

FINANCIAL RESULTS FOR THE HALF YEAR TO 30 SEPTEMBER 2022

PACIFIC EDGE INVESTMENT FOR GROWTH DELIVERS EARLY RESULTS

HIGHLIGHTS

- Operating revenue from test sales increases 62% to \$8.7 million when compared to the same period of the prior year (1H22); total revenue increases 102% to \$13.6 million when compared with 1H22, with increases from commercial test volume growth boosted by foreign exchange gains
- Total laboratory throughput rises 34% to 14,917 in line with analyst expectations, lifted by a 35% increase in commercial test volumes to 12,422, with growth led by the US market
- Investments driving Cxbladder adoption and lifting US clinician engagement; staff numbers increase from 86 at the end of March 2022 to 100 full-time-equivalents (FTE) at 30 September 2022
- Kaiser Permanente using Cxbladder Triage at 11 sites, two of which are in the Top 20 sites by volume during 1H23
- Net losses after tax increased to \$10.6 million, from \$9.0 million in 1H22 as Pacific Edge continues to invest for growth
- Cash, cash equivalents and short-term deposits of \$93.5 million as at 30 September 2022, down from \$105.4 million at 31 March 2022, provides strong foundation for continued investment
- Optimistic outlook tempered by proposed LCD from Novitas and the potential to affect Medicare reimbursement.

DUNEDIN, New Zealand – Pacific Edge (NZX, ASX PEB), today announces strong growth in revenue for the half year to the end of September 2022 as new growth investments begin to accelerate the adoption of Cxbladder, the company's suite of advanced genomic bladder cancer diagnostic tests.

Total operating revenue, the income generated from Cxbladder test sales, increased 62% to \$8.7 million from \$5.4 million in 1H22. Revenue growth resulted from a 35% increase in commercial tests to 12,422 from 9,192 tests in 1H22, and the sharp weakening New Zealand dollar against the US dollar. As reported in Pacific Edge's October quarterly shareholder update, total test volumes rose to 14,917, a 34% increase on the 11,136 tests processed in 1H22.

Total revenue, which includes government grants and other income, increased 102% to \$13.6 million from \$6.7 million in the same period of the prior year, assisted by a \$3.0 million foreign exchange gain on the mark to market of USD cash balances and increased interest income accruing on cash balances.

The half year net loss after tax increased to \$10.6 million, from \$9.0 million in 1H22, as Pacific Edge accelerated its investment to drive the adoption of tests. Net operating expenses increased to \$24.2 million from \$15.7 million as the company invested for growth particularly in the US market. Expenses were also lifted by \$1.7m due to the translation impact of a weaker New Zealand dollar.

Cash, cash equivalents and short-term deposits at 30 September 2022 were \$93.5 million compared to \$105.4 million at 31 March 2022 following a net cash outflow of \$12.0 million over the six months to the end of September 2022.

Pacific Edge Chairman Chris Gallaher said, “Over the last six months Pacific Edge has carefully invested in line with the program we outlined in May to drive the adoption of our tests around the world.

“We are starting to see the benefits of this program, particularly in the US market. Awareness of the role Cxbladder can play in the diagnosis and management of bladder cancer is growing and we are seeing early signs of an acceleration in the adoption of our tests by clinicians and healthcare providers.

“These successes have been tempered by the uncertainty over the continued reimbursement of our tests by the US Centers for Medicare & Medicaid Services (CMS), from which the company receives most of its US revenues.

“We are working to resolve this uncertainty, which followed the July release of a proposed Local Coverage Determination (LCD)¹ by Novitas, the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge’s US laboratory.

“Notwithstanding this possibility, given our technological leadership and the growing awareness for how Cxbladder improves clinical practice, we remain confident that our tests will, over the longer term, be integrated into global standards of bladder cancer care including those used by the key US market. Our company is well funded and remains well placed to deliver on these growth ambitions.”

STRATEGIC PROGRESS

Pacific Edge Chief Executive Dr Peter Meintjes said the company had made good progress on its strategic objectives.

“We have introduced new capability and energy into the business with the establishment of our new Medical Affairs and Virtual Sales teams and the recruitment of new account executives, marketing personnel and a VP of Market Access. Our global team has risen to 100 FTEs at the end of September from 86 at the end of March.

“These investments are aligned with the strategies for value creation that we outlined in May. As expected, they have resulted in an increase in cash outflow and a larger loss for the half year period as we continue to build capability and capacity that will underpin the next phase of success for Pacific Edge.

“As we look towards the long-term, the proposed LCD from Novitas has been factored into the phasing of our investment program. At present, we continue to be reimbursed by Medicare for our tests and have not seen any reduction in demand for Cxbladder since the release of the proposed LCD. Pacific Edge

¹ LCDs are decisions made by a Medicare Administrative Contractor (MAC) whether to cover a particular item or service in a MAC’s jurisdiction (region) in accordance with section 1862(a)(1)(A) of the US Social Security Act.

maintains that in the absence of any adverse reporting event on the performance of Cxbladder, it would be unprecedented to lose CMS coverage.

“We therefore continue to invest prudently and do so with clear targets for the adoption of our tests and operating revenue. We remain confident that these investments set the company up to capitalize on the significant opportunities the company enjoys in both in the US and further afield,” Dr Meintjes said.

The new Medical Affairs team is at the heart of our strategy to use the expanding body of clinical evidence that supports the validity and utility of Cxbladder to influence healthcare providers’ and payers' to adopt and cover of our tests while working to have Cxbladder accepted into global standards of care.

The Medical Affairs and Marketing teams have expanded our Key Opinion Leader (KOL) engagement program and placed clinical evidence generation at the core of how we engage with KOLs,” Dr Meintjes said. At the upcoming Society for Urologic Oncology (SUO) meeting in late 2022, Pacific Edge will run its first in-person Principle Investigator Meeting for STRATA, hold its first Clinical Advisory Board Meeting and will sponsor a Symposium Session titled: Real life impact of Cxbladder tests on the diagnosis and surveillance of bladder cancer moderated by VP of Medical Affairs, Dr. Tamer Aboushareb featuring presentations from the following KOLs:

- Dr. Sia Daneshmand: Overview, bladder biomarkers
- Dr. Sima Porten: Use of Cxbladder in-home sampling during COVID
- Dr. John Stafkianos: Cxbladder CU and real-life value in practice

REGIONAL PERFORMANCE

USA

The US business has made strong progress. For the six-month period, US test volumes were up 42% on the same period a year ago to 12,769, while commercial tests increased 42% to 10,622 from 7,476 in the same period of the prior year. The number of clinicians ordering our tests has meanwhile increased to 979 in the second quarter of FY23, a 42% increase on the 689 ordering clinicians at the same time a year ago and 10% ahead of the 894 ordering clinicians for the quarter ending June 2022.

The company is pleased with the progress it is making with Kaiser Permanente. During 1H FY23, Cxbladder tests were ordered from 11 of the 30 Kaiser Permanente Urology Centers in Southern California (SoCal), and of these clinics, two now count among our top 20 accounts.

From an operations standpoint, we have made meaningful progress implementing Cxbladder ordering and resulting from within Kaiser’s Electronic Medical Records (EMR) system, a move that is expected to accelerate Kaiser’s adoption of Cxbladder when the project is completed in the coming months. In support of this initiative, Kaiser has a dedicated project team with whom Pacific Edge meets weekly. This helps to provide good visibility into the organization.

We also continue to advance our strategy for the US Veterans Affairs (VA), the second largest integrated healthcare provider in the US. Our goal is to develop clinical evidence for medical policy within the VA

system with the DRIVE clinical study and to transition early adopting PIs from evaluation and clinical trials to broader adoption across the more than nine million veterans it covers.

ASIA PACIFIC

In the Asia Pacific, where test numbers are dominated by the relatively mature New Zealand market, total laboratory throughput volumes were flat versus the same period a year ago at 2,148 tests. Commercial test volumes increased 5% to 1,800 tests.

To increase test adoption, we continue to advocate for Cxbladder to be deployed in the New Zealand primary care setting. Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral and Te Whatu Ora Whanganui are the latest New Zealand regional public healthcare providers to adopt Cxbladder in primary care.

Pacific Edge believes Cxbladder represents a compelling case for the newly-established Te Whatu Ora – Health New Zealand and Te Aka Whai Ora, the new Māori Health Authority, as they seek to improve access to healthcare for all New Zealanders. There is clear evidence² from within the New Zealand healthcare system that the deployment of Cxbladder in primary care allows clinicians to reliably and safely identify patients that can be assessed in primary care with fewer referrals to secondary care and fewer invasive procedures.

Finally, the company has also taken further steps into new markets such as Australia and Singapore. We have seen a small number of tests beginning to flow out of Australia, while the company has recruited a new business development manager for Southeast Asia, based in Singapore.

OUTLOOK

Dr Meintjes said Pacific Edge is looking towards the final four months of the financial year with cautious optimism. The primary uncertainty is the range of potential outcomes from the proposed Novitas LCD.

“Our focus for the moment is continuing to cautiously execute on our strategy until we have certainty of continued CMS reimbursement. And while the loss of coverage would likely require a slowing in our intended hiring plan, we have identified a clear path to re-establish CMS coverage. In short, we remain confident, over time, of our success in the world’s largest healthcare market.

“Pacific Edge has a strong balance sheet and world leading technology for the evaluation of hematuria and the diagnosis and management of bladder cancer. Our Cxbladder tests are gaining traction in the US market and further afield while the evidence supporting their adoption continues to grow.

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

² Davidson P, McGeoch G, Shand B. Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. NZ Med J 2020. 133:1527

Company Announcement
24 November 2022



For more information:

Investors

Dr Peter Meintjes
Chief Executive
Pacific Edge
P: +6422 032 1263

Media

Richard Inder
The Project
P: +64 21 645 643

OVERVIEW www.pacificedgex.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.

About Cxbladder: www.cxbladder.com

Cxbladder is a non-invasive genomic urine test optimized for the detection and management 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 is reimbursed by CMS and has been trusted by over 2,000 US urologists in the diagnosis and management of more than 80,000 patients, including the option for in-home sample collection. In New Zealand, Cxbladder is accessible to 70% of the population via public healthcare and all residents have the option of buying the test online.