



Pacific Edge FY 24 FINANCIAL RESULTS

INVESTOR PRESENTATION

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21 May 2024



PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

*Pacific Edge's ordinary shares trade on the
NZX and the ASX under the ticker code: PEB*

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AGENDA

1. FY 24 HIGHLIGHTS
2. STRATEGIC DELIVERY
3. FINANCIAL PERFORMANCE
4. ESG & OUTLOOK
5. QUESTIONS



FY 24 HIGHLIGHTS: PREPARED FOR ALL OUTCOMES AS WE REDUCE CASH BURN

▲ **3%**¹

GLOBAL TESTING VOLUMES (TLT²) on FY 23

Global TLT of 32,633; global commercial volumes rise 2% to 27,347

▲ **22%**

GROWTH IN OPERATING REVENUE on FY 23

Operating revenue \$23.9M
Total revenue of \$29.3M up 12% on FY 23. FX gains of \$0.6m vs \$2.3m FY23

(\$29.5M)
NET LOSS AFTER TAX

Increase from (\$27.0M) on FY 23 lifted by increased investment in clinical evidence

▼ **24%**

DROP IN MONTHLY CASH BURN³ IN 2H 24 VS 1H 24

Cash and Cash Equivalents decreased \$11.9M in 2H 24 vs \$15.6M in 1H 24 after reorganization in Q2 24

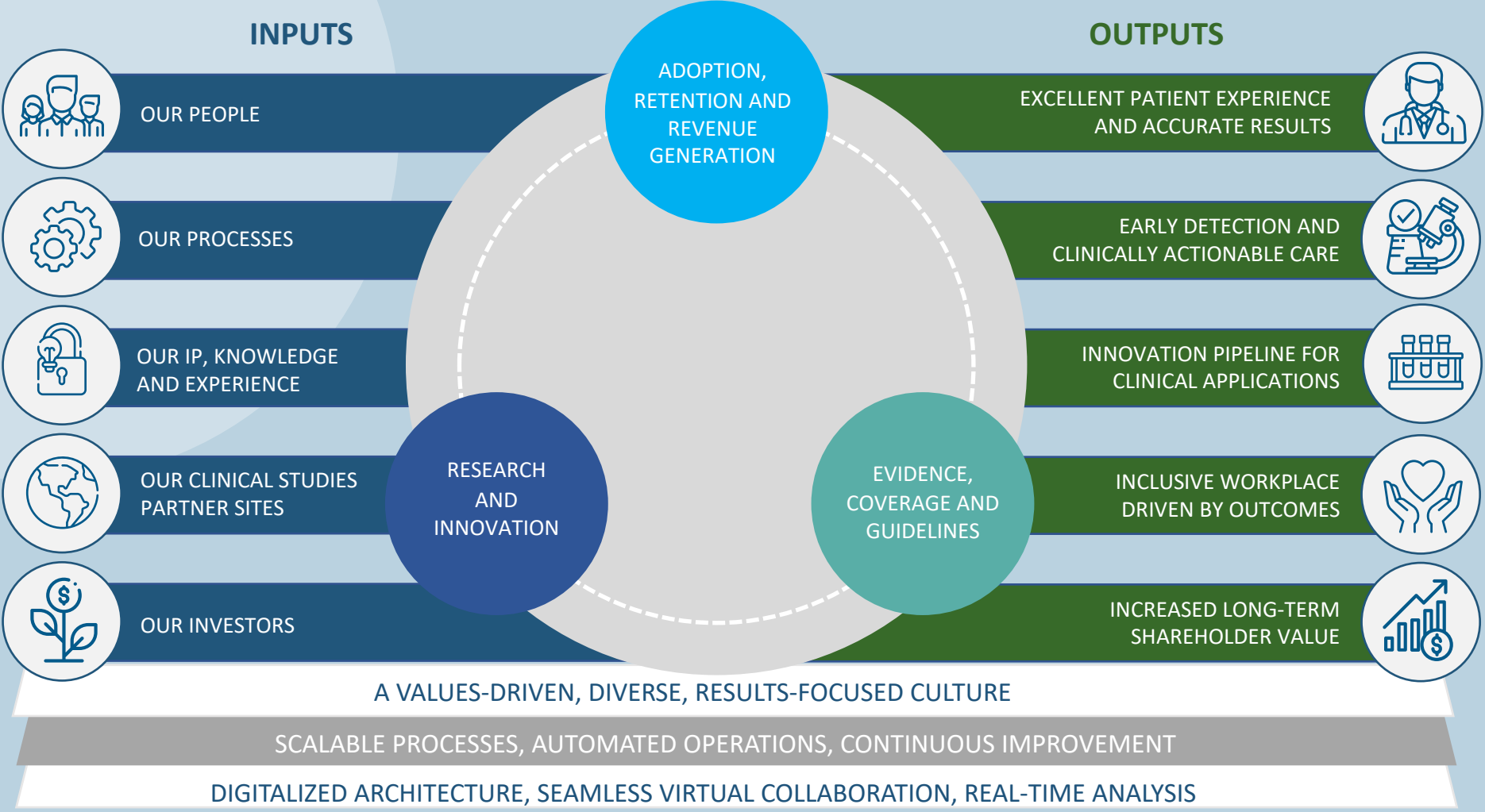
\$50.3M
CASH, CASH EQUIVALENTS³

Balance sheet is expected to provide sufficient runway to regain Medicare coverage (if withdrawn)

- Refocused the business on clinical development for Detect⁺ and Monitor⁺
- Published Clinical Utility for Triage from STRATA in The Journal of Urology and presented in paradigm shifting session at AUA 2024
- Restructured our commercial operations on profitable territories and non-Medicare revenue streams
- Reduced average monthly cash burn by 24% from \$2,603k in 1H 24 to \$1,985k in 2H 24
- Improved US cash collections by 18% with average sales price (ASP) increasing from US\$519 2H 23 to US\$613 in 2H 24
- Adjusted sales messaging to the clinical and economic value of Cxbladder
- Well prepared for all outcomes; awaiting decision on Medicare coverage

1. All comparisons are to the same period in the prior year unless otherwise stated
2. TLT is the Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing
3. Cash, cash equivalents and short-term deposits

VALUE CREATION THROUGH THREE PILLARS



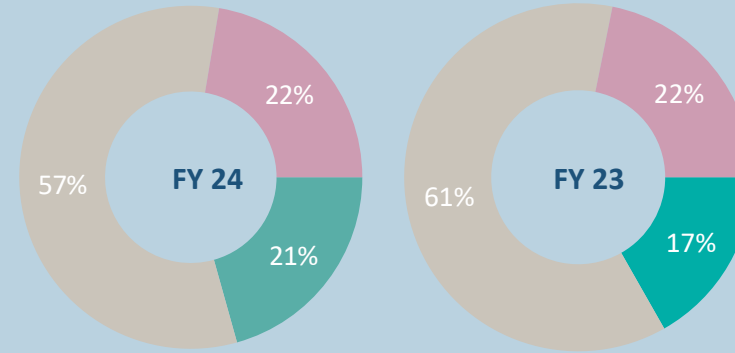
GROWTH SLOWED AMID MEDICARE DRAFT



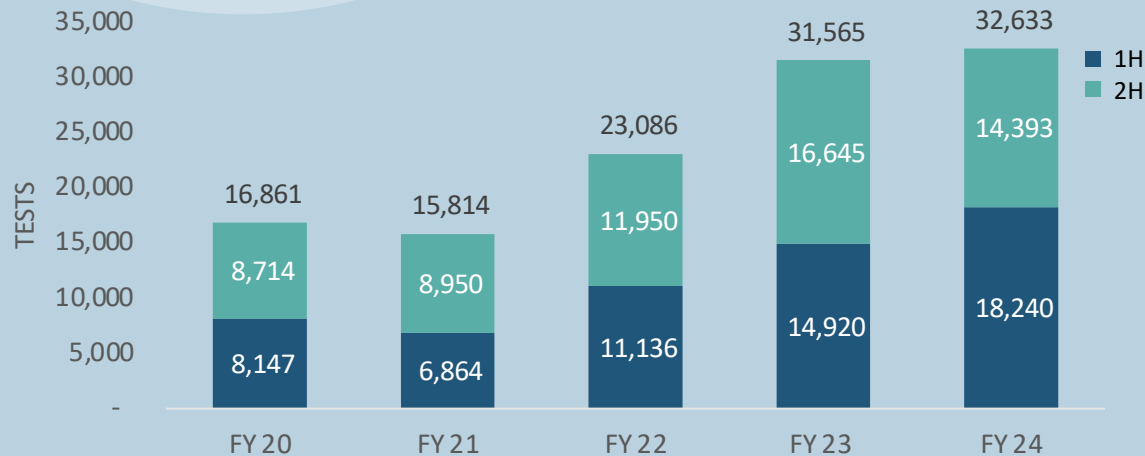
FY 24 TOTAL LAB THROUGHPUT (TLT*)

- Global TLT increased 3% to 32,633 with test demand moderating amid proposed Medicare coverage changes & sales force reductions.
- Global Commercial test volumes increased 2%. Global TLT is driven by US growth in the US (predominantly Detect).
- Risk stratification during hematuria evaluation using Triage & Detect is the largest market opportunity & reflected in current volume mix.

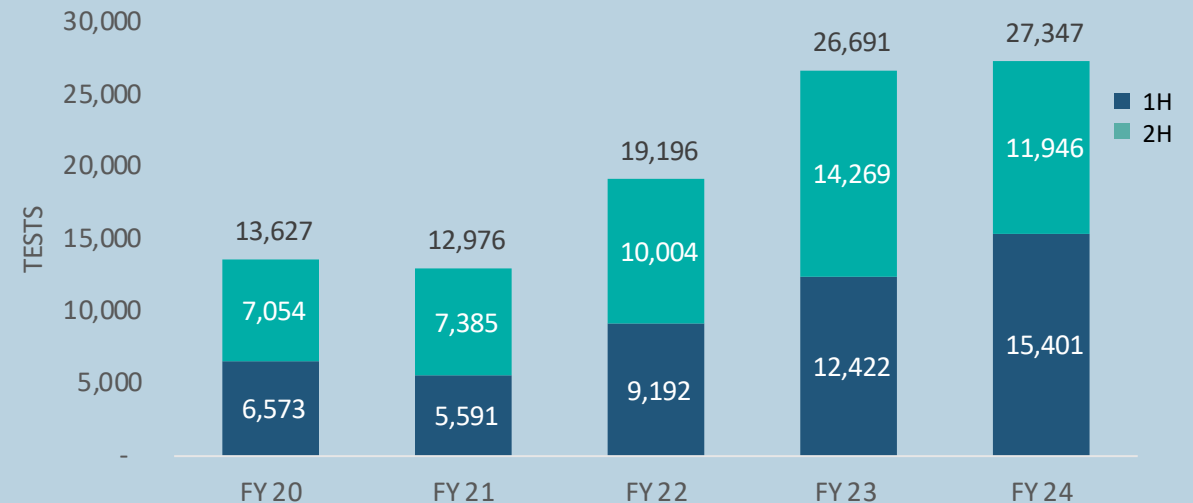
TEST VOLUMES BY TYPE (TLT*)



GLOBAL TOTAL TEST VOLUMES (TLT*)



GLOBAL COMMERCIAL TEST VOLUMES (TLT*)



*TLT is the Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing



CAPITAL PRESERVATION AND NEW REVENUE SOURCES DELIVERS RESILIENCE



COMMITTED TO MAINTAINING A STRONG BALANCE SHEET

- Pacific Edge continues to manage its cash reserves so - in the event of an adverse Medicare coverage decision - we have a cash runway to regain coverage.
- Cash reserves of \$50.3m; cash burn of \$11.9m in 2H 24 vs \$15.6m in 1H24.

STRATEGIC RESPONSE TO MEDICARE DELIVERING GAINS

- Restructured US sales operations and introduced patient responsibility.
- Deeper focus on larger or value-based institutional accounts and capitated systems (pop: ~13.2m patients).
- Refocused clinical evidence development, coverage and guidelines for coverage certainty.
- Ex-US opportunities through distributors: ProGenetics (Israel) and SouthGenetics (multiple LATAM countries).
- Considering alternative Medicare Administrative Contractor, LCD Challenge & new LCDs.

APAC & HEAD OFFICE STRATEGY SHIFT COMPLETE

- Cash burn is now driven almost entirely by long-term strategic imperatives.
- Development of growth markets in Australia and Asia.
- Distribution agreements Transviet (Vietnam), Hi-Precision (Philippines) and WellSpring (Malaysia) and Emmed (Brunei) delivering small but increasing volumes.

EXTENDING OUR REACH THROUGH DISTRIBUTION AGREEMENTS



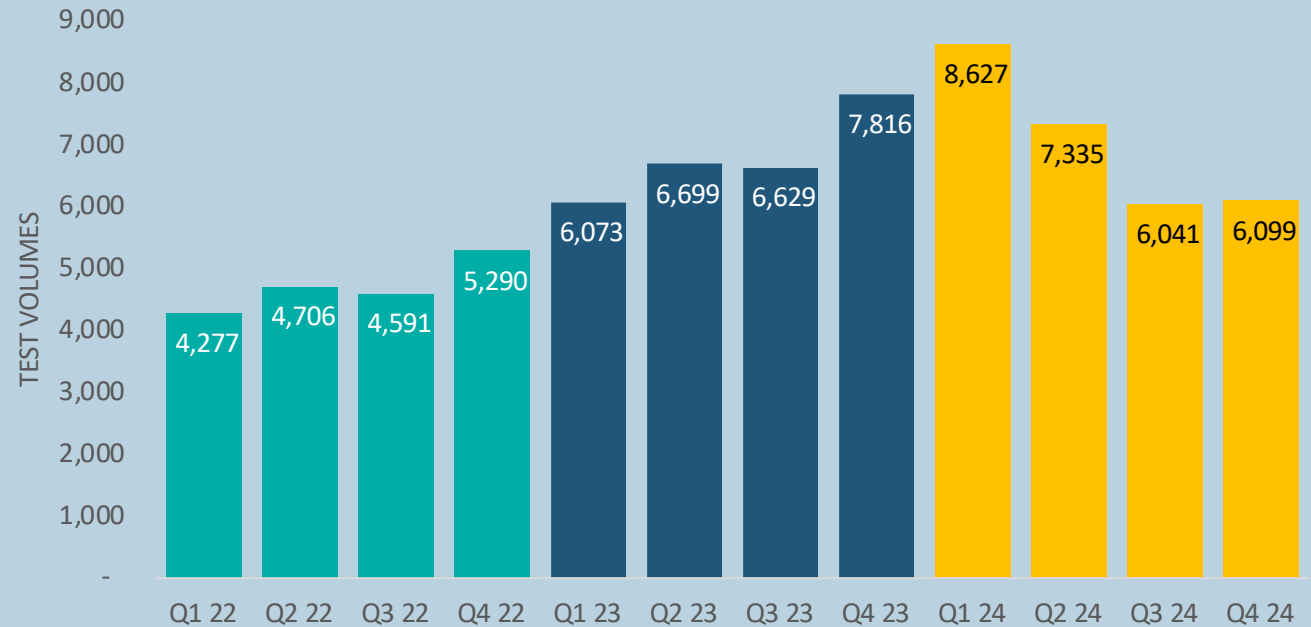
FOUNDATIONS FOR GROWTH - US TEST VOLUMES STABILISE



SMALLER SALES TEAM REDUCES TOP LINE THROUGHPUT

- Throughput has reduced by 22% from 7,816 test/quarter in Q4 23 to 6,099 in Q4 24 as the average sales team for the quarter has reduced by 51%.
- Most-recent QoQ throughput volume is steady (6,099 in Q4 24 over 6,041 in Q3 24) despite further reduction in sales FTEs.
- 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*



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

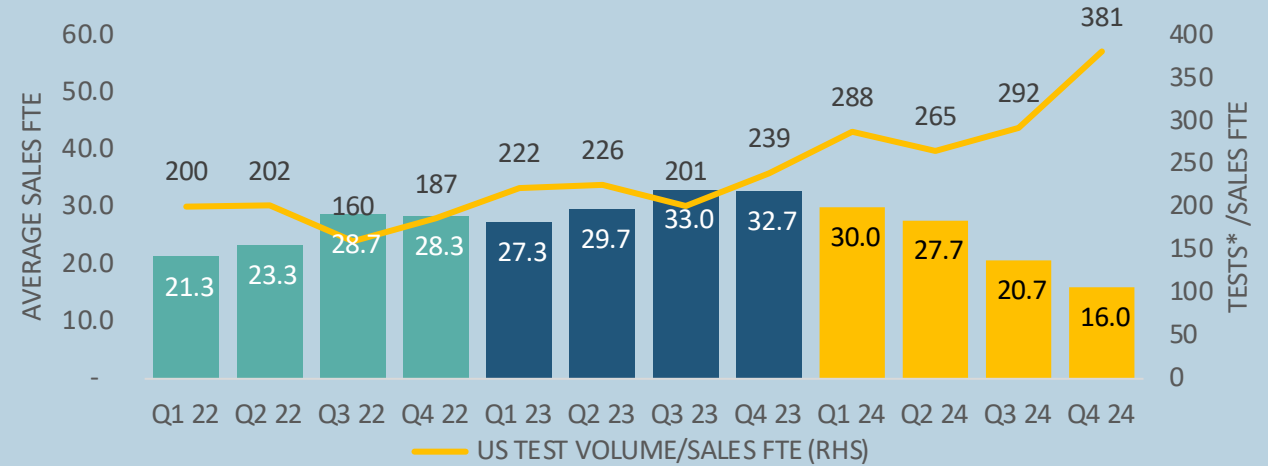
FOUNDATIONS FOR GROWTH – SALES TEAM PERFORMANCE IMPROVES



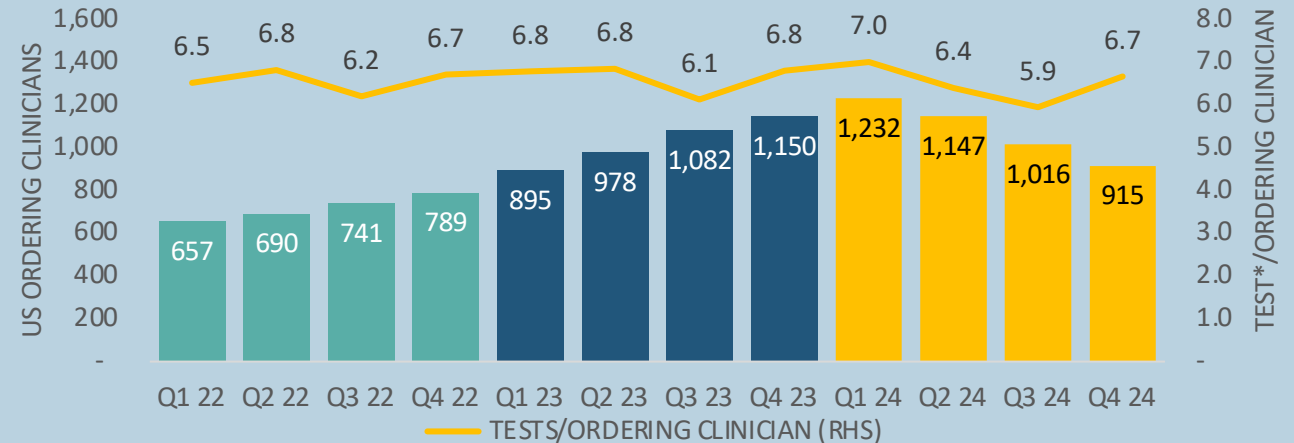
SALES TEAM FOCUSED ON KEY PERFORMANCE INDICATORS

- Sales FTE down to an average of 16.0 in Q4 24 from 32.7 in Q4 23 as we focused on cash conservation.
 - Sales FTEs were reduced by restructure in late Q2 24.
 - Sales FTEs have continued to leave the business and not currently backfilled due to focus on cash preservation.
- Sales force efficiency (total tests/average FTE) up 59% from Q4 23 to 381:
 - More effective core sales team.
 - Focus on the most profitable territories/accounts.
- Tests/US ordering clinician stable, but ordering clinicians fall reflecting:
 - 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



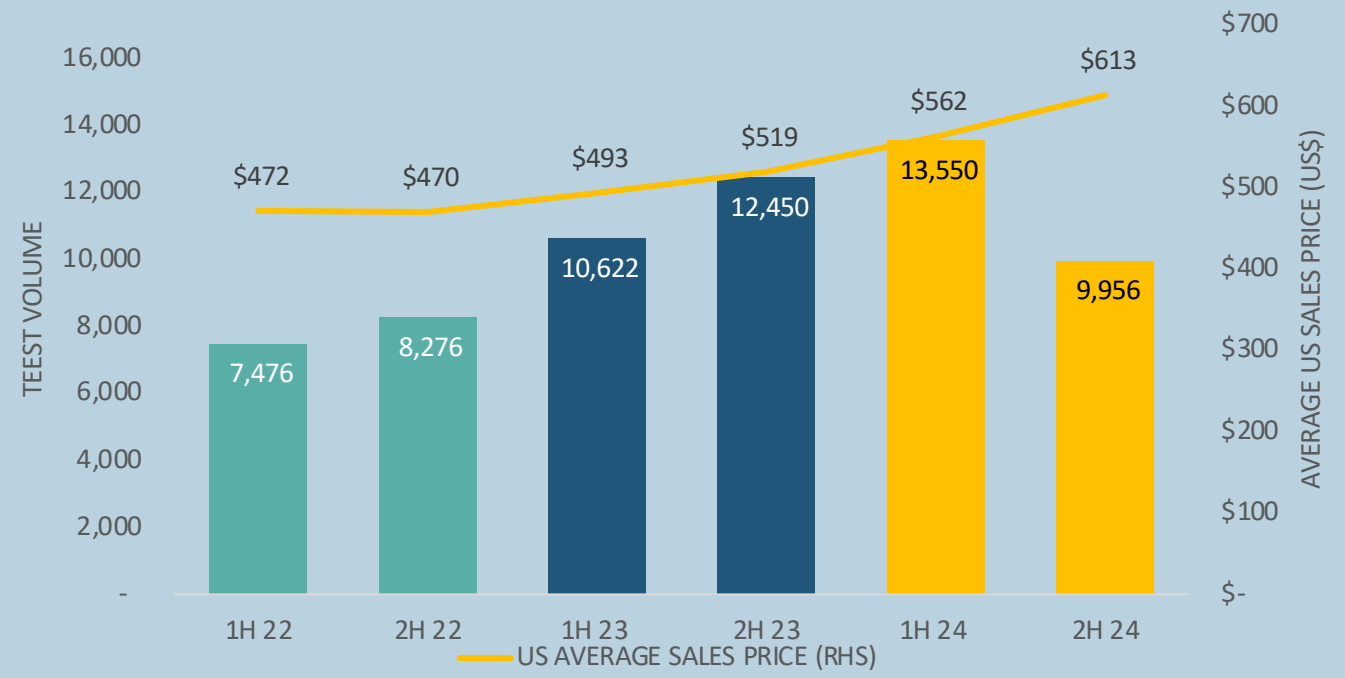
FOUNDATIONS FOR GROWTH - US CASH COLLECTIONS IMPROVE



REIMBURSEMENT & CASH COLLECTIONS – A CORE COMPETENCY

- Average Sales Price (ASP) per test increased 18% to US\$613 in 2H 24 from US\$519 in 2H 23 lifted by:
 - Enhanced Patient Responsibility - patients with non-contracted private insurance (i.e. non-Kaiser) sign patient responsibility notice agreeing to pay if their insurer does not.
 - 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\$)



* ASP: US Operating Revenue in USD / US Commercial Test Volumes



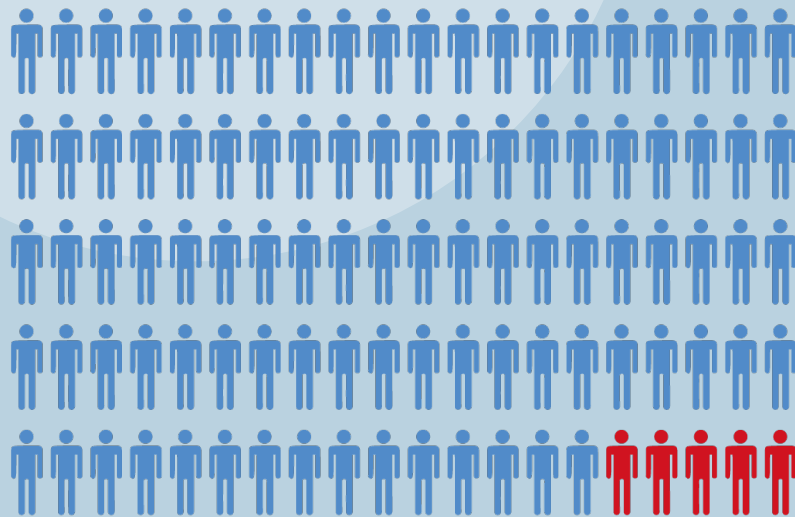
SELLING CXBLADDER'S CLINICAL, ECONOMIC AND PATIENT VALUE



For healthcare payers Cxbladder Detect offers substantial total cost savings per patient when used to intensify or de-intensify hematuria evaluation in patients presenting with microhematuria¹

CURRENT PRACTICE (AUA GUIDELINES)

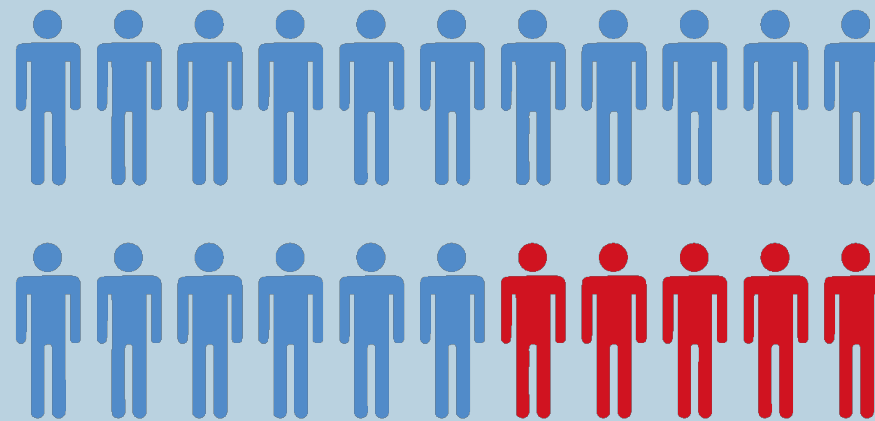
5% of patients with Microhematuria have Urothelial Cancer:
Must do 100 cystoscopies to find 5 cancers



■ Normal (95%) ■ Cancer (5%)

CXBLADDER INTRODUCED TO STANDARD OF CARE

Rule out 78 of the 95 patients without cancer:
Now do only 22 cystoscopies to find the same 5 cancers



■ Normal (77.3%) ■ Cancer (22.7%)

Pacific Edge modelling¹ suggests avoided procedures could save >US\$500 per patient with microhematuria

¹ Pacific Edge has developed a detailed budget impact model to understand costs to private practice, healthcare institutions and payers, over and above the Cxbladder test price of US \$760/test focused on microhematuria patients. [Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed \(PMID: 37914255\)](#)

DRIVING GROWTH IN ASIA PACIFIC AND CONSOLIDATING NEW ZEALAND

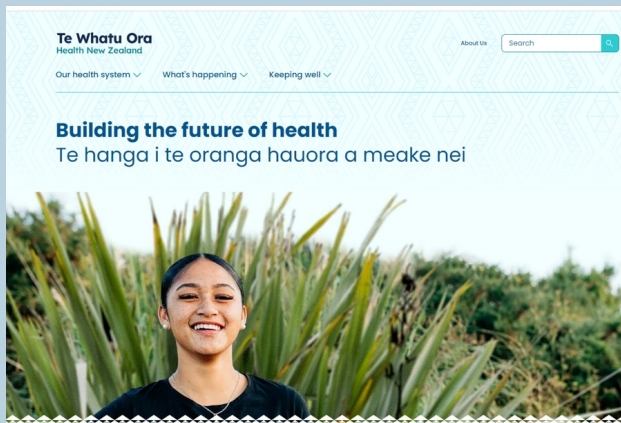


COMMERCIAL TEST VOLUME GROWTH IN NEW MARKETS

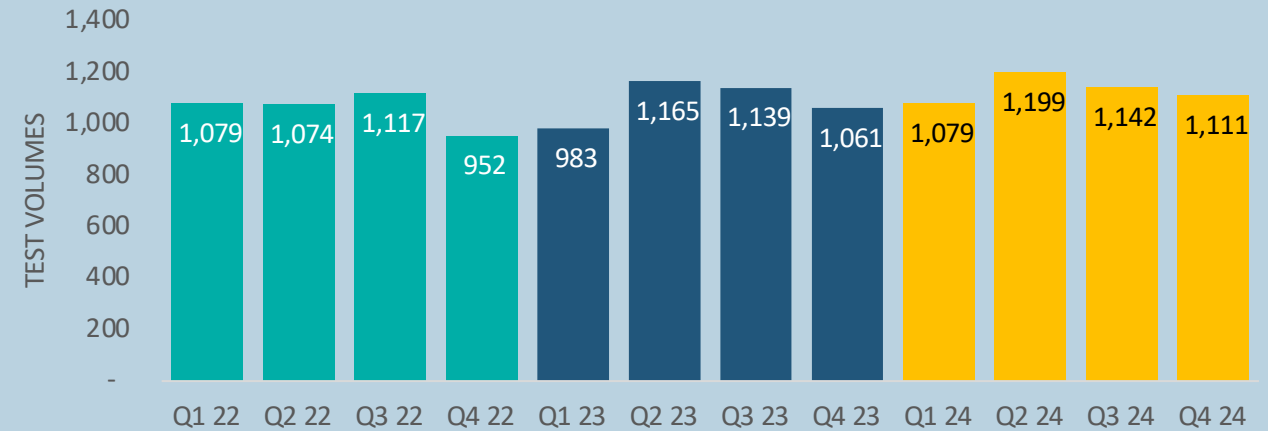
- Quarterly total test volumes steady across FY 24.
 - Fewer evaluations and non-billable tests.
 - Shift in emphasis to commercial tests.
- 2H 24 commercial test volumes rose 9% over 2H 23
- New Zealand is a mature market with Cxbladder utilized in 15 of the 20 Te Whatu Ora health regions covering >75% of the population.

AUSTRALIA & ASIA PACIFIC

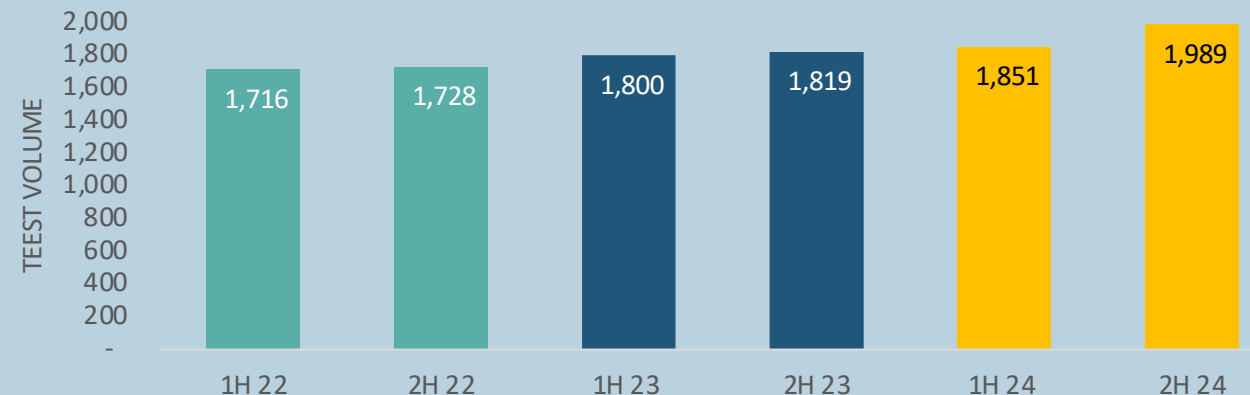
- Australia and Southeast Asia are still in business development.
- Initial commercial testing volume direct or via distributors in Singapore, Malaysia, and the Philippines.



APAC TOTAL TEST VOLUMES*



APAC COMMERCIAL TEST VOLUMES



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

STRENGTHENING OUR FOUNDATIONS

DIGITALIZATION, AUTOMATION & CUSTOMER EXPERIENCE

Customer facing systems

- Give customers options to connect with Pacific Edge to fit their needs and smooth workflows.
 - Electronic Medical Record (EMR) integrations.
 - Customer Portal.
- Improvement of end-to-end experience for patients and customers supported by digital workflows.

Internal systems

- Improve Lab Operations and Customer Service with focus on increasing automation and reducing turn around time.
- Organization-wide data warehouse for storage, access and reporting of all commercial data.
- Customer Relationship Management (CRM) rollout expanded beyond sales to all commercial teams.

EMR INTEGRATION DRIVES MOMENTUM AT KAISER

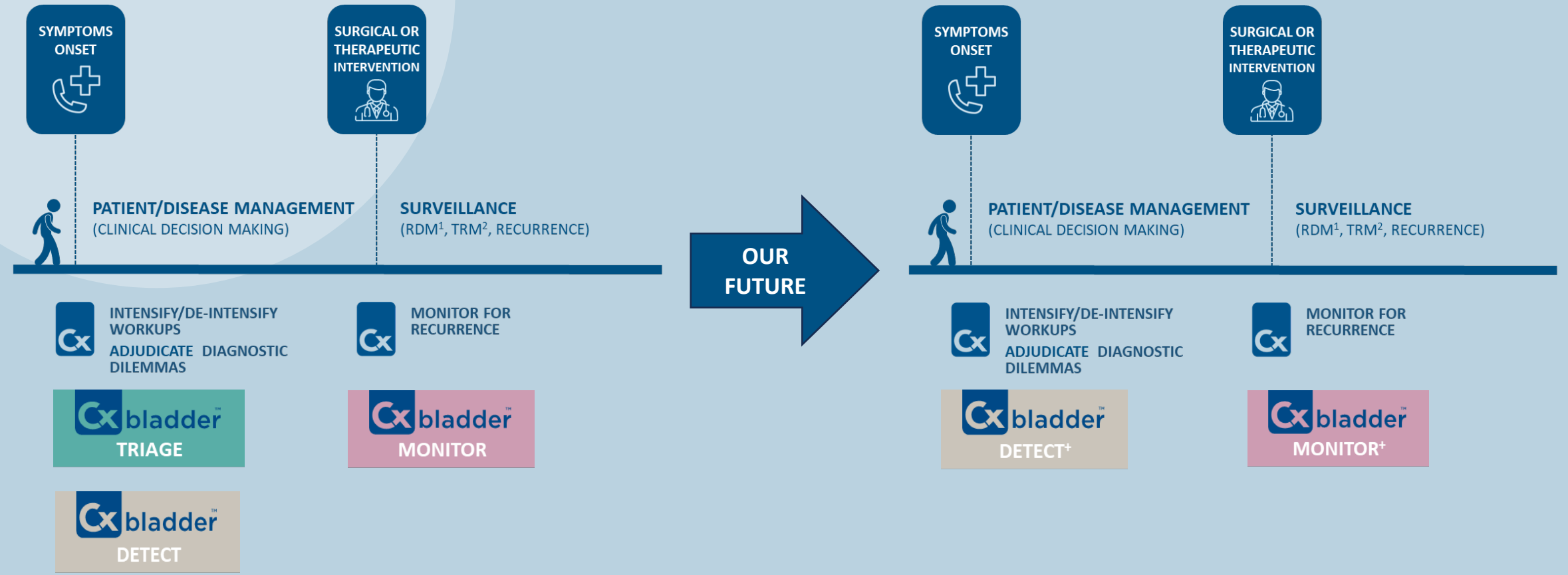


- EMR integration went live in Nov 2023 across the Southern California Permanente Medical Group (Kaiser SoCal) streamlining sample collection, test ordering and test resulting for Triage and Monitor.
- All 15 Kaiser SoCal sites are now ordering and volumes increasing steadily.
- Primarily adopted for Triage, Monitor volume is beginning to rise as clinicians become increasingly familiar with Cxbladder.
- Ordering by nurses and clinical assistants suggests accounts are following the protocols on all eligible patients for Triage and Monitor.
- Kaiser SoCal represents ~37% of the >12.6m members covered Kaiser Permanente means plenty of growth opportunity remains within SoCal.
- NorCal and other regions remain a longer-term priority following success in SoCal.



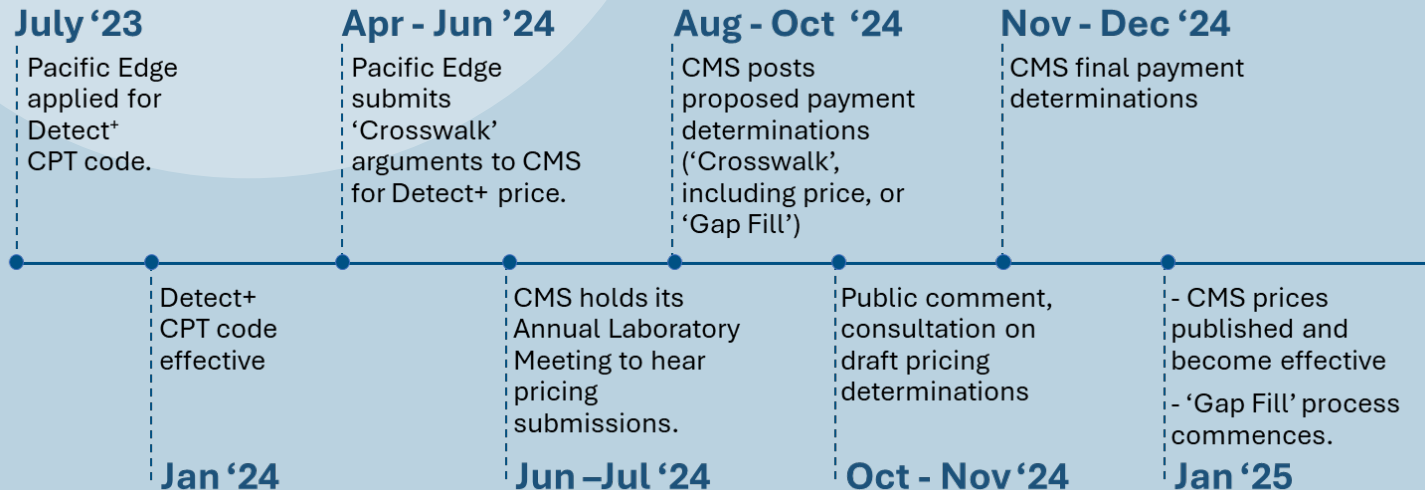
SIMPLIFYING THE CXBLADDER VALUE PROPOSITION – DETECT+ & MONITOR+

ADDITION OF DNA BIOMARKERS ENHANCES TEST PERFORMANCE³



1. RDM: Residual Disease Monitoring,
 2. TRM: Therapeutic Response Monitoring
 3. Lotan et al (2022) 'Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification'

DETECT+ PRICING VIA CROSSWALK COULD BOLSTER PACIFIC EDGE'S ECONOMICS



DETECT+ PRICING – A POTENTIAL STEP CHANGE

- Pricing of Detect+ is the next step in establishing reimbursement.
- Crosswalk strategy for Detect+ is based on technological similarities to previously priced tests:
 - Existing CMS price for Cxbladder is the best reference for RNA components of Detect+.
 - Considering alternatives for the DNA components based on multiplex ddPCR tests.
- Pacific Edge is seeking a higher price and higher gross margin, further enhancing the economics of our sales teams.
- Potential to set a precedent for Monitor+.

Anticipated timeframe for Detect+ pricing - dates may change



AWAITING 'GENETIC TESTING FOR ONCOLOGY' (DL 39365) RESPONSE



KEY OPINION LEADERS UNITED IN OPPOSITION TO DL39365

- Pacific Edge engaged with oncology diagnostics industry & urology community during the 'Review and Comment' period.
- We have undertaken further meetings with Novitas and the Coverage and Analysis Group at CMS (Centers for Medicare and Medicaid Services).
- We have enjoyed strong support from professional societies, diagnostics industry partners, individual clinicians and patient advocacy groups for our arguments that we retain coverage.



Medicare

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 FY 24 Medicare and Medicare Advantage delivered ~14,000 commercial tests (~60% of US commercial tests) and ~\$17.0m NZD in total operating revenue (~71% 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 US time

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.



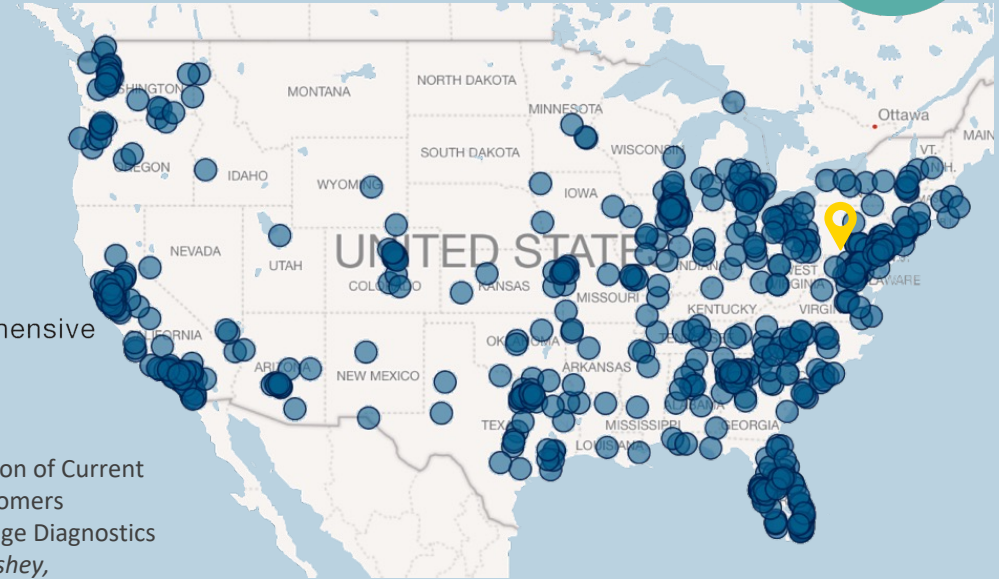
American Urological Association

OUR RESPONSE TO A LOSS OF COVERAGE

- Explore legal options supported by customers, industry partners and other impacted companies.
- Immediately extend our 'enhanced patient responsibility' from commercially insured patients to include patients covered by Medicare.
- 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.



National Comprehensive Cancer Network®



- 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 the National Comprehensive Cancer Network (NCCN) 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.



CLINICAL EVIDENCE UNDERPINS COVERAGE AND GUIDELINES DECISIONS



Recognition in national guidelines is the best way to entrench Medicare coverage of Cxbladder and its adoption by other independently contracted healthcare systems



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.



National Comprehensive
Cancer Network®

www.nccn.org

- US-based not-for-profit alliance of 32 leading US cancer centres. Novitas cited NCCN as sufficient for coverage in draft LCD.
- **Relevant standards of care:** High-risk non-muscle-invasive bladder cancer.
- **Review period:** annual submission every August.



European
Association
of Urology

www.uroweb.org

- Leading urologic authority in Europe and globally influential.
- **Relevant standards of care:** non-muscle invasive bladder cancer.
- **Review period:** with new evidence, last updated in March 2024.

RECENT GUIDELINE MOVEMENTS

- The AUA amended the NMIBC guidelines in Jan 2024 after reviewing the literature on urine biomarkers for surveillance of NMIBC. Cxbladder Monitor was not mentioned in the amendment, but explicitly named in “Future Directions” as a promising technology.¹
- The EAU updated their guidelines to say that biomarkers may have value in initial evaluation of hematuria, citing Cxbladder and three other technologies based on their publications.²

¹ <https://www.auanet.org/guidelines-and-quality/guidelines/bladder-cancer-non-muscle-invasive-guideline>

² <https://uroweb.org/guidelines/non-muscle-invasive-bladder-cancer>

STRATA¹ – THE STRONGEST EVIDENCE YET FOR GUIDELINE INCLUSION



PARADIGM-SHIFTING STUDY DEMONSTRATES CLINICAL UTILITY OF TRIAGE

- STRATA is the first ever randomized controlled trial of a urine biomarker for hematuria evaluation:
 - Peer reviewed study published in the AUA Journal of Urology² showed clinicians undertook 59% fewer cystoscopies, when provided a Cxbladder Triage test result.
 - Seeking to leverage data to demonstrate the clinical utility of Detect⁺.
- Publication submitted to Novitas as it considers finalization of draft LCD.
- New evidence for inclusion in the Pacific Edge Clinical Dossier that we use to engage with guideline committees, private payors, government payers, value-based clinician groups ex-US distributors.
- STRATA data to be deployed to further improve the Detect⁺ algorithm.

USING CLINICAL EVIDENCE TO DRIVE CXBLADDER ADOPTION



STRATA lead author Yair Lotan presenting the study to the 2024 AUA annual meeting, following publication of the study in Journal of Urology.

“Cxbladder Triage can help reduce the burden of unnecessary cystoscopies in this population resulting in less patient morbidity and discomfort, improved access to care, and reduced environmental impact.” – Lotan et al. (2024)



American
Urological
Association



National Comprehensive
Cancer Network®

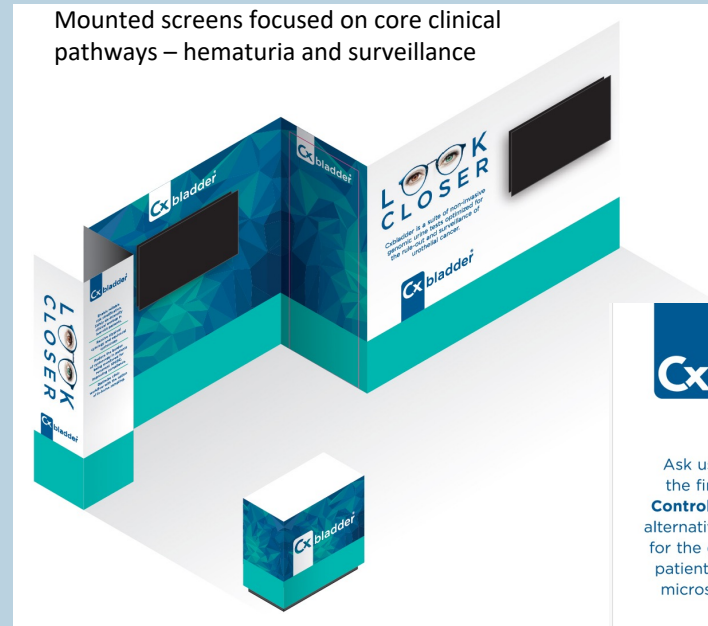
1. Safe Testing of Risk for Asymptomatic microhematuria
2. Lotan et al (2024) <https://doi.org/10.1097/JU.0000000000003991>



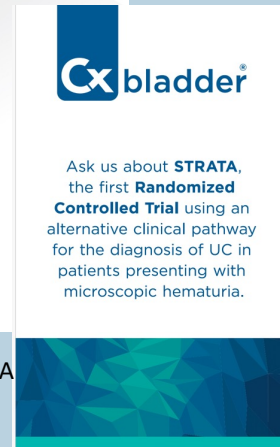
INCREASING CXBLADDER BRAND AWARENESS AT THE AUA CONFERENCE



- AUA annual meeting is the largest and most influential event in the US and global urological calendar. Provides opportunity to engage over 10,000 urologists, urologic oncologists, advanced practice providers, and other healthcare professionals.
- 2024 presence in San Antonio reinforced positioning and delivered core messaging, while promoting STRATA publication - both before and after Dr Lotan’s podium presentation. Activities included:
 - Prominent booth in main hall, staffed by the Pacific Edge Commercial Team for lead gathering and key account management
 - Elevator takeovers to engage clinicians as they waited at leading event venues – Marriott and Grant Hyatt
 - Targeted booth presence at the Urological Society for American Veterans (USAV) sub-meeting
 - Agenda-driven micro-meetings for medical affairs, clinical studies, business development and key account management



Mounted screens focused on core clinical pathways – hematuria and surveillance



Free standing pull-ups helped to promote STRATA



CLINICAL EVIDENCE CATALYSTS FOR COVERAGE CERTAINTY



MEDICARE RECONSIDERATION AND GUIDELINE INCLUSION REQUESTS

(Reconsideration requests take Novitas¹ approximately 12 months to process from the lodging of a valid request)

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. Analytical Validation of automated RNA and DNA extraction published	- AV of Triage, Detect, Detect ⁺ , Monitor and Monitor ⁺	Q3 2024
3. DRIVE data published	- CV of Detect ⁺ - CV of Triage	Q2 2025
4. Kaiser Permanente RWE⁴ published	- CU (RWE) of Triage	Q2 2025 ⁵
5. microDRIVE published	- CV of Detect ⁺	Q3 2025
6. AUSSIE data published	- CV of Detect ⁺	Q4 2025
7. Pooled CV data published⁶	- CV of Detect ⁺	Q1 2026
8. LOBSTER published	- CV of Monitor/Monitor ⁺	Q1 2026
9. CREDIBLE data published	- CU of Detect ⁺	Q1 2028

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

FDA PUBLISHES FINAL RULE TO REGULATE LAB DEVELOPED TESTS



US FDA REGULATION PUBLISHED. FACES HURDLES

- The FDA¹ published a final rule on 29 April 2024 asserting that it has the right to regulate LDTs like Cxbladder as Medical Devices under the Medical Device Amendments of 1976.
- Enforcement discretion for pre-market approval (PMA) has been proposed for currently marketed tests that are NYS accredited, meaning that existing Cxbladder tests will receive enforcement discretion.
- New Cxbladder tests may be required to follow the steps of the 'Phase Out' of enforcement discretion, but currently pose no risk to Detect+ launch plans
- Pacific Edge's position
 - Pacific Edge supports and welcomes FDA regulation through an Act of Congress, e.g. VALID² Act (failed to pass Congress in 2022).
 - Pacific Edge does not support regulation under the Medical Device Amendments of 1976.
- Pacific Edge is prepared and already adapting
 - While some requirements will be specific to the FDA, most are captured by other regulatory bodies (CLIA, CAP & NYS³) with which we already comply.
 - Pacific Edge continues to believe that the FDA will face legal and resourcing challenges and that timelines are likely to be adjusted.
 - Pacific Edge actively resources its R&D, clinical development, digital development and clinical operations to maintain compliance with all regulatory requirements.



1. FDA: Food and Drug Administration
2. VALID: Verifying Accurate Leading-edge IVCT Development Act
3. CLIA: Clinical Laboratory Improvement Amendments, CAP: College of American Pathologists, NYS: New York State

RESEARCH & INNOVATION – FOCUSED ON DNA ENHANCED PRODUCTS



READYING FOR THE LAUNCH OF NEW DETECT+ AND MONITOR+

- Ensure R&D, Digital and Lab Operations focus on the launch of Detect+ and Monitor+
- 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.
 - Publish AV Data on automated Cxbladder (Triage, Detect and Monitor) targeting publication in Q3 2024*.
- 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.



*Calendar quarter

FY 24 FINANCIAL PERFORMANCE

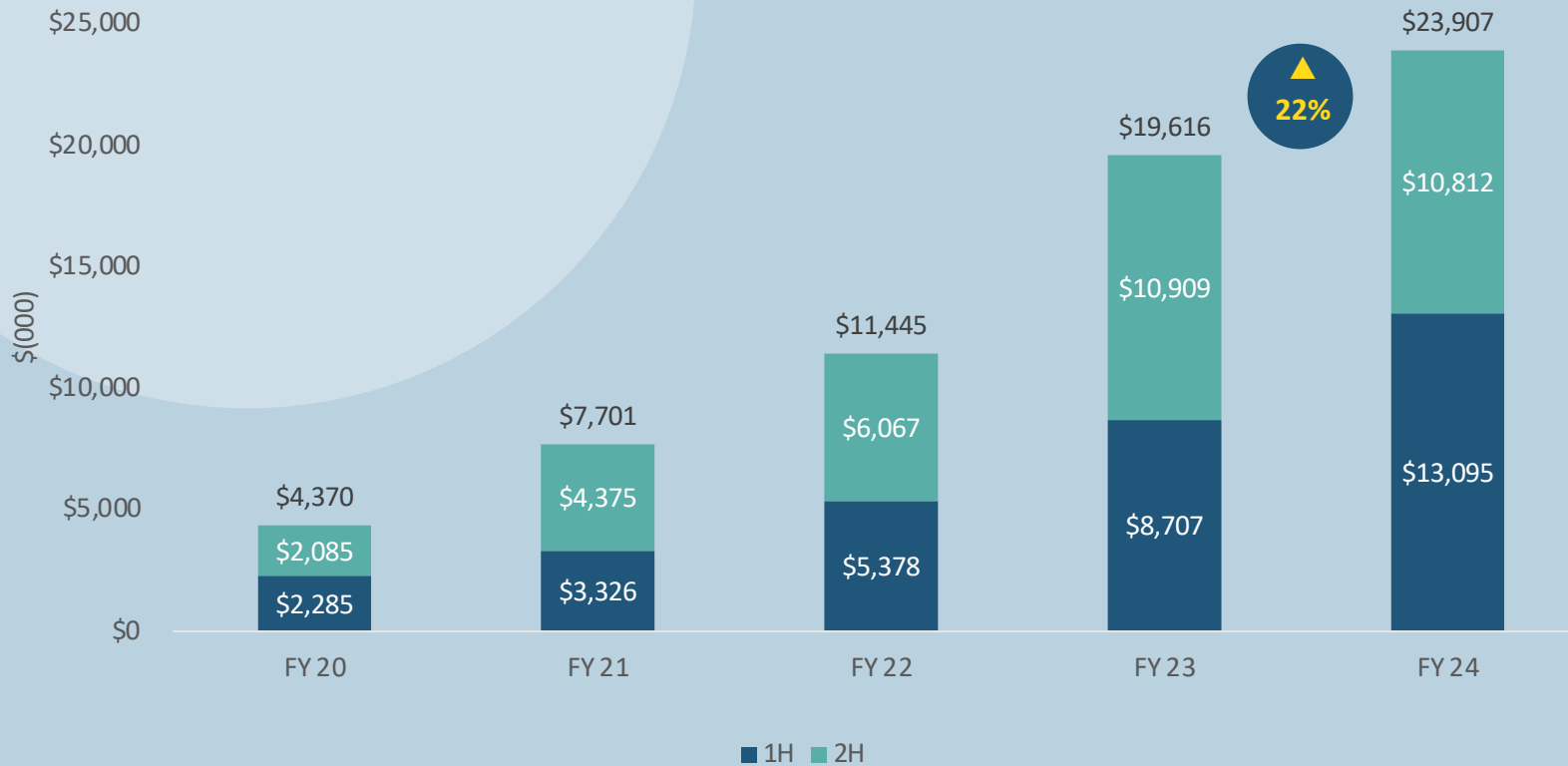


PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

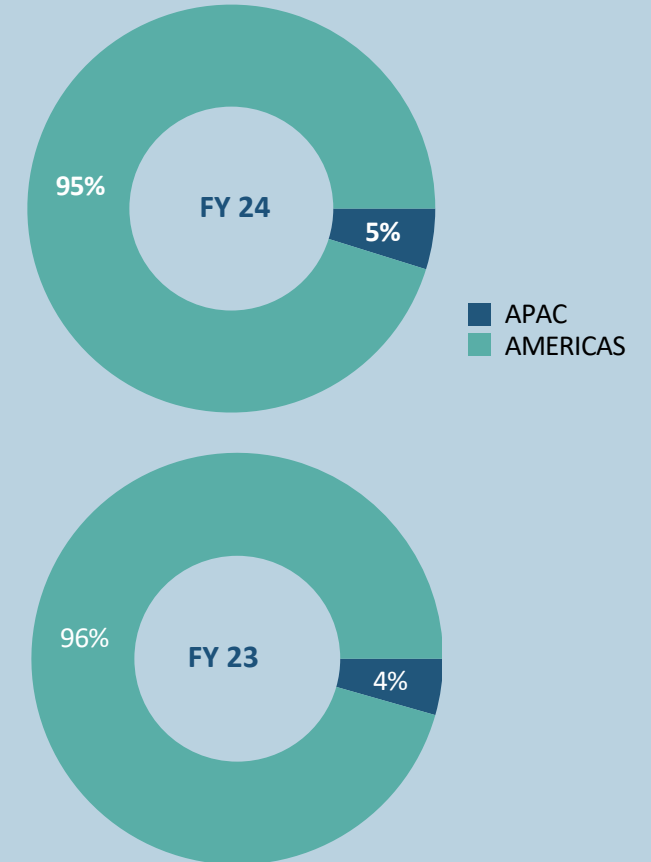
US COMMERCIAL TEST VOLUME GROWTH DRIVING REVENUE

RATE OF REVENUE GROWTH IN 2H 24 SLOWS AMID SALE FORCE REORGANIZATION

PACIFIC EDGE OPERATING REVENUE

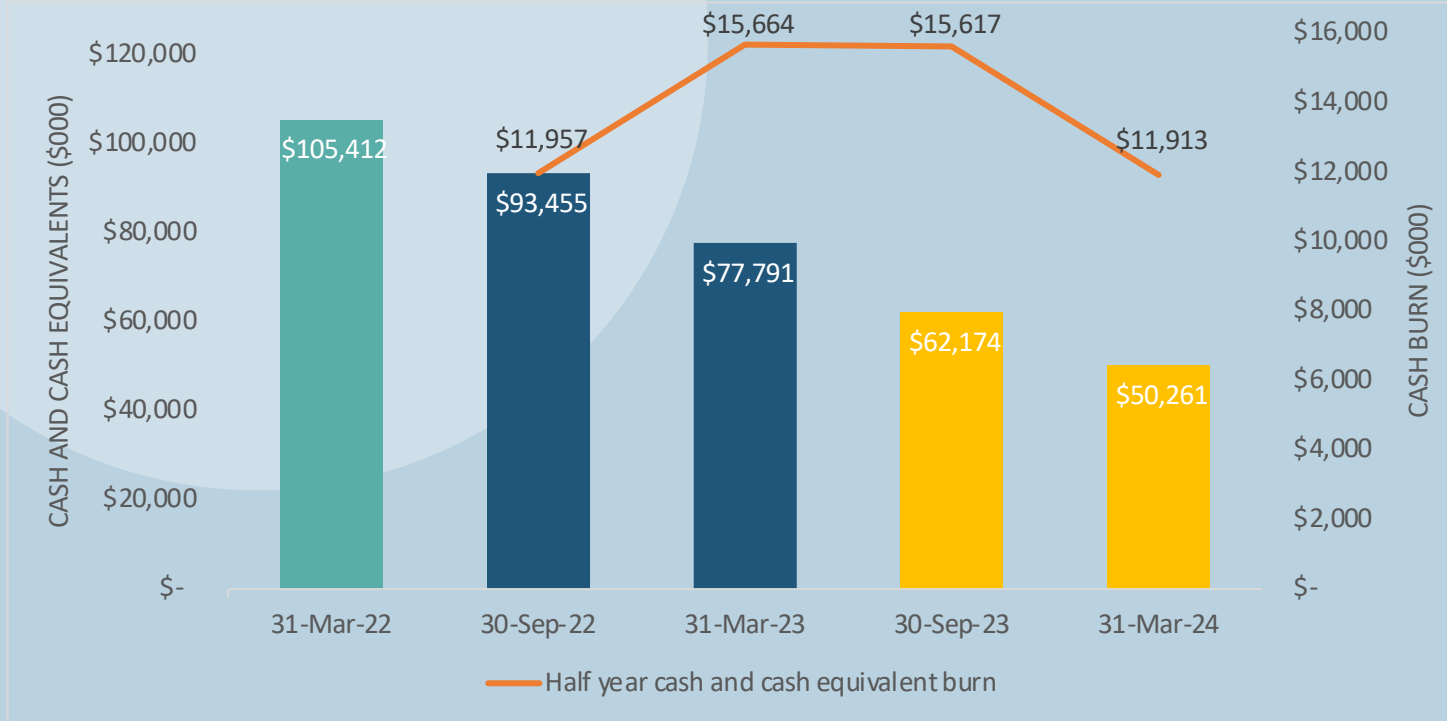


REGIONAL REVENUE CONTRIBUTION



A RUNWAY SUFFICIENT TO WEATHER A NON-COVERAGE DETERMINATION

CASH BURN SLOWS AS CAPITAL PRESERVATION PROGRAM DELIVERS



A STRONG BALANCE SHEET

- Cash, cash equivalents and short term deposits of \$50.3m as at 31 March 2024.
- Cash burn drops 24% on 1H 24 to \$11.9m as capital preservation and sales efficiency program delivers.
- Investment now primarily focused on long-term strategic initiatives.
- Cash runway is expected to be sufficient to regain coverage in the event of a non-coverage determination.

REVENUE GROWS WITH INCREASED ADOPTION OF CXBLADDER

GROWTH MODERATES IN 2H 24 WITH REORGANIZATION CRIMPING SALES

FINANCIAL PERIOD	2H 24	1H 24	FY24	FY 23	FY 24 vs. FY 23	2H 24 vs. 1H 24
	\$000	\$000	\$000	\$000	△ %	△ %
Operating revenue	\$10,812	\$13,095	\$23,907	\$19,616	22%	-17%
Total revenue	\$12,713	\$16,580	\$29,293	\$26,124	12%	-23%
Operating expenses	\$26,996	\$31,832	\$58,828	\$53,089	11%	-15%
Net Loss Before Tax	-\$14,283	-\$15,252	-\$29,535	-\$26,965	10%	-6%
Cash receipts from customers	\$10,561	\$13,576	\$24,137	\$18,468	31%	-22%
Net operating cash burn	\$10,758	\$14,992	\$25,750	\$25,575	1%	-28%
Net cash, cash equivalents and short term deposits	\$50,261	\$62,174	\$50,261	\$77,791	-35%	-19%

- Operating revenue increased 22% in FY 24 vs FY 23 with increased volumes and an increase in average receipts.
- Operating revenue in 2H 24 drops vs 1H 24 due to the restructuring to focus on profitable territories.
- Total revenue includes FX gains of \$0.6m in FY 24, lower than the \$2.3m in FY 23.
- Operating expenses are up 11% FY 24 vs FY 23, however are down 15% in 2H 24 vs 1H 24 due to the impact of the restructuring late Q2 24.
- Balance sheet remains strong and expected to be sufficient to regain coverage in the event of a non-coverage decision.

OPERATING EXPENSES FALL IN THE SECOND HALF

INVESTMENT NOW FOCUSED ON LONG-TERM STRATEGIC INITIATIVES

FINANCIAL PERIOD	2H 24	1H 24	FY24	FY 23	FY 24 vs. FY 23	2H 24 vs. 1H 24
	\$000	\$000	\$000	\$000	△ %	△ %
Laboratory operations	\$5,610	\$6,141	\$11,751	\$9,349	26%	-9%
Research	\$6,602	\$5,487	\$12,089	\$8,484	42%	20%
Sales and marketing	\$11,251	\$14,339	\$25,590	\$25,123	2%	-22%
General and administration	\$3,533	\$5,865	\$9,398	\$10,133	-7%	-40%
Total operating expenses	\$26,996	\$31,832	\$58,828	\$53,089	11%	-15%

- Operating expenses are up 11% for FY 24 vs FY 23.
- The 15% reduction in 2H vs. 1H 24 is due to the shift in focus to preserve cash while enhancing clinical evidence
 - Laboratory operations largely driven by volume.
 - Research expense is up 42% in FY 24 vs FY 23 and continued to increase 2H 24 vs 1H 24 demonstrating the importance placed on strong clinical evidence, providing catalysts for coverage.
 - Sales and marketing expense is up 2% FY 24 vs FY 23, but dropped 2H 24 vs 1H 24 due to the restructuring in late Q2 24.
 - General and administration expenses for FY 24 were down 7% on FY 23, with a decrease of 40% 2H 24 vs 1H 24 as initiatives to reduce cash burn were implemented.

ESG, SUMMARY AND OUTLOOK.



PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

ESG: PACIFIC EDGE IS FOUNDED ON IMPROVING SOCIAL OUTCOMES



Mission

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






Vision

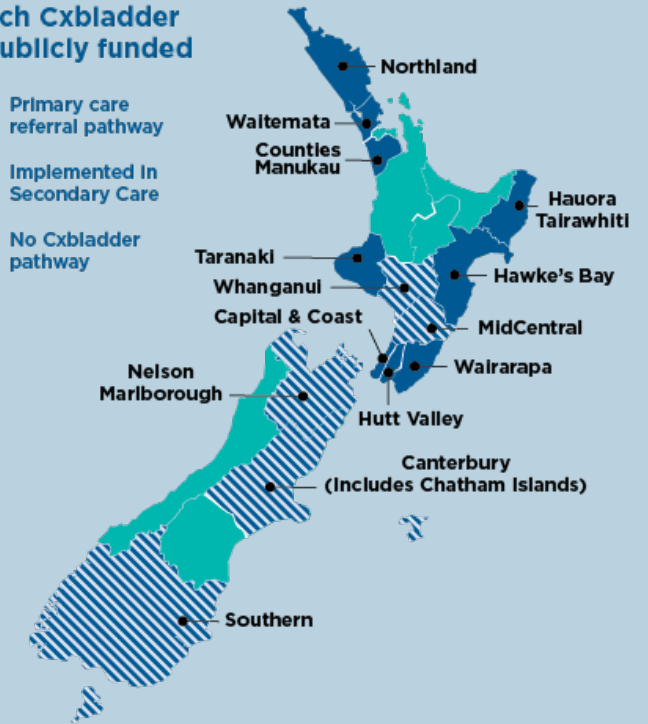
A world where the early diagnosis and better treatment of cancer is within reach of everyone

Cxbladder delivers actionable information that can:

- Advance the standard of care that physicians offer to patients
- Improve patient experience, quality of life and healthcare outcomes
- Reduce the total cost of care for value-based or capitated healthcare systems^{1,2}
- Deliver healthcare equity to poorer and/or rural communities
 - Improved access due to availability in primary care across New Zealand²
 - In *Te Whatu Ora* Canterbury, urological waiting lists fell by 25%² without compromising care
 - Patients can receive a kit delivered to their home with in-home sampling

Health Regions In which Cxbladder Is publicly funded

-  Primary care referral pathway
-  Implemented In Secondary Care
-  No Cxbladder pathway



1. [Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed \(nih.gov\)](#)

2. Davidson, Peter; [Presentation to Urofair, 2022](#), time to first specialist assessment.

ADVANCING SOCIAL, ENVIRONMENTAL AND GOVERNANCE GOALS



• SOCIAL

- **Culture:** High levels of staff engagement and participation in development opportunities; active promotion of diversity, inclusion and fair remuneration
- **Human Rights:** Major suppliers reviewed for compliance with modern slavery and human rights policies
- **Health and Safety:** Zero lost time due to injuries

• ENVIRONMENTAL

- **First year of mandatory reporting** under the Aotearoa New Zealand Climate Standards, delivered with FY24 as a baseline year
- **Environmentally sustainable procurement policy** introduced, reflecting new sustainable purchasing requirements

• GOVERNANCE

- **FMEA¹ risk management framework** embedded across the business with routine reporting
- **Compliance** with regulatory, quality, health & safety and manufacturing standards in every country we operate in

Put patients first with everything we do

WE:

Are committed to customer success

Are transparent and trusting

Are guided by data & evidence

Support our teammates

We celebrate successes, large and small

1 – FMEA: Failure Mode and Effects Analysis

GOVERNANCE – DELIVERING PACIFIC EDGE STABILITY



CHRIS GALLAHER
Chairman



MARK GREEN
Independent Director

AN ORDERLY SUCCESSION PROGRAM

- Board notices of retirement announced in March 2024 to deliver stability:
 - Chris Gallaher - appointed July 2016 - to retire from the Chair of Pacific Edge following the appointment of a successor and a structured handover later this year.
 - Mark Green - appointed May 2021 - will not seek re-election to the Board and will retire at the end of the Annual Shareholders Meeting in September.
- The Board's Nomination Committee has commenced a process to appoint a new Chair and consider the recruitment of new Independent Directors.

SUMMARY AND OUTLOOK: READY FOR ALL OUTCOMES

- We expect to manage cash reserves if Medicare coverage is retained or until re-coverage in the event of a negative determination.
- We will continue to:
 - Focus our business on the clinical development for Detect⁺ and Monitor⁺ 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

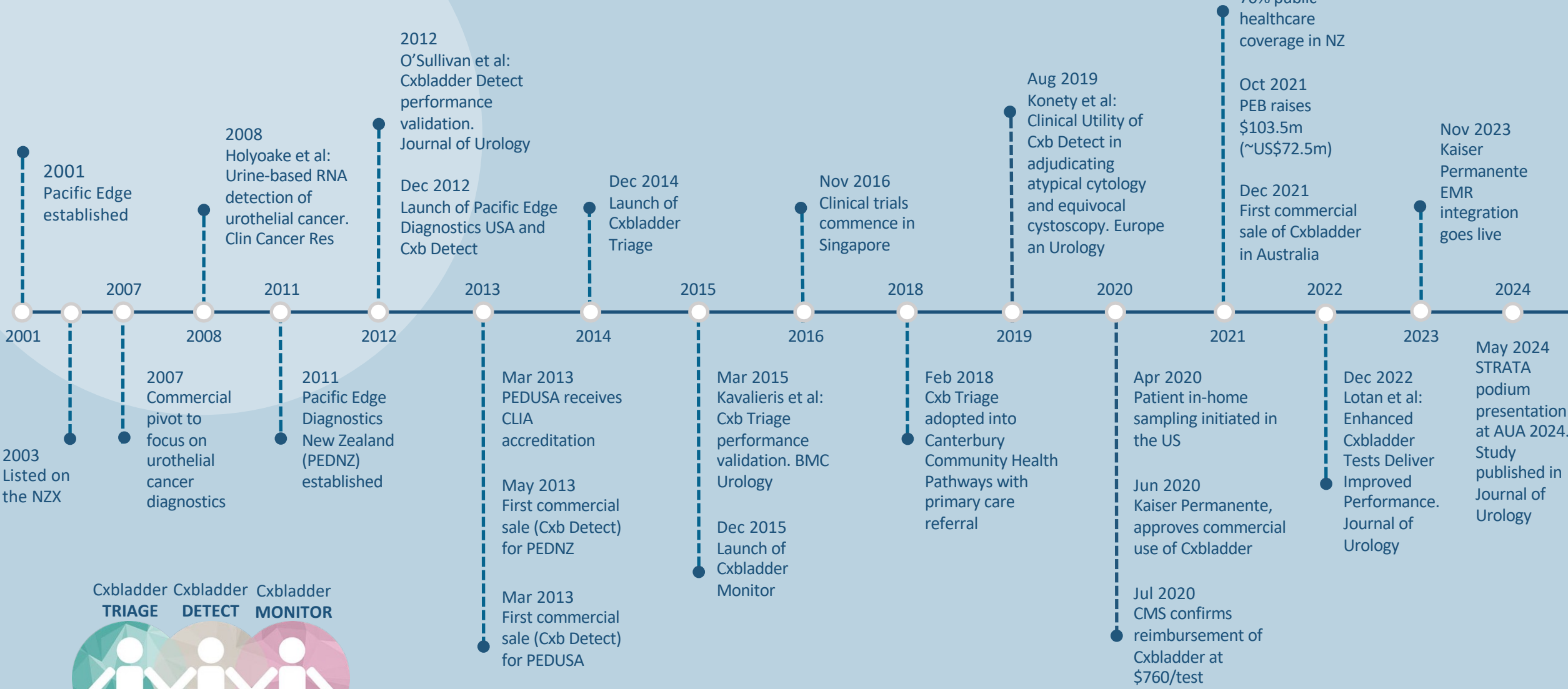
CATALYSTS:

- Possible re-coverage determination from Novitas on new proposed LCD after following appropriate procedure
- Cxbladder Detect⁺ pricing (via Crosswalk) on 25 June 2024 CMS Meeting
- New clinical evidence for driving local coverage certainty
- Cxbladder Detect⁺ commercial launch preparations
- Litigation success (in non-coverage scenario)



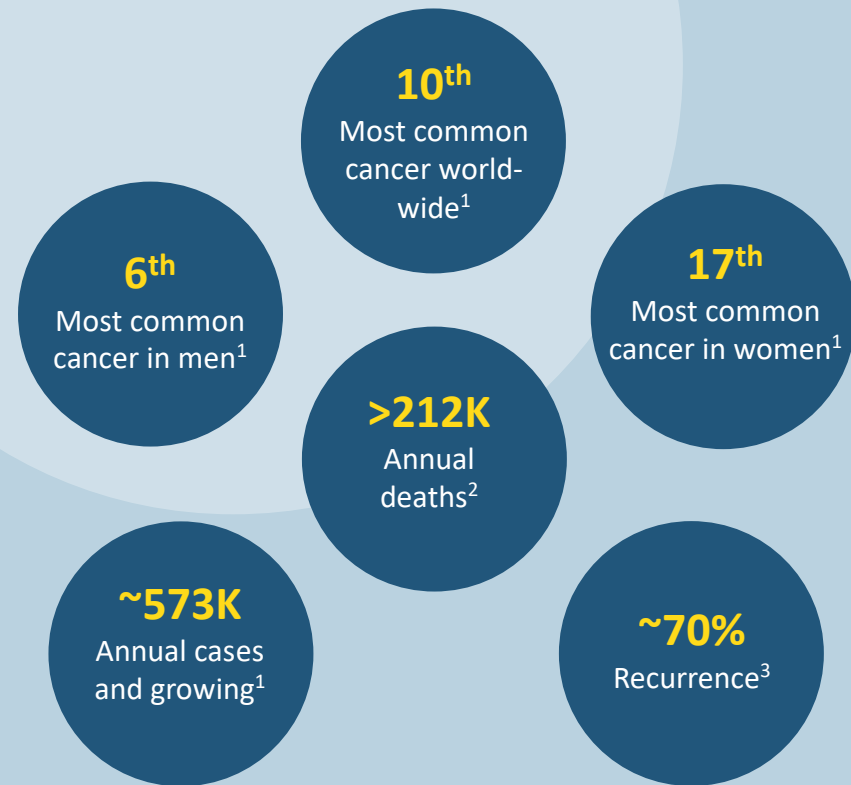
APPENDIX

PACIFIC EDGE: RESEARCH, INNOVATION, COMMERCIALIZATION



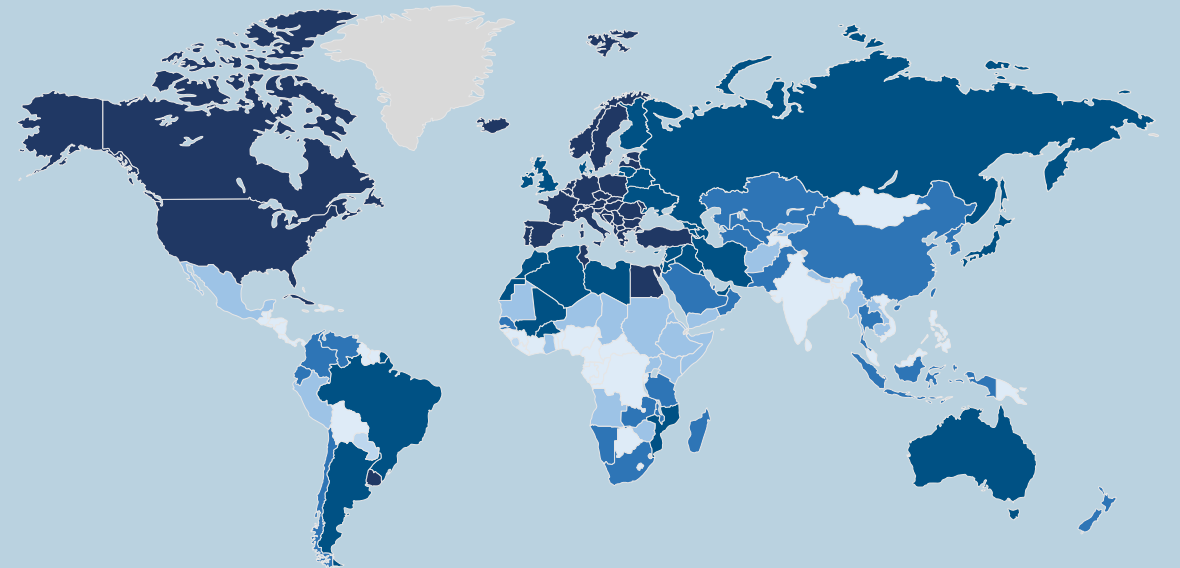
BLADDER CANCER

A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE



INCIDENCE PER 100,000 OF THE POPULATION⁴

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



1. [World Cancer Research Fund](#) Annual case figure is 2020.

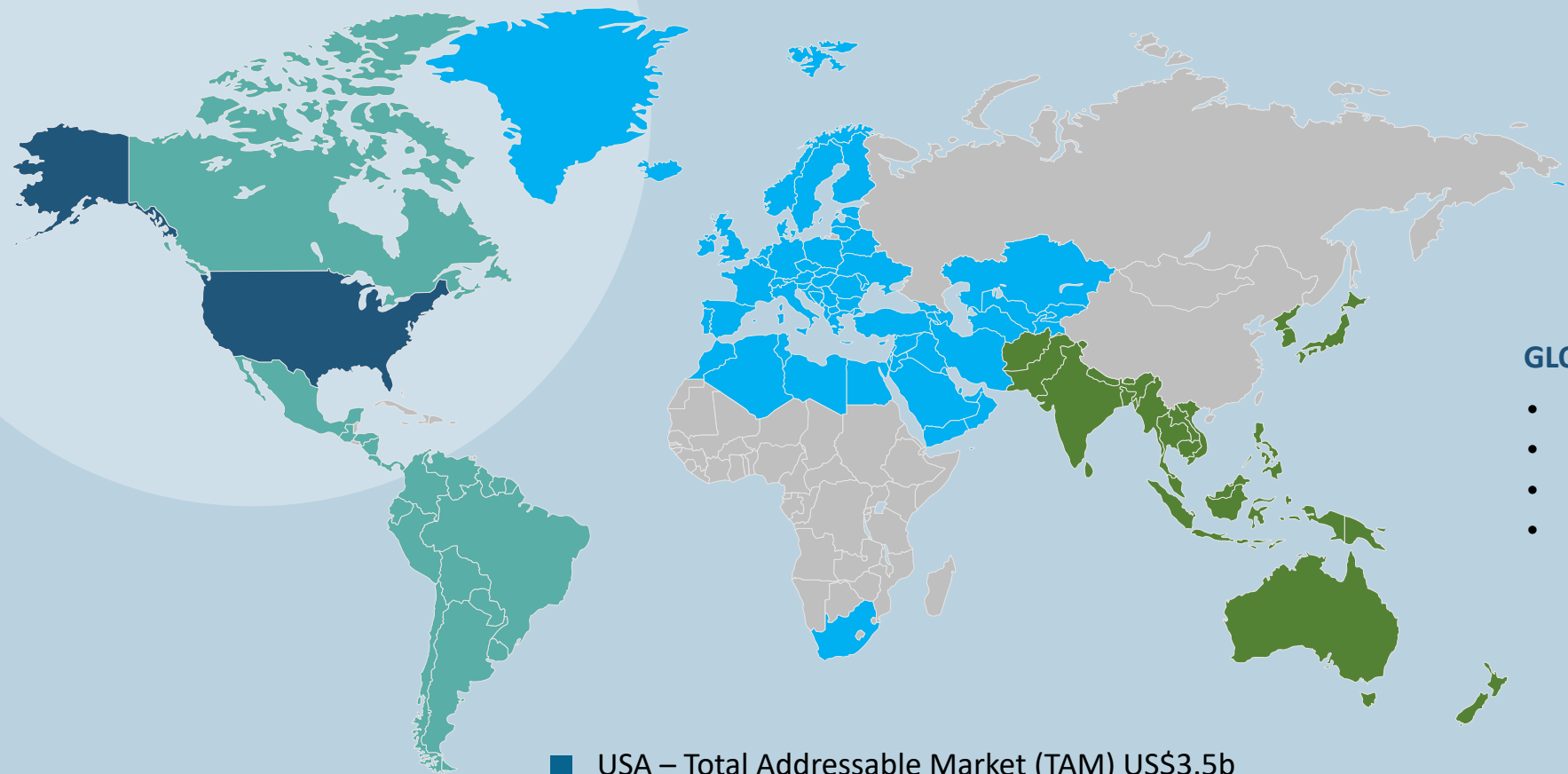
2. [American Society of Clinical Oncology](#) Annual death figure is 2020.

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. [International Agency for Research on Cancer](#)

CXBLADDER IS A GLOBAL OPPORTUNITY

US\$7.6b
Total
Addressable
Market¹



GLOBAL COMMERCIALIZATION

- US is the focus of our growth efforts
- New Zealand is a mature market
- APAC in business development
- Distribution considered in other markets on a case-by-case basis

- USA – Total Addressable Market (TAM) US\$3.5b
- Americas (non-US) – TAM US\$0.5b
- EMEA (w/o most of Africa) – TAM US\$1.4b
- APAC (w/o China) – TAM US\$2.2b

1. Pacific Edge estimates



SUMMARY OF CLINICAL EVIDENCE

		Study	Pop. Type	Sensitivity (Sn)	NPV	Specificity (Sp)	Comment
Detect+	AV	Lotan et al., 2022	MH + GH*	97%	99.7%	90%	Pooled data from US and Singapore cohorts (n=804)
	CV	DRIVE (unpublished) (1)	MH + GH*				Study in progress
		AUSSIE (unpublished) (4)	MH + GH*				Study to start this year
		microDRIVE (unpublished) (5)	MH*				Study to start this year
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)
	CU	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)
		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		
Detect⁺	1	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Detect ⁺).
	2	Observational study to validate performance characteristics of Cxb Detect ⁺ 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 Detect ⁺).
	5	Observational study to validate performance characteristics of Cxb Detect ⁺ 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

References	
Detect⁺	Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.
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.
	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.
	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.
	Konety et al., (2019). Evaluation of cxbladder and adjudication of atypical cytology and equivocal cystoscopy. European urology, 76(2), 238-243.
	Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.
	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. (In Press) The Journal of Urology Vol 212 1-8 Jul 2024.
Detect	Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.
	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.
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.
	Konety et al., (2019). Evaluation of cxbladder and adjudication of atypical cytology and equivocal cystoscopy. European urology, 76(2), 238-243.
	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.
	Lotan et al., (2017). Clinical comparison of non-invasive urine tests for ruling out recurrent urothelial carcinoma. Urologic Oncology: Seminars and Original Investigations, 35 (8), 531-539.
	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.

GLOSSARY

- **Sensitivity (S_n)** - the frequency with which a test correctly identifies patients with a disease.
- **Specificity (S_p)** - the frequency with which a test correctly identifies patients without a disease.
- **Negative Predictive Value (NPV)** - the percentage of negative tests being true negatives (by standard of care).
- **Positive Predictive Value (PPV)** - the percentage of positive tests being true positives (by standard of care).
- **Rule-out Rate (ROR)** - the percentage of tests that return a negative result.
- **Evidence definitions:**
 - **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 in the hands of a physician can usefully change patient management within the context of care for the defined population and indication.

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

INDEPENDENT DIRECTORS

SARAH PARK
ANATOLE MASFEN
BRYAN WILLIAMS
ANNA STOVE
MARK GREEN
TONY BARCLAY

SENIOR LEADERSHIP TEAM

GRANT GIBSON
Chief Financial Officer
GLEN COSTIN
President Asia Pacific
ANDY MCINTOSH
Chief Digital Officer

DAVID LEVISON
President Pacific Edge Diagnostics USA
DARELL MORGAN
Chief Operating Officer
PROFESSOR PARRY GUILFORD
Chief Scientific Officer

DR TAMER ABOUSHWAREB
Chief Medical Officer
DR JUSTIN HARVEY
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