

AUDITED FINANCIAL RESULTS FOR THE YEAR TO 31 MARCH 2022

PACIFIC EDGE SEES GROWTH INITIATIVES GAINING TRACTION

HIGHLIGHTS:

- Annual operating revenue increased 49% to \$11.4 million, while total revenue increased 33% to \$13.9 million
- Total laboratory throughput (TLT) of Cxbladder tests increased 46% to 23,086 tests, while commercial tests (CT) increased 48% to 19,196 tests
- COVID-19 healthcare restrictions constrained growth. The easing of those restrictions and new hires drove increases in TLT and clinician engagement in the final months of the financial year
- Net losses after tax increase to \$19.8 million from \$14.2 million, reflecting a 37% increase in operating expenses to \$33.7 million as the company invested to drive growth
- Initiatives of the Investment Program to drive customer retention, growth, and clinical evidence generation relevant to guideline inclusion announced
- The initiatives of the Investment Program in FY23 will be phased in proportion to business milestones to responsibly manage burn rate
- Pacific Edge is well funded with cash and cash equivalents and short-term deposits at \$105.4 million at the end of the financial year, following the successful \$103.5 million capital raise and dual listing on the ASX in 2021

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today announces financial and operational results for the year to 31 March 2022 showing strong growth in the adoption of its advanced genomic biomarker Cxbladder tests and early results suggesting initial traction can be translated into faster growth.

It also announces new initiatives to drive the adoption of Cxbladder around the world. These include increased investment in sales, marketing, innovation, and clinical evidence generation to advance the case for the incorporation Cxbladder into globally relevant standards of care.

TEST VOLUMES

Total laboratory throughput (TLT) of Cxbladder for the year to 31 March 2022 rose 46% to 23,086 tests from 15,814 tests in the prior financial year. Commercial test volumes increased 48% to 19,196, with the increase reflecting the growing adoption of Cxbladder by physicians and healthcare organizations. These results follow from the important milestones of obtain Medicare coverage and reimbursement from Kaiser Permanente in 2020.

Pacific Edge Chief Executive Dr Peter Meintjes said: "In spite of the pandemic, the strong year-on-year growth in Cxbladder test volumes demonstrates the value of Cxbladder to safely intensify or de-intensify clinical workup for patients presenting with hematuria, resolve diagnostic dilemmas during hematuria evaluation and monitor for the recurrence of urothelial cancer in post-treatment patients.



"Still, the last six months have been challenging. Restrictions in the healthcare sector have been more severe and longer lasting than those imposed on the community at large, and this has limited engagement with physicians ordering the tests and the organizations paying for them. It has also prevented patients from engaging with their clinicians.

"With the easing of COVID-19 restrictions, the virus becoming endemic in our target markets, and recent sales and marketing recruits beginning to hit their stride, we are seeing volumes begin to accelerate.

"Average weekly test throughput in the US from the start of April to last week were 455 tests per week, a figure 25% higher than the average of the last year. These objective indicators, and the subjective positive feedback from those regularly using Cxbladder, demonstrate that clinicians are gaining increasing confidence in the use of Cxbladder earlier in the patient care pathway.

"They also show that Pacific Edge has an excellent opportunity to capitalize on existing traction in a very large target market. The challenge before us is one of focus and execution to convert this enthusiasm and momentum to greater recurring use of Cxbladder."

FINANCIAL RESULTS

Total operating revenue - the income generated from Cxbladder test sales - increased 49% to \$11.4 million from \$7.7 million over the same period last year. Total Income of \$13.9m, an increase of 33% included higher levels of research incentives and interest revenue, offset by a reduction of Covid-19 support of \$1.1 million.

Net loss after tax increased to \$19.8 million from \$14.2 million over the same period a year ago as Pacific Edge accelerated its investment to drive the adoption of tests. Net operating expenses increased to \$33.7 million from \$24.7 million in the prior year.

Net operating cash outflow increased to \$17.5 million from \$13.6 million in the same period a year ago. Pacific Edge remains well funded following the successful \$103.5 million capital raising in 2021. Cash, cash equivalents and short-term deposits stood at \$105.4 million up from \$23.1 million at the same time last year.

REGIONAL PERFORMANCE

The US business is making steady progress, despite COVID creating barriers for in-person selling opportunities – a key activity for growth and retention. Total Lab Throughput (TLT) for the year was up 59% to 18,864, while commercial tests increased 62% to 15,752.

Pacific Edge is working closely with Kaiser Permanente, the largest integrated healthcare provider in the US with an estimated 12.5 million members covered by the Kaiser Health Plan, to roll Cxbladder out across more sites and to educate more clinicians at each site in the use of Cxbladder. Kaiser Permanente urologists familiar with Cxbladder through the evaluation continue to advocate for broader adoption internally through an EMR integration with our support. In parallel with the EMR integration efforts, we continue to focus our adoption efforts in Southern California adding new sites and ordering clinicians from



those involved in the initial evaluation. The adoption of Cxbladder Triage (CxbT) at Kaiser Permanente enhances the case for its subsequent reimbursement by CMS.

Meanwhile we are working with the US Veterans Affairs (VA), the second largest integrated healthcare provider in the US, to move from evaluation of our tests to widespread use across the more than nine million veterans it covers. The completion of our DRIVE clinical study, which is examining the clinical utility of Cxbladder in risk stratifying patients presenting with hematuria, is an important step towards this goal.

INITIATIVES OF THE INVESTMENT PROGRAM

"Since joining the company in January, my thoughts have coalesced around initiatives in three major areas of the business that have the capacity to drive increases in long-term shareholder value," Dr Meintjes said.

"Firstly, we must continue to invest in technology and product innovation to maintain our leadership position in urothelial cancer diagnostics. This means improving the performance characteristics of existing products and expanding the context of use for Cxbladder to other segments of the patient care pathway.

"Secondly, we must augment that evidence through real world, real time clinical studies to establish Cxbladder as a standard of care with clinicians, healthcare providers and funders ahead of inclusion of the tests in globally relevant guidelines.

"And finally, having secured the support of these urological key opinion leaders, we must continue to build awareness of the Cxbladder brand, taking our story to the wider clinician community and the patient community.

"Today we are announcing initiatives that deliver on these priorities," Dr Meintjes said.

Research and innovation

"We continue to evaluate new product concepts and cutting-edge technologies to determine if they can be applied to the market and address an unmet clinical need. As we develop this technology, we will continue to build a patent portfolio that we can subsequently develop into validated products for commercialization. This may include other cancers, prognostics, or other non-cancer diseases where there is strong biomarker signal in the urine – an existing core competency at Pacific Edge.

"The program will be staged and linked to the achievement of growth milestones. While we expect many of these investments to quickly begin contributing to Pacific Edge's business, we expect the aggregate of these changes to drive long-term value creation and have greater contribution to revenue in the 2024 financial year and beyond," Dr Meintjes said.

Evidence coverage and guidelines

Pacific Edge is accelerating its clinical evidence generation program to drive the inclusion of Cxbladder in the American Urological Association (AUA), European Association of Urologists (EAU), and the National



Comprehensive Cancer Network (NCCN) guidelines. Simultaneously, Pacific Edge continues to drive adoption in the absence of guidelines by demonstrating the utility of Cxbladder to urologists and uro-oncologists through product evaluations, clinical studies partnerships, and the strength of our existing clinical evidence.

Specifically, we are targeting evidence that demonstrates the value of Cxbladder in diagnosing asymptomatic hematuria, in resolving diagnostic dilemmas (most commonly equivocal cystoscopy and atypical cytology), detecting tumors in the upper tract, and reducing the patient burden of unnecessary surveillance cystoscopies.

We want to ensure that Cxbladder is embedded from the earliest possible point and across the breadth of the patient care pathway. The advancement of the LOBSTER study, which targets evidence to support the inclusion of the test in the AUA standard of care announced to the NZX and ASX earlier this month, is evidence of the program in action.

To support our evidence generation program, we have recently hired a VP of Medical Affairs, Dr Tamer Aboushwareb, who will lead a team of 3-5 Medical Science Liaisons that will be technology and/or urology specialists with a medical background.

The expanded team will increase our capacity to engage key opinion leaders on clinical studies; facilitate faster and greater patient enrolment in studies; communicate our increasing body of clinical evidence to drive the early adoption of Cxbladder and build momentum towards guideline inclusion. The team will also work alongside our sales and marketing teams to assist with the adoption of Cxbladder by strategic accounts; and work with the Clinical Science team to drive the generation of clinical utility evidence.

Adoption, retention, and revenue generation

We have a multi-pronged strategy for executing effectively in the market.

We are increasing the size of our sales team by up to 10 full time equivalents (FTE) to a planned total of 40 in FY24, as we know this direct sales model works and a controlled expansion will be a good use of capital. Additionally, we have already deployed a Virtual Sales team to focus on rural clinicians and patients and support the prospecting and onboarding for new accounts. The final number is dependent on milestones during the course of the year. We are working with tenured Account Executives to lift performance in established territories.

We are supporting market execution with investments in ancillary services, including the integration of test ordering and resulting with healthcare providers' electronic medical records (EMR) systems, driving the adoption of patient in home sampling systems (PIHSS) and greater marketing investment and new Managed Care initiatives.

Managed Care is an important element of customer care related to billing, explanation of benefits and claims processing in the USA – it speaks strongly to the experience patients have when they engage with Pacific Edge. "We want to drive towards seamless daily operations for healthcare providers, clinicians,



and patients as they order tests or collection kits, dispatch samples to our lab, and receive results," Dr Meintjes said.

Finally, we also plan to hire two FTE Strategic Account Sales people, who will work with the Virtual Sales teams on service delivery at the largest healthcare providers and seek to onboard Cxbladder with new providers.

Pacific Edge is investing to build the Cxbladder brand through partnerships with patient advocacy groups such as the Bladder Cancer Advocacy Network in the US and New Zealand's Cancer Society. Pacific Edge intends these efforts to educate patients on their options, empower patients to request non-invasive alternatives to cystoscopy and ultimately contribute to revenue.

We are continuing to develop our plans in Australia and in Asian markets. The advancement of clinical study collaborations in Singapore and the impending publication of data on a Singaporean cohort represent an important step towards this latter goal.

OUTLOOK

Chairman Chris Gallaher said the Board was pleased with the progress Pacific Edge has made, especially when the results are considered against the backdrop of the difficult selling environment the company has faced for much of the financial year.

"With the easing of COVID restrictions, the Board is pleased to see the investments the company has made to accelerate its growth are beginning to deliver results. The support we are seeing for CxBladder has reinforced our confidence in the investment program made possible by last year's capital raising," Mr Gallaher said.

"We are also delighted to have been able to attract back to New Zealand our new Chief Executive Dr Peter Meintjes, who over the last few months has quickly begun to build on the strong legacy left by his predecessor David Darling.

"Peter has brought to the company a deep understanding of the diagnostics market, a clear vision of what is required to drive success and great enthusiasm for the role. He has quickly established himself within the business and is bringing the team along with him.

"On behalf of shareholders, we thank all of the Pacific Edge team for their efforts in what has been an extremely challenging period."

Finally, Mr Gallaher thanked Pacific Edge's Directors for their commitment to the company over the last year.

"With the appointment of the respected healthcare leader Tony Barclay to the Board in March, Pacific Edge now has the full complement of skills and experience to provide the necessary oversight and guidance as the company moves into its next phase of growth. It is an exciting time for the company," Mr Gallaher said.



Dr Meintjes said Pacific Edge expects its investment in innovation, evidence, people, and brand to drive growth in test volumes and revenue, but it will also lift operating costs in the business.

"Based on the activities in R&D, clinical studies, and market execution, I am excited about the prospect for the company. Pacific Edge continues to realize the opportunities I observed when I was evaluating the opportunity to lead the company," Dr Meintjes said.

"The company is focused on long-term shareholder value and is well positioned to deliver that over the coming years. The steps we have announced today represent a significant focus of resources to deliver on our potential. We look forward to further updating shareholders at our annual meeting in late July."

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

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OVERVIEW <u>www.pacificedge.co.nz</u> <u>www.pacificedgedx.com</u>

Pacific Edge Limited (NZX/ ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialisation 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.