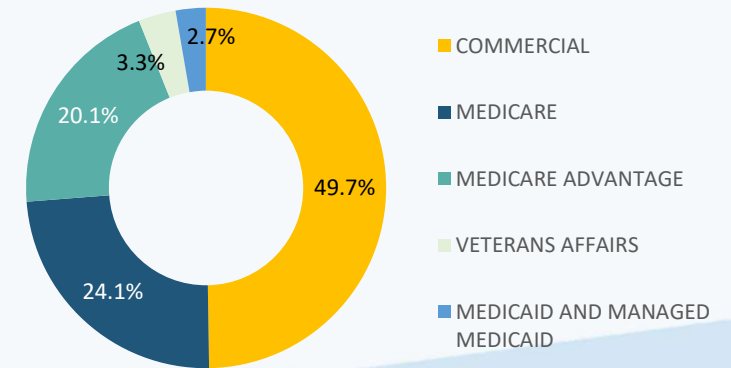
- Commercial payers are a significant opportunity covering almost four times more lives than Medicare. Microhematuria patients skew younger with commercial health insurance, thus represent the majority of the total serviceable market for hematuria evaluation
- Final coverage policy from Medicare expected to unlock revenue from Commercial Payers by 1) removing a key reason to deny, 2) providing language that commercial payers can adopt in their own policies and 3) leveraging State Biomarker Laws to mandate payment from commercial payers
- The commercial payer market is highly concentrated among the largest payers, particularly UnitedHealthcare and the Blue Cross Blue Shield (BCBS) network
  - Each insurer has multiple plans creating a complex coverage landscape
- We focus on establishing medical policy directly with payers or through third parties like Avalon, EviCore, Carelon, Concert Genetics and ECRI<sup>4</sup>
  - Pacific Edge has already received positive medical policy from Avalon and ECRI
  - In March 2026, BCBS North Carolina and BCBS South Carolina adopted Avalon's policy
- Commercial Policy achievements like BCBS NC and SC are typically considered a higher bar than Medicare LCD



## KAISER PERMANENTE – REAL WORLD CLINICAL AND ECONOMIC VALUE

- KP SoCal<sup>5</sup> 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; 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 (~800,000 members) for a pilot study with a Triage protocol that mirrors KP SoCal
- The partnership with KP has delivered compelling real-world evidence for Triage (See Appendix 3); new studies are expected to deliver similar value for Triage Plus

## PACIFIC EDGE PAYER MIX (1H 26)

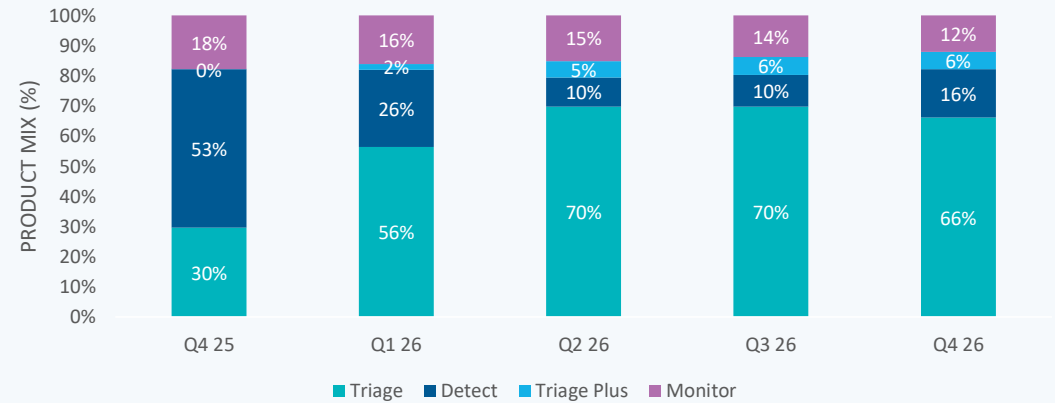


# FY 26 VOLUMES FALL DESPITE MEDICARE POLICY MOMENTUM

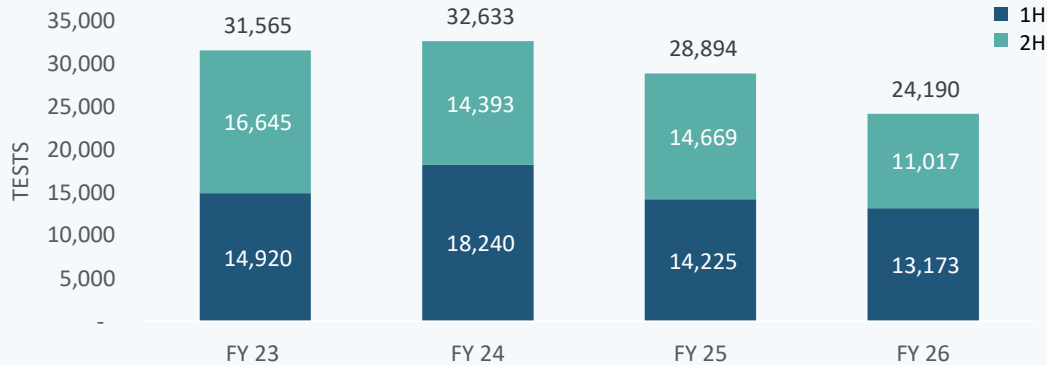
## FY 26 TOTAL LAB THROUGHPUT (TLT\*)

- Global TLT of 24,190 for FY 26 down 16.3% on FY 25 after Medicare non-coverage determination, reduced reach of the sales force and the US transition from Detect to Triage for hematuria evaluation
- APAC volumes showing steady increases with growing volumes ex-NZ
- Global Commercial test volumes of 18,783 for FY 26 down 23.8%
- Triage growing in share of volume validating risk stratification value proposition and investment in Triage Plus

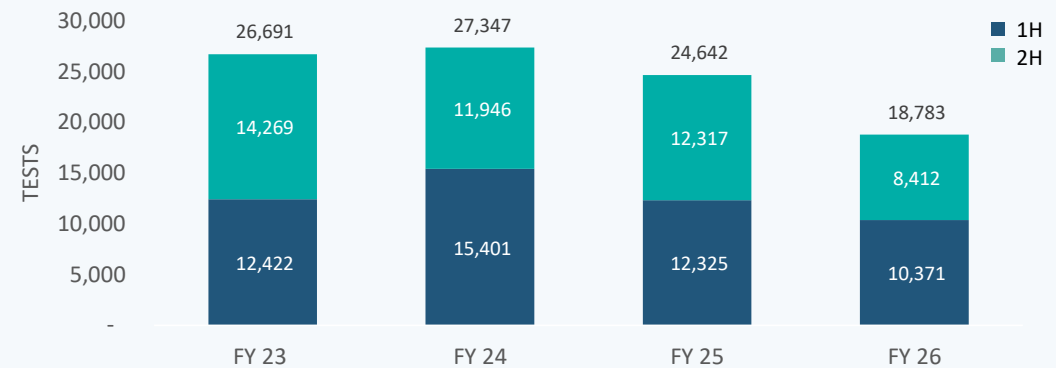
## TEST VOLUMES BY TYPE (TLT\*)



## GLOBAL TOTAL TEST VOLUMES (TLT\*)



## GLOBAL COMMERCIAL TEST VOLUMES

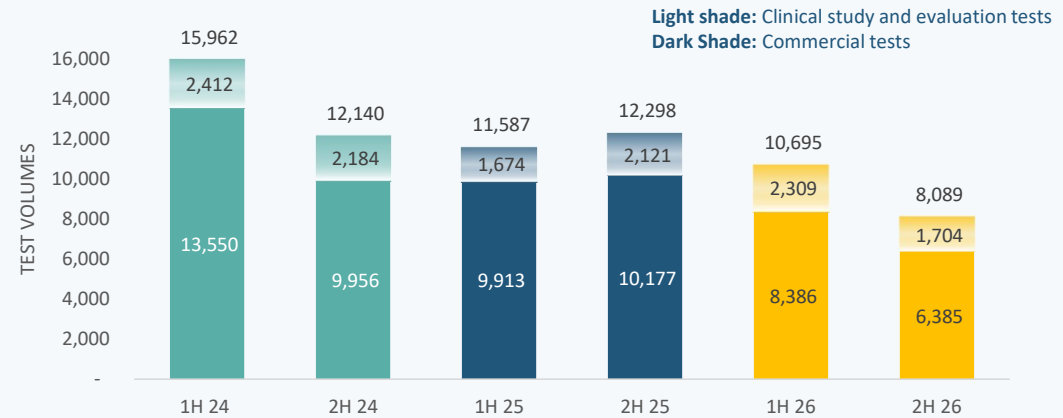


# MOUNTING POLICY MOMENTUM YET TO LIFT US VOLUMES

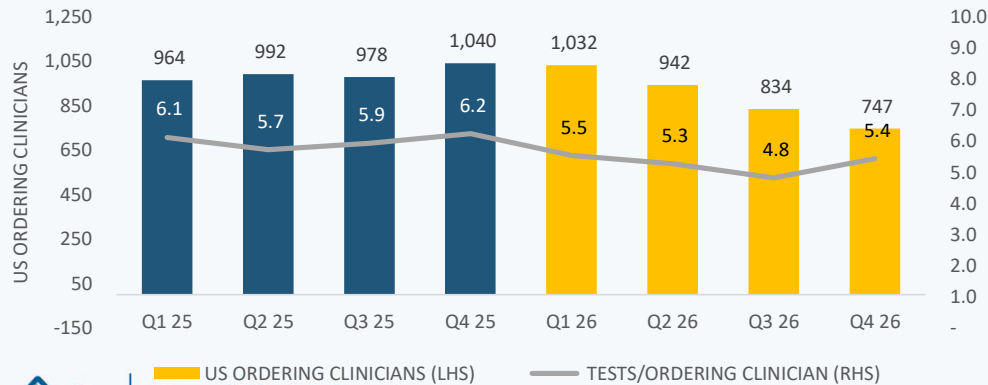
## SALES FORCE EFFICIENCY LAYS FOUNDATIONS FOR GROWTH

- US operations have faced numerous challenges in FY 26:
  - Constant headwind of selling a product not covered by Medicare
  - Disruption of transitioning US customers from Cxbladder Detect to Triage after non-coverage LCD in February 2025
  - Winter storms across large segments of the US reducing operating days in Q4 26
- Sales force efficiency metric rises with focus on profitable territories
  - 8 FTEs in Q4 26 vs 12 FTEs in Q3 26 and peak 33 in Q3 23
  - Sales force efficiency metric increased to 530 from 335 in Q3 26 lifted by a focus on the most profitable territories
  - Tests per unique ordering clinician were 5.4 up from 4.8 in Q3 26
  - Ordering clinicians fell to 747 from 834 ordering clinicians in Q3 26

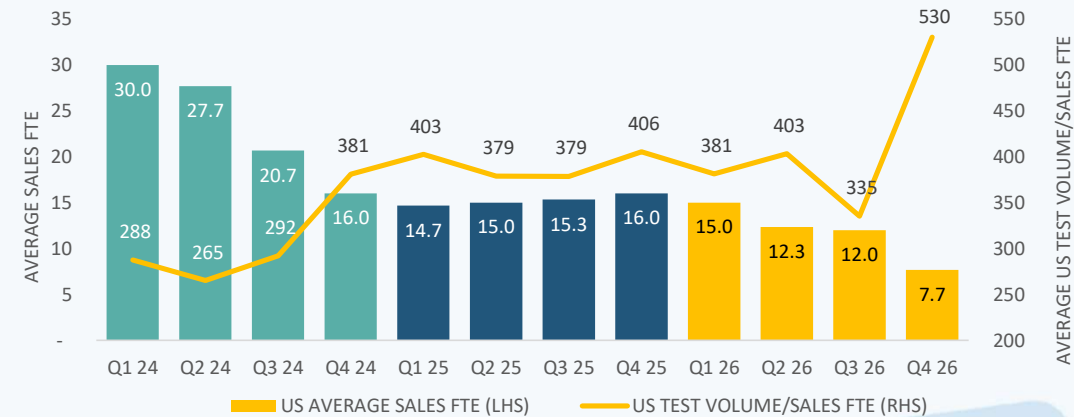
## US TOTAL LABORATORY THROUGHPUT



## US CLINICAL COMMITMENT



## US SALES FORCE EFFICIENCY



# CONSOLIDATING NEW ZEALAND AND DEVELOPING AUSTRALIA AND SEA

## APAC COMMERCIAL

- APAC Commercial and Clinical Operations (excluding R&D costs) is trending towards profitability (on a direct cost basis) with an FY 26 cash burn rate of \$0.6m, a ~40% improvement on the FY 25 year
- APAC revenue contributed 19% of operating revenue in 2H 26, an increase from 8% in FY 25
- Re-pricing in 2025 created on average 25% more revenue per test
- Wider adoption of Triage Plus over legacy products has the potential for 20% more revenue growth from the same testing volume, with testing volume also expected to continue to increase

## NEW ZEALAND: SEEKING A NATIONAL HEMATURIA EVALUATION PATHWAY

- ~70% of New Zealanders have access to Cxbladder testing
- Pacific Edge is establishing healthcare equity for all New Zealanders with a national pathway for hematuria evaluation with *Te Whatu Ora*

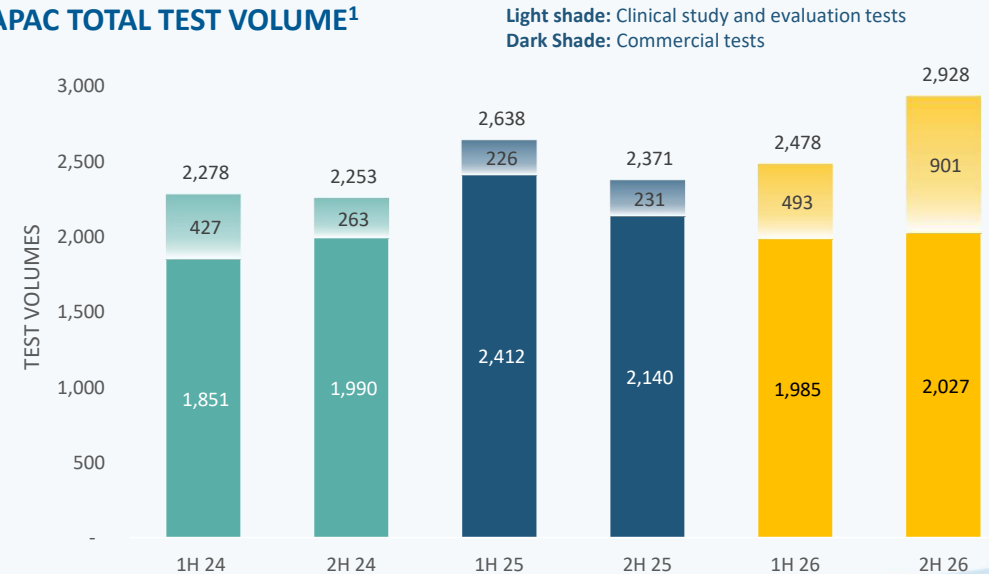
## AUSTRALIA: BUSINESS DEVELOPMENT WITH HOSPITAL CONTRACTING

- 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<sup>2</sup> reimbursement requires Cxbladder tests to be run in Australia
  - When developed, kit-based IVDs for Cxbladder can be run by partner labs in Australia

## SOUTHEAST ASIA: BUSINESS DEVELOPMENT WITH EARLY WINS

- In Southeast Asia we are establishing a network of lab partners for in-market promotion of our testing services
- We have processed commercial samples from seven 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

## APAC TOTAL TEST VOLUME<sup>1</sup>



# 3. OUTLOOK



**PacificEdge**<sup>®</sup>  
CANCER DIAGNOSTICS

# OUTLOOK

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

### COMMERCIAL CATALYSTS FOR NEAR-TERM VALUE CREATION

- Draft Local Coverage Determination (LCD) for hematuria evaluation, that includes coverage for Triage and potentially Triage Plus is currently expected anytime before September 2026
- Seeking claim-by-claim reimbursement for hematuria testing after draft coverage, noting draft policy language may differentiate hematuria from cancer
- Expert CAC panel gave clear endorsement of urine-based biomarkers as medically reasonable and necessary, citing Cxbladder clinical evidence
- Advancing medical policy for Triage with commercial payers, leveraging the AUA Guideline, ECRI<sup>2</sup> review and Avalon policy
- Cxbladder is under consideration by Health New Zealand for a National Pathway in FY 27

### CLINICAL EVIDENCE DRIVES MEDIUM-TERM VALUE CREATION

- DRIVE publication<sup>1</sup> supports Triage Plus validity; submitted to Novitas and AUA for coverage and guideline inclusion
- Kaiser Permanente study shows real world evidence for Cxbladder Triage in largest urine-based biomarker study of hematuria patients
- Four-year evidence generation program delivers stepwise milestones for sustained shareholder value
- AUA (Grade A Evidence), ECRI<sup>2</sup> (4/5 Evidence) and Avalon (Covered) have created the precedent for turning Cxbladder evidence into robust medical policy
- BCBS NC & SC commercial payers have adopted coverage policy for Triage based on Avalon's assessments

### INNOVATION DRIVES LONG-TERM VALUE CREATION

- Next generation products demonstrate superior performance that underpins better clinical performance, patient experience, healthcare system cost savings and is expected to substantially improve unit economics
- Triage Plus progressing through 'early access'; included in CAC meeting with US\$1,328 price — Medicare coverage is the final step
- Targeting CPT-PLA coding submission for Surveillance Plus in December, 2026 with claim-by-claim revenue expected after July 1, 2027
- Seeking claim-by-claim reimbursement at US\$1,800 with provisional pricing at Novitas; seeking US\$1,800 crosswalk price during FY 28
- Ongoing investment in product simplification and kitted IVD products to enable de-centralized international deployment

# 4. CAPITAL RAISING OVERVIEW

# CAPITAL RAISING OVERVIEW

<b>Transaction Overview</b>	<ul style="list-style-type: none"> <li>▪ Pacific Edge is undertaking an equity raise of NZ\$24 million by way of the offer of new shares, comprising:             <ul style="list-style-type: none"> <li>▪ A NZ\$18 million Placement; and</li> <li>▪ A NZ\$6 million Retail Offer</li> </ul> </li> <li>▪ Proceeds from the Offer will provide capital to:             <ul style="list-style-type: none"> <li>▪ strengthen the balance sheet to support ongoing operations and position for future growth</li> <li>▪ support the company to achieve Medicare re-coverage</li> <li>▪ continue evidence generation</li> <li>▪ continue product development and innovation</li> </ul> </li> <li>▪ New Shares under the Placement will be issued under Pacific Edge’s 15% placement capacity under NZX Listing Rule 4.5</li> </ul>
<b>Offer Price</b>	<ul style="list-style-type: none"> <li>▪ The Offer will be conducted at a fixed price of NZ\$0.170 per share (Offer Price), representing a:             <ul style="list-style-type: none"> <li>○ 2.3% discount to the Company’s last traded price on NZX on 8 May 2026;</li> <li>○ 2.0% discount to the Company’s 5-day VWAP on NZX (NZ\$0.1735)<sup>1</sup>; and</li> <li>○ 4.9% discount to the Company’s 30-day VWAP on NZX (NZ\$0.1788)<sup>2</sup></li> </ul> </li> </ul>
<b>Retail Offer details</b>	<ul style="list-style-type: none"> <li>▪ Pacific Edge is offering up to NZ\$6 million of shares (with the ability to scale applications or accept oversubscriptions at the Board’s discretion) to Pacific Edge’s eligible shareholders resident in New Zealand (up to a maximum of NZ\$50,000 per shareholder) under a Retail Offer, structured as a share purchase plan<sup>3</sup></li> <li>▪ The Retail Offer price will be NZ\$0.170 per share</li> </ul>
<b>Commitments</b>	<ul style="list-style-type: none"> <li>▪ Pacific Edge’s Chair, Simon Flood, intends to apply for NZ\$500,000 of shares under the Placement</li> <li>▪ All other Pacific Edge Directors also intend to participate in the Offer</li> </ul>
<b>Ranking</b>	<ul style="list-style-type: none"> <li>▪ New Shares to be issued under both the Placement and Retail Offer will be fully paid shares which, on allotment, will rank equally in all respects with Pacific Edge’s existing fully paid ordinary shares on issue</li> </ul>
<b>Risks</b>	<ul style="list-style-type: none"> <li>▪ Refer to Section 5 for a summary of key risks associated with an investment in Pacific Edge and the Offer</li> </ul>
<b>Underwriting</b>	<ul style="list-style-type: none"> <li>▪ Neither the Placement nor the Retail Offer are underwritten</li> </ul>

1. Volume weighted average price on NZX for the period 4 May 2026 to 8 May 2026 (dates inclusive)
2. Volume weighted average price on NZX for the period 25 March 2026 to 8 May 2026 (dates inclusive)
3. Pacific Edge intends to use its placement capacity under NZX Listing Rule 4.5 to ensure that eligible shareholders resident in New Zealand can each subscribe for up to NZ\$50,000 in new shares, even though some shareholders subscribed for shares under the previous share purchase plan undertaken within the last 12 months

## TIMETABLE

Placement	(NZ time)
Placement conducted under trading halt on the NZX and ASX	Monday, 11 to Tuesday, 12 May 2026
Announcement of the Placement results and trading halt lifted on the NZX and ASX	Wednesday, 13 May 2026
Settlement on the NZX	Friday, 15 May 2026
Settlement on the ASX (if required)	Friday, 15 May 2026
Allotment and commencement of trading of Placement shares on NZX and ASX	Friday, 15 May 2026
<b>Retail Offer</b>	
Record date	7:00pm on Friday, 8 May 2026
Retail Offer opens and documentation sent to eligible shareholders	Thursday, 14 May 2026
Retail Offer closes	5:00pm on Thursday, 28 May 2026
Announcement of results of Retail Offer	Wednesday, 3 June 2026
Settlement, allotment and commencement of trading of Retail Offer shares on NZX	Thursday, 4 June 2026

# 5. KEY RISKS

## KEY RISKS

### IMPORTANT:

Like any investment, there are risks associated with an investment in Pacific Edge shares. Before investing in Pacific Edge, you should be aware that an investment in Pacific Edge has a number of risks, some of which are specific to Pacific Edge and some of which relate to listed securities generally, and many of which are beyond the control of Pacific Edge. Additionally, some risks may be unknown and other risks, currently believed to be immaterial, could turn out to be material. Whilst the section below aims to highlight some of the key risks, it is not exhaustive.

Pacific Edge is a growth company that is currently making losses and it may need to raise more capital in the future, which may or may not be available at the time. Pacific Edge is currently assuming it will receive a positive draft LCD outcome anytime before September 2026 to regain Medicare re-coverage, which may or may not ultimately eventuate in the time envisaged, or at all. An investment in Pacific Edge is not for all investors and there is a risk you could lose all of your money.

Before deciding whether to invest in Pacific Edge shares, you must make your own assessment of the risks associated with the investment and consider whether such an investment is suitable for you having regard to all other Pacific Edge continuous disclosure announcements, financial statements and other publicly available information. This presentation is not a prospectus or a product disclosure statement or other offering document. It has been prepared without taking in account the objectives, financial situation or circumstances of investors. It may not contain all the information you require to make an investment decision. Accordingly, before making an investment decision, you should consult your financial adviser and other professional advisers.

## KEY RISKS (CONTINUED)

<p><b>Medicare coverage uncertainty</b></p>	<p>Pacific Edge currently has a Medicare non-coverage determination for Triage, Triage Plus, Detect and Monitor, and no coverage determination for Surveillance Plus. Medicare previously accounted for the majority of Pacific Edge's US test volumes and, therefore, a significant percentage of Pacific Edge's revenue. Although Pacific Edge is confident that it will regain coverage for Triage and potentially gain coverage for Triage Plus as a result of recent AUA guideline inclusion, new clinical evidence and the Contractor Advisory Committee (CAC) meeting held on 19 February 2026 (US time), there are no guarantees as to the timing or outcome of the re-coverage process, because these timelines are controlled by Novitas. Novitas has 12 months from the date of publishing the draft LCD to finalize or retire it, meaning Medicare coverage could still take some time or not be achieved at all. If the language is changed between the draft and the final version to non-cover or reduce coverage for Cxbladder Triage or Triage Plus, this would have a material adverse impact on Pacific Edge's financial performance and growth, and could result in the company using up all available cash before it is able to become profitable from its ongoing operations.</p> <p>If the final-effective LCD does not cover Cxbladder Triage and Triage Plus, Pacific Edge will likely need to complete further clinical studies to provide new published evidence when submitting another reconsideration request. Those clinical studies are underway, but may take a number of years to complete. Accordingly, Pacific Edge may need to undertake a restructure of its business to reduce costs and, potentially, seek to raise further capital and/or pursue other capital initiatives.</p>
<p><b>Ongoing Financial Viability</b></p>	<p>Pacific Edge is operating at a 'cash burn', which means that the company spends more cash that it generates. The capital raise outlined in this presentation is in part to provide sufficient cash to regain Medicare coverage. If the capital raise is undersubscribed, if Medicare re-coverage is not achieved or significantly delayed, or is only for Triage and not also Triage Plus, or the business is impacted adversely by other events, there is a risk to the ongoing financial viability of Pacific Edge, which may result in investors losing some or all of their investment.</p>
<p><b>Regulatory, industry body and guideline Risks</b></p>	<p>Pacific Edge's Cxbladder products and laboratories are regulated and certified by various government and industry entities in territories and markets in which the tests are performed and/or sold. Reimbursement for these tests may be influenced by reimbursement rulings from private and/or government payers. Guidelines issued by various industry bodies also influence the treatment and management regimes for patients, with the potential to impact on the uptake and use of Cxbladder. If Pacific Edge is unable to retain or, in certain markets, gain inclusion in guidelines, or the current regulatory approvals and reimbursement obtained for existing products are removed or reduced, such matters could have an adverse impact on Pacific Edge's financial performance and its ability to achieve its business plans. If Pacific Edge is unable to obtain the approvals required for new products in new territories, or is unable to obtain future reimbursement for new products, this could also have an adverse impact on Pacific Edge's financial performance and its ability to achieve its business plans.</p>
<p><b>Competition</b></p>	<p>The global cancer diagnostics industry is highly competitive, with research undertaken by a large number of commercial and not for profit institutions globally on new diagnostic tools. There are some smaller companies with minimal clinical evidence to support their use, or with no commercial presence in the USA, but there are also a large number of well capitalized diagnostics companies operating in the broader industry. There is a risk that the larger, better capitalized companies may discover, develop or introduce new products that compete with Pacific Edge's products, and if successful, could render Pacific Edge's products obsolete or otherwise uncompetitive, resulting in adverse effects on Pacific Edge's revenue, margins and profitability.</p>

## KEY RISKS (CONTINUED)

<b>Product and technology risk</b>	<p>Pacific Edge relies on laboratory operations, third party suppliers of test components, IT and technical systems to process and report results for Cxbladder tests. While the performance of Cxbladder has been demonstrated in various scientific journal publications, any change to the reliability, repeatability, reproducibility or accuracy of Cxbladder products and technology systems has the potential to impact Pacific Edge’s business and reputation. Cyber attacks on Pacific Edge digital systems and platforms also have the potential to impact the delivery of test results. Financial, reputational and litigation consequences relating to underperformance and unreliability, or the inability to deliver, test results (including due to adverse cyber incidents or quality issues with test components supplied by third parties) have the potential to be significant and could be materially adverse to the company’s financial performance and position.</p>
<b>New Product Development</b>	<p>Pacific Edge continues to leverage its suite of patents and intellectual property to explore new products and applications. There is a risk that those development efforts may not be successful or may take longer and be more expensive than anticipated, and as a result, Pacific Edge’s investment will be delayed or lost. This risk could arise due to a number of factors, including delays in commencement or completion of scientific studies. Any failure or significant delay in the development of one or more of Pacific Edge’s new products and product extensions may have a material negative impact on Pacific Edge’s financial performance and growth.</p>
<b>Litigation</b>	<p>In the ordinary course of conducting its business, Pacific Edge is exposed to potential litigation and other proceedings, including through claims of intellectual property infringement or breach of agreements. If such proceedings are brought against Pacific Edge, Pacific Edge could incur considerable defence costs (even if successful), with the potential for damages and costs awards against Pacific Edge if it were unsuccessful, which could have a significant adverse financial impact on Pacific Edge. Circumstances may also arise in which Pacific Edge considers that it is reasonable or necessary to initiate litigation or other proceedings, including for example to protect its intellectual property rights.</p>
<b>Key Person Risk</b>	<p>The success of our business depends significantly on the continued contributions of our executive team, scientific leaders, and key technical staff. The unexpected departure of any of these individuals could disrupt operations, delay research and development efforts, and negatively impact strategic initiatives. Attracting and retaining top talent in a competitive biotech labor market remains a critical challenge.</p>
<b>Market volatility of Pacific Edge’s shares</b>	<p>Any investment in equity capital markets carries general risks. Pacific Edge’s shares are currently listed on NZX and the ASX, and are subject to the usual market-related forces which impact on Pacific Edge’s share price. There can be no assurance that trading in the shares following the offer will be at a price at or above the price paid by investors in the offer. The equity markets can be subject to pronounced volatility. This volatility could have a materially adverse impact on the market price of Pacific Edge shares. Factors such as the risk factors disclosed in this presentation as well as other factors could cause the market price of Pacific Edge’s shares to decline or to materially fluctuate. It also is possible that new market risks may develop as a result of the New Zealand or Australian markets experiencing extreme stress, or due to existing risks manifesting themselves in ways that are not currently foreseeable. A weakening in the New Zealand or Australian dollar as against other currencies may cause the value of the shares to decline in any portfolio which is denominated in a currency other than New Zealand dollars.</p>
<b>General economic conditions</b>	<p>Pacific Edge’s operating and financial performance is influenced by a variety of general economic and business conditions in New Zealand, the United States, Southeast Asia and globally. A prolonged deterioration in general economic conditions, which may lead to a decrease or reprioritisation of healthcare spending, has the potential to have a material adverse effect on Pacific Edge’s business or financial condition (or both). In addition, uncertain and dynamic geopolitical risks, including international conflicts, sanctions, tariffs and political instability may disrupt Pacific Edge’s supply chains and access to, or costs to operate in, certain markets. Any of these may have an adverse effect on Pacific Edge’s business or financial performance (or both).</p>

# 6. FOREIGN SELLING RESTRICTIONS

# FOREIGN SELLING RESTRICTIONS

## Offer Selling Restrictions

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This document and the offer of New Shares are only made available in Australia to persons to whom an offer of securities can be made without disclosure in accordance with applicable exemptions in sections 761G (wholesale clients), 708(8) (sophisticated investors), 708(10) (experienced investors) and 708(11) (professional investors) of the Australian Corporations Act 2001 (Cth) (the "**Corporations Act**"). This document is not a prospectus, product disclosure statement or any other formal "disclosure document" for the purposes of Australian law and is not required to, and does not, contain all the information which would be required in a "disclosure document" under Australian law. This document has not been and will not be lodged or registered with the Australian Securities & Investments Commission. Prospective investors should not construe anything in this document as legal, business or tax advice nor as financial product advice for the purposes of Chapter 7 of the Corporations Act and the information provided does not take into account the investment objectives, financial situation or particular needs (including financial and tax issues) of any prospective investor. Prospective investors should review the risks set out on slides 26 to 28 before making any investment decision.

## FOREIGN SELLING RESTRICTIONS (CONTINUED)

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The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

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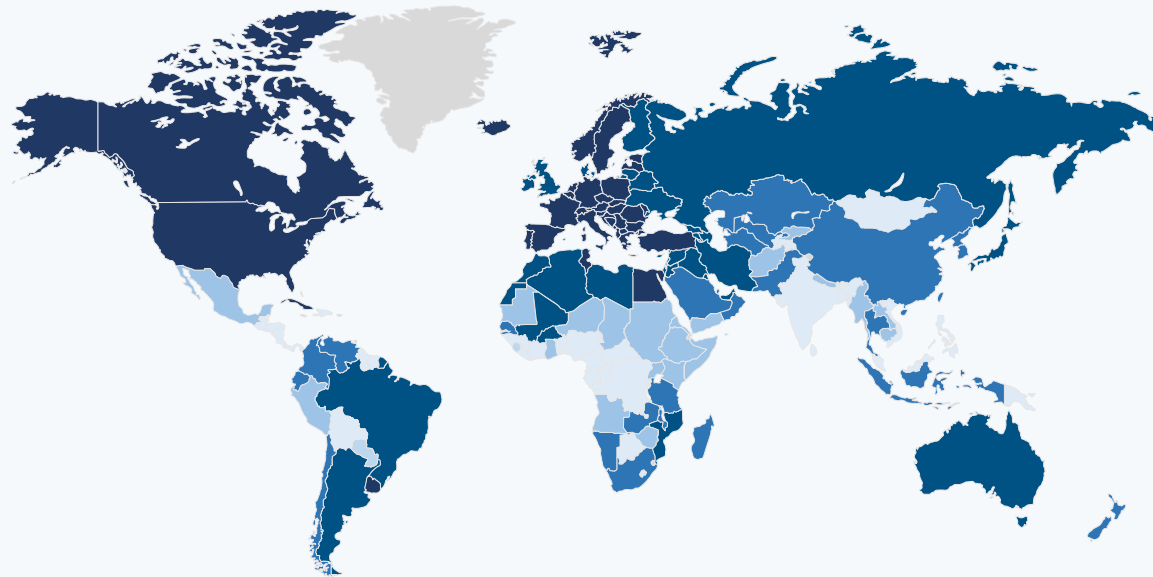
# 7. APPENDICES

## APPENDIX 1: Global Market Opportunity

# BLADDER CANCER – A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE

## INCIDENCE PER 100,000 OF THE POPULATION

■ <1.7   ■ 1.7 to 2.7   ■ 2.7 to 5.3   ■ 5.3 to 8.6   ■ >8.6



1st	6th	9th
Costliest cancer to treat on a per-patient basis <sup>1</sup>	Most common cancer in men <sup>2</sup>	Most common cancer world-wide <sup>2</sup>
<b>~614K</b> Annual cases and growing <sup>2</sup>	<b>&gt;220K</b> Annual Deaths <sup>2</sup>	<b>&gt;50%</b> Recurrence <sup>3</sup>

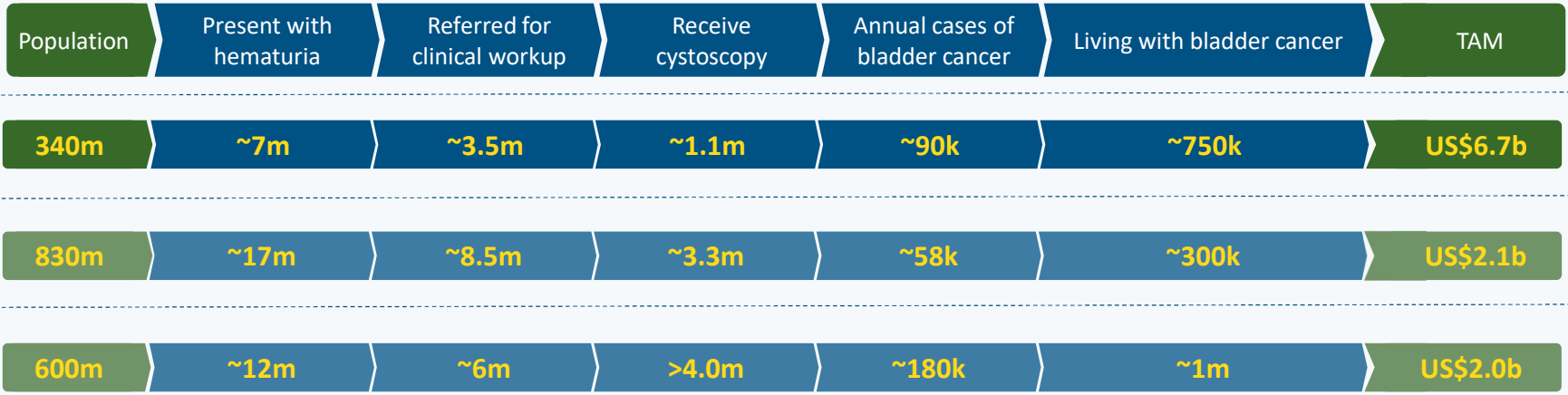
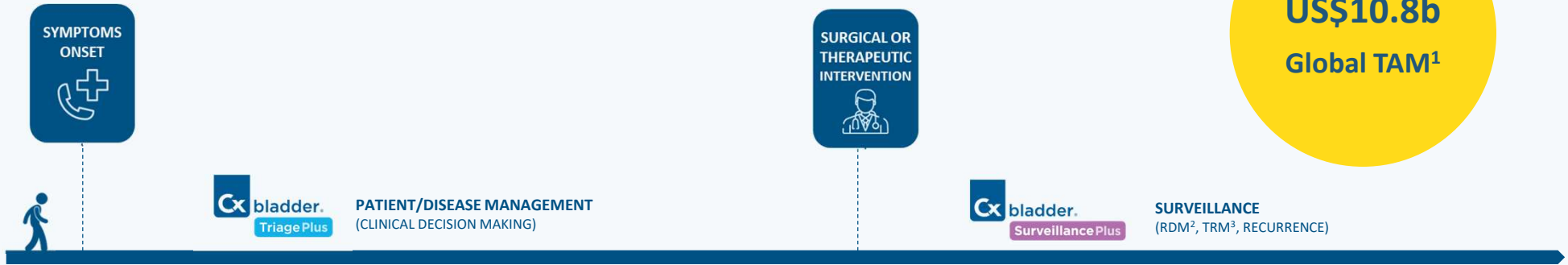
**US\$10.8b<sup>4</sup>**  
Global Market Opportunity

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. Pacific Edge estimate for Global Total Addressable Market (TAM) 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 43 for details.

# CXBLADDER MARKET OPPORTUNITY

CXBLADDER OFFERS A SIGNIFICANT ADDRESSABLE GLOBAL MARKET ANNUALLY

**US\$10.8b**  
Global TAM<sup>1</sup>



*Primary growth focus due to higher CMS pricing*

*NZ market mature. Australia and SEA in business development*

*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 42 for details.  
 2. RDM: Residual Disease Monitoring  
 3. TRM: Therapeutic Response Monitoring

# APPENDIX 2: Financial Performance



**PacificEdge**<sup>®</sup>  
CANCER DIAGNOSTICS

# POSITIONING PACIFIC EDGE FOR MEDICARE RE-COVERAGE

## COST SAVINGS MINIMIZE CASH BURN

Financial Period (\$000) <sup>1</sup>	2H 26 <sup>1</sup> (Draft)	1H 26 <sup>1</sup>	FY 26 <sup>1</sup> (Draft)	FY 25 (Audited)	2H 26 vs 1H 26	FY 26 vs FY 25
Operating Revenue	\$5,560	\$5,939	\$11,499	\$21,846	(6.4%)	(47.4%)
Total Revenue	\$6,456	\$7,123	\$13,579	\$24,616	(9.4%)	(44.8%)
Operating Expenses	\$23,040	\$26,239	\$49,279	\$54,552	(12.2%)	(9.7%)
<b>Net Loss After Tax</b>	<b>(\$16,584)</b>	<b>(\$19,116)</b>	<b>(\$35,700)</b>	<b>(\$29,936)</b>	<b>(13.2%)</b>	<b>19.3%</b>
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%
<b>Net Cash<sup>2</sup></b>	<b>\$7,776</b>	<b>\$22,121</b>	<b>\$7,776</b>	<b>\$22,568</b>	<b>(64.8%)</b>	<b>(65.5%)</b>
Monthly Cash Burn (NZ\$m)	\$2.4	\$3.3	\$2.8	\$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 FY 26 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 12.2% 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

# APPENDIX 3: Clinical Studies



**PacificEdge**<sup>®</sup>  
CANCER DIAGNOSTICS

# DRIVING CLINICAL VALUE FOR PHYSICIANS, HOSPITALS AND PAYERS

COMPELLING CLINICAL EVIDENCE CHANGES CLINICAL PRACTICE, MEDICAL POLICY AND GUIDELINES

STUDY	TEST AND EVIDENCE	PUBLICATION DATE <sup>(1)</sup>
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 <sup>7</sup>
5. STRATA second publication	- CU of Triage Plus (concordance <sup>2</sup> )	Q3 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 <sup>3</sup>	- CV of Triage Plus	Q1 2027
10. Pooled Analysis GH Clinical Validation <sup>3</sup>	- CV of Triage Plus	Q1 2027
11. LOBSTER Clinical Validation	- CV of Monitor/Surveillance Plus	Q2 2027
12. CREDIBLE Clinical Utility	- CU of Triage Plus	Q1 2028
13. OCTOPUS Clinical Utility	- CU Surveillance Plus	Q2 2028

<sup>1</sup> All dates are calendar year and our best current estimates

<sup>2</sup> Concordance will be demonstrated by comparing Triage and Triage Plus on identical samples

<sup>3</sup> 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)
- 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

Already published evidence

# 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 <sup>1</sup>
Real World Utility of Triage in MH: A Matched Cohort Study	Kaiser Permanente, US	CU Triage (RWE)	Q1 2026 <sup>2</sup>
Patient preference and satisfaction of “biomarkers vs cystoscopy”	Mayo Clinic, US	CU Monitor	Q2 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 CU Surveillance Plus	2027
Test utility in assessing response to BCG <sup>3</sup> in high-grade bladder cancer patients	University of Miami, US	CU Monitor CU Surveillance Plus	2027
Test utility for the surveillance of MIBC <sup>4</sup> 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

Already published evidence



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



## 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)

# HEMATURIA EVALUATION FIVE YEAR CLINICAL STUDIES ROADMAP

Calendar year	Pre 2023	2023				2024				2025				2026				2027				2028	
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
STRATA	▶*	▶				▶				▶				▶				▶				▶	
DRIVE	▶*	▶				▶				▶				▶				▶				▶	
AUSSIE	▶*	▶				▶				▶				▶				▶				▶	
microDRIVE	▶*	▶				▶				▶				▶				▶				▶	
Pooled CV		▶				▶				▶				▶				▶				▶	
CREDIBLE		▶				▶				▶				▶				▶				▶	

**Legend:**

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

# SURVEILLANCE FIVE YEAR CLINICAL STUDIES ROADMAP

Calendar year	Pre 2023	2023				2024				2025				2026				2027				2028		
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
"The 1800" <sup>1</sup>																								
LOBSTER	➡*	➡																						
OCTOPUS														CAB <sup>2</sup>										

**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

REGION	STATISTIC		SOURCE
US	Population	341,762,685	<a href="https://www.census.gov/popclock/">https://www.census.gov/popclock/</a>
	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	<a href="#">National Cancer Institute</a>
	Patients living with bladder cancer	744,044	<a href="#">National Cancer Institute</a>
	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
Incidence of hematuria		12,000,000	<a href="#">Science Direct</a>
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	<a href="#">Rindorf, D, et al. The extent of experiencing availability issues and deteriorating performance associated with reusable cystoscopies, a multicentre study.</a>
Annual cases of bladder cancer		180,000	<a href="#">Uroweb</a>
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
	Incidence of hematuria	16,600,000	<a href="#">Science Direct</a>
	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	<a href="#">WHO; Hong Kong</a>
	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	

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