

23 November 2023



UNAUDITED FINANCIAL RESULTS FOR THE HALF YEAR TO 30 SEPTEMBER 2023

## STRONG RISE IN REVENUE DESPITE MEDICARE UNCERTAINTY

### FINANCIAL AND PERFORMANCE HIGHLIGHTS<sup>1</sup>

- Operating revenue increases 50% to \$13.1 million; total revenue increases 22% to \$16.6 million lifted by a 28% rise in commercial Cxbladder test volumes in the US market.
- Total laboratory throughput<sup>2</sup> (TLT) of Cxbladder tests increases 22% to 18,229 tests, commercial tests increase to 15,401 tests; US ordering clinicians grow to 1,147, up 17.3% from the 978 at the end of Q2 23.
- Net loss after tax increases to \$15.1 million from \$10.2 million as the company had been investing to focus on top line growth. Expense growth has since been tempered through the restructure implemented in late Q2 24 that is not yet evident in operating expenditure.
- Cash and cash equivalents and short-term deposits at \$62.2 million from \$77.8 million at the end of March 2023. Pacific Edge expects the available cash to be sufficient to support the company through to regaining coverage in the event of a Medicare non-coverage determination, a process that may take up to four years.

### STRATEGIC HIGHLIGHTS

- Cxbladder testing volumes continued their growth trajectory despite uncertainty over continued Medicare coverage.
- Restructured the commercial organization to focus on profitable sales territories, alternative revenue streams and cash preservation over top line revenue growth alone.
- Cxbladder went live in Kaiser Permanente's electronic medical record (EMR) systems on 14 November (US time) across all urology medical centers in the Southern California Permanente Medical Group, which is expected to support test volumes in 2H 24.
- Developing a protocol for CREDIBLE – a randomized clinical trial focused on generating clinical utility evidence for Detect+ for guideline inclusion and increased coverage certainty.

**DUNEDIN, New Zealand** – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today reports strong growth in operating revenue in the half year to the end of September - up 50% to \$13.1 million from \$8.7 million in the same period a year ago - as it benefited from growing demand for its suite of Cxbladder tests.

Total revenue, which includes interest income on cash reserves and government grants, increased 22% to \$16.6 million from \$13.6 million in the same period a year ago. The net loss for the half year of \$15.1 million was wider than the \$10.2 million loss in the same period in the prior year. Restructuring and capital preservation initiatives implemented late in 2Q 24 are not yet evident in 1H 24 operating expenditure, which still reflects the company's prior orientation towards revenue growth. Additionally, the company incurred extra costs defending its coverage by Medicare.

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<sup>1</sup> All comparisons are to the same period of the prior financial year unless otherwise stated.

<sup>2</sup> Total Laboratory Throughput includes commercial, pre-commercial and clinical studies testing.

Pacific Edge has maintained a strong balance sheet with cash and cash equivalents of \$62.2 million. In the event of a Medicare non-coverage determination, the company expects the available cash to be sufficient to support the company through to regaining coverage, a process that may take up to four years, with interim coverage attempts with every piece of new clinical evidence. In the six-month period the company recorded a cash outflow of \$15.6 million, reducing its reserves from the \$77.8 million recorded at the end of March 2023.

Chairman Chris Gallaher said: “Pacific Edge has continued to grow test volumes and revenue through the first half of the 2024 financial year amid the ongoing uncertainty over Medicare coverage of Cxbladder. However, the company has adapted and will manage its capital reserves to weather a Medicare non-coverage decision, the most adverse outcome of the range of alternatives now possible.”

Chief Executive Dr Peter Meintjes said: “We are proud of our achievements for the first half of the 2024 financial year despite the well documented headwinds we’ve faced. The reorganization and other cost control measures have appropriately lowered our expense base, while continuing to focus on driving test throughput and revenue.”

#### STRATEGY REFINEMENT

Pacific Edge has refined its sales strategy to prioritize profitable sales territories, alternative revenue streams and cash preservation over top line revenue growth alone. It has aligned its sales messaging to embed the clinical value of Cxbladder to the physician and patient, and its economic value to health systems and payers. These benefits include a reduction in the number of unnecessary invasive cystoscopies and imaging, increasing access to specialist care for higher risk patients, and reduced healthcare payer expenditure on patients presenting with hematuria or in surveillance for bladder cancer recurrence.

It has reconfigured its evidence generation program within a structured framework for Analytical Validity (AV), Clinical Validity (CV) and Clinical Utility (CU). The current studies are orientated on defined patient populations, conventional end points and sample sizes that are sufficient for guidelines inclusion and coverage. The Medical Team is developing a protocol for a new randomized clinical trial called CREDIBLE (**C**ystoscopic **RED**uction In **BL**adder **E**valuations for micro-hematuria) which is expected to generate the clinical utility evidence for Cxbladder Detect<sup>+</sup>, needed for guidelines inclusion.

“Pacific Edge is also continuing its investment in digital systems that enhance the customer experience. The integration of Cxbladder into the EMR system of Kaiser Permanente, is the best example of these efforts. Having completed this effort, the company will now focus on scaling the digital customer experience with an EMR Program that includes bespoke solutions and a more generically deployable customer portal,” Dr Meintjes said.

“We expect these changes to allow a resumption of growth for the remainder of the financial year, assuming no change to our Medicare coverage status and to continue our focus on AV, CV and CU evidence generation in the event of a Medicare non-coverage decision.”

Finally, the company's research and development efforts have been orientated toward the launch of the tests enhanced by DNA markers Detect<sup>+</sup> and Monitor<sup>+</sup>. A key focus has been to ensure laboratory operations are optimised to reduce technician time, turnaround time and lower the cost of goods sold.

## OUTLOOK

Dr Meintjes said the finalization of the 'Genetic testing for oncology' Local Coverage Determination (DL39365) is the single biggest determinant of the company's prospects in the coming 12 months, with a decision due by 26 July 2024 (US Time).

"A non-coverage determination is likely to impact US volumes with the company considering processes that will see Medicare patients assuming responsibility for the payment for Cxbladder. Under such a scenario Pacific Edge, supported by its strong balance sheet, would continue to work towards regaining coverage within four years, with attempts made for re-coverage with every piece of new clinical evidence.

"Conversely, an affirmation of our status as covered by Medicare will be a catalyst for our US commercial operations, supported by a sales force that is now firmly focused on the Cxbladder proposition," Dr Meintjes said.

"Meanwhile, and irrespective of the Medicare outcome, we continue to expect an increase in volume from Kaiser Permanente, ex-US business serviced from our US laboratory and APAC business serviced from our New Zealand laboratory. We are continuing to work towards a national contract with Te Whatu Ora – Health New Zealand and to grow international testing volume in the medium term from our distribution agreements and growth markets in Australia, Latin America, Israel and Southeast Asia.

"We look forward to providing a further update in the New Year," Dr Meintjes said.

## CONFERENCE CALL

Pacific Edge is holding an investor briefing at 11.00am (NZT) today. It is available through the following link: [www.virtualmeeting.co.nz/pebhy23](http://www.virtualmeeting.co.nz/pebhy23) or by phone on the following toll-free numbers:

- **New Zealand:** 0800 449 170
- **Australia:** 1800 896 574

*Released for and on behalf of Pacific Edge by Grant Gibson, Chief Financial Officer.*

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## OVERVIEW

**Pacific Edge:** [www.pacifiedgedx.com](http://www.pacifiedgedx.com)

Pacific Edge Limited (NZX/ ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease. Headquartered in Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

**Cxbladder:** [www.cxbladder.com](http://www.cxbladder.com)

Cxbladder is a urine-based genomic biomarker test optimized for the detection and surveillance of bladder cancer. The Cxbladder evidence portfolio developed over the past 14 years includes more than 20 peer reviewed publications for primary detection, surveillance, adjudication of atypical urine cytology and equivocal cystoscopy. Cxbladder is the focal point of numerous ongoing and planned clinical studies to generate an ever-increasing body of clinical utility evidence supporting adoption and use in the clinic to improve patient health outcomes. Cxbladder has been trusted by over 4,400 US urologists in the diagnosis and management of more than 100,000 patients, including the option for in-home sample collection. In New Zealand, Cxbladder is accessible to 75% of the population via public healthcare and all residents have the option of buying the test online.



# Pacific Edge 1H 24 FINANCIAL RESULTS

INVESTOR PRESENTATION

*Dr Peter Meintjes*  
**Chief Executive Officer**

*Grant Gibson*  
**Chief Financial Officer**

**23 November 2023**



**PACIFIC EDGE**  
CANCER DIAGNOSTICS COMPANY

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

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# AGENDA

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



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

▲ **22%<sup>1</sup>**

GLOBAL TESTING  
VOLUMES  
(TLT<sup>2</sup>) on 1H 23

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

▲ **24%**

COMMERCIAL  
TEST VOLUMES  
on 1H 23

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

▲ **50%**

GROWTH IN  
OPERATING  
REVENUE on  
1H 23

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

**(\$15.1M)**

NET LOSS AFTER  
TAX

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

**\$62.2M**

CASH, CASH  
EQUIVALENTS<sup>3</sup>

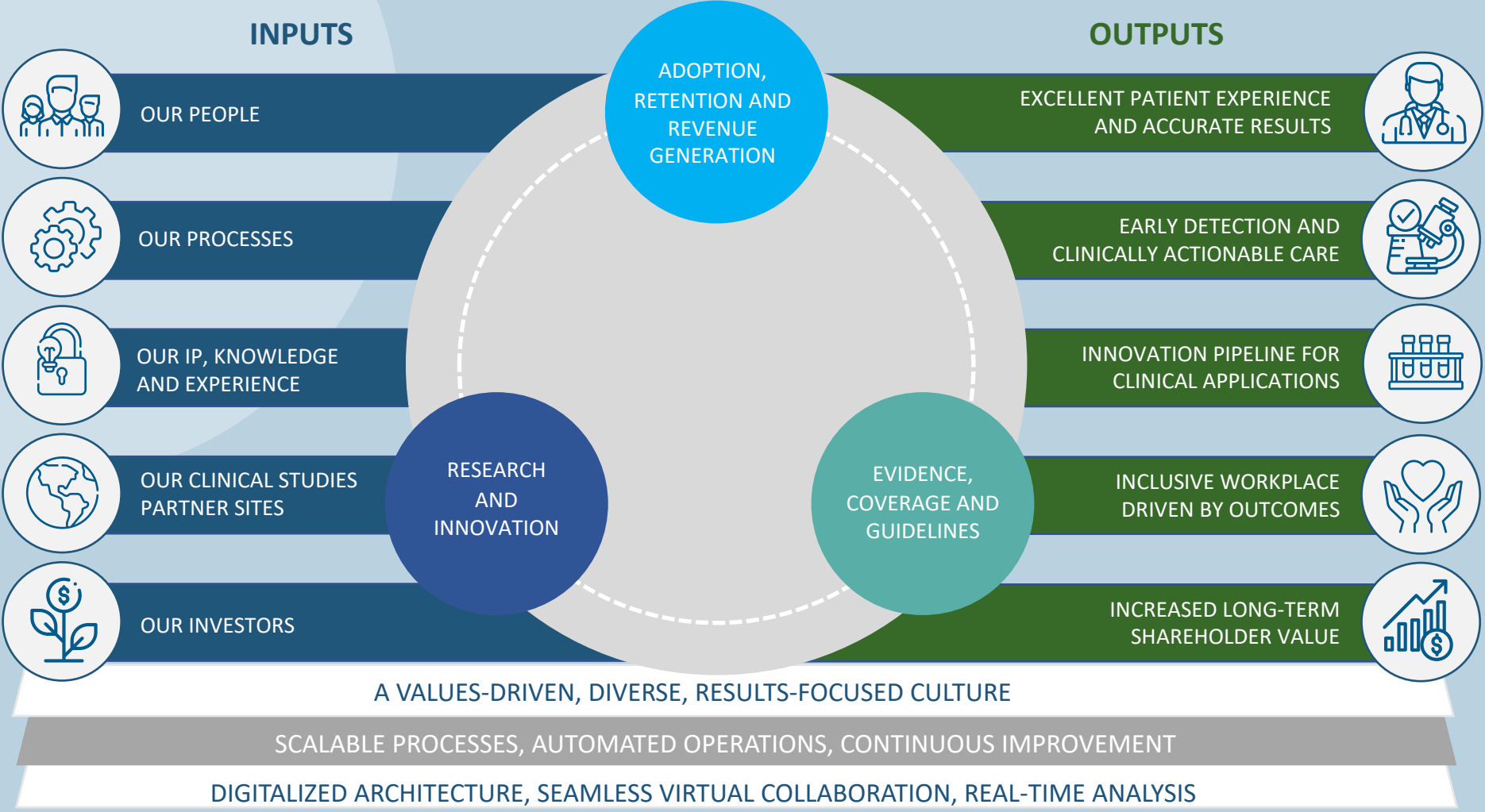
Strong Balance Sheet  
\$15.6M reduction in cash &  
cash equivalents<sup>3</sup> on Mar 23

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

1. All comparisons are to the same period in the prior year unless otherwise stated  
2. TLT is the Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing  
3. Cash, short-term deposits and term deposits  
4. EPR/PAP is the Enhanced Patient Responsibility / Patient Assistance Program



# VALUE CREATION THROUGH THREE PILLARS



# DEVELOPING A TRACK RECORD OF GROWTH

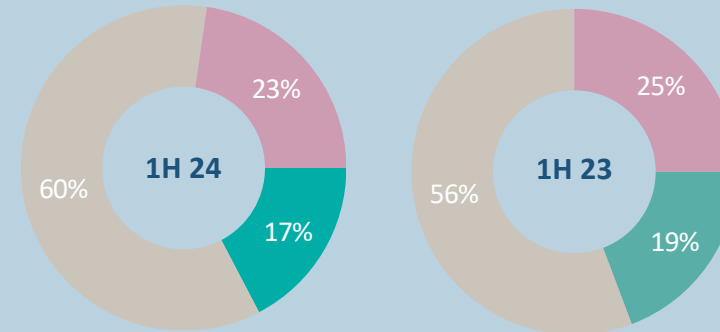
ABILITY TO EXECUTE DESPITE CHALLENGING MARKET HEADWINDS



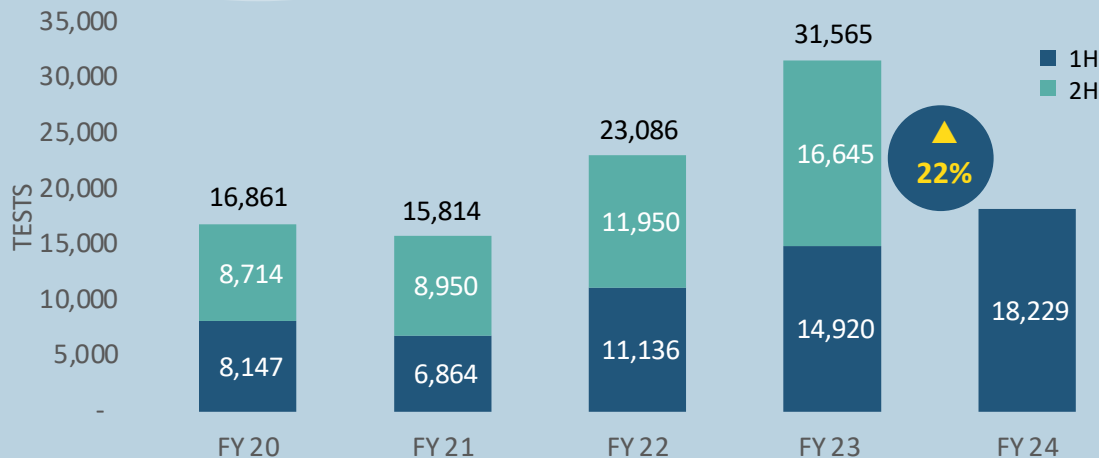
## 1H 24 TOTAL LAB THROUGHPUT (TLT\*)

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

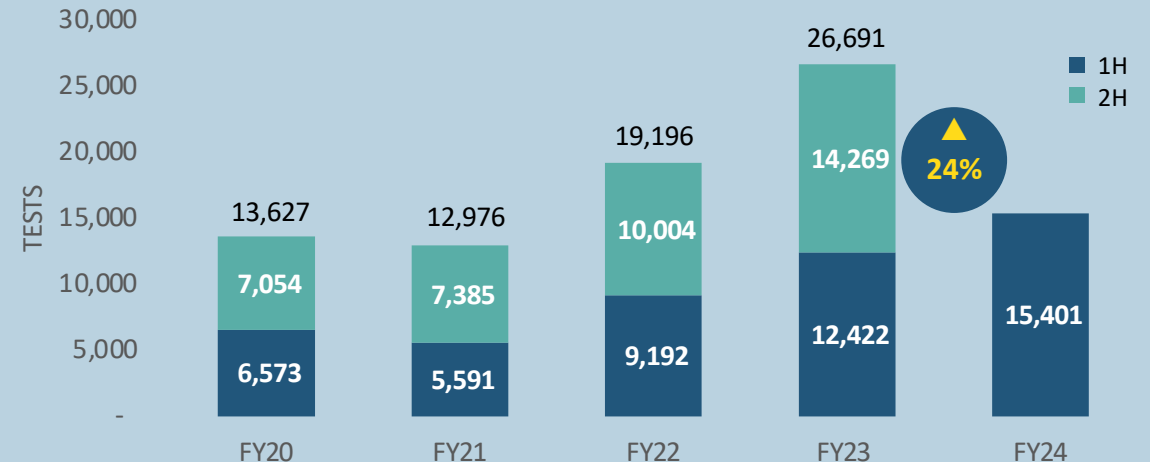
## TEST VOLUMES BY TYPE (TLT\*)



## GLOBAL TOTAL TEST VOLUMES (TLT\*)



## GLOBAL COMMERCIAL TEST VOLUMES (TLT\*)



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



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

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



## INDUSTRY AND UROLOGY KEY OPINION LEADERS UNITED TO OVERTURN DL39365

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



**REPUBLISHED DRAFT LCD**  
(27 July 2023)<sup>3</sup>



**REVIEW AND COMMENT PERIOD**  
(Closed 9 September 2023)<sup>2</sup>



### DECISION

Novitas must withdraw or finalize the LCD by 26 July 2024<sup>3</sup>  
LCD becomes effective (assuming no further protest) a minimum of 45 days after finalization

### PACIFIC EDGE'S LARGEST PAYER

- Medicare and Medicare Advantage is the largest global opportunity in bladder cancer diagnostics from a single coverage decision
- In 1H 24 Medicare and Medicare Advantage delivered ~7,850 commercial tests (~58% of US commercial tests) and ~\$9.9 m NZD in total operating revenue (~75%)



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

# BUILDING RESILIENCE TO WEATHER A MEDICARE NON-COVERAGE DECISION

PRESERVING CAPITAL, DIVERSIFYING REVENUE SOURCES, DRIVING PROFITABLE SALES OPERATIONS



## COMMITTED TO MAINTAINING A STRONG BALANCE SHEET

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

## PEDUSA STRATEGIC RESPONSE

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

## APAC & HEAD OFFICE STRATEGIC RESPONSE

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

## EXTENDING OUR REACH THROUGH DISTRIBUTION AGREEMENTS



# A FLEXIBLE AND GOAL FOCUSED SALES FORCE

REORGANISATION DISRUPTS SALES IN Q2 24



## WE HAVE REVIEWED OUR APPROACH TO THE US MARKET

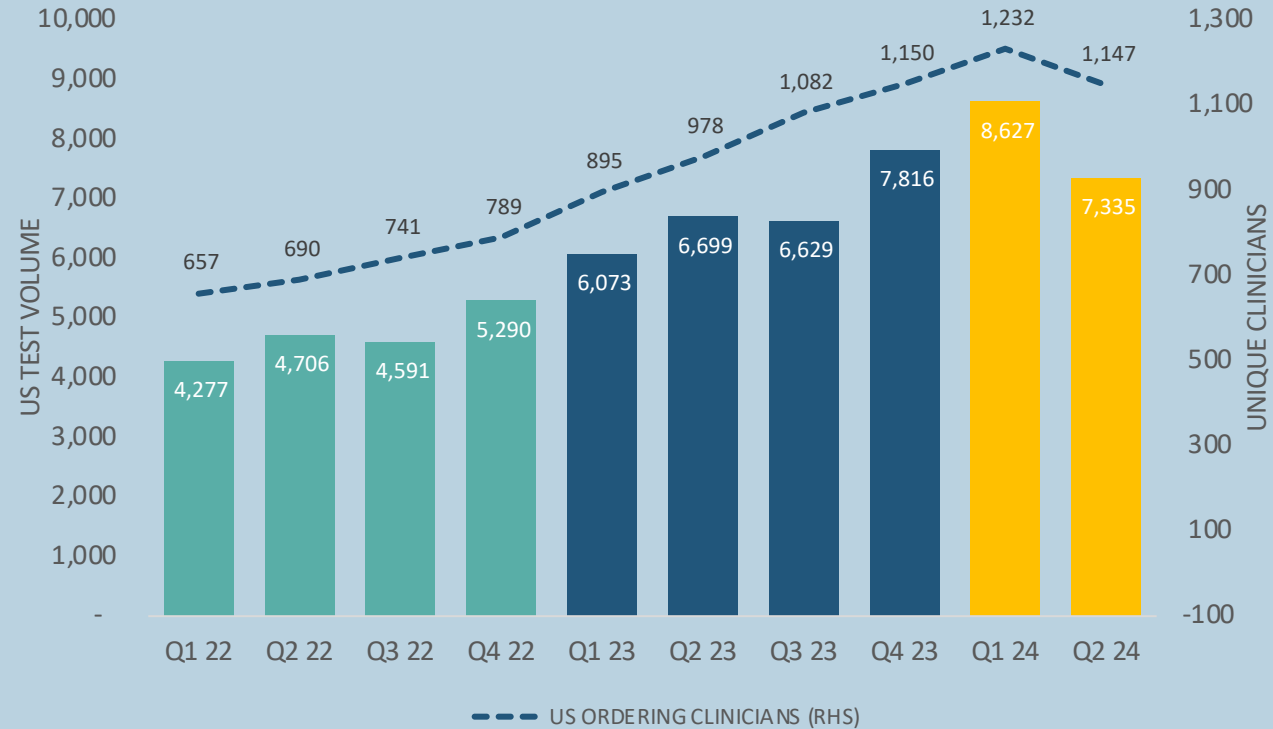
- Sales territories reduced from 29 to 17
- Sales initiatives focused on clinical value, economic value and patient value
- Increased expectations of throughput per sales force headcount
- Accelerate our clinical evidence generation program where possible with a focus on monitoring

## ENHANCED PATIENT RESPONSIBILITY AND SALES FORCE EFFICIENCY

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

## US TEST VOLUMES (TLT\*) AND ORDERING CLINICIANS

Commercial tests represent 84% of TLT in 1H 24



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



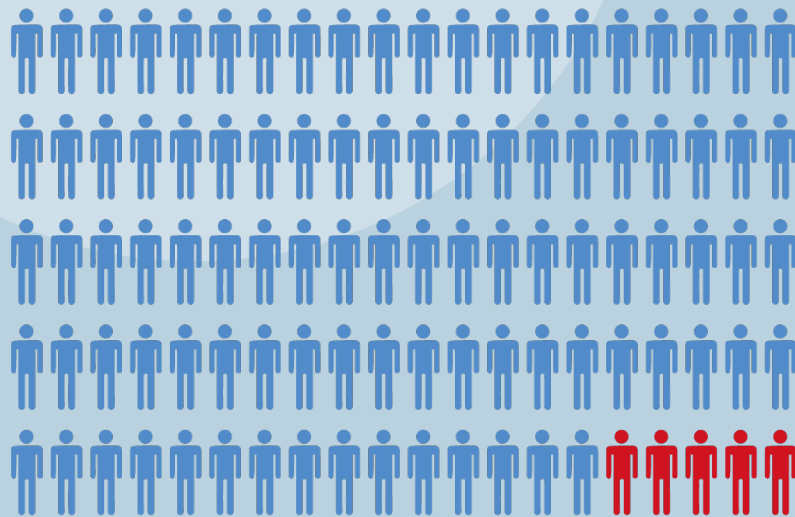
# SELLING CXBLADDER'S CLINICAL, ECONOMIC AND PATIENT VALUE



*For healthcare payers Cxbladder Detect offers substantial total cost savings per patient when used to intensify or de-intensify hematuria evaluation in patients presenting with microhematuria<sup>1</sup>*

## CURRENT PRACTICE (AUA GUIDELINES)

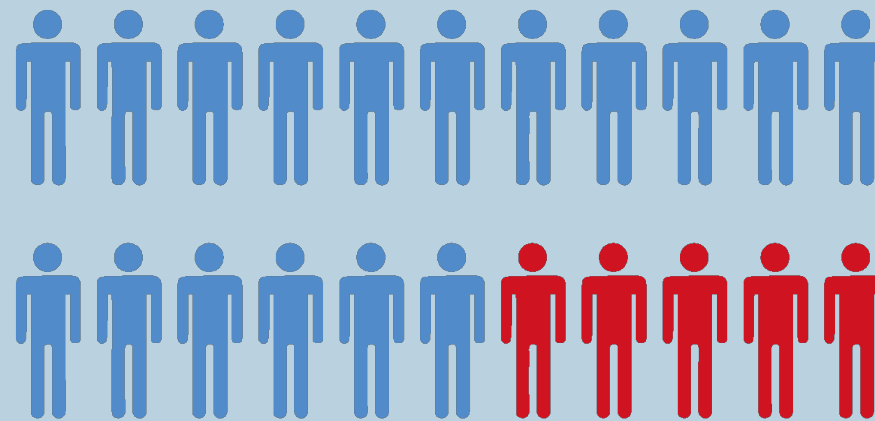
5% of patients with Microhematuria have Urothelial Cancer:  
Must do 100 cystoscopies to find 5 cancers



■ Normal (95%) ■ Cancer (5%)

## CXBLADDER 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 test price of US \$760/test focused on microhematuria patients. [Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed \(nih.gov\)](#)

# DRIVING GROWTH IN ASIA PACIFIC AND CONSOLIDATING NEW ZEALAND\*

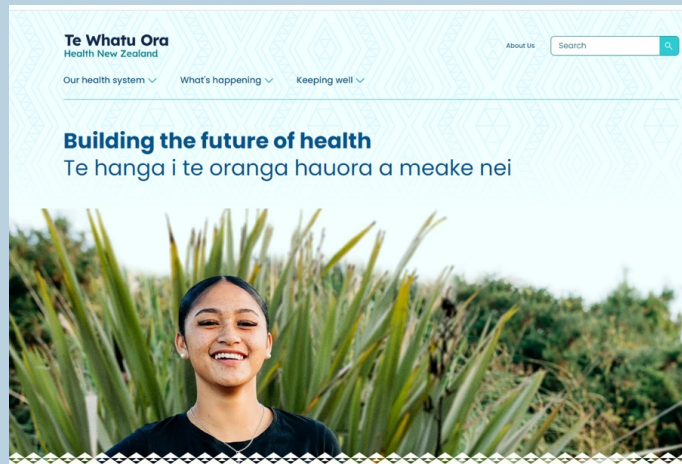


## NEW ZEALAND IS A MATURE MARKET

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

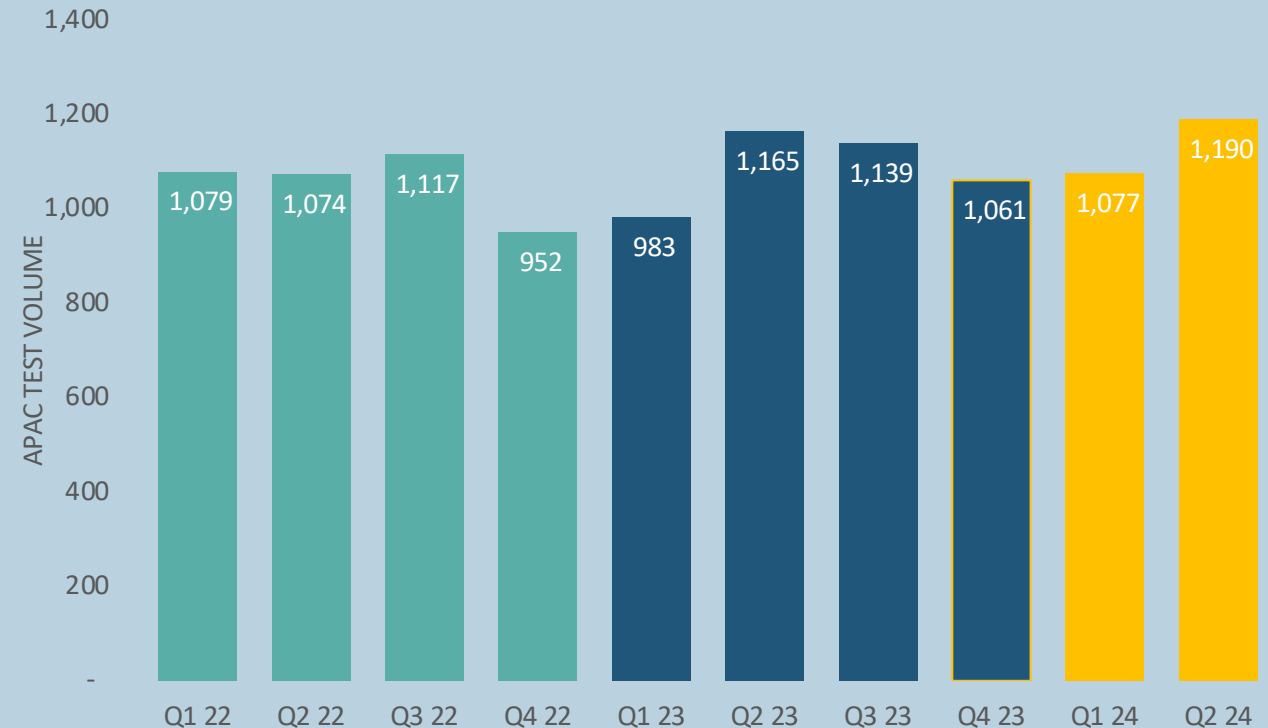
## AUSTRALIA & ASIA PACIFIC

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



## APAC TEST VOLUMES\*

Commercial tests represent 84% of TLT in 1H 24



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

# STRENGTHENING OUR FOUNDATIONS: PERFORMANCE EXCELLENCE



## DIGITALIZATION, AUTOMATION & CUSTOMER EXPERIENCE

### *Customer facing systems*

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

### *Internal systems*

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

## *CXBLADDER NOW LIVE IN KAISER PERMANENTE'S EMR*

*Achievement expected to drive volume in 2H 24*

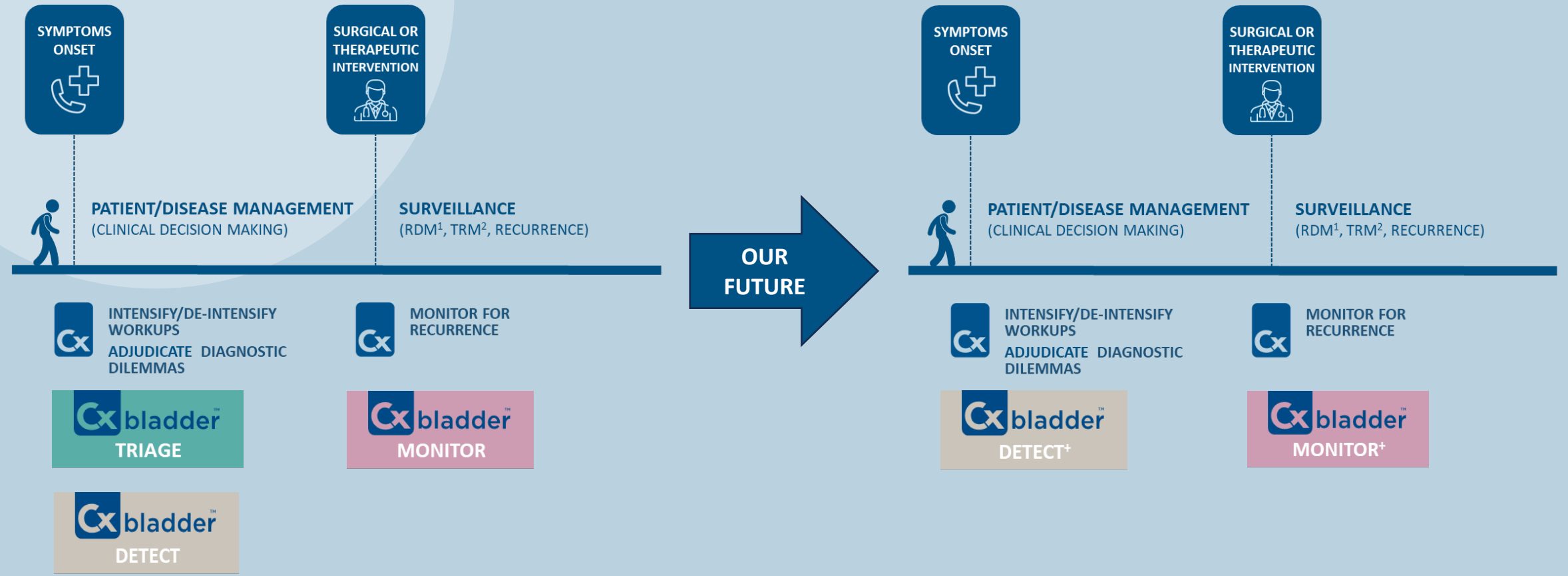


- EMR integration went live 14 November 2023 (US Time) that streamlines sample collection, test ordering and resulting
- Cxbladder Triage and Monitor introduced into Southern California Permanente Medical Group (Kaiser SoCal); 15 sites now eligible to order Cxbladder electronically
- Large opportunity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



# SIMPLIFYING THE CXBLADDER PROPOSITION – DETECT+ AND MONITOR+

LEVERAGING EVIDENCE SHOWING THE ADDITION OF DNA BIOMARKERS ENHANCES TEST PERFORMANCE<sup>3</sup>



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

3. Lotan et al 'Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification'

# CLINICAL EVIDENCE UNDERPINS COVERAGE AND GUIDELINES DECISIONS



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



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



National Comprehensive Cancer Network®

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

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



European Association of Urology

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

- Leading urologic authority in Europe and globally influential
- **Relevant standards of care:** non-muscle invasive bladder cancer
- **Review period:** with new evidence, last updated in March 2023

## PACIFIC EDGE'S CLINICAL STUDY PROGRAM

**STRATA**  
Safe Testing of Risk for AsymptomaTic microhematuria

**DRIVE**  
Detection and Risk stratification in Veterans presenting with hematuria

**AUSSIE**  
Australian Urologic risk Stratification of patientS with hEmaturia

**microDRIVE**  
Detection and Risk Stratification in Veterans Presenting with Microhematuria

**POOLED ANALYSIS**  
Pooled-analysis of Detect\* from multiple studies

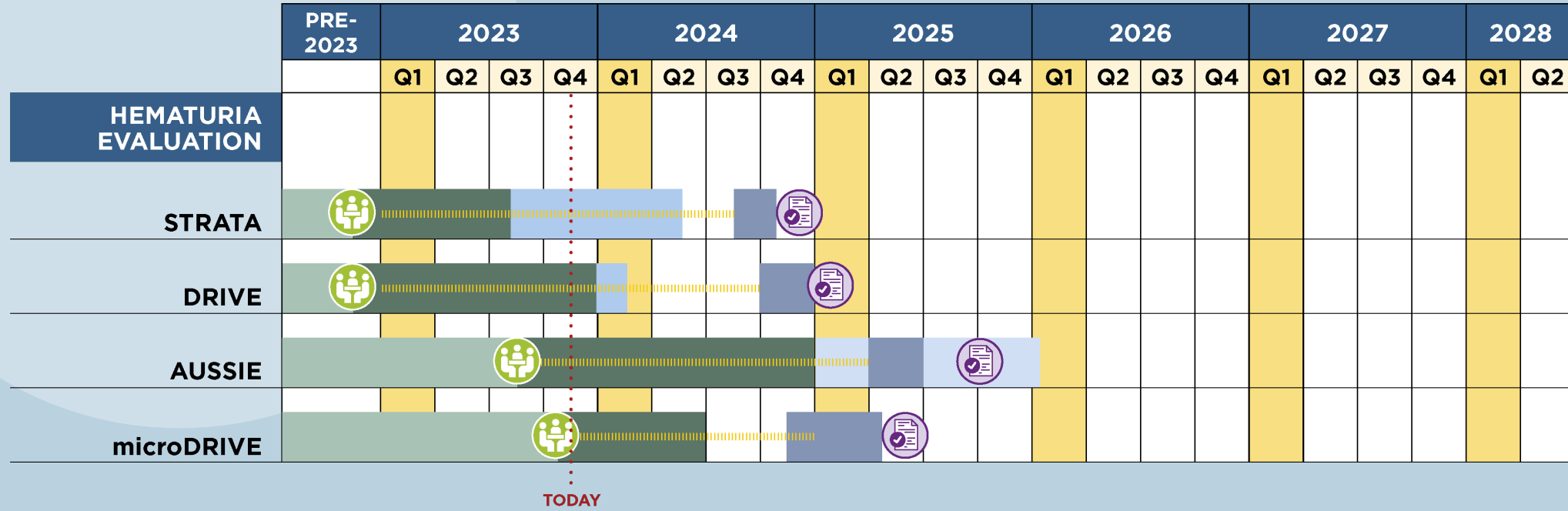
**LOBSTER**  
Longitudinal Bladder Cancer Study for Tumor RecurRence

**CREDIBLE**  
Cystoscopic REDuction In Bladder Evaluations for micro-hematuria



# FIVE YEAR CXBLADDER CLINICAL STUDY ROAD MAP

PACIFIC EDGE WILL SEEK GUIDELINE INCLUSION AS NEW EVIDENCE PRODUCED

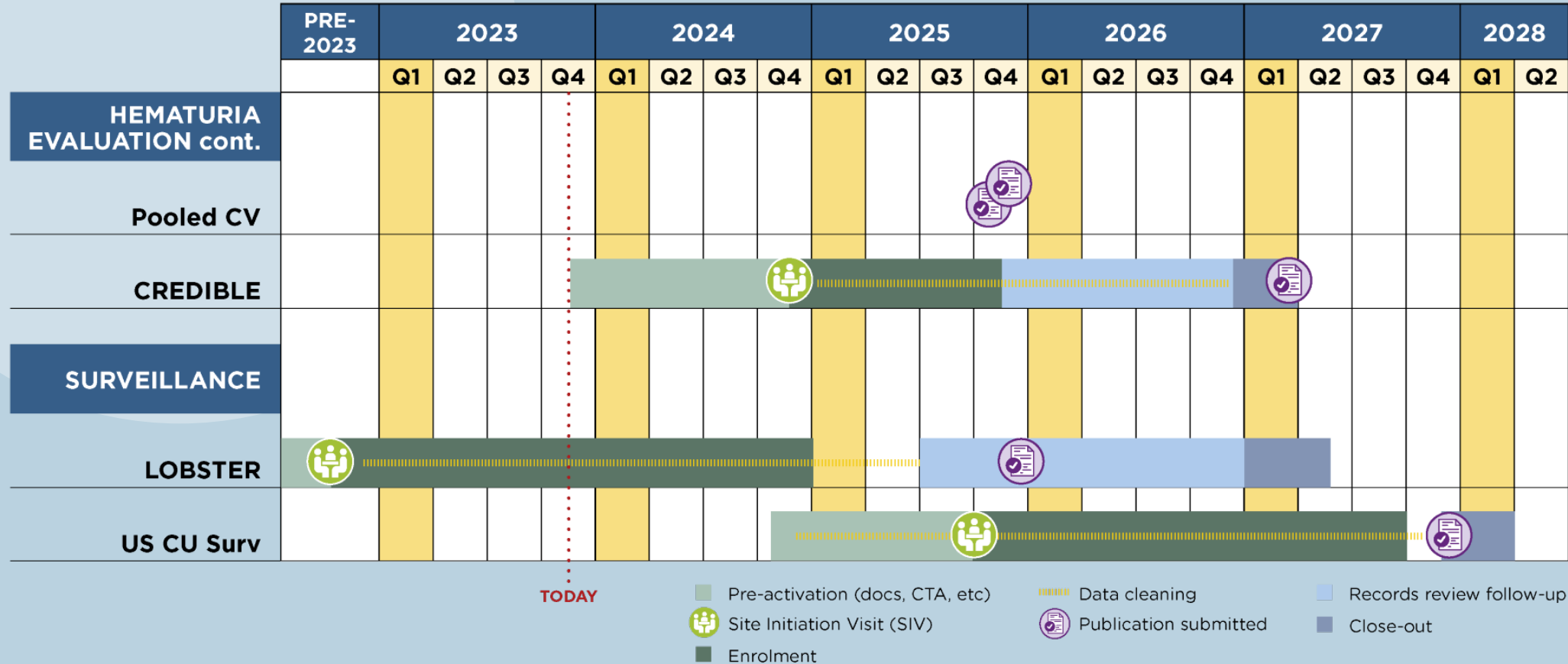


**Note: AUSSIE** - Interim analysis for primary objective occurs Q2-2025 and follow-up for secondary objective will continue to Q4-2025

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

# FIVE YEAR CXBLADDER CLINICAL STUDY ROAD MAP (continued)...

STUDIES FOR DETECT+ AND MONITOR+



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

# AMPLIFYING OUR EVIDENCE WITH UROLOGY OPINION LEADERS



## CLINICAL DOSSIER DEVELOPMENT

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

## PODIUMS, PRESENTATIONS, POSTERS AND PUBLICATIONS

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

## BUILDING KOL RELATIONSHIPS

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



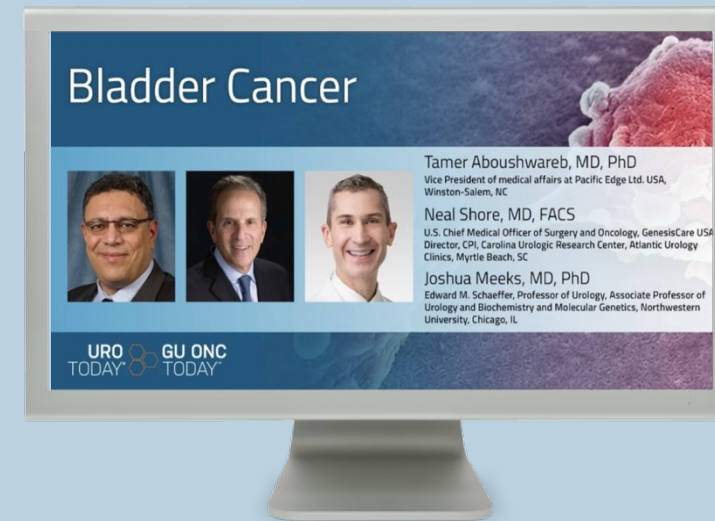
American  
Urological  
Association



National Comprehensive  
Cancer Network®



European  
Association  
of Urology



VIDEO VIEWS

4102

PUBLISHED  
12/2/22

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

# WE ARE PREPARED SHOULD FDA REGULATE LAB DEVELOPED TESTS



## FDA REGULATION FACES HURDLES

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



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

# RESEARCH & INNOVATION – FOCUSED ON DNA ENHANCED PRODUCTS



## READYING FOR THE LAUNCH OF NEW DETECT+ AND MONITOR+

- Ensure R&D, Digital and Lab Operations focus on the launch of Detect+ and Monitor+
- Simplifying Cxbladder to reduce technician time, lower cost of goods, lower turnaround time, increase throughput and increase automation
- Develop sufficient documentation for in-vitro diagnostic (IVD) regulation associated with product development and analytical validation of our next generation tests
- Continued engagement with industry and academic research and development collaborations to address unmet clinical needs in bladder cancer diagnosis and management



# 1H 24 FINANCIAL PERFORMANCE



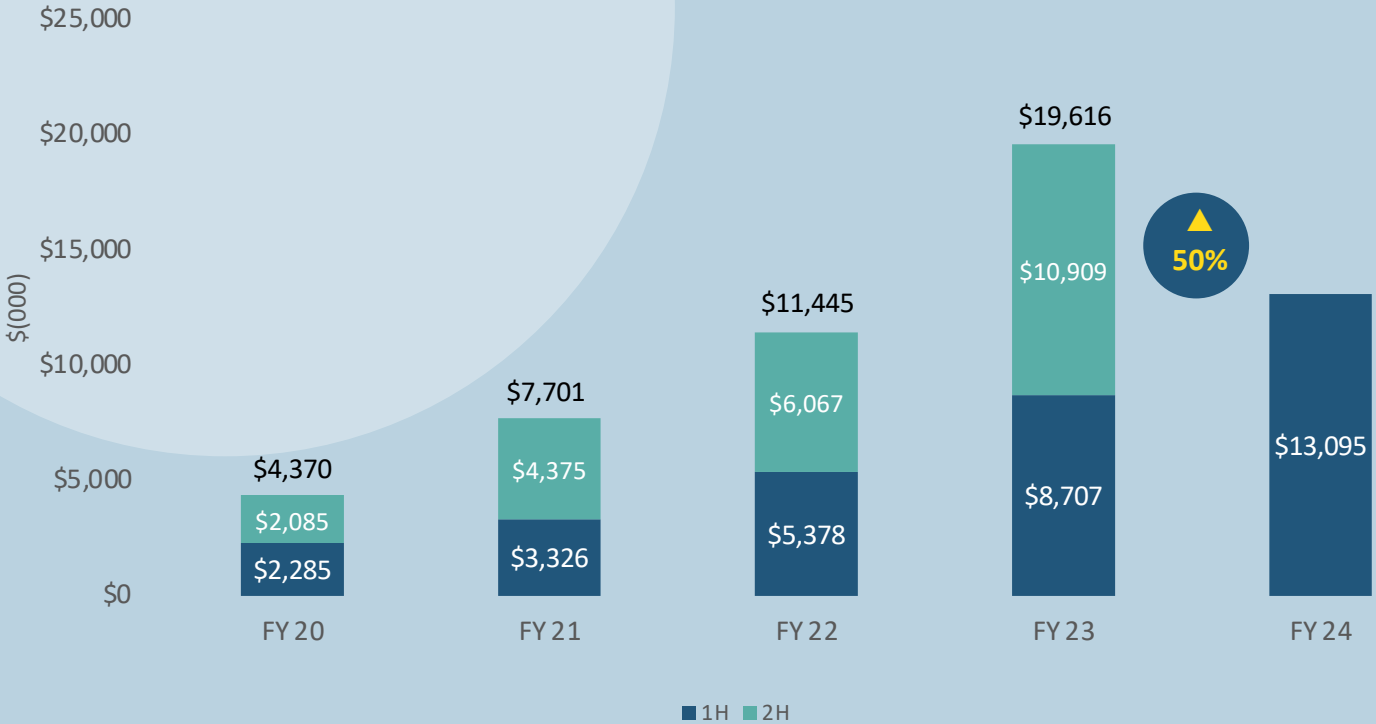
PACIFIC EDGE  
CANCER DIAGNOSTICS COMPANY



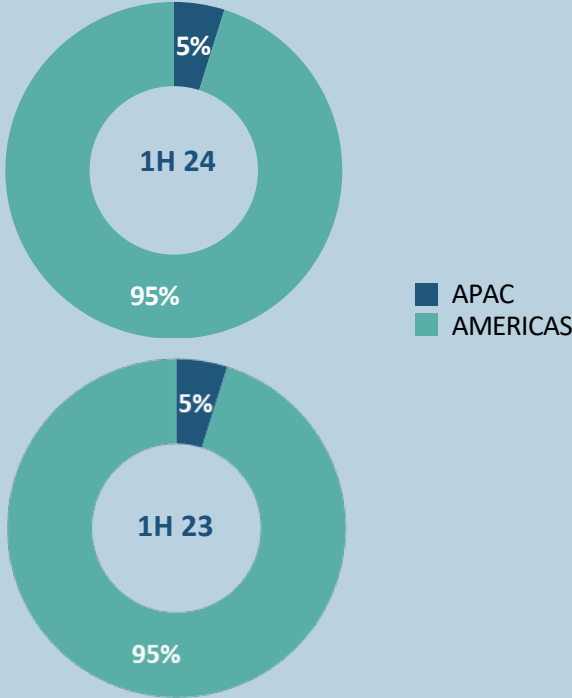
# US COMMERCIAL TEST VOLUME GROWTH DRIVING REVENUE

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

## PACIFIC EDGE OPERATING REVENUE



## REGIONAL REVENUE CONTRIBUTION



# REVENUE GROWS WITH INCREASED ADOPTION OF CXBLADDER

LOSSES REFLECT INVESTMENTS FOR TOP LINE REVENUE GROWTH IN FY23

Half year to 30 September	1H 24	2H 23	1H 23	1H 24 vs. 1H 23	1H 24 vs. 1H 23
	\$(000)	\$(000)	\$(000)	△ \$(000)	△%
Operating revenue	\$13,095	\$10,909	\$8,707	\$4,388	50%
Total revenue	\$16,580	\$12,531	\$13,593	\$2,987	22%
Operating expenses	\$31,832	\$28,925	\$24,164	\$7,668	32%
<b>Total comprehensive loss</b>	<b>-\$15,054</b>	<b>-\$16,873</b>	<b>-\$10,191</b>	<b>-\$4,863</b>	<b>48%</b>

Cash receipts from customers	\$13,576	\$11,152	\$7,316	\$6,260	86%
Net operating cash outflow	\$14,992	\$11,603	\$13,972	\$1,020	7%
<b>Net cash, cash equivalents and short-term deposits</b>	<b>\$62,174</b>	<b>\$77,791</b>	<b>\$93,455</b>	<b>-\$31,281</b>	<b>-33%</b>

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

# OPERATING EXPENSES RISE REFLECTING GROWTH CONFIGURATION

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

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

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

# ESG: PACIFIC EDGE IS FOUNDED ON IMPROVING SOCIAL OUTCOMES

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

## GOVERNANCE

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




## AOTEAROA NEW ZEALAND CLIMATE STANDARDS

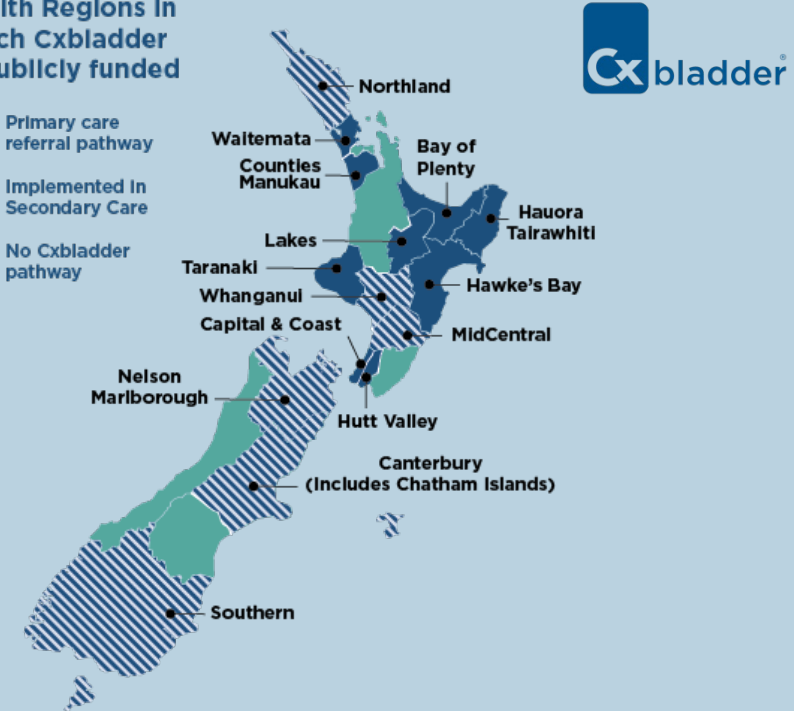
- Measured carbon emissions (Scope 1, 2, 3) in FY 23 and positioned to provide base year data in FY 24
- Working closely with expert advisors to accurately audit and measure our greenhouse gas emissions, as we work towards achieving certification in respect of FY 24
- Developing strategies and policies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

## ATTRACTING AND RETAINING TALENT AT PACIFIC EDGE

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

### Health Regions in which Cxbladder is publicly funded

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



### PROMOTING HEALTH CARE EQUITY

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

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

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

## OUTLOOK: FOCUSED ON FY24 EXECUTION

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

# APPENDIX



### **Mission**

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

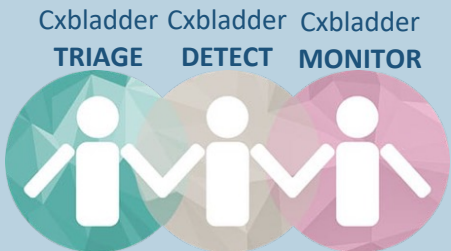
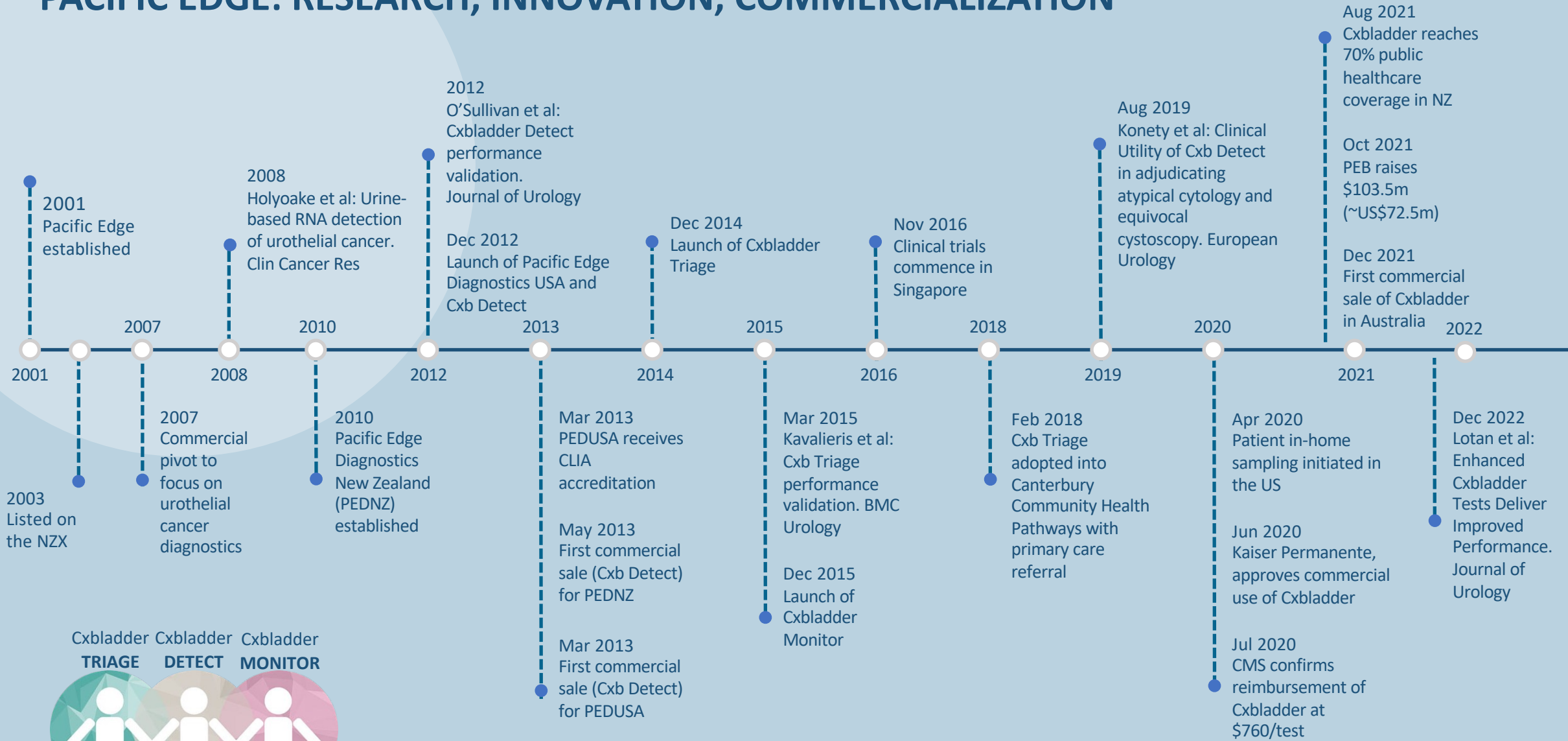


### **Vision**

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




# PACIFIC EDGE: RESEARCH, INNOVATION, COMMERCIALIZATION





# MOLECULAR DIAGNOSTICS VALUE CHAIN: PATIENT JOURNEY

**GENETIC RISK AT BIRTH**



**GENOMIC SCREENING**  
(PERSONALIZED GENETIC RISK)

**DISEASE MANIFESTS**



**ASYMPTOMATIC SCREENING**  
(EARLY DETECTION)

**SYMPTOMS ONSET**



**PATIENT/DISEASE MANAGEMENT**  
(CLINICAL DECISION MAKING)

**SURGICAL OR THERAPEUTIC INTERVENTION**



**SURVEILLANCE**  
(RDM<sup>1</sup>, TRM<sup>2</sup>, RECURRENCE)



**INTENSIFY/DE-INTENSIFY WORKUPS**



**ADJUDICATE DIAGNOSTIC DILEMMAS**



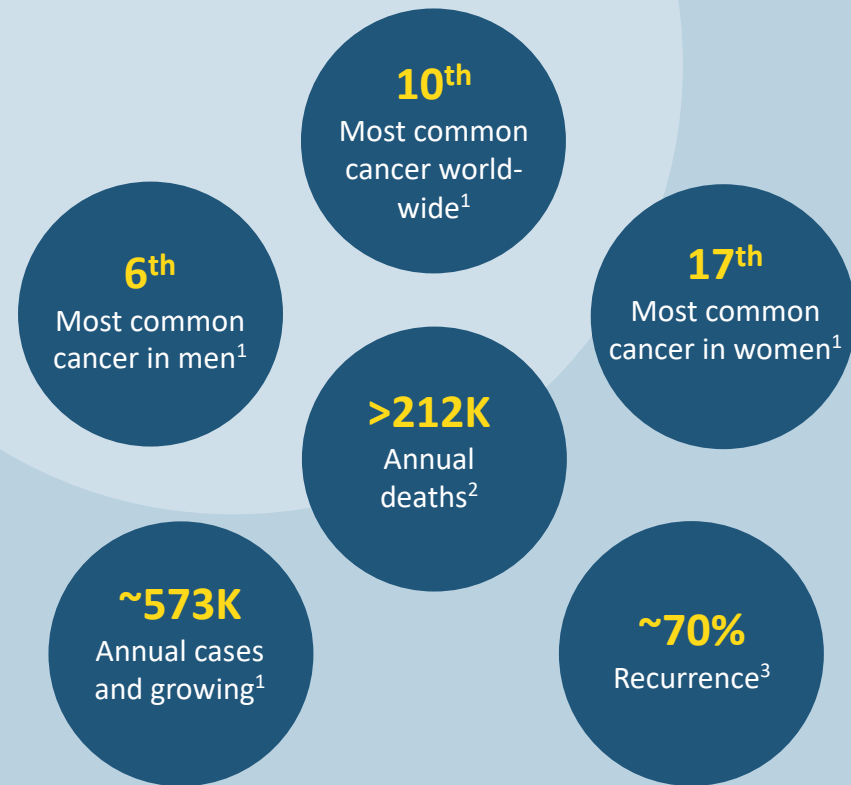
**MONITOR FOR RECURRENCE**



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

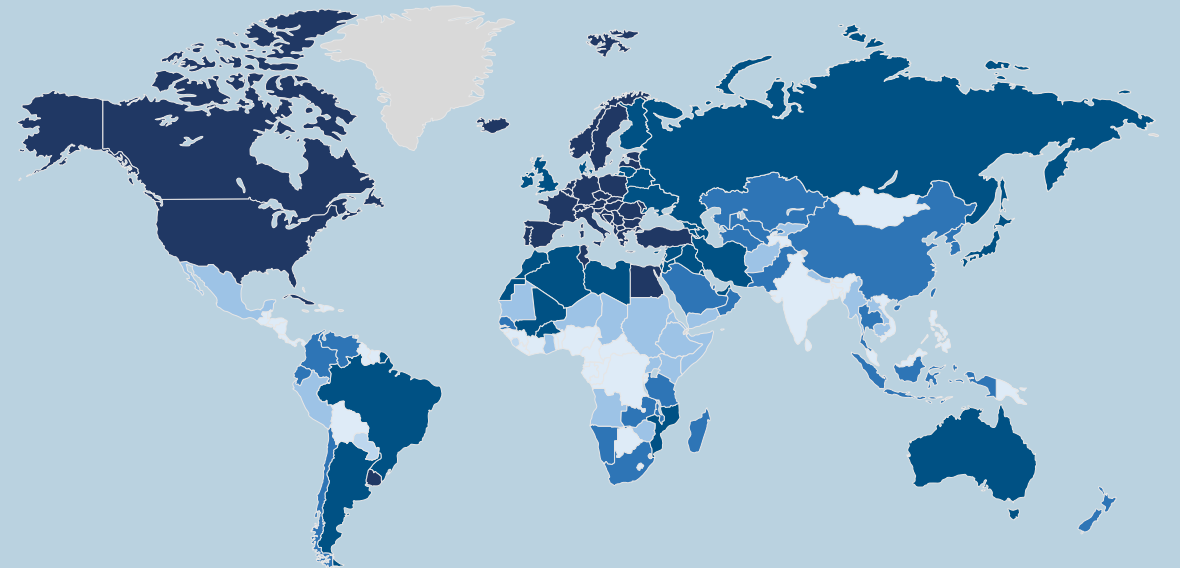
# BLADDER CANCER

A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE



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

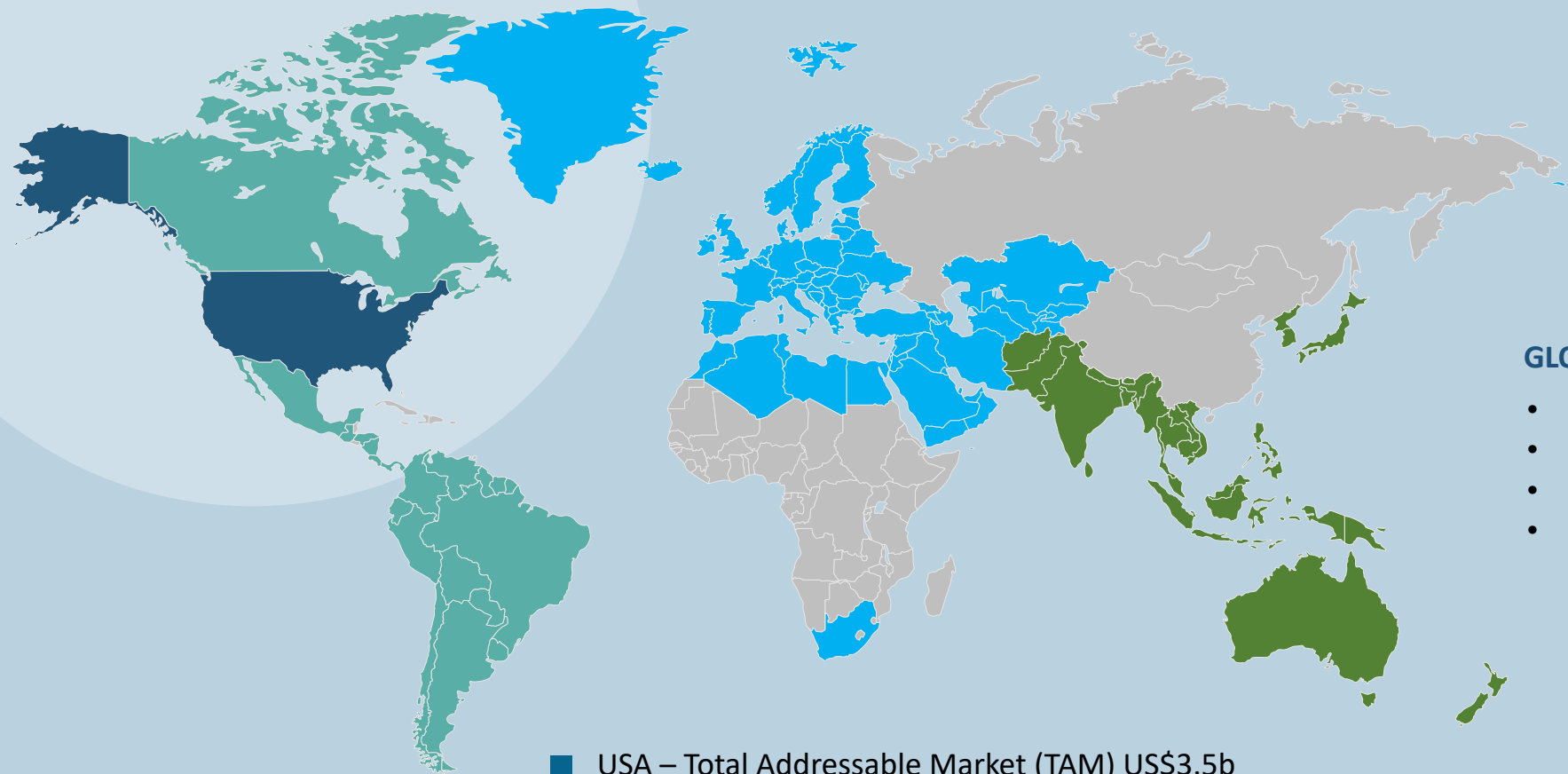
■ <1.7   ■ 1.7 to 2.7   ■ 2.7 to 5.3   ■ 5.3 to 8.6   ■ >8.6



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

# CXBLADDER IS A GLOBAL OPPORTUNITY

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



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

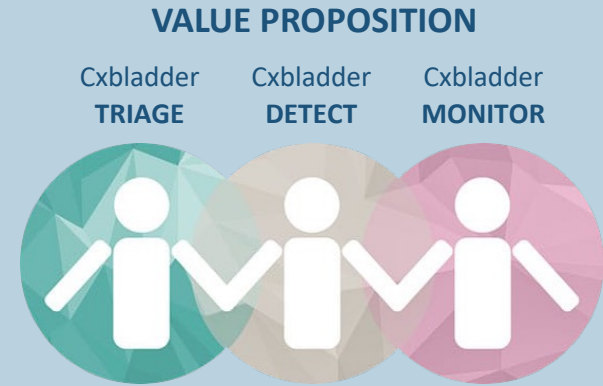
## GLOBAL COMMERCIALIZATION

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

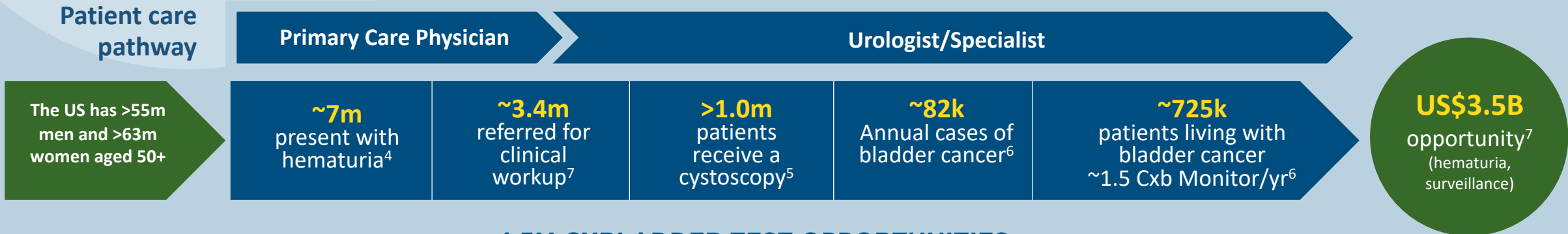
1. Pacific Edge estimates



# HEMATURIA EVALUATION AND SURVEILLANCE IN THE US MARKET



## Patient care pathway



**>4.5M CXBLADDER TEST OPPORTUNITIES**

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



# THE PRINCIPLES OF PACIFIC EDGE'S CLINICAL STUDY DESIGN PROGRAM

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



STUDY	GOAL*	USE CASE / INDICATION	POPULATION
<b>STRATA</b>	<ul style="list-style-type: none"> <li>• CU of Triage</li> <li>• CV of Detect<sup>+</sup> (retrospective)</li> </ul>	<ul style="list-style-type: none"> <li>• Risk stratification</li> </ul>	<ul style="list-style-type: none"> <li>• Microhematuria</li> </ul>
<b>DRIVE</b>	<ul style="list-style-type: none"> <li>• CV of Detect<sup>+</sup></li> <li>• CV of Triage</li> <li>• Data for pooled-analysis</li> </ul>	<ul style="list-style-type: none"> <li>• Risk stratification</li> </ul>	<ul style="list-style-type: none"> <li>• Microhematuria and gross hematuria</li> </ul>
<b>AUSSIE</b>	<ul style="list-style-type: none"> <li>• CV of Detect<sup>+</sup> with an Australian cohort</li> <li>• Data for pooled analysis</li> </ul>	<ul style="list-style-type: none"> <li>• Risk stratification</li> </ul>	<ul style="list-style-type: none"> <li>• Microhematuria and gross hematuria</li> </ul>
<b>microDRIVE</b>	<ul style="list-style-type: none"> <li>• CV of Detect<sup>+</sup></li> <li>• Data for pooled analysis</li> </ul>	<ul style="list-style-type: none"> <li>• Risk stratification</li> </ul>	<ul style="list-style-type: none"> <li>• Microhematuria</li> </ul>
<b>POOLED ANALYSIS (two groups)</b>	<ul style="list-style-type: none"> <li>• CV of Detect<sup>+</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Risk stratification</li> </ul>	<ul style="list-style-type: none"> <li>• Microhematuria / gross hematuria</li> </ul>
<b>LOBSTER</b>	<ul style="list-style-type: none"> <li>• CV of Monitor/Monitor<sup>+</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Risk stratification</li> </ul>	<ul style="list-style-type: none"> <li>• Surveillance</li> </ul>
<b>CREDIBLE</b>	<ul style="list-style-type: none"> <li>• CU of Detect<sup>+</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Risk stratification</li> </ul>	<ul style="list-style-type: none"> <li>• Microhematuria</li> </ul>

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

# SUMMARY OF CLINICAL EVIDENCE

		Study	Pop. Type	Sensitivity (Sn)	NPV	Specificity (Sp)	Comment
<b>Detect+</b>	<b>AV</b>	Lotan et al., 2022	MH + GH*	97%	99.7%	90%	Pooled data from US and Singapore cohorts (n=804)
	<b>CV</b>	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
	<b>CU</b>	CREDIBLE (not started) (6)	MH				Protocol in final development stages, site selection starting by the end of year.
<b>Triage</b>	<b>AV</b>	Kavalieris et al., 2015	MH + GH*	95.10%	98.50%	45%	<b>Sn, Sp, NPV</b> values when test-negative rate is 40%
	<b>CV</b>	Davidson et al., 2019	MH + GH*	95.5% (1)	98.6% (1)	34.3%	GH only: <b>Sn</b> (95.1%), <b>NPV</b> (98%), <b>Sp</b> (32.8%); MH only: <b>Sn</b> (100%), <b>NPV</b> (100%), <b>Sp</b> (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)
	<b>CU</b>	Davidson et al., 2020	MH + GH*	89.4% (5)	98.9% (5)	59% (5)	39% of patients testing negative for Cxb Triage & imaging did not get cystoscopy & were managed at primary care (6)
		STRATA (unpublished) (7)	MH + GH*				Study in progress
<b>Detect</b>	<b>AV</b>	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.
	<b>CV</b>	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
<b>Monitor</b>	<b>AV</b>	Kavalieris et al., 2017	(1)	88% (2)	97% (2)	N/A	(3)
	<b>CV</b>	Konety et al., 2019	(4)	100%			Cxbladder (5) correctly adjudicated all UC confirmed patients (n=26) with atypical urine cytology results (n=153, 6)
	<b>CU</b>	Koya et al., 2020	(7)				Integration of Cxb Monitor into the surveillance schedule reduced annual cystoscopies (39%) (8,9)
	<b>CU</b>	Li et al., 2023	(7)				Cxbladder Monitor safely postpones a patient's next scheduled cystoscopy, the current 'gold standard' for bladder cancer surveillance.

\*Referred patients.

Definitions - MH: Microhematuria, GH: Gross Hematuria. For Sensitivity, NPV and Specificity please see page 38 of this presentation

# FOOTNOTES FOR CLINICAL EVIDENCE SUMMARY

Footnotes		
<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	The intent of STRATA is to show that it is safe to risk stratify 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.
<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

# GLOSSARY

- **Sensitivity** - the frequency with which a test correctly identifies patients with a disease.
- **Specificity** - the frequency with which a test correctly identifies patients without a disease.
- **Negative Predictive Value (NPV)** - the percentage of negative tests being true negatives (by standard of care).
- **Positive Predictive Value (PPV)** - the percentage of positive tests being true positives (by standard of care).
- **Rule-out Rate (ROR)** - the percentage of tests that return a negative result.
- **Evidence definitions:**
  - **Analytical validity:** Evidence that a test is repeatable in the lab for a given indication and population.
  - **Clinical validity:** Evidence a test works in the same way on an independent eligible population for a given indication.
  - **Clinical utility:** Evidence that a test in the hands of a physician can usefully change patient management within the context of care for the defined population and indication.

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**CONSOLIDATED  
INTERIM FINANCIAL  
STATEMENTS**

**FOR THE SIX MONTHS ENDED  
30 SEPTEMBER 2023**



**PACIFIC EDGE** LTD  
CANCER DIAGNOSTICS COMPANY

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

## Consolidated Interim Financial Statements

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	NOTES	UNAUDITED SEPT 2023 6 MONTHS (\$'000)	UNAUDITED SEPT 2022 6 MONTHS (\$'000)	AUDITED MARCH 2023 12 MONTHS (\$'000)
<b>REVENUE</b>				
Operating Revenue	4	13,095	8,707	19,616
<b>Total Operating Revenue</b>		<b>13,095</b>	<b>8,707</b>	<b>19,616</b>
Other Income	4	859	761	1,417
Interest Income		1,892	1,099	2,761
Foreign Exchange Gain		734	3,026	2,330
<b>Total Revenue and Other Income</b>		<b>16,580</b>	<b>13,593</b>	<b>26,124</b>
<b>OPERATING EXPENSES</b>				
Laboratory Operations		6,141	4,467	9,349
Research		5,487	3,710	8,484
Sales and Marketing		14,339	11,375	25,123
General and Administration		5,865	4,612	10,133
<b>Total Operating Expenses</b>	5	<b>31,832</b>	<b>24,164</b>	<b>53,089</b>
<b>NET LOSS BEFORE TAX</b>		<b>(15,252)</b>	<b>(10,571)</b>	<b>(26,965)</b>
Income Tax Expense		-	-	-
<b>LOSS FOR THE YEAR AFTER TAX</b>		<b>(15,252)</b>	<b>(10,571)</b>	<b>(26,965)</b>
<i>Items that may be reclassified to profit or loss:</i>				
Translation of Foreign Operations		198	380	(99)
<b>TOTAL COMPREHENSIVE LOSS attributable to equity holders of the Company</b>		<b>(15,054)</b>	<b>(10,191)</b>	<b>(27,064)</b>
<b>Earnings per share for loss attributable to the equity holders of the Company during the year</b>				
Basic and Diluted Earnings per share		(0.019)	(0.013)	(0.033)

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements.

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

	NOTES	SHARE CAPITAL (\$'000)	ACCUMULATED LOSSES (\$'000)	SHARE BASED PAYMENTS RESERVE (\$'000)	FOREIGN CURRENCY TRANSLATION RESERVE (\$'000)	TOTAL EQUITY (\$'000)
<b>UNAUDITED 6 MONTHS TO 30 SEPT 2022</b>						
<b>Balance as at 31 March 2022</b>		<b>294,139</b>	<b>(189,849)</b>	<b>3,145</b>	<b>941</b>	<b>108,376</b>
Loss After Tax		-	(10,571)	-	-	(10,571)
Other Comprehensive Income		-	-	-	380	380
Total Comprehensive Loss attributable to equity holders of the Company		-	(10,571)	-	380	(10,191)
<i>Transactions with owners in their capacity as owners:</i>						
Issue of Share Capital	7	(2)	-	-	-	(2)
Share Based Payments - Employee Remuneration	7	93	-	-	-	93
Share Based Payment - Employee Share Options	7	-	-	567	-	567
<b>Balance as at 30 September 2022</b>		<b>294,230</b>	<b>(200,420)</b>	<b>3,712</b>	<b>1,321</b>	<b>98,843</b>
<b>AUDITED 12 MONTHS TO 31 MARCH 2023</b>						
<b>Balance as at 31 March 2022</b>		<b>294,139</b>	<b>(189,849)</b>	<b>3,145</b>	<b>941</b>	<b>108,376</b>
Loss After Tax		-	(26,965)	-	-	(26,965)
Other Comprehensive Income		-	-	-	(99)	(99)
Total Comprehensive Loss attributable to equity holders of the Company		-	(26,965)	-	(99)	(27,064)
<i>Transactions with owners in their capacity as owners:</i>						
Issue of Share Capital	7	(4)	-	-	-	(4)
Share Based Payments - Employee Remuneration	7	182	-	-	-	182
Share Based Payment - Employee Share Options	7	-	-	1,273	-	1,273
<b>Balance as at 31 March 2023</b>		<b>294,317</b>	<b>(216,814)</b>	<b>4,418</b>	<b>842</b>	<b>82,763</b>
<b>UNAUDITED 6 MONTHS TO 30 SEPT 2023</b>						
<b>Balance as at 31 March 2023</b>		<b>294,317</b>	<b>(216,814)</b>	<b>4,418</b>	<b>842</b>	<b>82,763</b>
Loss After Tax		-	(15,252)	-	-	(15,252)
Other Comprehensive Income		-	(8)	-	206	198
Total Comprehensive Loss attributable to equity holders of the Company		-	(15,260)	-	206	(15,054)
<i>Transactions with owners in their capacity as owners:</i>						
Issue of Share Capital	7	-	-	-	-	-
Share Based Payments - Employee Remuneration	7	38	-	-	-	38
Share Based Payment - Employee Share Options	7	-	-	555	-	555
<b>Balance as at 30 September 2023</b>		<b>294,355</b>	<b>(232,074)</b>	<b>4,973</b>	<b>1,048</b>	<b>68,302</b>

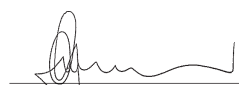
Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements.

## CONSOLIDATED BALANCE SHEET

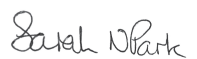
AS AT 30 SEPTEMBER 2023

	UNAUDITED SEPT 2023 6 MONTHS	UNAUDITED SEPT 2022 6 MONTHS	AUDITED MARCH 2023 12 MONTHS
NOTES	(\$000)	(\$000)	(\$000)
<b>CURRENT ASSETS</b>			
Cash and Cash Equivalents	20,469	37,989	33,229
Short Term Deposits	41,705	55,466	44,562
Receivables	5,239	6,017	5,493
Inventory	1,676	1,507	1,287
Other Assets	1,688	1,734	1,400
<b>Total Current Assets</b>	<b>70,777</b>	<b>102,713</b>	<b>85,971</b>
<b>NON-CURRENT ASSETS</b>			
Property, Plant and Equipment	2,945	1,753	2,768
Right of Use Assets	1,376	1,507	1,143
Intangible Assets	1,156	784	1,031
<b>Total Non-Current Assets</b>	<b>5,477</b>	<b>4,044</b>	<b>4,942</b>
<b>TOTAL ASSETS</b>	<b>76,254</b>	<b>106,757</b>	<b>90,913</b>
<b>CURRENT LIABILITIES</b>			
Payables and Accruals	6,539	5,983	6,928
Lease Liabilities	529	1,267	811
<b>Total Current Liabilities</b>	<b>7,068</b>	<b>7,250</b>	<b>7,739</b>
<b>NON-CURRENT LIABILITIES</b>			
Lease Liabilities	884	664	411
<b>Total Non-Current Liabilities</b>	<b>884</b>	<b>664</b>	<b>411</b>
<b>TOTAL LIABILITIES</b>	<b>7,952</b>	<b>7,914</b>	<b>8,150</b>
<b>NET ASSETS</b>	<b>68,302</b>	<b>98,843</b>	<b>82,763</b>
Represented by:			
<b>EQUITY</b>			
Share Capital	7	294,355	294,230
Accumulated Losses		(232,074)	(216,814)
Share Based Payments Reserve		4,973	3,712
Foreign Translation Reserve		1,048	1,321
<b>TOTAL EQUITY</b>		<b>68,302</b>	<b>98,843</b>
<b>FURTHER INFORMATION:</b>			
Net Tangible Assets Per Share (\$)	14	0.083	0.121

For and on behalf of the Board of Directors



Director



Director

Dated 22nd day of November 2023

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements.

## CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

	UNAUDITED SEPT 2023 6 MONTHS	UNAUDITED SEPT 2022 6 MONTHS	AUDITED MARCH 2023 12 MONTHS
NOTES	(\$000)	(\$000)	(\$000)
<b>CASH FLOWS TO OPERATING ACTIVITIES</b>			
Cash was provided from:			
Receipts from Customers	13,576	7,316	18,468
Receipts from Grant Providers	1,371	404	1,066
Interest Received	1,228	908	2,716
	16,175	8,628	22,250
Cash was disbursed to:			
Payments to Suppliers and Employees	31,080	22,611	47,869
Net GST outflow (inflow)	87	(11)	(44)
	31,167	22,600	47,825
<b>Net Cash Flows To Operating Activities</b>	<b>8</b>	<b>(14,992)</b>	<b>(25,575)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Cash was provided from:			
Proceeds from Short Term Deposits	35,703	71,784	143,490
	35,703	71,784	143,490
Cash was disbursed to:			
Purchase of Short Term Deposits	32,846	57,310	118,107
Capital Expenditure on Plant and Equipment	487	504	1,870
Capital Expenditure on Intangible Assets	302	487	1,039
	33,635	58,301	121,016
<b>Net Cash Flows From Investing Activities</b>	<b>2,068</b>	<b>13,483</b>	<b>22,474</b>
<b>CASH FLOWS (TO) FINANCING ACTIVITIES:</b>			
Cash was received from:			
Proceeds from Borrowings	-	314	-
Ordinary Shares Issued	7	-	(4)
	-	314	(4)
Cash was disbursed to:			
Repayment of Leases - Principal	675	553	1,195
Repayment of Leases - Interest	32	46	83
Issue Expenses	7	2	-
	707	601	1,278
<b>Net Cash Flows (To) Financing Activities</b>	<b>(707)</b>	<b>(287)</b>	<b>(1,282)</b>
<b>Net (Decrease) in Cash Held</b>	<b>(13,631)</b>	<b>(776)</b>	<b>(4,383)</b>
Add Opening Cash Brought Forward	33,229	35,412	35,412
Effect of Exchange Rate Changes on Net Cash	871	3,353	2,200
<b>Ending Cash Carried Forward</b>	<b>20,469</b>	<b>37,989</b>	<b>33,229</b>

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements.

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

**1. SUMMARY OF ACCOUNTING POLICIES**

The unaudited consolidated interim financial statements (“Interim Financial Statements”) presented are those of Pacific Edge Limited (“Company”) and its subsidiaries (“Group”). The Company is registered and domiciled in New Zealand. The Group’s purpose is to research, develop and commercialise new diagnostic and prognostic tools for the early detection and management of cancers. Pacific Edge Diagnostics New Zealand Limited and Pacific Edge Diagnostics USA Limited manage and operate the laboratories used for the detection of bladder cancer. Pacific Edge (Australia) Pty Limited’s purpose is to research and develop the Cxbladder products and other prognostic tools. Pacific Edge Diagnostics Singapore Pte Limited’s purpose is sales and marketing of bladder cancer products and assisting with research and development. Pacific Edge Analytical Services Limited is a dormant entity.

The Company is a for profit entity, registered in New Zealand under the Companies Act 1993 and is a reporting entity for the purposes of the Financial Markets Conduct Act 2013. The Company is dual listed, with its primary listing of ordinary shares quoted in New Zealand on the NZX Main Board, and a secondary listing in Australia as a Foreign Exempt Entity on the ASX.

**a) Basis of Preparation**

The Interim Financial Statements for the six months ended 30 September 2023 have been prepared in accordance with New Zealand Generally Accepted Accounting Practice (GAAP) and the Financial Markets Conduct Act 2013. They comply with the New Zealand Equivalents to International Financial Reporting Standards (NZ IFRS) and other guidance as issued by the External Reporting Board, as appropriate for entities, and with International Financial Reporting Standards.

The Interim Financial Statements have been prepared in accordance with NZ IAS 34 - Interim Financial Reporting. In complying with NZ IAS 34, these consolidated Interim Financial Statements also comply with IAS 34 - Interim Financial Reporting and should be read in conjunction with the Company’s 2023 Annual Report. The Interim Financial Statements for the six months ended 30 September 2023 are unaudited. Comparative balances for 30 September 2022 are unaudited, whilst the comparative balances for 31 March 2023 are audited.

The Interim Financial Statements are prepared on the basis of historical cost, except where otherwise identified. The presentational currency used in the preparation of the financial statements is New Zealand dollars and all values are rounded to the nearest thousand dollars (\$000).

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

**b) Accounting Policies**

All significant accounting policies have been applied on a basis consistent with those used in the audited financial statements of Pacific Edge Limited for the year ended 31 March 2023.

**c) Authorisation**

The Interim Financial Statements were authorised by the Board of Directors on 22 November 2023. The Annual Financial Statements for the year ended 31 March 2023 were authorised by the Board of Directors on 24 May 2023.

**d) Audit**

The Interim Financial Statements have not been audited. The comparative full year financial results for the year ended 31 March 2023 have been audited.

**e) Basis of Consolidation**

The following entities and the basis of their inclusion for consolidation in these Interim Financial Statements are as follows:

Name of Subsidiary	Place of Incorporation (or registration) and Operation	Principal Activity	Ownership Interests & Voting Rights	
			30 Sept 2023 (%)	30 Sept 2022 (%)
Pacific Edge Diagnostics New Zealand Limited	New Zealand	Commercial Sales and Diagnostic Laboratory Operation	100	100
Pacific Edge (Australia) Pty Limited	Australia	Commercial Sales and Biotechnology Research & Development	100	100
Pacific Edge Diagnostics USA Limited	USA	Commercial Sales and Diagnostic Laboratory Operation	100	100
Pacific Edge Singapore Pte Limited	Singapore	Commercial Sales and Biotechnology Research & Development	100	100
Pacific Edge Analytical Services Limited	New Zealand	Dormant Company	100	100



## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

**2. INVESTMENT AND ADVANCES IN SUBSIDIARIES**

The consolidated Interim Financial Statements incorporate the assets and liabilities and results of Pacific Edge Diagnostics New Zealand Limited, Pacific Edge (Australia) Pty Limited, Pacific Edge Diagnostics USA Limited, Pacific Edge Diagnostics Singapore Pte Limited and Pacific Edge Analytical Services Limited, all of which are 100% owned by the Company. Subsidiaries have a 31 March balance date. The investments in and advances to subsidiaries are eliminated on consolidation in the Group financial statements.

**3. DIVIDENDS**

The Company does not propose to pay dividends to shareholders similar to previous years. This policy continues.

**4. REVENUE AND OTHER INCOME**

	Unaudited Sept 2023 6 Months (\$000)	Unaudited Sept 2022 6 Months (\$000)	Audited March 2023 12 Months (\$000)
<b>Cxbladder Sales</b>			
- US - Accrual Accounting	11,403	7,383	16,362
- US - Cash Accounting	1,062	916	2,388
- Total US Sales	12,465	8,299	18,750
- Rest of World	630	408	866
<b>Total Operating Revenue</b>	<b>13,095</b>	<b>8,707</b>	<b>19,616</b>
<b>Other Income</b>			
Grant Income	3	300	44
Research Rebates and Tax Incentives	856	461	1,373
<b>Total Other Income</b>	<b>859</b>	<b>761</b>	<b>1,417</b>

Refer to note 13 for details on a proposed Local Coverage Determination change that has the potential to negatively impact future revenue.

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

**5. OPERATING EXPENSES**

The note below highlights total expenses shown within total operating expenses. These items are then split across functions laboratory, research, sales and marketing and general and administration as reported in the annual report.

	Unaudited Sept 2023 6 Months (\$000)	Unaudited Sept 2022 6 Months (\$000)	Audited March 2023 12 Months (\$000)
<b>Operating Expenses</b>			
Amortisation	178	123	427
Auditors Remuneration			
- Group year end financial statements	97	69	184
- Half year review of financial statements	34	29	30
- Foreign statutory financial statements	25	13	12
<b>Total Auditors Remuneration</b>	<b>156</b>	<b>111</b>	<b>226</b>
Consultant Costs	1,366	858	2,019
Depreciation	370	206	527
Depreciation on Right of Use Assets	635	569	1,179
Directors Fees	247	247	495
Employee Benefits	15,700	10,797	26,107
Employee Share Scheme Expenses	38	93	182
Employee Share Options	555	567	1,273
Interest on Lease Liabilities	32	46	83
Legal Expenses	620	388	695
NZX / ASX / Registry Fees	146	225	305
Rental and Lease Expense	68	38	122
Site Fees - Clinical Studies	1,358	636	1,094
Other Operating Expenses	10,363	9,260	18,355
<b>Total Operating Expenses</b>	<b>31,832</b>	<b>24,164</b>	<b>53,089</b>

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

**Employee Share Scheme**

Employee Share Scheme Expenses are a non-cash expense. These relate to shares issued to employees in lieu of cash bonuses.

**Employee Share Scheme Options**

Employee Share Options are a non-cash expense. Refer to Note 8 of the Annual Report for details of the accounting policy for Employee Share Schemes.

**Other Operating Expenses**

The major categories of expenditure which make up operating expenses, but are not disclosed separately above: Laboratory costs, Information Technology costs, Compliance and Regulatory costs, Investor Relations costs.

**6. SEGMENT INFORMATION**

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer who makes strategic decisions.

There are two operating segments at balance date:

- Commercial:** The sales, marketing, laboratory and support operations to run the commercial businesses worldwide; and
- Research:** The research and development of diagnostic and prognostic products for human cancer.

The reportable operating segment Commercial derives its revenue primarily from sales of Cxbladder tests and the reportable operating segment Research derives its revenue primarily from grant income. The Chief Executive Officer assesses the performance of the operating segments based on net loss for the period.

Segment income, expenses and profitability are presented on a gross basis excluding inter-segment eliminations to best represent the performance of each segment operating as independent business units. The segment information provided to the Chief Executive Officer for the reportable segments described above, for the six months ended 30 September 2023, is shown on the following page.

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

Unaudited 6 Months to 30 September 2023	Commercial (\$'000)	Research (\$'000)	Less: Eliminations (\$'000)	Total External Income (\$'000)
<b>Income</b>				
Operating Revenue - External	13,095	-	-	13,095
Other Income	276	1,403	(820)	859
Interest Income	14	1,878	-	1,892
Foreign Exchange Gain	-	734	-	734
<b>Total Income</b>	<b>13,385</b>	<b>4,015</b>	<b>(820)</b>	<b>16,580</b>
<b>Expenses</b>				
Expenses	21,791	9,678	(820)	30,649
Depreciation & Amortisation	801	382	-	1,183
<b>Total Operating Expenses</b>	<b>22,592</b>	<b>10,060</b>	<b>(820)</b>	<b>31,832</b>
<b>Loss Before Tax</b>	<b>(9,207)</b>	<b>(6,045)</b>	-	<b>(15,252)</b>
Income Tax Expense	-	-	-	-
<b>Loss After Tax</b>	<b>(9,207)</b>	<b>(6,045)</b>	-	<b>(15,252)</b>
<b>Net Cash Flow to Operating Activities</b>	<b>(9,114)</b>	<b>(5,878)</b>	-	<b>(14,992)</b>

Audited 12 Months to 31 March 2023	Commercial (\$'000)	Research (\$'000)	Less: Eliminations (\$'000)	Total External Income (\$'000)
<b>Income</b>				
Operating Revenue - External	19,616	-	-	19,616
Other Income	467	2,245	(1,295)	1,417
Interest Income	18	2,743	-	2,761
Foreign Exchange Gain	5	2,325	-	2,330
<b>Total Income</b>	<b>20,106</b>	<b>7,313</b>	<b>(1,295)</b>	<b>26,124</b>
<b>Expenses</b>				
Expenses	35,891	16,360	(1,295)	50,956
Depreciation & Amortisation	1,311	822	-	2,133
<b>Total Operating Expenses</b>	<b>37,202</b>	<b>17,182</b>	<b>(1,295)</b>	<b>53,089</b>
<b>Loss Before Tax</b>	<b>(17,096)</b>	<b>(9,869)</b>	-	<b>(26,965)</b>
Income Tax Expense	-	-	-	-
<b>Loss After Tax</b>	<b>(17,096)</b>	<b>(9,869)</b>	-	<b>(26,965)</b>
<b>Net Cash Flow to Operating Activities</b>	<b>(15,908)</b>	<b>(9,667)</b>	-	<b>(25,575)</b>

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

Unaudited 6 Months to 30 September 2022	Commercial (\$'000)	Research (\$'000)	Less: Eliminations (\$'000)	Total External Income (\$'000)
<b>Income</b>				
Operating Revenue - External	8,707	-	-	8,707
- Internal	-	-	-	-
Other Income	237	1,287	(763)	761
Interest Income	3	1,096	-	1,099
Foreign Exchange Gain	8	3,018	-	3,026
<b>Total Income</b>	<b>8,955</b>	<b>5,401</b>	<b>(763)</b>	<b>13,593</b>
<b>Expenses</b>				
Expenses	16,280	7,749	(763)	23,266
Depreciation & Amortisation	594	304	-	898
<b>Total Operating Expenses</b>	<b>16,874</b>	<b>8,053</b>	<b>(763)</b>	<b>24,164</b>
<b>Loss Before Tax</b>	<b>(7,919)</b>	<b>(2,652)</b>	-	<b>(10,571)</b>
Income Tax Expense	-	-	-	-
<b>Loss After Tax</b>	<b>(7,919)</b>	<b>(2,652)</b>	-	<b>(10,571)</b>
<b>Net Cash Flow to Operating Activities</b>	<b>(8,478)</b>	<b>(5,494)</b>	-	<b>(13,972)</b>

**Eliminations**

These are the intercompany transactions between the subsidiaries and the Parent. These are eliminated on consolidation of Group results. The Research segment of the business utilise consumables and other components that are purchased by the Commercial segments of the business, with the costs of these components allocated to Research segment, and the Commercial segment recognising revenue from the sale.

**Total Laboratory Throughput:**

Unaudited	Commercial # Tests	Research # Tests	Total # Tests
6 months ended 30 September 2023	15,401	2,828	18,229
12 months ended 31 March 2023	26,691	4,874	31,565
6 months ended 30 September 2022	12,422	2,495	14,917

Laboratory Throughput is a key metric for the Group: Laboratory Throughput provides evidence of the usage of Cxbladder products globally and the rates of adoption between different customer segments. Total Laboratory Throughput includes commercial tests, which are invoiced to customers, and research tests which are not considered to be billable as these tests relate to user programs or other non-chargeable activities.

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

Commercial test numbers are also a key metric for the Group. Commercial Tests are those tests for which the Company is actively seeking reimbursement and cash receipts, and tests performed at no charge in order to gain new customers.

**Segment Assets and Liabilities Information:**

Unaudited as at 30 September 2023	Commercial (\$'000)	Research (\$'000)	Total (\$'000)
Total Assets	8,152	68,102	76,254
Total Liabilities	4,585	3,367	7,952

Audited as at 31 March 2023	Commercial (\$'000)	Research (\$'000)	Total (\$'000)
Total Assets	9,375	81,538	90,913
Total Liabilities	5,853	2,297	8,150

Unaudited as at 30 September 2022	Commercial (\$'000)	Research (\$'000)	Total (\$'000)
Total Assets	8,906	97,851	106,757
Total Liabilities	5,990	1,924	7,914

**Additions to non current assets for the period include:**

	Commercial (\$'000)	Research (\$'000)	Total (\$'000)
Property, Plant & Equipment	479	10	489
Right of Use Assets	873	-	873
Intangible Assets	298	4	302
<b>Total Additions to Non Current Assets</b>	<b>1,650</b>	<b>14</b>	<b>1,664</b>

The amounts provided to the Chief Executive Officer with respect to total assets and total liabilities are measured in a manner consistent with that of the financial statements. These assets and liabilities are allocated based on the operation of the segment and the physical location of the asset.

There are no unallocated assets or liabilities.

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

## 7. SHARE CAPITAL

	Sept 2023 6 Months Shares (000)	Unaudited Sept 2023 6 Months (\$000)	Unaudited Sept 2022 6 Months (\$000)	Audited March 2023 12 Months (\$000)
<b>Opening Balance</b>	<b>810,365</b>	<b>294,317</b>	<b>294,139</b>	<b>294,139</b>
<b>Issue of Ordinary Shares</b>				
- Employee Remuneration <sup>1</sup>	352	38	93	182
Less: Issue Expenses	-		(2)	(4)
<b>Movement</b>	<b>352</b>	<b>38</b>	<b>91</b>	<b>178</b>
<b>Closing Balance</b>	<b>810,717</b>	<b>294,355</b>	<b>294,230</b>	<b>294,317</b>

<sup>1</sup> During the period 351,894 shares were issued as part of employees remuneration in lieu of cash payments at an average price of \$0.107 per share. (2023: 277,985 at \$0.65).

There are 810,717,112 (September 2022: 810,180,218 and March 2023: 810,365,218) ordinary shares on issue. All fully paid shares in the Company have equal voting rights and equal rights to dividends. All Ordinary Shares are fully paid and have no par value.

## 8. RECONCILIATION OF CASH FLOWS TO OPERATING ACTIVITIES WITH OPERATING NET LOSS

	Unaudited Sept 2023 6 Months (\$000)	Unaudited Sept 2022 6 Months (\$000)	Audited March 2023 12 Months (\$000)
Net Loss for the Period	(15,252)	(10,571)	(26,965)
<b>Add Non Cash Items:</b>			
Depreciation	370	206	527
Loss on disposal of Property, Plant and Equipment	2	16	24
Amortisation	178	123	427
Employee Share options	555	567	1,273
Employee bonuses paid in shares in lieu of cash	38	93	182
Depreciation on right of use assets	635	569	1,179
Interest on finance leases shown in lease repayments	32	46	83
<b>Total Non Cash Items</b>	<b>1,810</b>	<b>1,620</b>	<b>3,695</b>
<b>Add Movements in Other Working Capital items:</b>	<b>(37)</b>	<b>(2,493)</b>	<b>(1,641)</b>
(Increase) in Receivables and Other Assets	(389)	(500)	(280)
(Increase) Decrease in Inventory	(390)	998	1,946
Increase in Payables and Accruals	(734)	(3,026)	(2,330)
<b>Total Movement in Other Working Capital</b>	<b>(1,550)</b>	<b>(5,021)</b>	<b>(2,305)</b>
<b>Net Cash Flows to Operating Activities</b>	<b>(14,992)</b>	<b>(13,972)</b>	<b>(25,575)</b>

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

## 9. CONTINGENT LIABILITIES

There were no known contingent liabilities at 30 September 2023 (September 2022: Nil and March 2023: Nil). The Company and Group have not granted any securities in respect of liabilities payable by any other party whatsoever.

## 10. CAPITAL COMMITMENTS

There are no capital commitments at 30 September 2023 (September 2022: Nil and March 2023: Nil).

## 11. SUBSEQUENT EVENTS

There are no subsequent events.

## 12. RELATED PARTIES

Details of all related party relationships have been disclosed in the annual report for the year ended 31 March 2023. No new transactions with directors occurred that would be considered a related party.

## 13. PROPOSED LOCAL COVERAGE DETERMINATION (LCD) CHANGES - IMPACT ON REVENUE

On 2 June 2023\* Novitas, the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge's US laboratory issued a final Local Coverage Determination (LCD) L39365 that governs the reimbursement of Cxbladder in the US by the US Centres for Medicare & Medicaid Services (CMS). The LCD determined that Cxbladder would not qualify for coverage from Novitas for tests reimbursed by the CMS from 17 July 2023. These tests represent a significant portion of current Cxbladder testing revenue. Multiple companies that had existing coverage or are seeking coverage, were similarly impacted by this proposal.

On 6 July 2023\* Pacific Edge Limited received notification that LCD L39365 would not become final and Novitas would propose it again as a draft LCD DL39365. The new draft would be subject to 'notice and comment for 45 days including an open public meeting and a written comment submission period.

On 27 July 2023\* Pacific Edge Limited became aware that Novitas had published the LCD (DL39365) without any changes from LCD L39365, which if approved without further changes would mean Cxbladder (and multiple other products from various companies) would not qualify for coverage from Novitas for tests reimbursed by the CMS.

Novitas provided for the statutory requirement for a 45-day notice and comment period commencing 27 July 2023\* and finishing 9 September 2023\*, during which time all interested stakeholders were able to submit comments to Novitas. Pacific Edge, and a number of impacted parties submitted written submissions that argue Cxbladder Triage, Detect and Monitor tests should retain Medicare coverage based on the clinical value they offer to patients, clinicians, and healthcare payers.

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2023

Novitas may take up to 365 days from the original publication date (27 July 2023\*) to withdraw or finalize the LCD including a response to those comments. When finalized, Novitas must provide a minimum of 45 days' notice before the LCD becomes effective.

Pacific Edge received payment in line with the existing LCD/LCA (Local Coverage Article) for the six months ended 30 September 2023, and to the date of approval of these Consolidated Financial Statements. However, the Company is unable to determine the future impact, if any, at the date of approval of these Consolidated Financial Statements.

Refer to the Pacific Edge Limited 2023 Annual report issued 22 June 2023 for further history of the proposed Local Coverage Decision up to 22 June 2023.

\*All dates with an Asterix refer to US dates

### 14. NET TANGIBLE ASSETS

Net Tangible Assets per share is a non-GAAP measure that is required to be disclosed by the NZX Listing Rules. The calculation of the Group's Net Tangible Assets per share and its reconciliation to the consolidated balance sheet is presented below.

	Unaudited Sept 2023 6 Months (\$000)	Unaudited Sept 2022 6 Months (\$000)	Audited March 2023 12 Months (\$000)
Total Assets	76,254	106,757	90,913
Less Intangible Assets	1,156	784	1,031
Less Total Liabilities	7,952	7,914	8,150
<b>Net Tangible Assets</b>	<b>67,146</b>	<b>98,059</b>	<b>81,732</b>
Number of Shares Issued (000's)	810,717	810,180	810,365
<b>Net Tangible Assets Per Share</b>	<b>\$0.083</b>	<b>\$0.121</b>	<b>\$0.101</b>



## Independent auditor's review report

To the shareholders of Pacific Edge Limited

### Report on the consolidated interim financial statements

#### Our conclusion

We have reviewed the consolidated interim financial statements of Pacific Edge Limited (the Company) and its subsidiaries (the Group), which comprise the consolidated balance sheet as at 30 September 2023, and the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the six months ended on that date, and significant accounting policies and other explanatory information.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying consolidated interim financial statements of the Group do not present fairly, in all material respects, the financial position of the Group as at 30 September 2023, and its financial performance and cash flows for the six months then ended, in accordance with International Accounting Standard 34 *Interim Financial Reporting* (IAS 34) and New Zealand Equivalent to International Accounting Standard 34 *Interim Financial Reporting* (NZ IAS 34).

#### Basis for conclusion

We conducted our review in accordance with the New Zealand Standard on Review Engagements 2410 (Revised) *Review of Financial Statements Performed by the Independent Auditor of the Entity* (NZ SRE 2410 (Revised)). Our responsibilities are further described in the *Auditor's responsibilities for the review of the consolidated interim financial statements* section of our report.

We are independent of the Group in accordance with the relevant ethical requirements in New Zealand relating to the audit of the annual financial statements, and we have fulfilled our other ethical responsibilities in accordance with these ethical requirements. In addition to our role as auditor, our firm carried out other services for the Group in the area of generic treasury training. The provision of these other services has not impaired our independence.

#### Responsibilities of the Directors for the consolidated interim financial statements

The Directors of the Company are responsible on behalf of the Company for the preparation and fair presentation of these consolidated interim financial statements in accordance with IAS 34 and NZ IAS 34 and for such internal control as the Directors determine is necessary to enable the preparation and fair presentation of the consolidated interim financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's responsibilities for the review of the consolidated interim financial statements

Our responsibility is to express a conclusion on the consolidated interim financial statements based on our review. NZ SRE 2410 (Revised) requires us to conclude whether anything has come to our attention that causes us to believe that the consolidated interim financial statements, taken as a whole, are not prepared in all material respects, in accordance with IAS 34 and NZ IAS 34.

A review of consolidated interim financial statements in accordance with NZ SRE 2410 (Revised) is a limited assurance engagement. We perform procedures, primarily consisting of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. The procedures performed in a review are substantially less than those performed in an audit conducted in accordance with International Standards on Auditing and International Standards on Auditing (New Zealand) and consequently does not enable us to obtain assurance that we might identify in an audit. Accordingly, we do not express an audit opinion on these consolidated interim financial statements.



**Who we report to**

This report is made solely to the Company's shareholders, as a body. Our review work has been undertaken so that we might state those matters which we are required to state to them in our review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the shareholders, as a body, for our review procedures, for this report, or for the conclusion we have formed.

The engagement partner on the review resulting in this independent auditor's review report is Maxwell John Dixon.

For and on behalf of:

*FreewaterhouseCoopers*

Chartered Accountants  
22 November 2023

Christchurch



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NEW ZEALAND'S EXCHANGE  
TE PAEHOKO O AOTEAROA

Template

## Results announcement

(for Equity Security issuer/Equity and Debt Security issuer)

Updated as at June 2023

Please do not amend or delete individual rows. As this template relates to prescribed content, changes to content should only be made where it is clearly indicated that this is permitted, otherwise, if an Issuer considers a particular element does not apply, mark the row as N/A. Any other changes to this prescribed form must first be approved by NZX as required under NZX Listing Rule 3.26.1.

Results for announcement to the market		
Name of issuer	Pacific Edge Limited	
Reporting Period	6 months to 30 September 2023	
Previous Reporting Period	6 months to 30 September 2022	
Currency	NZD (New Zealand Dollar)	
	Amount (000s)	Percentage change
Revenue from continuing operations	Operating revenue \$13,095 Other income \$3,485	Operating revenue 50% increase Other income 29% decrease
Total Revenue	\$16,580	22% Increase
Net profit/(loss) from continuing operations	(\$15,252)	44% Increase in Loss
Total net profit/(loss)	(\$15,252)	44% Increase in Loss
Interim/Final Dividend		
Amount per Quoted Equity Security	The Company does not propose to pay dividends to shareholders	
Imputed amount per Quoted Equity Security	Not Applicable	
Record Date	Not Applicable	
Dividend Payment Date	Not Applicable	
	Current period	Prior comparable period
Net tangible assets per Quoted Equity Security	\$0.083	\$0.121
A brief explanation of any of the figures above necessary to enable the figures to be understood	For commentary on the results, please refer to the commentary in the accompanying NZX release. Further information is also set out in the unaudited financial statements of the Company for the 6 months to 30 September 2023 which accompany this Results Announcement.	
Authority for this announcement		
Name of person authorised to make this announcement	Grant Gibson – Chief Financial Officer	
Contact person for this announcement	Grant Gibson	
Contact phone number	0800 555 563	
Contact email address	grant.gibson@pelnz.com	
Date of release through MAP	23/11/2023	

Unaudited financial statements accompany this announcement.