Pacific Edge
1H 24 FINANCIAL RESULTS

INVESTOR PRESENTATION

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23 November 2023

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. 1H 24 HIGHLIGHTS
2. STRATEGY DELIVERY
3. FINANCIAL PERFORMANCE
4. OUTLOOK
5. QUESTIONS

Cx bladder®

PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

1H 24 HIGHLIGHTS: BUILDING TEST VOLUMES IN THE US DESPITE UNCERTAINTY

▲ 22%[1]
GLOBAL TESTING VOLUMES (TLT[2]) on 1H 23

Global TLT of 18,229
US TLT increase 25% on 1H 23 to 15,962 tests

▲ 24%
COMMERCIAL TEST VOLUMES on 1H 23

Commercial Tests of 15,401
US Commercial Tests rise 28% on 1H 23 to 13,550 tests

▲ 50%
GROWTH IN OPERATING REVENUE on 1H 23

Operating revenue $13.1M
Total revenue of $16.6M up 22% on 1H 23

($15.1M)
NET LOSS AFTER TAX

Increase from ($10.2M) on 1H 23 lifted by investments for future growth and Medicare objections

$62.2M
CASH, CASH EQUIVALENTS[3]

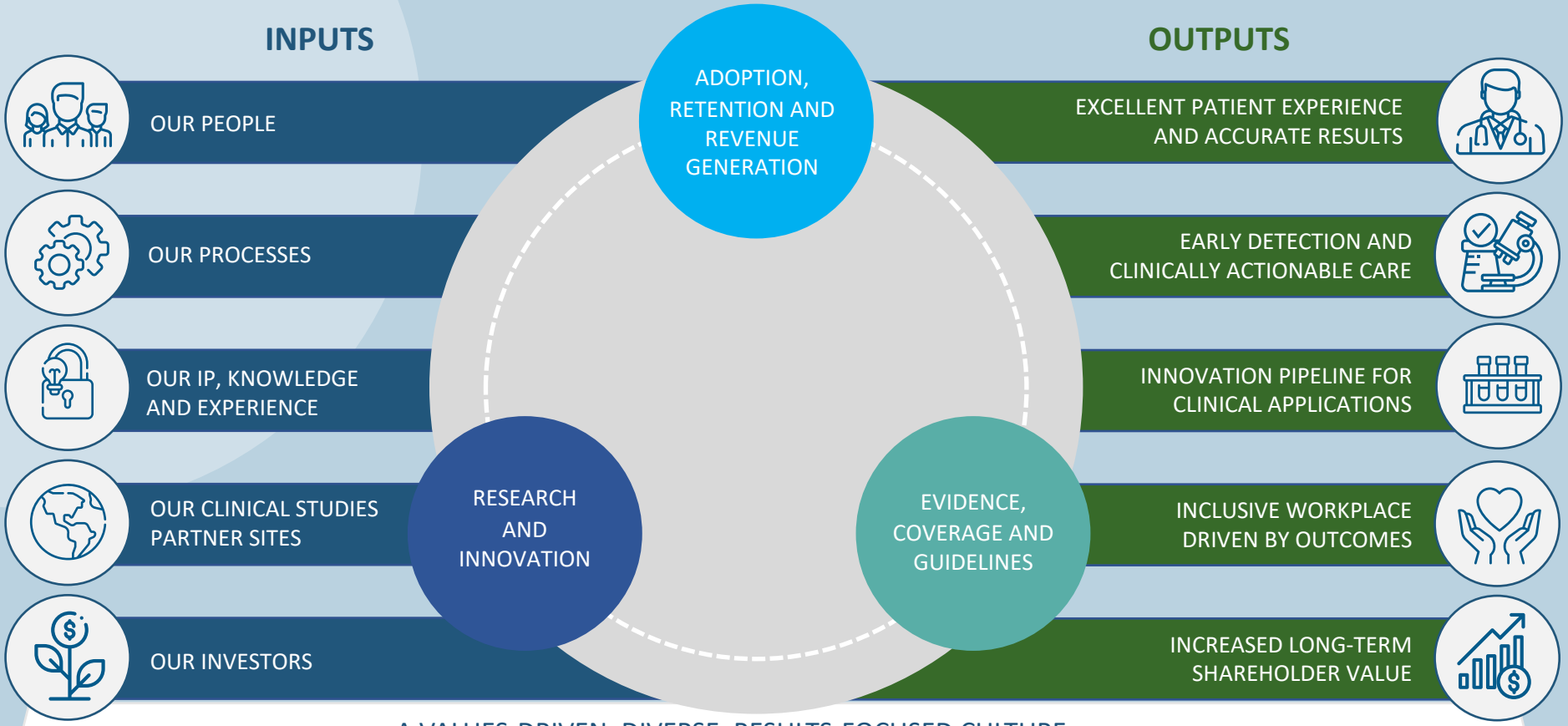
Strong Balance Sheet
$15.6M reduction in cash & cash equivalents[3] on Mar 23

- Volume growth tempered by reorganisation in 2Q 24 in response to Novitas' draft LCD & risk to Medicare coverage
- Immediate focus on profitable sales territories, alternative revenue streams and cash preservation over top line revenue growth alone
- Longer-term focus on clinical evidence development for guidelines inclusion and coverage certainty
- Sales messaging emphasis on clinical value proposition to support EPR/PAP[4], health economics, strategic accounts

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, short-term deposits and term deposits
4. EPR/PAP is the Enhanced Patient Responsibility / Patient Assistance Program

Cxbladder® | PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

VALUE CREATION THROUGH THREE PILLARS



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DEVELOPING A TRACK RECORD OF GROWTH

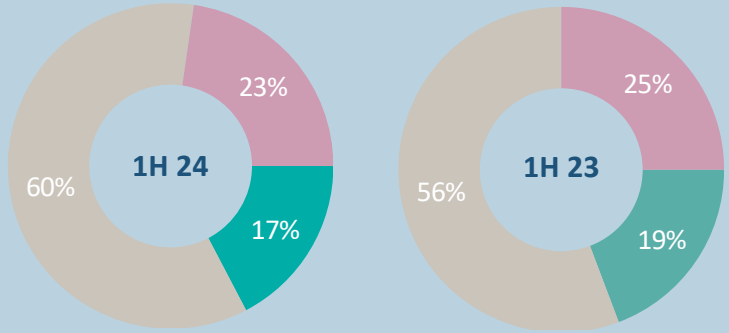
ABILITY TO EXECUTE DESPITE CHALLENGING MARKET HEADWINDS

ADOPTION, RETENTION AND REVENUE GENERATION

1H 24 TOTAL LAB THROUGHPUT (TLT*)

- Global TLT increased 22% to 18,229 tests
- Global Commercial test volumes increased 24% to 15,401 tests
- Global TLT is driven by US growth in the US (predominantly Detect)
- Hematuria evaluation (Triage & Detect) is the **largest market** opportunity, ~3x the size of bladder cancer surveillance (Monitor)

TEST VOLUMES BY TYPE (TLT*)

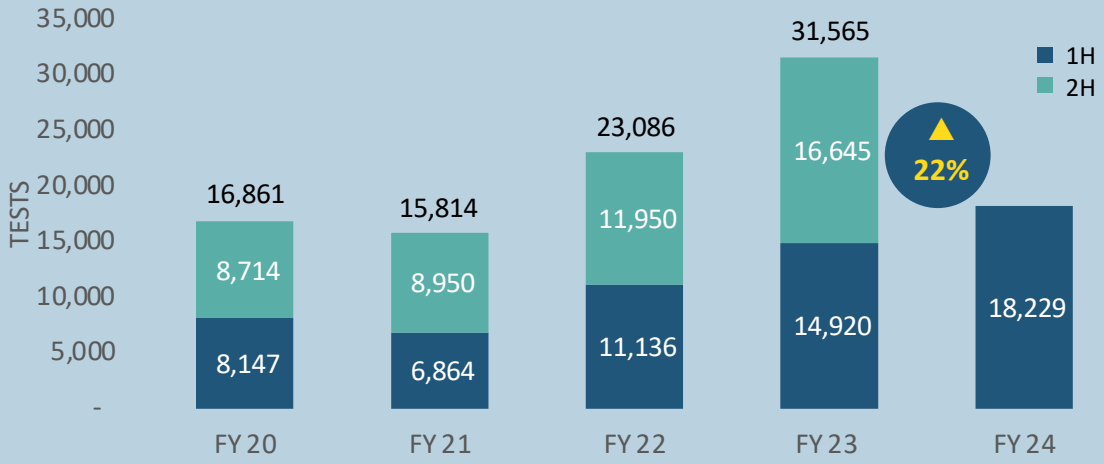


Cxbladder TRIAGE

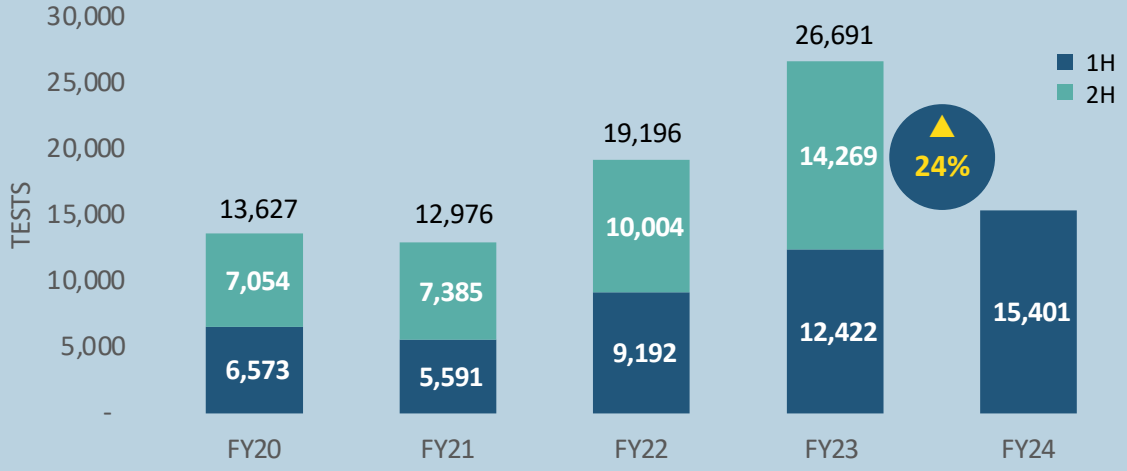
Cxbladder DETECT

Cxbladder MONITOR

GLOBAL TOTAL TEST VOLUMES (TLT*)



GLOBAL COMMERCIAL TEST VOLUMES (TLT*)



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

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MEDICARE: 'GENETIC TESTING FOR ONCOLOGY' (DL 39365) RESPONSE

PACIFIC EDGE AND INDUSTRY DELIVERED A POINT-BY-POINT REBUTTAL

ADOPTION, RETENTION AND REVENUE GENERATION

INDUSTRY AND UROLOGY KEY OPINION LEADERS UNITED TO OVERTURN DL39365

- Pacific Edge engaged with oncology diagnostics industry & urology community during the 'Review and Comment' period to assemble the strongest possible support
- Our representations to Novitas were strongly supported by:
  - The leading professional societies in urology - AUA, LUGPA and AACU[1]
  - Industry partners, the Coalition for 21st Century Medicine (C21), the American Clinical Laboratory Association (ACLA) and by many other key urologic opinion leaders
  - More than a dozen Urology Key Opinion Leaders (KOLs) wrote a response to Novitas that will be published in the Journal of Bladder Cancer[2] rallying against Novitas' approach
- Awaiting finalization before considering other legal/regulatory options

Medicare

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 24 Medicare and Medicare Advantage delivered ~7,850 commercial tests (~58% of US commercial tests) and ~$9.9 m NZD in total operating revenue (~75%)

NOVITAS SOLUTIONS

REPUBLISHED DRAFT LCD
(27 July 2023)[3]

REVIEW AND COMMENT PERIOD
(Closed 9 September 2023) [2]

DECISION
Novitas must withdraw or finalize the LCD by 26 July 2024[3]
LCD becomes effective (assuming no further protest) a minimum of 45 days after finalization

1. AUA: American Urological Association, LUGPA: Large Urology Group Practice Association, AACU: American Association of Clinical Urologists
2. A copy of the accept manuscript is available at https://www.pacificedgedx.com/assets/Investor-Files/Lotan-et-al-Commentary-on-Novitas-LCD-DL39365.pdf
3. All dates in this graphic refer to US Dates

BUILDING RESILIENCE TO WEATHER A MEDICARE NON-COVERAGE DECISION

PRESERVING CAPITAL, DIVERSIFYING REVENUE SOURCES, DRIVING PROFITABLE SALES OPERATIONS

ADOPTION, RETENTION AND REVENUE GENERATION

COMMITTED TO MAINTAINING A STRONG BALANCE SHEET

- Pacific Edge expects to manage its cash reserves in the event of an adverse Medicare coverage decision until we regain coverage, a process that could take up to 4 years with several earlier opportunities for re-coverage with new evidence

PEDUSA STRATEGIC RESPONSE

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

APAC & HEAD OFFICE STRATEGIC RESPONSE

- R&D investment weighted to Detect+ and Monitor+ launches
- Development of growth markets in Australia and Asia
- Distribution agreements Transviet (Vietnam), Hi-Precision (Philippines) and WellSpring (Malaysia)

EXTENDING OUR REACH THROUGH DISTRIBUTION AGREEMENTS

A FLEXIBLE AND GOAL FOCUSED SALES FORCE

REORGANISATION DISRUPTS SALES IN Q2 24

ADOPTION, RETENTION AND REVENUE GENERATION

WE HAVE REVIEWED OUR APPROACH TO THE US MARKET

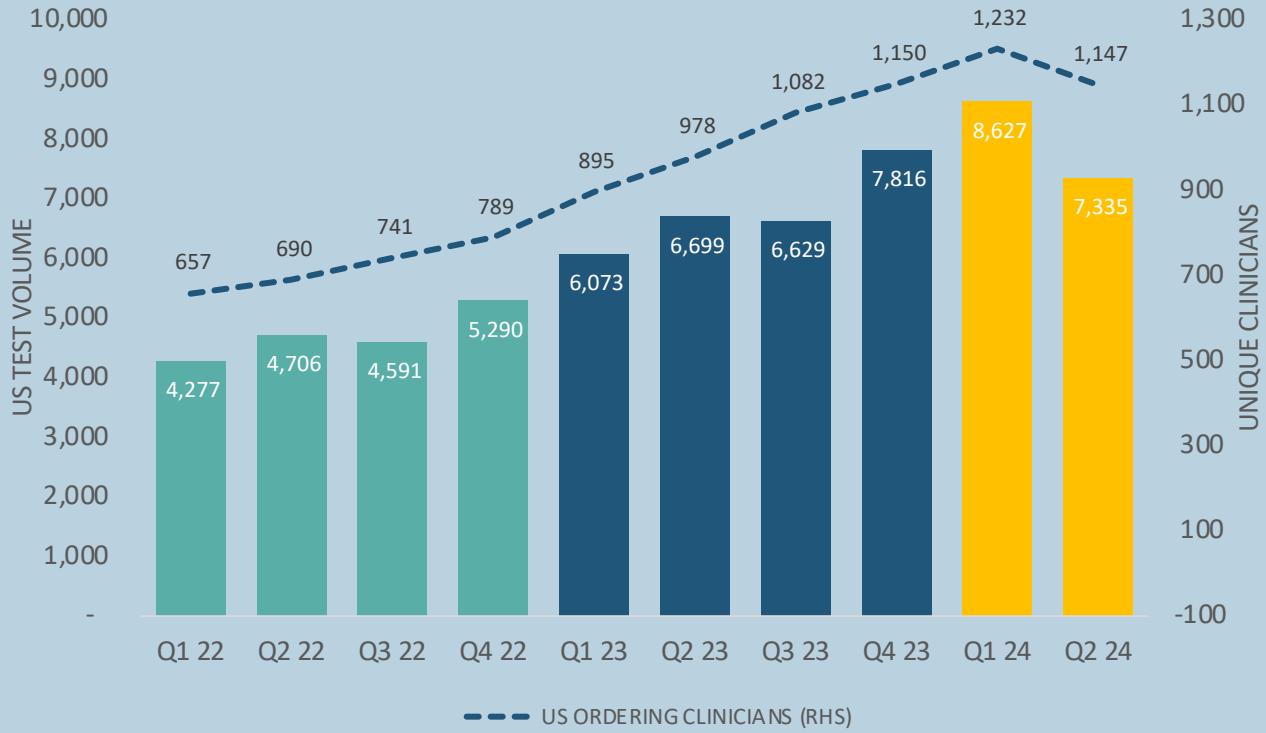
- Sales territories reduced from 29 to 17
- Sales initiatives focused on clinical value, economic value and patient value
- Increased expectations of throughput per sales force headcount
- Accelerate our clinical evidence generation program where possible with a focus on monitoring

ENHANCED PATIENT RESPONSIBILITY AND SALES FORCE EFFICIENCY

- Patients with non-contracted private insurance (i.e. non-Kaiser) to sign patient responsibility notice
  - Provides Pacific Edge with increased means to collect payment from the patient, as the patient acknowledges liability
- Patient Assist Program will offer customers discounts based on income benchmarked against US federal policy guidelines

US TEST VOLUMES (TLT*) AND ORDERING CLINICIANS

Commercial tests represent 84% of TLT in 1H 24



Medicare

KAISER PERMANENTE®

*1H 24 Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing

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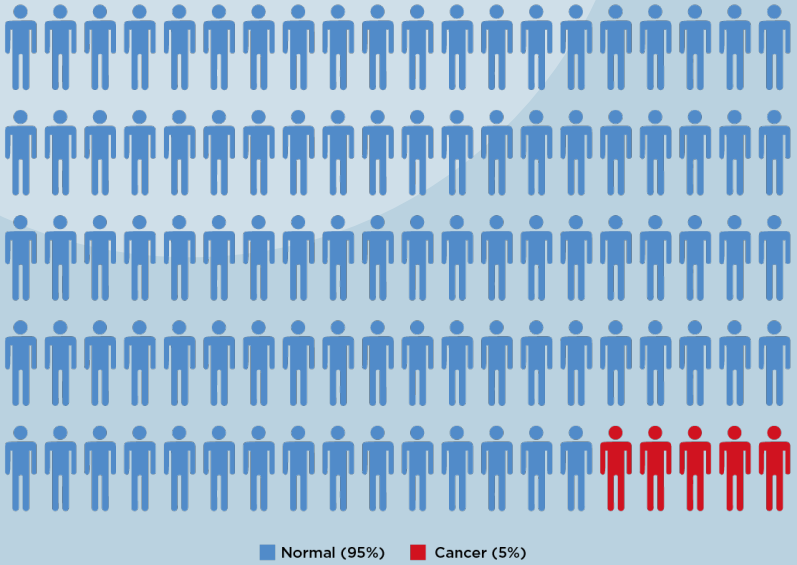
SELLING CXBLADDER'S CLINICAL, ECONOMIC AND PATIENT VALUE

ADOPTION, RETENTION AND REVENUE GENERATION

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 microhematuria[1]

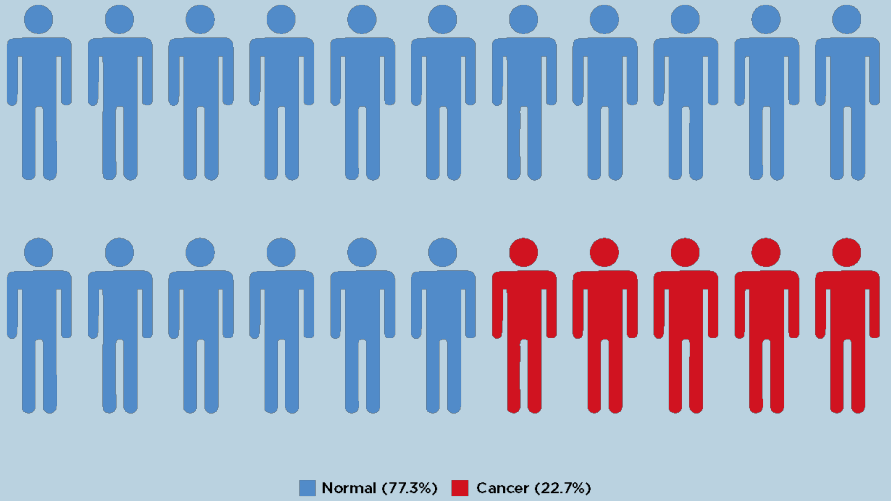
CURRENT PRACTICE (AUA GUIDELINES)

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



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



Pacific Edge modelling[1] 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 (nih.gov)

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DRIVING GROWTH IN ASIA PACIFIC AND CONSOLIDATING NEW ZEALAND*

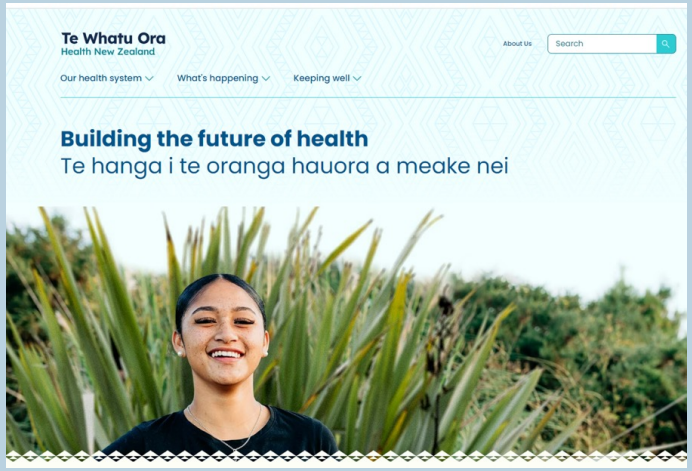
ADOPTION, RETENTION AND REVENUE GENERATION

NEW ZEALAND IS A MATURE MARKET

- Cxbladder is covered in 15 of the 20 new Te Whatu Ora - Health New Zealand health regions, representing >75% of the population
- Te Whatu Ora Nelson/Marlborough has advised Pacific Edge that it is introducing Cxbladder Triage in primary care
- We are seeking a national contract with Te Whatu Ora working through NZ KOLs

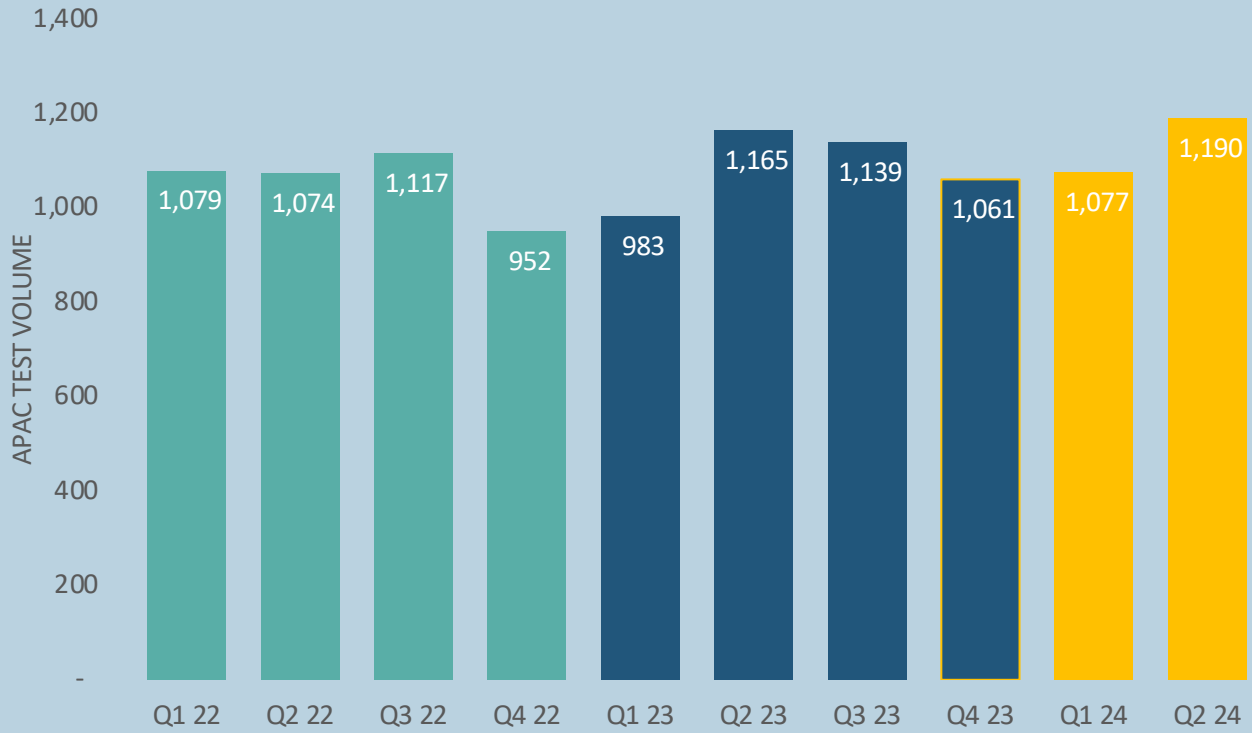
AUSTRALIA & ASIA PACIFIC

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



APAC TEST VOLUMES*

Commercial tests represent 84% of TLT in 1H 24



*1H 24 Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing, APAC generating ~12% of test volume

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STRENGTHENING OUR FOUNDATIONS: PERFORMANCE EXCELLENCE

ADOPTION, RETENTION AND REVENUE GENERATION

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

CXBLADDER NOW LIVE IN KAISER PERMANENTE'S EMR

Achievement expected to drive volume in 2H 24

- EMR integration went live 14 November 2023 (US Time) that streamlines sample collection, test ordering and resulting
- Cxbladder Triage and Monitor introduced into Southern California Permanente Medical Group (Kaiser SoCal); 15 sites now eligible to order Cxbladder electronically
- Large opportunity to reduce unnecessary cystoscopies for the evaluation of bladder cancer in hematuria patients and NMIBC patients
- Kaiser SoCal represents ~37% of the >12.6 million members covered by the Kaiser Health Plan nationally

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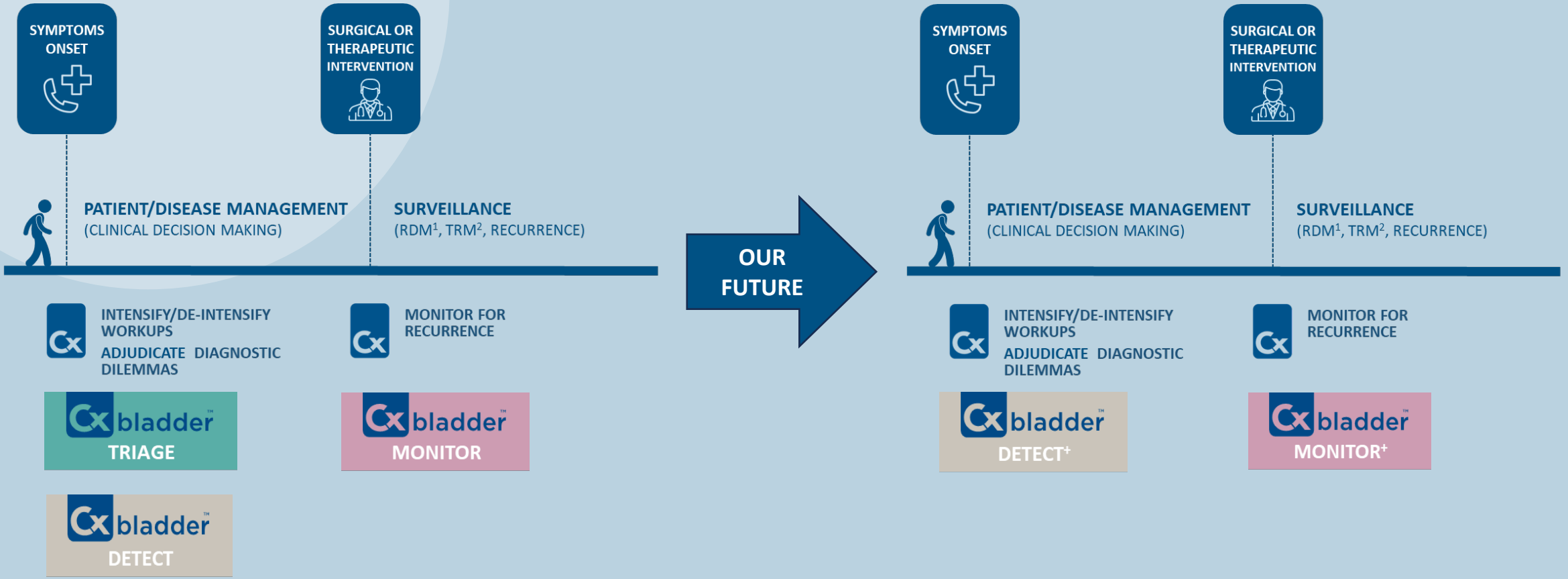
SIMPLIFYING THE CXBLADDER PROPOSITION – DETECT+ AND MONITOR+

LEVERAGING EVIDENCE SHOWING THE ADDITION OF DNA BIOMARKERS ENHANCES TEST PERFORMANCE[3]

EVIDENCE COVERAGE AND GUIDELINES



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

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CLINICAL EVIDENCE UNDERPINS COVERAGE AND GUIDELINES DECISIONS

EVIDENCE COVERAGE AND GUIDELINES

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
- **Review period**: with new evidence, last updated in 2020

NCCN National Comprehensive Cancer Network®

www.nccn.org

- US-based not-for-profit alliance of 32 leading US cancer centres
- **Relevant standards of care:** High-risk non-muscle-invasive bladder cancer
- **Review period:** annual submission every August

eau 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 2023

PACIFIC EDGE'S CLINICAL STUDY PROGRAM

STRATA
Safe **T**esting of **Ri**sk for **A**symptoma**T**ic microhematuri**A**

DRIVE
Detection and **RI**sk stratification in **VE**terans presenting with hematuria

AUSSIE
Australian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia

microDRIVE
Detection and **RI**sk Stratification in **VE**terans Presenting with **Micro**hematuria

POOLED ANALYSIS
Pooled-analysis of Detect⁺ from multiple studies

LOBSTER
LOngitudinal **B**ladder Cancer **S**tudy for **T**umor R**E**cur**R**ence

CREDIBLE
Cystoscopic **RED**uction **I**n **BL**adder **E**valu-ations for micro-hematuria

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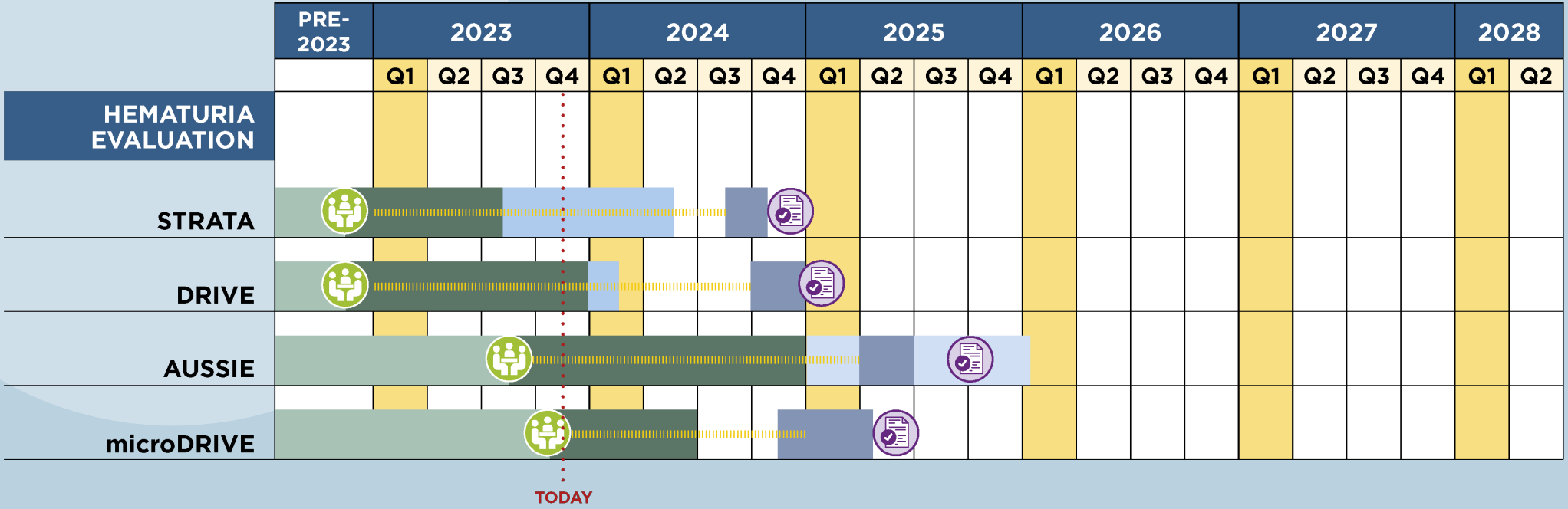
FIVE YEAR CXBLADDER CLINICAL STUDY ROAD MAP

PACIFIC EDGE WILL SEEK GUIDELINE INCLUSION AS NEW EVIDENCE PRODUCED

EVIDENCE COVERAGE AND GUIDELINES



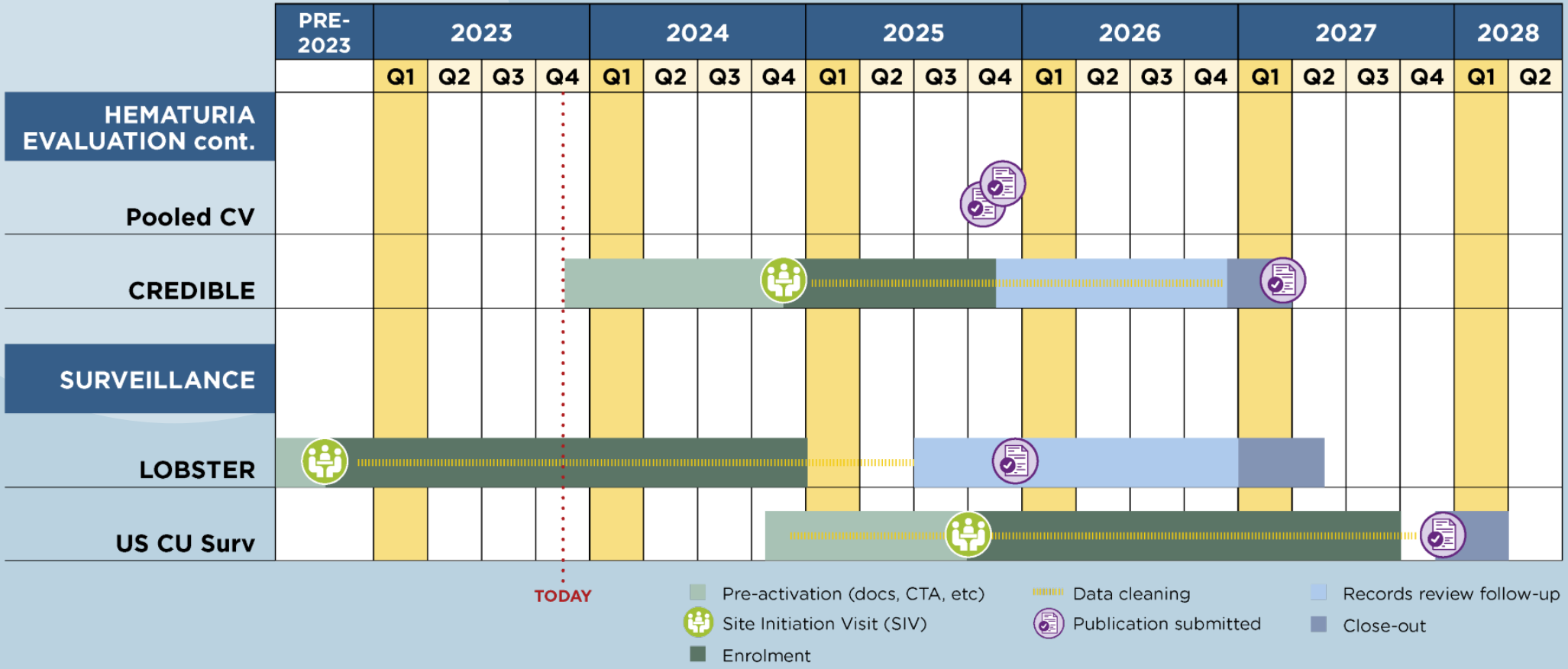
Pre-activation (docs, CTA, etc)
Site Initiation Visit (SIV)
Enrolment
Data cleaning
Publication submitted
Records review follow-up
Close-out

Note: AUSSIE - Interim analysis for primary objective occurs Q2-2025 and follow-up for secondary objective will continue to Q4-2025

FIVE YEAR CXBLADDER CLINICAL STUDY ROAD MAP (continued)…

STUDIES FOR DETECT+ AND MONITOR+

EVIDENCE COVERAGE AND GUIDELINES



***US CU-Surv** – proposed study that will focus on clinical utility of Monitor+ in surveillance NMIBC patients

AMPLIFYING OUR EVIDENCE WITH UROLOGY OPINION LEADERS

EVIDENCE COVERAGE AND GUIDELINES

CLINICAL DOSSIER DEVELOPMENT

- Contains all published Cxbladder data; externally reviewed
- Used to engage with guideline committees, private payors, government payers, value-based clinician groups, ex-US distributors, etc
- Annual National Comprehensive Cancer Network (NCCN) submission of new evidence

American Urological Association

NCCN National Comprehensive Cancer Network®

eau European Association of Urology

PODIUMS, PRESENTATIONS, POSTERS AND PUBLICATIONS

- Increase “share of voice” by presenting data on Cxbladder utility in multiple forums (AUA, SUO, ASCO GU[1]), clinicians, academic institutions
- Publications – support for data generated and published by our users and KOLs
- Speakers Bureau – trained, external KOLs and senior Medical Science Liaison team members

VIDEO VIEWS
4102

PUBLISHED
12/2/22

BUILDING KOL RELATIONSHIPS

- Academics, clinical leads in private practice, guidelines committees and other influential clinicians
- Educational events, journal clubs, and resident training for large institutions

1. AUA: American Urological Society, SUO: Society for Urologic Oncology, ASCO GU: American Society of Clinical Oncology Genitourinary

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WE ARE PREPARED SHOULD FDA REGULATE LAB DEVELOPED TESTS

EVIDENCE COVERAGE AND GUIDELINES

FDA REGULATION FACES HURDLES

- FDA has proposed LDTs like Cxbladder that are performed within a “single lab” as a CLIA/LDT are within its remit to regulate under the Medical Device Amendments of 1976
  - 60-day comment period is expected to close on 4 December 2023 (US time), but delays are widely anticipated as a result of legal action from industry groups
  - Proposed four-year phase in period, with a registry of all tests as the first step, with 510k/PMA[1] in the later years offers time to adapt
  - Pacific Edge supports and welcomes FDA regulation through an act of Congress, e.g. VALID[2] Act (failed to pass Congress in 2022)
  - Pacific Edge does not support regulation under the Medical Device Amendments of 1976
- Pacific Edge is prepared
  - While some requirements will be specific to the FDA, most are captured by other regulatory bodies (CLIA, CAP & NYS[3]) with which we already comply
  - Achieving FDA-approved status may make it more difficult for competitors to develop parity with Cxbladder’s level of evidence
  - Pacific Edge actively resources its R&D, clinical development, digital development and clinical operations to maintain compliance with all regulatory requirements

1. PMA is pre-market approval. 510k is a similar, but slightly shorter process in which the process follows a previously approved “predicate device”
2. VALID: Verifying Accurate Leading-edge IVCT Development Act
3. CLIA: Clinical Laboratory Improvement Amendments, CAP: College of American Pathologists, NYS: New York State

Cxbladder® PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

RESEARCH & INNOVATION – FOCUSED ON DNA ENHANCED PRODUCTS

RESEARCH & INNOVATION

READYING FOR THE LAUNCH OF NEW DETECT+ AND MONITOR+

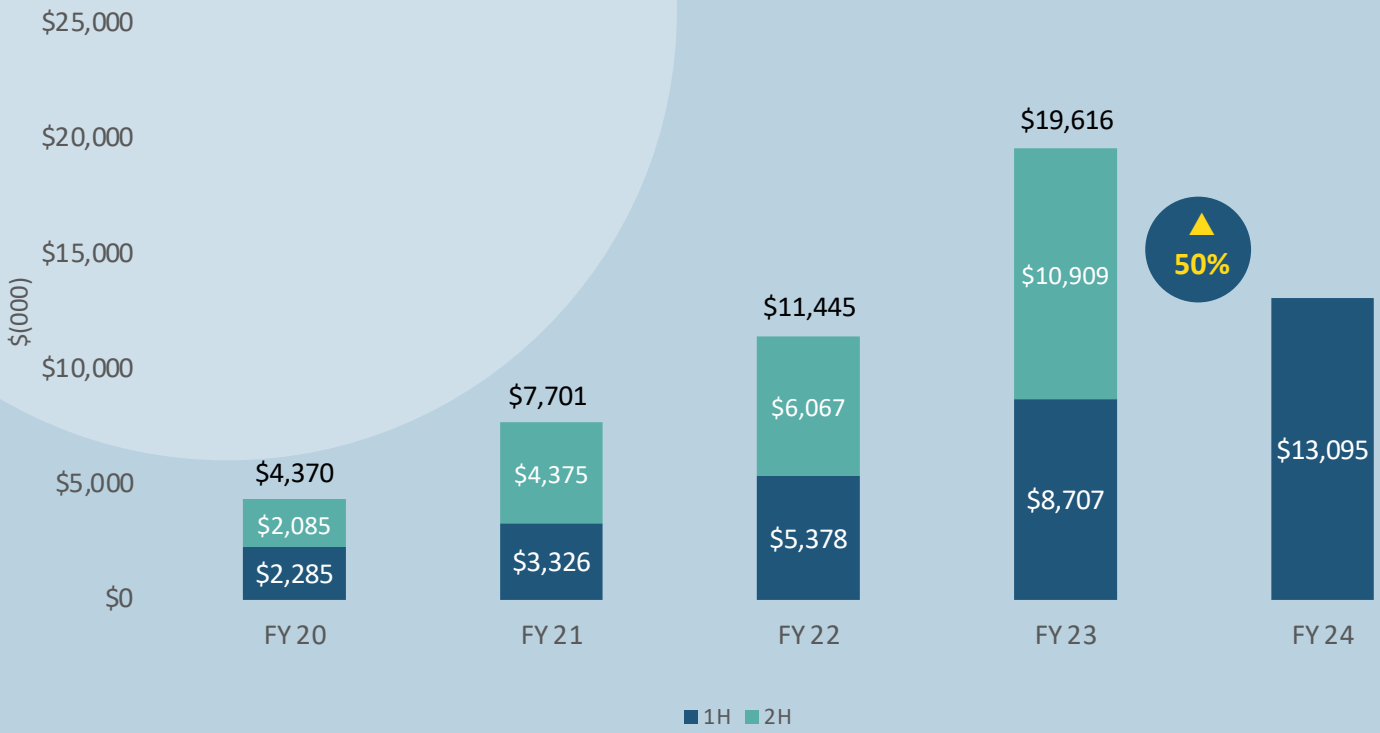
- Ensure R&D, Digital and Lab Operations focus on the launch of Detect+ and Monitor+
- Simplifying Cxbladder to reduce technician time, lower cost of goods, lower turnaround time, increase throughput and increase automation
- Develop sufficient documentation for in-vitro diagnostic (IVD) regulation associated with product development and analytical validation 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

1H 24 FINANCIAL PERFORMANCE

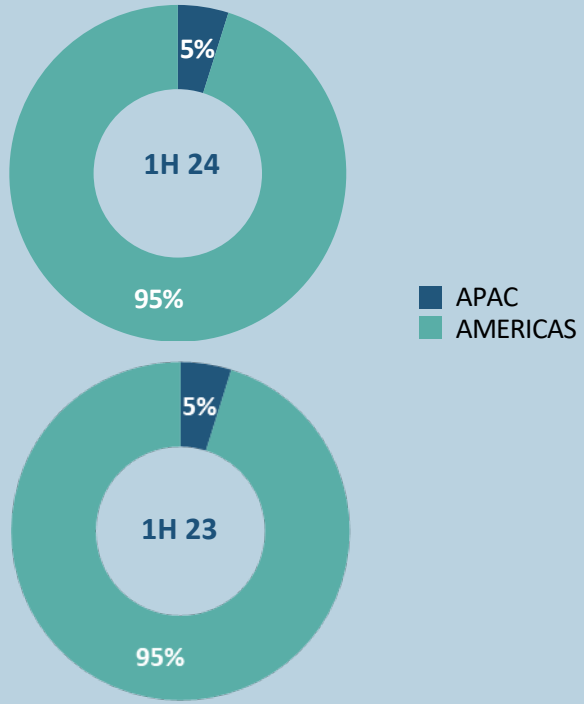
US COMMERCIAL TEST VOLUME GROWTH DRIVING REVENUE

RATE OF REVENUE GROWTH IN 2Q 24 EASES AMID SALE FORCE REORGANIZATION

PACIFIC EDGE OPERATING REVENUE



REGIONAL REVENUE CONTRIBUTION



REVENUE GROWS WITH INCREASED ADOPTION OF CXBLADDER

LOSSES REFLECT INVESTMENTS FOR TOP LINE REVENUE GROWTH IN FY23

Half year to 30 September	1H 24 $(000)	2H 23 $(000)	1H 23 $(000)	1H 24 vs. 1H 23 △ $(000)	1H 24 vs. 1H 23 △%
Operating revenue	$13,095	$10,909	$8,707	$4,388	50%
Total revenue	$16,580	$12,531	$13,593	$2,987	22%
Operating expenses	$31,832	$28,925	$24,164	$7,668	32%
Total comprehensive loss	**-$15,054**	**-$16,873**	**-$10,191**	-$4,863	48%
Cash receipts from customers	$13,576	$11,152	$7,316	$6,260	86%
Net operating cash outflow	$14,992	$11,603	$13,972	$1,020	7%
Net cash, cash equivalents and short-term deposits	**$62,174**	**$77,791**	**$93,455**	-$31,281	-33%

- Operating revenue rises with increased volumes and an increase in average receipts
- Total revenue includes FX gains of $0.7m 1H 24, lower than the $3.0m in 1H 23
- Interest revenue of $1.9m in 1H 24 up on the $1.6m in 2H 23 and $1.1m in 1H 23
- Increase in operating expenses driven by increased headcount as investments made for revenue growth in FY 23, and increased expenses relating to volume growth
- Reorganisation with reduction in sales territories late 1H 24 will flow through in 2H 24
- Balance sheet remains strong

OPERATING EXPENSES RISE REFLECTING GROWTH CONFIGURATION

2Q 24 REFOCUS ON PROFITABLE SALES, NEW REVENUE AND CASH PRESERVATION TO MODERATE EXPENSES

FINANCIAL PERIOD (March year-end)	**1H 24** **$(000)**	**2H 23** **$(000)**	**1H 23** **$(000)**	**1H 24 vs. 1H 23** **△$(000)**	**1H 24 vs. 1H 23** **△%**
Laboratory operations	$6,141	$4,882	$4,467	-$1,674	37%
Research	$5,487	$4,774	$3,710	-$1,777	48%
Sales and marketing	$14,339	$13,748	$11,375	-$2,964	26%
General and administration	$5,865	$5,521	$4,612	-$1,253	27%
Total operating expenses	**$31,832**	**$28,925**	**$24,164**	**-$7,668**	**32%**

- Lab operating expenses rise with increased test volumes and higher freight costs
- Research expenses reflect increased clinical study expenditure with commencement of microDRIVE
- Sales and marketing expenses reflect the impact of prior appointments focused on growth. Sales expenses to moderate in 2H 24 following reorganisation
- G&A expenditure in 1H 24 includes elevated legal fees related to the objections of the proposed Medicare loss of coverage

ESG: PACIFIC EDGE IS FOUNDED ON IMPROVING SOCIAL OUTCOMES

Cxbladder delivers actionable information that can: contribute to clinically meaningful improvements in cancer treatment; improve patient lives; healthcare equity and outcomes; and healthcare payer operating expenditure savings[1,2]

GOVERNANCE

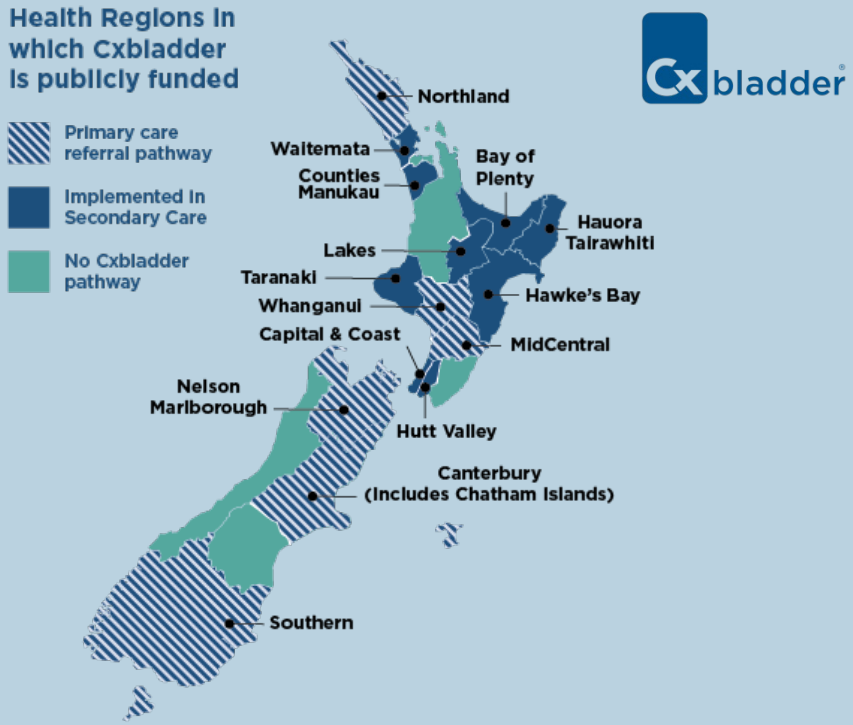
- Integrating oversight of Environmental, Social and Governance (ESG) matters, including carbon reporting, into the Audit and Risk Committee Charter

AOTEAROA NEW ZEALAND CLIMATE STANDARDS

- Measured carbon emissions (Scope 1, 2, 3) in FY 23 and positioned to provide base year data in FY 24
- Working closely with expert advisors to accurately audit and measure our greenhouse gas emissions, as we work towards achieving certification in respect of FY 24
- Developing strategies and policies and evolving our risk management framework to meet our reporting requirements

ATTRACTING AND RETAINING TALENT AT PACIFIC EDGE

- We actively promote diversity, inclusion, engagement and fair remuneration



PROMOTING HEALTH CARE EQUITY

Following the introduction of Cxbladder into primary care in Te Whatu Ora Canterbury, referrals to urologists were safely reduced, urological waiting lists fell by 25%[2]

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.

OUTLOOK: FOCUSED ON FY24 EXECUTION

- Pacific Edge expects the available cash to be sufficient to support the company in the event of an adverse Medicare coverage decision through to regaining coverage - a process that may take up to four years with interim coverage attempts with every piece of new evidence
- We have re-focused the business on clinical development for guidelines inclusion and increased coverage certainty for Detect+ & Monitor+
- Selling focus on clinical value as the driver of higher throughput/headcount and throughput/clinician
- **HEADWINDS:**
  - Possible non-coverage determination from Novitas on a new proposed LCD after following appropriate procedure
  - Possible negative physician or patient response to enhanced patient responsibility for commercially insured patients
- **CATALYSTS:**
  - Possible re-coverage determination from Novitas on new proposed LCD after following appropriate procedure
  - Possible Te Whatu Ora national contract
  - New clinician-generated CU evidence as studies completed
- We have world-leading technology, a strong balance sheet, are effectively navigating headwinds in the US and establishing footholds in new markets

APPENDIX

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

PACIFIC EDGE: RESEARCH, INNOVATION, COMMERCIALIZATION

2001
Pacific Edge established

2003
Listed on the NZX

2007
Commercial pivot to focus on urothelial cancer diagnostics

2008
Holyoake et al: Urine-based RNA detection of urothelial cancer. Clin Cancer Res

2010
Pacific Edge Diagnostics New Zealand (PEDNZ) established

2012
O'Sullivan et al: Cxbladder Detect performance validation. Journal of Urology

Dec 2012
Launch of Pacific Edge Diagnostics USA and Cxb Detect

Mar 2013
PEDUSA receives CLIA accreditation

May 2013
First commercial sale (Cxb Detect) for PEDNZ

Mar 2013
First commercial sale (Cxb Detect) for PEDUSA

Dec 2014
Launch of Cxbladder Triage

Mar 2015
Kavalieris et al: Cxb Triage performance validation. BMC Urology

Dec 2015
Launch of Cxbladder Monitor

Nov 2016
Clinical trials commence in Singapore

Feb 2018
Cxb Triage adopted into Canterbury Community Health Pathways with primary care referral

Aug 2019
Konety et al: Clinical Utility of Cxb Detect in adjudicating atypical cytology and equivocal cystoscopy. European Urology

Apr 2020
Patient in-home sampling initiated in the US

Jun 2020
Kaiser Permanente, approves commercial use of Cxbladder

Jul 2020
CMS confirms reimbursement of Cxbladder at $760/test

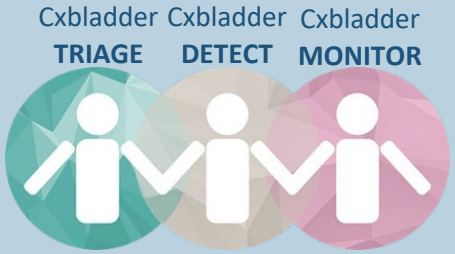
Aug 2021
Cxbladder reaches 70% public healthcare coverage in NZ

Oct 2021
PEB raises $103.5m (~US$72.5m)

Dec 2021
First commercial sale of Cxbladder in Australia

Dec 2022
Lotan et al: Enhanced Cxbladder Tests Deliver Improved Performance. Journal of Urology

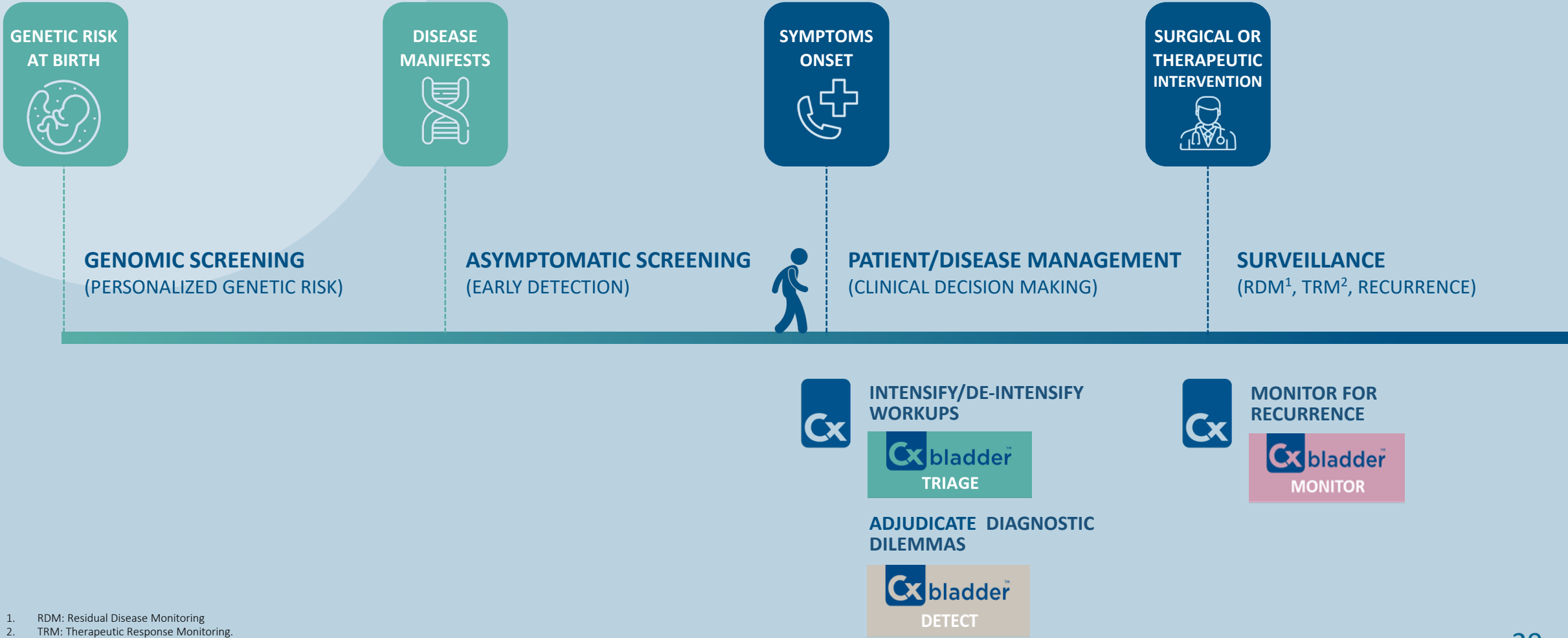
2001 2007 2008 2010 2012 2013 2014 2015 2016 2018 2019 2020 2021 2022



Cxbladder®

PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

MOLECULAR DIAGNOSTICS VALUE CHAIN: PATIENT JOURNEY



1. RDM: Residual Disease Monitoring
2. TRM: Therapeutic Response Monitoring.

BLADDER CANCER

A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE

10th
Most common cancer world-wide[1]

6th
Most common cancer in men[1]

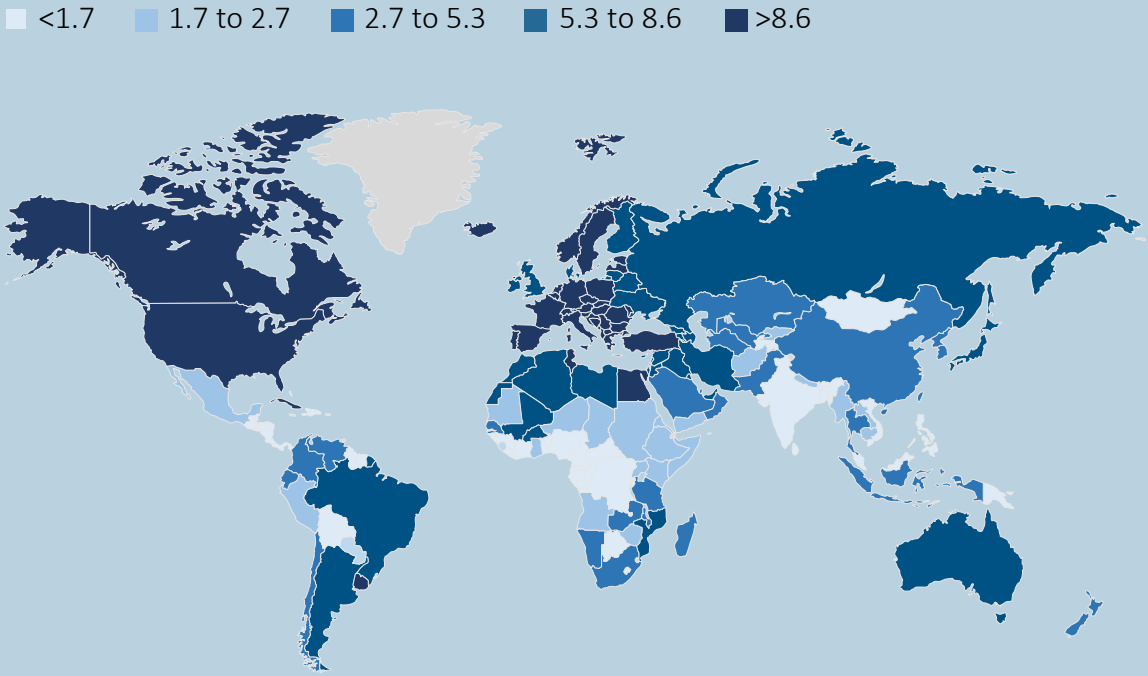
17th
Most common cancer in women[1]

>212K
Annual deaths[2]

~573K
Annual cases and growing[1]

~70%
Recurrence[3]

INCIDENCE PER 100,000 OF THE POPULATION[4]



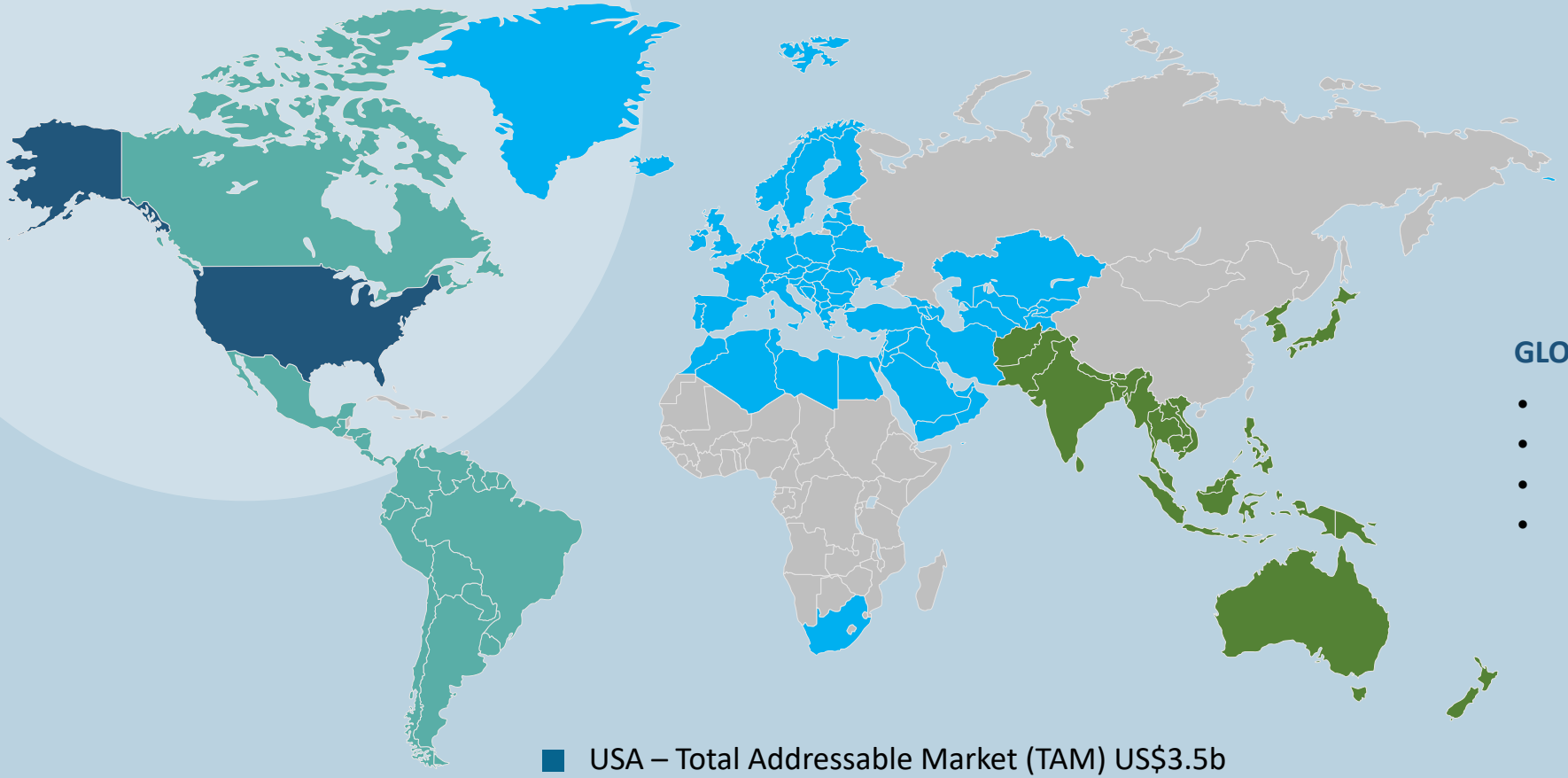
1. World Cancer Research Fund Annual case figure is 2020.
2. American Society of Clinical Oncology Annual death figure is 2020.
3. Average recurrence for low grade cancer
4. International Agency for Research on Cancer

Cxbladder®

PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

CXBLADDER IS A GLOBAL OPPORTUNITY

US$7.6b
Total Addressable Market[1]



- 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

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

1. Pacific Edge estimates

HEMATURIA EVALUATION AND SURVEILLANCE IN THE US MARKET

ADOPTION, RETENTION AND REVENUE GENERATION

90%
Five-year survival rate for NMIBC if detected early[1]

US$191K
Average lifetime cost per patient[2]

US$9.4B
Annual US spend on bladder cancer[3]

VALUE PROPOSITION

Cxbladder **TRIAGE** | Cxbladder **DETECT** | Cxbladder **MONITOR**

Patient care pathway

Primary Care Physician → **Urologist/Specialist**

The US has >55m men and >63m women aged 50+

- **~7m** present with hematuria[4]
- **~3.4m** referred for clinical workup[7]
- **>1.0m** patients receive a cystoscopy[5]
- **~82k** Annual cases of bladder cancer[6]
- **~725k** patients living with bladder cancer ~1.5 Cxb Monitor/yr[6]

US$3.5B opportunity[7] (hematuria, surveillance)

>4.5M CXBLADDER TEST OPPORTUNITIES

1. National Cancer Institute SEER.
2. Aly A et al. (2020) The Real-World Lifetime Economic Burden of Urothelial Carcinoma by Stage at Diagnosis. J Clin Pathw. 2020 May; 6(4):51-60
3. National Cancer Institute: Cancer Progress Trends Report
4. Journal of the American Medical Association
5. Kenigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29–34, 2021.
6. National Cancer Institute SEER.
7. Pacific Edge Estimate, opportunity estimated at US$760/Per test

Cxbladder® | PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

THE PRINCIPLES OF PACIFIC EDGE'S CLINICAL STUDY DESIGN PROGRAM

Pacific Edge will attempt to gain guideline inclusion (and coverage) with every new piece of clinical or economic evidence supporting the adoption of Cxbladder

STUDY	GOAL*	USE CASE / INDICATION	POPULATION
STRATA	• CU of Triage • CV of Detect⁺ (retrospective)	• Risk stratification	• Microhematuria
DRIVE	• CV of Detect⁺ • CV of Triage • Data for pooled-analysis	• Risk stratification	• Microhematuria and gross hematuria
AUSSIE	• CV of Detect⁺ with an Australian cohort • Data for pooled analysis	• Risk stratification	• Microhematuria and gross hematuria
microDRIVE	• CV of Detect⁺ • Data for pooled analysis	• Risk stratification	• Microhematuria
POOLED ANALYSIS (two groups)	• CV of Detect⁺	• Risk stratification	• Microhematuria / gross hematuria
LOBSTER	• CV of Monitor/Monitor⁺	• Risk stratification	• Surveillance
CREDIBLE	• CU of Detect⁺	• Risk stratification	• Microhematuria

*CU - Clinical Utility, CV - Clinical Validity, AV - Analytical validity. For a detailed definition of these terms please see the glossary on page 38 of this presentation.

Cxbladder® PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

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**)
		STRATA (unpublished) (**7**)	MH + GH*				*Study in progress*
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*
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 38 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	The intent of STRATA is to show that it is safe to risk stratify 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 idnetified 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.

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.

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

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ANATOLE MASFEN
BRYAN WILLIAMS
ANNA STOVE
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President Pacific Edge Diagnostics USA
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Chief Operating Officer
PROFESSOR PARRY GUILFORD
Chief Scientific Officer
DR TAMER ABOUSHWAREB
Chief Medical Officer
DR JUSTIN HARVEY
Chief Technology Officer

GLOSSARY

- ***Sensitivity*** - the frequency with which a test correctly identifies patients with a disease.
- ***Specificity*** - 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***: Evidence that a test is repeatable in the lab for a given indication and population.
  - ***Clinical validity:*** Evidence a test works in the same way on an independent eligible population for a given indication.
  - ***Clinical utility:*** 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.

FOR MORE INFORMATION:

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