



PacificEdge[®]
CANCER DIAGNOSTICS

1H 25 FINANCIAL RESULTS PRESENTATION

Dr Peter Meintjes
Chief Executive Officer

Grant Gibson
Chief Financial Officer

26 November 2024

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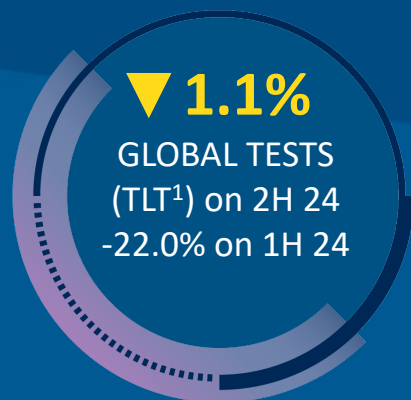
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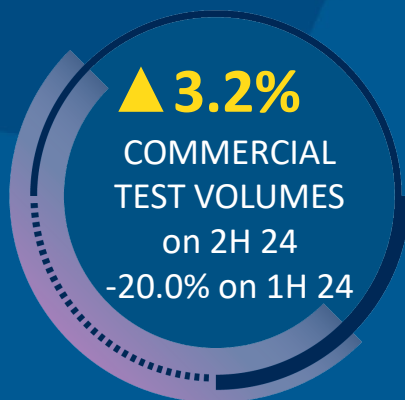
AGENDA

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

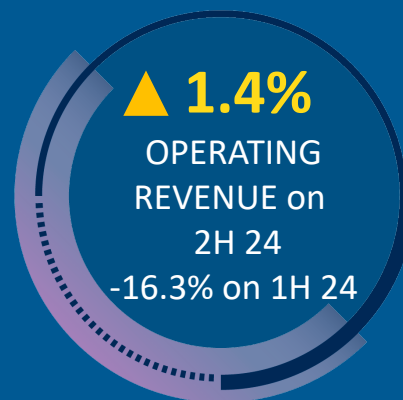
1H 25 HIGHLIGHTS: FOCUSED ON CATALYSTS FOR MEDICARE COVERAGE CERTAINTY



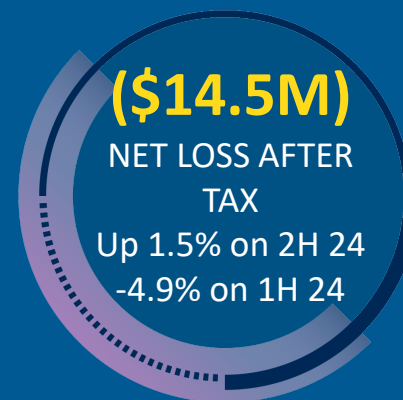
Global TLT of 14,233
US TLT 11,587, -4.6% on
2H 24 and -27.4% on 1H 24



Commercial Tests of 12,323
US Commercial Tests 9,911,
-0.5% on 2H 24 and -26.9%
on 1H 24



Operating revenue \$11.0M
Total revenue of \$12.2M
-4.4% on 2H 24



Steady on 2H 24 of (\$14.3M)
reflecting 'holding pattern' of
Medicare uncertainty



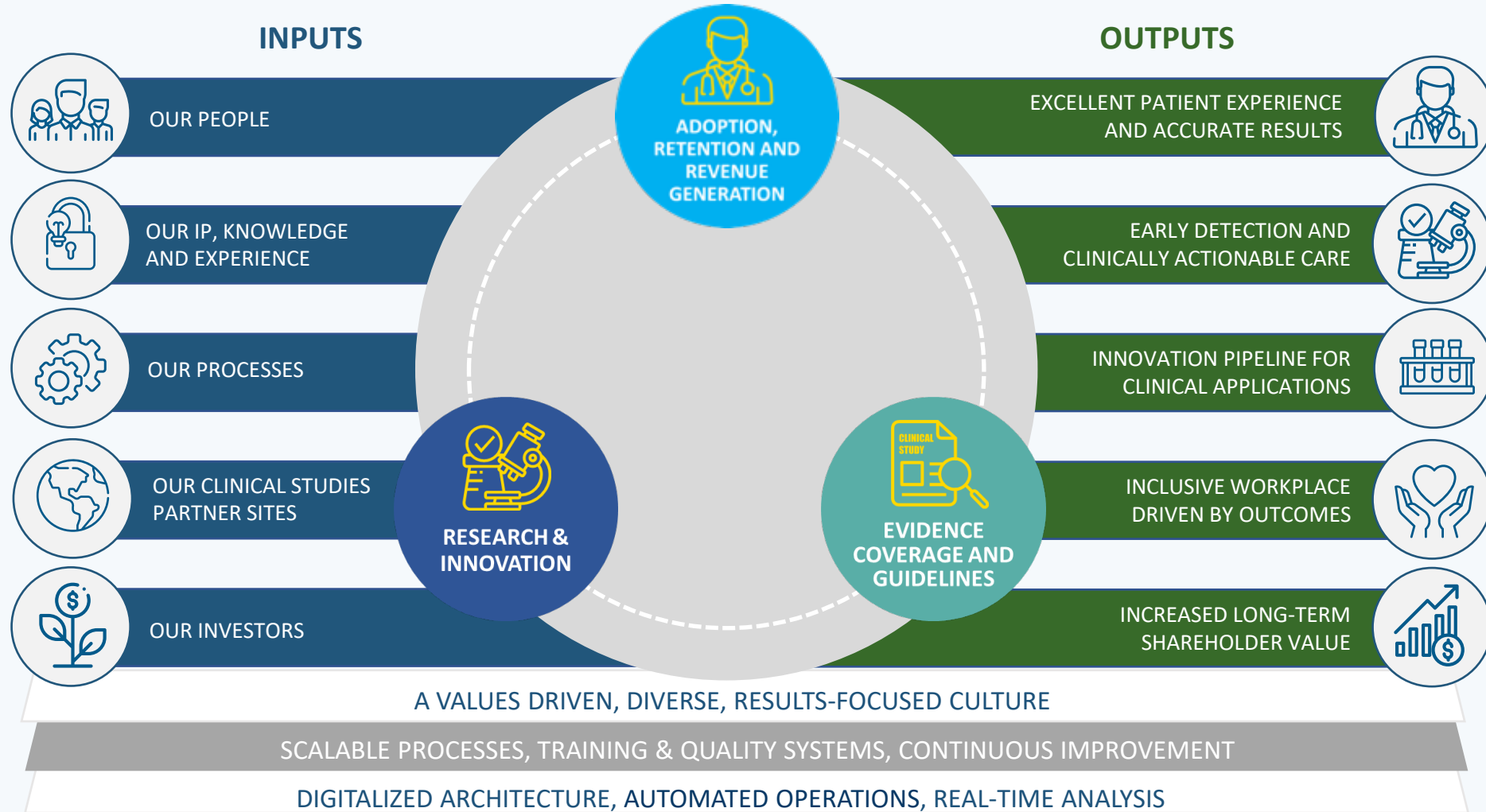
1H 25 cash burn of \$14.3M
increases on \$11.9M in 2H 24
but steady adjusting for
seasonal impact of costs

- Awaiting outcome on catalysts: Medicare coverage certainty, AUA hematuria guideline review and Triage Plus pricing
- Operating revenue, net losses, and operating cash burn steady as operating efficiencies and cash collection gains retained. US test sales/FTE of 379 in Q2 25, - 3.8% on Q1 25; US ASP³ increases to **US\$618** in 1H 25 vs **US\$613** in 2H 24
- Commercial operations focused on profitable territories, non-Medicare revenue streams and selling the clinical and economic value of Cxbladder; direct sales team efficiencies maintained - operating at break even
- Business focused on the clinical development for Triage Plus and Monitor Plus

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



VALUE CREATION THROUGH THREE PILLARS



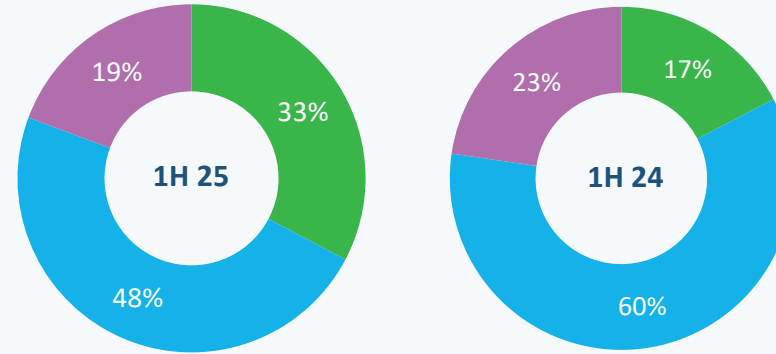
TEST VOLUMES STEADY AGAINST 2H 24 AMID MEDICARE UNCERTAINTY



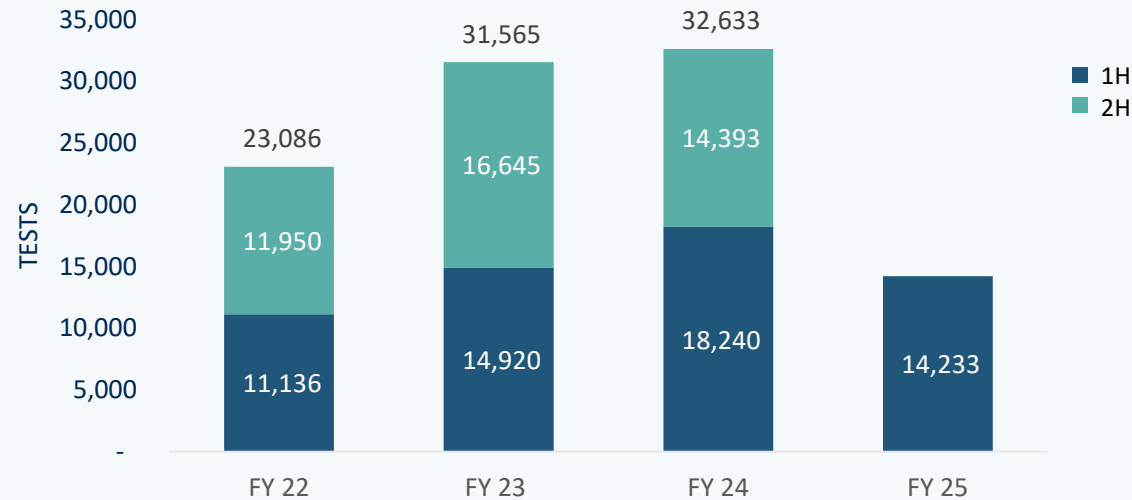
1H 25 TOTAL LAB THROUGHPUT (TLT*)

- Global TLT of 14,233 for 1H 25 steady (-1.1%) on 2H 24 and down 22% on 1H 24 amid ongoing Medicare coverage uncertainty and reduced reach of the sales force
- Global Commercial test volumes of 12,323 for 1H 25 up 3.2% on 2H 24 and down 20% on 1H 24
- Triage growing in share of volume validating risk stratification value proposition and investment in Triage Plus

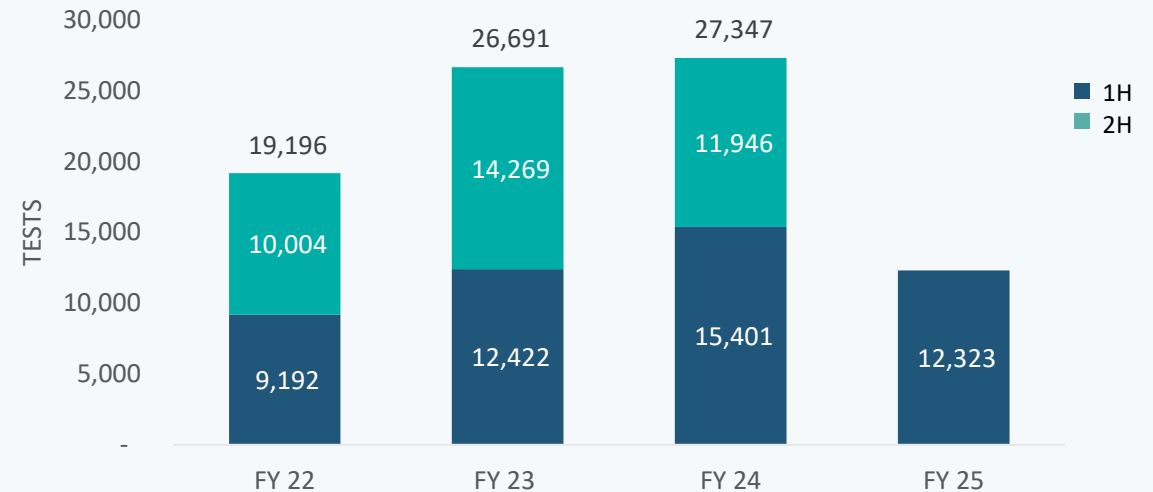
TEST VOLUMES BY TYPE (TLT*)



GLOBAL TOTAL TEST VOLUMES (TLT*)



GLOBAL COMMERCIAL TEST VOLUMES (TLT*)



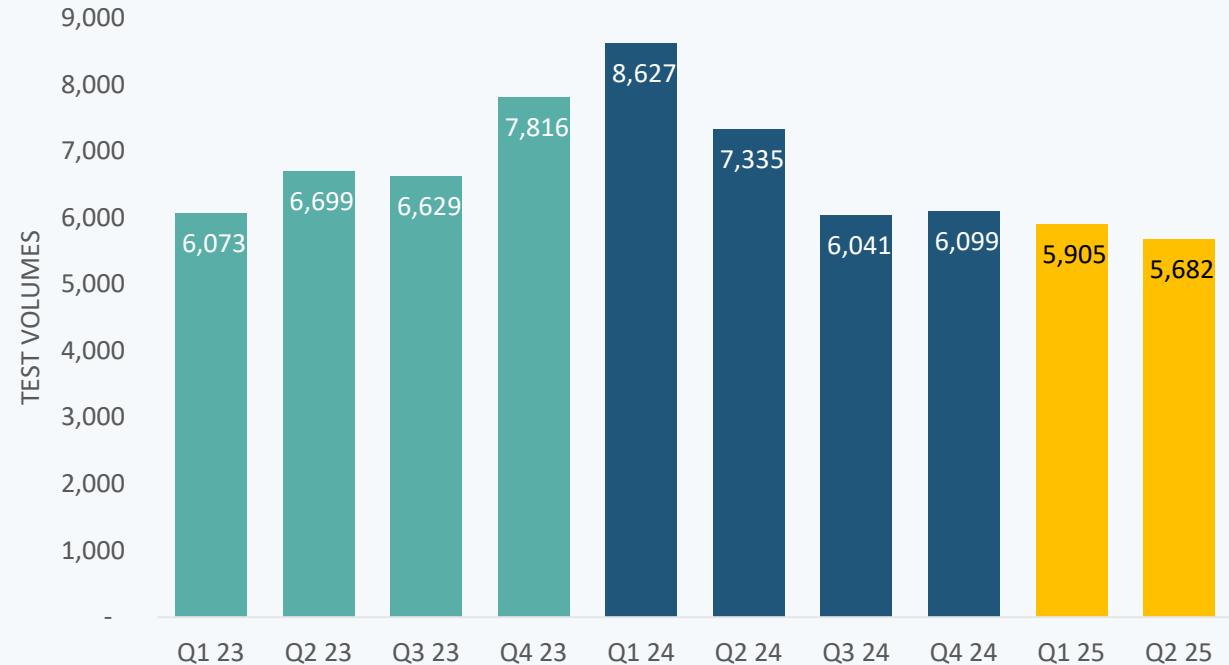
FOUNDATIONS FOR GROWTH - US TEST VOLUMES STEADY



KAISER PERMANENTE GAINS PARTIALLY OFFSET MEDICARE UNCERTAINTY

- US TLT in Q2 25 relatively stable on the prior quarter (Q1 25)
- Strong performance from the Southern California Permanente Medical Group and sustained sales force efficiency gains deliver some mitigation to the impact of Medicare uncertainty
- Throughput has reduced by 34.1% from a peak of 8,627 test/quarter in Q1 24 to 5,682 in Q2 25 as the sales team reduced in 2H 24 and no backfill appointments in sales force
- Sales territories are larger and more challenging for sales reps, but focus has been on larger, more reliable accounts
- Messaging has focused on communicating the clinical value of Cxbladder for risk stratification to reduce cystoscopies and the associated economics of adopting on all appropriate patients

US TOTAL TEST VOLUME*



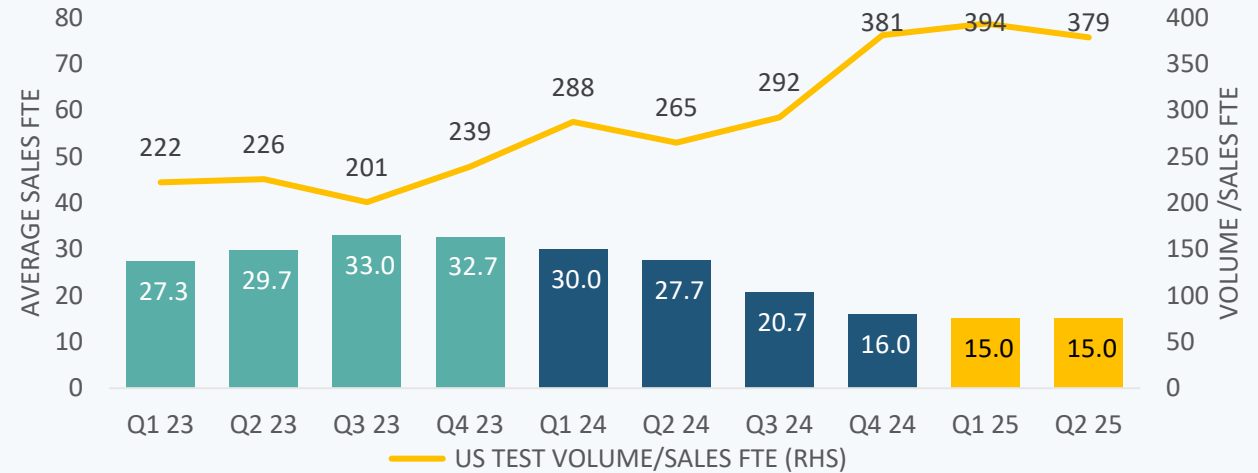
FOUNDATIONS FOR GROWTH – PERFORMANCE IMPROVEMENTS SUSTAINED



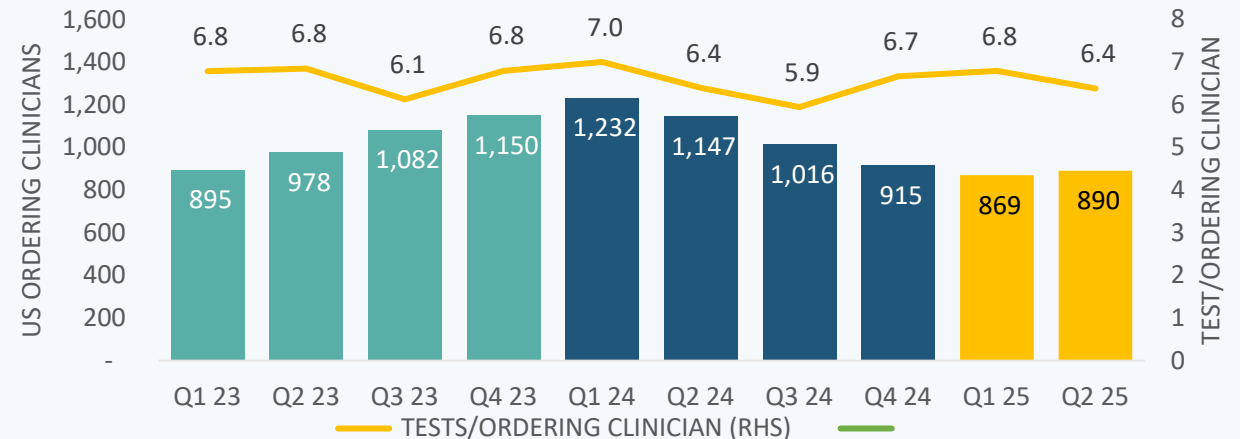
SALES TEAM FOCUSED ON KEY PERFORMANCE INDICATORS

- Sales FTE down to an average of 15.0 in Q2 25 from 32.7 in Q4 23 as we focused on cash conservation:
 - Sales FTEs were reduced by restructure in late Q2 24
 - Sales FTEs leaving the business are backfilled only when sales force breakeven can be maintained
- Sales force efficiency (total tests/average FTE) sustained up 59% from 239 in Q4 23 to 379 in Q2 25:
 - More effective core sales team
 - Focus on the most profitable territories/accounts
- Tests/US ordering clinician stable, but ordering clinicians fall against 1H 24:
 - Change in clinical mix in favor of clinicians that understand the clinical utility of Cxbladder
 - Reduced reach of the direct sales team
- Direct sales team have achieved operational break even

US SALES FORCE EFFICIENCY



US CLINICAL COMMITMENT



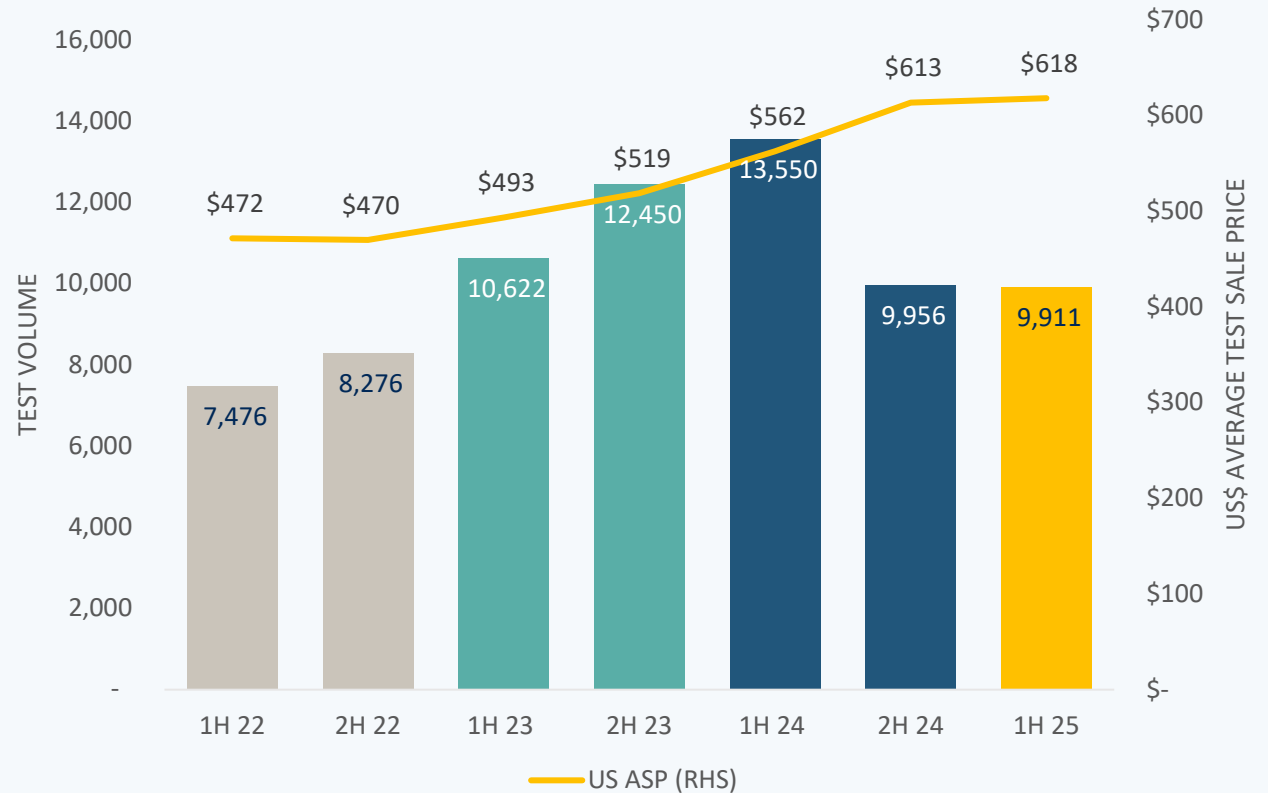
FOUNDATIONS FOR GROWTH - US CASH COLLECTIONS IMPROVE



REIMBURSEMENT & CASH COLLECTIONS – A CORE COMPETENCY

- Average Sales Price (ASP*) per test increased to US\$618 from US\$613 in 2H 24 and US\$519 in 2H 23 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

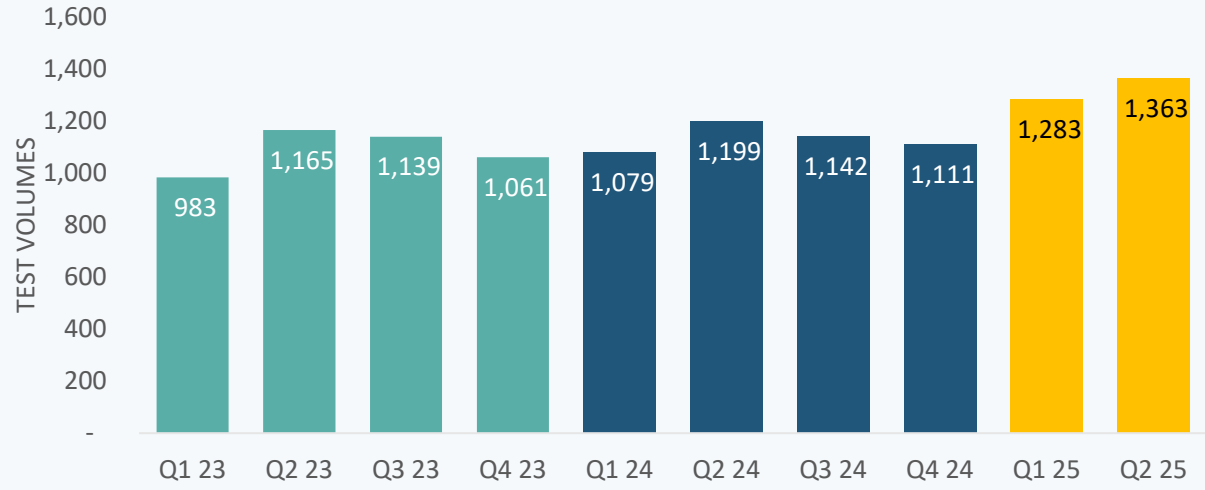
US COMMERCIAL TEST VOLUMES AND ASP* (US\$)



DRIVING GROWTH IN ASIA PACIFIC AND CONSOLIDATING NEW ZEALAND



APAC TOTAL TEST VOLUMES*



- Quarterly total test volumes benefit from:
 - Fewer evaluations and non-billable tests
 - Shift in emphasis to commercial tests
- New Zealand is a mature market with Cxbladder utilized in 15 of the 20 Te Whatu Ora health regions covering >75% of the population

AUSTRALIA & ASIA PACIFIC

- Australia and Southeast Asia are still in business development
- Initial commercial testing volume direct or via distributors in Singapore, Malaysia, Brunei, Thailand and the Philippines

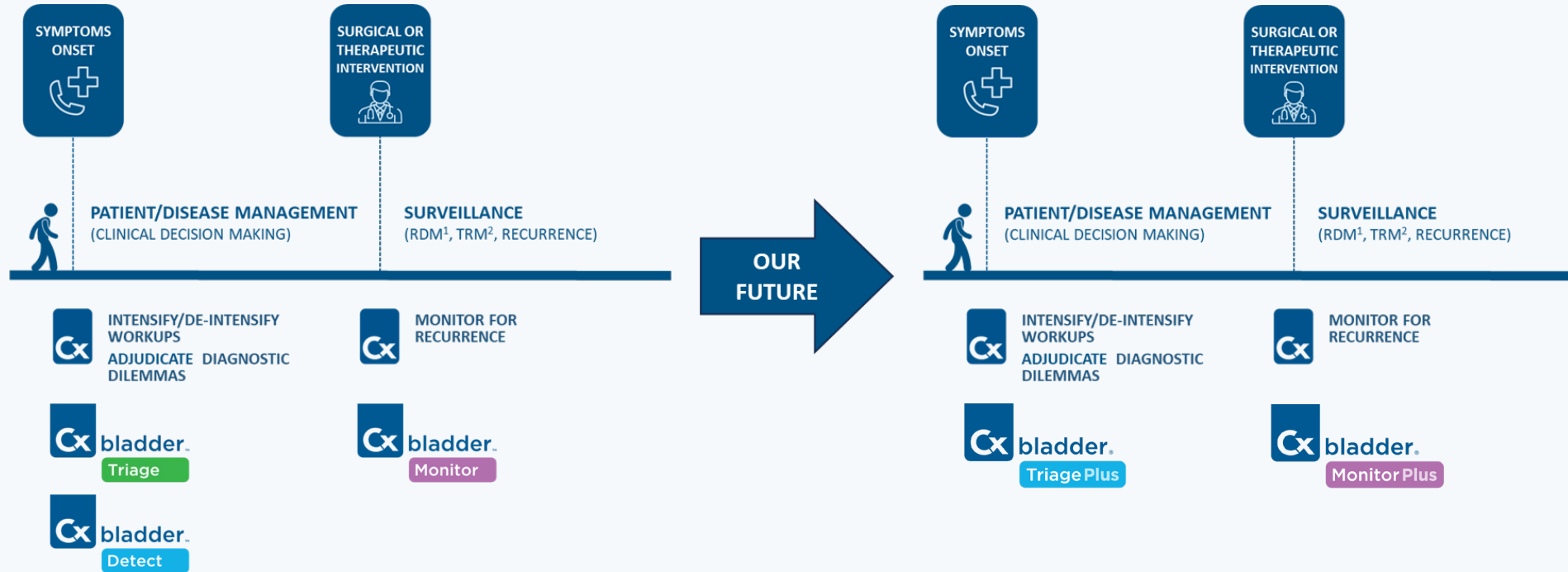


Sept '24 - ceremonial signing of partnership agreement with Malaysia's Premier Integrated Labs in Kuala Lumpur

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

SIMPLIFYING THE CXBLADDER VALUE PROPOSITION – TRIAGE PLUS

TRIASGE PLUS NAMING ALIGNS WITH CLINICAL POSITIONING AND STRATA¹ EVIDENCE



TRIASGE PLUS – THE ADDITION OF DNA BIOMARKERS LIFTS PERFORMANCE³

- Triage Plus combines the value propositions of the existing Triage and the Detect tests in a single test for the evaluation of hematuria, the largest market opportunity
- A negative test helps clinicians to rule out the presence of cancer due to the high Negative Predictive Value and Sensitivity
- A positive test can help clinicians to resolve diagnostic dilemmas and prioritize patients for a more intensive workup due to the high Specificity and Positive Predictive Value

Performance ³	Sens	Spec	NPV	PPV	ROR
Triage Plus	97%	90%	99.7%	44%	83%
Triage	89%	63%	99%	16%	59%
Detect	74%	82%	97%	25%	78%

PREPARING FOR THE COMMERCIALIZATION OF TRIAGE PLUS

EXPANDING AND EXTENDING OUR LEADERSHIP POSITION IN HEMATURIA EVALUATION

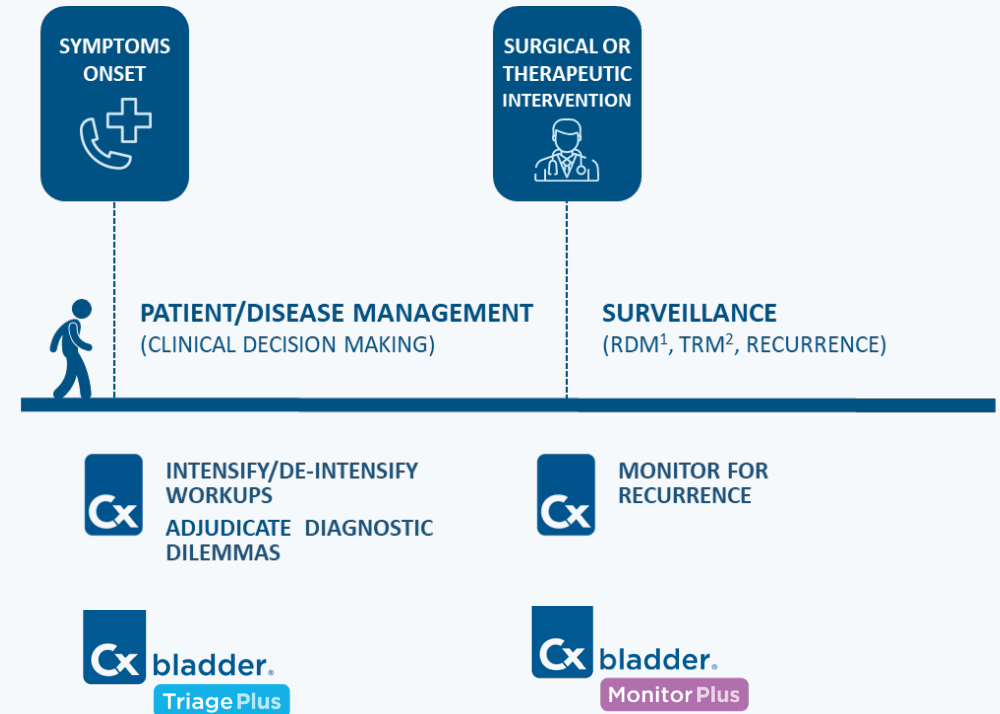


ESSENTIAL PRE-CONDITIONS TO LAUNCHING TRIAGE PLUS

- Pricing that reflects the clinical value and economic benefit of the test
- Reliable Medicare reimbursement via (existing) coverage of our tests or through new arrangements following Novitas policy decision on the draft 'Genetic testing for oncology' LCD (DL 39365)

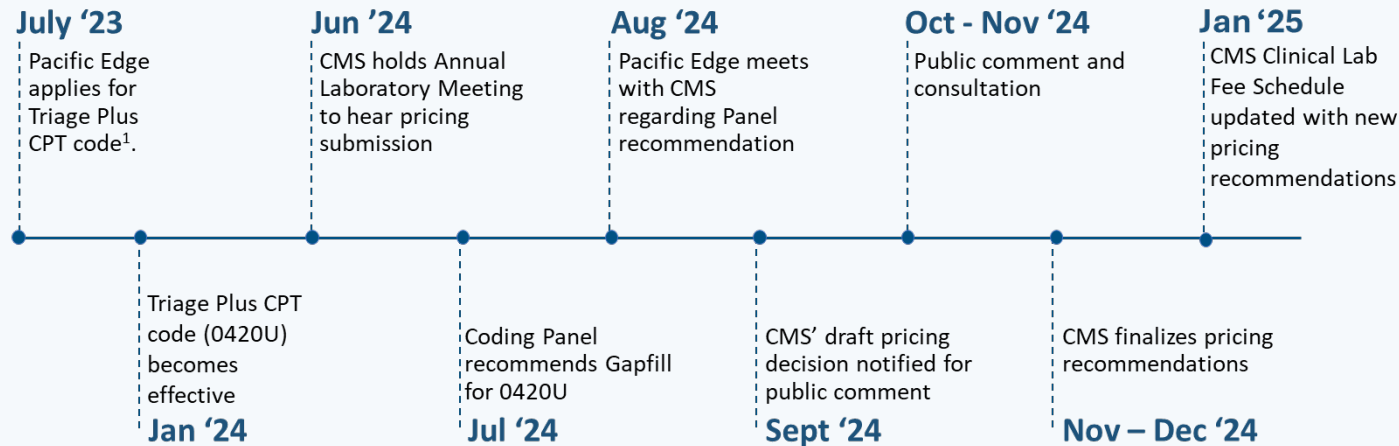
COMMERCIAL PREPARATORY WORK

- Driving for coverage and reimbursement of Triage Plus
- Adding capabilities and capacity to PEDUSA laboratory
- Simplifying laboratory workflow for improved efficiency
- Optimizing sales team structure for expanded product adoption
- Preparing sales and marketing training materials
- Enhancing medical education with a speaker bureau, podium presentations, and evidence development



TRIAGE PLUS PRICING STANDS TO BOLSTER PACIFIC EDGE'S ECONOMICS

PRICING OF TRIAGE PLUS IS THE NEXT STEP IN THE COMMERCIALISATION PROGRAM



- Determining a CMS price for Triage Plus (0420U) is the next step in establishing reimbursement
- Advisory Panel and CMS have recommended Gapfill for Triage Plus
- Pacific Edge and C21 have provided counter-arguments during public comment period supporting a Crosswalk recommendation
- Gapfill is the more likely outcome, requires all MACs to recommend a price and takes 12 months to finalize
- Pacific Edge will seek a 'provisional local price' for Triage Plus from Novitas during the Gapfill process to ensure Gapfill imposes no delays on the commercial launch of Triage Plus

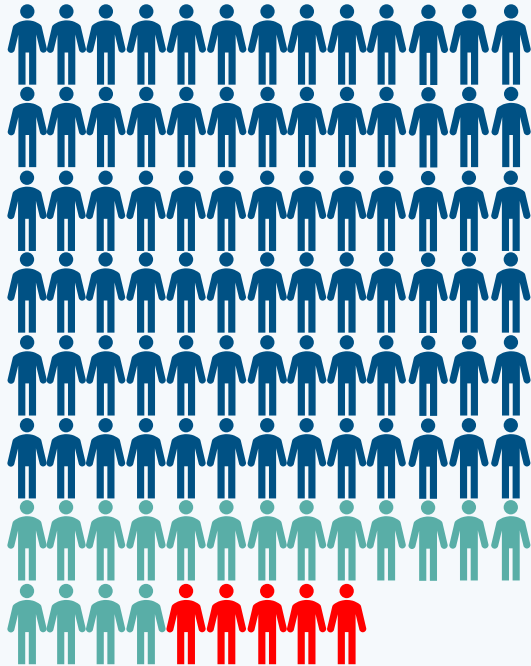
Dates future to this presentation are anticipated timeframes for Triage Plus pricing - dates may change

SELLING CXBLADDER'S CLINICAL, ECONOMIC AND PATIENT VALUE



Pacific Edge's budget impact modelling shows Cxbladder offers better care, avoids unnecessary procedures and improves workflow when used to intensify or de-intensify hematuria evaluation or in the surveillance for the recurrence of bladder cancer. For healthcare payers Cxbladder offers substantial total cost savings per patient^{1,2}

CXBLADDER DETECT VS AUA GUIDELINES



HEMATURIA EVALUATION¹

- Cxbladder Detect rules out 78 of the 95³ patients without cancer and requires only 22 cystoscopies to find the five patients with cancer
- This results in savings of >**US\$500** per patient presenting with hematuria



CXBLADDER MONITOR VS AUA GUIDELINES



CANCER RECURRENCE SURVEILLANCE²

- Cxbladder Monitor alternated with cystoscopy for surveillance of bladder cancer after nine months of treatment
- This results in 12.4% reduction in cystoscopies over a five-year surveillance period
- Savings estimated at as much as **US\$680** per patient over the five-years



STRENGTHENING OUR CUSTOMER EXPERIENCE

DRIVING 'STICKINESS' AND LONG-TERM MARKET SHARE

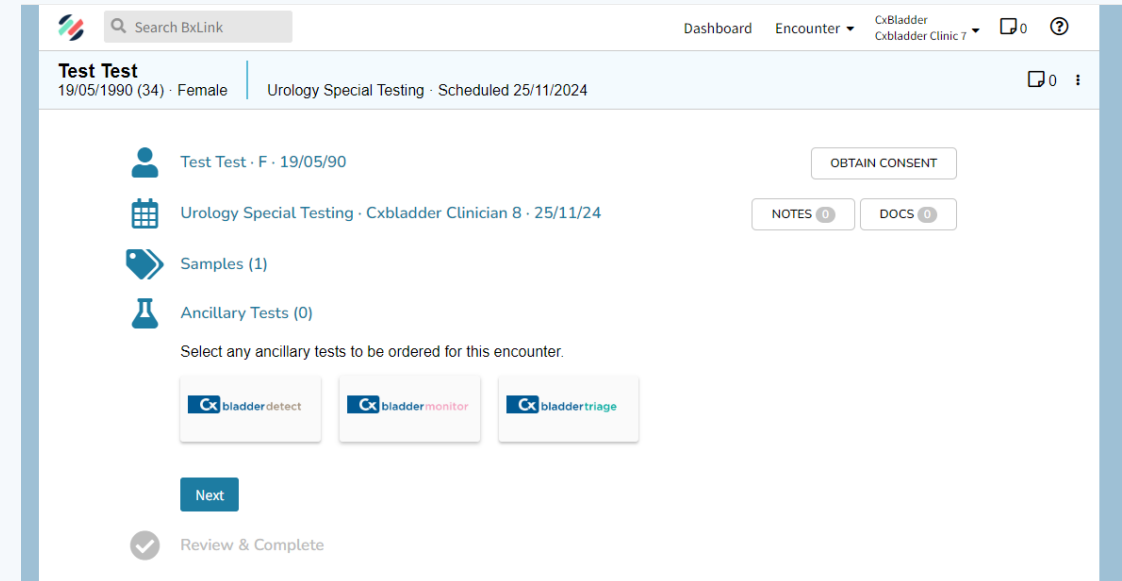


THE BEST AND MOST CUSTOMER-FRIENDLY TEST

- Give customers options to connect with Pacific Edge to fit their needs with easy-to-use digital workflows
 - Electronic Medical Record (EMR) integrations (Kaiser)
 - Pacific Edge Customer Portal
 - Pathology Lab LIS integrations (Lumea, Awanui)
- Improvement of end-to-end experience for patients and providers
- Example of “one-to-many” integrations to clinics

KAISER EMR SUPPORTING ADOPTION

- EMR integration went live in Nov 2023 across Kaiser’s Southern California Permanente Medical Group streamlining sample collection, test ordering and test resulting for Triage and Monitor
- All 15 Kaiser SoCal sites are now ordering and volumes increasing steadily
- Primarily adopted for Triage, Monitor volume is beginning to rise as clinicians become increasingly familiar with Cxbladder
- Kaiser SoCal represents ~37% of the >12.6m members covered by Kaiser Permanente, longer term we are targeting other regions



View of the Lumea BxLink interface



AUA HEMATURIA GUIDELINES – A COMPREHENSIVE REVIEW

AN APPROACH THAT SUPPORTS OUR DRIVE FOR GUIDELINE INCLUSION



- The AUA has commenced a review of the microhematuria guideline and has asked for professional comment on its initial draft; no timeframe provided
- The clinical utility of Cxbladder Triage demonstrated by the STRATA¹ study is expected to be considered as part of the deliberations
- A positive AUA Journal of Urology editorial in July 2024 suggests favorable direction of travel
- Clear/positive inclusion language would be used as the basis for a Medicare coverage re-consideration request (in the event of a non-coverage determination)



American
Urological
Association

www.auanet.org

- Globally the most influential and largest urological association
- **Relevant standards of care:** Hematuria, microhematuria management and non-muscle invasive bladder cancer (NMIBC)
- **Review period:** with new evidence, last updated in 2020

THE JOURNAL
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Editorials

What Is the Future of Cystoscopy for Detecting Urothelial Carcinoma?

Asymptomatic microscopic hematuria (AMH) is a common finding that leads to many urology referrals. Occasionally, patients with AMH harbor urothelial carcinoma of the bladder. The sensitivity of 98.6% with about a third of patients testing negative. For the microscopic hematuria group only, the sensitivity was 100%. The new...

“... these tests have the potential to improve the management of our patients with suspected [urothelial cancer] who would otherwise require an invasive procedure for diagnosis.”

– Journal of Urology editorial Sept 2024

'GENETIC TESTING FOR ONCOLOGY' LCD PROCESS EXTENDED

CMS¹ APPROVED THE EXTENSION TO GIVE NOVITAS¹ TIME TO RESPOND TO ALL COMMENTS



EXTENSION INCREASES CONFIDENCE TOWARDS MEDICARE COVERAGE CERTAINTY

- Cxbladder continues to receive reimbursement from Medicare and Medicare Advantage payers in line with historical reimbursement rates
- Novitas confirmed by email that they are reviewing all Pacific Edge submissions alongside the comments received during the comment period
- Pacific Edge continues to engage with Novitas and CMS with the support of professional societies, industry partners, clinicians and patient advocacy groups
- Pacific Edge and C21³ have taken separate but supporting actions to have DL39365 retired, including engagement with the Office of the General Counsel³
- We remain prepared to explore legal action in the event of a non-coverage determination



MEDICARE IS PACIFIC EDGE'S LARGEST PAYER

- Medicare and Medicare Advantage is the largest global opportunity in bladder cancer diagnostics from a single coverage decision
- In 1H 25 Medicare and Medicare Advantage delivered ~5,300 commercial tests (~54% of US commercial tests) and ~\$6.5m NZD in total operating revenue (~59% of total operating revenue)



1. Novitas is the Medicare Administrative Contractor for Pacific Edge's US laboratory. It is empowered by the Centers for Medicare and Medicaid Services (CMS) to make the coverage determination, but it is accountable to CMS for the decision.

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

3. C21 is a diagnostic industry lobby group the Coalition for 21st Century Medicine. The Office of the General Counsel (OGC) is the legal team for the US Department of Health and Human Services (HHS)

CLINICAL EVIDENCE CATALYSTS FOR COVERAGE CERTAINTY



MEDICARE RECONSIDERATION AND GUIDELINE INCLUSION REQUESTS

(Novitas¹ typically handles reconsideration requests on existing LCDs within three months of submission)

Catalyst	Test and evidence standard ⁽²⁾	Expected date of reconsideration request ⁽³⁾
1. STRATA data published	- CU of Triage	Novitas notified of the publication in April
2. Automated RNA and DNA extraction	- AV of Triage, Detect and Monitor	Q3 2024 (Published September, Novitas notified)
3. Triage Plus Analytical Validation	- AV of Triage Plus	Q2 2025
4. DRIVE data published	- CV of Triage Plus	Q2 2025
5. STRATA concordance	- CU of Triage Plus (concordance)	Q3 2025
6. Kaiser Permanente RWE ⁴ published	- CU of Triage (RWE)	Q3 2025 ⁵
7. AUSSIE data published	- CV of Triage Plus	Q4 2025
8. microDRIVE published	- CV of Triage Plus	Q1 2026
9. Monitor Plus Analytical Validation	- AV of Monitor Plus	Q2 2026
10. Pooled CV data published ⁶	- CV of Triage Plus	Q2 2026
11. LOBSTER published	- CV of Monitor/Monitor Plus	Q1 2027
12. CREDIBLE data published	- CU of Triage Plus	Q3 2027

¹ Novitas is the Medicare Administrative Contractor (MAC) charged with making the Medicare local coverage determination for Pacific Edge’s US laboratory

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

³ All dates are calendar year rather than financial year and our best current estimates

⁴ RWE is Real World Evidence

⁵ Timeline determined by Kaiser Permanente

⁶ The pooled analysis brings together data from DRIVE, AUSSIE and microDRIVE

Pacific Edge will also lodge a reconsideration request if Cxbladder is included in the American Urological Association (AUA) or National Comprehensive Cancer Network (NCCN) guidelines

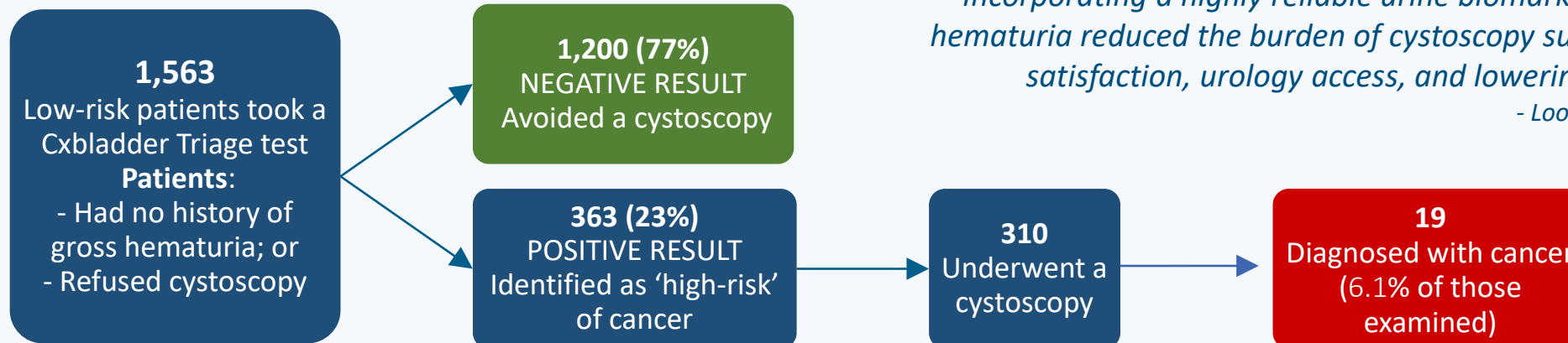
INDEPENDENT REAL-WORLD EVIDENCE OF CXBLADDER'S CLINICAL UTILITY

CLINICAL UTILITY EVIDENCE OF CXBLADDER TRIAGE THAT SUPPORTS MEDICARE COVERAGE



KAISER PERMANENTE ABSTRACT SHOWS CLINICAL VALUE IN REAL WORLD SETTING

- Kaiser Permanente presented an abstract to the Western Section AUA conference regarding their ongoing experience with Cxbladder Triage
- The abstract focuses on 1,563 low-risk patients in the Kaiser Southern California health system with no history of gross hematuria or who refused cystoscopy
 - 1,200 patients avoided invasive cystoscopy, improving patient satisfaction, urology access and lowering the overall cost of care
- A peer-reviewed publication is expected on the complete data set, targeting the AUA conference in 2025
- Pacific Edge will use this future publication for a Medicare reconsideration request (in the event of a non-coverage determination)



“Incorporating a highly reliable urine biomarker into clinical workflows for hematuria reduced the burden of cystoscopy substantially, improving patient satisfaction, urology access, and lowering overall cost of care,”

- Loo et al (2024)¹

STRATEGIC RESPONSES TO THE IMPENDING MEDICARE DETERMINATION

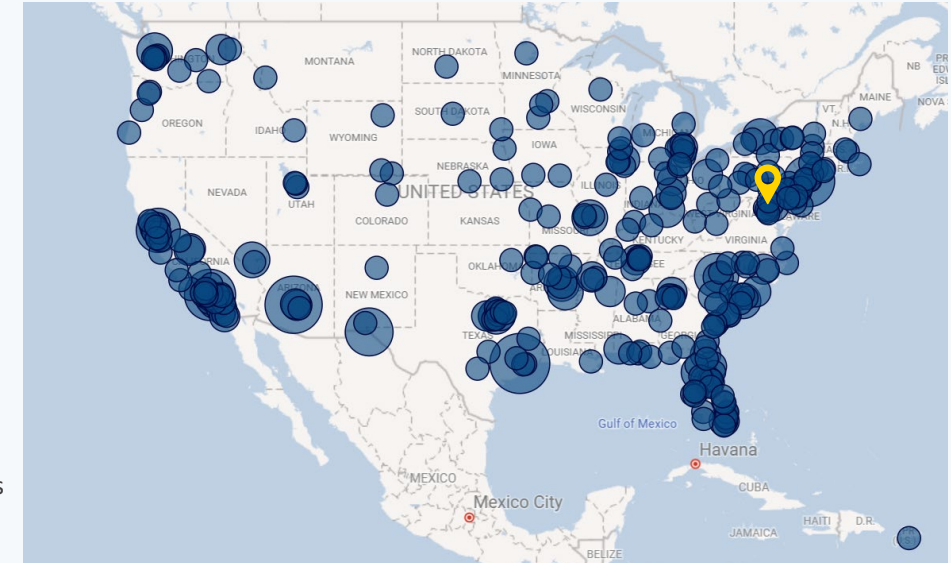


OUR RESPONSE TO AN AFFIRMATION OF COVERAGE

- Strategic review to accelerate the US adoption of Cxbladder among patients, clinicians, and healthcare payers

OUR RESPONSE TO A LOSS OF COVERAGE

- Explore legal options supported by customers, industry partners and other impacted companies
- Further review the structure of our operations and our strategy to reduce cash burn in line with our plan to regain Medicare coverage within our existing cash reserves
- Continue to explore other strategic alternatives for Pacific Edge that could support the company through to regaining Medicare coverage and advancing the commercialization of Cxbladder globally



● Distribution of Current U.S. Customers
📍 Pacific Edge Diagnostics USA, Hershey, Pennsylvania

LONG TERM VALUE CREATION STRATEGIES WILL CONTINUE

- Continue to advance our clinical evidence generation program for inclusion in AUA and NCCN¹ Guidelines for increased coverage certainty
- Continue to invest in medical affairs and the digitalization initiatives that will enable clinicians who continue to order Cxbladder to follow clinical pathways on all appropriate patient types

RESEARCH & INNOVATION – FOCUSED ON DNA ENHANCED PRODUCTS



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 Monitor Plus
- Simplifying Cxbladder:
 - Aim to reduce technician time, lower cost of goods, lower turnaround time, increase throughput and increase automation
 - Aim to be IVD-ready with “kittable” Cxbladder tests for decentralized deployment for international market expansion
 - Analytical Validation (AV) of automated end-to-end lab operations for RNA and DNA workflows.
 - AV data for the automated Cxbladder (Triage, Detect and Monitor), i.e. RNA is now published¹
- Establish in-vitro diagnostic (IVD) regulatory framework for R&D of our next generation tests
- Continued engagement with industry and academic research and development collaborations to address unmet clinical needs in bladder cancer diagnosis and management



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

FINANCIAL PERFORMANCE

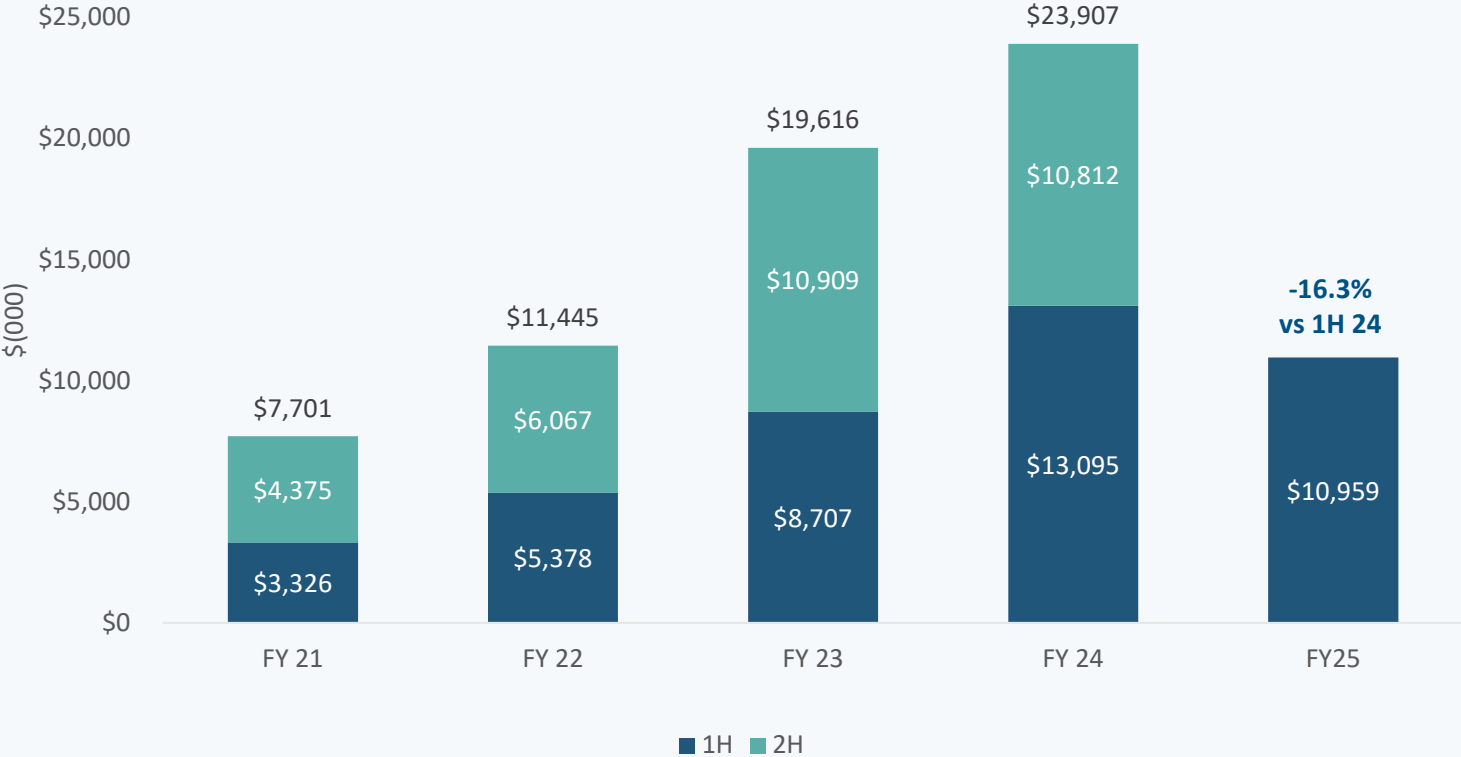


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CANCER DIAGNOSTICS

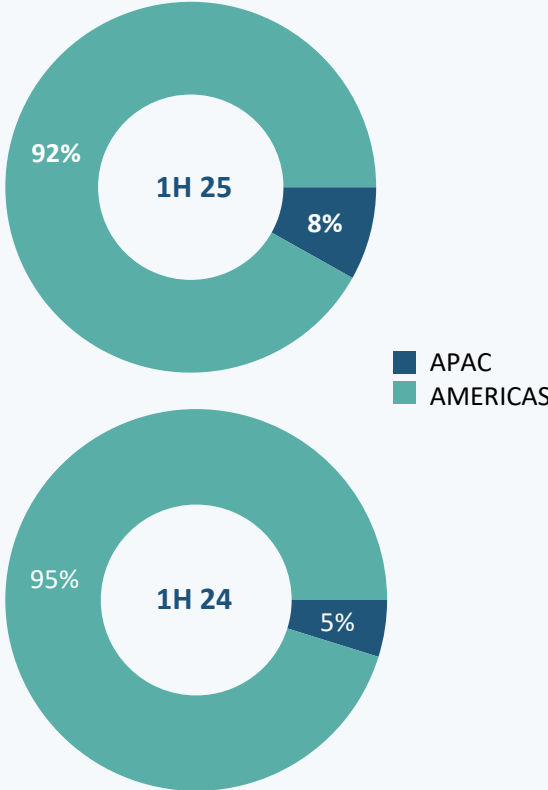
US COMMERCIAL TEST VOLUME GROWTH DRIVING REVENUE

LOOKING TO US CATALYSTS TO DRIVE A RECOVERY IN REVENUE GROWTH

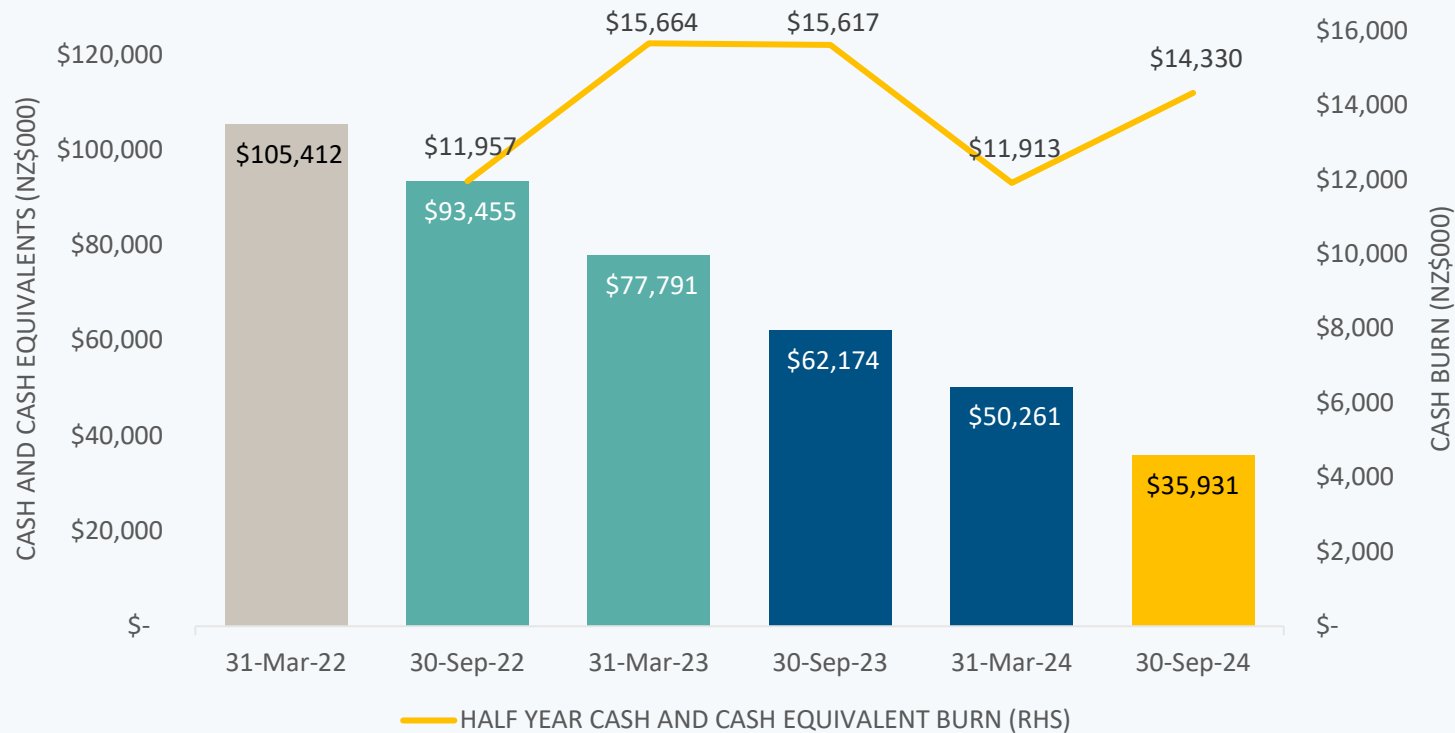
PACIFIC EDGE OPERATING REVENUE



REGIONAL REVENUE CONTRIBUTION



CAPITAL FOCUSED ON EVIDENCE GENERATION FOR RELIABLE REIMBURSEMENT



A STRONG BALANCE SHEET

- Cash, cash equivalents and short-term deposits of \$35.9M vs. \$50.3M as at 31 March 2024
- Cash burn of \$14.3M vs. \$12.0M in 2H 24 – Seasonal impact of higher weighting of costs in 1H 25 compared to the expectation for 2H 25
- The capital preservation initiatives continue to deliver
- Investment now primarily focused on long-term strategic initiatives
- Cash runway sufficient to re-establish reliable reimbursement¹



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

FINANCIAL PERIOD	1H 25	2H 24	1H 24	FY24	1H 25 vs. 1H 24	1H 25 vs. 2H 24
		\$000	\$000	\$000	△ %	△ %
Operating revenue	\$10,959	\$10,812	\$13,095	\$23,907	-16.3%	1.4%
Total revenue	\$12,155	\$12,713	\$16,580	\$29,293	-26.7%	-4.4%
Operating expenses	\$26,658	\$26,996	\$31,832	\$58,828	-16.3%	-1.3%
Net Loss After Tax	-\$14,503	-\$14,283	-\$15,252	-\$29,535	-4.9%	1.5%
Cash receipts from customers	\$11,125	\$10,561	\$13,576	\$24,137	-18.1%	5.3%
Net operating cash burn	\$12,474	\$10,758	\$14,992	\$25,750	-16.8%	16.0%
Net cash, cash equivalents and short-term deposits	\$35,931	\$50,261	\$62,174	\$50,261	-42.2%	-28.5%

- Operating revenue increases 1.4% on 2H 24 despite lower volumes following lift in ASP¹ to US\$618 vs. US\$613 in 2H 24
- Total revenue includes FX loss of \$0.4M, while 1H 24 recorded a \$0.7m FX gain and 2H 24 recorded a FX loss of \$0.1m
- Total operating expenses steady on 2H 24 as restructuring gains of late Q2 24 retained
- Balance sheet remains strong and expected to be sufficient to regain coverage in the event of a non-coverage decision

OPERATING EXPENSES STEADY ON PRIOR HALF

INVESTMENT NOW FOCUSED ON LONG-TERM STRATEGIC INITIATIVES

FINANCIAL PERIOD	1H 25	2H 24	1H 24	FY24	1H 25 vs. 1H 24	1H 25 vs. 2H 24
	\$000	\$000	\$000	\$000	△ %	△ %
	Laboratory operations	\$5,958	\$5,610	\$6,141	\$11,751	-3.0%
Research	\$7,230	\$6,602	\$5,487	\$12,089	31.8%	9.5%
Sales and marketing	\$8,245	\$11,251	\$14,339	\$25,590	-42.5%	-26.7%
General and administration	\$5,225	\$3,533	\$5,865	\$9,398	-10.9%	47.9%
Total operating expenses	\$26,658	\$26,996	\$31,832	\$58,828	-16.3%	-1.3%

- Operating expenses are steady on 2H 24
- The 16.3% reduction vs. 1H 24 is due to the shift in focus to preserve cash while enhancing clinical evidence
 - Laboratory operations largely driven by volume and preparing for the commercial launch of Triage Plus.
 - Rise in research expenses reflects continued investment in clinical evidence to create catalysts for coverage.
 - Sales and marketing expense reduction vs 2H 24 reflects the sharp focus on the most the profitable territories/accounts
 - General and administration expenses are higher as a result of receiving a higher proportion of overheads.

SUMMARY AND OUTLOOK



PacificEdge®
CANCER DIAGNOSTICS

READY FOR ALL OUTCOMES

- We continue to manage our cash prudently while we seek to maintain reliable reimbursement for existing products and establish reimbursement for future products
- We will continue to:
 - Engage directly and through industry partners with CMS/Novitas to preserve reimbursement of our existing portfolio of tests
 - Focus on the clinical development of Triage Plus and Monitor Plus for guidelines inclusion and increased coverage certainty
 - Focus our commercial operations on profitable territories, non-Medicare revenue streams and cash collections
 - Emphasize the clinical and economic value of Cxbladder in our sales messaging

HEADWINDS:

- Possible non-coverage determination from Novitas on a new proposed LCD after following appropriate 'notice and comment' procedure
- Possible negative physician or patient response to enhanced patient responsibility on commercial insurance

CATALYSTS:

- Possible inclusion of Cxbladder Triage in AUA microhematuria guidelines amendment
- Possible retirement of Novitas LCD (DL39365)
- Possible re-coverage determination from Novitas on new proposed LCD after following appropriate procedure
- Crosswalk or 'provisional pricing' for Cxbladder Triage Plus at greater margin than the current generation of products

APPENDIX



PacificEdge[®]
CANCER DIAGNOSTICS

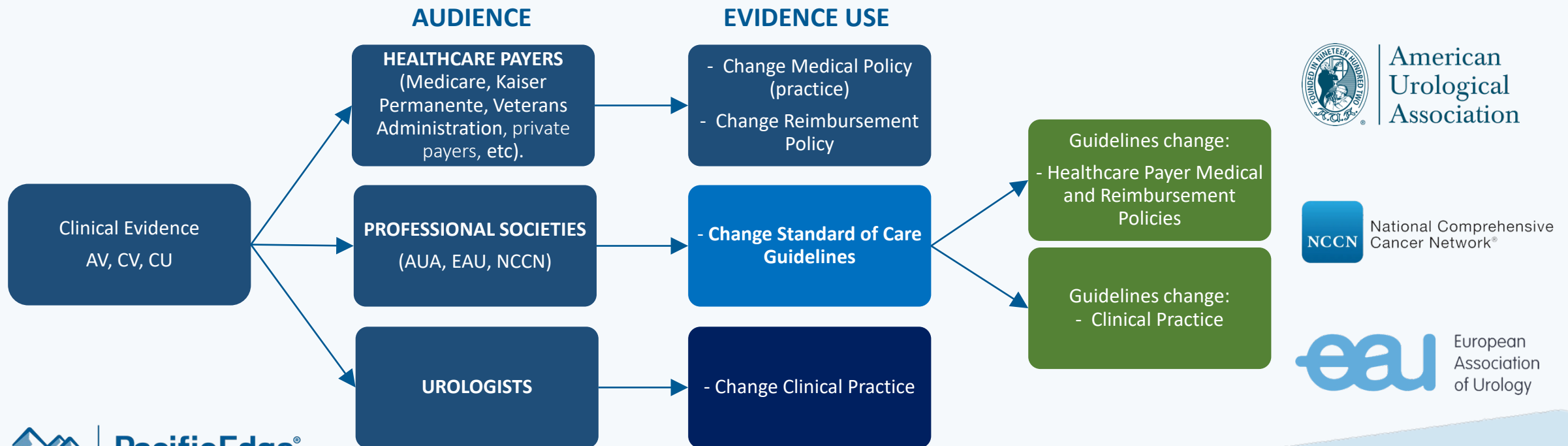
PACIFIC EDGE'S GLOBAL REACH



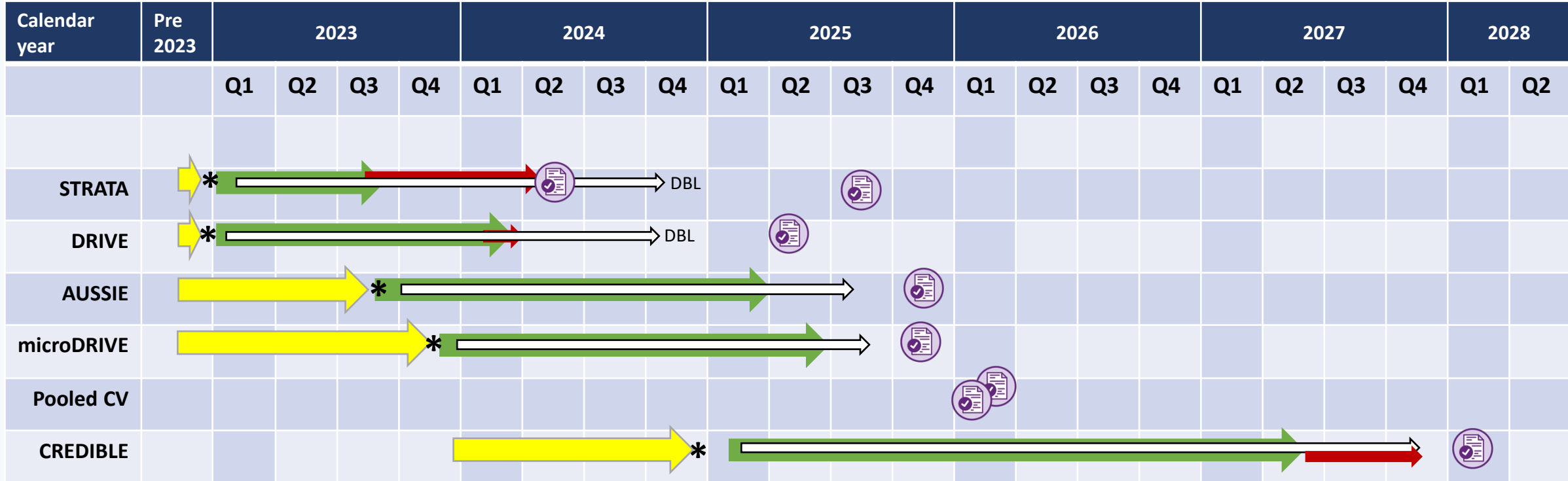
PACIFIC EDGE'S EVIDENCE PROGRAM SEEKS TO CHANGE CLINICAL PRACTICE

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)
- * 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"																							
LOBSTER																							
US CU Surv																							

Legend:

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

SUMMARY OF CLINICAL EVIDENCE

		Study	Pop. Type	Sensitivity (Sn)	NPV	Specificity (Sp)	Comment
Triage Plus	Proof of concept	Lotan et al., 2022	MH + GH*	97%	99.7%	90%	Pooled data from US and Singapore cohorts (n=804). Called Detect+ in publication.
	CV	DRIVE (unpublished) (1)	MH + GH*				Study in progress
		AUSSIE (unpublished) (4)	MH + GH*				Study in progress
		microDRIVE (unpublished) (5)	MH*				Study in progress
CU	CREDIBLE (not started) (6)	MH				Protocol in final development stages, site selection starting by the end of year.	
Triage	AV	Kavalieris et al., 2015	MH + GH*	95.10%	98.50%	45%	Sn, Sp, NPV values when test-negative rate is 40%
	CV	Davidson et al., 2019	MH + GH*	95.5% (1)	98.6% (1)	34.3%	GH only: Sn (95.1%), NPV (98%), Sp (32.8%); MH only: Sn (100%), NPV (100%), Sp (42.6%)
		Konety et al., 2019	(2)	100%			Cxbladder (3) correctly adjudicated all UC confirmed patients (n=26) with atypical urine cytology results (n=153, 4)
		Lotan et al., 2022	MH + GH*	89%	99%	63%	Pooled data from US and Singapore cohorts (n=804)
		Davidson et al., 2020	MH + GH*	89.4% (5)	98.9% (5)	59% (5)	39% of patients testing negative for Cxb Triage & imaging did not get cystoscopy & were managed at primary care (6)
	CU	Lotan et al., 2024 (7)	MH + GH*	90%	99%	56%	Showed clinicians using Triage undertook 59% fewer cystoscopies on low-risk patients presenting with hematuria.
Detect	AV	O'Sullivan et al., 2012	GH*	81.8%	97%	85.1%	Cxb Detect detected 97% of HG tumors & 100% of Stage 1 or greater tumors
	CV	Lotan et al., 2022	MH + GH*	74%	97%	82%	Pooled data from US and Singapore cohorts (n=804)
		DRIVE (unpublished) (1)	MH + GH*				Study in progress
	Health Economics	Tyson et al., 2023	MH				Published economic model shows significant savings for healthcare payers (median savings of \$559 in direct costs per patient)
Monitor	AV	Kavalieris et al., 2017	(1)	88% (2)	97% (2)	N/A	(3)
	CV	Konety et al., 2019	(4)	100%			Cxbladder (5) correctly adjudicated all UC confirmed patients (n=26) with atypical urine cytology results (n=153, 6)
	CU	Koya et al., 2020	(7)				Integration of Cxb Monitor into the surveillance schedule reduced annual cystoscopies (39%) (8,9)
	CU	Li et al., 2023	(7)				Cxbladder Monitor safely postpones a patient's next scheduled cystoscopy, the current 'gold standard' for bladder cancer surveillance

* Referred patients. Definitions - MH: Microhematuria, GH: Gross Hematuria. For Sensitivity, NPV and Specificity please see page 41 of this presentation

FOOTNOTES FOR CLINICAL EVIDENCE SUMMARY

Footnotes		
Triage Plus	1	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Triage Plus).
	2	Observational study to validate performance characteristics of Cxb Triage Plus in patients with UC of the upper tract.
	3	Patients with suspected upper tract UC (UTUC) or surveillance patients with a history of UTUC.
	4	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Triage Plus).
	5	Observational study to validate performance characteristics of Cxb Triage Plus in microhematuria (MH) patients.
	6	Clinical utility study comparing the reduction of cystoscopy use when implementing the new clinical pathway to SOC in a defined MH population.
Triage	1	Cxb Triage performance; Cxb Triage & imaging combined performance had a Sn of 97.7% & NPV of 99.8%.
	2	Patients included hematuria evaluation ($n=436$) or surveillance previously diagnosed with UC ($n=416$) with both Cxbladder & urine cytology results.
	3	Cxbladder includes Cxbladder Triage & Cxbladder Monitor.
	4	This included $n=70$ for patients with hematuria & $n=83$ for patients with previously diagnosed UC and overall test negative rate of 30.7%.
	5	Cxb Triage performance; Cxb Triage & imaging combined performance had a Sn of 98.1%, NPV of 99.9% & Sp of 98.4%.
	6	Cxb Triage negative rate was 53%; Follow-up period of 21-months showed no missed cancers, demonstrating safety.
	7	Cxb Triage demonstrated to have clinical utility in safely risk stratifying low risk microhematuria patients and not undertake cystoscopy.
Detect	1	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Detect+).
Monitor	1	Surveillance patients previously diagnosed with primary or recurrent UC.
	2	Cxb Monitor performance characteristics on surveillance patients diagnosed with primary UC; Cxb Monitor had a Sn of 93% and NPV of 94% on patients with recurrent UC.
	3	Using Kavalieris et al., (2017) data set, Lotan et al., (2017) compared relative performance of Cxb Monitor against NMP22 ELISA, NMP22 BladderChek and urine cytology.
	4	Patients included hematuria evaluation ($n=436$) or previously diagnosed UC ($n=416$) with both Cxbladder & urine cytology results.
	5	Cxbladder includes Cxbladder Triage & Cxbladder Monitor.
	6	This included $n=70$ for patients with hematuria & $n=83$ for patients with previously diagnosed UC; test negative rate of 30.7%.
	7	All patients were being evaluated for recurrence of UC ($n=309$ providing 443 samples).
	8	Cxb Monitor identified all seven confirmed recurrence events identified on the first cystoscopy.
	9	Patients returning negative Cxb Monitor results ($n=235$) had no pathology-confirmed recurrence at 1st cystoscopy

REFERENCES SUMMARY OF CLINICAL EVIDENCE

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Triage	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.
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	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.

KEY CLINICAL ADVISORS AND CONSULTANTS



Professor Yair Lotan, MD

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



Professor Sam Chang, MD, MBA

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



Assistant Professor John Sfakianos

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



Professor Dan Barocas, MD, MPH, FACS

Institution: Vanderbilt University Medical Center
 Relationship: Consultant, CAB member
 Brief Bio: Published >100 articles. AUA guidelines panel for microscopic hematuria. Reviewer for AUA educational materials



Associate Professor, Siamak Daneshmand, MD

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



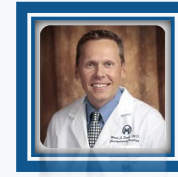
Associate Professor Katie Murray, DOMS, FACS

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



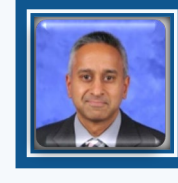
Professor Jonathan Wright, MD, MS, FACS

Institution: Fred Hutchinson Cancer Center at UW
 Relationship: Consultant, CAB member, CT PI
 Brief Bio: Member of ACS, SUO, AUA



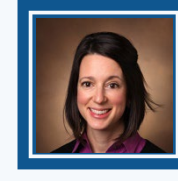
Professor Wade Sexton, MD

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



Professor Jay Raman, MD

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



Associate Professor Kristen Scarpato, MD, MPH, FACS

Institution: Vanderbilt University Medical Center
 Relationship: Consultant, CAB member, CT PI
 Brief Bio: SUO Education Committee, AUA Core Curriculum, Urology Practice Editorial Committee

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

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

PACIFIC EDGE – TAKING NEW ZEALAND INNOVATION GLOBAL



PACIFIC EDGE BOARD AND MANAGEMENT



CHRIS GALLAHER
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 New Zealand 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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DR TAMER ABOUSHWAREB
Chief Medical Officer
DR JUSTIN HARVEY
Chief Technology Officer



FOR MORE INFORMATION:

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

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

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

