

# Pacific Edge Limited (ASX: PEB): Delivered Strong Growth In Revenue Despite Medicare Uncertainty

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Reading Time: 5 Mins

By Team Ace Investors

Stock Code	ASX: PEB
Shares O/S	810.72 million
Closing Price	AUD 0.082
Market Cap	66.47 million
52 W H/L	0.490/0.076
One Year Stock Performance	-80.72%
Avg. Volume	0.055 million
EPS(TTM)	-0.039
P/E	-
Annual Dividend Yield	0.00%
Franking	-
Last Dividend Ex-Date	-
Last Dividend Pay Date	-
DPS (AUD)	-
ROE (%)	-37.87%

(Source: ASX)

## Company Overview

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. The company provides its suite of Cxbladder tests globally through its wholly-owned, and CLIA-certified, laboratories in New Zealand and the USA. Cxbladder is a urine-based genomic biomarker test optimized for the detection and surveillance of bladder cancer. 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.

## **Investment Rationale**

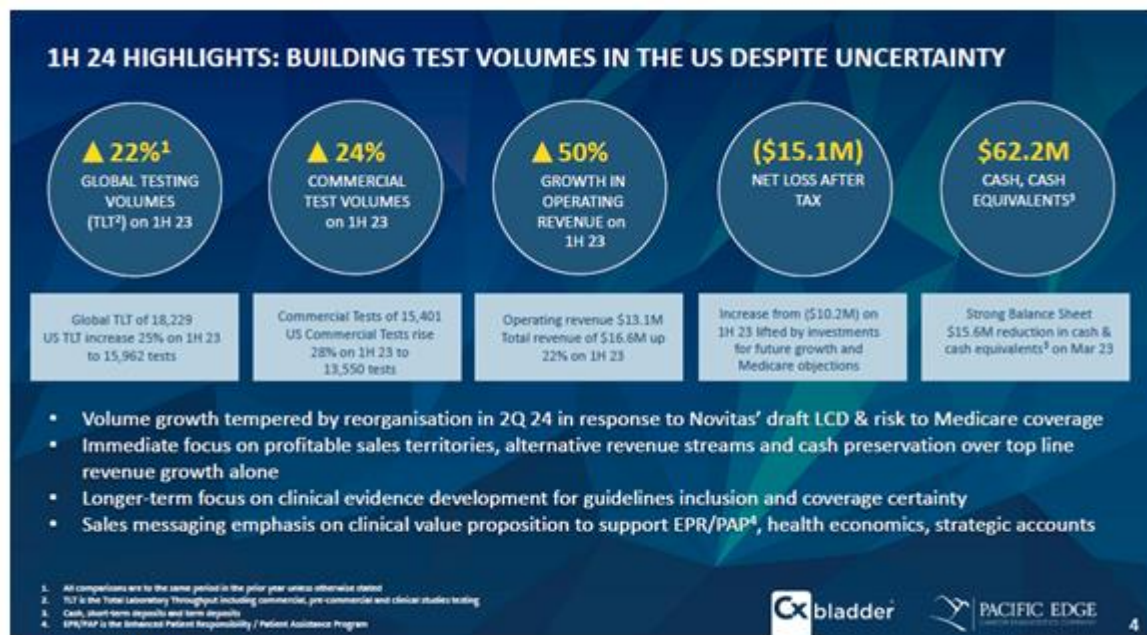
### **Announced the integration of Cxbladder tests with Kaiser Permanente EMR**

On 15 Nov 2023, PEB announced that the integration of Cxbladder tests within the Electronic Medical Records (EMR) system of Kaiser Permanente. Kaiser Permanente is the largest integrated healthcare provider in the US, serving 12.6 million members, which equates to approximately 3.7% of the population. Kaiser Permanente's Southern California region is the largest region by membership and manages the care for approximately 37% of all patients managed by the health plan. In aggregate Kaiser Permanente SoCal's urology team conducts ~25,000 cystoscopies each year across the relevant hematuria evaluation and bladder cancer surveillance clinical pathways. The integration of Cxbladder into these pathways, according to a Kaiser Permanente study, could allow the organization to safely avoid more than 70% of these examinations, saving money and sparing patients from the risks and discomfort of the invasive procedure. The integration, which has gone live within all 15 urology medical centers of the Southern California Permanente Medical Group (Kaiser Permanente SoCal), is a significant improvement to patient access for Cxbladder with sample collection at Kaiser facilities and offers electronic management of test ordering.

### **Delivered strong growth in revenue despite Medicare uncertainty**

For the half year ended on 30 June 2023(1H FY24), PEB delivered a 50% YoY growth in Operating revenue to \$13.1 million and a 22% YoY growth in total revenue to \$16.6 million, driven by a 28% increase in commercial Cxbladder test volumes in the US market. Cxbladder testing volumes continued their growth trajectory despite uncertainty over continued Medicare coverage. On 7<sup>th</sup> June, PEB announced that Medicare coverage of Cxbladder tests in the US market will cease from 17<sup>th</sup> July following the finalization of a Local Coverage Determination (LCD) (L39365) by Novitas, the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge's laboratory in Hershey Pennsylvania. Pacific Edge is currently unable to fully determine the impact of the new LCD on test volumes in the US market for FY24. The company believes that in the short term, it is prudent to continue to support Cxbladder as it determines the best path forward, but the approach will be accompanied by cost containment initiatives including, but not limited to an immediate hiring freeze and a halt on discretionary spending and new capital expenditure. For the half year that ended on 30 June'2023, the company recorded a 22% increase in total laboratory throughput (TLT) of Cxbladder tests to 18,229 tests, including 15,401 commercial tests, and 1,147 clinicians in the US. The company continued to grow test volumes and revenue through the first half of FY24 amid the ongoing uncertainty over Medicare coverage of Cxbladder. 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. The company also restructured the commercial organization to focus on profitable sales

territories, alternative revenue streams, and cash preservation over top-line revenue growth alone. The company reported a net loss of \$15.1 million in 1H23 versus \$10.2 million in the PCP and closed the half-year with cash and cash equivalents of \$62.2 million.



(Source: Company reports)

### Pacific Edge refined its strategy to prioritize profitable sales territories, alternative revenue streams

Pacific Edge has refined its sales strategy to prioritize profitable sales territories, alternative revenue streams, and cash preservation over top-line revenue growth alone. The company 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, increased 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 endpoints, and sample sizes that are sufficient for guidelines inclusion and coverage. Key highlights-

- The company's 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 for guideline inclusion and increased coverage certainty.
- 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 expects these changes to allow a resumption of growth for the remainder of the financial year, assuming no change to its Medicare coverage status.
- 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 optimized to reduce technician time, and turnaround time and lower the cost of goods sold.



(Source: Company reports)

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 its status as covered by Medicare will be a catalyst for PEB's US commercial operations, supported by a sales force that is now firmly focused on the Cxbladder proposition. Meanwhile, and irrespective of the Medicare outcome, PEB continues to expect an increase in volume from Kaiser Permanente, ex-US business serviced from its US laboratory, and APAC business serviced from its New Zealand laboratory. The company is 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 its distribution agreements and growth markets in Australia, Latin America, Israel, and Southeast Asia.

#### ACE's Recommendation:

Pacific Edge (NZX/ ASX: PEB) has refined its sales strategy to prioritize profitable sales territories, alternative revenue streams, and cash preservation over top-line revenue growth alone. The company 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. It has reconfigured its evidence-generation program within a structured framework for Analytical Validity (AV), Clinical Validity (CV), and Clinical Utility (CU). The company's medical team is developing a protocol for a new randomized clinical trial called CREDIBLE which is expected to generate the clinical utility evidence for Cxbladder Detect for guideline inclusion and increased coverage certainty. Pacific Edge is also continuing its investment in digital systems that enhance the customer experience. Cxbladder testing volumes continued their growth trajectory despite uncertainty over continued Medicare coverage. For 1H24, PEB delivered a 50% YoY growth in Operating revenue to \$13.1 million and a 22% YoY growth in total revenue to \$16.6 million, driven by a 28% increase in commercial Cxbladder test volumes in the US market. The

company continued to grow test volumes and revenue through the first half of FY24 amid the ongoing uncertainty over Medicare coverage of Cxbladder. 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 expected to support test volumes in 2H 24. We believe that the increasing Cxbladder testing volumes and refined strategy to prioritize profitable sales territories are expected to drive growth going forward. The stock closed the day near its 52-week low at A\$ 0.082/share today and presents an investment opportunity from a long-term view. So, we would like to recommend a **SPECULATIVE BUY** rating on the stock.

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