Pacific Edge
FY 23 FINANCIAL RESULTS
Investor presentation

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Chief Executive

25 May 2023

PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

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FY 23 HIGHLIGHTS: BUILDING MOMENTUM CXBLADDER ADOPTION

FINANCIAL PERFORMANCE AND TEST VOLUMES

▲ 37%[1]
GLOBAL TESTING VOLUMES (TLT[2]) on FY22

Global TLT of 31,565
US TLT increase 44% on FY 22 to 27,217 tests

▲ 39%
COMMERCIAL TEST VOLUMES on FY22

Commercial Tests of 26,691
US Commercial Tests rise 46% on FY 22 to 23,072 tests

▲ 71%
GROWTH IN OPERATING REVENUE on FY22

Operating revenue $19.6M
Total revenue of $26.1M up 88% on FY 22

($27.0M)
NET LOSS AFTER TAX

Increase from ($19.8M) in FY 22 amid investment for future growth

$77.8M
CASH, CASH EQUIVALENTS[3]

Strong Balance Sheet
$27.6M reduction in cash & cash equivalents[3] on FY 22

PACIFIC EDGE IS DELIVERING ON ITS STRATEGY

- ADOPTION, RETENTION & REVENUE GENERATION
- EVIDENCE, COVERAGE AND GUIDELINES
- RESEARCH AND INNOVATION

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

A YEAR OF STRATEGIC DELIVERY

SCALING FOR EXECUTION SUBSTANTIALLY COMPLETE, READY FOR THE NEXT PHASE OF GROWTH

ADOPTION, RETENTION AND REVENUE GENERATION

- Test volumes in the key US market rise 44% in FY 23 to 27,217
- US ordering clinicians rise 46% to 1,150 from 789 in Q4 22; tests/clinician steady
- Diversified commercial roles (incl. Medical Affairs & Market Access); FTE +27 to 114*
- 2 Kaiser Permanente accounts in PEB top 20; EMR technologically complete

EVIDENCE COVERAGE AND GUIDELINES

- Reconfigured & expanded clinical studies framed by AV, CV & CU**, focused on guidelines
- Increased enrolment & site monitoring resources for STRATA and DRIVE for faster completion
- Coding & coverage established for Cxbladder Triage, laying a path for Cxbladder Detect+

RESEARCH & INNOVATION

- Adding DNA SNPs to RNA products significantly improves performance: Cxbladder Detect+
- Technology transfer and validation of Detect+ to PEDNZ and PEDUSA labs (in progress)
- Investigating potential for a Monitor+ product for surveillance based on similar DNA SNPs

*FTE count at 31 March 2023
**AV = Analytical Validity, CV = Clinical Validity, CU = Clinical Utility

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BLADDER CANCER

A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE

10th
Most common cancer world-wide[1]

6th
Most common cancer in men[1]

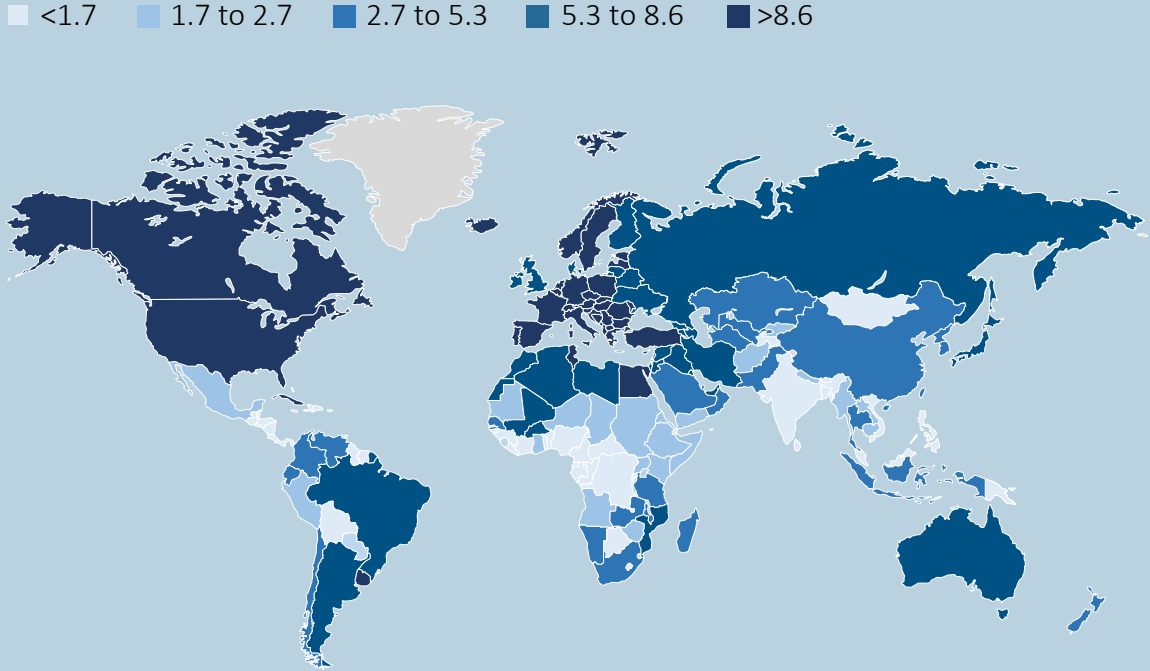
17th
Most common cancer in women[1]

>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

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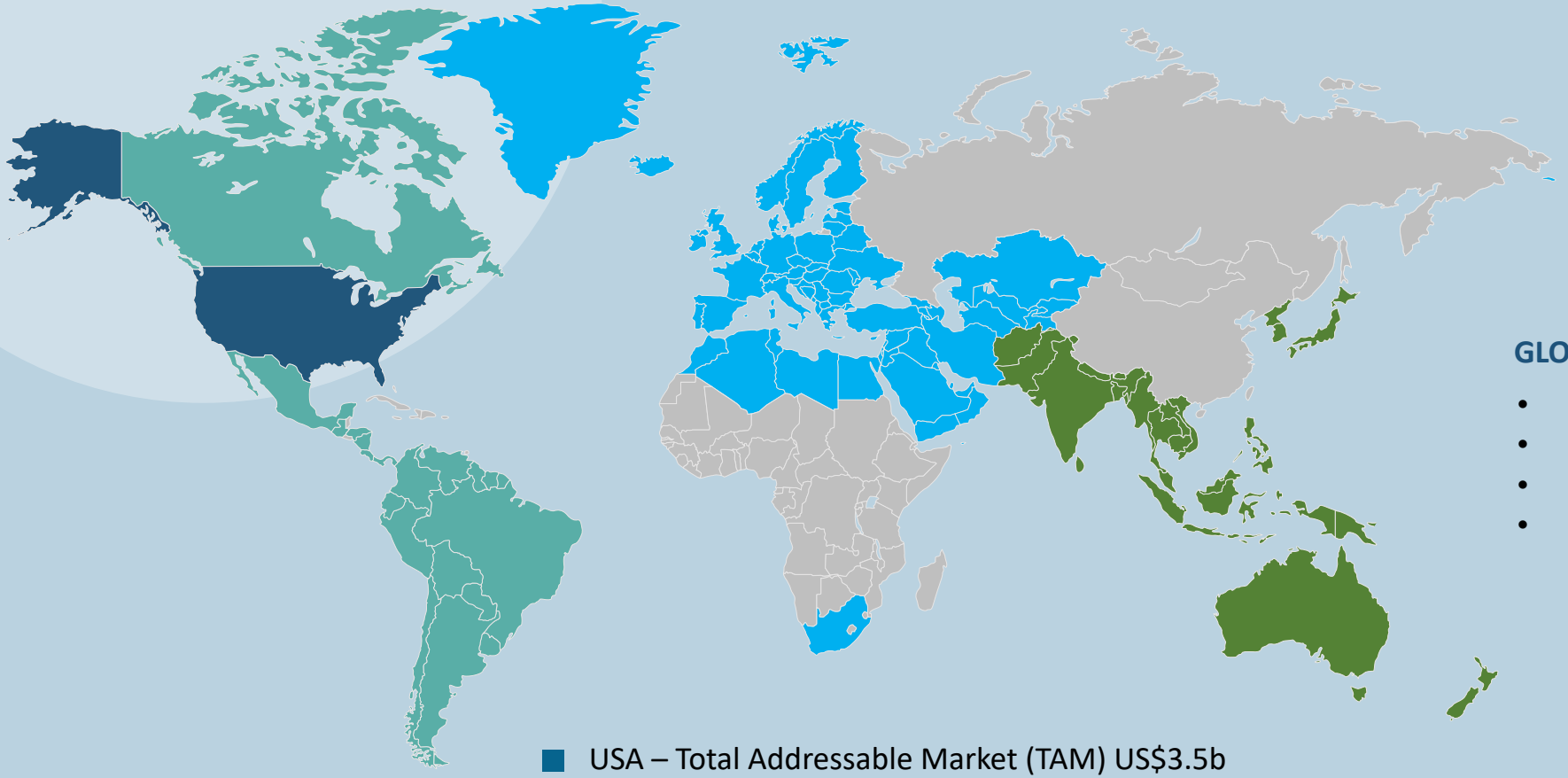
CXBLADDER IS A GLOBAL OPPORTUNITY

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

CxBladder® PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

PACIFIC EDGE AT A GLANCE: GROWING GLOBALLY

FROM IP DEVELOPMENT TO PATIENT

- **IP:** 4x patent families in bladder cancer, with >80 patents including RNA biomarkers and their analysis algorithms
- **Cxbladder:** Advanced genomic biomarker tests from a non-invasive urine sample for the early detection and management of bladder cancer
- **Clinical Evidence:** Peer-reviewed clinical validity and utility data that shows Cxbladder outperforms Standard of Care (SoC)
- **Reimbursement:** Cxbladder tests reimbursed by Medicare and Kaiser Health Plan in the USA
- **Patient Empowerment:** Non-invasive efficacious testing offers opportunity for increased patient compliance with surveillance and management regimes

>1,151[1]
Unique ordering clinicians in Q4 23

~300K[1]
Annual laboratory test capacity

114[1]
FTEs up 27 FTE since the end of Mar 22

1. Company data

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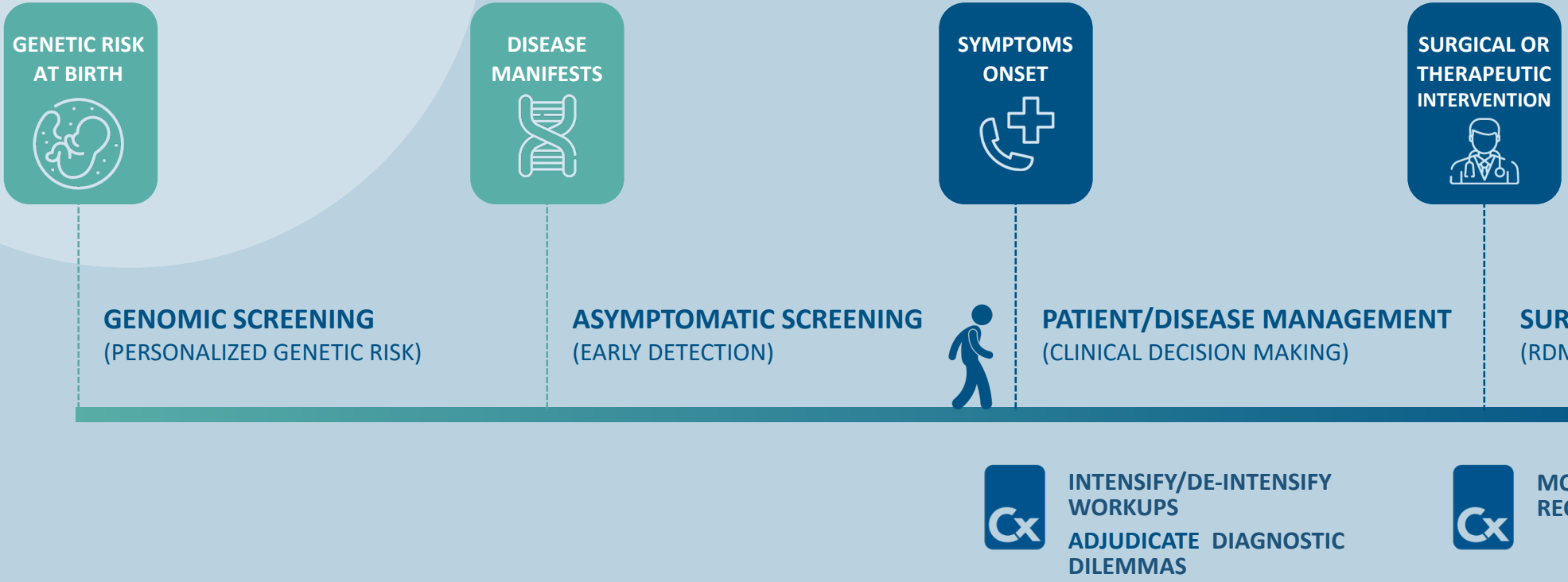
MOLECULAR DIAGNOSTICS VALUE CHAIN: PATIENT JOURNEY



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

PATIENT CARE PATHWAY: VALUE PROPOSITION

Typical standard of care on the patient care pathway

Primary Care Physician
Patient presents with hematuria and clinician cannot rule out cancer. Patient referred to urologist

Urologist/Specialist
Current guidelines for hematuria evaluation recommend ~95% get cystoscopy[1] ahead of diagnosis & treatment

Urologist/Specialist
Monitor for recurrence with cystoscopy, frequency varies according to patient presentation

VALUE PROPOSITION

Cxbladder TRIAGE | Cxbladder DETECT | Cxbladder MONITOR

Cxbladder™ TRIAGE

For use in the **PRIMARY CARE** and **SPECIALIST** settings to de-intensify hematuria workup or rule out urothelial cancer (UC)

Assists clinicians to **safely de-intensify** hematuria evaluation from low incidence populations
Sensitivity 95% / NPV 99%

Cxbladder™ DETECT

For use by **SPECIALISTS** to detect the presence of urothelial cancer and adjudicate diagnostic dilemmas

Assists clinicians to **adjudicate diagnostic dilemmas** (e.g., equivocal cystoscopy & atypical cytology) in any patient population
Sensitivity 82% / Specificity 85% / NPV 97%

Cxbladder™ MONITOR

For use by **SPECIALISTS** to monitor for recurrence at a frequency proportional to risk

Assists clinicians in **monitoring for UC recurrence**. Intended to reduce the frequency of surveillance cystoscopy and improve patient compliance
Sensitivity 93% / NPV 97%

Sensitivity: the likelihood of the test to be positive in a patient with the disease **Specificity:** the likelihood of the test to be negative when the patient does not have the disease; **NPV:** the likelihood of a negative test being a true negative.

[1] AUA Guidelines and Woldu SL, Ng CK, Loo RK, Slezak JM, Jacobsen SJ, Tan WS, et al. (2021a). "Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria." J Urol **205**(5): 1387-1393.

BLADDER CANCER IN THE US MARKET

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[4]
- **>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]

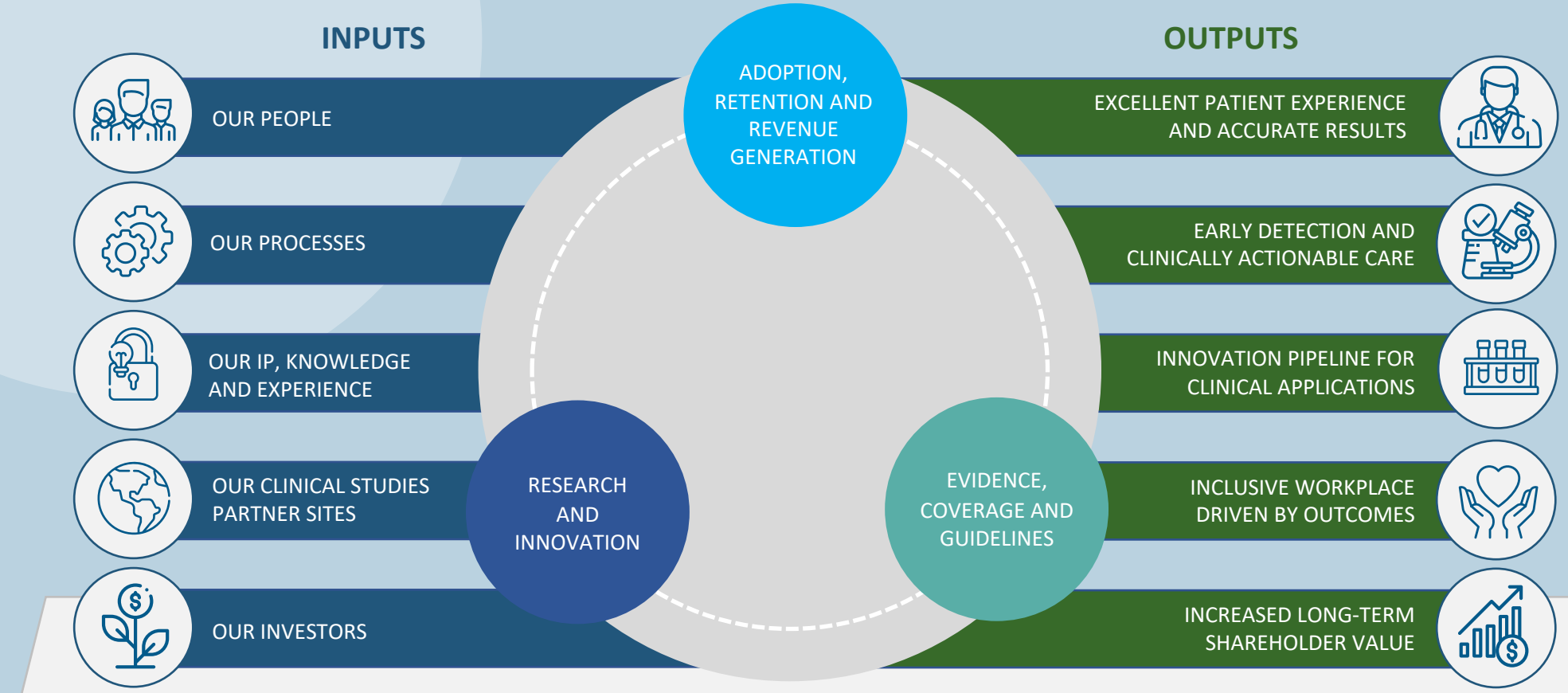
US$3.5B opportunity[7] (hematuria, surveillance)

>4.5M Cxbladder **TEST OPPORTUNITIES**

1. Bladder Cancer Advocacy Network
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. Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
5. Kenigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29–34, 2021.
6. National Cancer Institute
7. Pacific Edge Estimate, opportunity estimated at US$760/Per test

Cxbladder® | PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

OUR STRATEGY TO DRIVE LONG TERM GROWTH AND VALUE CREATION



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ADOPTION, RETENTION AND REVENUE GENERATION

ADOPTION, RETENTION AND REVENUE GENERATION

FOCUS AREAS:

1. Pursue structured sales process based on customer type supported by efficient digital architecture; engage KOLs with medical education and communication
2. Drive protocolized adoption of Cxbladder through patient use cases highlighting utility at the earliest point in patient care
3. Amplify our clinical evidence generation program within the urology and oncology communities with marketing, sponsorship and our medical affairs teams
4. Establish medical policy, then contracting for reimbursement by government and private payors; accurately documenting ‘medical necessity’ to improve payment objectives
5. Empower patients through patient awareness and patient advocacy initiatives through established societies and our Cxbladder website
6. **NEW:** Internal digitalization and Performance Excellence (PerfEx) initiatives to improve the effectiveness and efficiency of our operations

ADOPTION, RETENTION AND REVENUE GENERATION

EFFECTIVE INVESTMENTS FOR GROWTH: DIRECT SALES AND MARKETING

	INVESTMENTS FOR GROWTH

	**DIRECT SALES:**
	- New Direct Sales hires - Account Executives, Regional Sales Directors, National Accounts & Virtual Sales (contractors) **+9 FTE*** taking total to 37 FTE.
	ACHIEVEMENTS:
	- Diversified role types and created specializing sales roles and responsibilities
	  - National Accounts, Regional Sales, Virtual Sales, MSLs and Market Access
	  - Standardising our sales process across customer types
	- Established collaboration with Medical Affairs on education events focus on communicating clinical evidence
	- Improved our US geographic coverage in urban areas; leveraging virtual teams and PIHSS for under-served rural areas

	**MARKETING AND SALES SUPPORT:** - New hire in Event Management, Sales Training & Sales Operations **+3 FTE*** taking total to 4 FTE **ACHIEVEMENTS:** - Improved customer targeting and key opinion leader (KOL) identification - Improved new hire training and refresher training to focus on patient use cases - Supported a program of >50 urologic conferences/year (podiums, presentations, and PI Meetings) - Enhanced our advertising, patient outreach, advocacy (UroToday, Urology Time, BCAN, New Zealand Cancer Society) - Improved internal communications and employee engagement

* All staff counts are 31 March 2022 vs 31 March 2023

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CANCER DIAGNOSTICS COMPANY

ADOPTION, RETENTION AND REVENUE GENERATION

EFFECTIVE INVESTMENTS FOR GROWTH: MARKET ACCESS AND MEDICAL AFFAIRS

	INVESTMENTS FOR GROWTH
	**MEDICAL AFFAIRS:** - Chief Medical Officer, Medical science Liaisons and full-time US-based clinical trial monitors **+7 FTE** **ACHIEVEMENTS:** - Established a highly credible medical education program; scientific and medical communications to support sales, marketing efforts (alongside efforts to develop evidence, gain coverage and be included in guidelines) - Increased engagement with Key Opinion Leading (KOL) physicians and institutions (National Accounts) - Established a framework for US-led IITs, Registries and Research Partnerships - Aligned clinical development, patient enrolment, clinical trials monitoring and medical affairs education/communication
	**MARKET ACCESS AND REIMBURSEMENT:** - VP Market Access **+1 FTE** (taking total to 2) **ACHIEVEMENTS:** - Continuous improvement for Cxbladder ordering process and documentation for establishing medical intent/necessity - Improved documentation processes for 'medical necessity' – a requirement for Medicare coverage - Distribution agreement with Israel's ProGenetics (supported by PEDUSA) - Industry collaboration and representations to Novitas to drive clarity on continued Medicare coverage (current LCD) - Coding and coverage achieved for Cxbladder Triage, establishing a potential path for Detect+

*All staff counts are 31 March 2022 vs. 31 March 2023, headcount increase to 114 FTE includes ~12 additional FTE in laboratory, support and finance and back office and a new APAC President

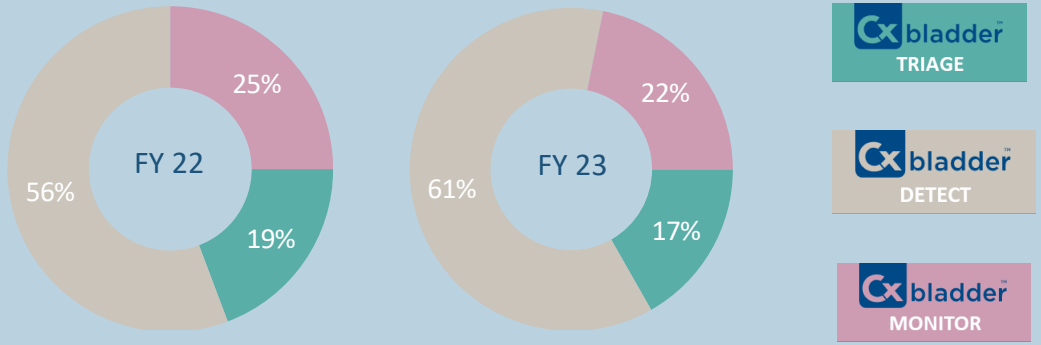
Cxbladder PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

GLOBAL: COMMERCIAL TESTS GROWING STRONGLY AS US ACCELERATES

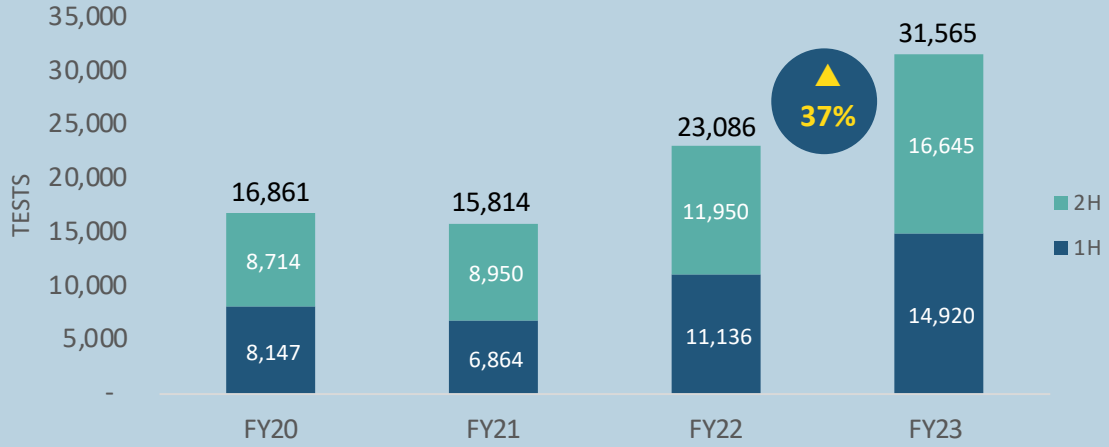
FY 23 Total Lab Throughput (TLT)

- Global TLT increased 37% to 31,565 tests
- Global Commercial test volumes increased 39% to 26,691
- Global TLT is driven by US growth in the US (predominantly Detect)
- Hematuria evaluation (Triage & Detect) is the larger market opportunity, ~3x the size of bladder cancer surveillance (Monitor)

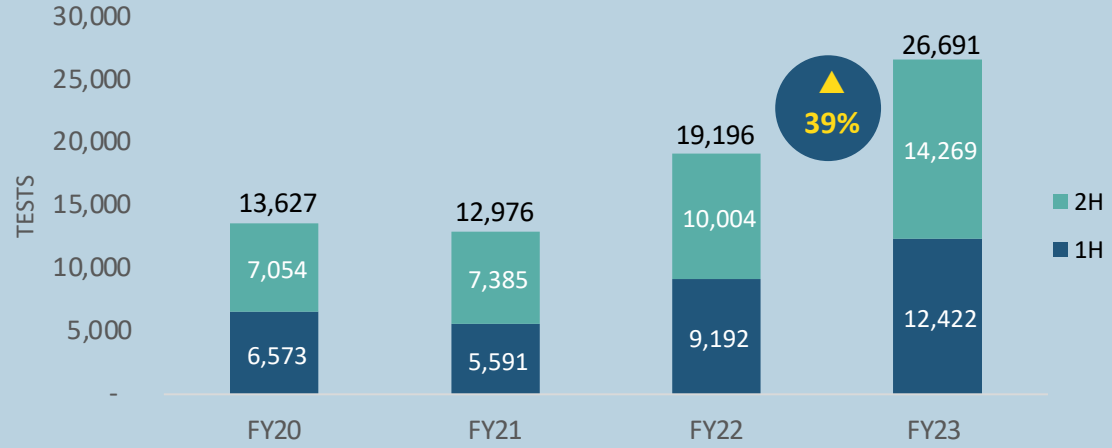
TEST VOLUMES BY TYPE (TLT*)



GLOBAL 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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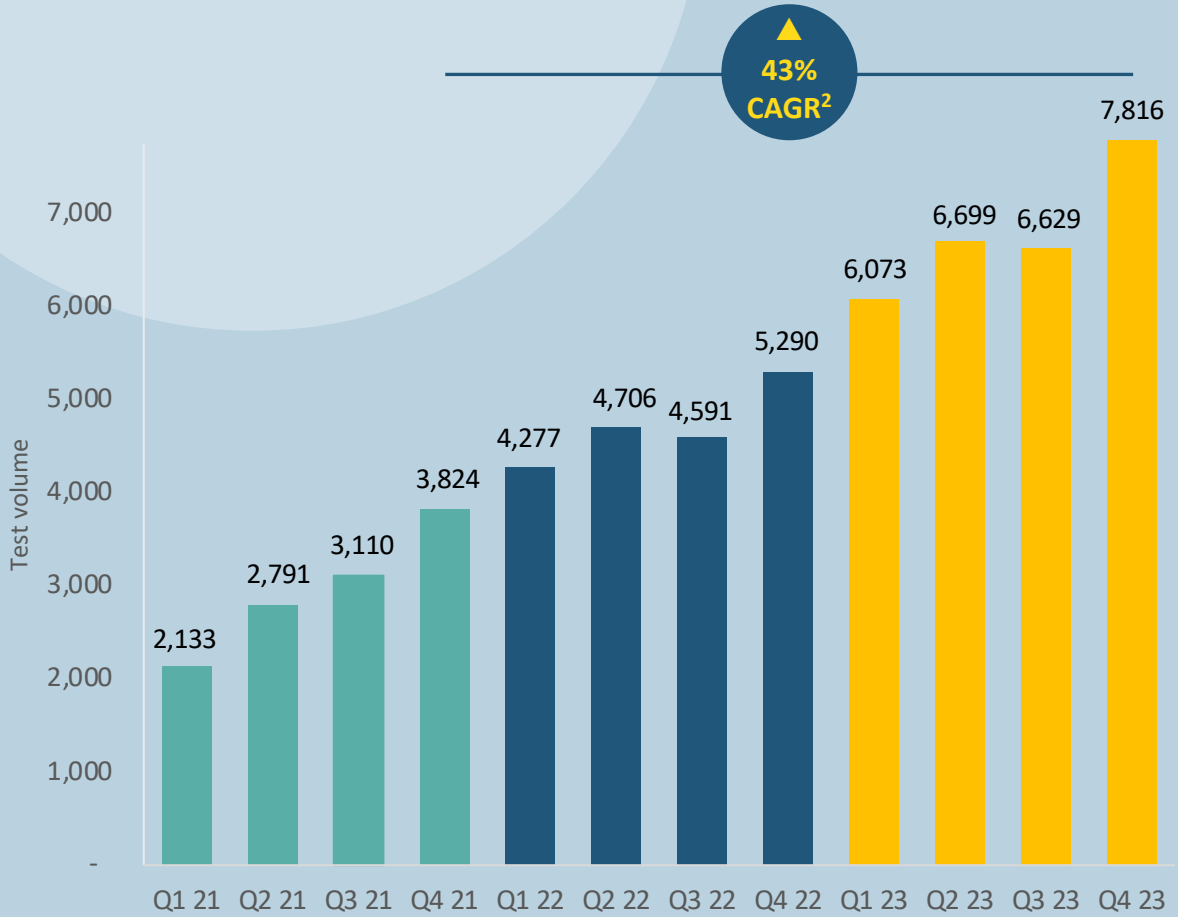
ADOPTION, RETENTION AND REVENUE GENERATION

STRONG GROWTH IN THE US: PACIFIC EDGE'S LARGEST MARKET

US GENERATING ~86% OF TOTAL TEST VOLUME[1]

USA TEST VOLUMES[1]

Commercial tests represent 85% of FY 23 TLT in the USA



[1] Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing
[2] CAGR compares Q4 21 to Q4 23

FY 23 PROGRESS WITH THE LARGEST US PAYORS

Medicare covers >61.5m US citizens over 65

- Cxbladder has a majority Medicare and MA population; average age of 73 for presentation with hematuria
- Medicare and MA represent ~20% of the population, but ~60% of US commercial tests for Cxbladder
- Pacific Edge's Medicare Administrative Contractor Novitas continues to reimburse at US$760/test, but the proposed LCD creates some uncertainty

The Kaiser Health Plan covers >12.5m members

- 2 Kaiser sites in PEB's Top 20 Accounts. 14 Kaiser sites across Southern California ordering in FY23
- EMR software development and integration testing complete; KP and PE working towards "go live"

The Veterans Administration serves >9m veterans each year

- DRIVE clinical study, has enrolled 80% of target patients
- DRIVE is a key engagement with VA urologists to determine clinical validity in a cohort of VA patients

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DIGITALIZATION & 'PERFEX' INITATIVES TO SIMPLIFY CLINICIAN ORDERING

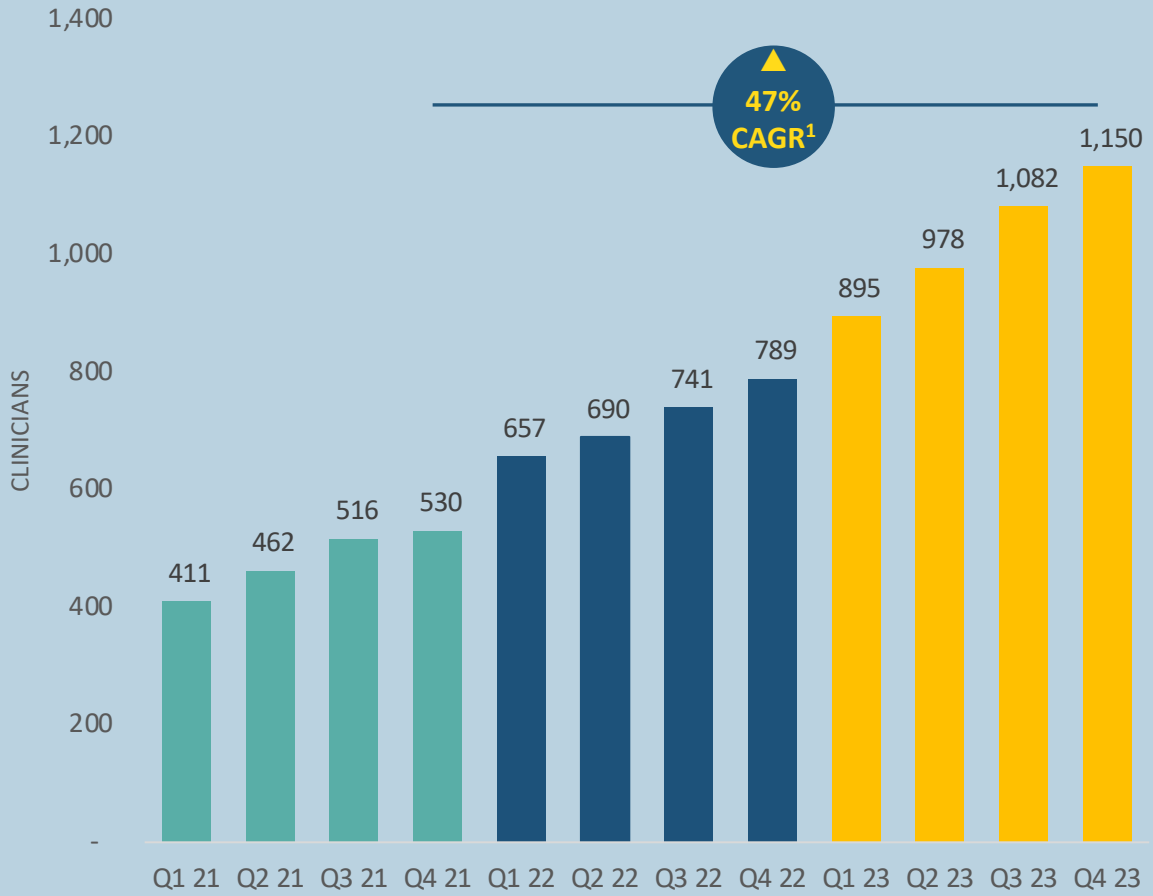
'STICKINESS' AND CUSTOMER EXPERIENCE INITIATIVES

1. Commercially-led product management for end-to-end customer experience, supported by digital workflows
2. EMR integrations and Customer Portal

FIT FOR GROWTH/DIGITALIZATION

1. Investment to upgrade older hardware and IT systems
2. EMR integrations and Customer Portal (as above)
3. Performance Excellence: Lab Operations and Customer Service

UNIQUE US CLINICIANS ORDERING CXBLADDER

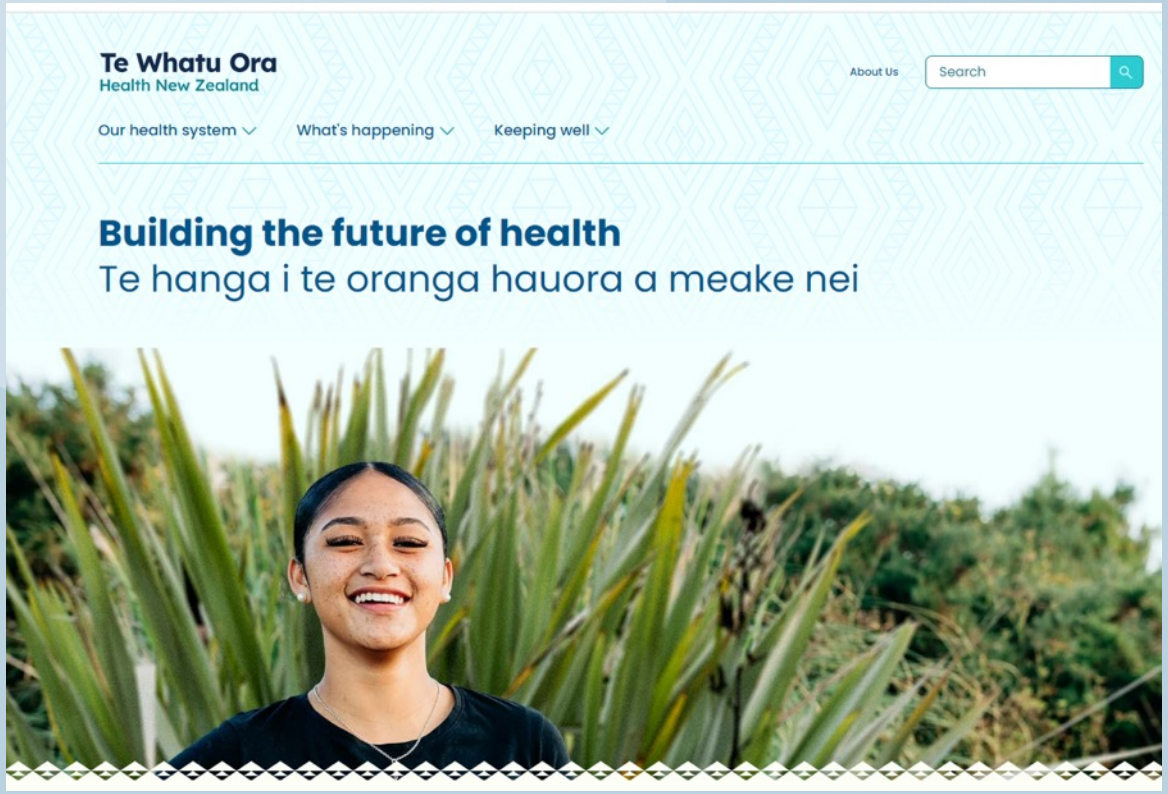


[1] CAGR compares Q4 21 to Q4 23

ADOPTION, RETENTION AND REVENUE GENERATION

APAC: NEW ZEALAND AT THE FOREFRONT WITH ADOPTION BY PRIMARY CARE

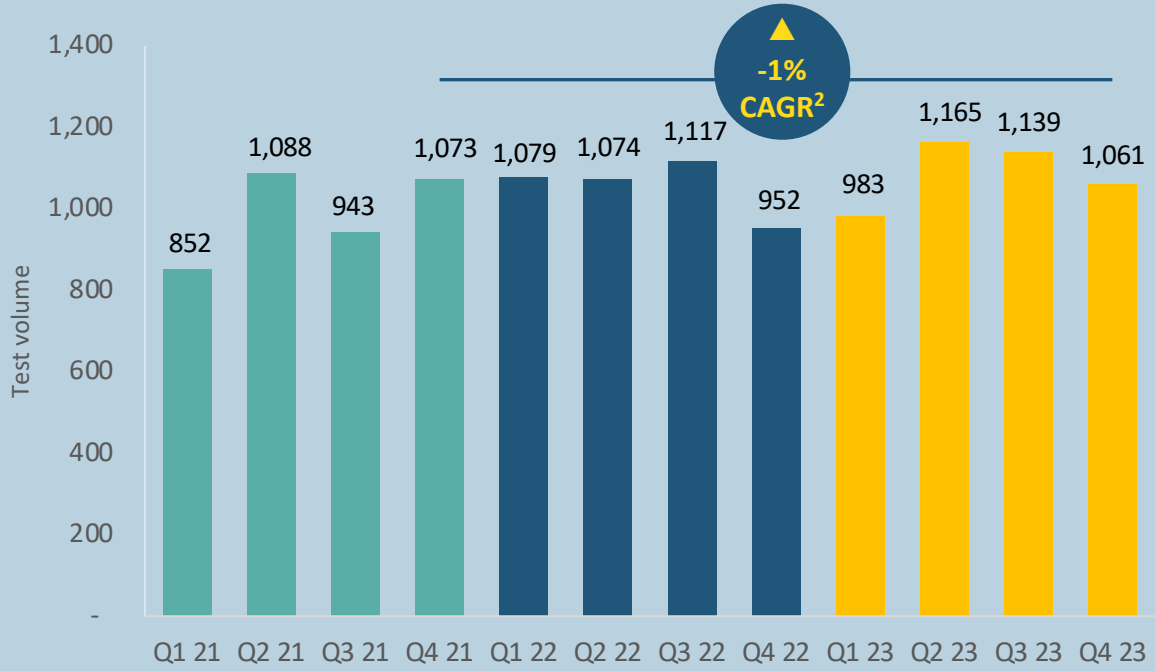
APAC GENERATING ~14% OF TEST VOLUME[1]



Pacific Edge has Cxbladder coverage in 15 of the 20 new Te Whatu Ora, Health New Zealand, regions, representing >75% of the country's population

APAC TEST VOLUMES[1]

Commercial tests represent 83% of TLT in FY 23 for APAC



- Volumes in APAC driven by slower growth in New Zealand
- Australia and Southeast Asia still in business development
- New APAC President recruited in March 2023

[1] Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing
[2] CAGR compares Q4 21 to Q4 23

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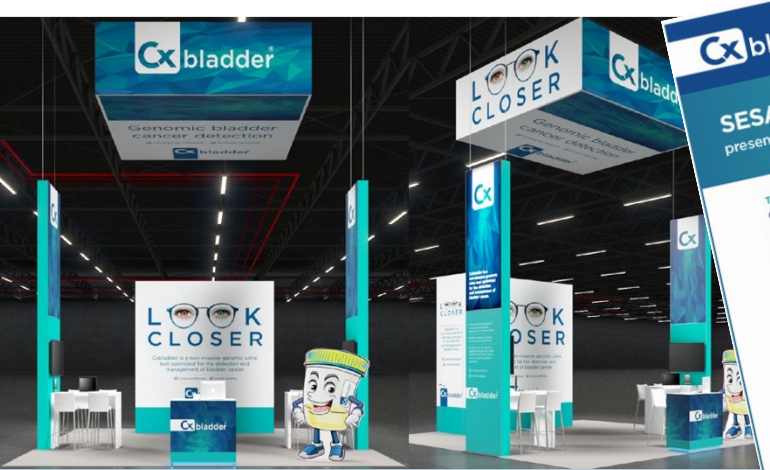
ADOPTION, RETENTION AND REVENUE GENERATION

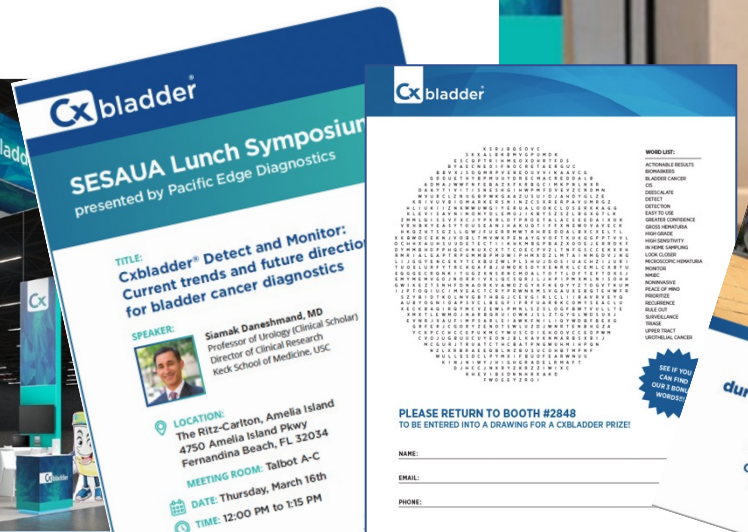
LOOK CLOSER

Genomic bladder cancer detection

Cxbladder

Pacific Edge Diagnostics, Booth# 2848





EVIDENCE, COVERAGE AND GUIDELINES: CHANGE CLINICAL PRACTICE

FOCUS AREAS:

Generate high-quality clinical validation and utility evidence through clinical studies

Use Clinical Utility evidence to:

Drive the adoption of Cxbladder by clinicians, insurers and hospitals ahead of guideline inclusion

- Pursue inclusion of Cxbladder in globally-relevant standards and guidelines of clinical care across the breadth of patient pathways
- Foster trusted relationships with key opinion leaders, relevant Urologic centers of excellence, professional societies and patient advocacy networks to drive a broader awareness and demand for Cxbladder
- Develop the scientific and clinical credibility of the Cxbladder brand

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EVIDENCE COVERAGE AND GUIDELINES

ADDITION OF DNA BIOMARKERS ENHANCES CXBLADDER PERFORMANCE

US and Singapore studies extend Pacific Edge's first mover advantage in bladder cancer diagnosis

- New study published in the AUA *Journal of Urology*[1]:
  - Found the addition of DNA biomarkers significantly enhances the performance of Cxbladder tests for hematuria evaluation.
  - Demonstrated analytical validity of the enhanced tests in a genetically diverse population (804 patients: 344 from the US, 460 Singapore)
- Cxb Detect⁺ is targeted for commercialization as a single product for hematuria evaluation in the US and requires:
  - New clinical validity and utility evidence:
    - DRIVE, microDRIVE, AUSSIE, STRATA and other planned studies
  - Its own coding, coverage and pricing decisions
- No impact is anticipated on existing Triage, Detect and Monitor revenues, because full commercial launch of Cxb Detect⁺ commences only after reimbursement is established
- Investigating the potential for Cxb Monitor⁺ for surveillance of NMIBC

Results of enhanced tests compared to existing tests[1]

Performance[2]	Sensitivity	Specificity	NPV	PPV	ROR
Cxbladder tests enhanced with DNA biomarkers					
Cxb Triage⁺	95%	78%	99.5%	26%	73%
Cxb Detect⁺	97%	90%	99.7%	44%	83%
Existing Cxbladder tests					
Cxb Triage	89%	63%	99%	16%	59%
Cxb Detect	74%	82%	97%	25%	78%

A **Cxb Detect⁺ negative** patient has a low probability of UC because Cxb Detect⁺ combines the characteristics of high Sensitivity (97%), NPV (99.7%) and Specificity (90%) with a Rule out rate (ROR) of 83%.

A **Cxb Detect⁺ positive** patient conversely has a higher probability of urothelial cancer for the same reasons. A positive test represents a justification for a full workup for the patient according to guidelines and assist the adjudication of diagnostic dilemmas such as equivocal cystoscopy or urine cytology.

1. Lotan et al 'Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification'
2.. For definitions, please refer to page 45 of this presentation

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CLINICAL EVIDENCE GENERATION TOWARDS GUIDELINE INCLUSION (1/2)

STUDY	AIM	LOCATIONS	ENROLLED SITES*	STATUS**
STRATA	**S**afe **T**esting of **R**isk for **A**symptoma**TI**c Microhematuri**A** Demonstrate the clinical utility (CU) of Cxbladder using a prospective, two-arm randomized design to risk-stratify patients and rule out from cystoscopy • Establish CU for Cxbladder Triage in MH populations to identify patients at low risk of bladder cancer that can safely avoid cystoscopy • Retrospective analysis with Cxbladder Detect+ to show equivalent or greater CU in MH populations with the improved performance characteristics • CU evidence supports AUA/NCCN guidelines inclusion using Cxbladder Triage and/or Cxbladder Detect+ to risk stratify MH populations	USA Canada	11 / 13	- Enrolment total is 492, including 113 'low risk' subjects that are the focus of the study - Target enrolment: ~600 patients, including 120 low risk subjects randomized to test arm - Last patient in: Q3 2023 - Follow up: until Q3 2024
DRIVE	**D**etection and **RI**sk Stratification in **VE**terans Presenting with Hematuria Prospective recruitment of patients to a single-arm observational study to demonstrate the CV of Cxbladder tests in risk stratifying Veterans presenting with hematuria • CV evidence for Triage in MH & GH patients supplementing NZ Studies • Demonstrate CV of Cxbladder Detect+ within a Veterans cohort • Retrospective analysis with Cxbladder Detect+ to demonstrate CV evidence supporting AUA/NCCN Guidelines inclusion in MH & GH patients • Contribute data to pooled-analysis to establish CV for Detect+ in MH patients	VA Sites (USA)	10 / 11	- Enrolment total is 562 - Target enrolment: ~600 patients - Last patient in: Q3 2023 - Follow up: until Q2 2025
AUSSIE	**A**ustralian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia Prospective recruitment of patients to a single-arm observational study to demonstrate CV in an Australian healthcare setting for patients presenting with hematuria • Demonstrate CV of Cxbladder Detect+ with an Australian cohort • Demonstrate accurate risk stratification of hematuria patients to intensify or de-intensify evaluation • Contribute data to pooled-analysis to establish CV for Detect+ in MH patients	Australia	1 / 1	- Enrolment due to start May 2023

*Estimated number of enrolled sites
**All dates are best-case estimates and subject to change

CLINICAL EVIDENCE GENERATION TOWARDS GUIDELINE INCLUSION (2/2)

STUDY	AIM	LOCATIONS	ENROLLED SITES*	STATUS**
Microhematuria Pooled-analysis	Pooled-analysis of Cxbladder Detect+ performance from multiple studies involving prospectively recruited patients from single-arm observational studies including eligible microhematuria patients • CV of Cxbladder Detect+ with microhematuria (MH) patients • Combines data from DRIVE, AUSSIE and a future MH-focused clinical trial • CV evidence supports AUA/NCCN guidelines inclusion using Cxbladder Detect+ to risk stratify MH populations	USA, Aus	N/A	- DRIVE underway, AUSSIE and microDRIVE projected to start in 2023
microDRIVE	**D**etection and **RI**sk Stratification in **VE**terans Presenting with **Micro**hematuria • Demonstrate the clinical validity of Cxbladder Detect^{+} in detecting urothelial cancer in patients presenting with microhematuria. • MicroDRIVE will compare the performance of Detect^{+} against the current gold-standard for the detection of urothelial cancer, diagnostic cystoscopy and pathology.	USA	0/1	- Projected to start recruitment Sep/Oct 2023 - Target is 1000 patients and 50 tumour confirmed - Last patient in: March/April 2024
LOBSTER	**LO**ngitudinal **B**ladder Cancer **S**tudy for **T**umor R**E**cur**R**ence Prospective recruitment of patients to a single-arm observational study to evaluate the clinical validity of CxbM • To safely risk stratify patients under surveillance for recurrence of UC • To demonstrate that it is safe to alternate CxbM with cystoscopy for intermediate and high-risk patients under surveillance for recurrence of UC • Targeting AUA/NCCN guidelines inclusion for biomarkers as an alternative to cystoscopy in a surveillance setting	USA (including some VA sites) Australia	3 / 10	- Three sites are open - Two due to open in April - Another 6 are at pre-activation. - Enrolment is now 63 patients with 98 samples collected to date - Each site will enroll 100 patients within 12 months and follow up for another 12 months

*Estimated number of enrolled sites
**All dates are best-case estimates and subject to change

Cxbladder

PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

EVIDENCE COVERAGE AND GUIDELINES

MEDICAL AFFAIRS: SPEAKING THE LANGUAGE OF CLINICAL OPINION LEADERS

American Urological Association

NCCN National Comprehensive Cancer Network®

European Association of Urology

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 NCCN submission of new evidence in August 2023

PODIUMS, PRESENTATIONS, POSTERS AND PUBLICATIONS

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

BUILDING KOL RELATIONSHIPS

- Academics, clinical leads in private practice, guidelines committees and other influential clinicians

VIDEO VIEWS
4102

PUBLISHED
12/2/22

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EVIDENCE COVERAGE AND GUIDELINES

MEDICAL AFFAIRS: INVESTIGATOR INITIATED TRIALS AND REGISTRIES

SUPPLEMENTING OUR EVIDENCE GENERATION PROGRAM

INVESTIGATOR INITIATED TRIALs (IITs)

- Proposed by investigators and supported by Pacific Edge to provide clinical utility evidence at modest scale for medical communications
- Promote familiarity and confidence with Cxbladder, the interpreting the test result and how Cxbladder can be used to manage patients
- Supports local data development for market access

PACIFIC EDGE'S CXBLADDER REGISTRY

- Multi-site, real-world evidence clinical trial, capturing wide-ranging patient data, including follow up and outcomes data
- Assists independent investigators with study design and provides a data repository to support coverage and guideline decisions

Left to right:
***Royal Prince Alfred Hospital (Sydney)**, UT Southwestern (Dallas), Canberra Hospital (ACT)*

INVESTIGATOR INITIATED TRIALS UNDERWAY AND AIMS	SITES	PUBLICATIONS
Hematuria Evaluation: Local clinical validity evidence for internal hospital guidelines and budget development	6	2x Conference Abstracts
Surveillance: Local clinical validity evidence for internal hospital guidelines and budget development	7	2x Conference Abstracts
CU of Cxbladder to identify subclinical tumors in white light negative patients, confirmed by blue light	1	Pending
Risk-based hematuria evaluation of microhematuria patients by Cxbladder	1	Pending
Prioritization of surveillance patients by Cxbladder monitor for surveillance cystoscopy vs skipping one visit	2	1x Conference Abstract

EVIDENCE COVERAGE AND GUIDELINES

MARKET ACCESS: EXPANDING COVERAGE

WORKING WITH PUBLIC AND PRIVATE HEALTHCARE PAYORS GLOBALLY

MEDICARE STRATEGY

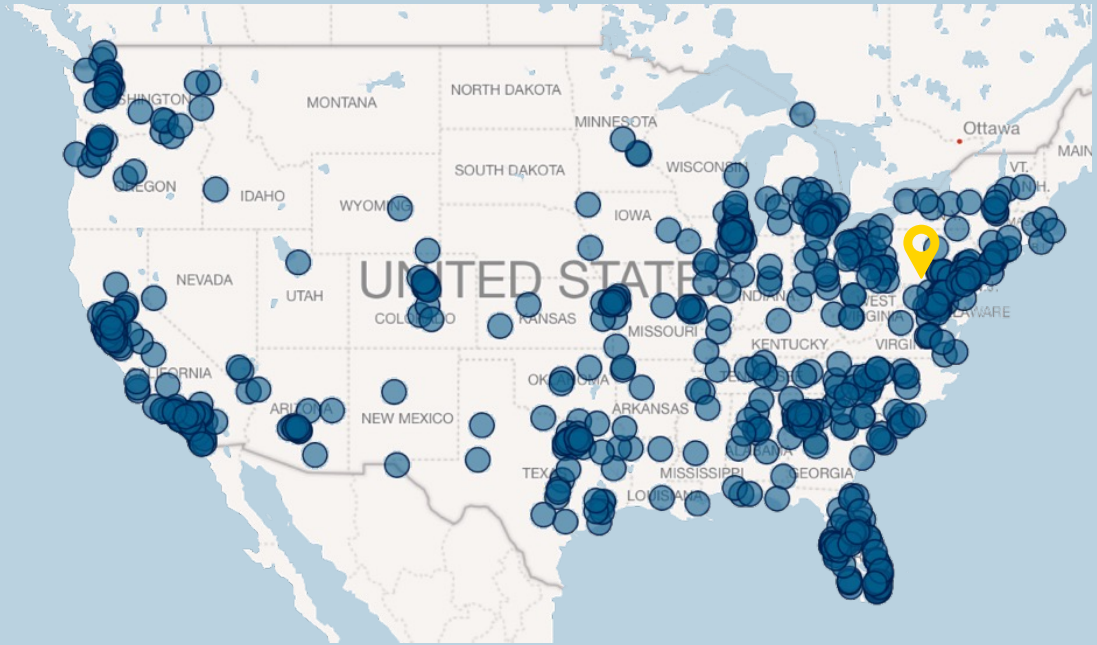
- Triage joins Monitor & Detect on LCA58917 with coverage at US$760/test*
- Reconsideration request with Novitas for all Cxbladder tests
- Working towards PLA-coding, coverage and pricing for Detect+
- Active program of appeals and prior-authorization workflows to increase payment rates from Medicare Advantage Plans

PRIVATE PAYOR STRATEGY

- Localized, demand-based approach focused on establishing medical policy, then contracting with individual private payors
- Health Economics – documenting the economic benefits to healthcare payors of adopting Cxbladder as a standard of care

EX-US DISTRIBUTORS SUPPORTED BY PEDUSA

- ProGenetics (Israel) distribution agreement signed
- Other geographies under consideration on a case-by-case basis



Distribution of Current U.S. Customers

Pacific Edge Diagnostics USA, *Hershey, Pennsylvania*

*The coverage position of Cxbladder may change. Proposed LCD (DL39365 – Genetic Testing for Oncology) issued in July 2022, must be finalized or withdrawn within 12 months of proposal

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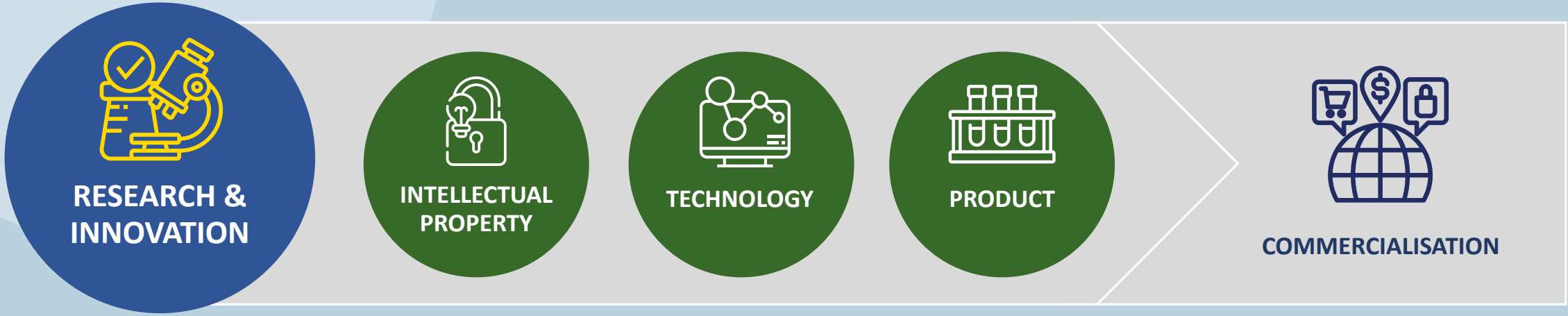
PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

RESEARCH AND INNOVATION:

UNDERSTANDING THE ENTIRE COMMERCIALISATION PATHWAY



FOCUS AREAS:

1. Evaluate ‘product concepts’ to address unmet clinical needs through market research and scientific/clinical advisory boards
2. Evaluate cutting-edge technologies to meet the market requirements of desired product concepts
3. Continue to build a patent portfolio for novel clinical applications of cutting-edge molecular technologies
4. Turn patented technology into clinically-validated molecular diagnostic tools that address an unmet clinical need

RESEARCH & INNOVATION

RESEARCH AND INNOVATION

DRIVING IP TO TECHNOLOGY

- Technology transfer of Detect+ from R&D to PEDNZ and PEDUSA clinical labs
- Evaluate 'product concepts' to address unmet clinical needs
- Simplify & productize Cxbladder workflows for performance excellence
- Adding DNA SNP markers to Cxbladder Monitor to evaluate the possibility of enhanced performance characteristics
- **MONSTER:** identifying additional markers of disease in surveillance patients
  - Rationale: Gene expression markers perform poorly within 6 months of surgical intervention (TURBT) and after administration of therapeutics
  - Opportunities within 6 months of intervention:
    - **Minimum Residual Disease** (MRD)
    - **Therapeutic Response Monitoring** (TRM)

Christchurch Hospital

MONSTER	**MON**itoring **S**tudy of post-**T**reatment **E**ffectiveness for **R**esidual Disease Single-arm, observational study to validate the performance characteristics of Cxbladder against white light cystoscopy during surveillance of UC • Christchurch-based sample collection to measure residual disease • To understand the potential of Cxbladder in identifying therapeutic response for surgical and non-surgical treatments of bladder cancer.	- Protocol under development, consulting with medical experts and pharma partners to guide the best study design

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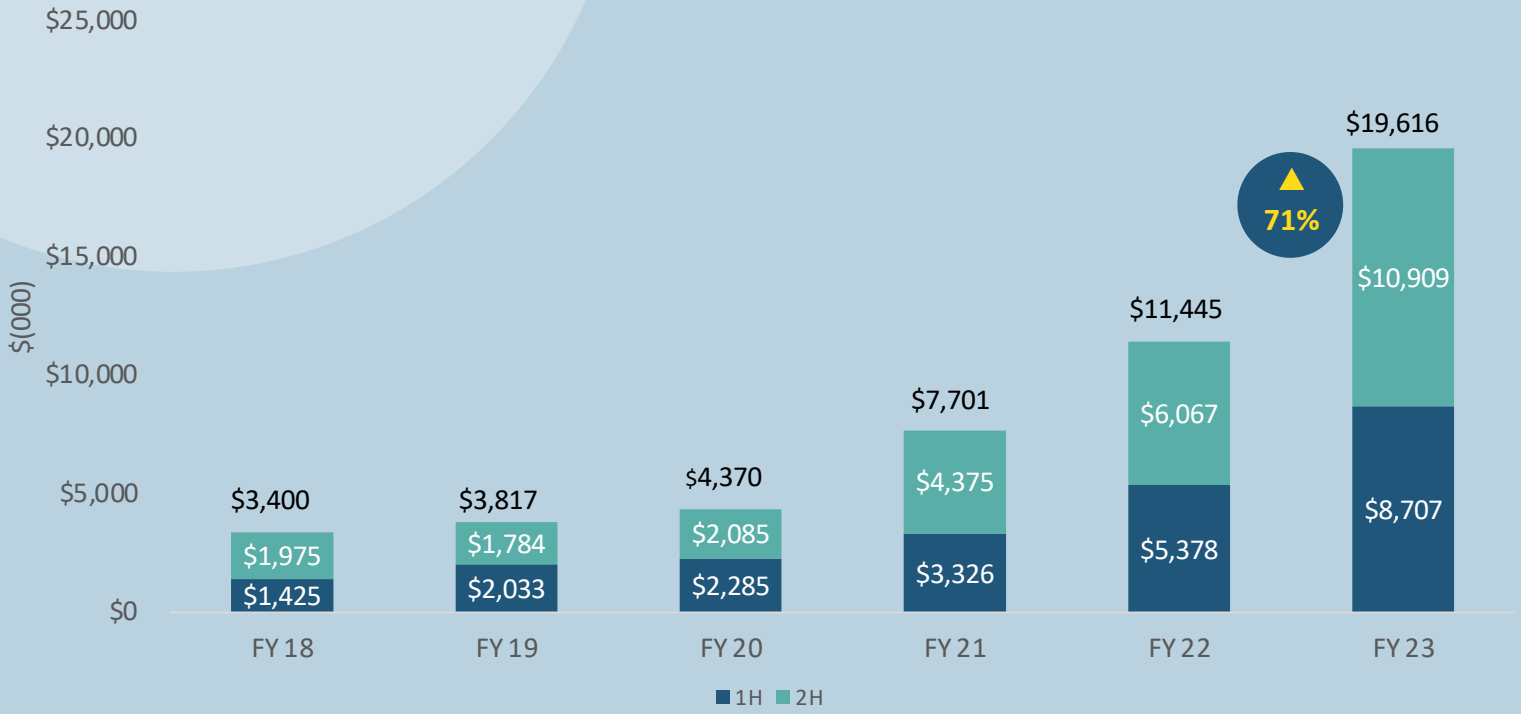
PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

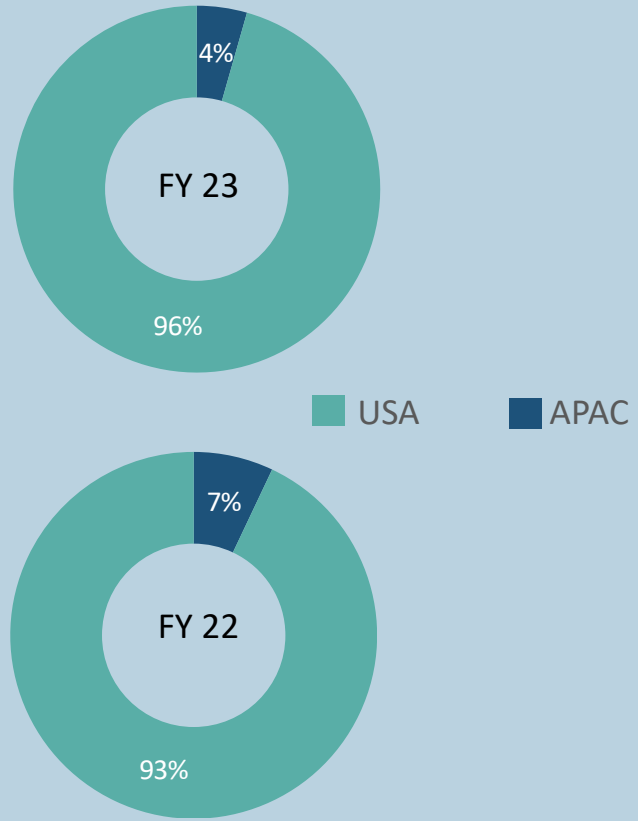
FINANCIAL RESULTS OVERVIEW

US TEST COMMERCIAL TEST VOLUME GROWTH DRIVING FY 23 REVENUES

Pacific Edge Operating Revenue



Regional Revenue Split



A STRONG BALANCE SHEET SUPPORTING GROWTH INVESTMENT

FINANCIAL PERIOD (March Year)	FY 23	FY 22	FY 21	FY 23 vs FY 22
	$000	$000	$000	△ %
Operating revenue	$19,616	$11,445	$7,701	71%
Total revenue	$26,124	$13,878	$10,439	88%
Operating expenses	$53,089	$33,666	$24,662	58%
Total comprehensive loss	**-$27,064**	**-$19,674**	**-$14,177**	**38%**
Cash receipts from customers	$18,468	$10,942	$6,747	69%
Net operating cash outflow	-$25,575	-$17,552	-$13,570	46%
Net cash, cash equivalents and short term deposits	**$77,791**	**$105,412**	**$23,129**	**-26%**

- Operating revenue growth of 71% driven by growth in US testing volumes
- Operating expenses increased 58% due primarily to investment for growth in sales and marketing and research (~73%) and volume increase of Cxbladder (~15%)
- Cash and cash equivalents of $77.8m down $15.7m on $93.5m in 1H 23[1] and $27.6m on FY 22
- Removing the impact of changes in foreign exchange between FY 22 and FY 23:
  - Operating revenue grew 55%
  - Operating expenses increased 47%
  - Total comprehensive loss increased 31%

[1] 30 September 2022

OPERATING EXPENSES RISE WITH INVESTMENT AND VOLUME GROWTH

FINANCIAL PERIOD (March Year)	FY 23	FY 22	FY 21	FY 23 vs FY 22
	$000	$000	$000	△ %
Laboratory operations	$9,349	$6,498	$5,466	44%
Research	$8,484	$5,135	$4,584	65%
Sales and marketing	$25,123	$14,277	$9,202	76%
General and administration	$10,133	$7,756	$5,410	31%
Total operating expenses	$53,089	$33,666	$24,662	58%

- Investment in people accounted for ~52% of the expense growth, e.g. headcount, salary increases and recruitment costs
- Sales and Marketing investment accounted for ~56% of the expense growth, including the majority of Medical Affairs expense
- Laboratory operations expenses increased ~ 44% following higher throughput and freight costs
- Research costs have increased ~ 65% as increased clinical evidence generation focuses on guideline inclusion

ENVIRONMENTAL SOCIAL AND GOVERNANCE STRATEGY

ESG: PACIFIC EDGE IS FOUNDED ON IMPROVING SOCIAL OUTCOMES

Pacific Edge is delivering actionable information that can contribute to a clinically meaningful improvements in cancer treatment, improving lives, improving healthcare equity across populations and healthcare outcomes for patients

GOVERNANCE

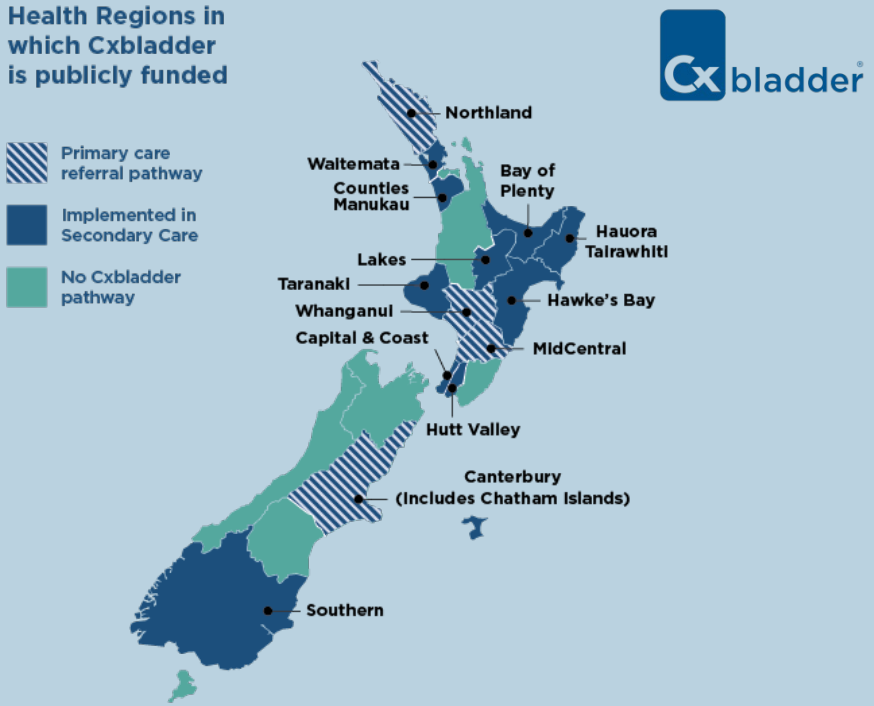
- Integrating oversight of Environmental, Social and Governance (ESG) matters, including carbon reporting, into the Audit and Risk Committee Charter

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 Toitū Envirocare 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%[1]

1. Davidson, Peter; Presentation to Urofair, 2022, time to first specialist assessment.

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OUTLOOK: FOCUSED ON FY24 EXECUTION

- Building on steady growth in FY23, investing prudently to improve effectiveness metrics (e.g. throughput/headcount, throughput/clinician)

- **HEADWINDS:**
  - No response by Novitas to comments submitted by Pacific Edge or other companies on proposed LCD

- **CATALYSTS:**
  - Novitas publishes a final LCD retaining coverage under LCA58917
  - Kaiser EMR integration “go live” in Southern California
  - Sales force maturity & territory stability improve effectiveness
  - *Te Whatu Ora* national contract
  - New clinician-generated CU evidence as studies completed

- We have world-leading technology, a strong balance sheet and we are building momentum in the US and establishing footholds in new markets

QUESTIONS

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.

"Nobody should die of cancer"

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

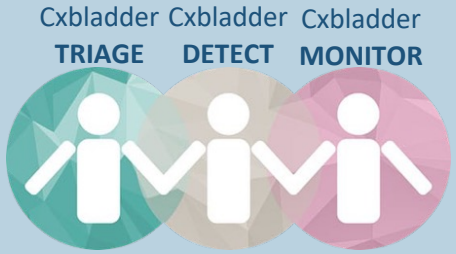
Aug 2021 Cxbladder reaches 70% public healthcare coverage in NZ

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 2011 2012 2013 2014 2015 2016 2018 2019 2020 2021 2022



Cxbladder®

GLOBAL GUIDELINES PIVOTAL TO THE WIDESPREAD ADOPTION OF CXBLADDER

Recognition in national guidelines deepens and accelerates commercial use of Cxbladder tests and entrenches coverage by nationally relevant healthcare institutions.

American Urological Association

- Most influential and largest urological association in the world
- U.S. based - 23,000 members worldwide.
- Standards of care relevant to Cxbladder:
  - Hematuria and micro-hematuria management
  - Non-muscle invasive bladder cancer (NMIBC). (Standard makes an allowance for the use of biomarkers in surveillance)
- Guidelines reviewed as new evidence emerges
- Pacific Edge can influence this process by publishing new clinical evidence

www.auanet.org

European Association of Urology

- Leading urologic authority in Europe
- Netherlands-based, 18,000 members
- Standards relevant to Cxbladder
  - Non-muscle invasive bladder cancer (NMIBC)
  - Guidelines loosely followed in New Zealand, Australia and Singapore, but localised at a national and regional level
- Guidelines recently reviewed with favourable biomarker language and are updated regularly

www.uroweb.org

NCCN National Comprehensive Cancer Network®

- US-based not-for-profit alliance of 32 leading US cancer centres
- Bladder cancer standard suggests biomarkers may be considered during surveillance of high-risk non-muscle-invasive bladder cancer
- Guidelines reviewed annually. PEB will resubmit in every year where there is new peer-reviewed evidence for Cxbladder

www.nccn.org

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*
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)

* Referred

MH: Microhematuria, GH: Gross Hematuria. For definitions of Sensitivity, NPV and Specificity please see the glossary on page 33 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.

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 out patients 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 noninvasive urine tests for ruling out recurrent urothelial carcinoma. *Urologic Oncology: Seminars and Original Investigations*, 35 (8), 531-539.

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 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 USA
DARELL MORGAN
Chief Operating 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***: Develop a test that is repeatable in the lab for a given indication and population.
  - ***Clinical validity:*** Make sure the test works in the same way on an independent eligible population for the given indication.
  - ***Clinical utility:*** Put the test in the hands of a physician to establish that it can usefully change patient management within the context of care for the defined population and indication.

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