

23 November 2023



UNAUDITED FINANCIAL RESULTS FOR THE HALF YEAR TO 30 SEPTEMBER 2023

## STRONG RISE IN REVENUE DESPITE MEDICARE UNCERTAINTY

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

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

### STRATEGIC HIGHLIGHTS

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

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

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

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

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

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

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

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

## STRATEGY REFINEMENT

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

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

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

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

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

## OUTLOOK

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

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

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

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

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

## CONFERENCE CALL

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

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

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

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## OVERVIEW

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

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

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

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