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

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[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.

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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.