



PacificEdge[®]
CANCER DIAGNOSTICS

FY 25 RESULTS PRESENTATION

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29 May 2025

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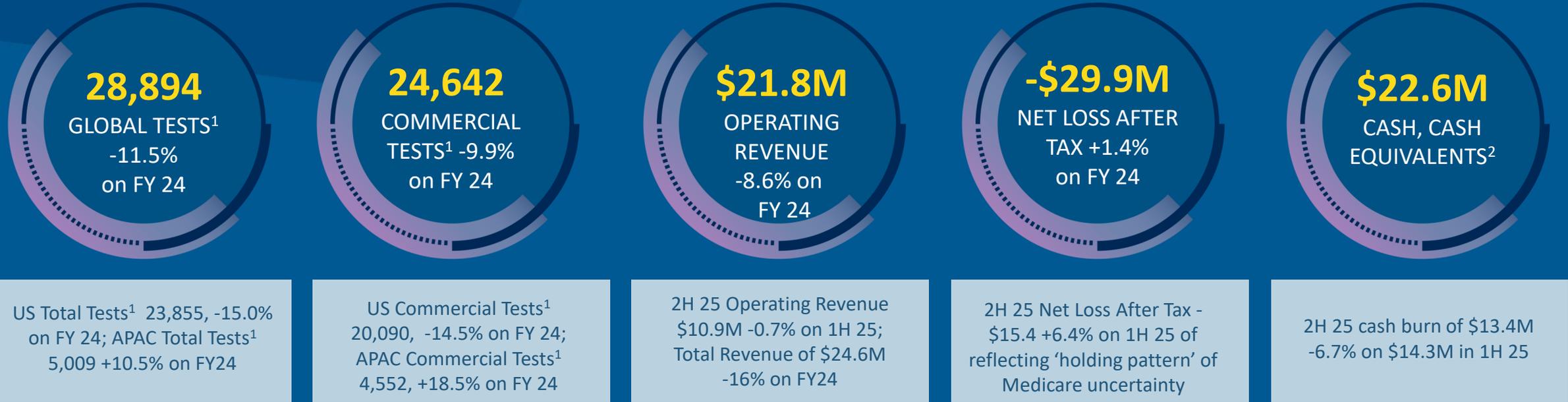
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AGENDA

1. HIGHLIGHTS
2. STRATEGIC DELIVERY
3. FINANCIAL PERFORMANCE
4. OUTLOOK

MEDICARE COVERAGE UNCERTAINTY OVERSHADOWS FY 25 STRATEGIC GAINS



- Resilient operating performance amid Medicare uncertainty; adverse Medicare Local Coverage Determination in effect after balance date
- Operating revenue, net losses, and cash burn steady 2H 25 vs 1H 25 as operating efficiencies and cash collection gains retained
- US test sales/FTE rise to 405.6 in Q4 25, +6.4% on Q4 24 and +69.5% on Q4 23; US ASP³ increases to **US\$594** in FY 25 vs **US\$584** in FY 24
- Non-Medicare revenues represent **57%** of US volumes and growing, supported by Triage inclusion in the AUA microhematuria guideline
- Longer term economics reinforced by draft CMS pricing of Triage Plus at US\$1,018 per test vs. US\$760 per test for the current generation of tests

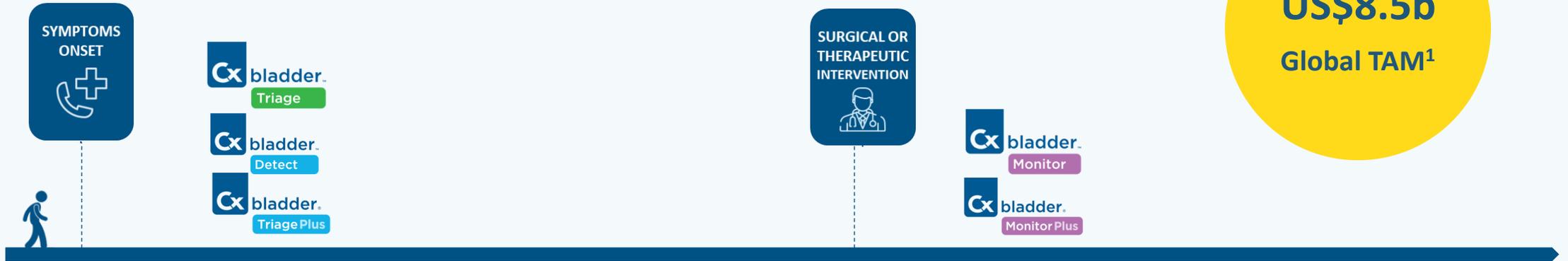
1. Total Laboratory Throughput (TLT) including commercial, pre-commercial and clinical studies testing
 2. Cash, short-term deposits and term deposits
 3. ASP: US Operating Revenue in USD / US Commercial Test Volumes

PACIFIC EDGE OVERVIEW

CXBLADDER OFFERS A SIGNIFICANT ADDRESSABLE GLOBAL MARKET ANNUALLY

THE PATIENT CARE PATHWAY

US\$8.5b
Global TAM¹



Focus of our growth efforts



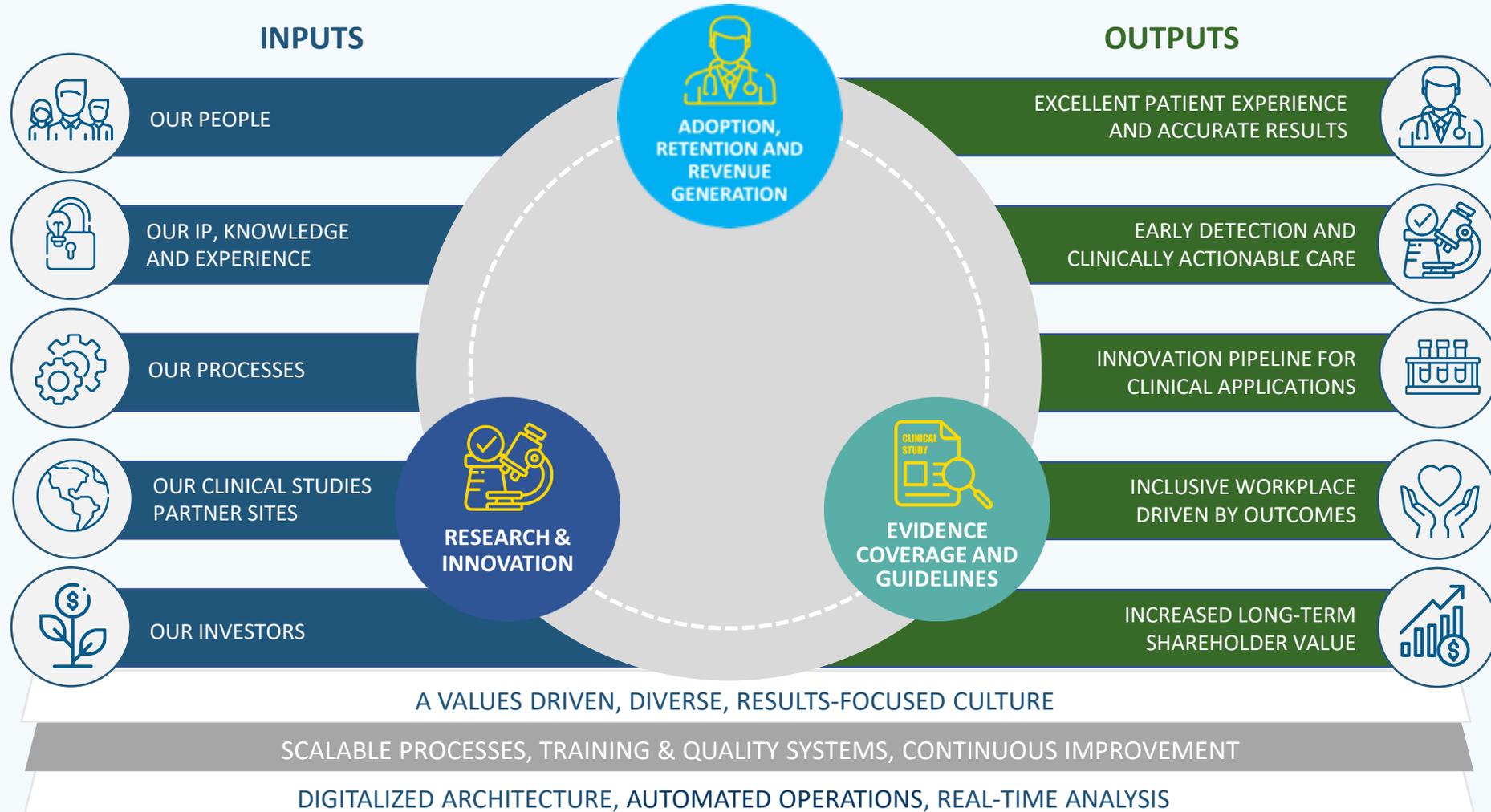
NZ market mature. Australia and SE Asia in business development



New market accessed via IVD / kitted tests

1. Pacific Edge estimate using US\$1,018 price for hematuria testing in the US and \$760 for Non-Muscle Invasive Bladder Cancer (NIMBC) surveillance and other market assumptions for APAC and Europe. See slide 38 of this presentation for the sources and assumptions for the calculation of TAM

VALUE CREATION THROUGH THREE PILLARS



AUA MICROHEMATURIA GUIDELINE INCLUSION

A COMPANY-DEFINING STRATEGIC MILESTONE ACHIEVED IN FEBRUARY 2025



The 2025 amendment to the AUA microhematuria guideline supports the use of urine-based biomarkers for intermediate-risk patients as an alternative to a cystoscopy

- Primary driver for the change in the guidelines was clinical utility evidence for Cxbladder Triage from a randomized controlled trial, i.e. the STRATA Study¹
- Cxbladder Triage specifically mentioned as the only urine-based biomarker test that has 'Grade A'² evidence cementing first-mover advantage and building a moat vs competitors
- The change was significant:
 - The 2020 guideline expressly prohibited the use of urine-based biomarkers in lieu of a cystoscopy
 - The 2025 guideline brings genomic testing to hematuria evaluation for bladder cancer as already established for prostate, breast, colon and other cancers
- Intermediate-risk patients represent a large cohort (~70%)³ of microhematuria patients (up to 3.5 million patients annual in the US)
- Offers significant benefits to patients, reduces the burden of unnecessary cystoscopies, improves access to care at a lower cost and reduces legal liability for using biomarker alternatives

AUA guideline inclusion provides significant global clinical validation for Cxbladder which is expected to pave the way for further wider global adoption by healthcare providers and payers – we have already noticed increased interest from physicians



American
Urological
Association

*"... [for] intermediate-risk patients who want to avoid cystoscopy and accept the risk of forgoing direct visual inspection of the bladder urothelium, **clinicians may offer urine cytology or validated urine-based tumor markers to facilitate the decision regarding utility of cystoscopy.**"*
– 2025 AUA Microhematuria Guideline Amendment

MEDICARE NON-COVERAGE IN APRIL 2025 INCONSISTENT WITH AUA GUIDELINE

AUA GUIDELINE INCLUSION PROVIDES THE BASIS FOR GREATER SUCCESS WITH COMMERCIAL PAYERS



MEDICARE COVERAGE COMMENCED IN 2020 BUT CEASED IN 2025

- Medicare reimbursed Cxbladder tests >98% since 2020 at US\$760 per test – these tests have accounted for the majority of US volumes and ~61% of revenue in FY25
- Novitas – the Medicare Administrative Contractor that determines Medicare coverage for our tests – proposed non-coverage for Cxbladder in July 2022 (2H 23)
- We challenged this determination with more recent evidence and support from the American Urological Association (AUA), but Novitas finalized its non-coverage determination in January 2025 without considering the most-current evidence available
- This decision removed coverage for AUA guideline-recommended testing, after following a process that failed to review the most-current evidence

OUR RESPONSE: DRIVING CXBLADDER DEMAND WITH AUA GUIDELINE INCLUSION

- ~47% of US volumes are from other contracted payers (e.g. Kaiser Permanente, the US Veterans Administration and various Blue Cross Blue Shield plans) and non-contracted private payers – **these volumes are expected to continue to grow without interruption**
- Our commercial team will continue to promote and supply tests to existing US users and drive demand to maintain the momentum building from the guideline
- Seeking reimbursement through the Medicare Appeals Process and Client Billing



Medicare

Medicare is the US national insurance payer for all US citizens over 65 years of age – the most at risk age demographic for bladder cancer

SEEKING RE-COVERAGE VIA LCD RECONSIDERATION AND MEDICARE APPEALS

RECONSIDERATION REQUESTS FOR TRIAGE AND MONITOR; APPEALS TO RELY ON GUIDELINE INCLUSION



RESTORING MEDICARE COVERAGE FOR TRIAGE AND MONITOR

- **Cxbladder Triage:** A reconsideration request was submitted to Novitas in March 2025 consisting of STRATA¹ and the AUA Microhematuria guideline and is under review
- **Cxbladder Monitor:** A reconsideration request was submitted to Novitas in May 2025 consisting of two new real-world studies from Australia and is under review
- **Cxbladder Detect:** Detect users are being migrated to Triage, accelerating a plan previously intended to coincide with the commercial launch of Triage Plus
- Industry experts typically estimate it is likely to take 6-9 months for Novitas to consider a valid submission of a single product with only a small number of new supporting publications to be reviewed.
- We will attempt to get reimbursed on all Triage tests based on the 2025 AUA microhematuria guideline through the Medicare appeal process; the guideline supports our claim for reimbursement on the grounds of being “medically reasonable and necessary” despite a non-coverage determination

ESTABLISHING MEDICARE COVERAGE FOR TRIAGE PLUS

- The analytical validation (AV) and clinical validation (CV) publications for Triage Plus have been submitted for peer review in appropriate scientific journals seeking publication in FY26 Q1
- Pacific Edge will submit a reconsideration request for Triage Plus when the AV and CV is published
- Inclusion of Triage in the AUA microhematuria guideline provides medical policy for Medicare coverage of Triage Plus, meaning AV and CV should be sufficient for coverage
- Further evidence for Triage published by Kaiser Permanente as a presentation at AUA and in peer review by FY26 Q3 further confirms Triage and Triage Plus clinical utility and health economics
- Draft Triage Plus pricing at US\$1,018 is expected to become effective from January 2026

MEDICARE RE-COVERAGE: ESTIMATED TIMELINES

COVERAGE DECISIONS, PRIOTIZATION AND TIMELINES ARE AT THE DISCRETION OF NOVITAS¹



MEDICARE RECONSIDERATION REQUEST	CATALYST	2025*				2026*			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Reconsideration request for Triage	STRATA Study (May 2024) AUA Macrohematuria guideline (Feb 2025)								
Reconsideration request for Monitor	AV of Triage, Detect & Monitor (Sept 2024) 2x RWE of Monitor (March 2025)								
Reconsideration request Triage Plus	AV of Triage Plus (Q2E 25)** CV of Triage Plus – DRIVE Study (Q2 25)**								

*Calendar year

** Estimated publication quarter

Expected Novitas determination window

FUTURE CATALYSTS FOR GUIDELINES INCLUSION AND MEDICARE COVERAGE

Publication	Test and evidence standard ²	Expected date ³
1. STRATA Concordance	- CU of Triage Plus (concordance)	Q4 2025
2. Kaiser Permanente Triage RWE ⁴	- CU of Triage (RWE)	Q3 2025 ⁵
2. Kaiser Permanente Monitor RWE ⁴	- CU of Monitor	Q1 2026 ⁵
4. AUSSIE	- CV of Triage Plus	Q1 2026
5. microDRIVE	- CV of Triage Plus	Q2 2026
6. Monitor Plus Analytical Validation	- AV of Monitor Plus	Q2 2026
7. Pooled Analysis ⁶	- CV of Triage Plus	Q2 2026
8. LOBSTER interim analysis	- CV of Monitor/Monitor Plus	Q1 2027
9. CREDIBLE	- CU of Triage Plus	Q1 2028

¹ Novitas is the Medicare Administrative Contractor (MAC) that covers Pacific Edge Diagnostics USA's lab in Pennsylvania

² AV, CV, CU, respectively Analytical Validity, Clinical Validity, Clinical Utility

³ Calendar year

⁴ RWE is Real World Evidence

⁵ Timeline determined by Kaiser Permanente

⁶ The pooled analysis uses data from DRIVE, AUSSIE and microDRIVE studies

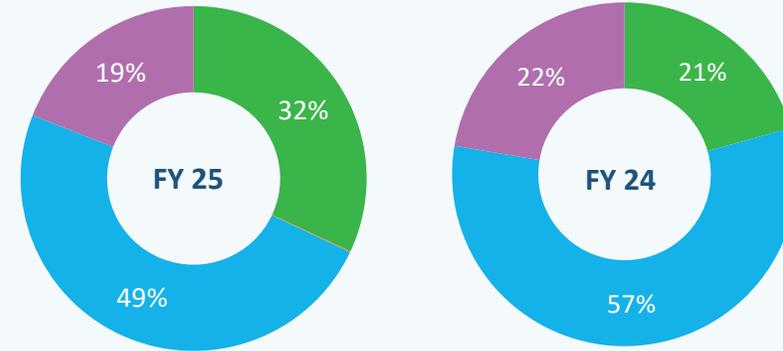
FY 25 VOLUMES FALL AMID REDUCED SALES FORCE REACH AND UNCERTAINTY



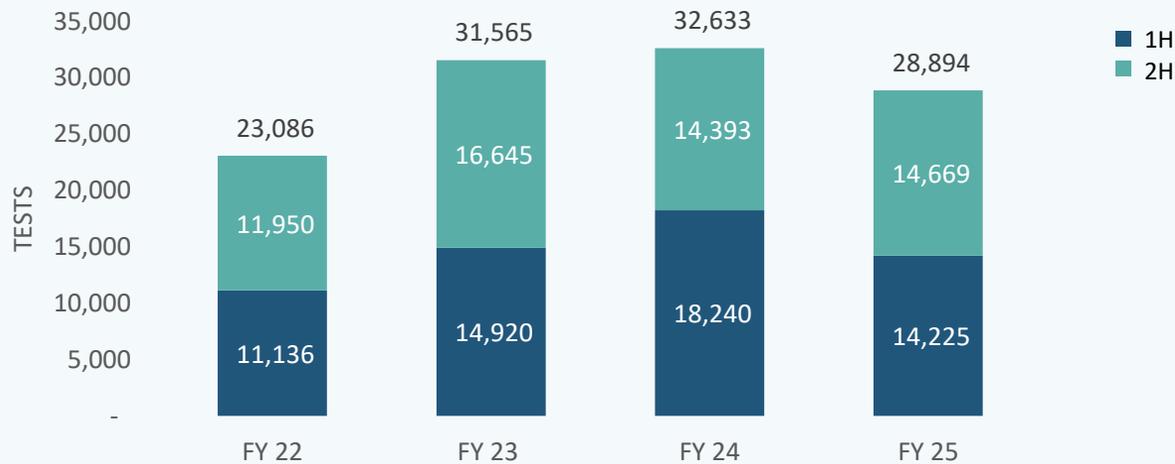
FY 25 TOTAL LAB THROUGHPUT (TLT*)

- Global TLT of 28,894 for FY 25 down 11.5% on FY 24 amid Medicare coverage uncertainty and reduced reach of the sales force
- Global Commercial test volumes of 24,642 for FY 25 down 9.9% on FY 24 with falling US volumes offset by 18.5% uplift in APAC
- Triage growing in share of volume validating risk stratification value proposition and investment in Triage Plus

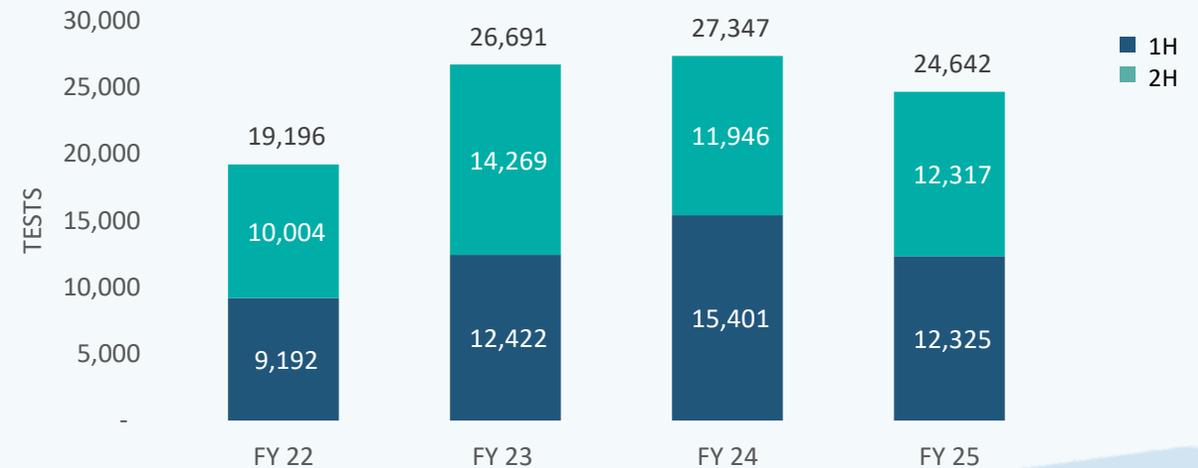
TEST VOLUMES BY TYPE (TLT*)



GLOBAL TOTAL TEST VOLUMES (TLT*)



GLOBAL COMMERCIAL TEST VOLUMES



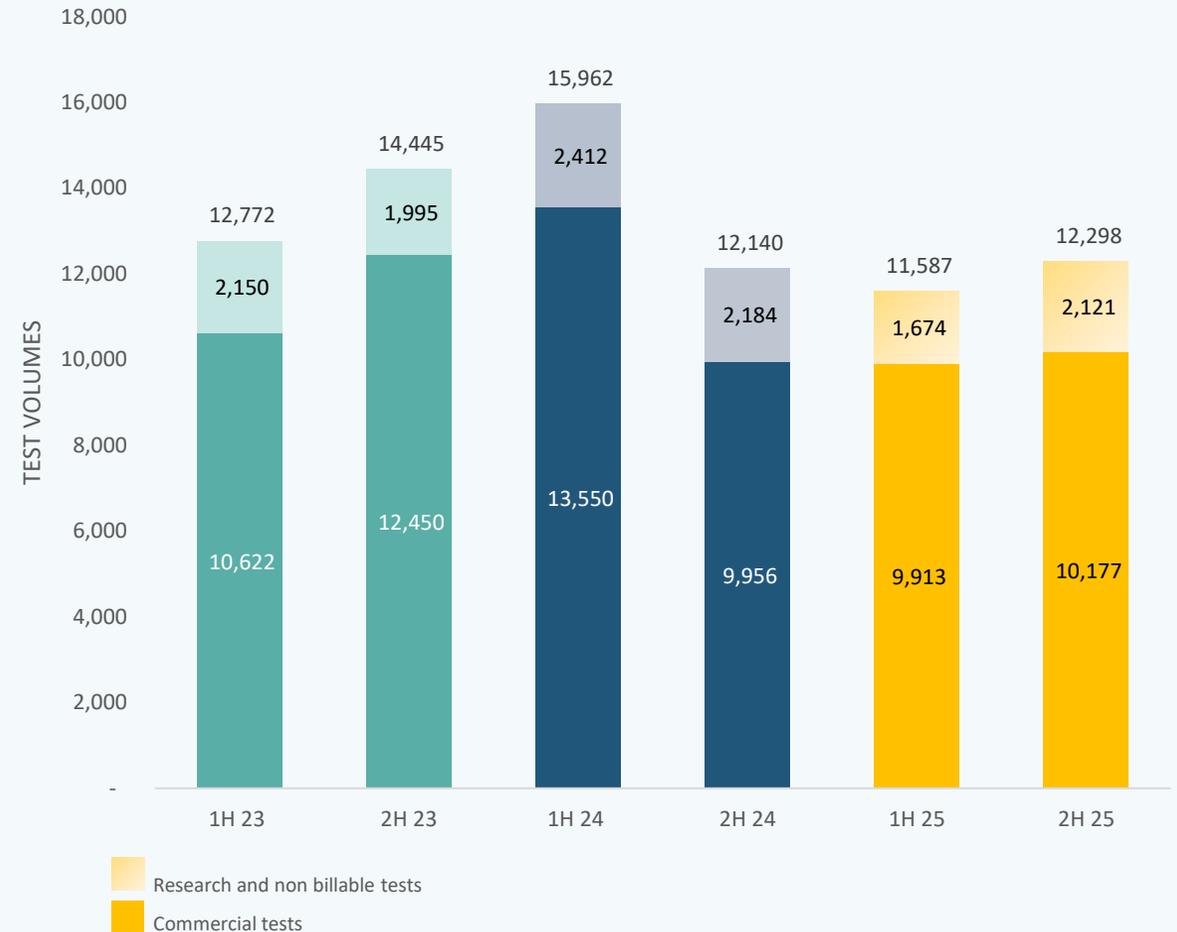
US CONTRACTED PAYER DEMAND SUPPORTS VOLUME GROWTH



CONTRACTED PAYERS HELP TO OFFSET MEDICARE UNCERTAINTY

- US commercial volumes in 2H 25 increased 2.7% against 1H 25 supported by contracted payer volumes
- Non-Medicare volumes represented 47% of US commercial volumes (~9,366) in FY 25 vs 40% (~5,358) in 1H 24
- Strong performance from the Southern California Permanente Medical Group and sustained sales force efficiency gains mitigated impact of Medicare uncertainty
 - All 15 Kaiser SoCal sites are ordering, dominated by Triage volumes, but Monitor also increasing
 - Real World Evidence from Kaiser Permanente² confirming clinical utility established in STRATA³
- We have begun to see the impact of the Medicare LCD on post LCD effective date volumes and the substitution of Triage for Detect in line with the AUA guideline

US TOTAL TEST VOLUME¹



1. Total Laboratory Throughput in the US including commercial, pre-commercial and clinical studies testing

2. Real World Clinical Utility of a Urinary Biomarker (Cxbladder Triage) for Hematuria Referrals in an Integrated Managed Care Health System. Abstract accepted for presentation to the Western Section of the American Urological Association annual conference.

3. Lotan et al. (2024) . A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.

SALES PERFORMANCE IMPROVEMENTS EMBEDDED

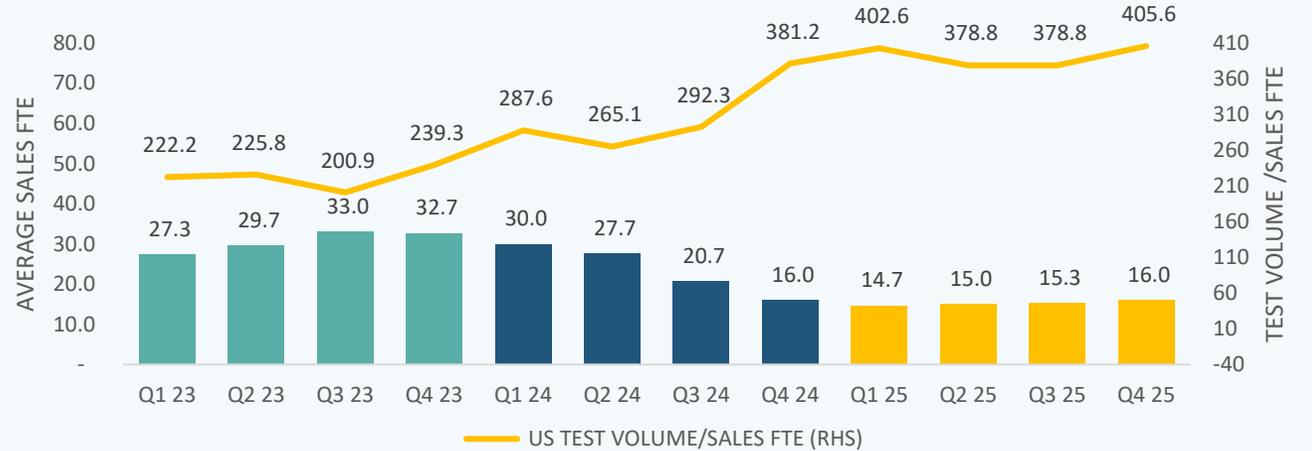
US COMMERCIAL TEAM DELIVERS STEADY INCREASE IN TESTS/SALES FTE



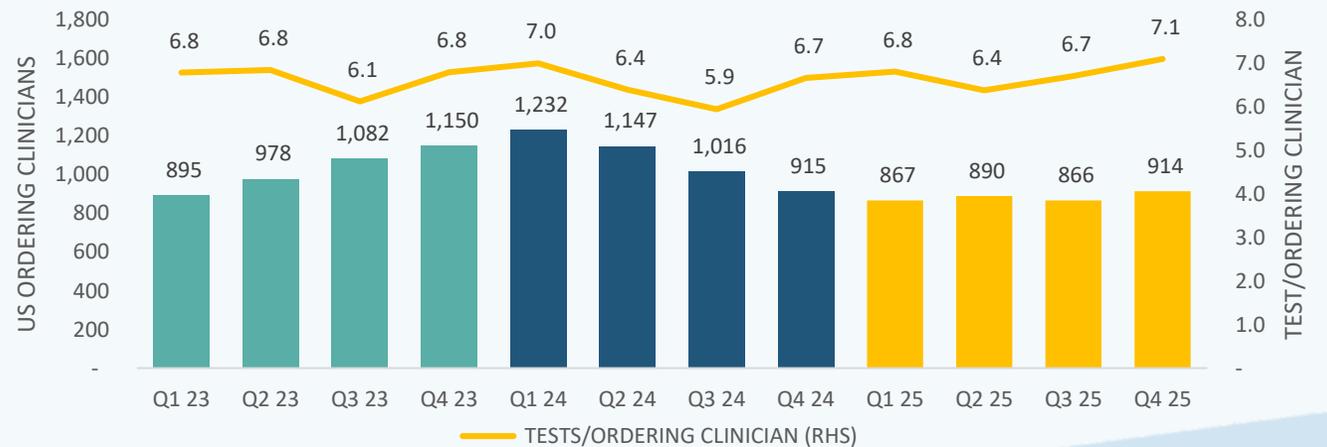
SALES TEAM FOCUSED ON KEY PERFORMANCE INDICATORS

- Sales FTE down to an average of 16.0 in Q4 25 from 32.7 in Q4 23 as we focused on cash conservation
- Sales force efficiency (total tests/average FTE) sustained up 69% from 239 in Q4 23 to 405.6 in Q4 25
- Focus on the most profitable territories/accounts
- Tests/US ordering clinician stable, ordering clinicians steady on Q4 24
- Change in clinical mix in favor of clinicians that understand the clinical utility of Cxbladder

US SALES FORCE EFFICIENCY



US CLINICAL COMMITMENT



FOUNDATIONS FOR GROWTH – US CASH COLLECTIONS IMPROVE



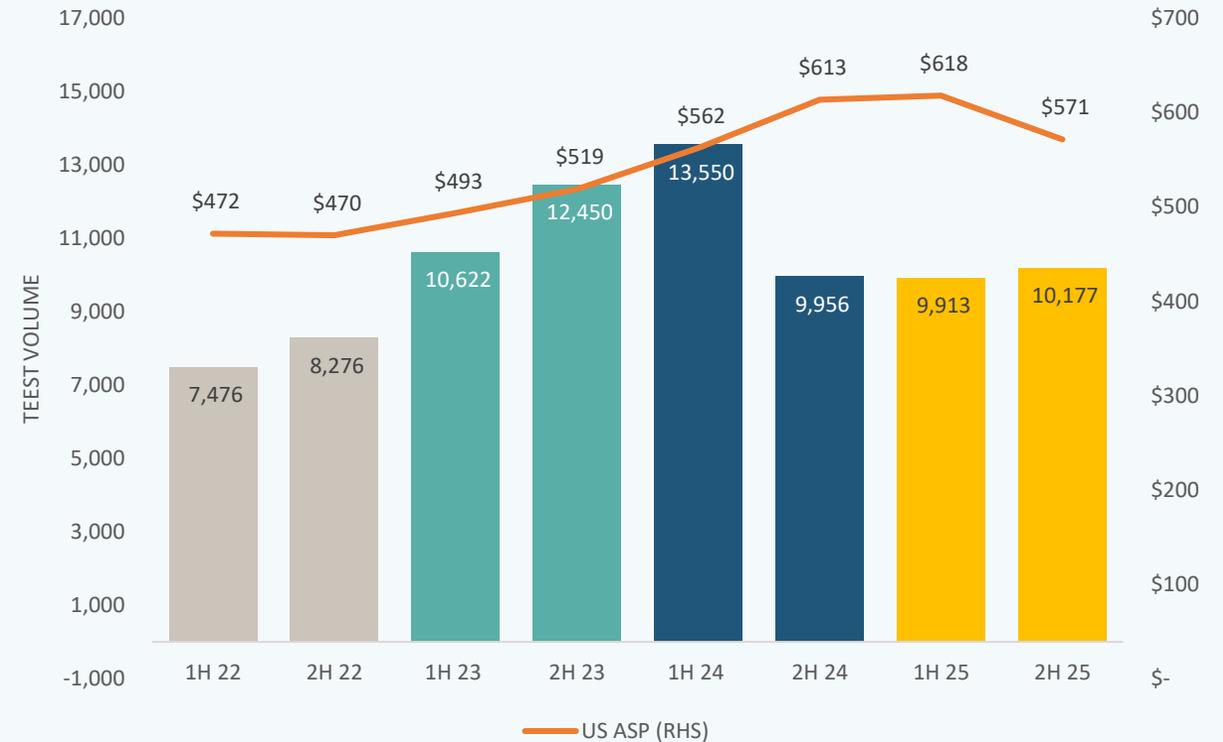
REIMBURSEMENT & CASH COLLECTIONS – A CORE COMPETENCY

- Despite the dip in 2H 25 Average Sales Price (ASP¹) due to timing variances related to accruals and increased provisions against revenue, ASP per test has increased to US\$594 in FY 25 from US\$584 in FY 24 lifted by:
 - Enhanced Patient Responsibility - patients with non-contracted private insurance (i.e. non-Kaiser) pay a fixed dollar amount “maximum out of pocket”
 - Increased utilization of appropriate patient types from Kaiser Permanente after EMR integration
 - Medicare reimbursement of Triage since Jan 2023
 - Improved medical necessity documentation to improve billing and appeals processes for Medicare Advantage
- Improved cash collections are typically permanent improvements that we expect to maintain as we scale

AUA GUIDELINE OFFERS NEW OPPORTUNITIES FOR CLIENT BILLING

- With AUA guideline inclusion, a new opportunity exists to get paid per test by hospitals and large urology group practices (LUGPAs) and let them handle the commercial reimbursement
- This provides a revenue incentive to hospitals/LUGPAs and has the potential to drive volume, since they are commonly "in-network" with commercial payers and have sophisticated billing teams

US COMMERCIAL TEST VOLUMES AND ASP* (US\$)



MEDICARE PRICE FOR TRIAGE PLUS ACCELERATES PATH TO PROFITABILITY

DRAFT PRICE FOR TRIAGE PLUS OF US\$1,018 PER TEST PUBLISHED APRIL 2025

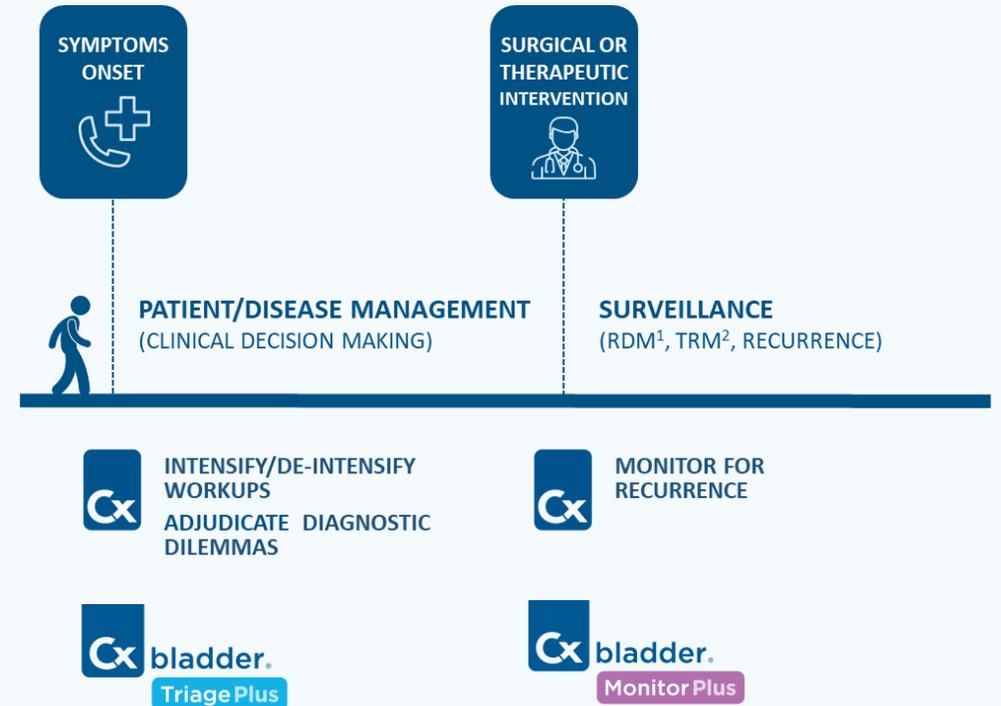


MEDICARE COVERAGE NEEDED BEFORE FULL-SCALE COMMERCIAL LAUNCH

- The Centers for Medicare & Medicaid Services (CMS) draft price of US\$1,018 for Triage Plus materially lifts margin per test from the previous pricing at US\$760, expected to become effective in Jan 2026
- Lowers the profitability threshold for number of tests per Account Executive, facilitating more rapid scaling and a faster path to profitability
- A reconsideration request will be made to Novitas for coverage of Triage Plus as soon as the analytical validation (AV) and clinical validation (CV) studies have been published (estimated in June 2025)

ACCELERATING THE PATH TO PROFITABILITY

- Adding digital capabilities and FTE capacity to PEDUSA laboratory
- Simplifying laboratory workflow for improved efficiency
- Optimizing sales team structure for expanded product adoption
- Sales and marketing materials to reflect AUA Guideline messaging
- Enhancing medical education with a speaker bureau, podium presentations, and evidence development



DRIVING GROWTH IN ASIA PACIFIC AND CONSOLIDATING NEW ZEALAND



SEEKING A NATIONAL HEMATURIA EVALUATION PATHWAY IN NZ

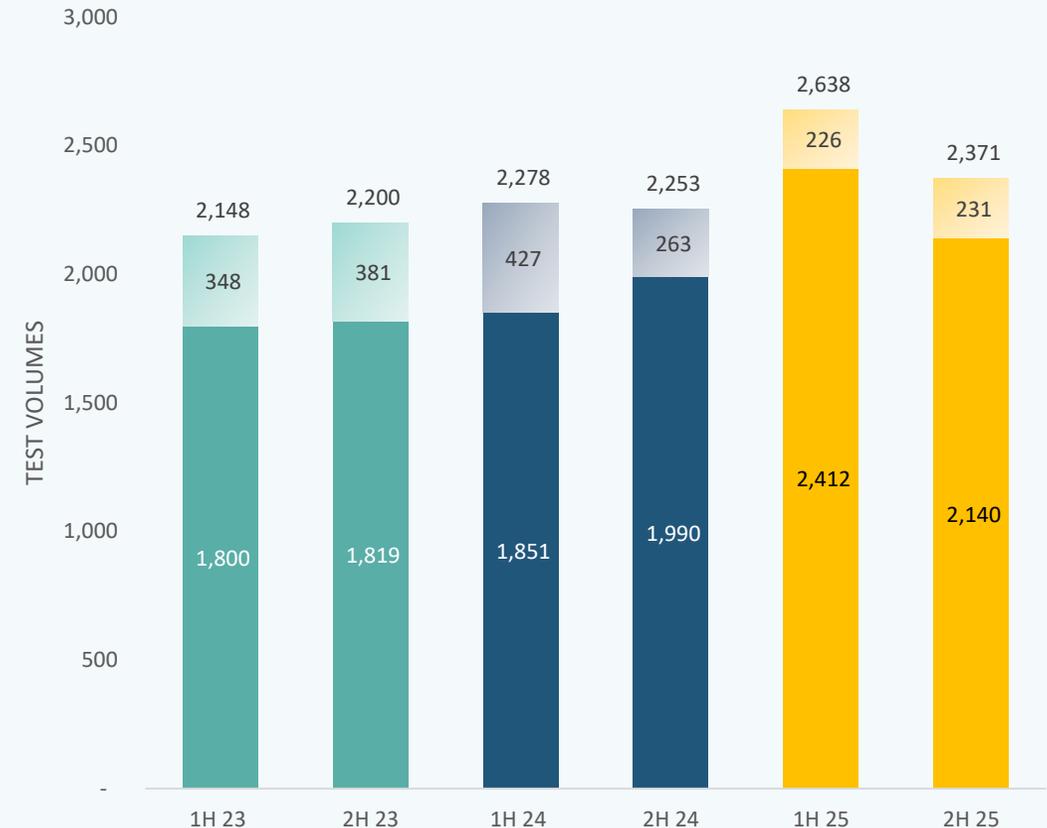
- Quarterly total test volumes benefit from:
 - Fewer evaluations and non-billable tests
 - Shift in emphasis to commercial tests from evaluations
- STRATA¹ and AUA microhematuria guideline are well understood in *Te Whatu Ora*/Health New Zealand; Pacific Edge is focused on a national pathway for hematuria evaluation

AUSTRALIA & ASIA PACIFIC

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



APAC TOTAL TEST VOLUMES*



■ Research and non billable tests
■ Commercial tests

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

1. Lotan et al. (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.

CUSTOMER EXPERIENCE INITIATIVES DELIVERING VALUE

DIGITALIZATION OF INFORMATION FLOWS EMBEDS CXBLADDER IN CLINICAL PRACTICE



ENHANCING CXBLADDER'S EASE OF USE

- We give customers options to connect with Pacific Edge to fit their needs with easy-to-use digital integrations
- Digital channels for test ordering and results delivery
 - **1-to-1 EMR Integration**, e.g. Kaiser interface
 - **1-to-many Integration**, e.g. Lumea Digital Pathology, Awanui
 - **Customer portal** – available to any Customer Account
- Improves the end-to-end experience for physicians
 - Easier ordering in-clinic or for in-home sampling systems
 - Optimized test kit management and workflow
 - Enhanced order visibility and tracking
 - Streamlined access to results
- Pacific Edge's operations benefit
 - Fewer errors, faster handling and results delivery
 - Reduced demand on the sales force and customer service

THE PACIFIC EDGE CUSTOMER PORTAL

The screenshot displays the CXbladder Customer Portal interface. On the left is a navigation menu with options: Home, New Test Order (highlighted), Test Status & Results, Request New Sampling Systems, Learning & Resources, and Contact Us. The main content area is titled 'Create A New Test Order' and features two buttons: 'Triage' (selected) and 'Monitor'. Below these is a form titled 'Please Fill In All Information' with a 'Collapse All Sections' link. The form contains six numbered sections, each with a dropdown arrow: 1. SPECIMEN INFORMATION, 2. PATIENT INFORMATION, 3. IMPORTANT PATIENT HISTORY, 4. INSURANCE INFORMATION, 5. ORDERING CLINICIAN, and 6. AUTHORIZATION. At the bottom of the form are three buttons: 'Save as draft', 'Cancel', and 'Submit'. The footer includes the CXbladder logo and a 'Privacy Policy' link.

FOCUSED ON THE DNA ENHANCED PRODUCT LAUNCH AND THE IVD STRATEGY

AN IVD PRODUCT MAY EXTEND THE MARKET OPPORTUNITY AND THE 'MOAT' AROUND CXBLADDER



READYING FOR THE LAUNCH OF TRIAGE PLUS AND MONITOR PLUS

- Ensure R&D, Digital and Lab Operations focus on the commercial scaling of Triage Plus and development of Monitor Plus
- Simplifying Cxbladder:
 - Aim to reduce technician time, lower cost of goods, lower turnaround time, increase throughput and increase automation of our lab testing services
 - Aim to automate lab operations from end-to-end lab for RNA and DNA workflows of our lab testing services
- Continued engagement with industry and academic research and development collaborations to address unmet clinical needs in bladder cancer diagnosis and management

ADVANCING OUR IN-VITRO STRATEGY FOR INTERNATIONAL MARKETS

- Accelerating the development of a kitted IVD (in vitro diagnostic) product from our existing lab service called Triage Plus IVD, for decentralized lab deployment and international market expansion
 - Establish IVD regulatory framework for our next generation tests that includes IVD-R (Europe), FDA (USA) and ISO-13485¹ (Rest of World)
 - Targeting prototypes by the end of CY 25; manufacture and commencement of clinical and analytical validation commencing in CY 26
- Achieving IVD-approved status may make it more difficult for competitors to develop parity with Cxbladder's level of evidence



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



FINANCIAL PERFORMANCE

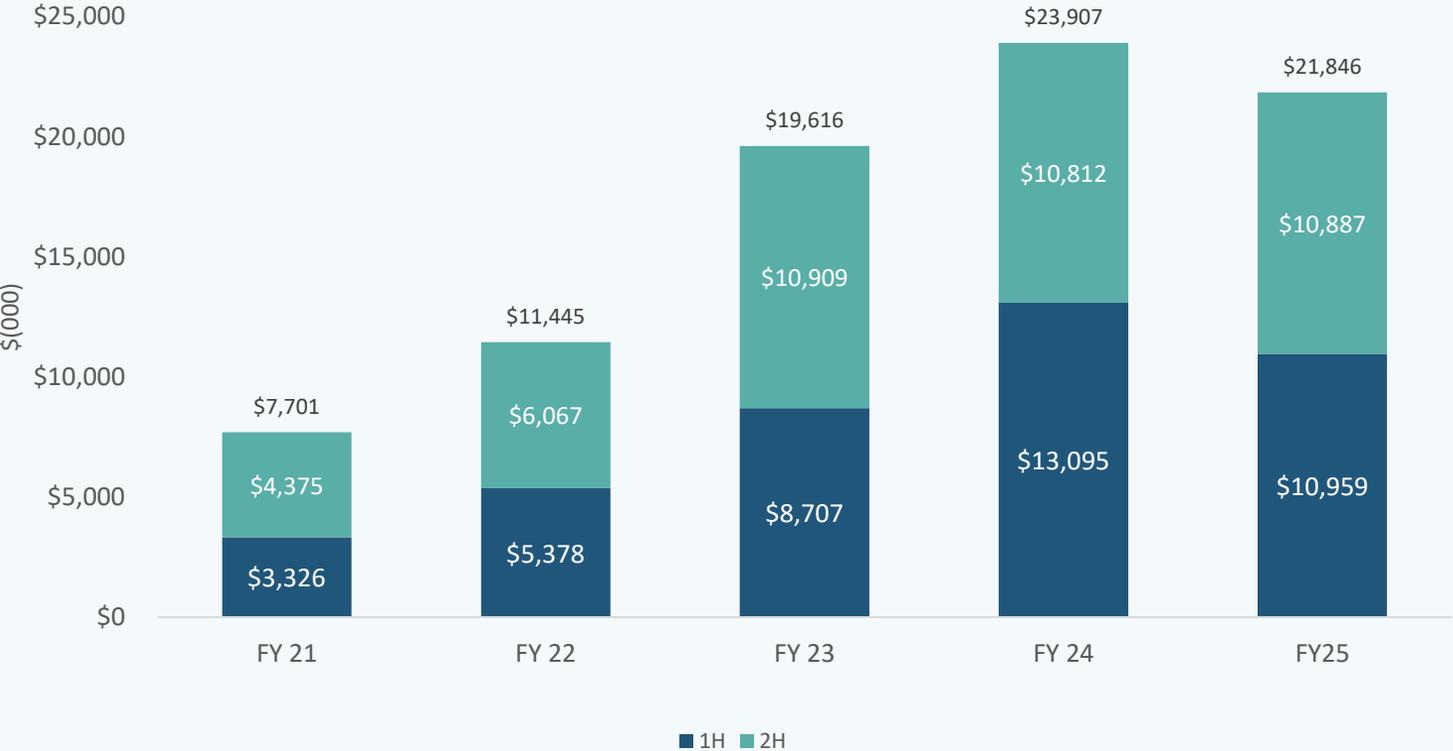


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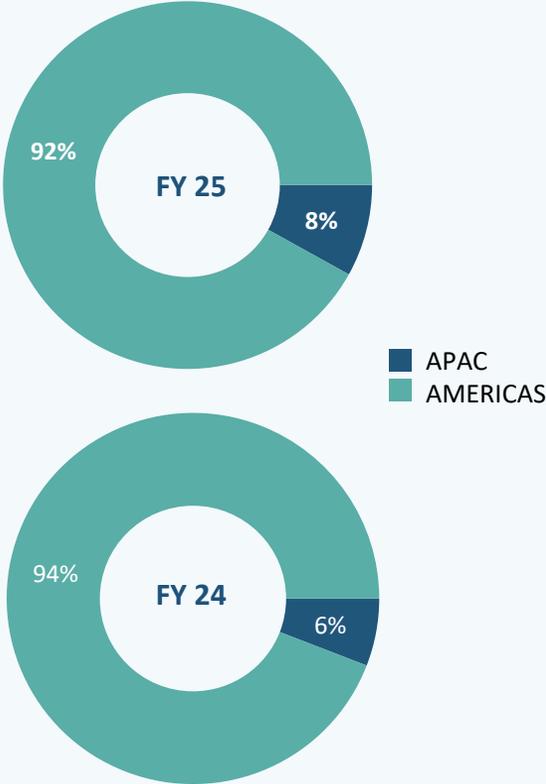
US COMMERCIAL TEST VOLUME GROWTH DRIVING REVENUE

LOOKING TO US CATALYSTS TO DRIVE A RECOVERY IN REVENUE GROWTH

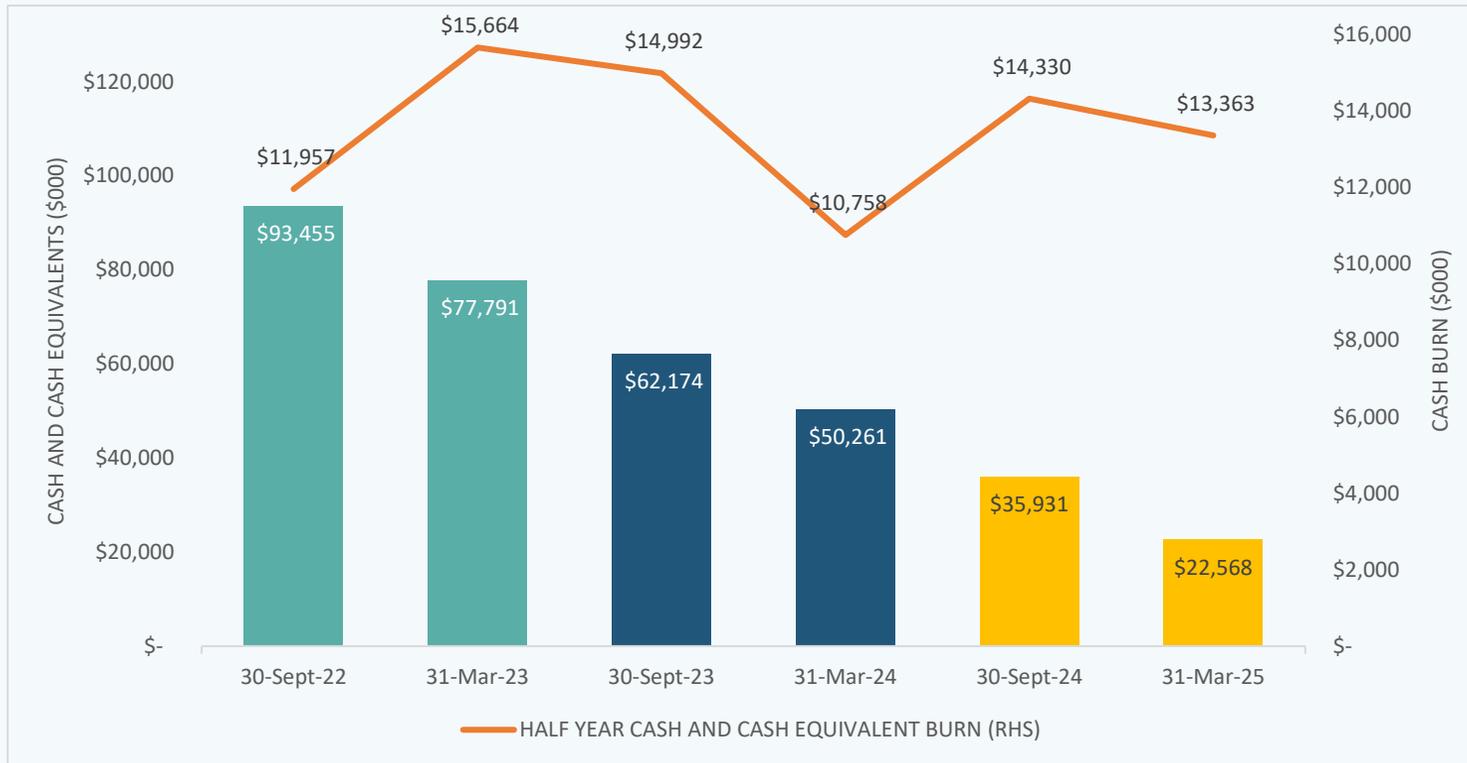
PACIFIC EDGE OPERATING REVENUE



REGIONAL REVENUE CONTRIBUTION



CAPITAL FOCUSED ON EVIDENCE GENERATION FOR RELIABLE REIMBURSEMENT



CAPITAL NEEDED TO SUPPORT MOMENTUM

- Cash, cash equivalents and short-term deposits of \$22.6M at 31 March 2025 vs \$50.3M as at 31 March 2024
- Cash burn in 2H 25 reduces to \$13.4M vs \$14.3M in 1H25, with underlying trend steady after adjusting for the higher weighting of costs in 1H 25
- Investment now primarily focused on long-term strategic initiatives
- Capital needed to support business momentum

REVENUE STEADY; INCREASE IN ASP OFFSETS THE IMPACT OF LOWER VOLUME

FINANCIAL PERIOD	FY 25	2H 25	1H 25	FY24	FY 25 vs. FY 24	2H 25 vs. 1H 25
	\$000	\$000	\$000	\$000	△ %	△ %
	Operating revenue	\$21,846	\$10,887	\$10,959	\$23,907	-8.6%
Total revenue	\$24,616	\$12,461	\$12,155	\$29,293	-16.0%	2.5%
Operating expenses	\$54,552	\$27,894	\$26,658	\$58,828	-7.3%	4.6%
Net Loss After Tax	-\$29,936	-\$15,433	-\$14,503	-\$29,535	1.4%	6.4%
Cash receipts from customers	\$21,572	\$10,447	\$11,125	\$24,137	-10.6%	-6.1%
Net operating cash burn	\$24,740	\$13,363	\$14,330	\$25,750	-3.9%	-6.7%
Net cash, cash equivalents and short-term deposits	\$22,568	\$22,568	\$35,931	\$50,261	-55.1%	-37.2%

- Operating revenue steady through FY 25; following lift in ASP¹ to US\$594 vs US\$584 in FY 24
- Total revenue includes FX gain of \$0.3M in 2H 25 vs loss of \$0.4M in 1H 25
- Total operating expenses increase 2H 25 vs 1H 25 led by clinical research, Triage Plus commercialisation and legal fees to challenge Novitas LCD
- Capital required to maintain momentum in the business

EXPENSES INCREASE ON 1H 25 LED BY CLINICAL RESEARCH TRIAGE PLUS EXPENSES

INVESTMENT NOW FOCUSED ON LONG-TERM STRATEGIC INITIATIVES

FINANCIAL PERIOD	FY 25	2H 25	1H 25	FY24	FY 25 vs. FY 24	2H 25 vs. 1H 25
	\$000	\$000	\$000	\$000	△ %	△ %
	Laboratory operations	\$12,490	\$6,532	\$5,958	\$11,751	6.3%
Research	\$14,631	\$7,401	\$7,230	\$12,089	21.0%	2.4%
Sales and marketing	\$17,530	\$9,285	\$8,245	\$25,590	-31.5%	12.6%
General and administration	\$9,901	\$4,676	\$5,225	\$9,398	5.4%	-10.5%
Total operating expenses	\$54,552	\$27,894	\$26,658	\$58,828	-7.3%	4.6%

- Operating expenses down 7.3% as FY24 capital preservation efforts cycle into FY25
- Expenses increase 4.6% in 2H 25 vs. 1H 25 amid
 - Six months impact of salary increases in 2H 25 (Only three months included in 1H 25)
 - Rise in research expenses reflecting continued investment in clinical evidence to create catalysts for coverage.
 - Laboratory operations increases reflecting preparations for the commercial launch of Triage Plus
 - Sales and marketing increased with increased activity in 2H 25
 - General and administration expenses down 10.5% reflecting capital preservation efforts and higher allocations of management time to Sales and Laboratory Operations

OUTLOOK



PacificEdge[®]
CANCER DIAGNOSTICS

OUTLOOK

RECENT CATALYSTS FOR STRONG GROWTH – VOLUME AND PRICING

- AUA microhematuria guideline enables sales, marketing and reimbursement activities. We are determined to maximize this milestone through existing and new initiatives
- Triage Plus draft pricing at US\$1,018 supports stronger unit economics, margins and sales force efficiency for a faster path to cash flow breakeven if successful in re-establishing Medicare coverage

GROWTH STRATEGY – TO BE ACCELERATED WITH NEW CAPITAL

- Entrench first-mover advantage and “moat” for Triage given AUA guideline inclusion
- Continue clinical evidence generation in an AV, CV and CU framework for coverage, guidelines and medical policy for Triage Plus and Monitor Plus
- Increase Triage throughput, throughput/sales headcount and throughput/clinician
- Seek reimbursement through the Medicare Appeals process, relying on the AUA guideline, ahead of the resolution of multiple reconsideration requests
- Increase the percentage of electronically ordered tests and patients with commercial insurance
- Emphasize the clinical and economic value of Cxbladder as a value-based care solution in our sales messaging for selling to institution, integrated hospital systems and payers
- “Client Billing” program to allow LUGPAs and hospitals to pay Pacific Edge for a test and bill commercial insurers themselves for reimbursement
- Invest in innovation and product development for IVD kits to support entry into international markets in a de-centralized deployment model

FURTHER CATALYSTS

- Cxbladder is under consideration by *Te Whatu Ora* for a National Pathway in New Zealand



APPENDIX



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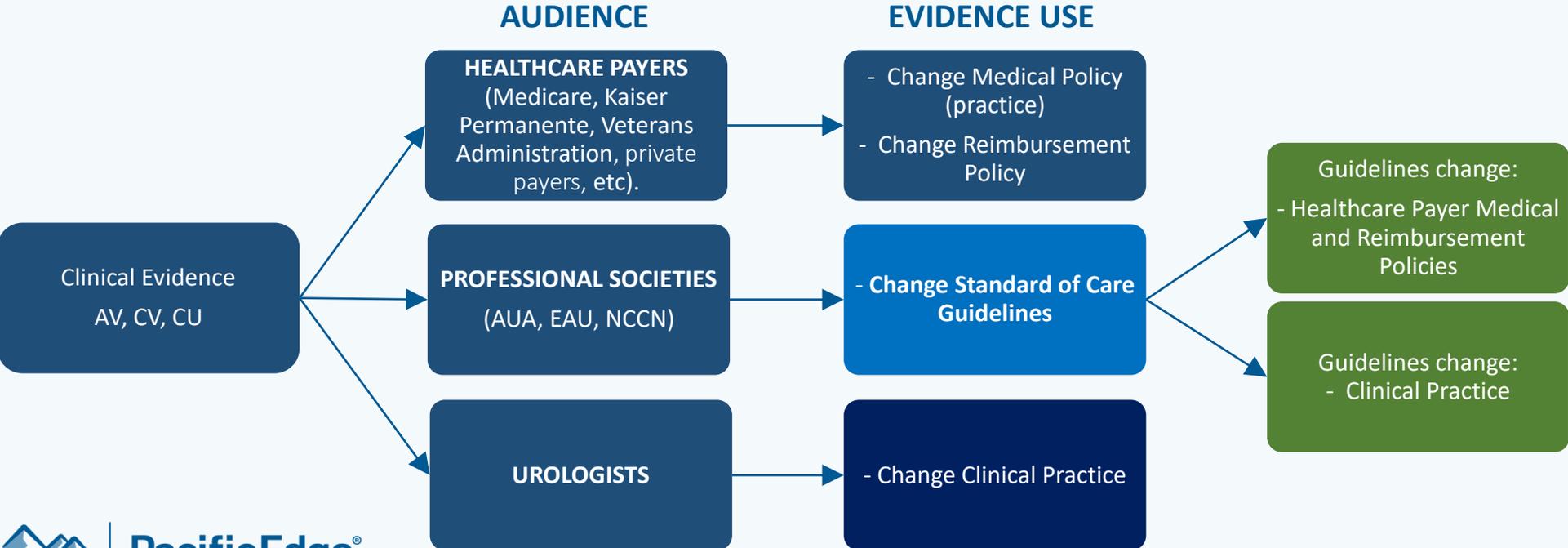
PACIFIC EDGE'S GLOBAL REACH



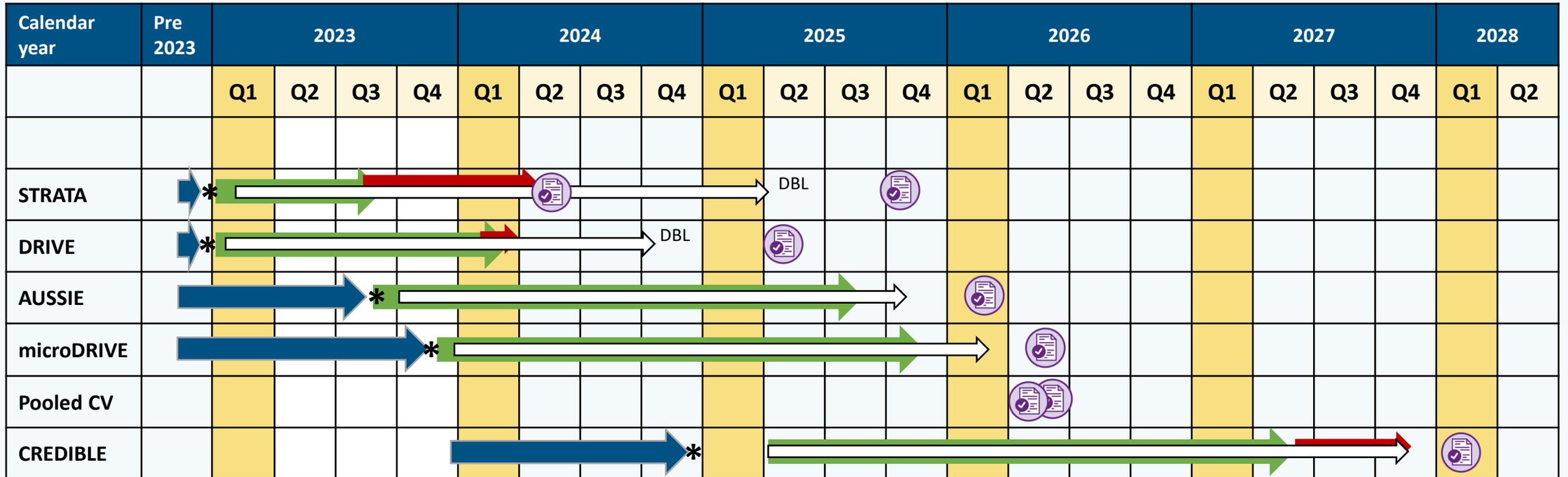
PACIFIC EDGE'S EVIDENCE PROGRAM SEEKS TO CHANGE CLINICAL PRACTICE

STRUCTURED CLINICAL EVIDENCE DEVELOPMENT

- Pacific Edge's clinical study program is focused on developing clinical evidence for Cxbladder tests in a structured framework
 - **Analytical Validity (AV):** Evidence that a test is repeatable in the lab for a given indication and population
 - **Clinical Validity (CV):** Evidence a test works in the same way on an independent eligible population for a given indication
 - **Clinical Utility (CU):** Evidence that a test changes clinical practice in the hands of a physician, typically in prospectively recruited RCTs
 - **Real World Evidence (RWE):** CU verification of the real-world use of the test in clinical practice, usually through regular use of the test by physicians
- Clinical Utility evidence obtained through randomized control trials is required to change standard of care guidelines (in addition to AV and CV evidence)



HEMATURIA EVALUATION FIVE YEAR CLINICAL STUDIES ROADMAP



Legend:

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

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"																							
LOBSTER	 *																						
OCTOPUS																							

Legend:

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

SUMMARY OF CXBLADDER CLINICAL EVIDENCE

		Publication or Study	Population	Sensitivity (Sn)	NPV	Specificity (Sp)	Comment
Triage Plus	AV	Harvey et al., submitted	Synthetic Analytes MH + GH	93.6%	99.4%	90.8%	Publication submitted; development dataset (n=987) including MH (38.7%) & GH (61.3%) producing defined Sn, NPV and Sp. TNR in development data set is 84.1%
	CV	DRIVE (Savage et al., submitted)	MH + GH	94%	99.3%	77%	Publication submitted; TNR 71%; PPV 26% at lower cut-point, 51% at higher cut-point with a Sp of 97%
		AUSSIE	MH + GH	TBC	TBC	TBC	Study in progress on MH and GH patients
		microDRIVE	MH	TBC	TBC	TBC	Study in progress on MH patients
CU	CREDIBLE	MH	TBC	TBC	TBC	Study in progress on MH patients	
Triage	AV	Harvey et al., 2024	Synthetic Analytes	N/A	N/A	N/A	Multi-product analytical validation of Cxbladder Triage, Detect and Monitor
	CV	Kavalieris et al., 2015	MH + GH	95%	98.5%	45%	Sn, Sp, NPV values when TNR is 40%
		Davidson et al., 2019	MH + GH	95.5%	98.6%	34.3%	GH only: Sn (95.1%), NPV (98%), Sp (32.8%); MH only: Sn (100%), NPV (100%), Sp (42.6%); Cxb Triage & imaging combined performance had a Sn of 97.7% & NPV of 99.8%
		Lotan et al., 2023	MH + GH	89%	99%	63%	Pooled data from US and Singapore cohorts (n=804); TNR 59%; PPV 16%
		DRIVE (Savage et al., submitted)	MH + GH	93%	98.5%	38%	Publication submitted and under peer review; TNR 35%; PPV 11%
	CU	Davidson et al., 2020	MH + GH	89.4%	98.9%	59%	39% of patients testing negative for Cxb Triage & imaging did not get cystoscopy & were managed at primary care; Study wide CV: Cxb Triage & imaging combined performance: Sn 98.1%, NPV 99.9%, Sp 98.4%
Lotan et al., 2024		MH + GH	90%	99%	56%	Clinicians using Triage used 59% fewer cystoscopies on low-risk patients presenting with MH; CV was provided study wide (UC, n=22): Sn 90%, Sp 56%, PPV 15%, NPV 99%	
Monitor	AV	Harvey et al., 2024	Synthetic Analytes	N/A	N/A	N/A	Multi-product analytical validation of all Cxbladder products
	CV	Kavalieris et al., 2017	NMIBC	93%	97%	N/A	Internally validated "bootstrap corrected estimates" from development dataset (n=1036), TNR 34%; Sn of CxbM was 97% (N = 70/72) for HG tumors and 85% (N = 66/78) for LG tumors.
		LOBSTER	NMIBC	TBC	TBC	TBC	Study in progress on NMIBC patients
	CU	Koya et al., 2020	NMIBC	100	100	77.8	Integration of Cxb Monitor into the surveillance schedule reduced annual cystoscopies (39%)
		Li et al., 2023	NMIBC	100	100	72	Cxbladder Monitor safely postpones a patient's next scheduled cystoscopy, the current 'gold standard' for bladder cancer surveillance
Guduguntla et al., 2025		NMIBC	N/A	N/A	N/A	Australian single-center study in NMIBC patients showed that alternating Cxbladder Monitor with cystoscopy safely reduced cystoscopy use without increasing recurrence risk	

NOTE #1: Full references provided on following slide

NOTE #2: Development, feasibility and/or proof of concept studies are detailed within the references on the following slide

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

REFERENCES SUMMARY OF CLINICAL EVIDENCE

	References	Comment
Proof of Concept	Holyoake et al., (2008). Development of a Multiplex RNA Urine Test for the Detection and Stratification of Transitional Cell Carcinoma of the Bladder. Clin Cancer Res 14(3): 742-749	Feasibility of urine-based assay including biomarker discovery for urothelial cancer detection initial algorithm development
	O'Sullivan et al., (2012). A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. The Journal of urology, 188(3), 741-747.	Development/feasibility of Cxbladder Detect assay and algorithm based on RNA expression biomarkers
	Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.	Pooled data from MH and GH cohorts (n=804) for 'multi-modal' (RNA+DNA) assay and algorithm development for next generation Cxbladder product including TERT and FGFR3 SNPs. Called Detect+ in publication.
	Tyson et al., (2024). Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients. Urol Prac 11(1):54-60	Budget impact model for hematuria pathway, incorporating Cxbladder Detect into patient management
Triage Plus	Harvey et al., submitted. Analytical Validation of Cxbladder® Triage Plus Assay for risk stratification of hematuria patients for urothelial carcinoma	Analytical validation of Triage Plus
	Savage et al., submitted. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.	Clinical validation of Triage Plus (DRIVE Study)
Triage	Kavalieris et al., (2015). A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to triage outpatients presenting with hematuria who have a low probability of urothelial carcinoma. BMC urology, 15(1), 1-12.	Algorithm development and clinical validation of Cxbladder Triage
	Harvey et al., (2024). Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.	Analytical validation of all Cxbladder products Triage, Detect and Monitor
	Davidson et al., (2019). Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of haematuria may reduce the need for cystoscopy. NZ Med J, 132(1497), 55-64.	Clinical validation of Cxbladder Triage
	Davidson et al., (2020). Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. The New Zealand Medical Journal (Online), 133(1527), 71-82.	Clinical utility of Cxbladder Triage
	Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.	Clinical validation of Cxbladder Triage from pooled data (USPrimary and Singapore pooled analysis; n=804)
	Lotan et al., (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.	Clinical utility of Cxbladder Triage from STRATA study showing a 59% relative reduction in cystoscopy when comparing test and control arms
Monitor	Harvey et al., (2024). Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.	Analytical validation of all Cxbladder products Triage, Detect and Monitor
	Kavalieris et al., (2017). Performance characteristics of a multigene urine biomarker test for monitoring for recurrent urothelial carcinoma in a multicenter study. The Journal of Urology, 197(6), 1419-1426.	Algorithm development and clinical validation of Cxbladder Monitor
	Koya et al., (2020). An evaluation of the real-world use and clinical utility of the Cxbladder Monitor assay in the follow-up of patients previously treated for bladder cancer. BMC urology, 20(1), 1-9.	Clinical utility of Cxbladder Monitor with low risk NMIBC patients
	Li et al., (2023). Cxbladder Monitor testing to reduce cystoscopy frequency in patients with bladder cancer. Urologic Oncology: Seminars and Original Investigations, 41 (7), 326.e1 – 326.38.	Clinical utility of Cxbladder Monitor with NMIBC patients
	Tyson et al., accepted. Economic Impact Model of Incorporating Cxbladder Monitor in the Surveillance of Non-Muscle Invasive Bladder Cancer. JU Open Plus, accepted	Budgetary impact model when Cxbladder Monitor was incorporated into patient management

SOURCES AND ASSUMPTIONS - TOTAL ADRESSABLE MARKET

REGION	STATISTIC		SOURCE
US	Population	341,762,685	https://www.census.gov/popclock/
	Incidence of hematuria	7,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Referred for clinical workup	3,500,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Receive a cystoscopy	>1,000,000	Kenigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29–34, 2021
	Annual cases of bladder cancer	84,870	National Cancer Institute
	Patients living with bladder cancer	744,044	National Cancer Institute
	Test opportunities	4,616,066	Pacific Edge estimate
	Price of Cxbladder (US\$)	US\$1,018 (Triage Plus), US\$760 (Monitor)	
	TAM (US\$b)	US\$4.4	
Europe (excluding Russia)	Population	600,000,000	World-population - Europe; World-population – Russia
	Incidence of hematuria	12,000,000	Science Direct
	Referred for clinical workup	6,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Receive a cystoscopy	4,000,000	Rindorf, D, et al. The extent of experiencing availability issues and deteriorating performance associated with reusable cystoscopies, a multicentre study.
	Annual cases of bladder cancer	180,000	Uroweb
	Patients living with bladder cancer	900,000	Pacific Edge estimate - 5 years of annual cases
	Test opportunities	7,350,000	Pacific Edge estimate
	Price of Cxbladder EURO	€ 245	Pacific Edge estimate
	TAM (US\$b)	US\$2.0	
APAC (excluding India and China)	Population	830,000,000	World population - Southeast Asia; Population Pyramid - Japan;
	Incidence of hematuria	16,600,000	Science Direct
	Referred for clinical workup	8,300,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Receive a cystoscopy	3,320,000	Pacific Edge estimate
	Annual cases of bladder cancer	58,000	WHO; Hong Kong
	Patients living with bladder cancer	290,000	Pacific Edge estimate - 5 years of annual cases
	Test opportunities	3,755,000	Pacific Edge estimate
	Price of Cxbladder (US\$)	550	Pacific Edge estimate
	TAM (US\$b)	US\$2.1	

KEY CLINICAL ADVISORS AND CONSULTANTS



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ASCO: American Society of Clinical Oncology
 ASTRO: American Society of Radiation Oncology
 AUA: American Urological Association
 BCAN: Bladder Cancer Advocacy Network
 CAB: Clinical Advisory Board
 CT PI: Clinical Trials Principal Investigator

FACS: Fellow of the American College of Surgeons
 IIT PI: Investigator Initiated Trial Principal Investigator
 J Urol: Journal of Urology
 KOL: Key Opinion Leader
 MPH: Master of Public Health
 SUO: Society of Urologic Oncology

PACIFIC EDGE – TAKING NEW ZEALAND INNOVATION GLOBAL



APPROVED BY THE AUA BOARD OF DIRECTORS FEBRUARY 2025

Authors' disclosure of potential conflicts of interest and authorial contributions appear at the end of the article.

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

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PACIFIC EDGE BOARD AND MANAGEMENT



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Chairman

Chris has held senior positions in both CEO and CFO roles with large international companies and was a partner in Arthur Young, Chartered Accountants. Prior to retiring from full time corporate life, he was CFO of Fulton Hogan, a large Australasian civil contractor



DR PETER MEINTJES
Chief Executive Officer

Peter is a molecular diagnostics and genomics leader focused on nascent market development of disruptive innovations to drive commercial success. Prior to joining Pacific Edge, he was based in Boston in a succession of diagnostic leadership roles. Most recently he was the Chief Commercial Officer at Eurofins Transplant Genomics and before that he was CEO at Omixon

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