

**Pacific Edge**

**ANNUAL SHAREHOLDERS  
MEETING**

**24 September 2024**

**Auckland**



**PACIFIC EDGE**  
CANCER DIAGNOSTICS COMPANY

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

# IMPORTANT NOTICE AND DISCLAIMER

This presentation has been prepared by Pacific Edge Limited (PEL) solely to provide interested parties with further information about PEL and its activities at the date of this presentation.

## Information of a general nature

The information in this presentation is of a general nature and does not purport to be complete nor does it contain all the information which a prospective investor may require in evaluating a possible investment in PEL or that would be required in a product disclosure statement, prospectus or other disclosure document for the purposes of the New Zealand Financial Markets Conduct Act 2013 (FMCA) or the Australian Corporations Act 2001. PEL is subject to a disclosure obligation that requires it to notify certain material information to NZX Limited (NZX) and ASX Limited (ASX) for the purpose of that information being made available to participants in the market and that information can be found by visiting [www.nzx.com/companies/PEB](http://www.nzx.com/companies/PEB) and [www2.asx.com.au/markets/company/PEB](http://www2.asx.com.au/markets/company/PEB). This presentation should be read in conjunction with PEL's other periodic and continuous disclosure announcements released to NZX and ASX.

## Not an offer

This presentation is for information purposes only and is not an invitation or offer of securities for subscription, purchase or sale in any jurisdiction where such offer purchase or sale would not be permitted.

## Not financial product advice

This presentation does not constitute legal, financial, tax, financial product advice or investment advice or a recommendation to acquire PEL securities and has been prepared without taking into account the objectives, financial situation or needs of investors. Before making an investment decision, prospective investors should consider the appropriateness of the information having regard to their own objectives, financial situation and needs and consult an NZX Firm, solicitor, accountant or other professional advisor if necessary.

## Forward-looking statements

This presentation may contain forward-looking statements that reflect

PEL's current views with respect to future events. Forward-looking statements, by their very nature, involve inherent risks and uncertainties. Many of those risks and uncertainties are matters which are beyond PEL's control and could cause actual results to differ from those predicted. Variations could either be materially positive or materially negative. The information is stated only as at the date of this presentation. Except as required by law or regulation (including the NZX Listing Rules and ASX Listing Rules), PEL undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. To the maximum extent permitted by law, the directors of PEL, PEL and any of its related bodies corporate and affiliates, and their respective officers, partners, employees, agents, associates and advisers do not make any representation or warranty, express or implied, as to the accuracy, reliability or completeness of such information, or the likelihood of fulfilment of any forward-looking statement or any event or results expressed or implied in any forward-looking statement, and disclaim all responsibility and liability for these forward-looking statements (including, without limitation, liability for negligence).

## Financial data

All dollar values are in New Zealand dollars unless otherwise stated. This presentation should be read in conjunction with, and subject to, the explanations and views of future outlook on market conditions, earnings and activities given recent announcements to the NZX and ASX.

## Effect of rounding

A number of figures, amounts, percentages, estimates, calculations of value and fractions in this presentation are subject to the effect of rounding. Accordingly, the actual calculation of these figures may differ from the figures set out in this presentation.

## Past performance

Investors should note that past performance, including past share price performance, cannot be relied upon as an indicator of (and provides no guidance as to) future PEL performance, including future financial position or share price performance.

## Investment risk

An investment in securities of PEL is subject to investment risk and other known and unknown risks, some of which are beyond the control of PEL. PEL does not guarantee any particular return or the performance of PEL.

## Disclaimer

None of PEL or PEL's advisers or any of their respective affiliates, related bodies corporate, directors, officers, partners, employees and agents, have authorised, permitted or caused the issue, submission, dispatch or provision of this presentation and, except to the extent referred to in this presentation, none of them makes or purports to make any statement in this presentation and there is no statement in this presentation which is based on any statement by any of them. To the maximum extent permitted by law, none of PEL and its advisers, affiliates, related bodies corporate, nor their respective directors, officers, partners, employees and agents makes any representation or warranty, express or implied, as to the currency, accuracy, reliability or completeness of information in this presentation; and none of them shall have any liability (including for negligence) for:

- any errors or omissions in this presentation; or
- any failure to correct or update this presentation, or any other written or oral communications provided in relation to this presentation; or
- any claim, loss or damage (whether foreseeable or not) arising from the use of any information in this presentation or otherwise arising in connection with this presentation or the information contained in it.

By receiving this presentation, you agree to the above terms and conditions.





**CHRIS GALLAHER**  
Chairman



# DIRECTORS



**SARAH PARK**



**ANATOLE MASFEN**



**BRYAN WILLIAMS**



**ANNA STOVE**



**MARK GREEN**



**TONY BARCLAY**



# AGENDA

1. CHAIRMAN'S ADDRESS
2. CHIEF EXECUTIVE'S ADDRESS
3. QUESTIONS
4. US OPERATIONS
5. OUR CLINICAL PROGRAM
6. QUESTIONS
7. RESOLUTIONS
8. VOTING AND GENERAL BUSINESS
9. MEETING CLOSE



# PACIFIC EDGE – TAKING NEW ZEALAND INNOVATION GLOBAL



2011  
Pacific Edge Diagnostics New Zealand (PEDNZ) established

Dec 2012  
Launch of Pacific Edge Diagnostics USA and Cxb Detect

May 2013  
First commercial sale (Cxb Detect) for PEDNZ

Mar 2013  
First commercial sale (Cxb Detect) for PEDUSA

Dec 2014  
Launch of Cxbladder Triage

Dec 2015  
Launch of Cxbladder Monitor

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

Jun 2020  
Kaiser Permanente, approves commercial use of Cxbladder

Jul 2020  
Medicare 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 2022  
Lotan et al: Enhanced Cxbladder Tests Deliver Improved Performance. Journal of Urology

Nov 2023  
Kaiser Permanente EMR integration goes live

May 2024  
STRATA podium presentation at AUA 2024. Study published in Journal of Urology





## FY 24 - CONSERVING CASH AMID COVERAGE UNCERTAINTY

**32,633**

GLOBAL TEST  
VOLUMES<sup>1</sup> UP  
3% VS FY 23

**\$23.9m**

OPERATING  
REVENUE UP  
22% VS  
FY 23

**▼ 24%**

DROP IN MONTHLY  
CASH BURN<sup>2</sup> IN 2H  
24 VS 1H 24

**(\$29.5M)**

NET LOSS AFTER  
TAX INCREASED  
9% VS FY23

**\$50.3M**

CASH, CASH  
EQUIVALENTS<sup>2</sup>

## FY 25 - CATALYSTS FOR GROWTH

### POSITIONED FOR GROWTH

- Commercial operations focused on profitable territories, non-Medicare revenue streams and selling the clinical and economic value of Cxbladder
- Direct sales team efficiency improves - operating at break even
- Refocused the business on the clinical development for Detect<sup>+</sup> and Monitor<sup>+</sup>

### CATALYSTS

- **Medicare coverage**
  - Clinical evidence program positioned to deliver additional evidence for coverage certainty
  - Novitas makes a policy decision to continue Cxbladder Medicare coverage
- **Guidelines**
  - AUA is presently reviewing the microhematuria guidelines; no timeframe provided
- **Detect<sup>+</sup> Medicare pricing**
  - Cautiously confident of receiving a Medicare price greater than the current tests, a result that will bolster our economics
  - Commercial launch targeted towards the end of the current financial year (FY 25)



1. TLT is the Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing  
2. Cash, cash equivalents and short-term deposits



**Dr PETER MEINTJES**  
Chief Executive Officer



# PACIFIC EDGE IS FOUNDED ON DELIVERING POSITIVE OUTCOMES FOR SOCIETY

WE CREATE VALUE BY PRIORITISING OUR PATIENTS, OUR PHYSICIANS AND OUR PEOPLE




## Our Vision

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

## Our Values:

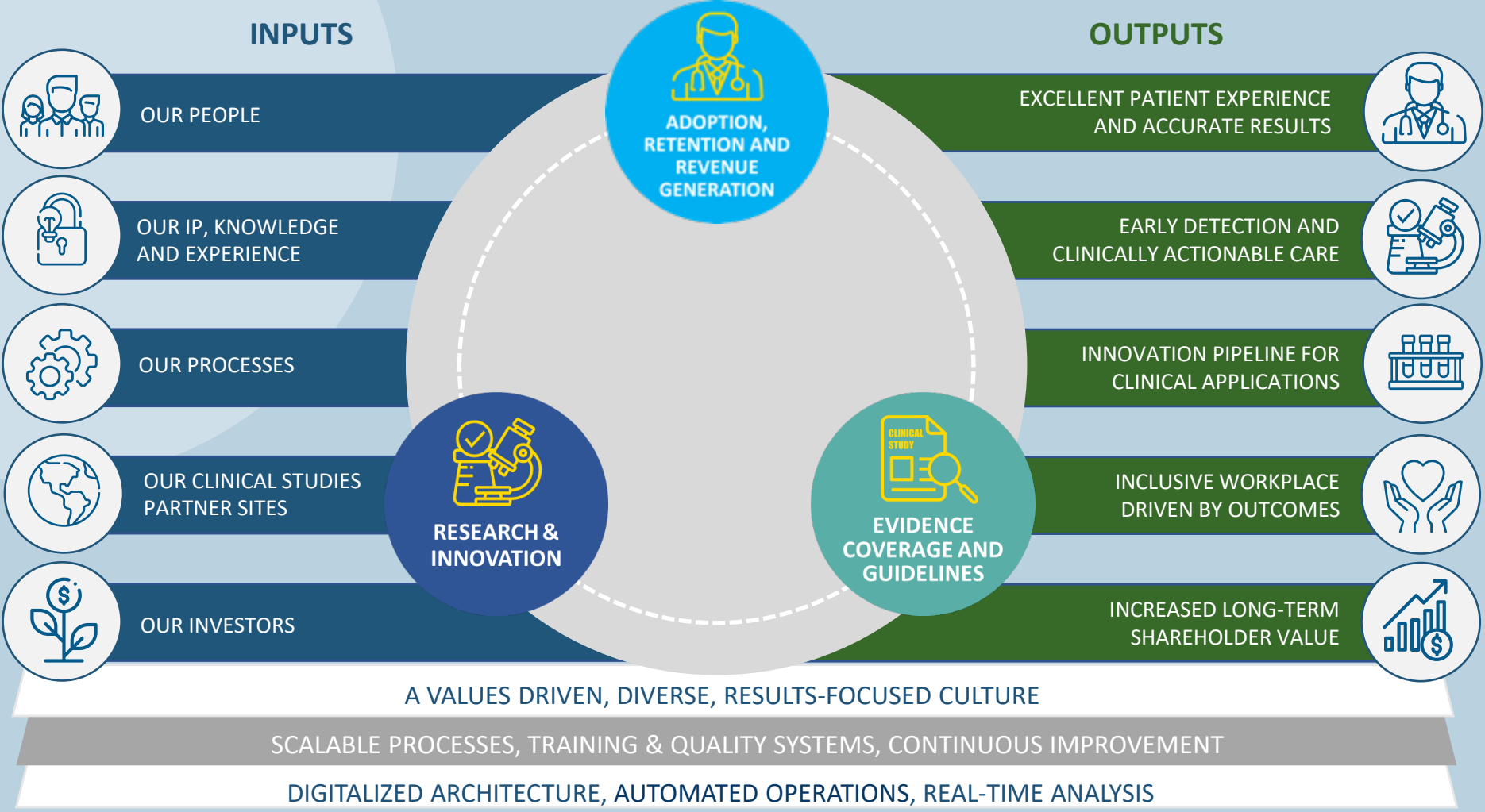
-  We are committed to customer success
-  We are guided by data and evidence
-  We support our teammates
-  We are transparent and trusting
-  We celebrate successes, large and small

## Our Sustainability Priorities:

 OUR SOCIAL IMPACT	 OUR ENVIRONMENTAL IMPACT	 OUR GOVERNANCE PRACTICES
Improving healthcare access, quality of care and patient outcomes	Product environment stewardship	Risk management
An inclusive, engaged and safe workforce	Emissions reduction	Operational quality and compliance
Responsible supply chain	Climate-related disclosures	Engaging our stakeholders
Supporting our communities		



# VALUE CREATION THROUGH THREE PILLARS





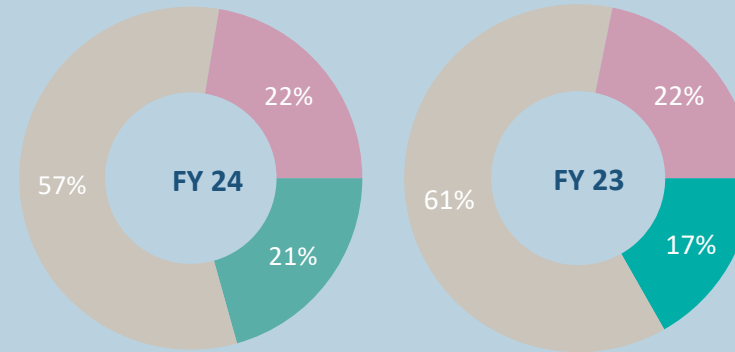
# GROWTH SLOWED AMID MEDICARE DRAFT



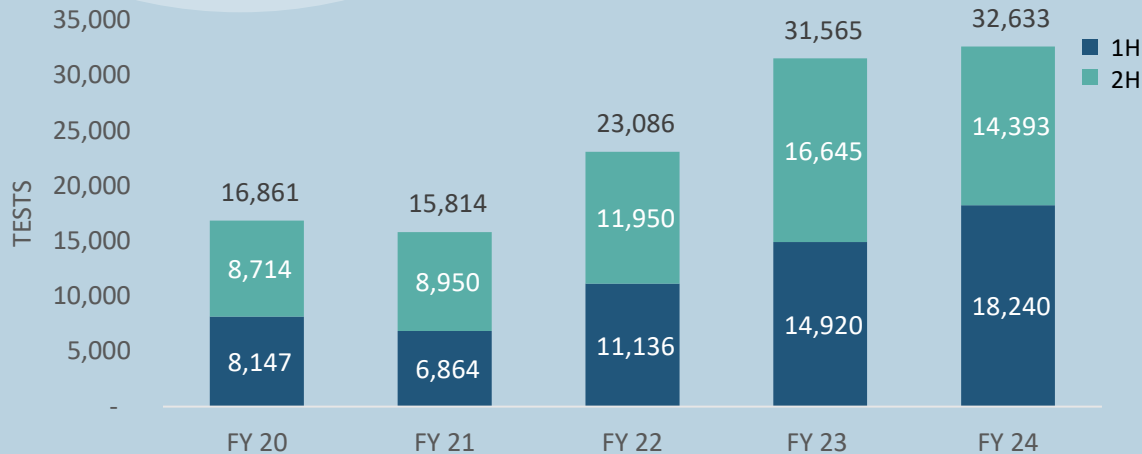
## FY 24 TOTAL LAB THROUGHPUT (TLT\*)

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

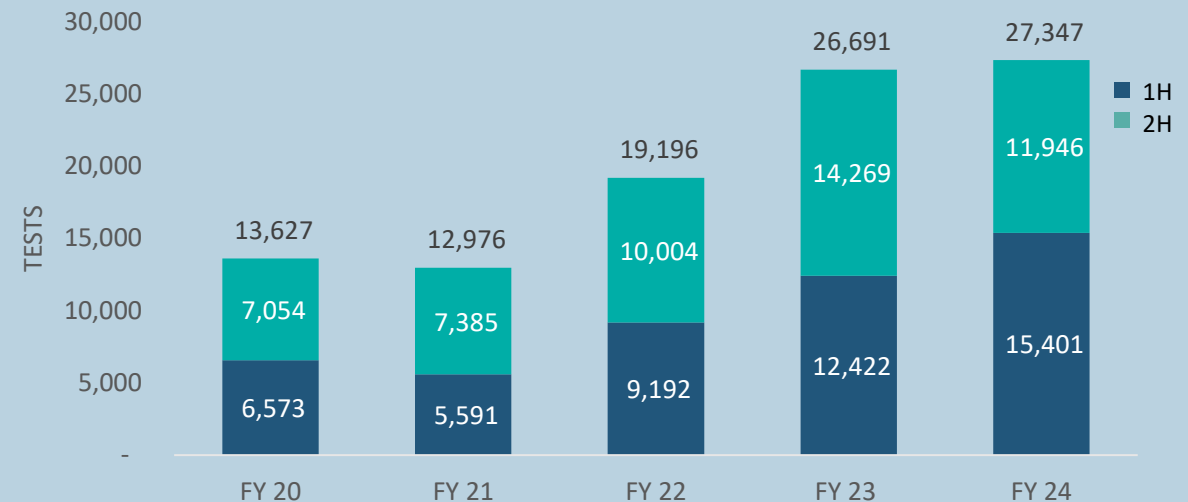
## TEST VOLUMES BY TYPE (TLT\*)



## GLOBAL TOTAL TEST VOLUMES (TLT\*)



## GLOBAL COMMERCIAL TEST VOLUMES (TLT\*)



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



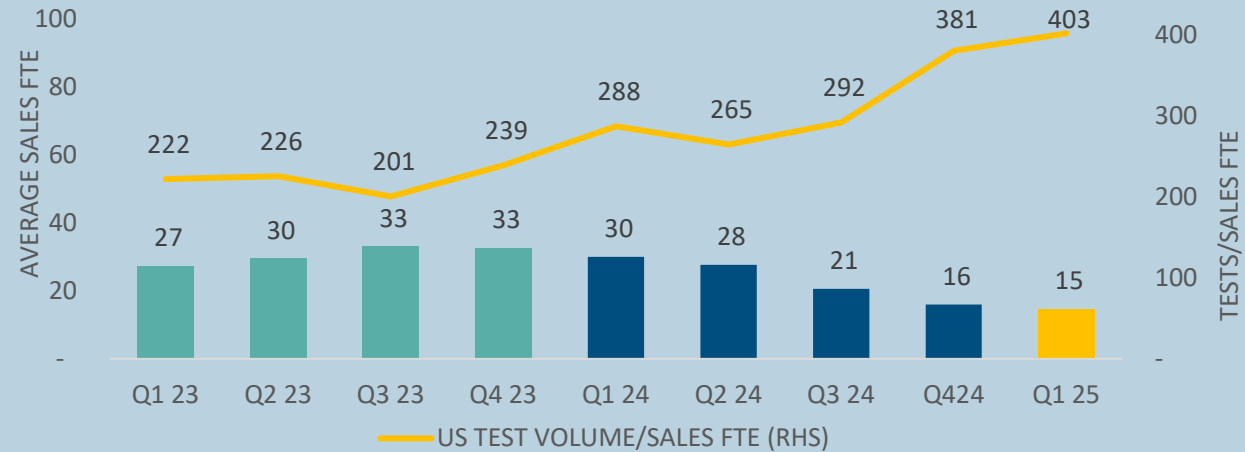
# FOUNDATIONS FOR GROWTH – US SALES TEAM PERFORMANCE IMPROVES

US SALES TEAM REDUCTIONS TO CONSERVE CASH DAMPEN VOLUME GROWTH IN FY24

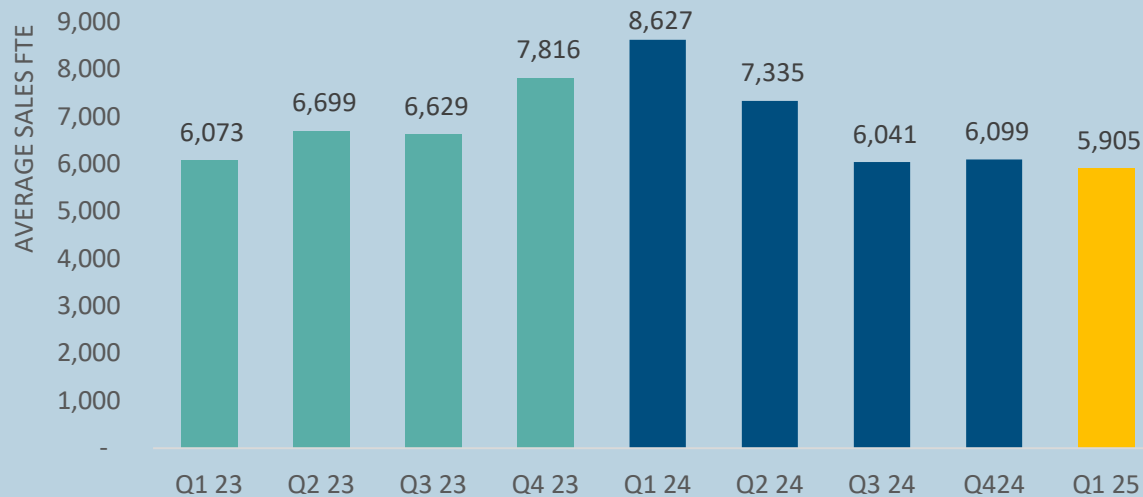


- Commercial volumes stabilizing with a focus on profitable sales territories and non-Medicare revenue streams (Kaiser Permanente and Veteran’s Affairs and others)
- Sales messaging focused on the clinical and economic value of Cxbladder
- KP volume stepped up after EMR integration, now growing steadily month on month (every month has been a record)
- Sales force efficiency (sales/FTE) has improved dramatically
- US clinical commitment (tests/clinician) steady, though ordering clinicians is lower due to reduced sales force reach

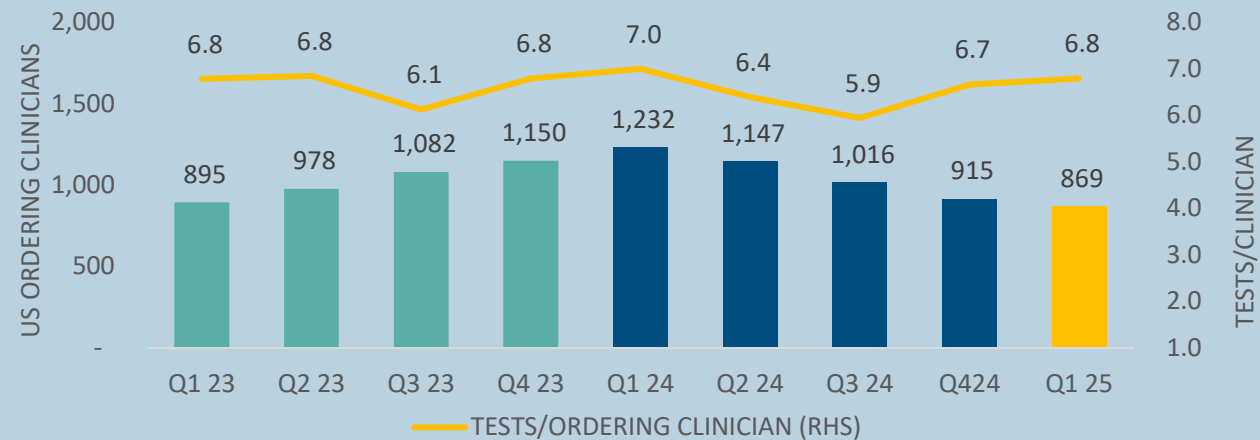
## US SALES FORCE EFFICIENCY



## US COMMERCIAL VOLUMES



## US CLINICAL COMMITMENT

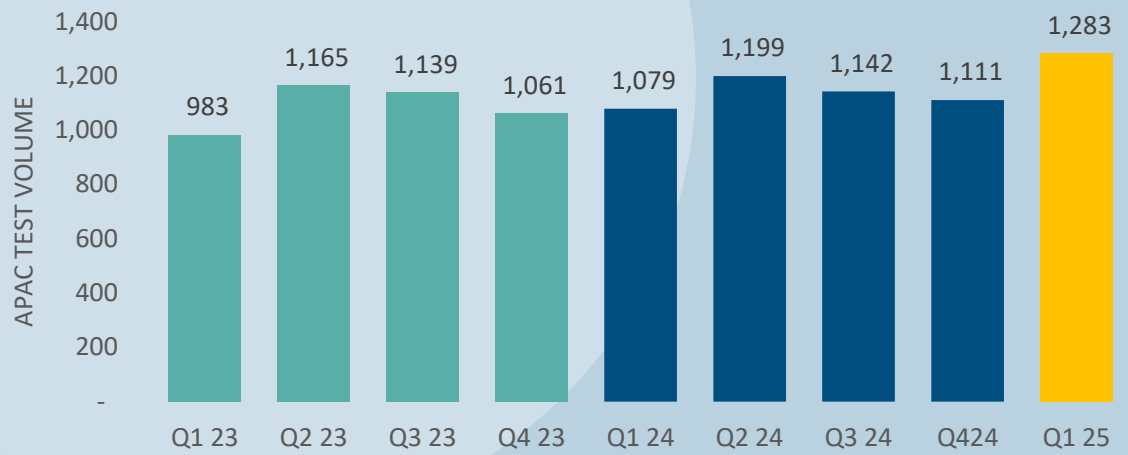




# DRIVING GROWTH IN ASIA PACIFIC AND CONSOLIDATING NEW ZEALAND



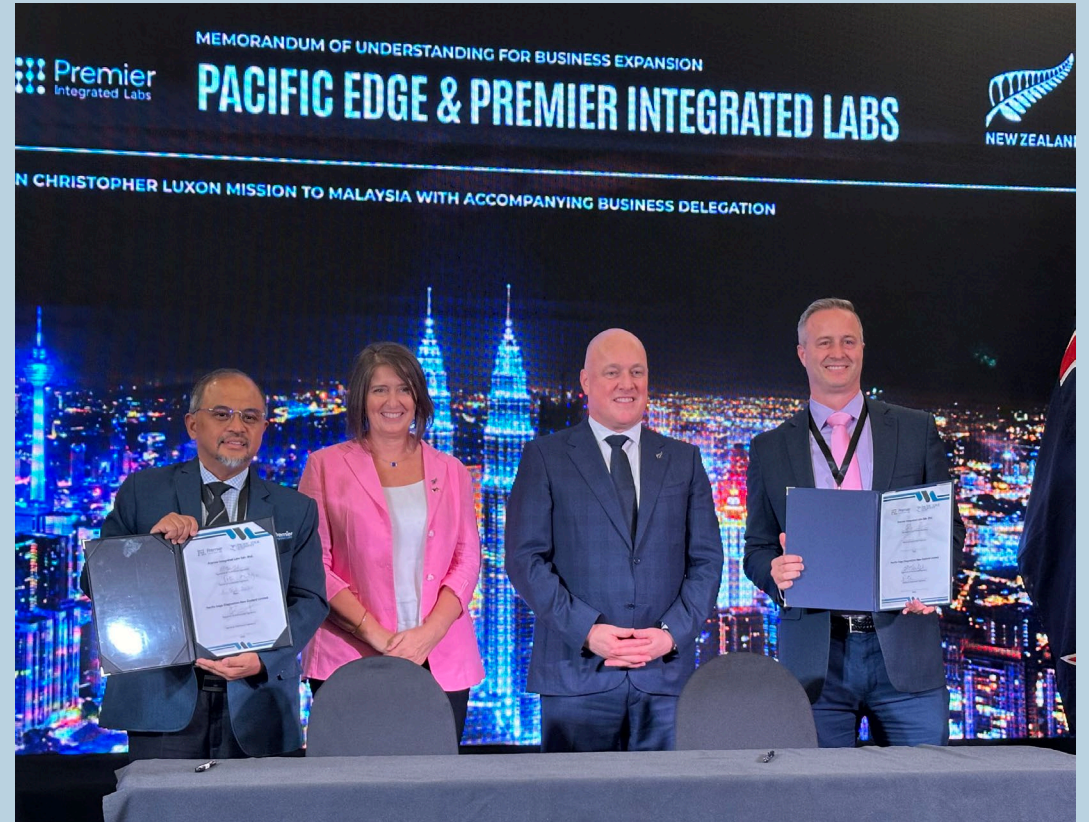
## APAC TOTAL TEST VOLUMES\*



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

## AUSTRALIA & ASIA PACIFIC

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



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

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



# EXTENDING OUR REACH THROUGH GLOBAL DISTRIBUTION AGREEMENTS





# STRATA<sup>1</sup> – THE STRONGEST EVIDENCE YET FOR GUIDELINES INCLUSION

A MILESTONE IN OUR DRIVE FOR MEDICARE COVERAGE CERTAINTY



## PARADIGM-SHIFTING STUDY DEMONSTRATES CLINICAL UTILITY OF TRIAGE

- STRATA is the first ever randomized controlled trial of a urine biomarker for hematuria evaluation:
  - This peer-reviewed study published in the AUA Journal of Urology<sup>1</sup> showed clinicians undertook 59% fewer cystoscopies, when provided a Cxbladder Triage test result
  - Seeking to leverage data to demonstrate the clinical utility of Detect<sup>+</sup>
- Publication submitted to Novitas as it considers finalization of draft LCD
- New evidence for inclusion in the Pacific Edge Clinical Dossier that we use to engage with guideline committees, private payors, government payers, value-based clinician groups and ex-US distributors
- STRATA data available to further improve the Detect<sup>+</sup> algorithm

## USING CLINICAL EVIDENCE TO DRIVE CXBLADDER ADOPTION



STRATA lead author Yair Lotan presenting STRATA to the 2024 AUA annual meeting.

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



American Urological Association



National Comprehensive Cancer Network®

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



# AUA HEMATURIA GUIDELINES – A COMPREHENSIVE REVIEW

AN APPROACH THAT SUPPORTS OUR DRIVE FOR GUIDELINE INCLUSION

- The AUA has commenced a review of the microhematuria guideline and has asked for professional comment on its initial draft; no timeframe provided
- Our Chief Medical Officer Dr Tamer Aboushwareb is participating in the consultation under confidentiality and with his conflict of interest documented – no disclosure to Pacific Edge or others is allowed
- The clinical utility of Cxbladder Triage demonstrated by the STRATA study is expected to be considered as part of the deliberations
- A positive AUA Journal of Urology editorial in July suggests favorable direction of travel
- Clear/positive inclusion language would be used as the basis for a Medicare coverage re-consideration request (in the event of a non-coverage determination)



American  
Urological  
Association

[www.auanet.org](http://www.auanet.org)

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

THE JOURNAL  
of UROLOGY®

[www.auajournals.org/journal/juro](http://www.auajournals.org/journal/juro)

Editorials

## What Is the Future of Cystoscopy for Detecting Urothelial Carcinoma?

Asymptomatic microscopic hematuria (AMH) is a common finding that leads to many urology referrals. Occasionally, patients with AMH harbor urothelial carcinoma of the bladder.

of 98.6% with about a third of patients testing negative. For the microscopic hematuria group only, the sensitivity was 100%. The new...

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

– Journal of Urology editorial, July 2024





# 'GENETIC TESTING FOR ONCOLOGY' LCD PROCESS EXTENDED

CMS<sup>1</sup> APPROVED THE EXTENSION TO GIVE NOVITAS<sup>1</sup> TIME TO RESPOND TO ALL COMMENTS

## EXTENSION INCREASES CONFIDENCE TOWARDS MEDICARE COVERAGE CERTAINTY

- Cxbladder continues to receive reimbursement from Medicare and Medicare Advantage payers in line with historical reimbursement rates
- We are increasingly confident that STRATA<sup>2</sup> is being considered as part of Novitas deliberations
- We are seeking to publish new and independent evidence to support coverage in the coming months
- Pacific Edge continues to engage with Novitas and CMS with the support of professional societies, industry partners, clinicians and patient advocacy groups



## MEDICARE IS PACIFIC EDGE'S LARGEST PAYER

- Medicare and Medicare Advantage is the largest global opportunity in bladder cancer diagnostics from a single coverage decision
- In FY 24 Medicare and Medicare Advantage delivered ~14,000 commercial tests (~60% of US commercial tests) and ~\$17.0m NZD in total operating revenue (~71% of total operating revenue)



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

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



# CLINICAL EVIDENCE CATALYSTS FOR COVERAGE CERTAINTY



## MEDICARE RECONSIDERATION AND GUIDELINE INCLUSION REQUESTS

(Novitas<sup>1</sup> typically handles reconsideration requests on existing LCDs within three months of submission)

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

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

<sup>2</sup> AV, CV CU, respectively Analytical Validity, Clinical Validity, Clinical Utility

<sup>3</sup> All dates are calendar year rather than financial year and our best current estimates

<sup>4</sup> RWE is Real World Evidence

<sup>5</sup> Timeline determined by Kaiser Permanente

<sup>6</sup> The pooled analysis brings together data from DRIVE, AUSSIE and microDRIVE

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

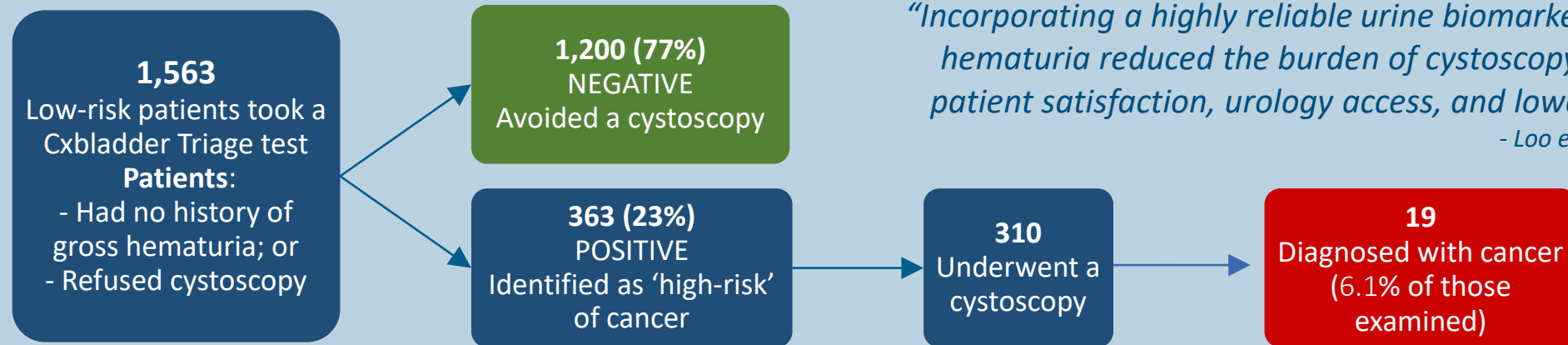
# INDEPENDENT REAL-WORLD EVIDENCE OF CXBLADDER'S CLINICAL UTILITY

## CLINICAL UTILITY EVIDENCE OF CXBLADDER TRIAGE THAT SUPPORTS MEDICARE COVERAGE



### KAISER PERMANENTE ABSTRACT SHOWS CLINICAL VALUE IN REAL WORLD SETTING

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



*“Incorporating a highly reliable urine biomarker into clinical workflows for hematuria reduced the burden of cystoscopy substantially, improving patient satisfaction, urology access, and lowering overall cost of care,”*  
- Loo et al (2024)<sup>1</sup>

<sup>1</sup> Real World Clinical Utility of a Urinary Biomarker (Cxbladder Triage) for Hematuria Referrals in an Integrated Managed Care Health System. Abstract accepted for presentation to the Western Section of the American Urological Association annual conference.



# STRATEGIC RESPONSES TO THE IMPENDING MEDICARE DETERMINATION

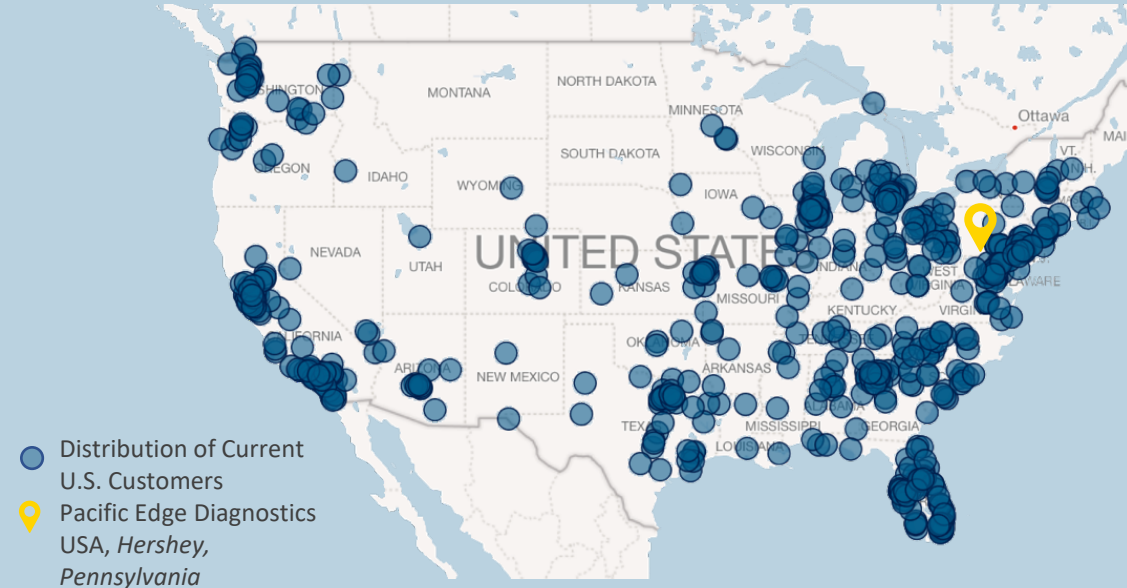


## OUR RESPONSE TO AN AFFIRMATION OF COVERAGE

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

## OUR RESPONSE TO A LOSS OF COVERAGE

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



## LONG TERM VALUE CREATION STRATEGIES WILL CONTINUE

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



# RESEARCH & INNOVATION – FOCUSED ON DNA ENHANCED PRODUCTS



## READYING FOR THE LAUNCH OF DETECT<sup>+</sup> AND MONITOR<sup>+</sup>

- Ensure R&D, Digital and Lab Operations focus on the launch of Detect<sup>+</sup> and Monitor<sup>+</sup>
- Simplifying Cxbladder:
  - Aim to reduce technician time, lower cost of goods, lower turnaround time, increase throughput and increase automation
  - Aim to be IVD-ready with “kittable” Cxbladder tests for decentralized deployment for international market expansion
  - Analytical Validation (AV) of automated end-to-end lab operations for RNA and DNA workflows.
  - AV data for the automated Cxbladder (Triage, Detect and Monitor), i.e. RNA is now published<sup>1</sup>
- Establish in-vitro diagnostic (IVD) regulatory framework for R&D of our next generation tests
- Continued engagement with industry and academic research and development collaborations to address unmet clinical needs in bladder cancer diagnosis and management



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

1. Harvey et al (2024). Analytical Validation of Cxbladder<sup>®</sup> Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. *Diagnostics*. 2024; 14(18):2061. <https://doi.org/10.3390/diagnostics14182061>



# PACIFIC EDGE USA - OPERATIONS

**DAVID LEVISON**  
President  
Pacific Edge Diagnostics USA



**PACIFIC EDGE**  
CANCER DIAGNOSTICS COMPANY

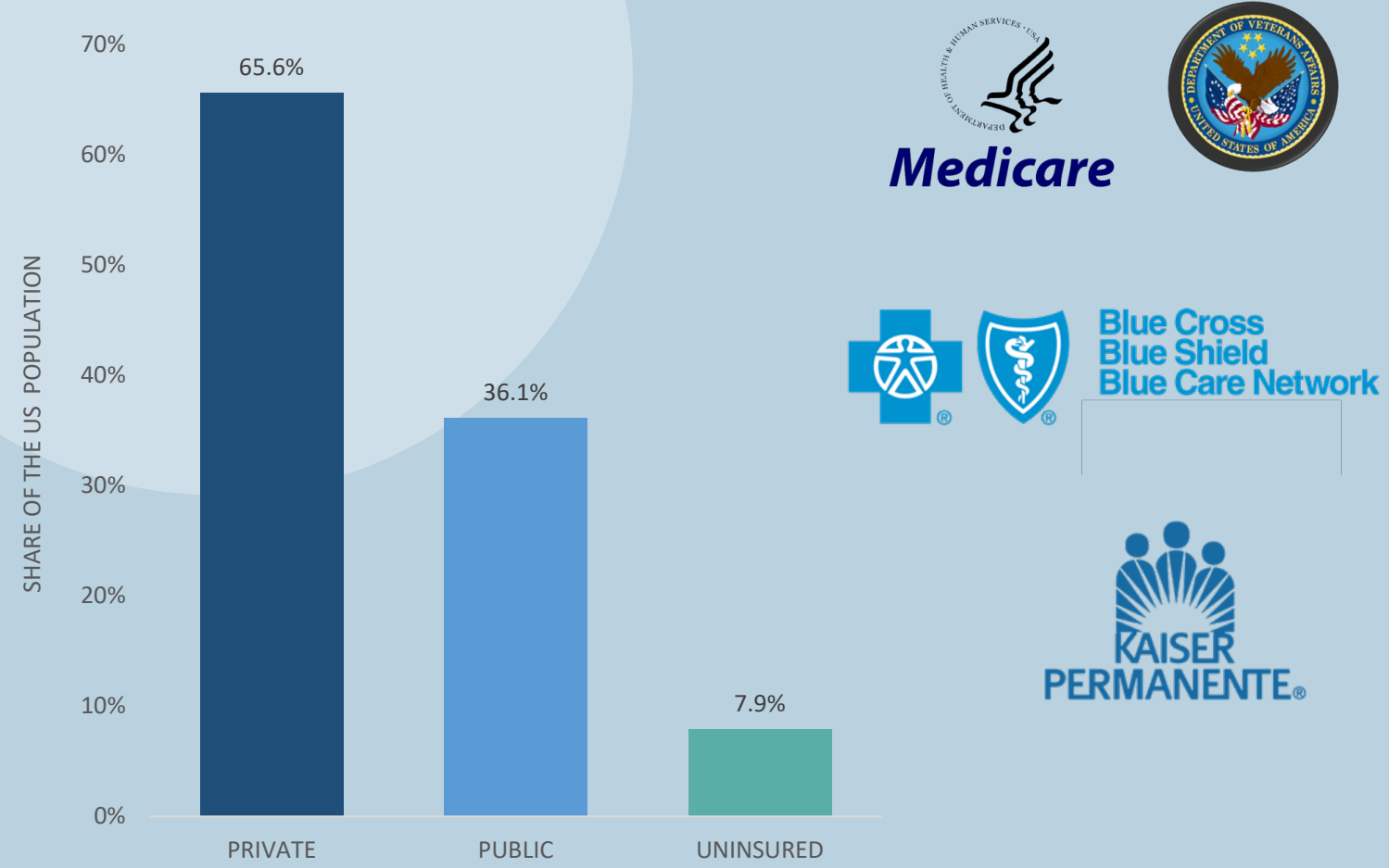


# MEDICARE & MEDICAID – THE LARGEST VOLUME FROM SINGLE DECISION

HEALTH INSURANCE IN THE US MARKET – SERVING 335 MILLION PEOPLE<sup>1</sup>



## US HEALTH INSURANCE COVERAGE<sup>1</sup>



### PUBLIC FUNDED INSURANCE:

Medicare, Medicaid, Veterans Admin, etc.

- Limited options for plan design
- Little or no out of pocket expense for patient
- Coverage decisions decentralized

### COMMERCIAL INSURANCE

Preferred Provider Organizations (PPO)

- Cigna, United Health, Aetna, Blue Cross Blue Shield
- Wide choice of plan designs
- Wide choice of physicians and services
- Wide variance in cost to patient

Health Maintenance Organizations (HMO)

- Kaiser, Geisinger, Intermountain Health
- Kaiser is a capitated HMO
- Limited plan designs and services offered
- Must use specific clinicians
- Lower cost to patient, often fixed costs

1. United States Census Bureau



# FOCUSING OUR EFFORTS ON CONCENTRATIONS OF DEMAND

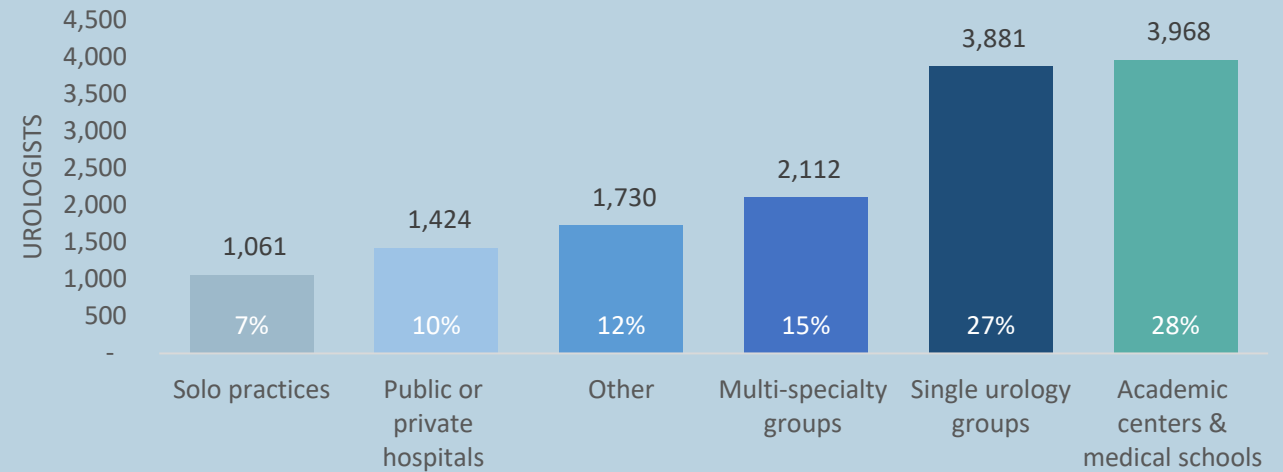


## HOW THESE MARKET FEATURES INFLUENCE OUR EFFORTS

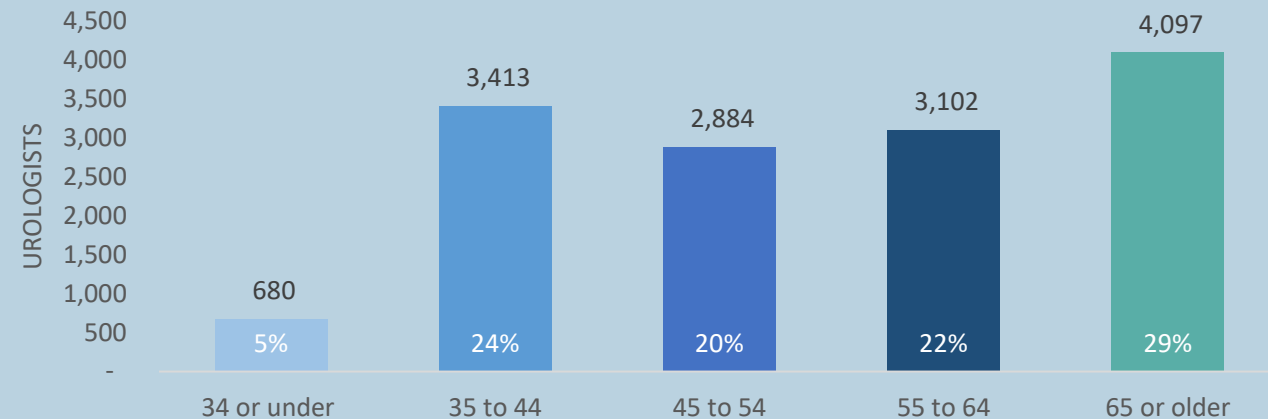
- We serve a population of 14,176 US practicing urologists<sup>1</sup>
- >60% of those urologists practice in small, private groups
- Consistent clinical education is key to developing lasting clinical patterns
- Improving patient workflow / office efficiency drives demand and stickiness
- Macro trends are highlighting the need for less invasive treatment options



## UROLOGISTS PLACE OF WORK<sup>1</sup>



## UROLOGISTS AGE<sup>1</sup>



1. AUA Census 2023

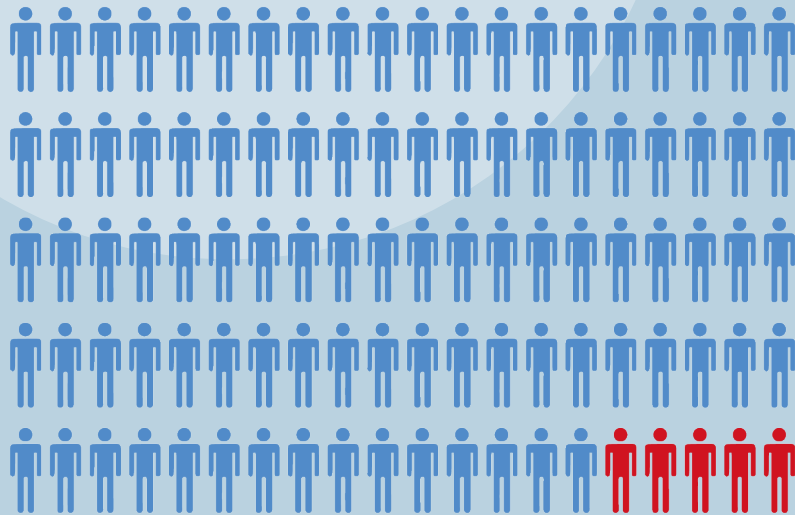
# SELLING CXBLADDER'S CLINICAL, ECONOMIC AND PATIENT VALUE



*For clinicians and patients, Cxbladder offers better care, avoids unnecessary procedures & improves workflow. For healthcare payers it offers substantial total cost savings per patient when used to intensify or de-intensify hematuria evaluation<sup>1</sup>*

## CURRENT PRACTICE (AUA GUIDELINES)

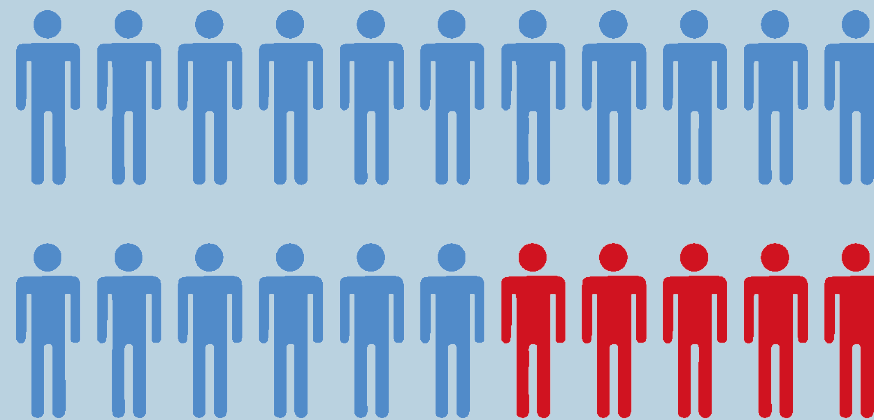
5% of patients with Microhematuria have Urothelial Cancer:  
Must do 100 cystoscopies to find 5 cancers



■ Normal (95%) ■ Cancer (5%)

## CXBLADDER DETECT INTRODUCED TO STANDARD OF CARE

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



■ Normal (77.3%) ■ Cancer (22.7%)

Pacific Edge modelling<sup>1</sup> suggests avoided procedures could save >US\$500 per patient with microhematuria

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



# PACIFIC EDGE USA FUNCTIONAL CAPABILITIES

ACTIVITIES THAT TRAVERSE SALES AND MEDICAL AFFAIRS TO LAB OPERATIONS



## MEDICAL AFFAIRS

- Clinical education
- Sales support



## SALES

- Growing test volume
- Direct customer engagement



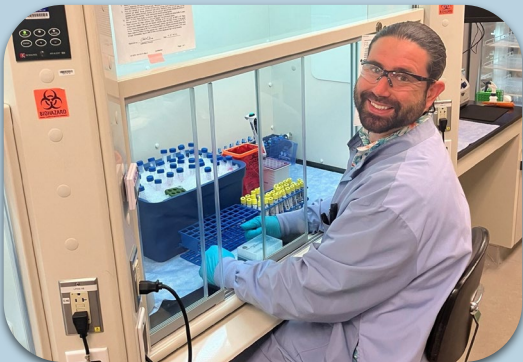
## MARKETING

- Sales support
- Conference planning
- Product management



## CUSTOMER CARE

- Issue resolution
- Logistics
- Administration



## LAB OPERATIONS

- Sample management and processing
- Quality and regulatory management



## MARKET ACCESS AND REIMBURSEMENT

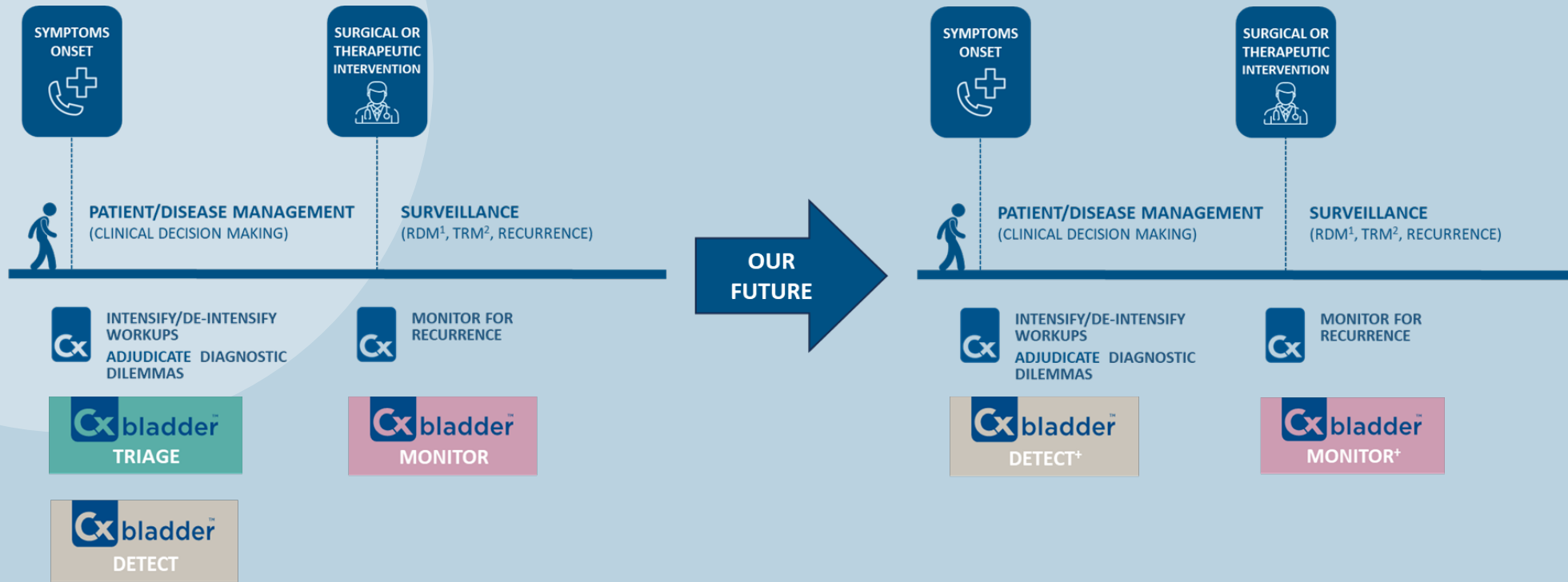
- Revenue cycle management
- Payor relationships

## AN AVERAGE WEEK

- ~1,000 direct sales interactions
- 400-500 samples processed
- 5-10 Medical Affairs educational sessions with clinicians
- Customer care issues managed with ~300 phone calls and emails

# SIMPLIFYING THE CXBLADDER VALUE PROPOSITION – DETECT+ & MONITOR+

ADDITION OF DNA BIOMARKERS ENHANCES TEST PERFORMANCE<sup>3</sup>



Performance <sup>3</sup>	Sensitivity	Specificity	NPV	PPV	ROR
<b>CxbDetect+</b>	97%	90%	99.7%	44%	83%
<b>CxbTriage</b>	89%	63%	99%	16%	59%
<b>CxbDetect</b>	74%	82%	97%	25%	78%

## HEMATURIA EVALUATION TEST PERFORMANCE

The improved performance characteristics of Detect+ mean it can do the job of Triage (a negative test rules out the presence of urothelial cancer) and Detect (a positive test suggests a higher probability of cancer and justification for an intensification of a urologic workup)

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

# PREPARING FOR DETECT+ COMMERCIALIZATION

EXPANDING AND EXTENDING OUR LEADERSHIP POSITION IN HEMATURIA EVALUATION

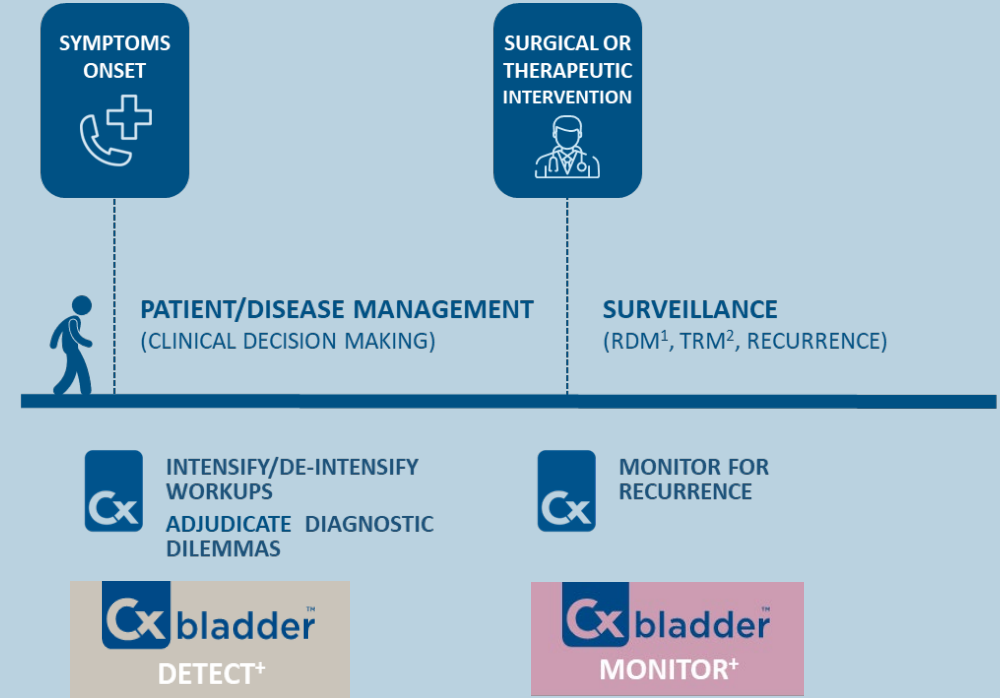


## ESSENTIAL PRE-CONDITIONS TO LAUNCHING DETECT+

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

## COMMERCIAL PREPARATORY WORK

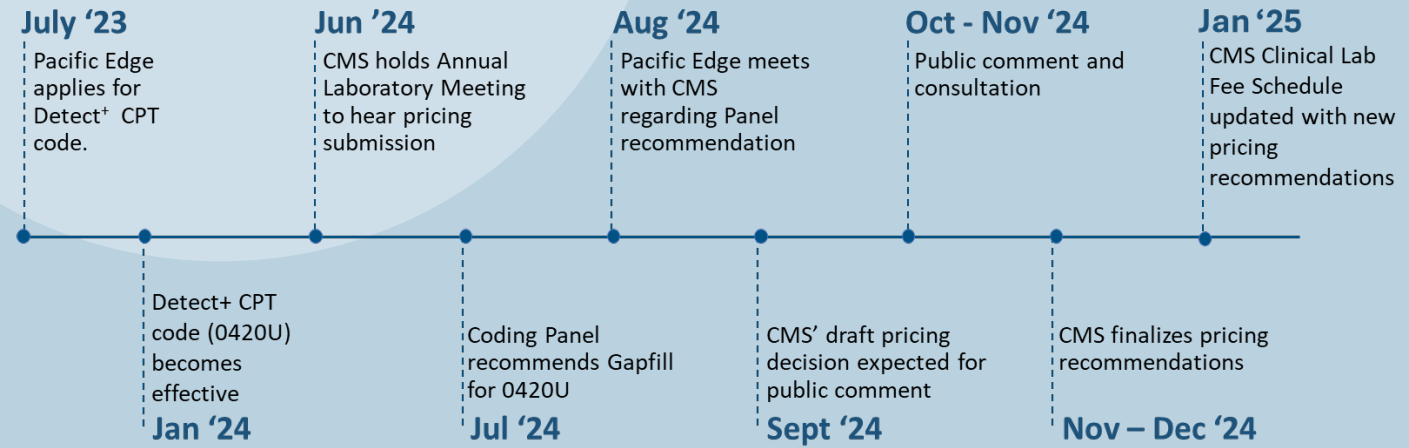
- Driving for coverage and reimbursement of Detect+
- Adding capabilities and capacity to PEDUSA laboratory
- Simplifying laboratory workflow for improved efficiency
- Optimizing sales team structure for expanded product adoption
- Preparing sales and marketing training materials
- Enhancing medical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





# DETECT+ PRICING STANDS TO BOLSTER PACIFIC EDGE'S ECONOMICS

PRICING OF DETECT+ IS THE NEXT STEP IN THE COMMERCIALISATION PROGRAM



- Pricing of Detect+ is the next step in establishing reimbursement
- The Crosswalk strategy for pricing of Detect+ is based on technological similarities to previously priced tests:
  - Existing CMS price for Cxbladder (\$760) is the best reference for RNA components of Detect+
  - A highly-similar match for the DNA/ddPCR component has been identified at \$1,800
- Based on this approach we are seeking a Crosswalk price of US\$2,560 with CMS
- If CMS disagree with the Crosswalk candidate and prefer Gapfill, we will seek a 'provisional local price' for Detect+ from Novitas and follow the Gapfill process
- Gapfill requires all MACs to recommend a price and takes 12 months to finalize

Anticipated timeframe for Detect+ pricing - dates may change



# STRENGTHENING OUR CUSTOMER EXPERIENCE

## DRIVING 'STICKINESS' AND LONG-TERM MARKET SHARE



### THE BEST AND MOST CUSTOMER-FRIENDLY TEST

- Give customers options to connect with Pacific Edge to fit their needs with easy-to-use digital workflows
  - Electronic Medical Record (EMR) integrations
  - Pacific Edge Customer Portal
  - Pathology Lab LIS integrations
- Improvement of end-to-end experience for patients and providers



### INTEGRATED HEALTHCARE – THE POTENTIAL LONG-TERM OPPORTUNITY

PATIENT JOURNEY	PRE-APPOINTMENT	PHYSICIAN EVALUATION	TEST ORDERING <sup>1</sup>	INSURANCE COVERAGE	APPOINTMENT SCHEDULING	RECEIVING RESULTS <sup>1</sup>	ONGOING SURVEILLANCE
<b>PATIENT BENEFIT</b>	Pre-visit screening questionnaire	Facilitates communication of treatment options	Real time information on test ordering and sample collection	Informed on medical coverage, deductibles and copays	Scheduling of sample collection in home or in lab	Results notified	Scheduling future recurring appointments
<b>HEALTH PROVIDER BENEFIT</b>	Identify testing eligibility for patients New result/info incorporated into EMR automatically	Physician prompts (e.g. smoking history)	No additional data entry for paperless test ordering	Informed on medical coverage, deductibles and copays	Scheduling, compliance and follow up	Results notified. Next steps identified	Appointments, compliance and follow up

1 – Current areas of functionality where Pacific Edge provides a digital experience to physicians and patients



# OUR CUSTOMER PORTAL – STREAMLINING THE CUSTOMER EXPERIENCE



Step into a world of  
**convenience** with our portal

Please click the image above to launch the customer portal video





# EMR SUPPORTING ADOPTION AT KAISER PERMANENTE



The screenshot displays the EMR interface for a patient named Benefitstwo, Fifty R. The top section shows the patient's name and a visit date of 1/17/2023. Below this, there are various tabs and sections for medical history, including 'Evaluate Dx', 'Vitals', 'Allergies', and 'Diagnoses'. A prominent window shows the results of a 'BLADDER CANCER SURVEILLANCE PANEL' test. The test result is categorized as 'Normal' and includes a 'Study result' section with a 'Narrative' and 'Component results' table.

Component	Your value	Standard range
BLADDER CANCER MRNA MONITOR TEST SCORE, URINE	3.4	<3.5

The 'Narrative' section provides an interpretation: 'Low Probability of recurrent urothelial carcinoma (UC) 97% NPV'. The 'Assay Description' explains that the test is a quantitative assay for recurrent UC that combines the gene expression from five mRNA biomarkers (CDK1, MDK, IGF1BP5, HMOX1S, and CXCR2) as measured by reverse transcription quantitative polymerase chain reaction (RT-qPCR).

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

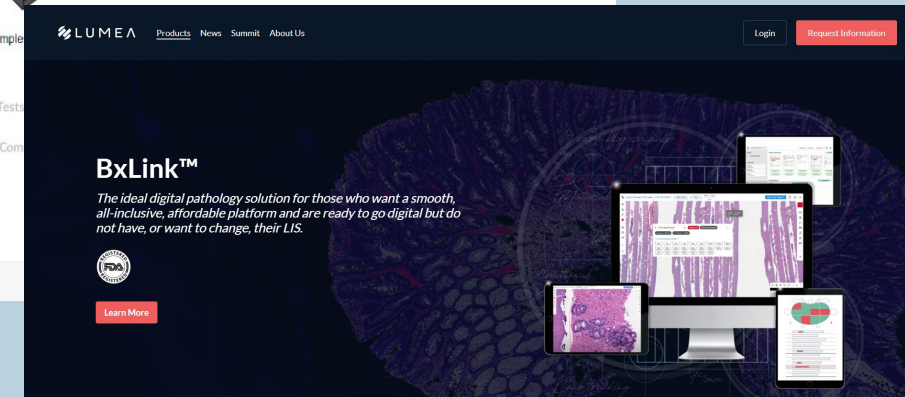
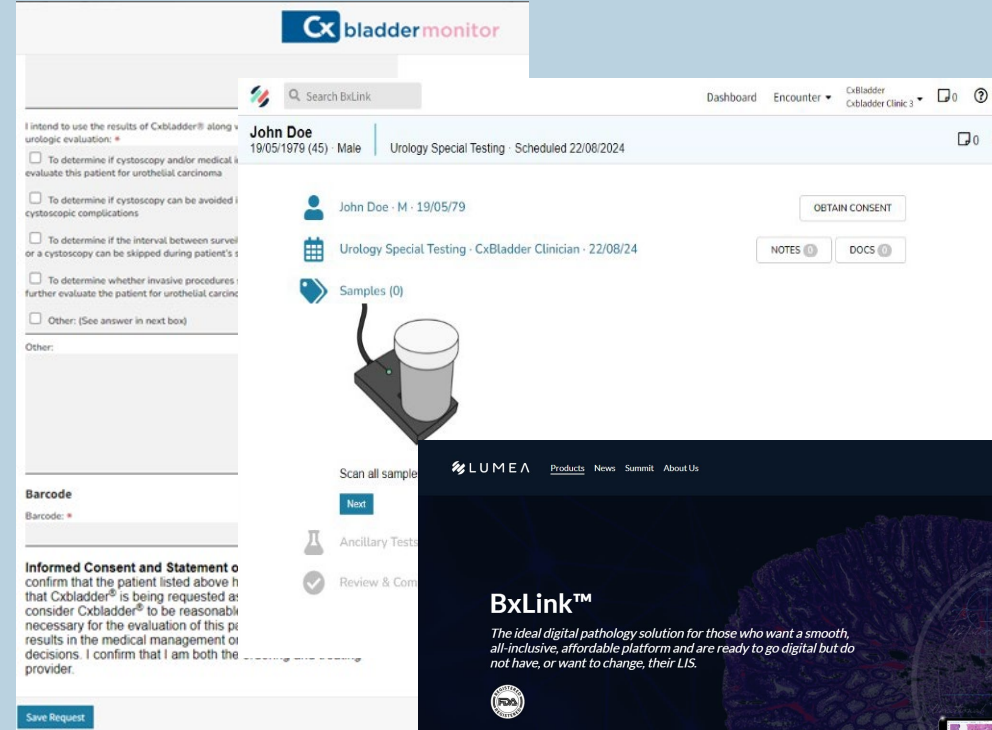


# LUMEA – ESTABLISHING DIGITAL LINKS WITH 450 CLINICS

## ALIGNING OUR SYSTEMS WITH PRE-EXISTING EMRS AND CUSTOMER PORTALS



- Lumea BxLink is a Digital Pathology Lab Information System for pathology labs that is integrated with approximately 450 clinics (not all of which are urology)
- Approximately 200 of these clinics have previously ordered a Cxbladder test
- BxLink is a Digital Pathology solution for those who do not want to change their LIS<sup>1</sup>
- By integrating with BxLink, Pathology Labs can offer their customers the option to order a Cxbladder test from their EMR or from BxLink
- The integration went live on 12 September US time and is following a phased rollout plan
- The integration gives clinics the ability to electronically order the Cxbladder tests and have the results returned as part of the patient record in the EMR
- We expect the integration to result in a greater market adoption and greater ordering stickiness by improving customer experience and reducing barriers to adopt



# STRENGTHENING OUR FOUNDATIONS – OPERATIONAL EXCELLENCE



## DIGITALIZATION, AUTOMATION & CUSTOMER EXPERIENCE

### *Readying our operations to scale*

- Improve Lab Operations and Customer Service with focus on increasing automation and reducing turn around time
- An operational plan to scale to more than 250k samples after gaining Medicare certainty and guidelines inclusion:
  - Investing in people with more recruiting, training and professional development
  - Optimizing equipment utilization with swing shifts, second shifts and extra lab operating days
  - Product development to accommodate increase in throughput/FTE
  - Supply Chain review to drive down COGS, reduce wastage and shorten lead times

### *Data Management and Digital Information infrastructure*

- 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







# OUR CLINICAL RESEARCH PROGRAM

**Dr TAMER ABOUSHWAREB**  
Chief Medical Officer  
Pacific Edge Diagnostics USA



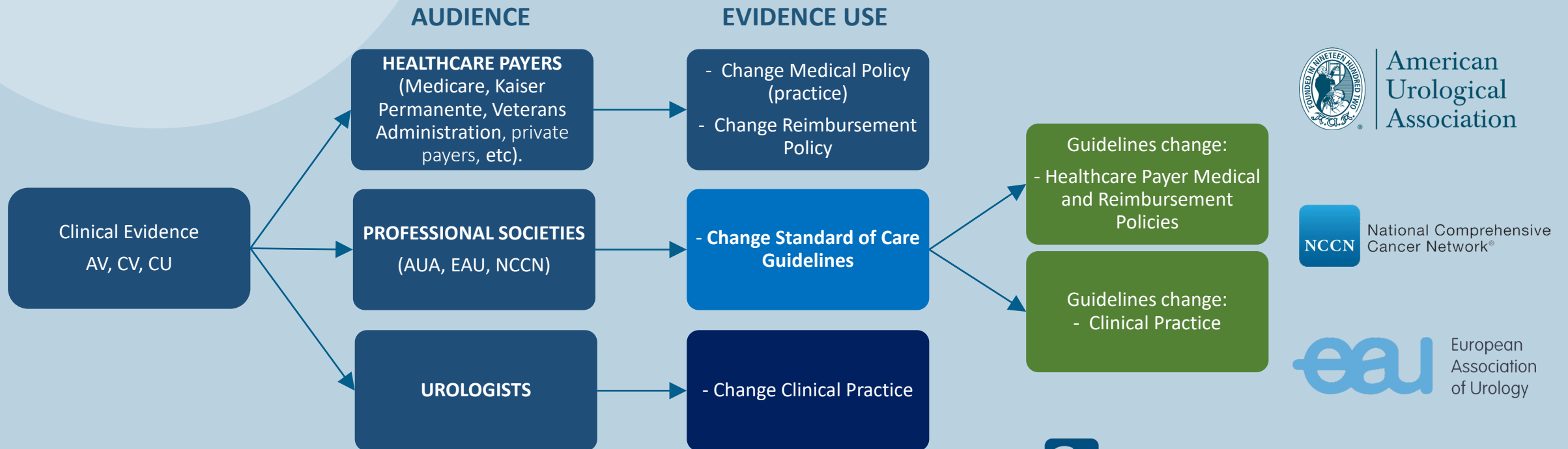
**PACIFIC EDGE**  
CANCER DIAGNOSTICS COMPANY

# PACIFIC EDGE'S EVIDENCE PROGRAM SEEKS TO CHANGE CLINICAL PRACTICE



## STRUCTURED CLINICAL EVIDENCE DEVELOPMENT

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



# FOCUSED ON CLINICAL EVIDENCE FOR DETECT+ AND MONITOR+

DELIVERING CLINICAL EVIDENCE THAT DRIVES BEHAVIOR CHANGE AND GUIDELINES INCLUSION



EVIDENCE STANDARD DEMONSTRATED <sup>1</sup>			
TEST	ANALYTICAL VALIDITY	CLINICAL VALIDITY	CLINICAL UTILITY
Cxb Triage	√	√	√
Cxb Detect	√	√	√
Cxb Monitor	√	√	√
Cxb Detect+			
Cxb Monitor+			

*NOTE: The evidence standard may have been demonstrated in one or multiple publications*

## PROGRAM TARGETS CU AND CV OF DETECT+

- Cxb Triage, Detect and Monitor are already well established in clinical practice
- Our Clinical Dossier becomes increasingly impactful with higher grades of evidence, e.g. CU evidence from randomized control trials like STRATA
- The evidence generation program is now weighted to demonstrating the CV and CU of Detect+ for the risk stratification of hematuria patients
- CV evidence for Detect+ will be established with DRIVE, AUSSIE & microDRIVE
- Concordant CU for Detect+ can be demonstrated by comparison with Triage:
  - Concordance study (direct comparison of performance characteristics in identical clinical conditions)
  - Shared clinical pathway
  - Superior performance characteristics
  - Targeting completion in Q2 2025
- CREDIBLE to deliver 'level 1' CU evidence of Detect+ as a gold-standard, standalone, randomized control trial to strengthen the evidence to support guideline inclusion
- Monitor+ (surveillance) is in the early stages of development and requires more time to generate the requisite evidence for adoption and guidelines

1. For detail of the studies and timelines to completion please see the appendix to this presentation



# PACIFIC EDGE'S PROGRAM SUPPLEMENTED BY INDEPENDENT RESEARCH



## INDEPENDENT STUDIES UNDERWAY

STUDY	INSTITUTION/LOCATION	TEST AND EVIDENCE STANDARD	EXPECTED PUBLICATION
Patient preference and satisfaction of “bio-markers vs cystoscopy”	Mayo Clinic, US	Monitor – CU	2025
Review of the Canterbury experience of Cxbladder Triage in the primary care setting	Canterbury DHB, New Zealand	Triage – CU (RWE)	2025
Can biomarkers (Detect <sup>+</sup> ) be used to screen patients at risk for bladder cancer	UT Southwestern, US	Detect <sup>+</sup> – CU	2027
Can biomarkers (Monitor) be used to report on therapy success in a reduced chemotherapy protocol for the management of upper tract tumors	Israel Institute of Technology, Israel	Monitor – CU Monitor <sup>+</sup> – CU	2027
Can Cxbladder monitor be used to assess response to BCG in high grade UC patients	University of Miami, US	Monitor – CU Monitor <sup>+</sup> – CU	2027
Can Cxbladder be used for surveillance of muscle invasive bladder cancer patients treated with bladder sparing methods. (PRESERVE Trial)	Cleveland Clinic, US	Monitor – CU Monitor <sup>+</sup> – CU	2028
A Randomized Trial of Apalutamide in Non-Muscle Invasive Bladder Cancer	National Institutes of Health, US	Monitor – CU Monitor <sup>+</sup> – CU	2029

## INVESTIGATOR INITIATED TRIALS (IITS)

- IITs extend the Cxbladder clinical dossier with evidence for new indications of existing tests that may inform new ‘core’ clinical trials
- IITs are independent but we offer support from study conception through to publication. We may provide free testing and some other support for the basic needs of the study
- IITs are a part of KOL engagement and lead to publications or podium presentations that give profile to Cxbladder and Pacific Edge
- The costs to Pacific Edge are low - typically no more than the cost of running the tests in our lab

# ENGAGING KEY OPINION LEADERS FOR CLINICAL EXCELLENCE AND ADVOCACY



- Managing Key Opinion Leaders is a core responsibility of the Medical Affairs Team
  - All members of the team are non-practicing physicians, or have similar qualifications like PhDs in biology or a Pharm D
- We engage our KOLs to:
  - Review protocols of our clinical trials
  - Advocate for our product's inclusion into guidelines based on the published clinical evidence
  - Provide guidance informally as part of routine business
  - Provide guidance formally as part of our Clinical Advisory Board (CAB)
  - Speak to other physicians on our behalf as speakers in our Speakers Bureau
  - Lead a clinical trial site (core evidence generation, ITTs, registries)
  - Author research publications on basic science or health economics



# KEY CLINICAL ADVISORS AND CONSULTANTS



## Professor Yair Lotan, MD

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



## Professor Sam Chang, MD, MBA

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



## Assistant Professor John Sfakianos

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



## Professor Dan Barocas, MD, MPH, FACS

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



## Associate Professor, Siamak Daneshmand, MD

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



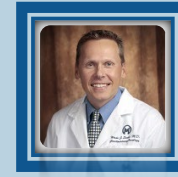
## Associate Professor Katie Murray, DOMS, FACS

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



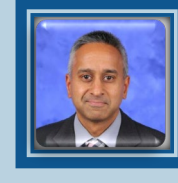
## Professor Jonathan Wright, MD, MS, FACS

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



## Professor Wade Sexton, MD

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



## Professor Jay Raman, MD

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



## Associate Professor Kristen Scarpato, MD, MPH, FACS

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

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

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







**Dr PETER MEINTJES**  
Chief Executive Officer

# SUMMARY AND OUTLOOK: READY FOR ALL OUTCOMES

- We continue to manage our cash prudently while we establish coverage certainty
- We will continue to:
  - Preserve reimbursement of our existing portfolio of tests
  - Focus on the clinical development of Detect<sup>+</sup> and Monitor<sup>+</sup> for guidelines inclusion and increased coverage certainty
  - Focus our commercial operations on profitable territories, non-Medicare revenue streams and cash collections
  - Emphasize the clinical and economic value of Cxbladder in our sales messaging

## HEADWINDS:

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

## CATALYSTS:

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



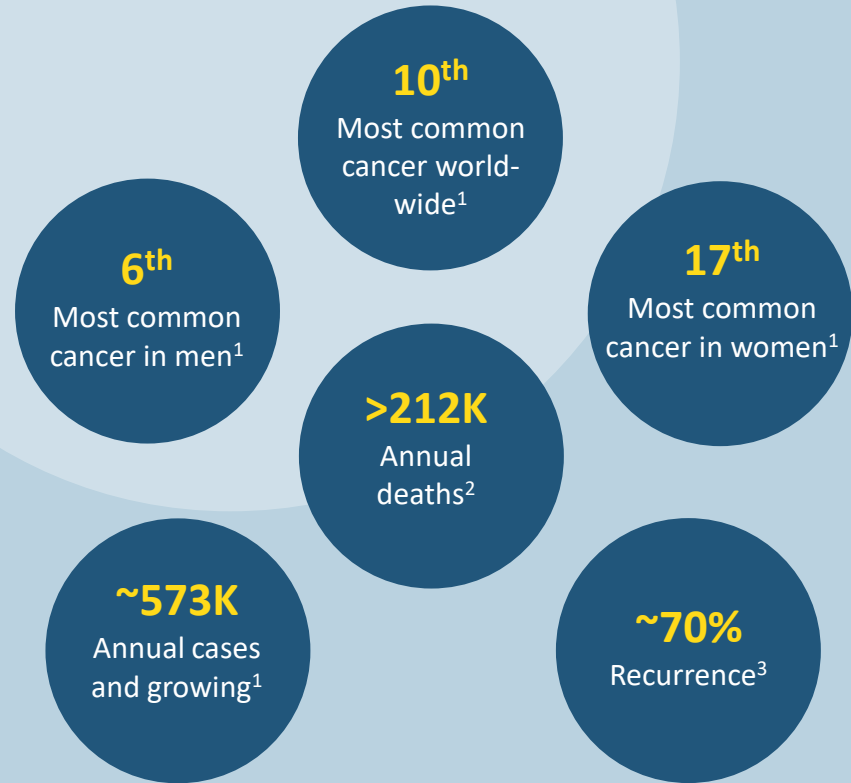
# APPENDIX





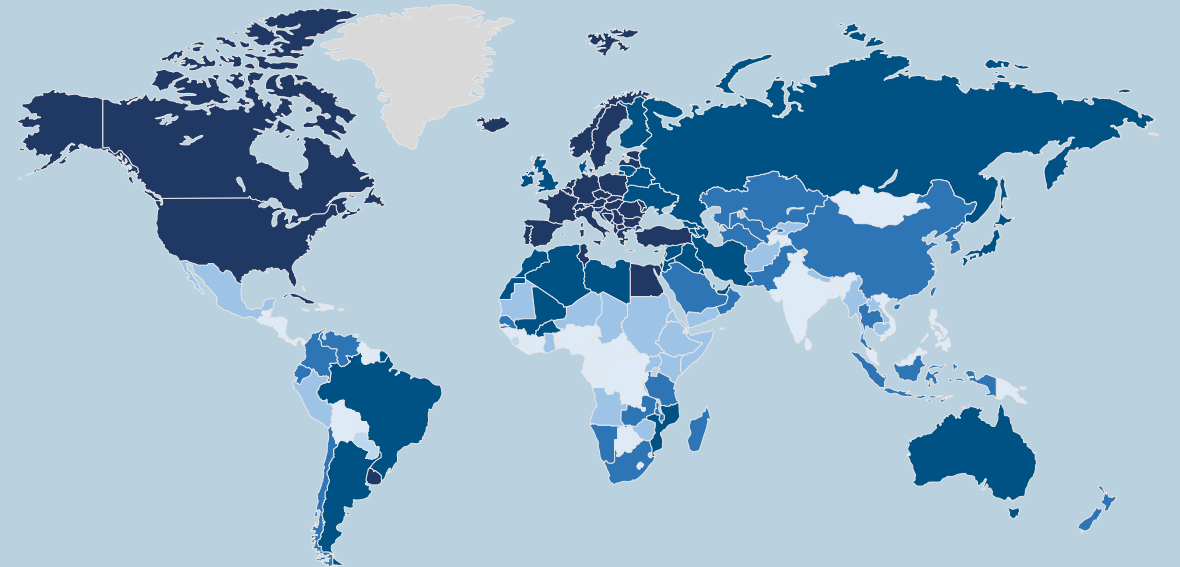
# BLADDER CANCER

A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE



## INCIDENCE PER 100,000 OF THE POPULATION<sup>4</sup>

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



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

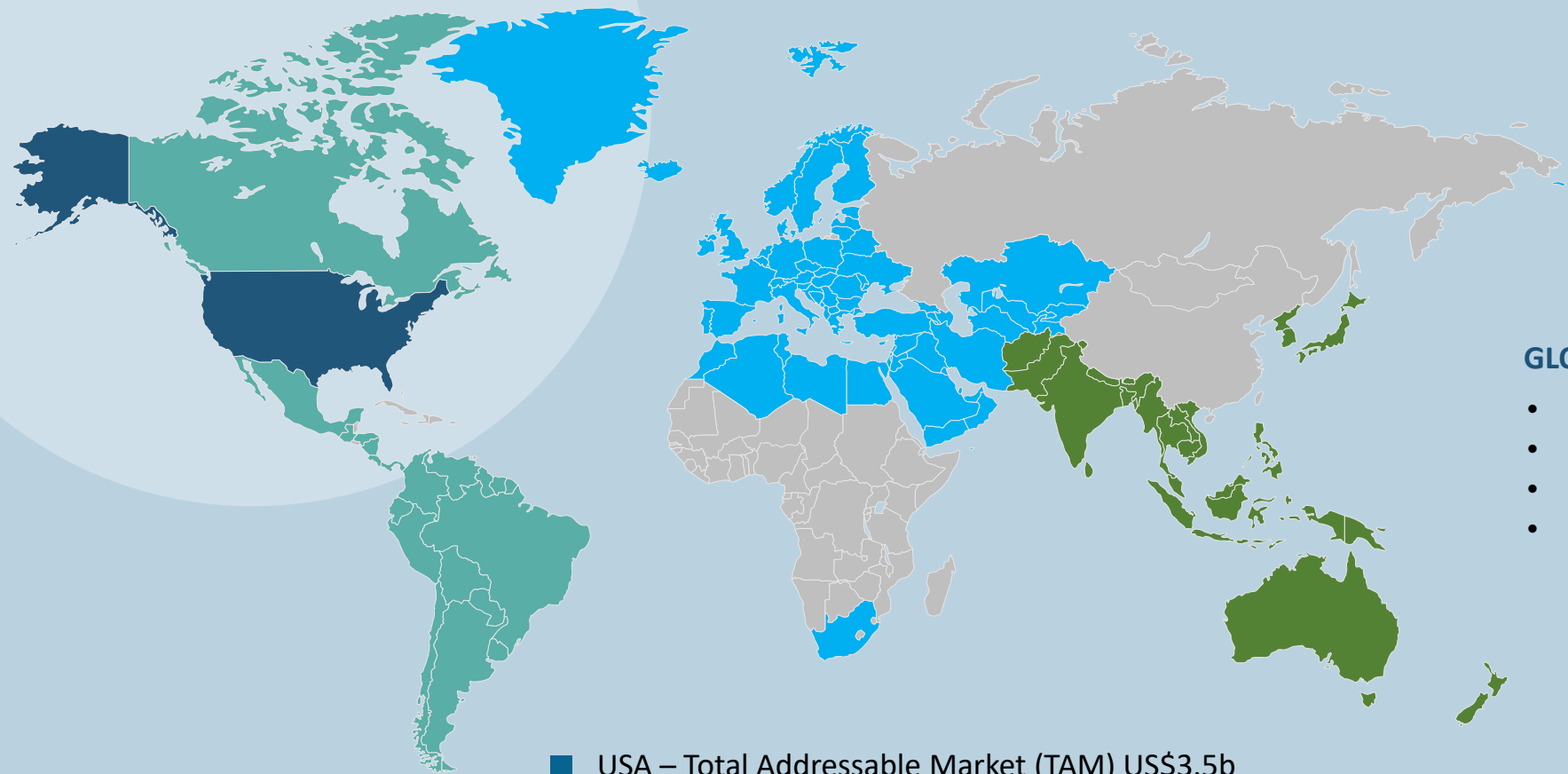
2. [American Society of Clinical Oncology](#) Annual death figure is 2020.

3. Average recurrence for low grade non-muscle invasive bladder cancer as published in [Palou J et al \(2012\): Eur Urol 2012; 62: 118.](#)

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

# CXBLADDER IS A GLOBAL OPPORTUNITY

**US\$7.6b**  
Total  
Addressable  
Market<sup>1</sup>



## GLOBAL COMMERCIALIZATION

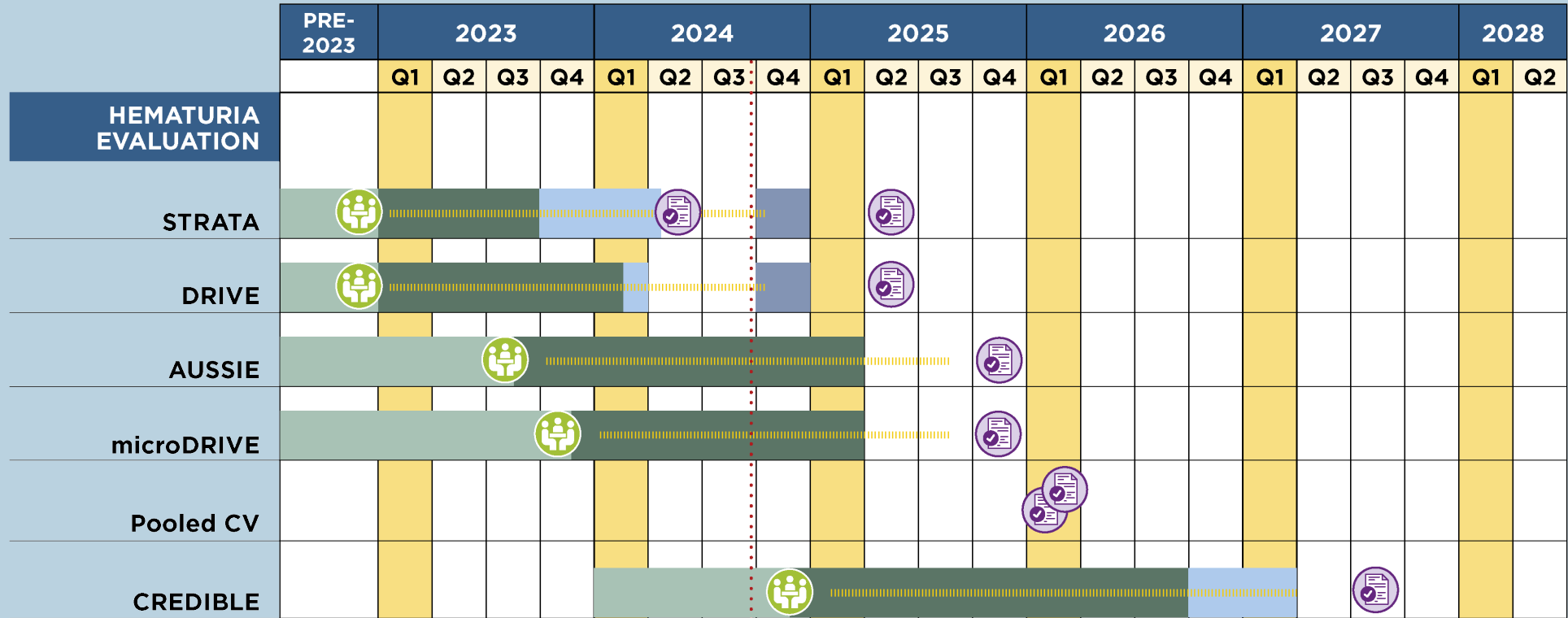
- US is the focus of our growth efforts
- New Zealand is a mature market
- APAC in business development
- Distribution considered in other markets on a case-by-case basis

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

1. Pacific Edge estimates



# PACIFIC EDGE FIVE YEAR CLINICAL STUDY ROAD MAP

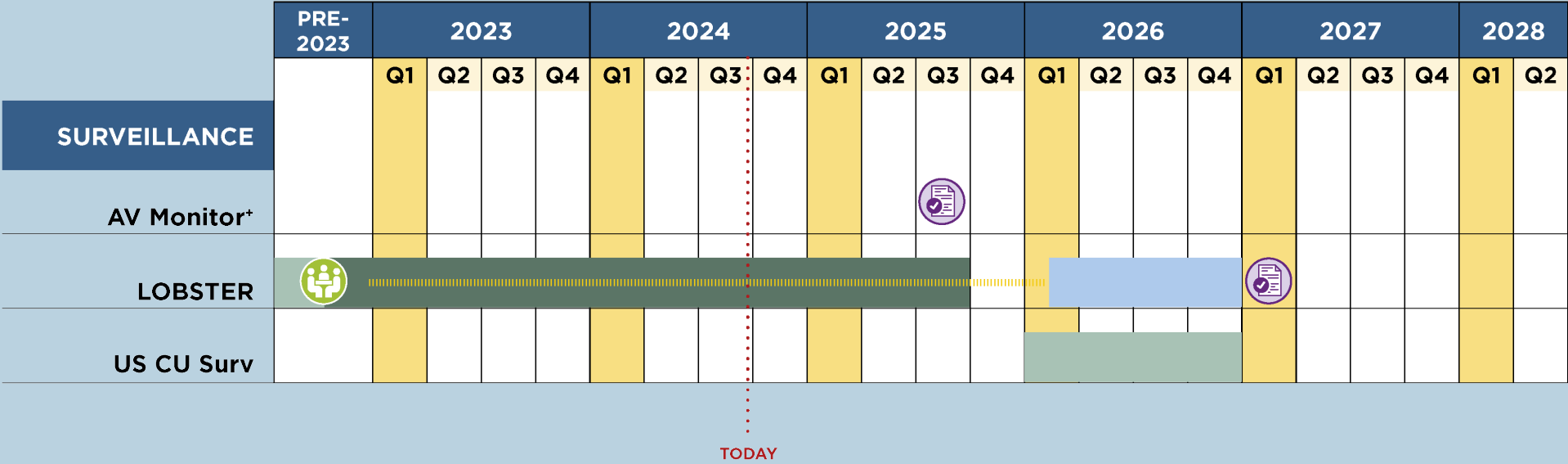


TODAY

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



# PACIFIC EDGE FIVE YEAR CLINICAL STUDY ROADMAP (continued...)



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

# FY 24: REVENUE GROWS WITH INCREASED ADOPTION OF CXBLADDER

GROWTH MODERATES IN 2H 24 WITH REORGANIZATION CRIMPING SALES

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

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

# SUMMARY OF CLINICAL EVIDENCE

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

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



# FOOTNOTES FOR CLINICAL EVIDENCE SUMMARY

Footnotes		
<b>Detect<sup>+</sup></b>	1	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Detect <sup>+</sup> ).
	2	Observational study to validate performance characteristics of Cxb Detect <sup>+</sup> 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 <sup>+</sup> ).
	5	Observational study to validate performance characteristics of Cxb Detect <sup>+</sup> 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.
<b>Triage</b>	1	Cxb Triage performance; Cxb Triage & imaging combined performance had a <b>Sn</b> of 97.7% & <b>NPV</b> of 99.8%.
	2	Patients included hematuria evaluation ( <i>n</i> =436) or surveillance previously diagnosed with UC ( <i>n</i> =416) with both Cxbladder & urine cytology results.
	3	Cxbladder includes Cxbladder Triage & Cxbladder Monitor.
	4	This included <i>n</i> =70 for patients with hematuria & <i>n</i> =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 <b>Sn</b> of 98.1%, <b>NPV</b> of 99.9% & <b>Sp</b> of 98.4%.
	6	Cxb Triage negative rate was 53%; Follow-up period of 21-months showed no missed cancers, demonstrating safety.
	7	Cxb Triage demonstrated to have clinical utility in safely risk stratifying low risk microhematuria patients and not undertake cystoscopy.
<b>Detect</b>	1	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Detect <sup>+</sup> ).
<b>Monitor</b>	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 <b>Sn</b> of 93% and <b>NPV</b> 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 ( <i>n</i> =436) or previously diagnosed UC ( <i>n</i> =416) with both Cxbladder & urine cytology results.
	5	Cxbladder includes Cxbladder Triage & Cxbladder Monitor.
	6	This included <i>n</i> =70 for patients with hematuria & <i>n</i> =83 for patients with previously diagnosed UC; test negative rate of 30.7%.
	7	All patients were being evaluated for recurrence of UC ( <i>n</i> =309 providing 443 samples).
	8	Cxb Monitor identified all seven confirmed recurrence events identified on the first cystoscopy.
	9	Patients returning negative Cxb Monitor results ( <i>n</i> =235) had no pathology-confirmed recurrence at 1st cystoscopy

# REFERENCES SUMMARY OF CLINICAL EVIDENCE

References	
<b>Detect<sup>+</sup></b>	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.
<b>Triage</b>	Davidson et al., (2019). Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of haematuria may reduce the need for cystoscopy. NZ Med J, 132(1497), 55-64.
	Davidson et al., (2020). Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. The New Zealand Medical Journal (Online), 133(1527), 71-82.
	Kavalieris et al., (2015). A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to triage outpatients presenting with hematuria who have a low probability of urothelial carcinoma. BMC urology, 15(1), 1-12.
	Konety et al., (2019). Evaluation of Cxbladder and adjudication of atypical cytology and equivocal cystoscopy. European urology, 76(2), 238-243.
	Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.
	Lotan et al. (2024) . A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.
<b>Detect</b>	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.
<b>Monitor</b>	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

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

## SENIOR LEADERSHIP TEAM

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

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

**DR TAMER ABOUSHWAREB**  
Chief Medical Officer  
**DR JUSTIN HARVEY**  
Chief Technology Officer



**FOR MORE INFORMATION:**

Dr. Peter Meintjes  
Chief Executive Officer  
email: [peter.meintjes@pelnz.com](mailto:peter.meintjes@pelnz.com)

Grant Gibson  
Chief Financial Officer  
email: [grant.gibson@pelnz.com](mailto:grant.gibson@pelnz.com)

Pacific Edge  
87 St David Street, PO Box 56, Dunedin, New Zealand  
P +64 3 577 6733 Within NZ 0800 555 562  
email: [investors@pacificedge.co.nz](mailto:investors@pacificedge.co.nz)  
[www.pacificedgedx.com](http://www.pacificedgedx.com)