

29 MAY 2025

AUDITED FINANCIAL RESULTS FOR THE YEAR TO 31 MARCH 2025

## PACIFIC EDGE REPORTS RESILIENT PERFORMANCE IN FY25

**DUNEDIN, New Zealand** – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today reports a resilient financial result for the year to the end of March 2025. Improvements in the performance of the sales force, operating efficiencies and cash collection gains over the financial year have positioned the company well as it works towards regaining Medicare coverage of its tests.

Pacific Edge today also announces a NZ\$20 million equity raising to capitalize on recent clinical and commercial milestones, grow in non-Medicare channels and regain Medicare coverage. The details of the capital raising are covered in a separate announcement to the NZX and ASX today.

### FY25 FINANCIAL PERFORMANCE<sup>1</sup>

- Operating revenue down 8.6% on FY 24 to \$21.8 million, reflecting Medicare uncertainty. Total revenue is down 16% on FY 24 to \$24.6 million
- Total laboratory throughput<sup>2</sup> (TLT) of Cxbladder tests fell 11.5% on FY 24 to 28,894; commercial tests fell 9.9% on FY 24 to 26,42 tests
- Tests/Sales FTE in the US for Q4 25 were reported at 405.6, up 6.4% on Q4 24; ASP<sup>3</sup> for all commercial tests in the US increases to US\$594 in FY 25 vs US\$584 in FY 24 as operating efficiencies and cash collection gains continue to improve
- Strong performance from the Southern California Permanente Medical Group, increased APAC volume and sustained sales force efficiencies reduce the impact of Medicare uncertainty and the reduced sales team reach
- Net loss after tax +1.4% on FY 24 to \$29.9 million, 2H 25 net loss +6.4% on 1H 25 led by increased expenditure on clinical research, Triage Plus commercialization and legal fees
- Cash, cash equivalents and short-term deposits of \$22.6 million at the end of FY25; cash burn of \$13.4 million in 2H 25 down 6.7% on 1H 25

### FY 25 STRATEGIC PERFORMANCE

- Cxbladder Triage included in the American Urological Association (AUA) guidelines with a 'Grade A' evidence rating, the only biomarker to achieve this status
- Triage Plus achieves a draft Medicare price of US\$1,018.44, a significant premium to the current US\$760 per test; full scale commercial launch is now contingent on re-coverage
- Medicare coverage discontinued following Genetic Tests for Oncology (Specific Tests) (L39365) becoming effective after balance date (24 April 2025); Pacific Edge is now focused on regaining coverage for Triage and Monitor and obtaining coverage and launch of new products Triage Plus and Monitor Plus

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

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

<sup>3</sup> ASP: US Average Sales Price (US Operating Revenue in USD / US Commercial Test Volumes)

- Commercial team focused on profitable territories, non-Medicare revenue streams and selling the clinical and economic value of Cxbladder; Cxbladder Detect discontinued
- FY25 Climate Disclosures released in compliance with NZCS

Chairman Chris Gallaher said: “While a significant disappointment, the adverse determination based on out-dated evidence on Genetic Testing for Oncology: Specific Tests (L39365) LCD should not overshadow the major strategic progress we’ve made over the past year.

“Cxbladder Triage was included in the American Urological Association’s new microhematuria guideline with a ‘Grade A’ evidence rating<sup>4</sup> – the only biomarker to receive that level of endorsement.

“Meanwhile, with the US Centers for Medicare & Medicaid Services (CMS) announcing a draft price of US\$1,018.44 for Cxbladder Triage Plus – a significant premium over the current US\$760 price for our existing tests – Pacific Edge is positioned for a rapid acceleration of revenue growth in the US once Medicare coverage is achieved<sup>5</sup>.

Chief Executive Dr Peter Meintjes added: “The AUA guideline cements Pacific Edge’s position as the market leader in non-invasive bladder cancer diagnostics, reinforcing our first-mover advantage. In combination with evidence not considered during the finalization of L39365, the guideline puts Pacific Edge in a strong position to regain Medicare coverage for Cxbladder Triage. We also believe we can make a strong case for Medicare coverage of Cxbladder Monitor, and longer-term Triage Plus and Monitor Plus tests.

“Supported by our peer-reviewed clinical evidence – and the capital we are seeking – we are confident we can continue to advance the commercialization of our tests in the US. And, as we advance the development of in vitro diagnostic (IVD) kitted versions of Cxbladder, we are also confident we can deliver the same performance and value in other markets with kits run in partner labs.”

## FINANCIAL RESULTS

Operating revenue of \$21.8 million was down 8.6% from \$23.9 million in FY24, but steady against 1H 25 reflecting the ongoing Medicare uncertainty and the reduced reach of the sales team following the restructuring at the start of 2H 24.

FY 25 TLT of 28,894 tests was down 11.5% on the 32,633 tests in FY 24, but 2H 25 volume steady against 1H 25. Commercial test volumes was down 9.9% on FY 24 to 24,642 tests, but steady against 1H 25. However, since the LCD became effective, we have seen its impact in reduced volumes.

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<sup>4</sup> The AUA defines ‘Grade A’ evidence as evidence with a high certainty rating and notes evidence of this grade makes it “very confident that the true effect lies close to that of the estimate of the effect”

<sup>5</sup> Although Pacific Edge is confident that it will regain coverage for Triage as a result of recent AUA guideline inclusion and new clinical evidence, there are no guarantees as to the timing or outcome of the re-coverage process. Regaining Medicare coverage could be delayed or not achieved at all.

Tests for Medicare and Medicare Advantage – those affected by L39365 – represented 53% of commercial tests in FY25 vs 60% in 1H 24. This improvement reflects rising demand from contracted payers such as the Southern California Permanente Medical Group, rising APAC volumes and sustained sales force efficiencies.

The Average Sales Price for US testing increased to US\$594 in FY 25 vs US\$584 in FY 24 as cash collection improvements were sustained. Throughput per Sales FTE improved again to 405.6 tests in Q4 25 from 381.2 in Q4 24. Tests per unique ordering clinician (our preferred metric for measuring customer commitment to Cxbladder) was 7.1 in Q4 25 compared to 6.7 in Q4 24 as we focused efforts on profitable accounts and territories.

The net loss after tax of \$29.9 million was steady on FY 24 (down 1.4%), reflecting the benefits of the cash conservation initiatives. Costs were higher in 2H 25 led by the increased investment in clinical research, the costs associated with the commercialization of Triage Plus and an increase in legal fees as we challenged the LCD.

Cash and cash equivalents and short-term deposits stood at \$22.6 million at the end of March 2025, down from \$35.9 million at the end of September 2024. The 2H 25 cash burn of \$13.4 million was lower than the \$14.3 million in 1H 25, but after considering the higher cash spend related to payments that cover a 12-month period, the underlying cash burn was steady as operating cash conservation initiatives continued to deliver.

## STRATEGIC PROGRESS

Pacific Edge has taken steps to mitigate the uncertainty linked to L39365 by focusing commercial operations on profitable territories, non-Medicare revenue streams and selling the clinical and economic value of Cxbladder. This has delivered tangible improvements in the performance metrics we track for sales force efficiency and customer stickiness.

With L39365 becoming effective on 24 April 2025 – despite Pacific Edge undertaking vigorous political advocacy efforts and pursuing potential legal avenues – we have two paths forward.

The first is the definitive path to change the non-coverage determination to a coverage determination by submitting a reconsideration request to Novitas with the evidence that has previously not been reviewed.

We submitted a reconsideration request for Cxbladder Triage in March 2025, based on evidence not considered in the LCD, including the groundbreaking STRATA<sup>6</sup> study and the AUA microhematuria guideline. We lodged a reconsideration request for Cxbladder Monitor in May 2025 supported by two new real-world studies out of Australia.

The second is to appeal claim denials through the Medicare Appeals Process providing the AUA guideline as evidence to an Administrative Law Judge to reverse the claim denial. Our

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<sup>6</sup> 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.

success is not guaranteed, but guideline inclusion has typically been viewed as more than sufficient to meet the standard of medically reasonable and necessary.

The AUA microhematuria guideline provides Pacific Edge with a number of options to build momentum despite the non-coverage determination on L39365. We expect to continue to receive reimbursement from contracted commercial US payers without interruption, notably Kaiser Permanente, the US Veterans Administration, Blue Cross Blue Shield plans under a group purchasing agreement and from non-contracted private payers.

Similarly, we expect to improve collections from non-contracted private payers through two initiatives. The first is to appeal denied claims to “external review”, using the AUA microhematuria guideline as evidence to reverse the initial claim denial. The second is to establish ‘client billing’ relationships with hospitals and large urology group practices that are committed to Cxbladder Triage and agree to seek reimbursement from the commercial payers rather than Pacific Edge. For commercial claims that ultimately result in a denial, we intend to continue our enhanced patient responsibility and patient assistance programs to drive some payment from patients for our test.

Beyond the challenges of the new operating environment and these new initiatives, our clinical evidence program will continue to generate published evidence for further reconsideration requests or to embed them in guidelines. Importantly, our DRIVE Study and STRATA Concordance Study<sup>7</sup> are on track for publication later this year. The publication from the DRIVE study is expected to be sufficient to establish coverage of Triage Plus and the STRATA Concordance Study will confirm the clinical utility of Triage Plus in the microhematuria patient population.

Recognising that no new evidence has been published that can be submitted for reconsideration of Cxbladder Detect, we have decided to discontinue the test in the US. Users are being migrated to Triage, accelerating a plan previously intended to coincide with the commercial launch of Triage Plus.

In New Zealand – our largest market outside of the US – we are seeking to further entrench Cxbladder with a national pathway for hematuria evaluation. The moves to extend our global reach and diversify our revenue with distribution agreements in Israel, Latin America and Southeast Asia continue to offer promise, delivering still small but steadily growing test volumes from these markets. We are targeting the development of a kit-based IVD to accelerate momentum in these markets and other markets globally.

Finally, we have continued to invest in the digitalization initiatives that will further drive the adoption of our tests and improve the experience for clinicians and patients. We are seeing evidence that these initiatives are embedding Cxbladder in clinical practice, with tests ordered and resulted through our digital integrations being less impacted by the adverse LCD.

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<sup>7</sup> The concordance study seeks to demonstrate the clinical utility of the test by comparison of Triage Plus to Triage.

## OUTLOOK

In the short-term Pacific Edge expects to see a reduction in US test volumes reflecting the impact of L39365. However, in the medium to long-term we see a resumption of growth as we increasingly change physician behavior off the back of guidelines inclusion.

“The AUA microhematuria guideline, the positive Triage Plus price, and the efficiency and operational improvements we have driven over the last two years position Pacific Edge to accelerate the company on the path to profitability after re-establishing Medicare coverage,” Dr Meintjes said.

“The capital raising we have announced today will assist our commercialization efforts in the US, our digitalization initiatives that improve the customer experience, our clinical evidence generation, and our innovation in R&D to bring Cxbladder to more physicians and more patients globally,” Dr Meintjes said.

“We look forward to updating investors on our progress.”

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

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## OVERVIEW

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

Cxbladder is a suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with microhematuria and those being monitored for recurrent disease. The tests help improve the overall patient experience, while prioritizing time and clinical resources to optimize practice workflow and improve efficiency.

Supported by over 20 years of research, Cxbladder’s evidence portfolio extends to more than 25 peer reviewed publications, and Cxbladder Triage is now included in the American Urological Association’s Microhematuria Guideline. To drive increased adoption and improved

patient health outcomes, Cxbladder is the focal point of numerous ongoing and planned studies designed to generate further clinical utility evidence.

Cxbladder is available in the US, Australasia, and Israel and in markets throughout Asia and South America. In the US, the test has been used by over 5,000 urologists who have ordered more than 130,000 tests. In New Zealand, Cxbladder is accessible to around 70% of the population via public healthcare and all residents have the option of buying the test online.