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## **PACIFIC EDGE**

Annual Shareholders Meeting  
Fullwood Room  
1 Harrop Street  
Dunedin  
28 July 2022



**PACIFIC EDGE**  
CANCER DIAGNOSTICS COMPANY

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**CHRIS GALLAHER**  
Chairman





## DIRECTORS



SARAH PARK



ANATOLE MASFEN



BRYAN WILLIAMS



ANNA STOVE



MARK GREEN



TONY BARCLAY

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## MEETING AGENDA

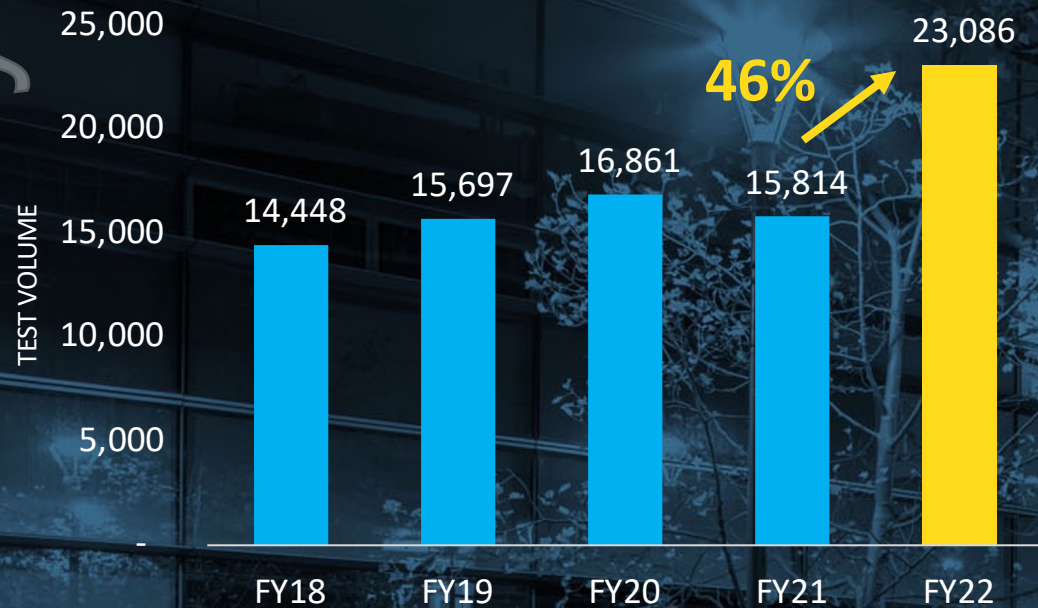
1. CHAIRMAN AND CEO PRESENTATIONS
2. SHAREHOLDER DISCUSSION
3. RESOLUTIONS
4. GENERAL BUSINESS
5. MEETING CLOSE





# FY 22 HIGHLIGHTS: TEST VOLUMES ACCELERATE IN THE PIVOTAL US MARKET

PACIFIC EDGE GLOBAL TEST VOLUMES<sup>1</sup>



PACIFIC EDGE OPERATING REVENUE



▲ **59%**  
US TEST  
VOLUMES<sup>1</sup>

**\$19.8M**  
NET LOSS AFTER  
TAX

**\$105.4M**  
CASH, CASH  
EQUIVALENTS<sup>2</sup>

<sup>1</sup> Testing volume is measure by Total Laboratory (TLT) Throughput including commercial, pre-commercial and clinical studies testing

<sup>2</sup> Cash, cash equivalents and short-term deposits

## NEW EXECUTIVE AND BOARD LEADERSHIP



**TONY BARCLAY**  
Independent Director



**DR PETER MEINTJES**  
Chief Executive Officer



# OUTLOOK: INVESTING FOR LONG TERM GROWTH

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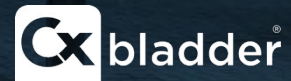
- Directors have noted the sharp shift in global share market sentiment since the start of the year and the impact that this has had on company valuations, particularly among growth companies such as Pacific Edge.
- We remain focused on the things that we can control and that is building long-term sustainable value through the execution of our strategy and prudent management of the capital shareholders have entrusted us with.
- We expect our investment in innovation, evidence, people, and brand to drive growth in total testing volumes, clinical studies enrolment and revenue generation and shareholder value.



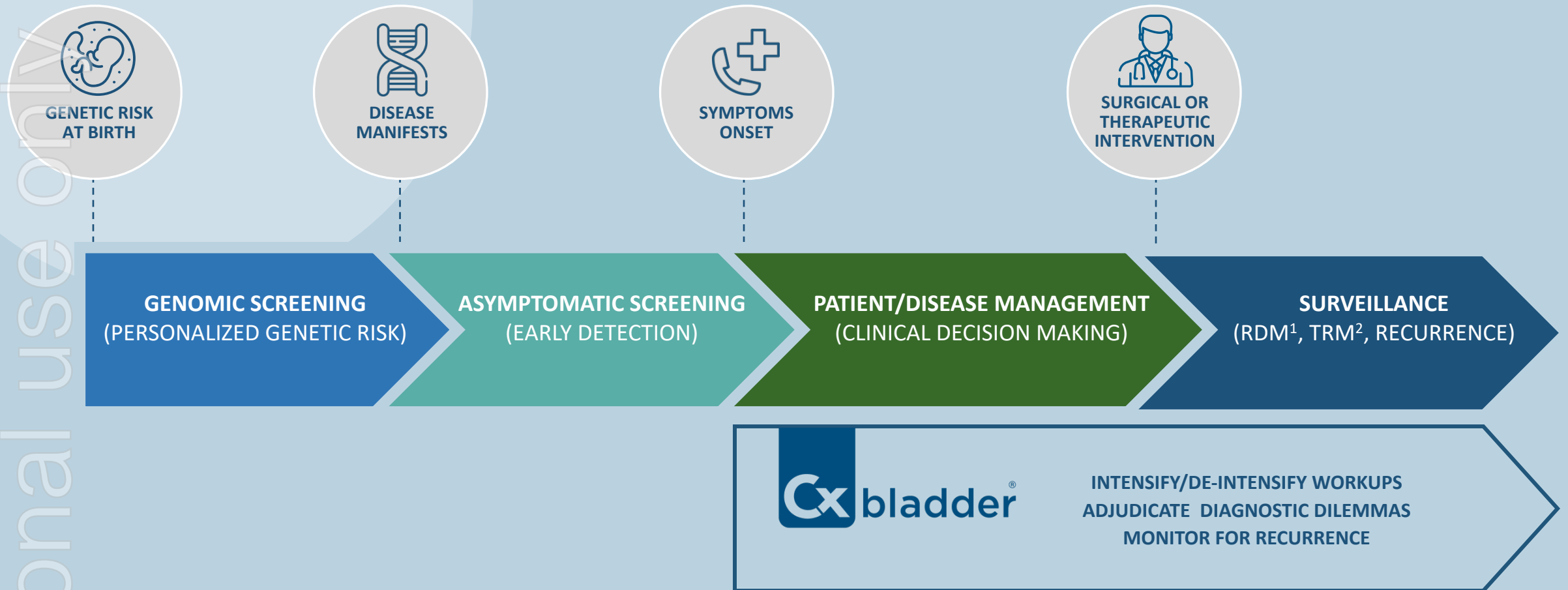
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**DR PETER MEINTJES**  
Chief Executive Officer



# MOLECULAR DIAGNOSTICS VALUE CHAIN: PATIENT JOURNEY



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



# CXBLADDER IN THE PATIENT CARE PATHWAY

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

Current guidelines for hematuria evaluation recommend ~95% get cystoscopy<sup>1</sup> ahead of diagnosis & treatment

## Urologist

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

**Cx bladder™**  
TRIAGE

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

**Cx bladder™**  
DETECT

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

**Cx bladder™**  
MONITOR

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

## VALUE PROPOSITION

Cxbladder  
**TRIAGE**  
(CxbT)

Cxbladder  
**DETECT**  
(CxbD)

Cxbladder  
**MONITOR**  
(CxbM)



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

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

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.

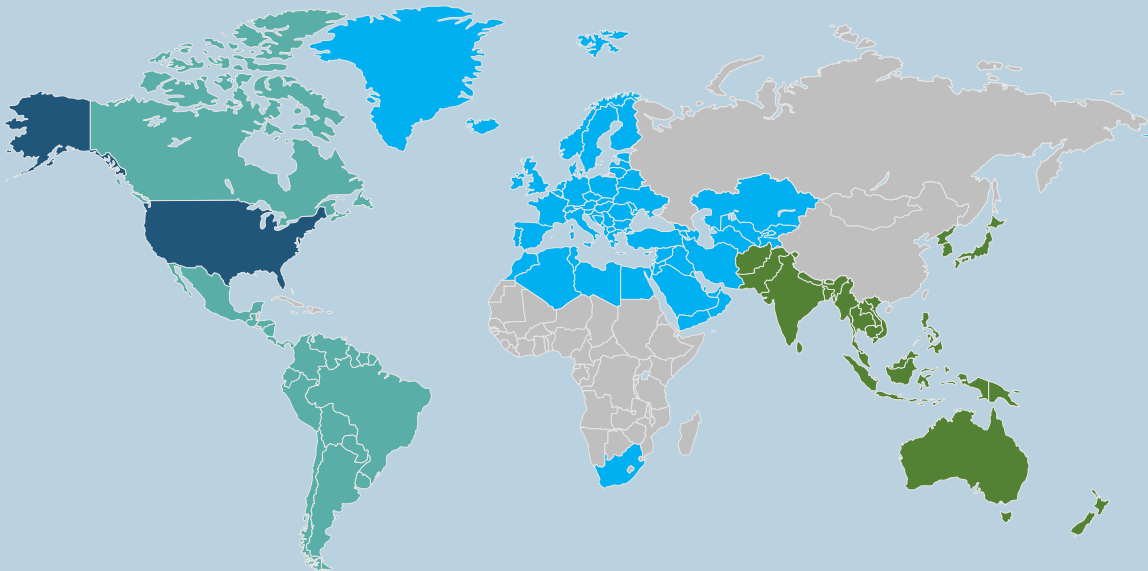
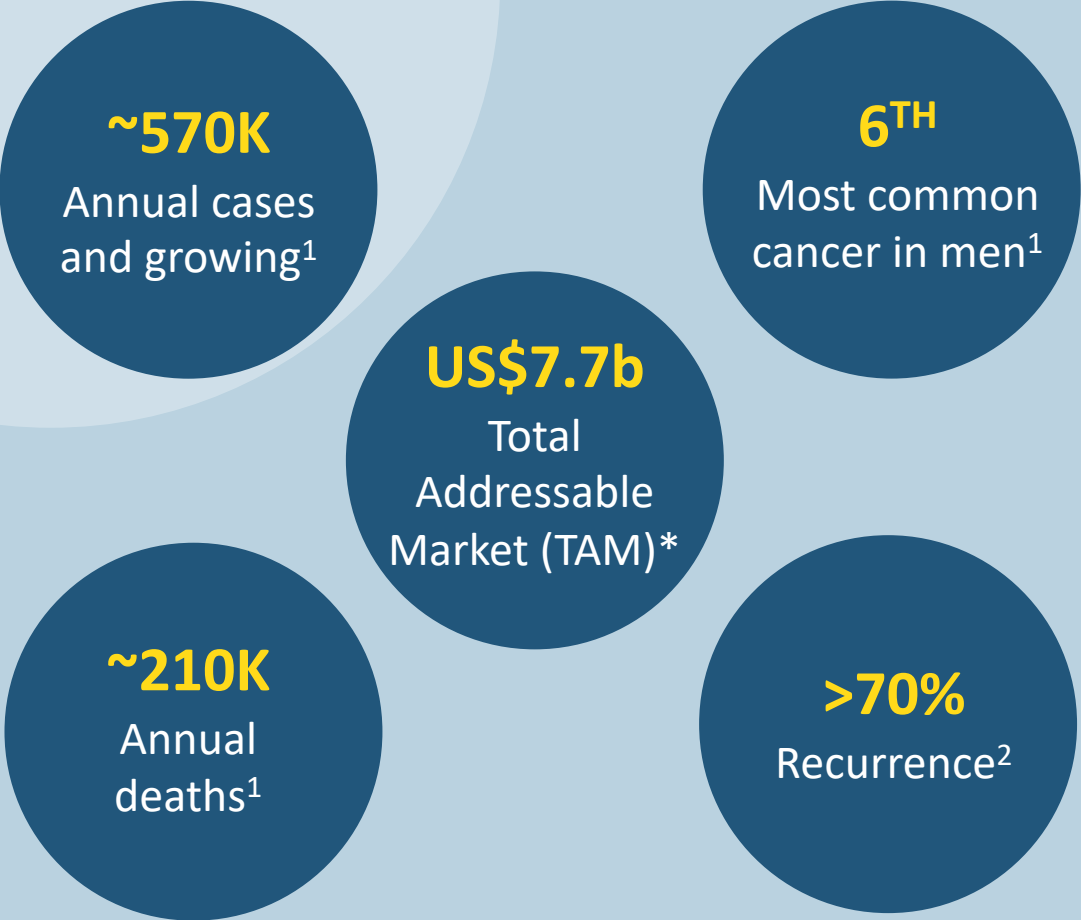
<sup>1</sup> AUA Guidelines and Woldu SL, Ng CK, Loo RK, Slezak JM, Jacobsen SJ, Tan WS, et al. (2021a). "Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria." *J Urol* 205(5): 1387-1393.

**Cx bladder®**

**PACIFIC EDGE**  
CANCER DIAGNOSTICS COMPANY

# UROTHELIAL CANCER

## IS A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE



Market opportunity	TAM (\$US)
United States	\$3.5bn
Americas (non-US)	\$0.5bn
EMEA (w/o most of Africa)	\$1.5bn
APAC (w/o China)	\$2.2bn

1. Sung et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries CA: A Cancer Journal for Clinicians 2021; 71: 209-249  
2. Chamie K, Litwin MS, Bassett JC, et al. Recurrence of high-risk bladder cancer: a population-based analysis. Cancer. 2013;119:3219-3227.  
3. \*TAM is the Total Addressable Market based on Pacific Edge estimates.



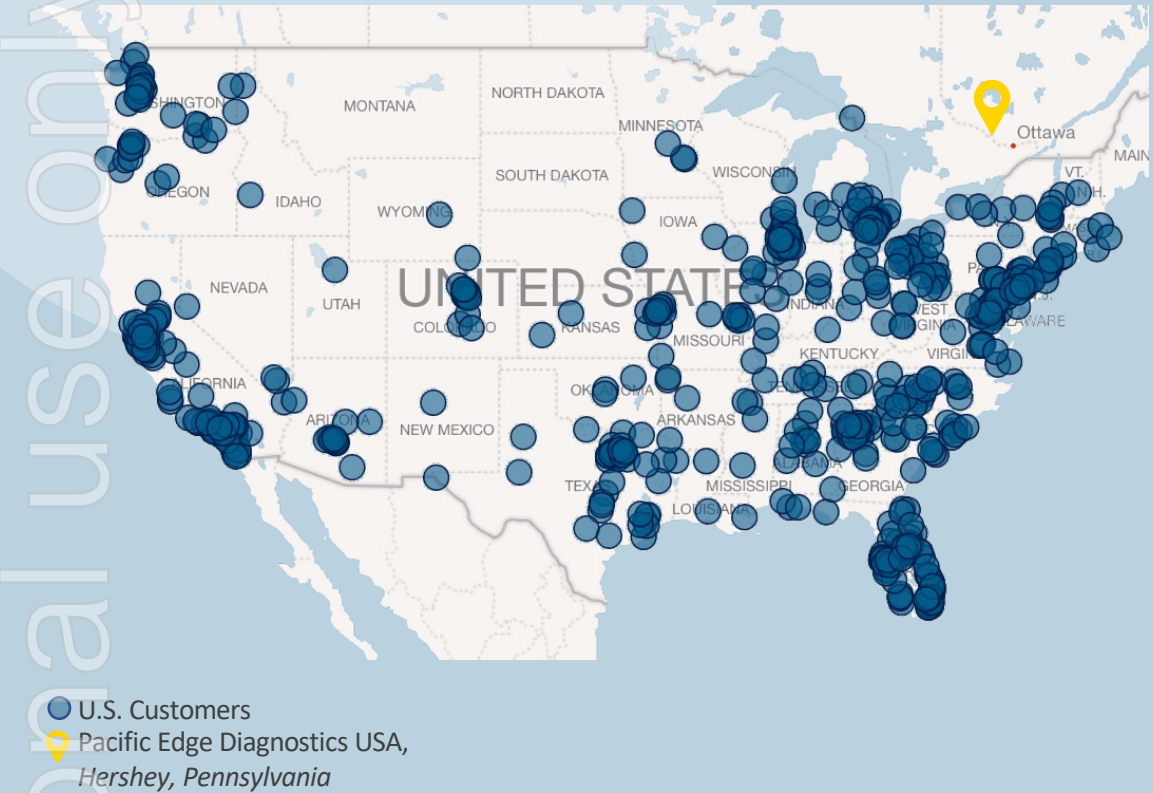
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## OPERATIONAL AND FINANCIAL PERFORMANCE



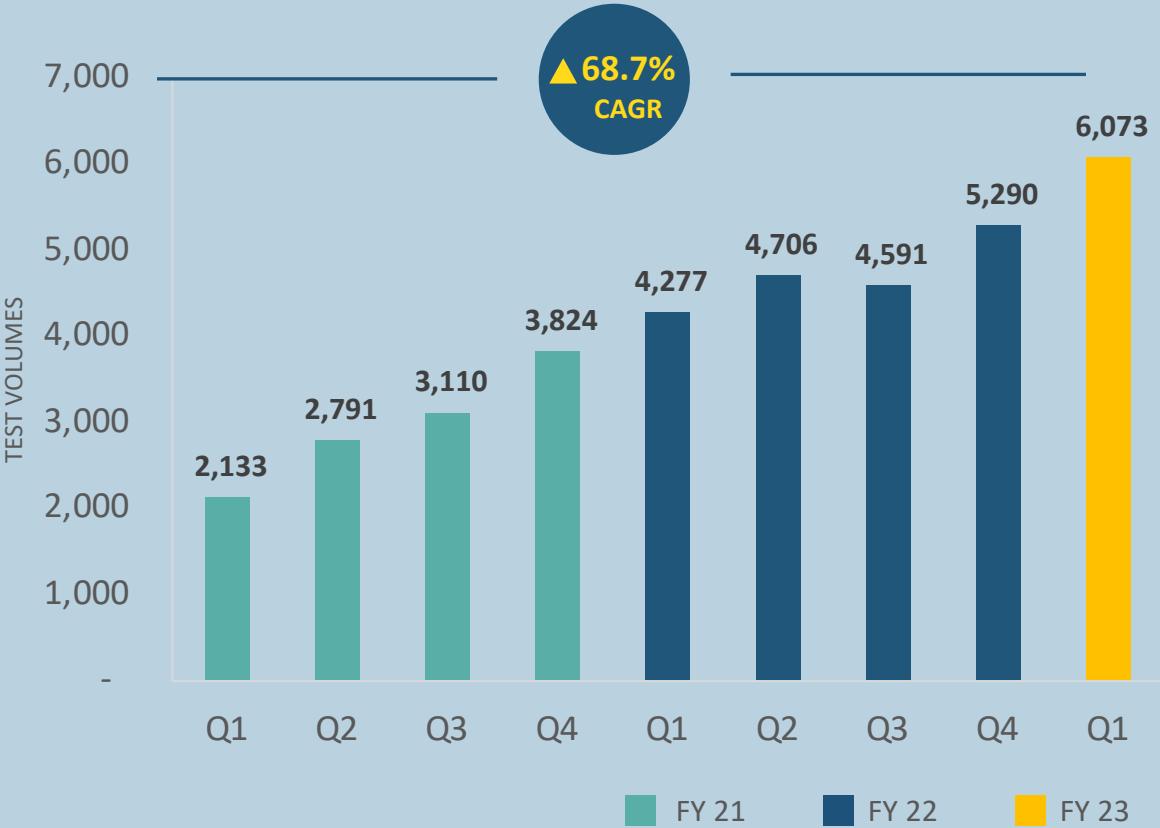
# STRONG GROWTH IN THE USE PACIFIC EDGE'S LARGEST MARKET

## CXBLADDER USED ACROSS THE US



## AMERICAS QUARTERLY TEST VOLUMES<sup>1</sup>

Americas' Commercial Testing represent 84% of FY22 volumes

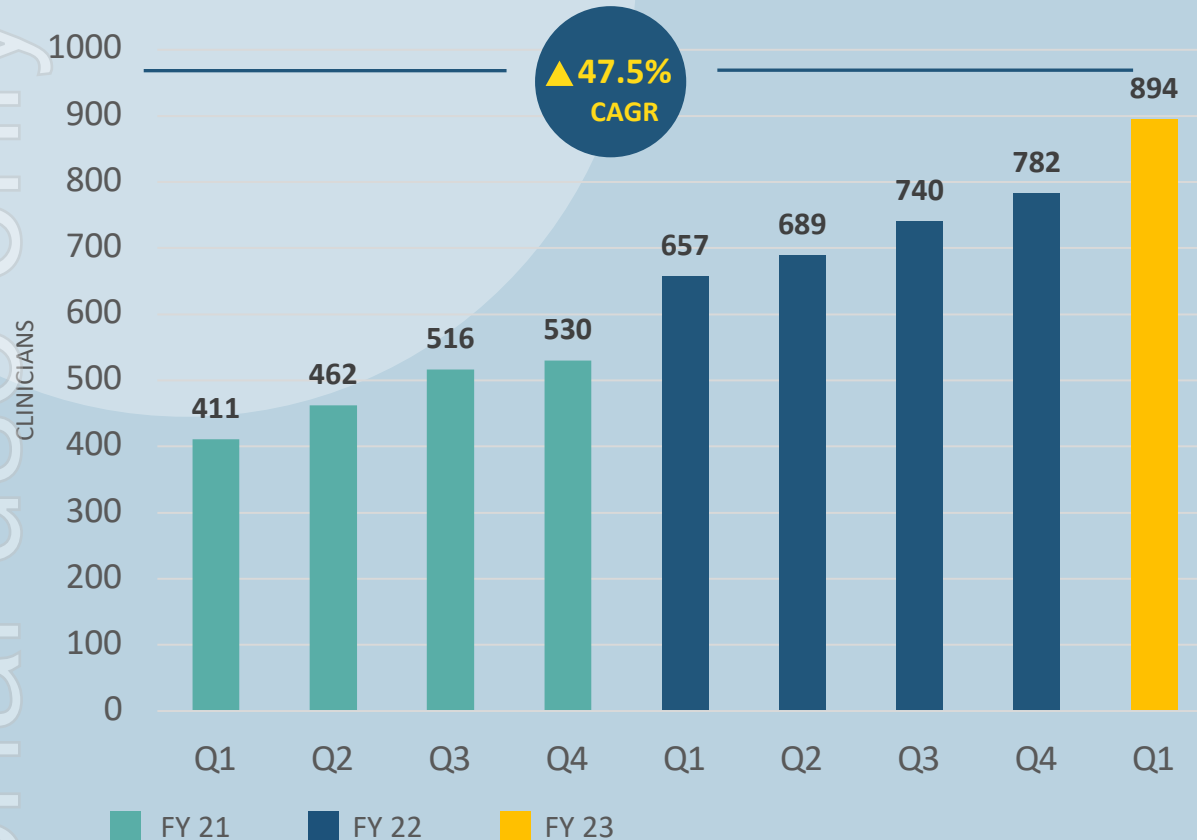


<sup>1</sup> Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing



# BUILDING THE ADOPTION OF CXBLADDER BY CLINICIANS

## UNIQUE ORDERING CLINICIANS (US)



## KEY US PAYORS ACTIVATED



- Centers for Medicare and Medicaid Services (CMS) covers more than 61.5m US citizens over 65 and people on low incomes
- >2/3 of patient population covered by Medicare

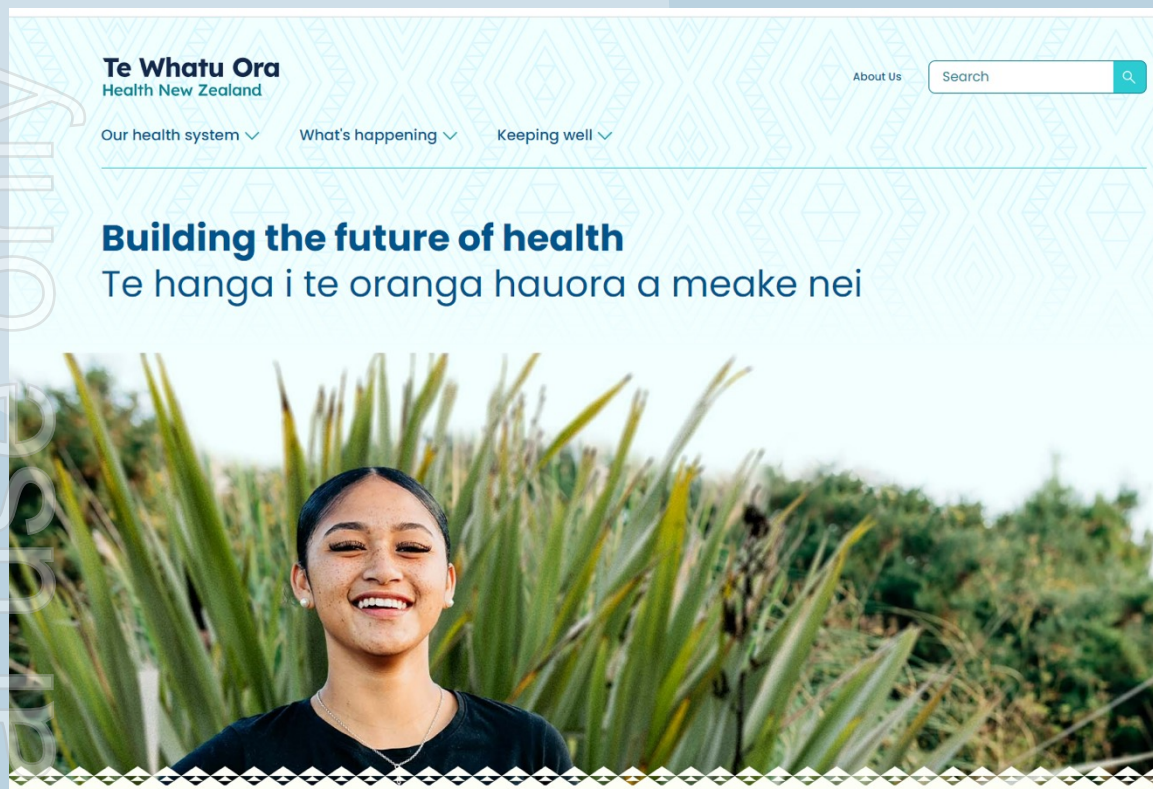


- The Kaiser Health Plan covers over 12.5m members, with >85% of those members in California
- Cxbladder rolled out across clinics in Southern California and being integrated into Kaiser EMR



- The Veterans Health Administration (VHA) within is the second largest integrated healthcare system in the US serving >9m veterans each year
- The DRIVE clinical study is an important engagement with VA urologists to determine utility in a cohort of VA patients

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



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

## APAC QUARTERLY TEST VOLUMES<sup>1</sup>

Commercial tests represent 82% of FY22 volumes



<sup>1</sup> Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing



## ACCELERATING INVESTMENT TO CAPTURE THE US OPPORTUNITY

Year to 31 March	2022 \$000	2021 \$000	Variance \$000	Change %
Operating revenue	11,445	7,701	3,744	49%
Total revenue	13,878	10,439	3,439	33%
Operating expenses	(33,666)	(24,662)	(9,004)	37%
<b>Total comprehensive loss</b>	<b>(19,674)</b>	<b>(14,177)</b>	<b>(5,497)</b>	<b>39%</b>
Cash receipts from customers	10,942	6,747	4,195	62%
Net operating cash outflow	(17,552)	(13,570)	(3,982)	29%
Net cash, cash equivalents and short-term deposits	105,412	23,129	82,283	356%

- Operating revenue growth of 49%
- Operating expenses up 37%, with sales and marketing making up 56% of this growth as we invest in future growth
- Cash receipts rise strongly year on year (up 62%), as reimbursement rates continue to increase
- Strong balance sheet following the \$103.5m capital raise in September / October 2021

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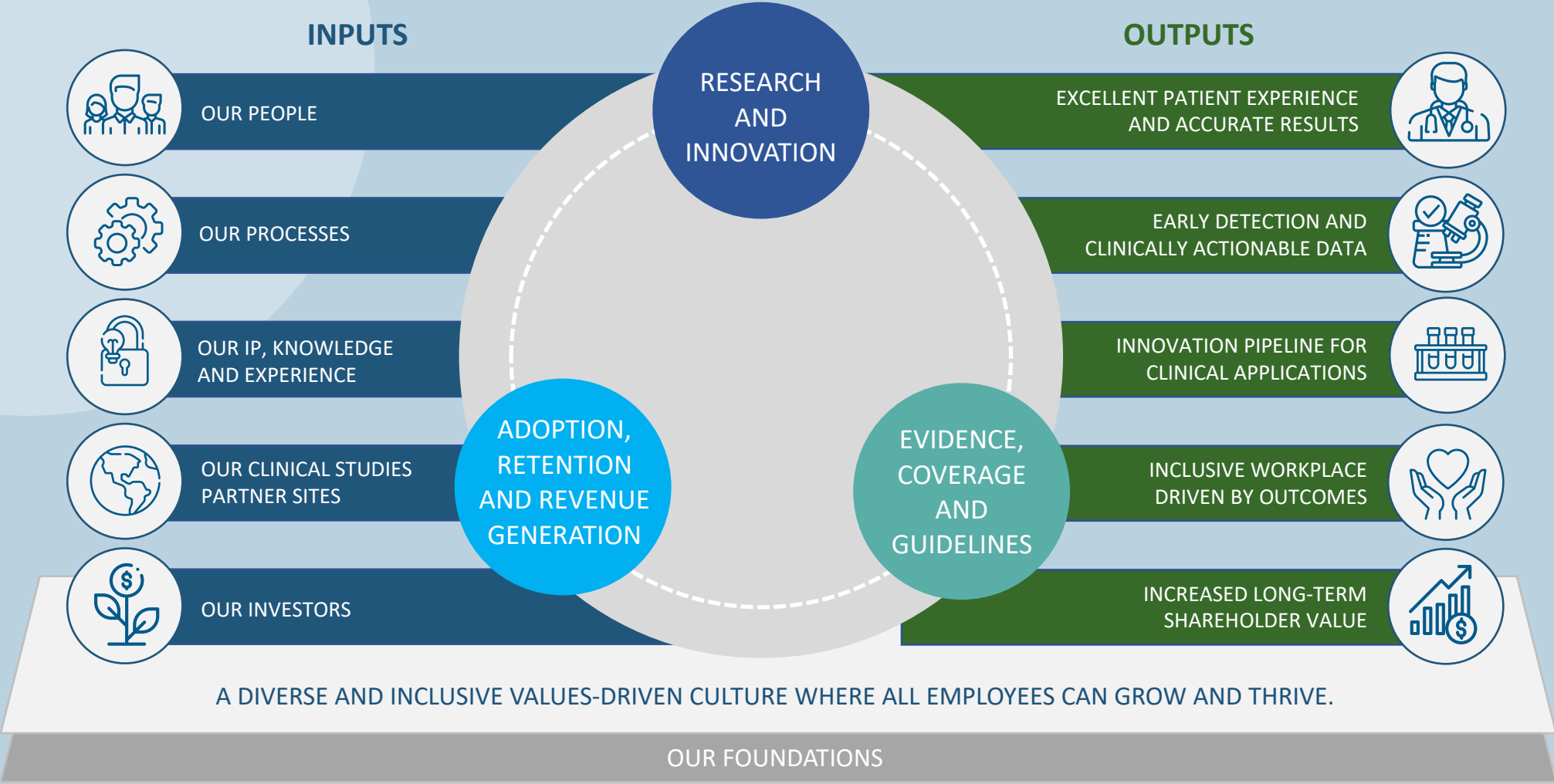
## THE FUTURE: PACIFIC EDGE INVESTING FOR GROWTH



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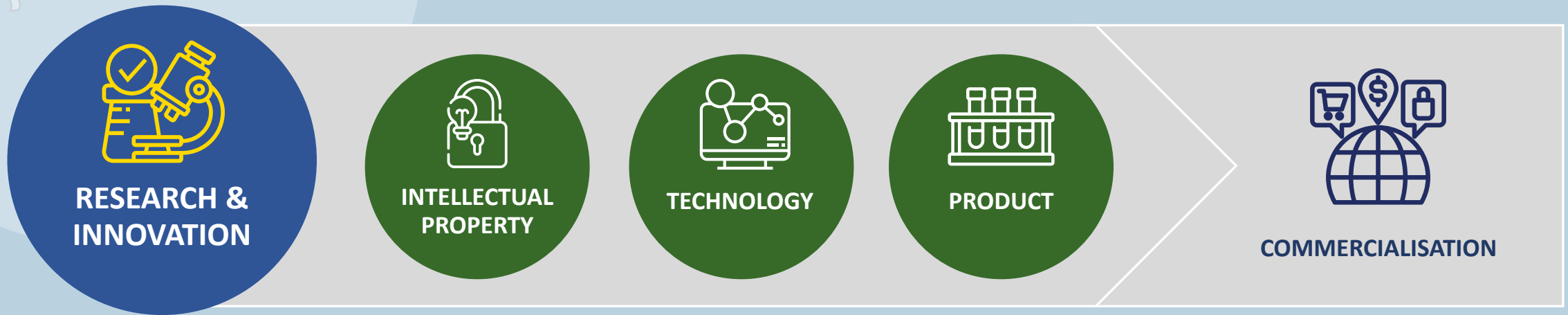


# FRAMING OUR INVESTMENT PROGRAM



## RESEARCH AND INNOVATION:

### UNDERSTANDING THE ENTIRE COMMERCIALISATION PATHWAY

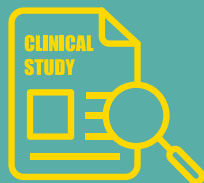


#### FOCUS AREAS:

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



# EVIDENCE, COVERAGE AND GUIDELINES: CHANGE CLINICAL PRACTICE



EVIDENCE  
COVERAGE AND  
GUIDELINES

## 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 uro-oncology 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



# STRENGTHENING THE CASE FOR CXBLADDER IN KEY GUIDELINES

## BEFORE INCLUSION

We use clinical validity and utility evidence to attract interest from opinion-leading clinicians, and payers, drive early adoption of Cxbladder and build momentum for guideline inclusion

- Two studies pending publication
- Five more studies underway
  - STRATA
  - DRIVE
  - DEDUCT
  - LOBSTER
  - MONSTER

## INCLUSION

Review



American  
Urological  
Association



European  
Association  
of Urology



National Comprehensive  
Cancer Network®

## AFTER INCLUSION

We use clinical validity and utility evidence to strengthen the language in guidelines supporting the use of Cxbladder to expand patient types eligible for testing

MORE INCLUSIVE GUIDELINES LANGUAGE,  
MORE PATIENT TYPES ELIGIBLE FOR SOC TESTING

MORE AND STRONGER UTILITY EVIDENCE



### 3) ADOPTION, RETENTION AND REVENUE GENERATION



ADOPTION,  
RETENTION AND  
REVENUE  
GENERATION

#### FOCUS AREAS:

1. Diversify sales process to target Strategic Accounts differently, including education and Key Opinion Leader (KOL) engagement activities by our Medical Affairs team
2. Drive protocolized adoption of Cxbladder at the earliest point in the patient care pathway
3. Increase event marketing, sponsorship and marketing communications to amplify our clinical evidence generation within the urology and oncology communities
4. Establish “in-network” or contracted relationships for the reimbursement of Cxbladder with government healthcare funders and private payors
5. Empower patients through patient awareness and patient advocacy initiatives through established societies and our Cxbladder website



# FY23 INVESTMENT PROGRAM LINKED TO REVENUE MILESTONES

## AMERICAS INITIATIVES

- Expanding Direct Selling Team
- Adding Strategic Account Selling Team
- Adding a new Medical Affairs Team
- Lifting marketing investment
- Improving the Customer experience

## APAC INITIATIVES

- Adding remaining DHBs and positioning Cxbladder for nation-wide coverage under *Te Whatu Ora* Health New Zealand
- Driving Cxbladder adoption to primary care in NZ
- Market development through clinical studies in Australia, Singapore
- Commencement of commercial revenue in Australia through hospital and state contracting



*Providing actionable clinical information at the earliest point in the patient care pathway*



# PATIENTS: BUILDING THE CX BRAND AND ADVOCACY



**The Bladder Cancer Advocacy Network represents the voice of the patient in the USA**

## Partnership activity:

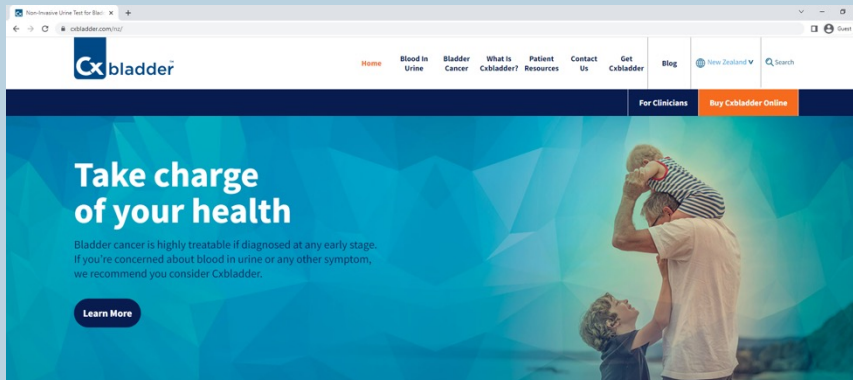
- Sponsorship of Walk to End Bladder Cancer events around the country and thought leadership and networking events
- Co-development of leading patient resources



**New Zealand's leading organisation dedicated to reducing cancer incidence, and care**

## Partnership activity:

- Collaboration on patient resources.
- Promote awareness of bladder cancer symptoms and risk factors among high-risk groups



## Evolution of Cxbladder.com as a resource hub for patients and caregivers:

- Growing library of clinical and care-focused articles designed to design to address topics of interest and common questions



# A DIVERSE AND INCLUSIVE PERFORMANCE CULTURE

## ATTRACTING AND RETAINING TALENT

- Building a performance culture through a shared mission and vision
- Driving engagement across all departments, and management levels for tenured and new staff
- Celebrating and driving diversity at all levels

## ESG

- Pacific Edge has a social purpose of improving the detection and management of cancer
- Management of ESG factors are fundamental to our success
- Aiming to improve disclosure, including charting our carbon footprint

## BLADDER CANCER AWARENESS MONTH AT PACIFIC EDGE





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**DAVID LEVISON**  
Executive Chairman  
Pacific Edge Diagnostics USA





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## SPOTLIGHT ON: STRATEGIES AND TACTICS FOR US MARKET EXECUTION



# EXPANDING CAPACITY AND CAPABILITY

## TARGET US RELATIONSHIPS

**13,790**

Practicing urologists<sup>1</sup>

**1,900**

Large urology group practice sites<sup>2</sup>

**>2,000**

Clinicians that used Cxbladder in FY22<sup>3</sup>

## AMERICAS INITIATIVES

- **Direct Sales Force:**
  - Up to 9 additional Account Executives and 1 Regional Sales Director to be added to the sales team taking the total to up to 40\*
  - New Marketing & Sales Support Managers (+3 FTE)\*
  - New Virtual Sales Team (up to +5 FTE)\* to enhance the customer experience and streamline test ordering and results delivery
  - Strategic Accounts Sales personnel (up to +2 FTE)
- **Medical Affairs Team:**
  - VP Medical Affairs, leading a team of Medical Science Liaison (MSL) (3-5 FTE)\*
  - MSLs are educators and experts on clinical, scientific and medical matters relevant to products and urology in general
  - Drive Key Opinion Leader (KOL) engagement with speakers' bureaus, advisory boards and similar
  - Targeting podium presentations of our clinical evidence at major conferences



<sup>1</sup> American Urological Assn Census 2021, <sup>2</sup> BHN Network <sup>3</sup> Company data  
\*All planned hires subject to achievement of business milestones.



# TARGETED AND TACTICAL EXECUTION

## ENGAGING WITH CLINICIANS AND CUSTOMERS

50

Urology conferences across the US and APAC

4 + 36

Planned total Sales Execs\*

5

New virtual sales team members\*

## AMERICAS INITIATIVES

- **Marketing Activities:**
  - Conference podiums, presentations, posters
  - Conference advertising/sponsorship
  - Increased and targeted marcom activities
- **Customer Experience:**
  - Electronic Medical Records (EMR) integration – streamlining customer ordering and reporting.
  - PIHSS – continued promotion of our patient in-home sampling system
- **Market Access and Reimbursement:**
  - Establishing medical intent for simplifying EOB, billing and claims processing
  - Agreeing medical policy, prior to “in-network” contracting at VA and Private Payors
  - Ex-US business opportunities in the Americas
- **Performance Management:**
  - Extending access to performance data for sales and service organizations
  - Adoption of focused selling strategies
  - Tracking impact of key activities in sales process



<sup>1</sup> American Urological Assn Census 2021, <sup>2</sup> BHN Network <sup>3</sup> Company data  
\*36 Account Execs and 4 Regional Sales Directors. Executives All planned hires subject to achievement of business milestones.

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**DR PETER MEINTJES**  
Chief Executive Officer





# BUILDING SHAREHOLDER VALUE

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- We are setting the foundations for strong throughput and revenue growth over the upcoming years.
- Operating costs will rise the business, but investment is linked to growth milestones.
- We are focused on long-term shareholder value and we are well positioned to deliver that over the coming years.



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**CHRIS GALLAHER**  
Chairman

## QUESTIONS





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## RESOLUTIONS





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**BRYAN WILLIAMS**  
Independent Director





**RESOLUTION 1:**

**That Chris Gallaher, who retires by rotation and is eligible for re-election, be re-elected as a director of the company.**

**RESOLUTION 1:**

That Chris Gallaher, who retires by rotation and is eligible for re-election, be re-elected as a director of the company.

**Proxy Votes Received**

FOR	OPEN	AGAINST	TOTAL	ABSTAIN
312,476,188 (96.0%)	8,772,307 (2.7%)	4,168,995 (1.3%)	325,417,490	15,039

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**CHRIS GALLAHER**  
Chairman





**RESOLUTION 2:**

**That Sarah Park, who retires by rotation and is eligible for re-election, be re-elected as a Director of the Company**

**RESOLUTION 2:**

**That Sarah Park, who retires by rotation and is eligible for re-election, be re-elected as a Director of the Company**

**Proxy Votes Received**

<b>FOR</b>	<b>OPEN</b>	<b>AGAINST</b>	<b>TOTAL</b>	<b>ABSTAIN</b>
315,139,015 (96.9%)	8,795,835 (2.7%)	1,262,324 (0.4%)	325,197,174	235,355



**RESOLUTION 3:**

**That Tony Barclay, who was appointed as a Director by the Board during the year, be elected as a Director of the Company.**

### RESOLUTION 3:

That Tony Barclay, who was appointed as a Director by the Board during the year, be elected as a Director of the Company.

#### Proxy Votes Received

FOR	OPEN	AGAINST	TOTAL	ABSTAIN
315,303,523 (97.0%)	8,810,804 (2.7%)	1,062,847 (0.3%)	325,177,174	255,355



**RESOLUTION 4:**

**To record the re-appointment of PricewaterhouseCoopers as auditor of the Company and to authorise the Directors to fix the auditors' remuneration for the ensuing year.**

**RESOLUTION 4:**

**To record the re-appointment of PricewaterhouseCoopers as auditor of the Company and to authorise the Directors to fix the auditors' remuneration for the ensuing year.**

**Proxy Votes Received**

FOR	OPEN	AGAINST	TOTAL	ABSTAIN
313,744,228 (96.4%)	8,803,443 (2.7%)	2,861,689 (0.9%)	325,409,360	23,169

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VOTING





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GENERAL BUSINESS



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MEETING CLOSE





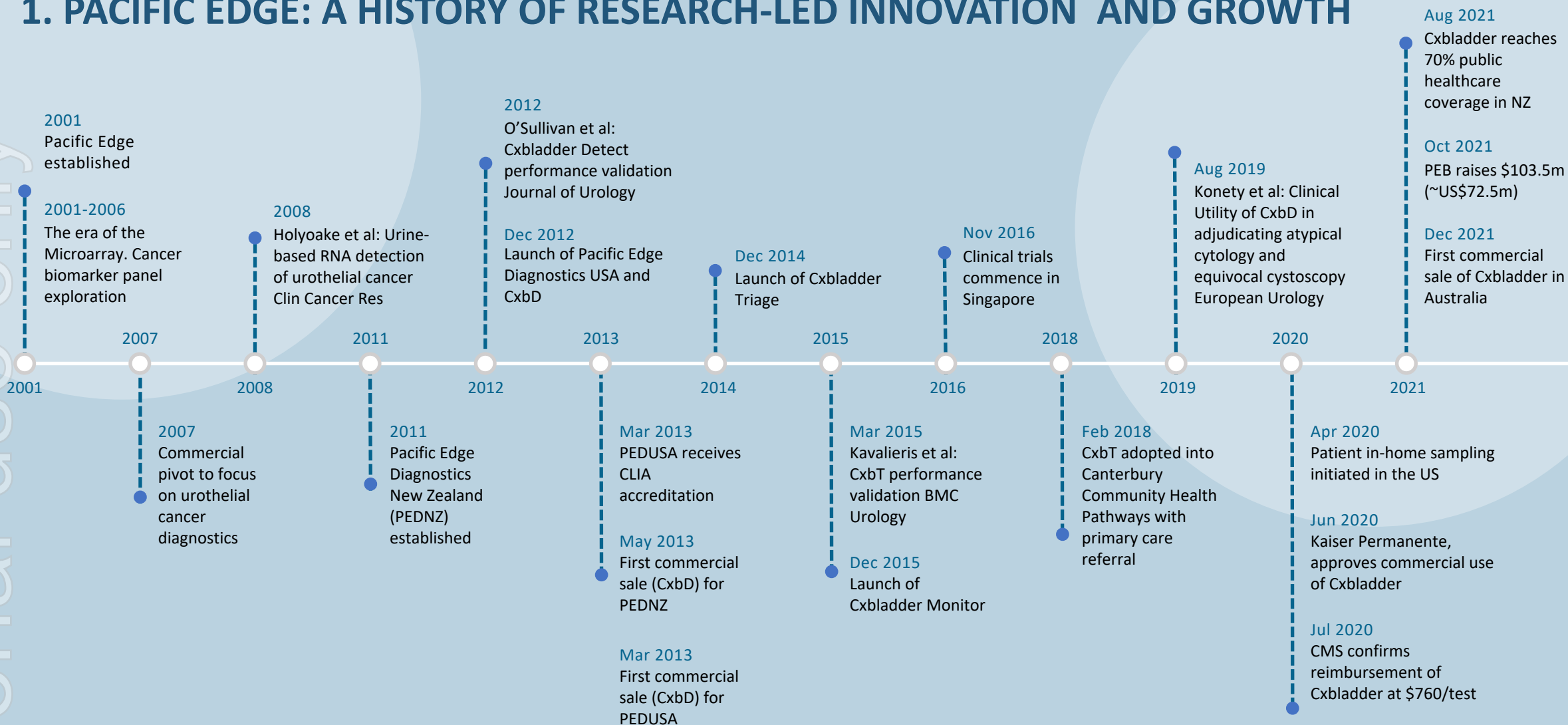
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## APPENDIX





# 1. PACIFIC EDGE: A HISTORY OF RESEARCH-LED INNOVATION AND GROWTH



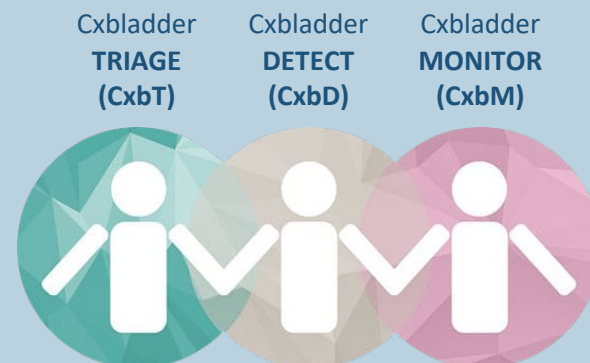
## 2. UROTHELIAL CANCER IN THE US MARKET

**4TH**  
Most common  
cancer in men  
in the US<sup>1</sup>

**US\$220,000**  
Average lifetime  
cost<sup>2</sup> per patient

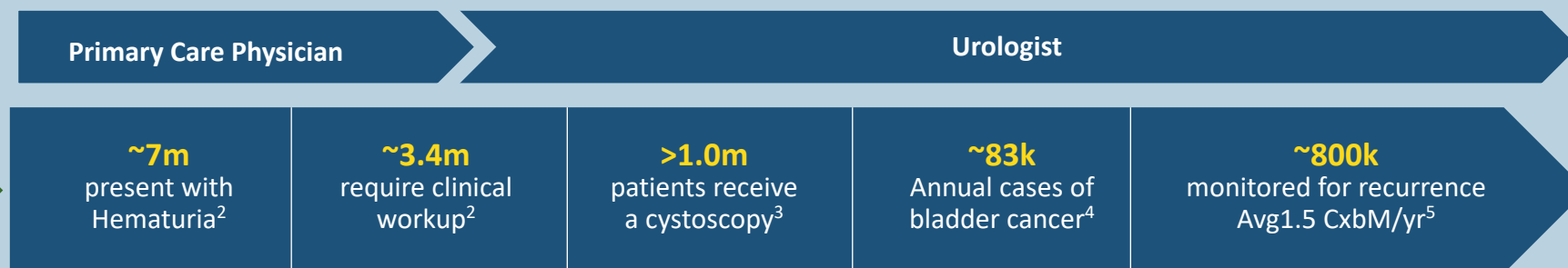
**US\$4.9B**  
Forecast direct costs  
associated with  
urothelial cancer  
in 2020<sup>2</sup>

### VALUE PROPOSITION



### Patient care pathway

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



**US\$3.5B**  
opportunity<sup>6</sup>  
(hematuria,  
surveillance)

**Cxbladder®** MORE THAN 4.6M TEST OPPORTUNITIES

<sup>1</sup> American Cancer Society

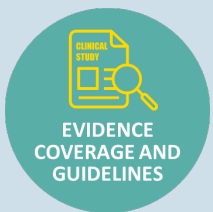
<sup>2</sup> Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019 2. NIH National Cancer Institute, 2021 4. Bladder Cancer Advocacy Network, 2017

<sup>3</sup> Kenigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29-34, 2021.

<sup>4</sup> National Cancer Institute 2021 forecast

<sup>5</sup> Pacific Edge Estimate

<sup>6</sup> Pacific Edge estimates at US\$760/Per test



## 3a. 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](http://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](http://www.uroweb.org)



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

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





## 3b. CLINICAL EVIDENCE GENERATION TOWARDS GUIDELINE INCLUSION (1/2)

STUDY	AIM	LOCATIONS	ENROLLED SITES*	STATUS**
US Primary study	Prospective, single-arm, observational study to develop clinical evidence for Cxbladder tests in facilitating early detection, intensifying or de-intensify hematuria evaluation and assistance in adjudicating equivocal cystoscopy	USA	12/12	Enrolment complete Analysis complete Publication pending
Singapore Study	Prospective, single-arm, observational study to develop clinical evidence for Cxbladder tests in facilitating early detection, intensifying or de-intensify hematuria evaluation and assistance in adjudicating equivocal cystoscopy	Singapore	4 / 4	Enrolment complete Analysis complete Publication pending
STRATA (formerly RCT)	<p><u>S</u>afe <u>T</u>esting of <u>R</u>isk for <u>A</u>symptomatic <u>T</u>ic Microhematuria <u>A</u></p> <p>Demonstrate the clinical utility of Cxbladder using a prospective, two-arm randomized design to safely risk-stratify patients and rule out from further hematuria evaluation</p> <ul style="list-style-type: none"> <li>Safely risk stratifying patients in order to rule out from cystoscopy</li> <li>Demonstrate the clinical utility of Cxbladder against the AUA guidelines</li> </ul>	USA Canada	10 / 11	Recruitment re-started after COVID-related delays Full data collected 2023 Q4
DRIVE (formerly VA Study)	<p><u>D</u>etection and <u>R</u>isk Stratification in <u>V</u>eterans Presenting with Hematuria</p> <p>Prospective, single-arm, observational study to demonstrate the performance and utility of Cxbladder tests in risk stratifying Veterans presenting with hematuria</p> <ul style="list-style-type: none"> <li>Demonstrate performance with Veterans and contribute to commercial adoption of Cxbladder for use with Veterans</li> <li>Pivotal for the adoption of Cxbladder by Veterans Affairs but relevant to the AUA</li> <li>Recruitment re-started after COVID-related delays</li> <li>Targeting inclusion of all veterans presenting for evaluation of hematuria</li> </ul>	VA Sites (USA)	7 / 11	Study expanded to get more data on low-risk patients Full data collected mid 2025

\*Estimated number of enrolled sites

\*\*All dates are best-case estimates and subject to change

### 3c. CLINICAL EVIDENCE GENERATION TOWARDS GUIDELINE INCLUSION (2/2)

STUDY	AIM	LOCATIONS	ENROLLED SITES*	STATUS**
DEDUCT	<p><b><u>D</u>etection of <u>D</u>isease in the <u>U</u>pper tra<u>CT</u></b>            Prospective, single-arm, observational study to validate performance of Cxbladder for the detection of urothelial carcinoma (UC) in the upper tract (UTUC)</p> <ul style="list-style-type: none"> <li>Evaluate Cxbladder to safely avoid ureteroscopy</li> <li>Safely risk stratify patients suspected to have UTUC and avoid unnecessary ureteroscopy and radiation exposure through imaging</li> <li>Targeting inclusion of Cxbladder utility for UTUC in AUA guidelines</li> </ul>	USA	0 / 4	Pilot data analysed in early 2024 – decision point to expand the study
LOBSTER	<p><b><u>L</u>ongitudinal <u>B</u>ladder Cancer <u>S</u>tudy for <u>T</u>umor <u>R</u>ecur<u>R</u>ence</b>            Prospective, single-arm, observational study to evaluate the performance characteristics and clinical utility of CxbM in a new surveillance protocol vs standard of care over four visits</p> <ul style="list-style-type: none"> <li>Safely risk stratify patients under surveillance for recurrence of UC</li> <li>Safely alternate CxbM with cystoscopy for intermediate and high-risk patients under surveillance for recurrence of UC</li> <li>Targeting AUA guidelines inclusion for biomarkers as an alternative to cystoscopy in a surveillance setting</li> </ul>	USA (including some VA sites) Australia	2 / 10	First patient expected in 2022 Q2
MONSTER	<p><b><u>M</u>onitoring <u>S</u>tudy of post-<u>T</u>reatment <u>E</u>ffectiveness for <u>R</u>esidual Disease</b>            Single-arm, observational study to validate the performance characteristics of Cxbladder against white light cystoscopy during surveillance of UC</p> <ul style="list-style-type: none"> <li>Christchurch District Health Board study to measure tumor burden</li> <li>To safely risk stratify patients for residual disease prior to the 6-week re-resection for high grade patients or the 3-month flexible cystoscopy check for all patients</li> </ul>	NZ	0 / 1	In planning, once pilot analysed then consider expansion to USA

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

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