26 November 2024

AUDITED FINANCIAL RESULTS FOR THE SIX MONTHS TO 30 SEPTEMBER 2024

MEDICARE COVERAGE CATALYSTS IN FOCUS

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today announces steady financial performance for the six months to the end of September 2024 as it awaits the outcome of several events that have the potential to renew growth in Cxbladder test volume and revenue.

These catalysts include Medicare Administrative Contractor, Novitas, making a favorable policy decision on the draft 'Genetic testing for oncology' Local Coverage Determination (DL39365); the American Urological Association (AUA) ongoing review of microhematuria standards of care leading to language favorable to Cxbladder in its new guidelines; and the Centers for Medicare & Medicaid Services (CMS) finalizing pricing recommendations for the company's next generation test, Cxbladder Triage Plus, that recognize its clinical and economic value.

1H 25 FINANCIAL AND PERFORMANCE HIGHLIGHTS[1]

- Operating revenue increases 1.4% on 2H 24 to $11.0 million; down 16.3% on 1H 24 reflecting Medicare uncertainty and the reduced reach of a smaller sales team. Total revenue is down 4.4% on 2H 24 to $12.2 million
- Total laboratory throughput[2] (TLT) of Cxbladder tests down 1.1% on 2H 24 to 14,233; down 22.0% on 1H 24, commercial tests increased 3.2% on 2H 24 to 12,323 tests
- Strong performance from the Southern California Permanente Medical Group, increased APAC volume and sustained sales force efficiencies dilute the impact of Medicare uncertainty on test volume demand
- US test sales/FTE of 379, down 3.8% on Q1 25; US ASP[3] increases to US$618 vs US$613 in 2H 24 and $562 in 1H 24 as operating efficiencies and cash collection gains achieved in 2H 24 retained
- Net loss after tax of $14.5 million, steady on the $14.3 million net loss in 2H 24, down 4.9% on 1H 24 net loss of $15.3 million
- Cash and cash equivalents and short-term deposits at $35.9 million; cash burn of $14.3 million is higher than $11.9 million in 2H 24, but steady after adjusting for the seasonal impact of higher weighting of costs in 1H 25

1H 25 STRATEGIC HIGHLIGHTS

- Commercial operation retains its focus on profitable territories, non-Medicare revenue streams and selling the clinical and economic value of Cxbladder
- Triage Plus launch plans advance; awaiting Medicare reimbursement clarity and CMS pricing that reflects the test's clinical and economic value

---

[1] All comparisons are to the same period of the prior financial year unless otherwise stated.
[2] Total Laboratory Throughput (TLT) includes commercial, pre-commercial and clinical studies testing.
[3] ASP: US Average Sales Price (US Operating Revenue in USD / US Commercial Test Volumes)

- STRATA published in the Journal of Urology (May 2024) establishing clinical utility of Cxbladder Triage; DRIVE study for the clinical validation of Triage Plus has completed enrolment and is on track for publication in Q1 FY26; STRATA concordance study on track for publication by 2Q FY 26
- Maintained dialogue with CMS, Novitas, C21[4], AUA, LUGPA[5] and others regarding 'Genetic testing for oncology' LCD (DL39365)
- Integrated Cxbladder with Lumea Digital (US) laboratory information system and preparing for the launch of the Pacific Edge customer portal to digitalize the customer experience for patients and healthcare providers

Chair Chris Gallaher said: "While testing volume remains subdued as a consequence of our efforts to preserve capital, operating revenue has increased on the second half of FY 2024, net losses and operating cash burn have been steady on the same period. With $35.9 million in reserves as at the end of September, the company has sufficient capital to re-establish reliable reimbursement for our tests in the event of a negative determination from Novitas."

Chief Executive Dr Peter Meintjes said: "I am delighted with the progress we have made against our strategic objectives in all areas of the business. We have sustained our improved sales force efficiency and cash collections metrics, advanced our core priorities in clinical evidence generation, digitalization, lab operations and customer experience, while continuing to conserve capital wherever possible.

FINANCIAL RESULTS

Operating revenue of $11.0 million was up 1.4% from $10.8 million in 2H 24, but down 16.3% on 1H 24 reflecting the reduction in test volume in the wake of the ongoing Medicare uncertainty and the reduced reach of the sales team following the restructuring at the start of 2H 24.

TLT of 14,233 tests was down 1.1% on the 14,393 tests in 2H 24 and down 22.0% on the 18,240 tests in 1H 24. Rising demand from the Southern California Permanente Medical Group, rising APAC volumes and the sustained sales force efficiencies achieved as part of the restructuring provided some mitigation to the impact of Medicare uncertainty. Commercial test volumes rose 3.2% on 2H 24 to 12,323 tests.

The average sales price of commercial tests in the half year increased to US$618 vs US$613 in 2H 24 and $562 in 1H 24 demonstrating that we have cemented these improvements in cash collection. As disclosed in our Q2 25 investor update, sales per average FTE in Q2 25 was down to 379 tests from 394 in the prior quarter, consistent with the lower US volumes. Tests per unique ordering clinician (our preferred metric for measuring customer commitment to Cxbladder) was down slightly to 6.4 in Q2 25 from 6.8 in Q1 25 reflecting the lower volume in the quarter (ordering clinicians in Q2 25 was slightly higher at 890).

[4] The Coalition for 21st Century Medicine, a diagnostic industry lobby organisation
[5] The US Large Urology Group Practice Association

The net loss after tax of $14.5 million was steady on the 2H 24 net loss after tax of $14.3 million, but 4.9% lower than 1H 24 reflecting the benefits of the cash conservation initiatives. Cash and cash equivalents and short-term deposits stood at $35.9 million at the end of September 2024, down from $50.3 million at the end of March 2024. The cash burn of $14.3 million in 1H 25 was higher than the $11.9 million in 2H 24, with the first half of each financial year incurring a higher cash spend related to payments that cover a 12-month period. Excluding this higher weighting of spend in the first half of the financial year, the underlying cash burn was steady as operating cash conservation initiatives continued to deliver.

STRATEGIC PROGRESS

Our US commercial operations remain focused on profitable territories, non-Medicare revenue streams and selling the clinical and economic value of Cxbladder. Our front-line sales team is operating at break even.

The moves to extend our global reach and diversify our revenue with distribution agreements in Israel, Latin America and Southeast Asia are showing early promise, delivering still small but steadily growing test volumes from these markets.

Supported by urological professional societies, industry partners, clinicians, and patient advocacy groups, we believe we have made every effort to assist Novitas and the AUA to make pragmatic decisions that recognize the clinical and economic value of our tests.

Notably we brought forward the publication of our STRATA study – the first randomized control trial of a urine biomarker – to ensure Novitas and the AUA's timely consideration of what is the strongest evidence yet of Cxbladder's clinical utility. We have also prepared plans to revert to growth as reliable reimbursement milestones are achieved.

We have advanced our clinical evidence generation program, and we remain confident that, over time, it will assist us to embed our existing and next generation tests in clinical guidelines, change clinical practice among physicians and drive changes to medical policy at Medicare and other healthcare payers.

The DRIVE Study and STRATA Concordance Study are on track for publication by mid-2025. DRIVE has completed patient enrolment and is targeted at demonstrating the clinical validation of Triage Plus, while the concordance study seeks to demonstrate the clinical utility of the test by comparison of Triage Plus to Triage. In the event of a Medicare non-coverage determination, these publications will be used as the basis of a Medicare coverage reconsideration request.

Finally, we have continued to invest in medical affairs and the digitalization initiatives that will further drive the adoption of our tests and improve the experience for clinicians and patients. During 1H 25 we have completed an integration of our systems with Lumea Digital – a pathology lab in the US with deep ties to hundreds of urology clinics in the US and made great advancements towards deploying our customer portal, expected before the end of the calendar year.

OUTLOOK

Pacific Edge is focused on establishing reliable reimbursement for Triage Plus as a precursor to a broader commercial launch, which we anticipate in 2025.

“While headwinds remain a possibility, there are more potential catalysts to renew growth in the US than headwinds for Pacific Edge ahead in 2025. We also benefit from a more effective, efficient and disciplined team to drive growth with improved underlying economics. We look forward to updating investors on our progress,” Dr Meintjes said.

For more information:

Investors:
Dr Peter Meintjes
Chief Executive
Pacific Edge
P: 022 032 1263

Media:
Richard Inder
The Project
P: +64 21 645 643

OVERVIEW

Pacific Edge: www.pacificedgedx.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

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.

PacificEdge®
CANCER DIAGNOSTICS

1H 25 FINANCIAL RESULTS PRESENTATION

Dr Peter Meintjes
Chief Executive Officer

Grant Gibson
Chief Financial Officer

26 November 2024

IMPORTANT NOTICE AND DISCLAIMER

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

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

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

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

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

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

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

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

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

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

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

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

AGENDA

1. HIGHLIGHTS
2. STRATEGIC DELIVERY
3. FINANCIAL PERFORMANCE
4. OUTLOOK
5. QUESTIONS

PacificEdge®
CANCER DIAGNOSTICS

1H 25 HIGHLIGHTS: FOCUSED ON CATALYSTS FOR MEDICARE COVERAGE CERTAINTY

▼1.1%
GLOBAL TESTS (TLT[1]) on 2H 24
-22.0% on 1H 24

Global TLT of 14,233
US TLT 11,587, -4.6% on 2H 24 and -27.4% on 1H 24

▲3.2%
COMMERCIAL TEST VOLUMES on 2H 24
-20.0% on 1H 24

Commercial Tests of 12,323
US Commercial Tests 9,911, -0.5% on 2H 24 and –26.9% on 1H 24

▲1.4%
OPERATING REVENUE on 2H 24
-16.3% on 1H 24

Operating revenue $11.0M
Total revenue of $12.2M
-4.4% on 2H 24

($14.5M)
NET LOSS AFTER TAX
Up 1.5% on 2H 24
-4.9% on 1H 24

Steady on 2H 24 of ($14.3M) reflecting 'holding pattern' of Medicare uncertainty

$35.9M
CASH, CASH EQUIVALENTS[2]

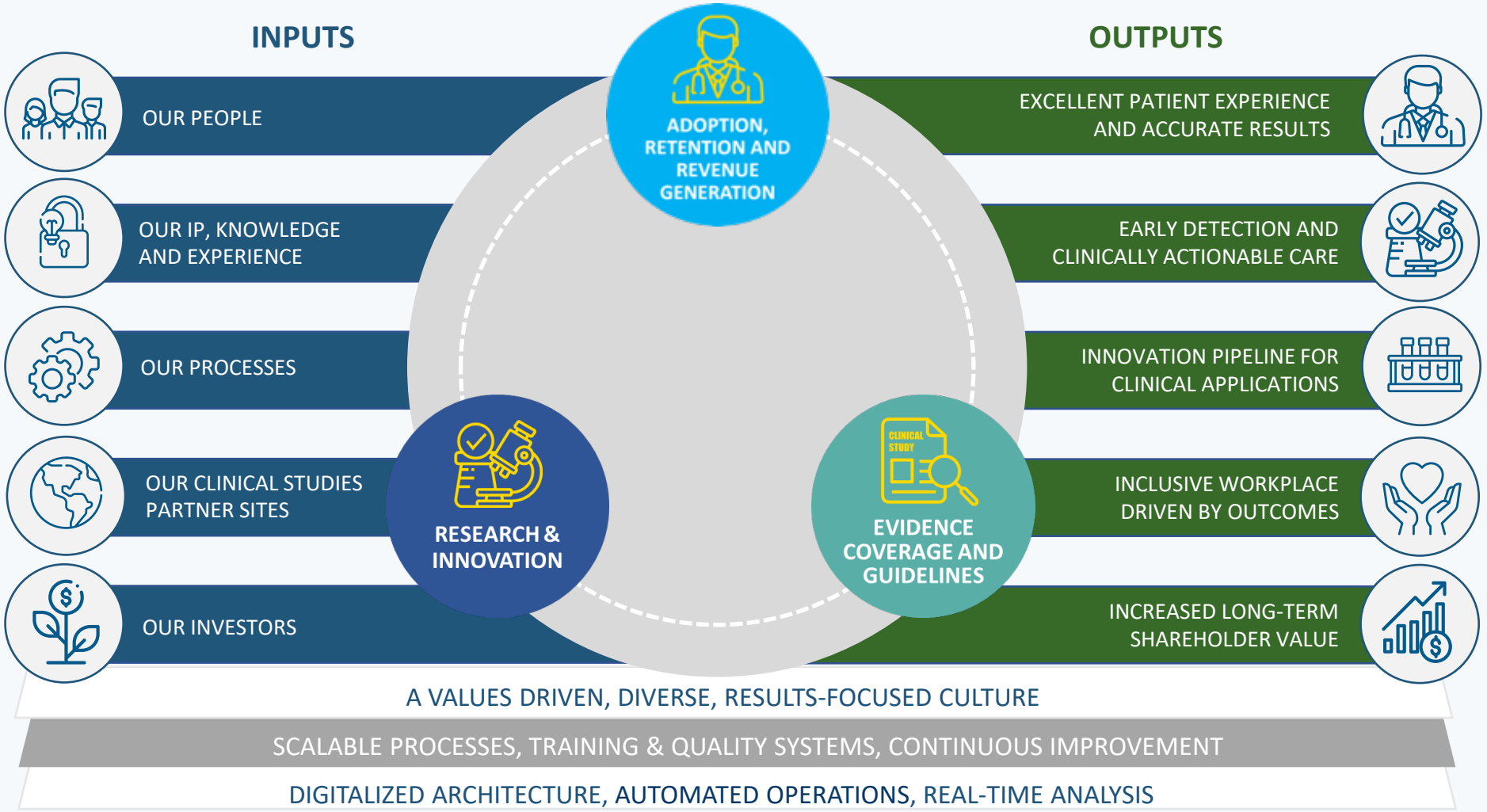
1H 25 cash burn of $14.3M increases on $11.9M in 2H 24 but steady adjusting for seasonal impact of costs

- Awaiting outcome on catalysts: Medicare coverage certainty, AUA hematuria guideline review and Triage Plus pricing
- Operating revenue, net losses, and operating cash burn steady as operating efficiencies and cash collection gains retained. US test sales/FTE of 379 in Q2 25, - 3.8% on Q1 25; US ASP[3] increases to **US$618 in** 1H 25 vs **US$613** in 2H 24
- Commercial operations focused on profitable territories, non-Medicare revenue streams and selling the clinical and economic value of Cxbladder; direct sales team efficiencies maintained - operating at break even
- Business focused on the clinical development for Triage Plus and Monitor Plus

1. Total Laboratory Throughput (TLT) including commercial, pre-commercial and clinical studies testing
2. Cash, short-term deposits and term deposits
3. ASP: US Operating Revenue in USD / US Commercial Test Volumes

PacificEdge® CANCER DIAGNOSTICS

VALUE CREATION THROUGH THREE PILLARS



PacificEdge®
CANCER DIAGNOSTICS

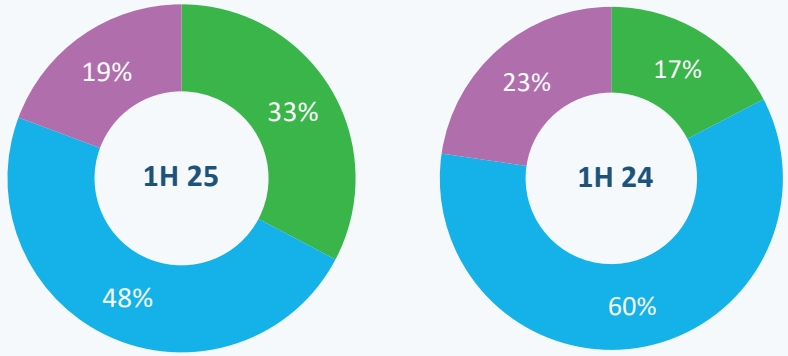
TEST VOLUMES STEADY AGAINST 2H 24 AMID MEDICARE UNCERTAINTY

ADOPTION, RETENTION AND REVENUE GENERATION

1H 25 TOTAL LAB THROUGHPUT (TLT*)

- Global TLT of 14,233 for 1H 25 steady (-1.1%) on 2H 24 and down 22% on 1H 24 amid ongoing Medicare coverage uncertainty and reduced reach of the sales force
- Global Commercial test volumes of 12,323 for 1H 25 up 3.2% on 2H 24 and down 20% on 1H 24
- Triage growing in share of volume validating risk stratification value proposition and investment in Triage Plus

TEST VOLUMES BY TYPE (TLT*)

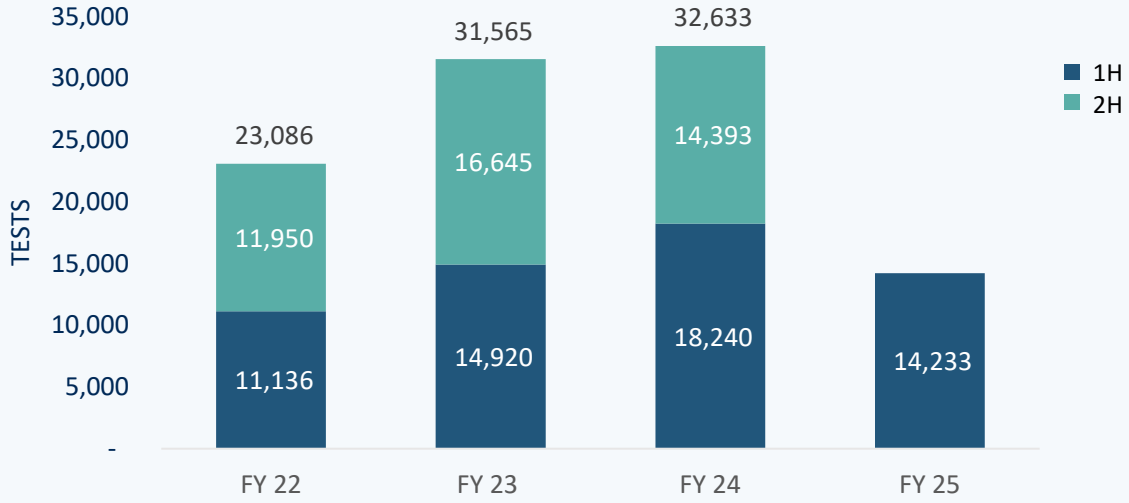


Cxbladder Triage

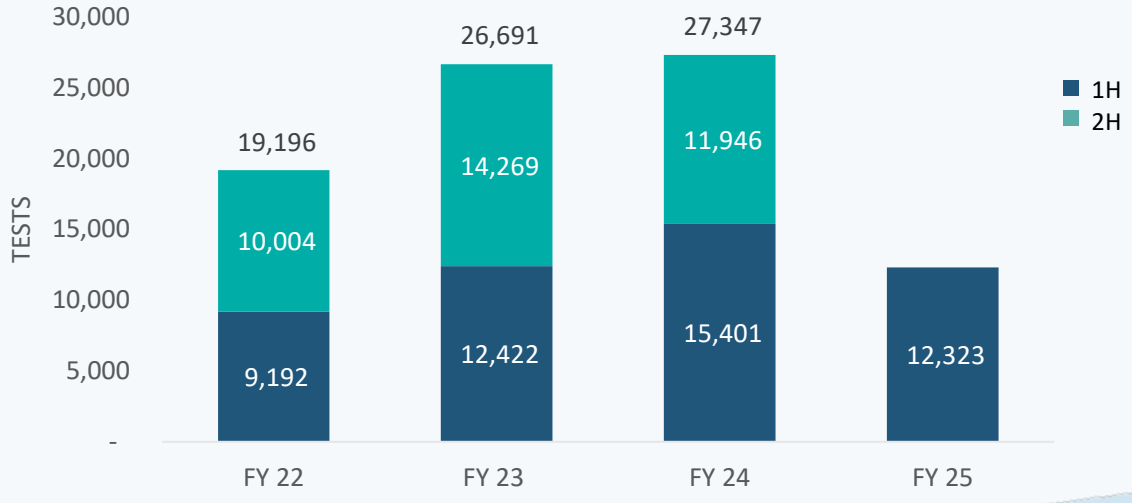
Cxbladder Detect

Cxbladder Monitor

GLOBAL TOTAL TEST VOLUMES (TLT*)



GLOBAL COMMERCIAL TEST VOLUMES (TLT*)



PacificEdge® CANCER DIAGNOSTICS

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

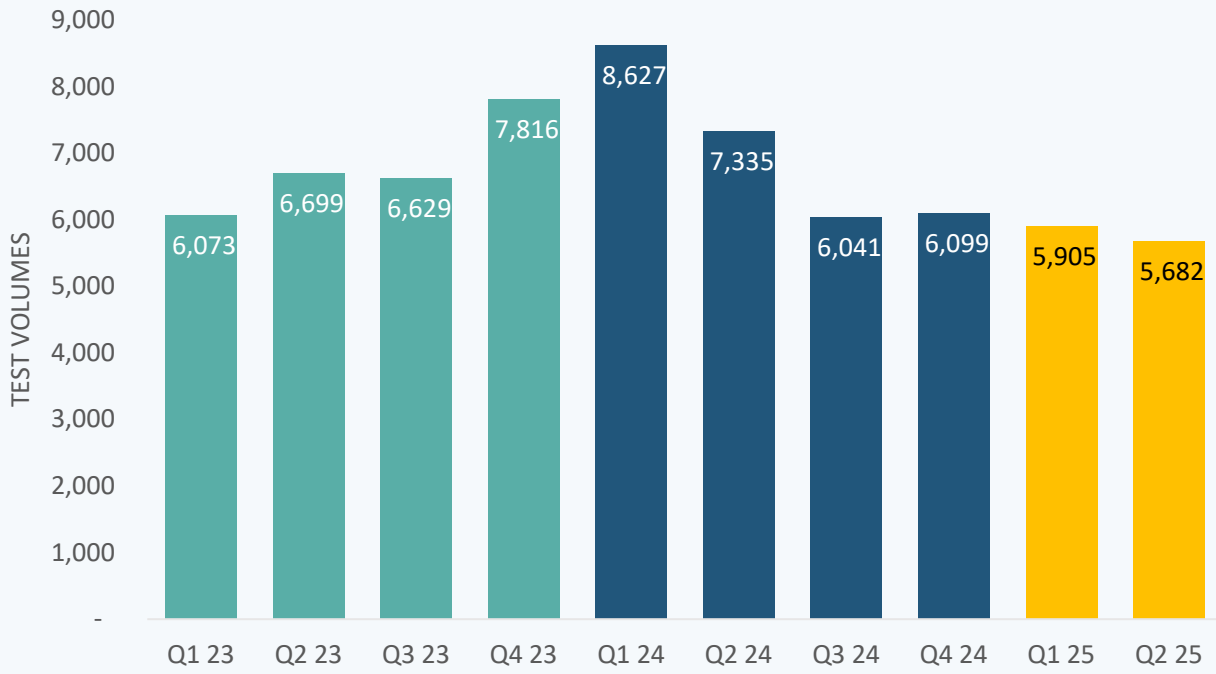
FOUNDATIONS FOR GROWTH - US TEST VOLUMES STEADY

ADOPTION, RETENTION AND REVENUE GENERATION

KAISER PERMANENTE GAINS PARTIALLY OFFSET MEDICARE UNCERTAINTY

- US TLT in Q2 25 relatively stable on the prior quarter (Q1 25)
- Strong performance from the Southern California Permanente Medical Group and sustained sales force efficiency gains deliver some mitigation to the impact of Medicare uncertainty
- Throughput has reduced by 34.1% from a peak of 8,627 test/quarter in Q1 24 to 5,682 in Q2 25 as the sales team reduced in 2H 24 and no backfill appointments in sales force
- Sales territories are larger and more challenging for sales reps, but focus has been on larger, more reliable accounts
- Messaging has focused on communicating the clinical value of Cxbladder for risk stratification to reduce cystoscopies and the associated economics of adopting on all appropriate patients

US TOTAL TEST VOLUME*



PacificEdge® CANCER DIAGNOSTICS

* Total Laboratory Throughput in the US including commercial, pre-commercial and clinical studies testing

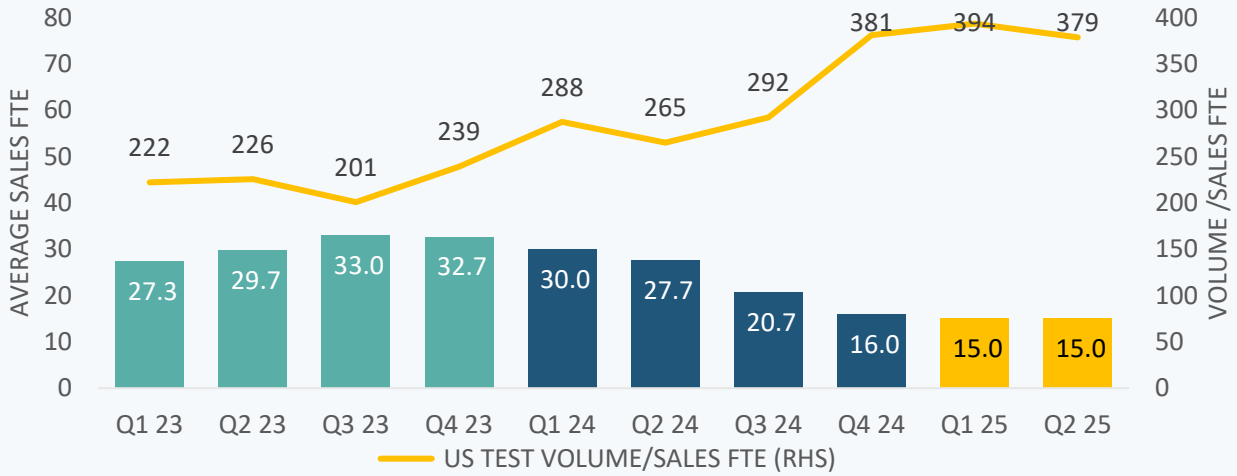
FOUNDATIONS FOR GROWTH – PERFORMANCE IMPROVEMENTS SUSTAINED

ADOPTION, RETENTION AND REVENUE GENERATION

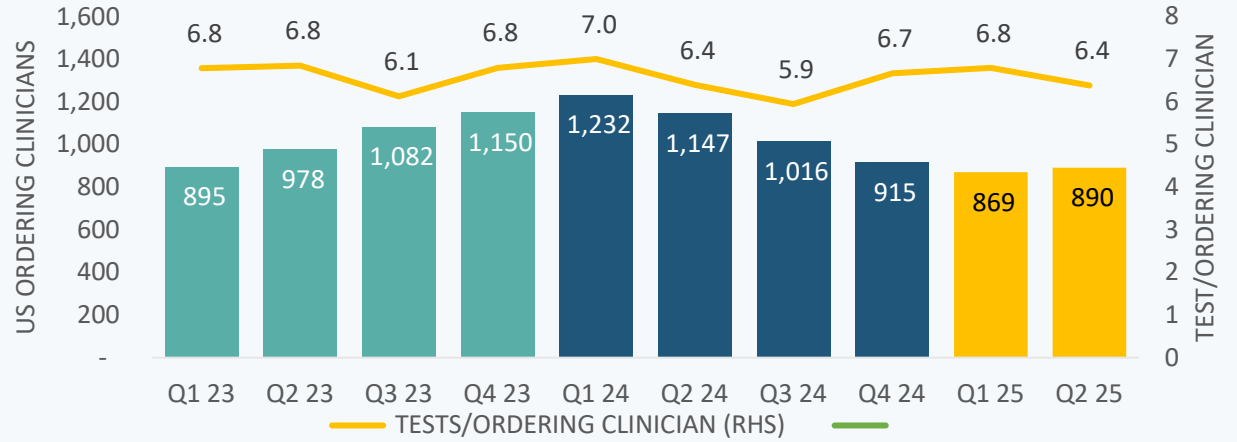
SALES TEAM FOCUSED ON KEY PERFORMANCE INDICATORS

- Sales FTE down to an average of 15.0 in Q2 25 from 32.7 in Q4 23 as we focused on cash conservation:
  - Sales FTEs were reduced by restructure in late Q2 24
  - Sales FTEs leaving the business are backfilled only when sales force breakeven can be maintained
- Sales force efficiency (total tests/average FTE) sustained up 59% from 239 in Q4 23 to 379 in Q2 25:
  - More effective core sales team
  - Focus on the most profitable territories/accounts
- Tests/US ordering clinician stable, but ordering clinicians fall against 1H 24:
  - Change in clinical mix in favor of clinicians that understand the clinical utility of Cxbladder
  - Reduced reach of the direct sales team
- Direct sales team have achieved operational break even

US SALES FORCE EFFICIENCY



US CLINICAL COMMITMENT



PacificEdge® CANCER DIAGNOSTICS

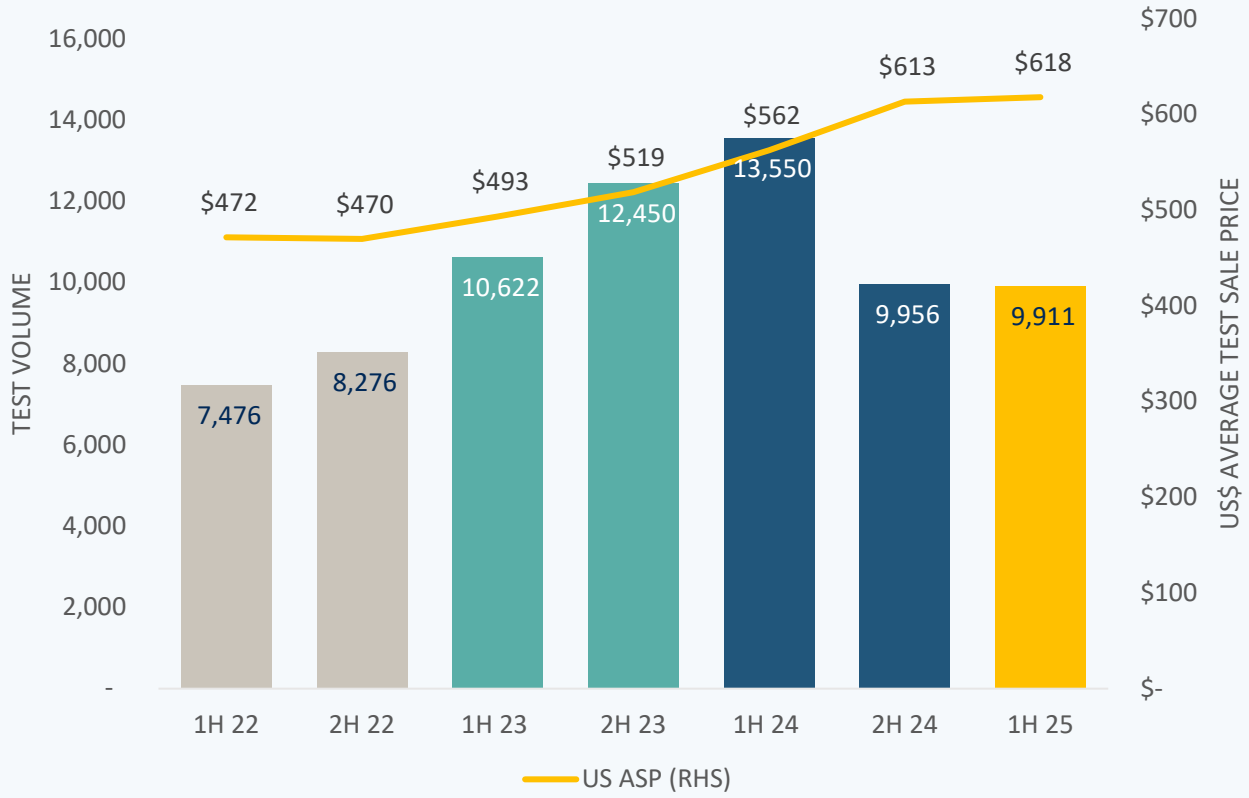
FOUNDATIONS FOR GROWTH - US CASH COLLECTIONS IMPROVE

ADOPTION, RETENTION AND REVENUE GENERATION

REIMBURSEMENT & CASH COLLECTIONS – A CORE COMPETENCY

- Average Sales Price (ASP*) per test increased to US$618 from US$613 in 2H 24 and US$519 in 2H 23 lifted by:
  - Enhanced Patient Responsibility - patients with non-contracted private insurance (i.e. non-Kaiser) pay a fixed dollar amount “maximum out of pocket”
  - Increased utilization of appropriate patient types from Kaiser Permanente after EMR integration
  - Medicare reimbursement of Triage since Jan 2023
  - Improved medical necessity documentation to improve billing and appeals processes for Medicare Advantage
- Improved cash collections are typically permanent improvements that we expect to maintain as we scale

US COMMERCIAL TEST VOLUMES AND ASP* (US$)



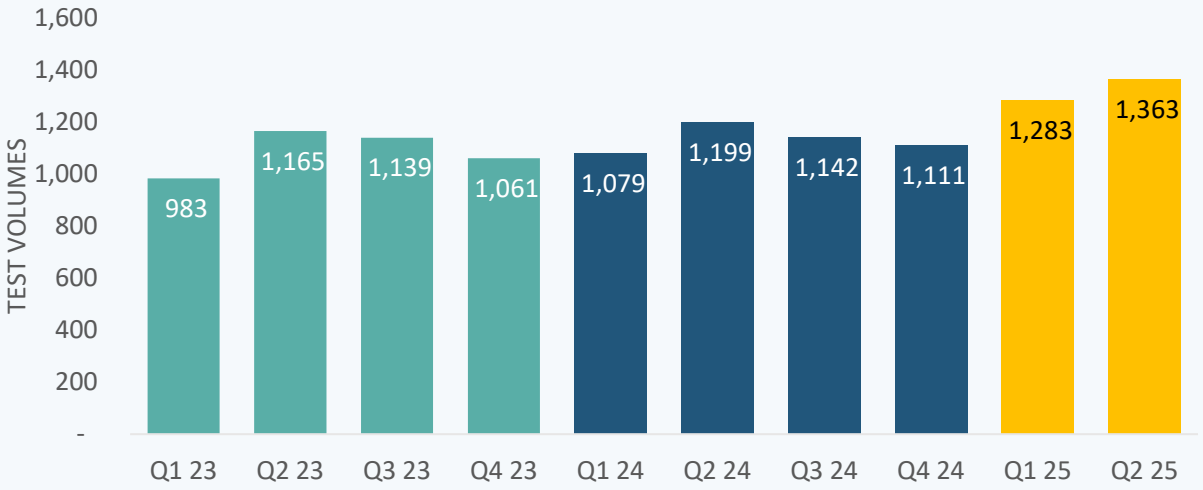
PacificEdge® CANCER DIAGNOSTICS

* ASP: US Operating Revenue in USD / US Commercial Test Volumes

DRIVING GROWTH IN ASIA PACIFIC AND CONSOLIDATING NEW ZEALAND

ADOPTION, RETENTION AND REVENUE GENERATION

APAC TOTAL TEST VOLUMES*



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

AUSTRALIA & ASIA PACIFIC

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

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

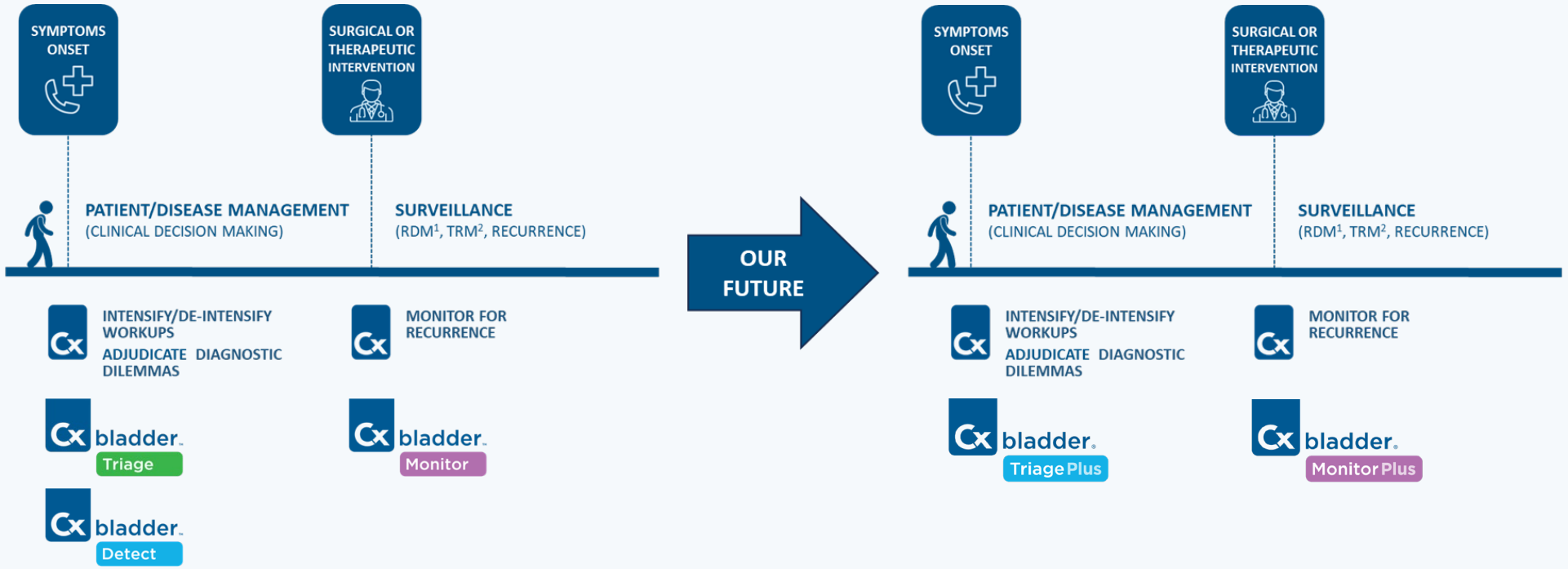
PacificEdge® CANCER DIAGNOSTICS

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

SIMPLIFYING THE CXBLADDER VALUE PROPOSITION – TRIAGE PLUS

TRIAGE PLUS NAMING ALIGNS WITH CLINICAL POSITIONING AND STRATA[1] EVIDENCE

ADOPTION, RETENTION AND REVENUE GENERATION



TRIAGE PLUS – THE ADDITION OF DNA BIOMARKERS LIFTS PERFORMANCE[3]

- Triage Plus combines the value propositions of the existing Triage and the Detect tests in a single test for the evaluation of hematuria, the largest market opportunity
- A negative test helps clinicians to rule out the presence of cancer due to the high Negative Predictive Value and Sensitivity
- A positive test can help clinicians to resolve diagnostic dilemmas and prioritize patients for a more intensive workup due to the high Specificity and Positive Predictive Value

Performance[3]	Sens	Spec	NPV	PPV	ROR
Triage Plus	**97%**	**90%**	**99.7%**	**44%**	**83%**
Triage	89%	63%	99%	16%	59%
Detect	74%	82%	97%	25%	78%

PacificEdge® CANCER DIAGNOSTICS

1. RDM: Residual Disease Monitoring,
2. TRM: Therapeutic Response Monitoring
3. Lotan et al (2022) 'Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification'; NPV: Negative Predictive Value; PPV: Positive Predictive Value; ROR: Rule out Rate

PREPARING FOR THE COMMERCIALIZATION OF TRIAGE PLUS

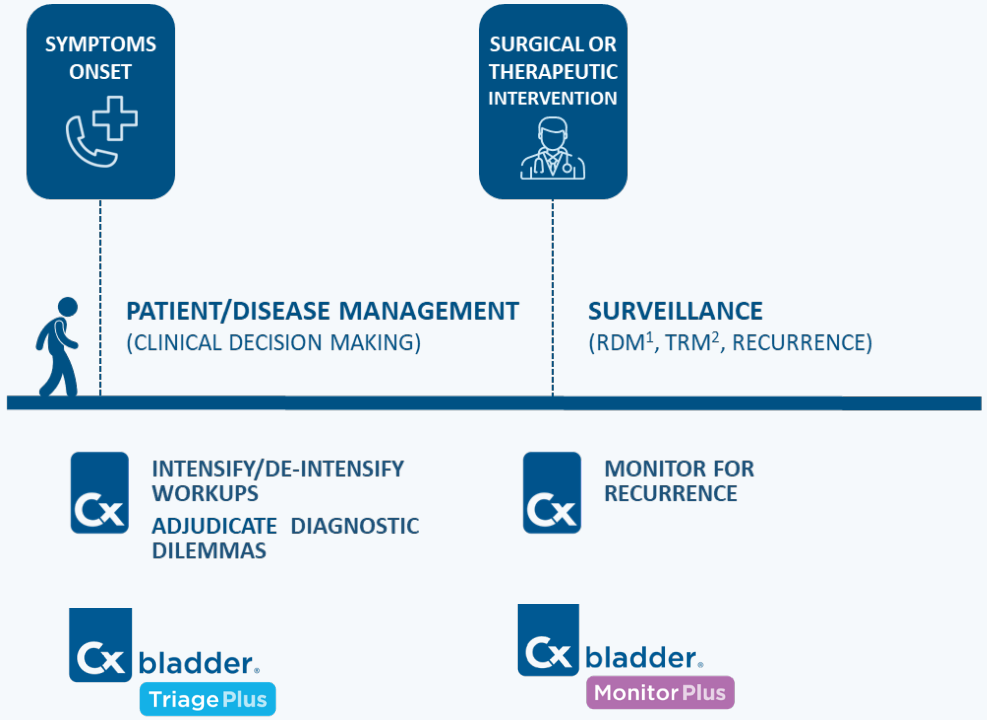
EXPANDING AND EXTENDING OUR LEADERSHIP POSITION IN HEMATURIA EVALUATION

ESSENTIAL PRE-CONDITIONS TO LAUNCHING TRIAGE PLUS

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

COMMERCIAL PREPARATORY WORK

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

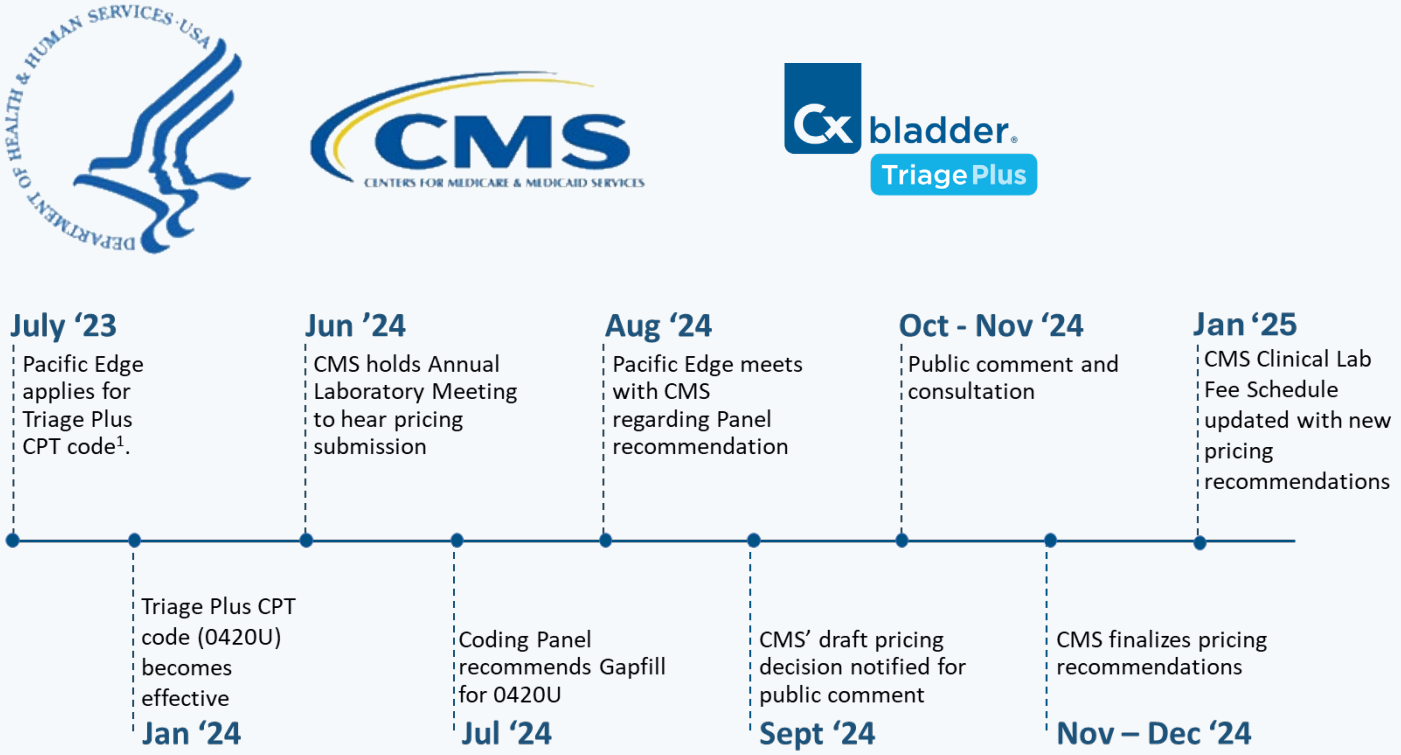


PacificEdge® CANCER DIAGNOSTICS

TRIAGE PLUS PRICING STANDS TO BOLSTER PACIFIC EDGE'S ECONOMICS

PRICING OF TRIAGE PLUS IS THE NEXT STEP IN THE COMMERCIALISATION PROGRAM

ADOPTION, RETENTION AND REVENUE GENERATION



Dates future to this presentation are anticipated timeframes for Triage Plus pricing - dates may change

- Determining a CMS price for Triage Plus (0420U) is the next step in establishing reimbursement
- Advisory Panel and CMS have recommended Gapfill for Triage Plus
- Pacific Edge and C21 have provided counter-arguments during public comment period supporting a Crosswalk recommendation
- Gapfill is the more likely outcome, requires all MACs to recommend a price and takes 12 months to finalize
- Pacific Edge will seek a 'provisional local price' for Triage Plus from Novitas during the Gapfill process to ensure Gapfill imposes no delays on the commercial launch of Triage Plus

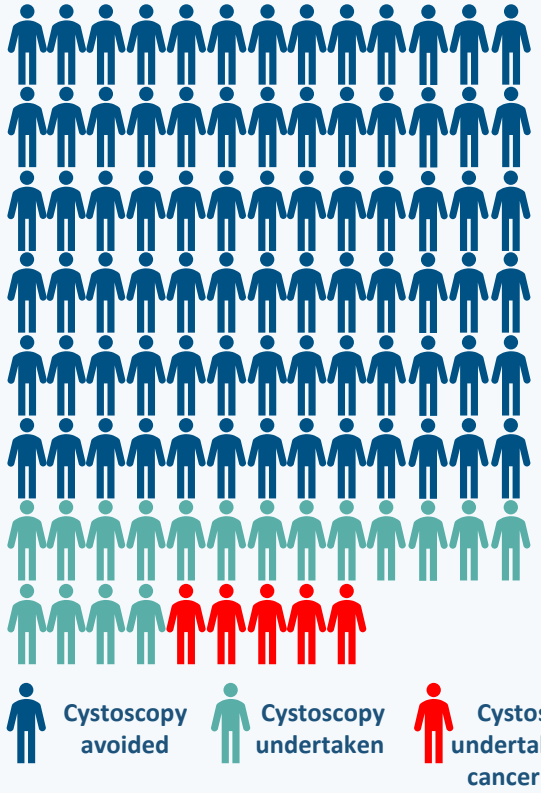
[1] In November 2024 Pacific Edge changed the name of Detect+ to Triage Plus. We may continue to use the former name in certain formal documents as necessary, and will seek to amend the descriptor for CPT Code 0420U CPT to Triage Plus through the quarterly administrative process with CMS

SELLING CXBLADDER'S CLINICAL, ECONOMIC AND PATIENT VALUE

ADOPTION, RETENTION AND REVENUE GENERATION

Pacific Edge's budget impact modelling shows Cxbladder offers better care, avoids unnecessary procedures and improves workflow when used to intensify or de-intensify hematuria evaluation or in the surveillance for the recurrence of bladder cancer. For healthcare payers Cxbladder offers substantial total cost savings per patient[1,2]

CXBLADDER DETECT VS AUA GUIDELINES



HEMATURIA EVALUATION[1]

- Cxbladder Detect rules out 78 of the 95[3] patients without cancer and requires only 22 cystoscopies to find the five patients with cancer
- This results in savings of >**US$500** per patient presenting with hematuria

CXBLADDER MONITOR VS AUA GUIDELINES

CANCER RECURRENCE SURVEILLANCE[2]

- Cxbladder Monitor alternated with cystoscopy for surveillance of bladder cancer after nine months of treatment
- This results in 12.4% reduction in cystoscopies over a five-year surveillance period
- Savings estimated at as much as **US$680** per patient over the five-years

PacificEdge® CANCER DIAGNOSTICS

1. Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)
2. Tyson et al (2024). Modelling the impact of incorporating Cxbladder Monitor in the surveillance of patients after non-muscle invasive bladder cancer in the US. abstract presented to the WSAUA in Kauai, Hawaii
3. Pacific Edge's model assumes a 5% incidence of bladder cancer in patients presenting with hematuria and referred to a specialist for a urological work up.

STRENGTHENING OUR CUSTOMER EXPERIENCE

DRIVING 'STICKINESS' AND LONG-TERM MARKET SHARE

ADOPTION, RETENTION AND REVENUE GENERATION

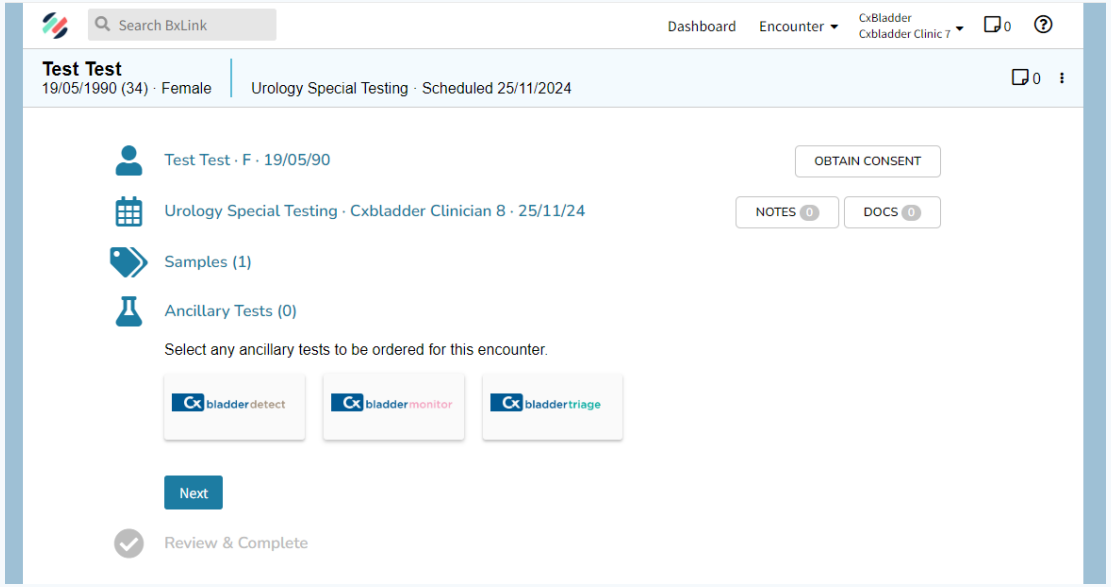
THE BEST AND MOST CUSTOMER-FRIENDLY TEST

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

KAISER EMR SUPPORTING ADOPTION

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

LUMEA™



View of the Lumea BxLink interface

KAISER PERMANENTE®

Awanui

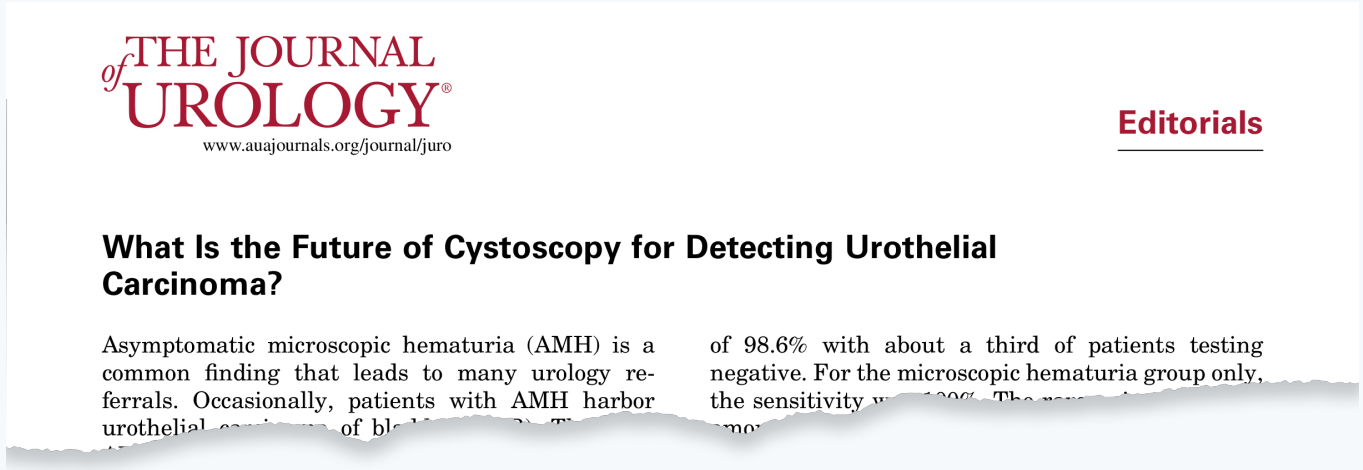
PacificEdge® CANCER DIAGNOSTICS

AUA HEMATURIA GUIDELINES – A COMPREHENSIVE REVIEW

AN APPROACH THAT SUPPORTS OUR DRIVE FOR GUIDELINE INCLUSION

EVIDENCE COVERAGE AND GUIDELINES

- The AUA has commenced a review of the microhematuria guideline and has asked for professional comment on its initial draft; no timeframe provided
- The clinical utility of Cxbladder Triage demonstrated by the STRATA[1] study is expected to be considered as part of the deliberations
- A positive AUA Journal of Urology editorial in July 2024 suggests favorable direction of travel
- Clear/positive inclusion language would be used as the basis for a Medicare coverage re-consideration request (in the event of a non-coverage determination)



THE JOURNAL of UROLOGY®
www.auajournals.org/journal/juro

Editorials

What Is the Future of Cystoscopy for Detecting Urothelial Carcinoma?

Asymptomatic microscopic hematuria (AMH) is a common finding that leads to many urology referrals. Occasionally, patients with AMH harbor urothelial [illegible] of bl[illegible]

of 98.6% with about a third of patients testing negative. For the microscopic hematuria group only, the sensitivity w[illegible]

American Urological Association

www.auanet.org

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

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

– Journal of Urology editorial Sept 2024

PacificEdge® CANCER DIAGNOSTICS

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

‘GENETIC TESTING FOR ONCOLOGY’ LCD PROCESS EXTENDED

CMS[1] APPROVED THE EXTENSION TO GIVE NOVITAS[1] TIME TO RESPOND TO ALL COMMENTS

EXTENSION INCREASES CONFIDENCE TOWARDS MEDICARE COVERAGE CERTAINTY

- Cxbladder continues to receive reimbursement from Medicare and Medicare Advantage payers in line with historical reimbursement rates
- Novitas confirmed by email that they are reviewing all Pacific Edge submissions alongside the comments received during the comment period
- Pacific Edge continues to engage with Novitas and CMS with the support of professional societies, industry partners, clinicians and patient advocacy groups
- Pacific Edge and C21[3] have taken separate but supporting actions to have DL39365 retired, including engagement with the Office of the General Counsel[3]
- We remain prepared to explore legal action in the event of a non-coverage determination

27 July 2023
Novitas[1] republishes draft LCD

9 September 2023
Review and comment period closes

Nov 2023 – Jan 2024
Meetings between Pacific Edge and CMS

26 - 29 July 2024
Pacific Edge learns CMS has granted Novitas an extension beyond statutory 365-day finalization timeline

DECISION (STILL) PENDING
July 2024 - Present
Pacific Edge and industry partners engage with Novitas and CMS
CMS says extension is “not indefinite”
Finalization or retirement remain possible

MEDICARE IS PACIFIC EDGE’S LARGEST PAYER

- Medicare and Medicare Advantage is the largest global opportunity in bladder cancer diagnostics from a single coverage decision
- In 1H 25 Medicare and Medicare Advantage delivered ~5,300 commercial tests (~54% of US commercial tests) and ~$6.5m NZD in total operating revenue (~59% of total operating revenue)

1. Novitas is the Medicare Administrative Contractor for Pacific Edge’s US laboratory. It is empowered by the Centers for Medicare and Medicaid Services (CMS) to make the coverage determination, but it is accountable to CMS for the decision.
2. Lotan et al. (2024) . A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.
3. C21 is a diagnostic industry lobby group the Coalition for 21st Century Medicine. The Office of the General Counsel (OGC) is the legal team for the US Department of Health and Human Services (HHS)

CLINICAL EVIDENCE CATALYSTS FOR COVERAGE CERTAINTY

EVIDENCE COVERAGE AND GUIDELINES

MEDICARE RECONSIDERATION AND GUIDELINE INCLUSION REQUESTS

(Novitas[1] typically handles reconsideration requests on existing LCDs within three months of submission)

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

[1] Novitas is the Medicare Administrative Contractor (MAC) charged with making the Medicare local coverage determination for Pacific Edge's US laboratory

[2] AV, CV CU, respectively Analytical Validity, Clinical Validity, Clinical Utility

[3] All dates are calendar year rather than financial year and our best current estimates

[4] RWE is Real World Evidence

[5] Timeline determined by Kaiser Permanente

[6] The pooled analysis brings together data from DRIVE, AUSSIE and microDRIVE

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

Pacific Edge® CANCER DIAGNOSTICS

INDEPENDENT REAL-WORLD EVIDENCE OF CXBLADDER'S CLINICAL UTLITY

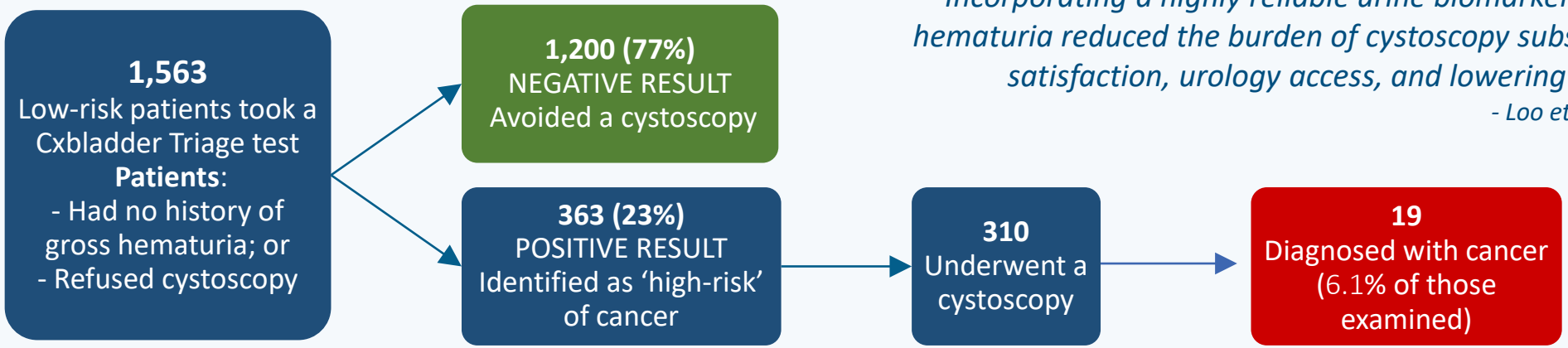
CLINICAL UTILITY EVIDENCE OF CXBLADDER TRIAGE THAT SUPPORTS MEDICARE COVERAGE

EVIDENCE COVERAGE AND GUIDELINES

KAISER PERMANENTE ABSTRACT SHOWS CLINICAL VALUE IN REAL WORLD SETTING

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

KAISER PERMANENTE®



"Incorporating a highly reliable urine biomarker into clinical workflows for hematuria reduced the burden of cystoscopy substantially, improving patient satisfaction, urology access, and lowering overall cost of care,"

- Loo et al (2024)[1]

PacificEdge® CANCER DIAGNOSTICS

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

STRATEGIC RESPONSES TO THE IMPENDING MEDICARE DETERMINATION

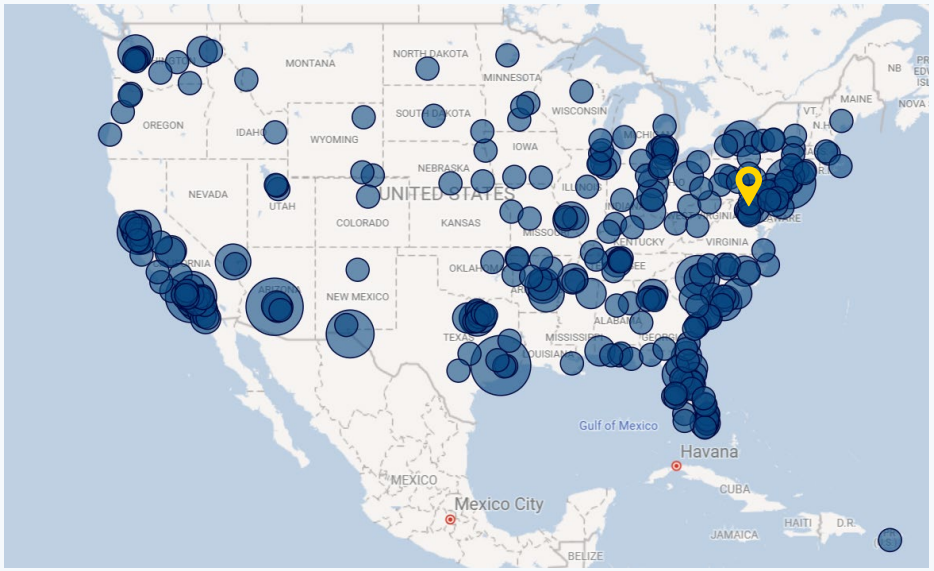
EVIDENCE COVERAGE AND GUIDELINES

OUR RESPONSE TO AN AFFIRMATION OF COVERAGE

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

OUR RESPONSE TO A LOSS OF COVERAGE

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



Distribution of Current U.S. Customers

Pacific Edge Diagnostics USA, *Hershey, Pennsylvania*

LONG TERM VALUE CREATION STRATEGIES WILL CONTINUE

- Continue to advance our clinical evidence generation program for inclusion in AUA and NCCN[1] Guidelines for increased coverage certainty
- Continue to invest in medical affairs and the digitalization initiatives that will enable clinicians who continue to order Cxbladder to follow clinical pathways on all appropriate patient types

PacificEdge® CANCER DIAGNOSTICS

1. AUA: American Urological Association; NCCN: National Comprehensive Cancer Network

RESEARCH & INNOVATION – FOCUSED ON DNA ENHANCED PRODUCTS

RESEARCH & INNOVATION

READYING FOR THE LAUNCH OF TRIAGE PLUS AND MONITOR PLUS

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

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

PacificEdge® CANCER DIAGNOSTICS

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

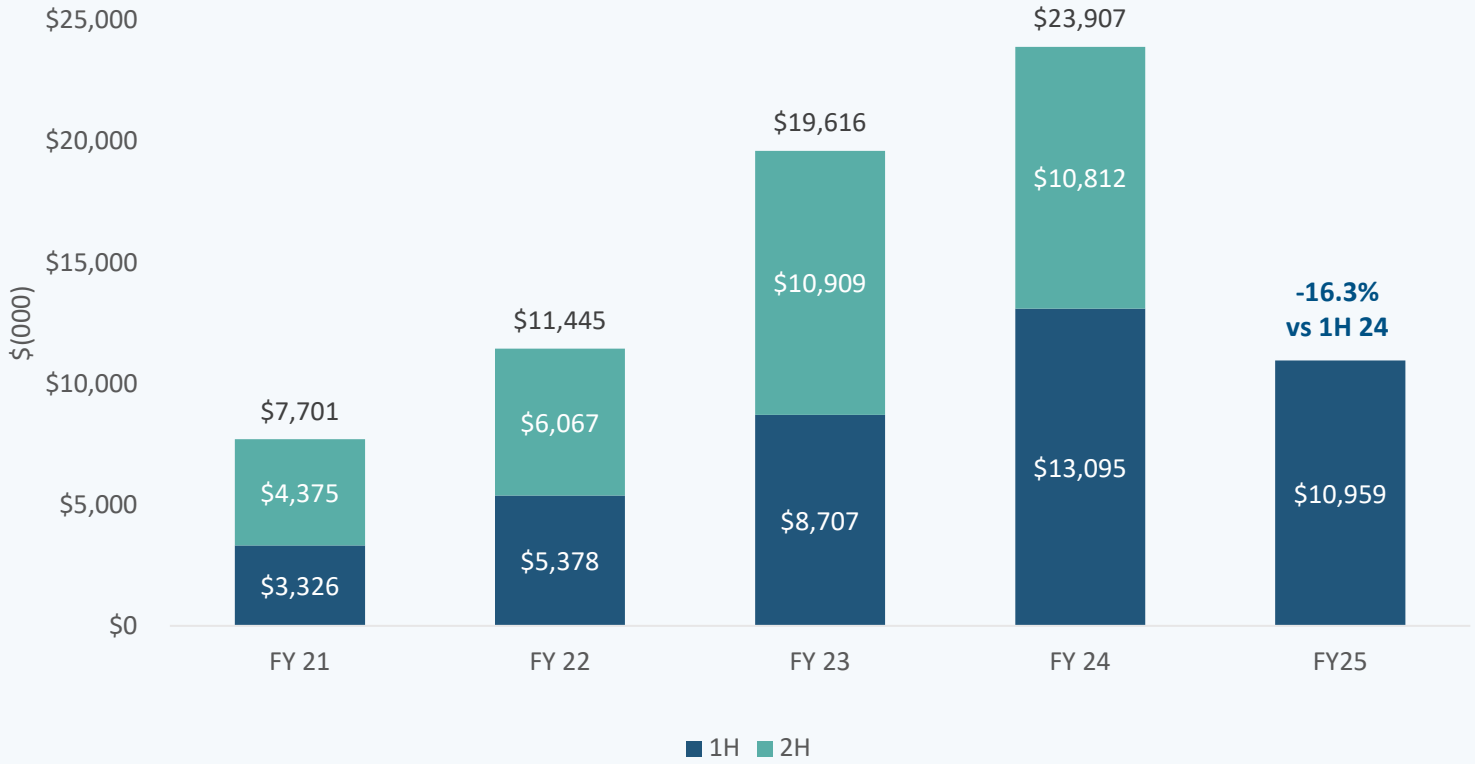
FINANCIAL PERFORMANCE

PacificEdge®
CANCER DIAGNOSTICS

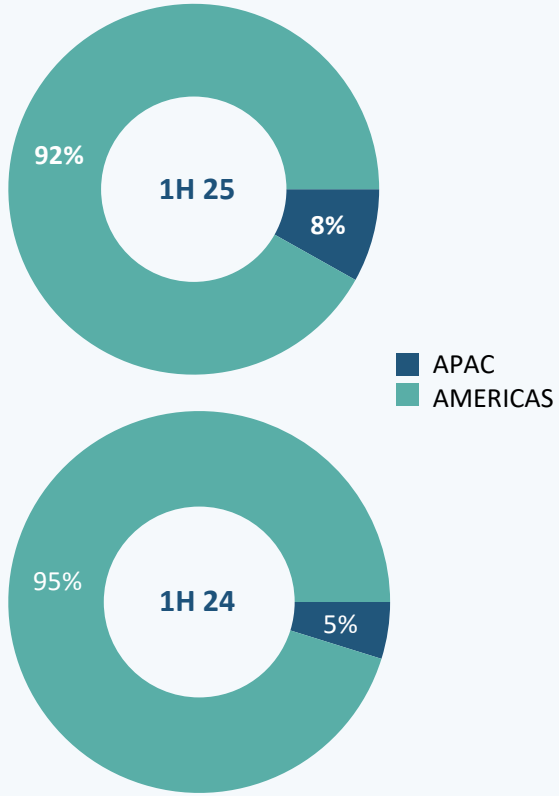
US COMMERCIAL TEST VOLUME GROWTH DRIVING REVENUE

LOOKING TO US CATALYSTS TO DRIVE A RECOVERY IN REVENUE GROWTH

PACIFIC EDGE OPERATING REVENUE

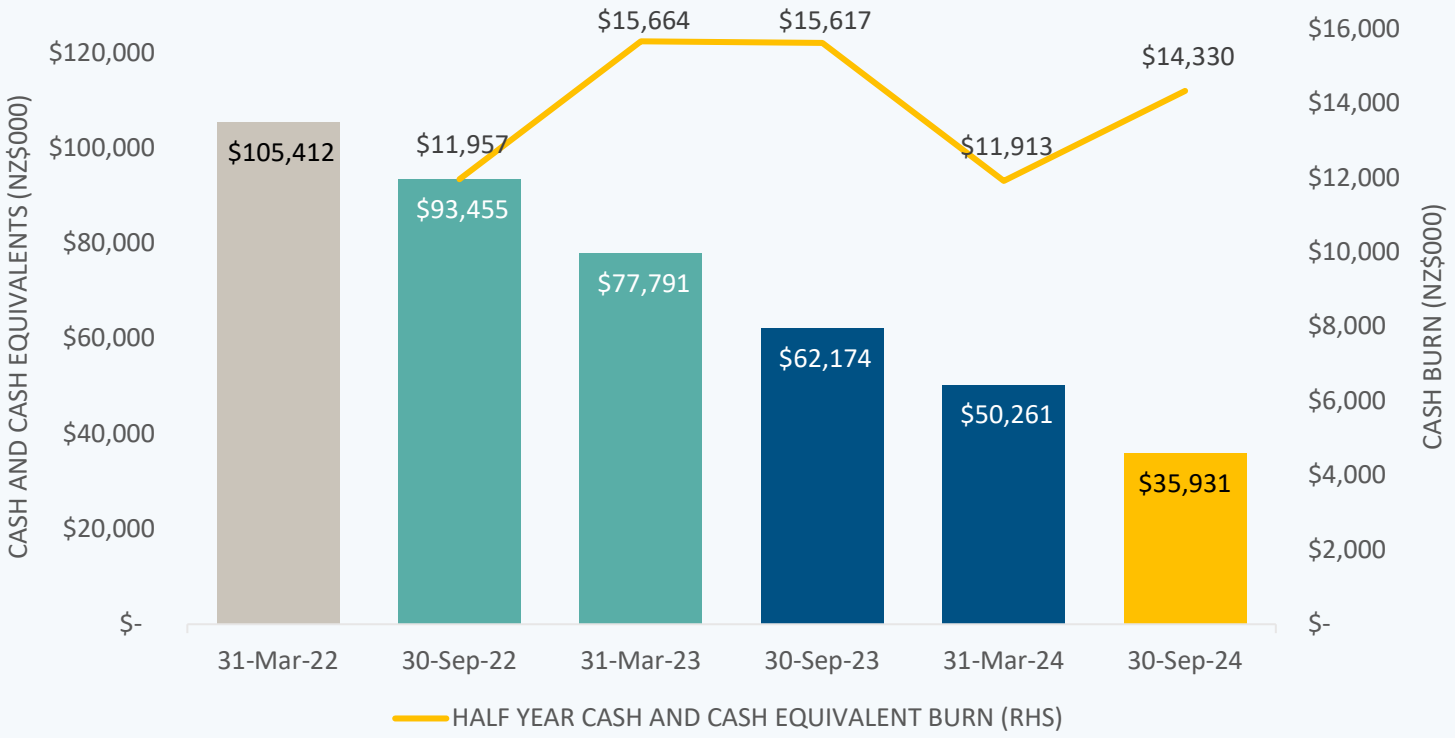


REGIONAL REVENUE CONTRIBUTION



PacificEdge®
CANCER DIAGNOSTICS

CAPITAL FOCUSED ON EVIDENCE GENERATION FOR RELIABLE REIMBURSEMENT



A STRONG BALANCE SHEET

- Cash, cash equivalents and short-term deposits of $35.9M vs. $50.3M as at 31 March 2024
- Cash burn of $14.3M vs. $12.0M in 2H 24 – Seasonal impact of higher weighting of costs in 1H 25 compared to the expectation for 2H 25
- The capital preservation initiatives continue to deliver
- Investment now primarily focused on long-term strategic initiatives
- Cash runway sufficient to re-establish reliable reimbursement[1]

PacificEdge® CANCER DIAGNOSTICS

1. Refers to scenarios that model a loss of Medicare reimbursement

REVENUE STEADY; INCREASE IN ASP OFFSETS THE IMPACT OF LOWER VOLUME

FINANCIAL PERIOD	1H 25	2H 24	1H 24	FY24	1H 25 vs. 1H 24	1H 25 vs. 2H 24
		$000	$000	$000	△ %	△ %
Operating revenue	$10,959	$10,812	$13,095	$23,907	-16.3%	1.4%
Total revenue	$12,155	$12,713	$16,580	$29,293	-26.7%	-4.4%
Operating expenses	$26,658	$26,996	$31,832	$58,828	-16.3%	-1.3%
Net Loss After Tax	**-$14,503**	**-$14,283**	**-$15,252**	**-$29,535**	**-4.9%**	**1.5%**
Cash receipts from customers	$11,125	$10,561	$13,576	$24,137	-18.1%	5.3%
Net operating cash burn	$12,474	$10,758	$14,992	$25,750	-16.8%	16.0%
Net cash, cash equivalents and short- term deposits	**$35,931**	**$50,261**	**$62,174**	**$50,261**	**-42.2%**	**-28.5%**

- Operating revenue increases 1.4% on 2H 24 despite lower volumes following lift in ASP[1] to US$618 vs. US$613 in 2H 24
- Total revenue includes FX loss of $0.4M, while 1H 24 recorded a $0.7m FX gain and 2H 24 recorded a FX loss of $0.1m
- Total operating expenses steady on 2H 24 as restructuring gains of late Q2 24 retained
- Balance sheet remains strong and expected to be sufficient to regain coverage in the event of a non-coverage decision

PacificEdge® CANCER DIAGNOSTICS

1. ASP: US Operating Revenue in USD / US Commercial Test Volumes

OPERATING EXPENSES STEADY ON PRIOR HALF

INVESTMENT NOW FOCUSSED ON LONG-TERM STRATEGIC INITIATIVES

FINANCIAL PERIOD	1H 25	2H 24	1H 24	FY24	1H 25 vs. 1H 24	1H 25 vs. 2H 24
	$000	$000	$000	$000	△ %	△ %
Laboratory operations	$5,958	$5,610	$6,141	$11,751	-3.0%	6.2%
Research	$7,230	$6,602	$5,487	$12,089	31.8%	9.5%
Sales and marketing	$8,245	$11,251	$14,339	$25,590	-42.5%	-26.7%
General and administration	$5,225	$3,533	$5,865	$9,398	-10.9%	47.9%
Total operating expenses	**$26,658**	**$26,996**	**$31,832**	**$58,828**	**-16.3%**	**-1.3%**

- Operating expenses are steady on 2H 24
- The 16.3% reduction vs. 1H 24 is due to the shift in focus to preserve cash while enhancing clinical evidence
  - Laboratory operations largely driven by volume and preparing for the commercial launch of Triage Plus.
  - Rise in research expenses reflects continued investment in clinical evidence to create catalysts for coverage.
  - Sales and marketing expense reduction vs 2H 24 reflects the sharp focus on the most the profitable territories/accounts
  - General and administration expenses are higher as a result of receiving a higher proportion of overheads.

SUMMARY AND OUTLOOK

PacificEdge®
CANCER DIAGNOSTICS

READY FOR ALL OUTCOMES

- We continue to manage our cash prudently while we seek to maintain reliable reimbursement for existing products and establish reimbursement for future products
- We will continue to:
  - Engage directly and through industry partners with CMS/Novitas to preserve reimbursement of our existing portfolio of tests
  - Focus on the clinical development of Triage Plus and Monitor Plus for guidelines inclusion and increased coverage certainty
  - Focus our commercial operations on profitable territories, non-Medicare revenue streams and cash collections
  - Emphasize the clinical and economic value of Cxbladder in our sales messaging

HEADWINDS:

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

CATALYSTS:

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

APPENDIX

PacificEdge®
CANCER DIAGNOSTICS

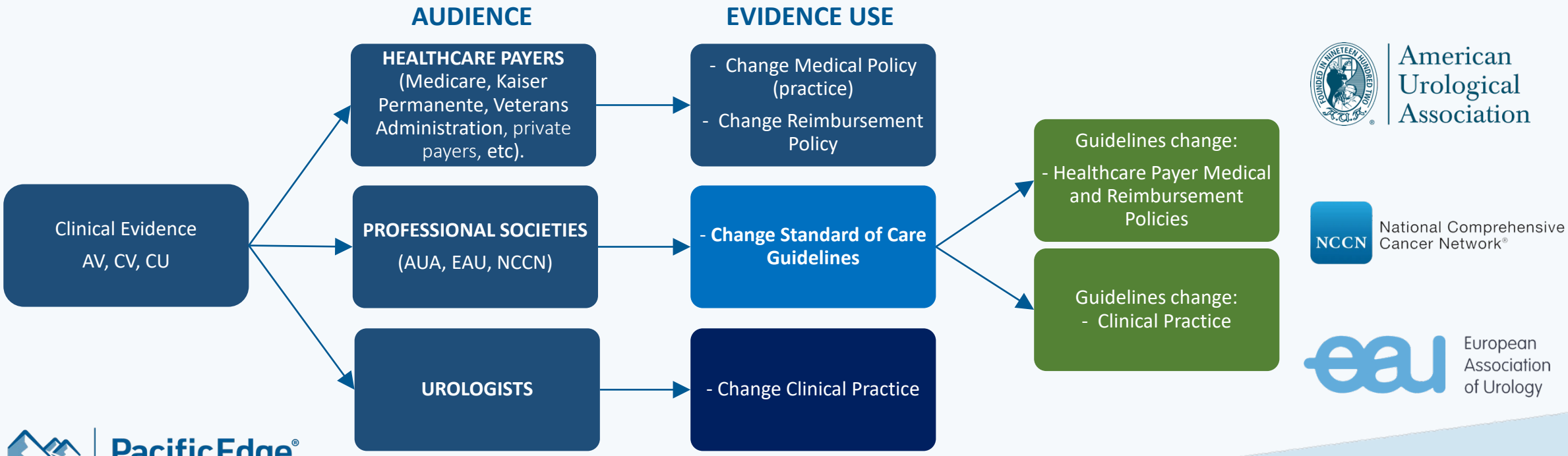
PACIFIC EDGE'S GLOBAL REACH

PacificEdge®
CANCER DIAGNOSTICS

PACIFIC EDGE'S EVIDENCE PROGRAM SEEKS TO CHANGE CLINICAL PRACTICE

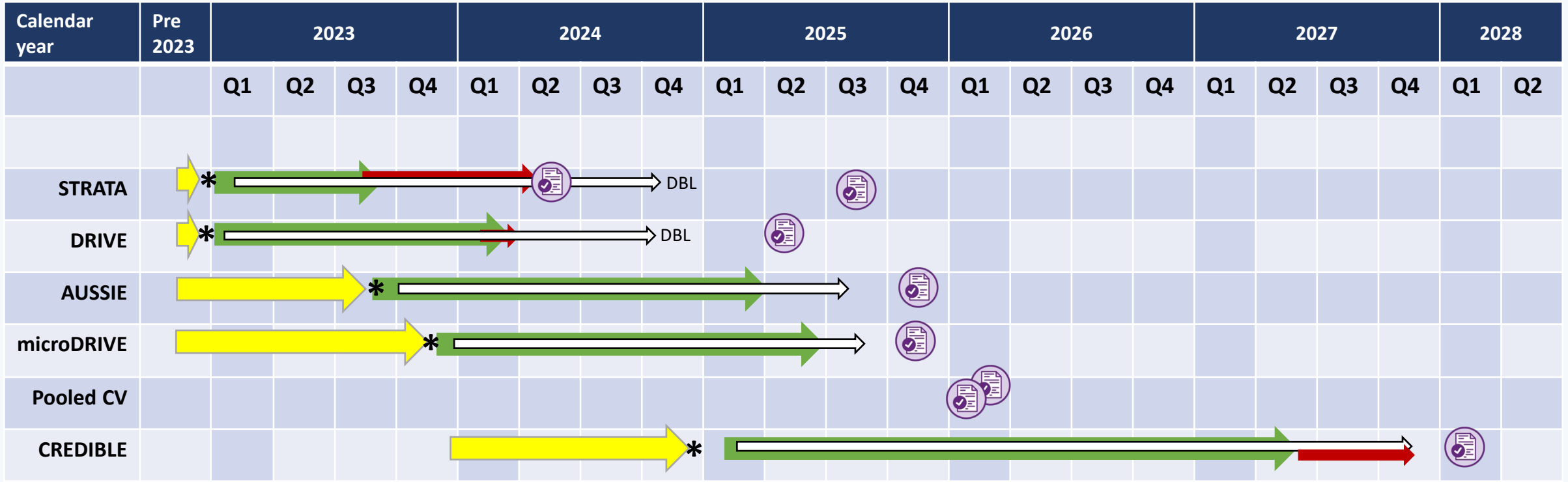
STRUCTURED CLINICAL EVIDENCE DEVELOPMENT

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



PacificEdge® CANCER DIAGNOSTICS

HEMATURIA EVALUATION FIVE YEAR CLINICAL STUDIES ROADMAP



Legend:

- Pre-activation (docs, CTA etc)
- SIV
- Enrollment
- Data Cleaning
- Publication Submitted
- Records review / follow-up
- DBL — Database lock

PacificEdge® CANCER DIAGNOSTICS

SURVEILLANCE FIVE YEAR CLINICAL STUDIES ROADMAP

Calendar year	Pre 2023	2023				2024				2025				2026				2027				2028	
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
"The 1800"																							
LOBSTER																							
US CU Surv																							

Legend:

- Pre-activation (docs, CTA etc)
- SIV
- Enrollment
- Data Cleaning
- Publication Submitted
- Records review / follow-up
- DBL Database lock

PacificEdge® CANCER DIAGNOSTICS

SUMMARY OF CLINICAL EVIDENCE

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

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

FOOTNOTES FOR CLINICAL EVIDENCE SUMMARY

	Footnotes	
Triage Plus	1	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Triage Plus).
	2	Observational study to validate performance characteristics of Cxb Triage Plus 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 Triage Plus).
	5	Observational study to validate performance characteristics of Cxb Triage Plus in microhematuria (MH) patients.
	6	Clinical utility study comparing the reduction of cystoscopy use when implementing the new clinical pathway to SOC in a defined MH population.

Triage	**1**	Cxb Triage performance; Cxb Triage & imaging combined performance had a **Sn** of 97.7% & **NPV** of 99.8%.
	2	Patients included hematuria evaluation (*n*=436) or surveillance previously diagnosed with UC (*n*=416) with both Cxbladder & urine cytology results.
	3	Cxbladder includes Cxbladder Triage & Cxbladder Monitor.
	4	This included *n*=70 for patients with hematuria & *n*=83 for patients with previously diagnosed UC and overall test negative rate of 30.7%.
	5	Cxb Triage performance; Cxb Triage & imaging combined performance had a **Sn** of 98.1%, **NPV** of 99.9% & **Sp** of 98.4%.
	6	Cxb Triage negative rate was 53%; Follow-up period of 21-months showed no missed cancers, demonstrating safety.
	7	Cxb Triage demonstrated to have clinical utility in safely risk stratifying low risk microhematuria patients and not undertake cystoscopy.

Detect	**1**	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Detect^{+}).

Monitor	**1**	Surveillance patients previously diagnosed with primary or recurrent UC.
	2	Cxb Monitor performance characteristics on surveillance patients diagnosed with primary UC; Cxb Monitor had a **Sn** of 93% and **NPV** of 94% on patients with recurrent UC.
	3	Using Kavalieris et al., (2017) data set, Lotan et al., (2017) compared relative performance of Cxb Monitor against NMP22 ELISA, NMP22 BladderChek and urine cytology.
	4	Patients included hematuria evaluation (*n*=436) or previously diagnosed UC (*n*=416) with both Cxbladder & urine cytology results.
	5	Cxbladder includes Cxbladder Triage & Cxbladder Monitor.
	6	This included *n*=70 for patients with hematuria & *n*=83 for patients with previously diagnosed UC; test negative rate of 30.7%.
	7	All patients were being evaluated for recurrence of UC (*n*=309 providing 443 samples).
	8	Cxb Monitor identified all seven confirmed recurrence events idnetified on the first cystoscopy.
	9	Patients returning negative Cxb Monitor results (n=235) had no pathology-confirmed recurrence at 1st cystoscopy

REFERENCES SUMMARY OF CLINICAL EVIDENCE

	References
Triage Plus	Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification[1]. The Journal of Urology, 10-1097.

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

Detect	Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.
	O'Sullivan et al., (2012). A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. The Journal of urology, 188(3), 741-747.

Monitor	Kavalieris et al., (2017). Performance characteristics of a multigene urine biomarker test for monitoring for recurrent urothelial carcinoma in a multicenter study. The Journal of Urology, 197(6), 1419-1426.
	Konety et al., (2019). Evaluation of cxbladder and adjudication of atypical cytology and equivocal cystoscopy. European urology, 76(2), 238-243.
	Koya et al., (2020). An evaluation of the real-world use and clinical utility of the Cxbladder Monitor assay in the follow-up of patients previously treated for bladder cancer. BMC urology, 20(1), 1-9.
	Lotan et al., (2017). Clinical comparison of non-invasive urine tests for ruling out recurrent urothelial carcinoma. Urologic Oncology: Seminars and Original Investigations, 35 (8), 531-539.
	Li et al., (2023). Cxbladder Monitor testing to reduce cystoscopy frequency in patients with bladder cancer. Urologic Oncology: Seminars and Original Investigations, 41 (7), 326.e1 – 326.38.

1. Triage Plus was called Detect+ in this publication

KEY CLINICAL ADVISORS AND CONSULTANTS

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

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

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

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

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

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

Professor Jonathan Wright, MD, MS, FACS
Institution: Fred Hutchinson Cancer Center at UW
Relationship: Consultant, CAB member, CT PI
Brief Bio: Member of ACS, SUO, AUA

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

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

Associate Professor Kristen Scarpato, MD, MPH, FACS
Institution: Vanderbilt University Medical Center
Relationship: Consultant, CAB member, CT PI
Brief Bio: SUO Education Committee, AUA Core Curriculum, Urology Practice Editorial Committee

ASCO: American Society of Clinical Oncology
ASTRO: American Society of Radiation Oncology
AUA: American Urological Association
BCAN: Bladder Cancer Advocacy Network
CAB: Clinical Advisory Board
CT PI: Clinical Trials Principal Investigator
FACS: Fellow of the American College of Surgeons
IIT PI: Investigator Initiated Trial Principal Investigator
J Urol: Journal of Urology
KOL: Key Opinion Leader
MPH: Master of Public Health
SUO: Society of Urologic Oncology

PacificEdge® CANCER DIAGNOSTICS

PACIFIC EDGE – TAKING NEW ZEALAND INNOVATION GLOBAL

2011
2011 Pacific Edge Diagnostics New Zealand (PEDNZ) established

2012
Dec 2012 Launch of Pacific Edge Diagnostics USA and Cxb Detect

2013
May 2013 First commercial sale (Cxb Detect) for PEDNZ

Mar 2013 First commercial sale (Cxb Detect) for PEDUSA

2014
Dec 2014 Launch of Cxbladder Triage

2015
Dec 2015 Launch of Cxbladder Monitor

2016

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

2019

2020
Jun 2020 Kaiser Permanente, approves commercial use of Cxbladder

Jul 2020 Medicare reimbursement of Cxbladder at $760/test

2021
Aug 2021 Cxbladder reaches 70% public healthcare coverage in NZ

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

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

2023
Nov 2023 Kaiser Permanente EMR integration goes live

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

PacificEdge® CANCER DIAGNOSTICS

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
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

PacificEdge® CANCER DIAGNOSTICS

FOR MORE INFORMATION:

Dr. Peter Meintjes
Chief Executive Officer
email: peter.meintjes@pelnz.com

Grant Gibson
Chief Financial Officer
email: grant.gibson@pelnz.com

Pacific Edge
87 St David Street, PO Box 56, Dunedin, New Zealand
P +64 3 577 6733 Within NZ 0800 555 563
email: investors@pacificedge.co.nz
www.pacificedgedx.com

PacificEdge® CANCER DIAGNOSTICS

CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED
30 SEPTEMBER 2024

PacificEdge
CANCER DIAGNOSTICS

Consolidated Interim Financial Statements

Notes to the Financial Statements

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

	NOTES	UNAUDITED SEPT 2024 6 MONTHS ($000)	UNAUDITED SEPT 2023 6 MONTHS ($000)	AUDITED MARCH 2024 12 MONTHS ($000)
REVENUE				
Operating Revenue	4	10,959	13,095	23,907
Total Operating Revenue		**10,959**	**13,095**	**23,907**
Other Income	4	385	859	1,322
Interest Income		1,193	1,892	3,433
Foreign Exchange Gain / (Loss)		(382)	734	631
Total Revenue and Other Income		**12,155**	**16,580**	**29,293**
OPERATING EXPENSES				
Laboratory Operations		5,958	6,141	11,751
Research		7,230	5,487	12,089
Sales and Marketing		8,245	14,339	25,590
General and Administration		5,225	5,865	9,398
Total Operating Expenses	5	**26,658**	**31,832**	**58,828**
NET LOSS BEFORE TAX		**(14,503)**	**(15,252)**	**(29,535)**
Income Tax Expense		-	-	-
LOSS FOR THE YEAR AFTER TAX		**(14,503)**	**(15,252)**	**(29,535)**
Items that may be reclassified to profit or loss:				
Translation of Foreign Operations		(155)	198	142
Disposal of Foreign Operation		-	-	(20)
TOTAL COMPREHENSIVE LOSS atttributable to equity holders of the Company		**(14,658)**	**(15,054)**	**(29,413)**
Earnings per share for loss attributable to the equity holders of the Company during the year				
Basic and Diluted Earnings per share		(0.018)	(0.019)	(0.036)

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

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2024

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

	NOTES	SHARE CAPITAL ($000)	ACCUMULATED LOSSES ($000)	SHARE BASED PAYMENTS RESERVE ($000)	FOREIGN CURRENCY TRANSLATION RESERVE ($000)	TOTAL EQUITY ($000)
UNAUDITED 6 MONTHS TO 30 SEPT 2023						
Balance as at 31 March 2023		**294,317**	**(216,814)**	**4,418**	**842**	**82,763**
Loss After Tax		-	(15,252)	-	-	(15,252)
Other Comprehensive Income		-	(8)	-	206	198
Total Comprehensive Loss atttributable to equity holders of the Company		-	(15,260)	-	206	(15,054)
Transactions with owners in their capacity as owners:						
Share Based Payments - Employee Remuneration	7	38	-	-	-	38
Share Based Payment - Employee Share Options	7	-	-	555	-	555
Balance as at 30 September 2023		**294,355**	**(232,074)**	**4,973**	**1,048**	**68,302**
AUDITED 12 MONTHS TO 31 MARCH 2024						
Balance as at 31 March 2023		**294,317**	**(216,814)**	**4,418**	**842**	**82,763**
Loss After Tax		-	(29,535)	-	-	(29,535)
Other Comprehensive Income		-	-	-	122	122
Total Comprehensive Loss atttributable to equity holders of the Company		-	(29,535)	-	122	(29,413)
Transactions with owners in their capacity as owners:						
Share Based Payments - Employee Remuneration	7	83	-	-	-	83
Share Based Payment - Employee Share Options	7	-	-	1,189	-	1,189
Balance as at 31 March 2024		**294,400**	**(246,349)**	**5,607**	**964**	**54,622**
UNAUDITED 6 MONTHS TO 30 SEPT 2024						
Balance as at 31 March 2024		**294,400**	**(246,349)**	**5,607**	**964**	**54,622**
Loss After Tax		-	(14,503)	-	-	(14,503)
Other Comprehensive Income		-	-	-	(155)	(155)
Total Comprehensive Loss atttributable to equity holders of the Company		-	(14,503)	-	(155)	(14,658)
Transactions with owners in their capacity as owners:						
Share Based Payments - Employee Remuneration	7	58	-	-	-	58
Share Based Payment - Employee Share Options	7	-	63	571	-	634
Balance as at 30 September 2024		**294,458**	**(260,789)**	**6,178**	**809**	**40,656**

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

CONSOLIDATED BALANCE SHEET

AS AT 30 SEPTEMBER 2024

	NOTES	UNAUDITED SEPT 2024 6 MONTHS ($000)	UNAUDITED SEPT 2023 6 MONTHS ($000)	AUDITED MARCH 2024 12 MONTHS ($000)
CURRENT ASSETS				
Cash and Cash Equivalents		21,931	20,469	29,261
Short Term Deposits		14,000	41,705	21,000
Receivables		5,143	5,239	4,698
Inventory		1,335	1,676	1,688
Other Assets		1,905	1,688	1,228
Total Current Assets		**44,314**	**70,777**	**57,875**
NON-CURRENT ASSETS				
Property, Plant and Equipment		2,728	2,945	2,925
Right of Use Assets		2,902	1,376	3,698
Intangible Assets		907	1,156	950
Total Non-Current Assets		**6,537**	**5,477**	**7,573**
TOTAL ASSETS		**50,851**	**76,254**	**65,448**
CURRENT LIABILITIES				
Payables and Accruals		6,869	6,539	6,753
Borrowings		300	-	300
Lease Liabilities		1,260	529	1,264
Total Current Liabilities		**8,429**	**7,068**	**8,317**
NON-CURRENT LIABILITIES				
Lease Liabilities		1,766	884	2,509
Total Non-Current Liabilities		**1,766**	**884**	**2,509**
TOTAL LIABILITIES		**10,195**	**7,952**	**10,826**
NET ASSETS		**40,656**	**68,302**	**54,622**
Represented by:				
EQUITY				
Share Capital	7	294,458	294,355	294,400
Accumulated Losses		(260,789)	(232,074)	(246,349)
Share Based Payments Reserve		6,178	4,973	5,607
Foreign Translation Reserve		809	1,048	964
TOTAL EQUITY		**40,656**	**68,302**	**54,622**
FURTHER INFORMATION:				
Net Tangible Assets Per Share ($)	14	0.049	0.083	0.066

For and on behalf of the Board of Directors:

Director **Director**

Dated 25th day of November 2024

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 2024

	NOTES	UNAUDITED SEPT 2024 6 MONTHS ($000)	UNAUDITED SEPT 2023 6 MONTHS ($000)	AUDITED MARCH 2024 12 MONTHS ($000)
CASH FLOWS TO OPERATING ACTIVITIES				
Cash was provided from:				
Receipts from Customers		11,125	13,576	24,137
Receipts from Research Tax Incentives and Grant Providers		16	1,371	1,856
Interest Received		995	1,228	3,441
		12,136	16,175	29,434
Cash was disbursed to:				
Payments to Suppliers and Employees		24,567	31,080	55,196
Net GST outflow (inflow)		43	87	(12)
		24,610	31,167	55,184
Net Cash Flows To Operating Activities	8	**(12,474)**	**(14,992)**	**(25,750)**
CASH FLOWS FROM INVESTING ACTIVITIES:				
Cash was provided from:				
Proceeds from Short Term Deposits		34,000	35,703	83,084
		34,000	35,703	83,084
Cash was disbursed to:				
Purchase of Short Term Deposits		27,145	32,846	59,523
Capital Expenditure on Plant and Equipment		278	487	832
Capital Expenditure on Intangible Assets		252	302	540
		27,675	33,635	60,895
Net Cash Flows From Investing Activities		**6,325**	**2,068**	**22,189**
CASH FLOWS TO FINANCING ACTIVITIES:				
Cash was received from:				
Proceeds from Borrowings		-	-	300
		-	-	300
Cash was disbursed to:				
Repayment of Leases - Principal		614	675	1,268
Repayment of Leases - Interest		118	32	138
		732	707	1,406
Net Cash Flows To Financing Activities		**(732)**	**(707)**	**(1,106)**
Net Decrease in Cash Held		**(6,881)**	**(13,631)**	**(4,667)**
Add Opening Cash Brought Forward		29,261	33,229	33,229
Effect of Exchange Rate Changes on Net Cash		(449)	871	699
Ending Cash Carried Forward		**21,931**	**20,469**	**29,261**

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 2024

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 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 of Financial Statements

The Interim Financial Statements for the six months ended 30 September 2024 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 2024 Annual Report.

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).

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2024

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

b) Accounting Policies and Accounting Estimates

All material 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 2024.

c) Authorisation

The Interim Financial Statements were authorised by the Board of Directors on 25 November 2024. The Annual Financial Statements for the year ended 31 March 2024 were authorised by the Board of Directors on 20 May 2024.

d) Audit

The Interim Financial Statements for the six months ended 30 September 2024 are unaudited. Comparative balances for 30 September 2023 are unaudited, whilst the comparative balances for 31 March 2024 are audited.

e) Basis of Consolidation

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

			Ownership Interests & Voting Rights	
Name of Subsidiary	**Place of Incorporation (or registration) and Operation**	**Principal Activity**	**30 Sept 2024 (%)**	**30 Sept 2023 (%)**
Pacific Edge Diagnostics New Zealand Limited	New Zealand	Commercial Sales and Diagnostic Laboratory	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	100	100
Pacific Edge Singapore Pte Limited	Singapore	Dormant - In the process of being dissolved as at 30 September 2024 (FY24: Commercial Sales)	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 2024

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 2024 6 Months ($000)	Unaudited Sept 2023 6 Months ($000)	Audited March 2024 12 Months ($000)
Cxbladder Sales			
- US - Accrual Accounting	8,889	11,403	19,288
- US - Cash Accounting	1,178	1,062	3,214
- Total US Sales	10,067	12,465	22,502
- Rest of World	892	630	1,405
Total Operating Revenue	**10,959**	**13,095**	**23,907**
Other Income			
Grant Income	-	3	24
Research Rebates and Tax Incentives	385	856	1,298
Total Other Income	**385**	**859**	**1,322**

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

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 2024 6 Months ($000)	Unaudited Sept 2023 6 Months ($000)	Audited March 2024 12 Months ($000)
Operating Expenses			
Amortisation	295	178	621
Auditors Remuneration			
- Group year end financial statements	99	97	194
- Half year review of financial statements	35	34	34
- Foreign statutory financial statements	-	25	-
Other services provided by PricewaterhouseCoopers New Zealand	1		2
Total Auditors Remuneration	**135**	**156**	**230**
Consultant Costs	1,149	1,366	2,432
Depreciation	390	370	716
Depreciation on Right of Use Assets	661	635	1,267
Directors Fees	247	247	500
Employee Benefits	12,784	15,700	29,097
Employee Share Scheme Expenses	58	38	83
Employee Share Options	635	555	1,189
Interest on Lease Liabilities	118	32	138
Legal Expenses	256	620	826
NZX / ASX / Registry Fees	124	146	274
Rental and Lease Expense	75	68	151
Site Fees - Clinical Studies	2,062	1,358	3,154
Other Operating Expenses	7,669	10,363	18,150
Total Operating Expenses	**26,658**	**31,832**	**58,828**

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

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 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:

1. **Commercial**: The sales, marketing, laboratory and support operations to run the commercial businesses worldwide; and
2. **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 2024 is shown on the following page.

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

Unaudited 6 Months to 30 September 2024	Commercial ($000)	Research ($000)	Less: Eliminations ($000)	Total External Income ($000)
Income				
Operating Revenue - External	10,959	-	-	10,959
Other Income	617	785	(1,017)	385
Interest Income	7	1,186	-	1,193
Foreign Exchange Gain	-	(382)	-	(382)
Total Income	**11,583**	**1,589**	**(1,017)**	**12,155**
Expenses				
Expenses	15,814	10,516	(1,017)	25,313
Depreciation & Amortisation	890	455	-	1,345
Total Operating Expenses	**16,704**	**10,971**	**(1,017)**	**26,658**
Loss Before Tax	**(5,121)**	**(9,382)**	**-**	**(14,503)**
Income Tax Expense	-	-	-	-
Loss After Tax	**(5,121)**	**(9,382)**	**-**	**(14,503)**
Net Cash Flow to Operating Activities	**(4,109)**	**(8,365)**	**-**	**(12,474)**

Unaudited 6 Months to 30 September 2023	Commercial ($000)	Research ($000)	Less: Eliminations ($000)	Total External Income ($000)
Income				
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
Total Income	**13,385**	**4,015**	**(820)**	**16,580**
Expenses				
Expenses	21,791	9,678	(820)	30,649
Depreciation & Amortisation	801	382	-	1,183
Total Operating Expenses	**22,592**	**10,060**	**(820)**	**31,832**
Loss Before Tax	**(9,207)**	**(6,045)**	**-**	**(15,252)**
Income Tax Expense	-	-	-	-
Loss After Tax	**(9,207)**	**(6,045)**	**-**	**(15,252)**
Net Cash Flow to Operating Activities	**(9,114)**	**(5,878)**	**-**	**(14,992)**

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

Audited 12 Months to 31 March 2024	Commercial ($000)	Research ($000)	Less: Eliminations ($000)	Total External Income ($000)
Income				
Operating Revenue - External	23,871	-	36	23,907
Other Income	489	4,400	(3,567)	1,322
Interest Income	21	3,412	-	3,433
Foreign Exchange Gain	1	666	(36)	631
Total Income	**24,382**	**8,478**	**(3,567)**	**29,293**
Expenses				
Expenses	40,008	19,781	(3,567)	56,222
Depreciation & Amortisation	1,629	977	-	2,606
Total Operating Expenses	**41,637**	**20,758**	**(3,567)**	**58,828**
Loss Before Tax	**(17,255)**	**(12,280)**	**-**	**(29,535)**
Income Tax Expense	-	-	-	-
Loss After Tax	**(17,255)**	**(12,280)**	**-**	**(29,535)**
Net Cash Flow to Operating Activities	**(14,447)**	**(11,303)**	**-**	**(25,750)**

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 2024	12,323	1,910	14,233
6 months ended 30 September 2023	15,401	2,839	18,240
12 months ended 31 March 2024	27,347	5,286	32,633

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 2024

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 2024	Commercial ($000)	Research ($000)	Total ($000)
Total Assets	10,359	40,492	50,851
Total Liabilities	6,106	4,089	10,195

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 2024	Commercial ($000)	Research ($000)	Total ($000)
Total Assets	11,443	54,005	65,448
Total Liabilities	6,871	3,955	10,826

Additions to non current assets for the six months ended 30 September 2024 include:

	Commercial ($000)	Research ($000)	Total ($000)
Property, Plant & Equipment	274	4	278
Intangible Assets	252	-	252
Total Additions to Non Current Assets	**526**	**4**	**530**

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 2024

Segment Assets and Liabilities Information

The Group generates most of the operating revenue from Commercial tests from the US and New Zealand and also receives Grant revenue from New Zealand. Rest of World consists of Revenue from Australia and Southeast Asia.

	Unaudited Sept 2024 6 Months ($000)	Unaudited Sept 2023 6 Months ($000)	Audited March 2024 12 Months ($000)
Operating and Grant Revenue			
US	10,067	12,465	22,502
New Zealand	1,228	1,436	2,641
Rest of World	49	53	86
Total Operating and Grant Revenue	**11,344**	**13,954**	**25,229**

	Unaudited Sept 2024 6 Months ($000)	Unaudited Sept 2023 6 Months ($000)	Audited March 2024 12 Months ($000)
Non-Current Assets			
US	3,469	1,736	4,343
New Zealand	3,066	3,740	3,229
Rest of World	2	1	1
Total Non-Current Assets	**6,537**	**5,477**	**7,573**

7. SHARE CAPITAL

	6 Months Shares (000)	Unaudited Sept 2024 6 Months ($000)	Unaudited Sept 2023 6 Months ($000)	Audited March 2024 12 Months ($000)
Opening Balance	**811,271**	**294,400**	**294,317**	**294,317**
Issue of Ordinary Shares				
- Employee Remuneration[1]	645	58	38	83
Movement	**645**	**58**	**38**	**83**
Closing Balance	**811,916**	**294,458**	**294,355**	**294,400**

[1] During the period 644,630 shares were issued as part of employees remuneration in lieu of cash payments at an average price of $0.090 per share. (September 2023: 351,894 at $0.107 and March 2024: 906,126 at $0.091).

There are 811,915,974 (September 2023: 810,717,112 and March 2024: 811,271,344) 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.

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

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

	Unaudited Sept 2024 6 Months ($000)	Unaudited Sept 2023 6 Months ($000)	Audited March 2024 12 Months ($000)
Net Loss for the Period	(14,503)	(15,252)	(29,535)
Add Non Cash Items:			
Depreciation	390	370	716
Loss on disposal of Property, Plant and Equipment	-	2	14
Amortisation	295	178	621
Employee Share options	635	555	1,189
Employee bonuses paid in shares in lieu of cash	58	38	83
Depreciation on right of use assets	661	635	1,267
Interest on finance leases shown in lease repayments	118	32	138
Total Non Cash Items	**2,157**	**1,810**	**4,028**
Add Movements in Other Working Capital items:	**(978)**	**(37)**	**964**
(Increase) Decrease in Receivables and Other Assets	353	(389)	(401)
(Increase) Decrease in Inventory	116	(390)	(174)
Increase (Decrease) in Payables and Accruals	381	(734)	(632)
Total Movement in Other Working Capital	**(128)**	**(1,550)**	**(243)**
Net Cash Flows to Operating Activities	**(12,474)**	**(14,992)**	**(25,750)**

9. CONTINGENT LIABILITIES

There were no known contingent liabilities at 30 September 2024 (September 2023: Nil and March 2024: 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 2024 (September 2023: Nil and March 2024: Nil).

11. SUBSEQUENT EVENTS

There are no subsequent events.

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

12. RELATED PARTIES

Details of all related party relationships have been disclosed in the annual report for the year ended 31 March 2024. No new transactions with directors occurred that would be considered a related party.

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

On 3 July 2020* Pacific Edge received notice of inclusion in the LCD resulting in the Company receiving reimbursement for Cxbladder Monitor and Detect tests from that date.

On 29 July 2022*, Pacific Edge became aware of proposed changes to the LCD/LCA whereby if the proposed changes were issued as published then Cxbladder would no longer have coverage and the Company would not qualify for reimbursement.

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 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 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 became aware that Novitas had republished 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.

Novitas was expected to withdraw or finalize the LCD within 365 days from the original publication date (27 July 2023*) and include a response to those comments. On 26 July 2024* Novitas confirmed it had been granted an extension to finalize or withdraw the LCD. At the time of signing these interim financial statements, the Board does not have a revised date that Novitas will finalize or withdraw the LCD.

If finalized, Novitas must provide a minimum of 45 days' notice before the LCD becomes effective.

NOTES TO THE FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2024

Pacific Edge received payment in line with the existing LCD/LCA (Local Coverage Article) for the six months ended 30 September 2024, and to the date of approval of these consolidated interim financial statements.

In the six months to 30 September 2024, tests processed through our laboratory for Medicare and Medicare Advantage patients represented approximately 54% of US commercial test volumes and generated approximately NZ $6.5m, or 59% of Pacific Edge's total operating revenue.

During the six months to 30 September 2024, Pacific Edge continued to progress initiatives that will assist in mitigating reimbursement risk, including the development of further clinical evidence validating the performance of Cxbladder and providing the catalyst for language supportive of Cxbladder in the American Urological Association microhematuria guideline currently under review. In addition, the company has continued to progress commercialization of Triage Plus which has demonstrated improved performance characteristics and has the expectation of delivering an improved margin.

Whilst the LCD has yet to be finalised and the full impact on the Group is unable to be determined, management and the Board have modelled a number scenarios relating to possible LCD outcomes. Under all modelled scenarios there is sufficient liquidity in the form of cash and short term deposits to meet obligations and continue for the foreseeable future, being at least 12 months from the date of approval of the consolidated interim financial statements. Accordingly, it is the Board's view that there are no material uncertainties related to events or conditions that may cast significant doubt upon the entity's ability to continue as a going concern for the purpose of these financial statements.

*All dates with an asterisk 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 2024 6 Months ($000)	Unaudited Sept 2023 6 Months ($000)	Audited March 2024 12 Months ($000)
Total Assets	50,851	76,254	65,448
Less Intangible Assets	907	1,156	950
Less Total Liabilities	10,195	7,952	10,826
Net Tangible Assets	**39,749**	**67,146**	**53,672**
Number of Shares Issued (000's)	811,916	810,717	811,271
Net Tangible Assets Per Share	**$0.049**	**$0.083**	**$0.066**

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 2024, 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 notes, comprising material accounting policy information 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 2024, 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 carries out other services for the Group including training workshop. The provision of this other service has not impaired our independence.

Responsibilities of 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:

PricewaterhouseCoopers Christchurch
25 November 2024

PacificEdge

CANCER DIAGNOSTICS

87 St David Street, PO Box 56, Dunedin, New Zealand
P +64 3 577 6733 (overseas) | 0800 555 563 (NZ)
F +64 3 974 9393
www.pacificedgedx.com

NZX
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 2024	
Previous Reporting Period	6 months to 30 September 2023	
Currency	NZD (New Zealand Dollar)	
	Amount (000s)	**Percentage change**
Revenue from continuing operations	$10,959	16% Decrease
Total Revenue	$12,155	27% Decrease
Net profit/(loss) from continuing operations	($14,503)	5% Smaller Loss
Total net profit/(loss)	($14,503)	5% Smaller 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	$0.049	$0.083
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 2024 which accompany this Results Announcement.	
Authority for this announcement		
Name of person authorised to make this announcement	Grant Gibson	
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	26/11/2024	

Unaudited financial statements accompany this announcement.