

21 May 2024



AUDITED FINANCIAL RESULTS FOR THE YEAR TO 31 MARCH 2024

CASH BURN SLOWS; COVERAGE CATALYSTS IN FOCUS

FINANCIAL AND PERFORMANCE HIGHLIGHTS¹

- Operating revenue increases 22% to \$23.9 million; total revenue increases 12% to \$29.3 million lifted by a 2% rise in commercial Cxbladder test volumes in the US market and increased collections.
- Average US Sales Price (ASP)² per test increased 18% from US\$519 in 2H 23 to US\$613 in 2H 24 following improvements in cash collection and increased volumes from our major private payer Kaiser Permanente.
- Total laboratory throughput³ (TLT) of Cxbladder tests increases 3% to 32,633 tests, commercial tests increased 2% to 27,347 with the rate of growth slowing in 2H 24 as the sales team was reduced and further attrition of the team was not backfilled to preserve capital.
- Cash burn reduced in 2H 24 to \$11.9 million, down 24% on 1H 24 following reorganization; use of capital tightly focused on long-term strategic imperatives. Net loss after tax increases to \$29.5 million from \$27.0 million.
- End of period cash and cash equivalents of \$50.3 million down from \$62.2 million in September 2023; a runway expected to be sufficient to support the company through to regaining coverage in the event of a Medicare non-coverage determination.

STRATEGIC HIGHLIGHTS

- Refocused our operations on clinical development for Detect⁺ and Monitor⁺ for guidelines inclusion and coverage certainty.
- STRATA⁴ published in the Journal of Urology on May 3, 2024, 9 months ahead of prior target; the study provides the strongest evidence yet for the inclusion of Cxbladder in guidelines and featured prominently at the American Urological Association (AUA) annual conference.
- Restructured our commercial operations on profitable territories and non-Medicare revenue streams; sales messaging focused on clinical and economic value of Cxbladder.
- Achieved strong improvements in commercial team performance: sales force efficiency (total tests/average FTE) rises 59% from Q4 23 to Q4 24; and the team is now operating at breakeven.
- Awaiting a finalization of the draft 'Genetic testing for oncology' (DL39365) Medicare Local Coverage Determination; Pacific Edge is prepared for all outcomes.

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

² ASP is US Operating Revenue in USD/US Commercial Test Volumes

³ Total Laboratory Throughput includes commercial, pre-commercial and clinical studies testing.

⁴ STRATA means the Safe Testing of Risk for Asymptomatic Microhematuria study undertaken by Pacific Edge

DUNEDIN, New Zealand – Pacific Edge (NZX, ASX: PEB) today reports successful execution of strategic initiatives to focus the company on the development of its advanced cancer diagnostic tests for inclusion in clinical guidelines and gaining coverage certainty from Medicare and other healthcare payers.

Operating revenue increased 22% to \$23.9 million from \$19.6 million in FY 23, slowed by the underlying reduction in commercial test volume in 2H 24. Total laboratory throughput (TLT) growth slowed in the second half of the year. This followed the reduction of the sales team in Q2 24 to drive efficiency and preserve capital as the company waits for the finalization of the draft 'Genetic testing for oncology' (DL 39365) Medicare coverage determination. TLT increased 3% to 32,633 tests from 31,565 in FY 23 while commercial test volumes increased 2% to 27,347 tests from 26,691 in FY 23.

Operating revenue was also supported by an 18% improvement in the US average sales price (ASP; average US dollar revenue/commercial tests) from US\$519 in 2H 23 to US\$613 in 2H 24. This result followed from improvements in collection processes (see below), an increase in volume of tests from our major US customer Kaiser Permanente and Medicare coverage of Triage since January 2023. Total revenue, which includes interest income on cash reserves, government grants and foreign exchange movements, increased 12% to \$29.3 million from \$26.1 million in the same period a year ago. The net loss for the year of \$29.5 million was wider than the \$27.0 million in the prior year as the company continued to invest in long-term growth initiatives and incurred one-off restructuring costs.

Cash burn fell sharply in 2H 24 to \$11.9 million, down 24% on 1H 24 following the reorganization. Pacific Edge ended the period with cash, cash equivalents and short-term deposits of \$50.3 million down from \$62.2 million in September 2023.

Chairman Chris Gallaher said: "The Board is pleased with the progress Peter and his team have made as we work towards gaining certainty on Medicare coverage of our tests. They have acted swiftly regarding the need to preserve capital through uncertainty and retained their focus on the strategic imperatives in clinical evidence generation that will underpin our future success and prepare the company for all outcomes.

"As announced in March, I will be stepping down as the Chairman of Pacific Edge at the end of the year. The Board is working through the Nominations Committee to identify my successor who will lead the Company into the next phase of its development."

Chief Executive Dr Peter Meintjes said: "I remain confident in our ability to navigate the challenges we've faced regarding coverage and the normal hurdles faced by fast-growing companies. We are a more efficient organization and will continue to execute on the strategies that justify confidence in our long-term prospects."

STRATEGIC PROGRESS

Pacific Edge has refocused on the clinical development of our new Detect⁺ and Monitor⁺ tests for guidelines inclusion and coverage certainty, no matter the outcome of the impending

Medicare local coverage determination. We are delighted to report that this strategy is already delivering on its goals.

Our sales strategy prioritizes profitable sales territories, non-Medicare revenue streams and cash preservation over top line revenue growth alone. We have aligned our sales messaging to embed the clinical value of Cxbladder to the physician and patient, and its economic value to health systems and payers.

The shift in focus has delivered improvements in the US commercial team's performance: sales force efficiency (total tests/average FTE) has risen 59% from 239 in Q4 23 to 381 in Q4 24. The sales team is now operating at breakeven.

US clinical commitment to Cxbladder is steady at 6.7 tests per unique ordering clinician although the number of ordering clinicians has fallen. This result reflects the reduced reach of our team but demonstrates the improvement in clinical mix in favor of clinicians that understand the clinical utility of our tests.

Improved US collection processes have delivered what we believe will be an enduring lift in ASP from US\$519 in 2H 23 to US\$613 in 2H 24. These processes include initiatives to ensure patients with non-contracted private payers take responsibility for test payments (a program that will be rolled out to Medicare patients in the event of a non-coverage determination). The ASP has also been supported by ongoing initiatives to digitalize Cxbladder information flows that improve test ordering, resulting in improved payment collection.

More broadly we have diversified our revenue streams reaching out to new growth territories in Asia, the Middle East, Latin America and Australia that over the longer term can be developed to deliver meaningful demand for Cxbladder. In the last year this has seen the appointment of six distributors of our tests.

We have continued to advance the commercialization of Detect⁺, the first of our tests to be brought to market deploying performance enhancing DNA biomarkers. The test's CPT⁴ code became effective at the start of this calendar year and our attention is now focused on Medicare pricing of the test. This price will set a benchmark price for all other US healthcare payers.

If we are successful in our goal to have the test priced via the Centers for Medicare & Medicaid Services (CMS) 'Crosswalk' process, we see the potential for a higher price and higher margin than our existing tests, a result that would strengthen the underlying economics of the direct sales team and the company.

Our clinical evidence generation program is operating within a structured framework for Analytical Validity (AV), Clinical Validity (CV) and Clinical Utility (CU), the endpoints required for coverage decisions and guideline inclusion.

⁴ A CPT (Current Procedural Terminology) code is a medical code used to describe medical, surgical, and diagnostic services and procedures in the US healthcare system.

Our STRATA study achieved the significant milestone of publication in the Journal of Urology in May, nine months ahead of schedule. The study headlined at the American Urological Association (AUA) annual conference, the world's largest urological meeting, and provides the strongest evidence yet for the inclusion of Cxbladder in guidelines for hematuria evaluation. Specifically, it demonstrated Cxbladder can safely and more effectively risk-stratify low risk hematuria patients when compared to AUA guidelines, thereby reducing the number of unnecessary invasive cystoscopies.

Over the next two years the publication of results from our DRIVE and microDRIVE studies are expected to provide new CV evidence for Triage and Detect⁺, while a separate study will demonstrate the Analytical Validity of all our current generation of tests under a new protocol that automates the RNA extraction. All publications offer new opportunities for guideline inclusion and, in the event of a non-coverage determination, an opportunity to seek reconsideration of coverage.

Finally, the company's research and development efforts have been orientated toward the launch of Detect⁺ and Monitor⁺. Simultaneously, we have focused on our Cxbladder simplification projects that aim to reduce technician operator times, reduce sample turnaround times and lower the cost of goods. These changes simplify the workflow for a potential kit-based product distribution and decentralized deployment as an IVD in international markets.

GOVERNANCE

Pacific Edge has continued to evolve its governance framework. A key focus is now on the succession plans for Mr Gallaher and Independent Director Mark Green, who both notified Pacific Edge of their intention to retire later this year. The Board's Nomination Committee has begun a process to recruit new Directors.

Meanwhile, in our Annual Report to be published in late June we will release our first Climate Related Disclosure report in compliance with the new Aotearoa New Zealand Climate Standards. We will also detail the changes we have made to deliver on the environmental, social and governance expectations of our stakeholders.

OUTLOOK

Dr Meintjes said the finalization of the Medicare coverage determination remains the biggest determinant of the company's prospects for the immediate future, with a decision due by 26 July 2024⁵.

"A non-coverage determination is likely to impact US volumes, but we are well prepared with plans to regain coverage and, should coverage be affirmed, rebuild the momentum in the clinical adoption of Cxbladder in the US and around the world.

"In the event of a non-coverage determination, these strategies include a potential legal challenge to the determination; Medicare patients assuming responsibility for the payment of

⁵ US time (27 July New Zealand time)

Cxbladder tests; and the continued advancement of our clinical evidence program, which will give us multiple opportunities to seek a Medicare coverage reconsideration,” Dr Meintjes said.

“Meanwhile, we see several catalysts to the company accelerating the adoption of Cxbladder and driving improvements in shareholder value. In addition to a positive Medicare determination, these include the favorable pricing of Detect+ and then the launch of the test, targeted for early 2025. The publication of new clinical evidence, meanwhile, offers new opportunities for the inclusion of our tests in clinical guidelines.

“We remain confident of our prospects in both the short and long-term and look forward to updating you on our progress in the coming months,” 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/pebfy24 or by phone on the following toll-free numbers:

- **New Zealand:** 0800 005 652
- **Australia:** 1800 953 093
- **USA & Canada:** 888 672-2415

Conference ID: 7745991

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

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OVERVIEW

Pacific Edge: 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

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 twenty 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.