Company Announcement
25 May 2022

AUDITED FINANCIAL RESULTS FOR THE YEAR TO 31 MARCH 2023

PACIFIC EDGE DELIVERS ON GROWTH STRATEGY IN FY 2023

FINANCIAL AND PERFORMANCE HIGHLIGHTS:

- Annual operating revenue increases 71% to $19.6 million; total revenue increases 88% to $26.1 million lifted by a 39% rise in commercial test volumes and favorable currency movements.
- Total laboratory throughput (TLT) of Cxbladder tests increases 37% to 31,565 tests, commercial tests increase 39% to 26,691 tests; US ordering clinicians grow 46% to 1,150 at the end of Q4 23
- Net loss after tax increases to $27.0 million from $19.8 million, reflecting a 58% increase in operating expenses to $53.1 million as the company invested to drive growth.
- Pacific Edge is well funded; cash and cash equivalents and short-term deposits at $77.8 million from $93.5 million at the end of September 2022 and $105.4 million at the end of March 2022

STRATEGIC HIGHLIGHTS:

- Diversified commercial roles, creating specialized sales roles and increasing headcount across commercial teams; updated sales process to meet the needs of different customer types; scaling largely complete for announced strategic initiatives
- Established medical education program; scientific and medical communications to support sales and marketing efforts; reconfigured the clinical evidence generation program within the analytical validity (AV), clinical validity (CV) and clinical utility (CU) framework to focus on retaining coverage and inclusion in guidelines
- New product enhanced with DNA biomarkers, Cxbladder Detect^{+}, developed as a single product for hematuria evaluation
- FY 24 focus on execution – growth catalysts include clarity on Medicare coverage, the 'go-live' of the Kaiser Permanente Electronic Medical Records (EMR) integration and the maturation of the new sales force

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today announces financial and operational results for the year to 31 March 2023 and reports a year of delivery on its strategic goals.

Through FY 23 Pacific Edge has advanced initiatives to drive the adoption and more frequent use by clinicians of Cxbladder, the company's suite of advanced genomic tests, and generate clinical evidence to support Cxbladder coverage and the inclusion of the tests in global standards of care.

Operating revenue, the income generated from Cxbladder test sales, increased 71% to $19.6 million from $11.4 million in the prior financial year. Revenue growth followed a 39% increase in commercial tests to 26,691 from 19,196 tests in the prior year, with US commercial test numbers growing 46% to 23,072 from 15,752 for FY 22. Favorable exchange rate movements also positively impacted FY 23 operating revenue. Without this favorable movement, operating revenue increased 55% on FY 22.

As reported in Pacific Edge's Q4 shareholder update in April, total test volumes for FY 23 rose to 31,565, a 37% increase on the 23,086 tests processed in FY 22. Total revenue, which includes government grants and other income, increased 88% to $26.1 million from $13.9 million in the prior financial year assisted by higher interest income, up $2.2 million to $2.8 million and foreign exchange gains, up $2.1 million to $2.3 million.

The net loss after tax increased to $27.0 million, from $19.7 million in the prior year. This result followed a 58% increase in net operating expenses to $53.1 million from $33.7 million in the prior year as the company invested in

growth, particularly in the US market. While exchange rate movements have increased reported revenue from the US, expenses in the US were also increased due to these movements. Removing the impact of the exchange rate movements, underlying operating expenses increased 47%.

These increased expenses reflected the expansion of the company's global team including direct sales, marketing and sales support teams and the introduction of new Medical Affairs and Market access capabilities to the business. Investment in people accounted for 52% of operating expense growth. The company has now largely completed scaling for its next phase of growth.

Pacific Edge retains a strong balance sheet with cash, cash equivalents and short-term deposits at 31 March 2023 of $77.8 million, compared to $93.5 million at the end of September 2022 and $105.4 million at the end of March 2022.

Chairman Chris Gallaher said: "Pacific Edge has successfully executed on the strategic priorities we outlined to investors a year ago to drive the adoption of Cxbladder and to work towards the entrenchment of our tests as a global standard of care for bladder cancer.

"Our efforts have been rewarded with a strong increase in commercial test volumes in the US, our most important market; increased Cxbladder adoption by US clinicians and a significant improvement in operating revenues. Following the introduction of new capabilities and the building of the team to the point that we are able to deliver on the next phase of growth, Pacific Edge is well positioned to accelerate this momentum in the current financial year.

"Our successes have been tempered by the ongoing lack of clarity over Cxbladder's continued coverage by Medicare. While unlikely, an unfavorable final version of the LCD has the potential to significantly reduce revenue from patients with Medicare and Medicare Advantage insurance plans. Still, with cash reserves of $77.8 million we are well positioned to execute on the significant opportunities we see, whatever the Medicare outcome," Mr Gallaher said.

Chief Executive Dr Peter Meintjes said the 2023 financial year had been one of enormous change and achievement for the company.

"I am immensely proud of what we have achieved over my first full financial year leading Pacific Edge. The team has embraced change and the new approaches we are taking to drive the commercial success of the company in the US, our most significant market, and around the world.

"We have scaled the global team to execute on the immediate opportunities with new hires in direct sales, marketing, and sales support. We have brought in new capabilities, including the recruitment of a Medical Affairs team, which is tasked with engaging the urological opinion leaders that exert significant influence over the adoption of Cxbladder tests by healthcare providers and payors. The team is also at the heart of our strategy to embed Cxbladder in global standards of care, notably playing a key role in the design and execution of the clinical evidence program that is foundational to that goal.

"We have enhanced our Market Access capability to drive coverage and reimbursement by national healthcare providers and build resilience into our business in the face of complex healthcare regulatory and funding systems in all the markets where we operate. We have also stepped up our business development capabilities in APAC and introduced a variety of roles in digital technologies and innovation to support the company's strategic growth plans.

"We have gained coding and coverage for Cxbladder Triage. We have developed Cxbladder Detect+, a new test enhanced with DNA biomarkers that we are now advancing as a single product for hematuria evaluation. Cxbladder Detect+ delivers performance superior to our existing Triage and Detect tests and is well positioned to change the standard of care.

"Pacific Edge is geared for growth. While the draft LCD from Novitas[1] has created some uncertainty, Cxbladder remains a covered test by Medicare, and we have observed little impact on demand for Cxbladder from customers.

"Supported, however, by the advice and feedback we have received from our legal advisors, industry, academics and clinicians and following numerous representations to Novitas, we remain optimistic that Cxbladder will retain coverage," Dr Meintjes said.

"We are looking forward to the deadline on July 28 when Novitas must either finalize or withdraw the proposed Local Coverage Determination (DL 39365) and the associated Local Coverage Article (DA 59125) that cast Cxbladder's continued Medicare coverage into doubt."

ADOPTION RETENTION AND REVENUE GENERATION

Our US business is making steady progress. US Total Lab Throughput (TLT) for the year was up 44% to 27,217 from 18,864 tests in FY 22. Commercial tests increased 46% to 23,072 from 15,752 in the prior year.

We are already seeing the benefits of expanding the direct sales force and creating differentiated commercial roles to meet the needs of different customer types. We now have dedicated teams for national accounts, regional sales, virtual sales and market access.

The Medical Affairs team has changed the narrative on biomarker utility in bladder cancer detection and patient surveillance, driving increased engagement with key opinion leaders, department heads and the chairs at leading institutions, or owners and partners at private practices.

The team is also driving clinical behavior change. This is most evident at Kaiser Permanente, our largest US customer with an estimated 12.5 million members covered by its health plan. Pacific Edge is a valued innovation partner for Kaiser Permanente, underpinned by our shared desire to reduce unnecessary cystoscopies during hematuria evaluation and surveillance.

Adoption within Kaiser is growing steadily. Two of its clinics were in the top 20 Pacific Edge accounts by volume in the last quarter. A catalyst of further acceleration in growth will be the 'go-live' of Cxbladder's integration with Kaiser's EMR system. We have completed the software development and integration testing on the project and are now focussed on completing the required administrative and review processes.

Our New Zealand business has delivered a steady performance. Our tests are available to more than 75% of New Zealand's population, but there remains an opportunity to drive the utility to primary care, to increase adoption for hematuria evaluation among surveillance users and increase adoption for surveillance among hematuria evaluation users.

[1] Novitas is the Medicare Administrative Contractor with jurisdiction for our US laboratory,

Over the last year we added contracts with *Te Whatu Ora* Health New Zealand Southern District and expanded coverage in Tairawhiti on the East Coast of New Zealand. The most significant catalyst in the New Zealand market is an opportunity to expand access through a national contract with *Te Whatu Ora*.

The rest of the APAC market is in the early stages of development. We recently appointed a President APAC charged with building on the company's presence in Australasia in the broader APAC region. APAC TLT for the year rose 3% to 4,348 from 4,222 tests in FY 22. Commercial tests increased 5% to 3,619 from 3,444 in the prior year.

Our strategic focus across both regions for the year ahead remains the same, although we are embarking on a new range of digitalization and performance excellence initiatives to improve the effectiveness and efficiency of our operations.

EVIDENCE COVERAGE AND GUIDELINES

We reviewed and reconfigured our evidence generation program. Our aim is to ensure it achieves our goals of assisting the clinical adoption of Cxbladder and the inclusion of the tests in global standards of care. Clinical evidence is also at the heart of our goals to foster trusted relationships with key urologic opinion leaders and enhance the scientific credibility of the Cxbladder brand.

Our focus is on generating data to demonstrate the analytical and clinical validity and ultimately the clinical utility[2] of Cxbladder, including the new product Cxbladder Detect+. We have six key studies underway directed towards these goals and have accelerated enrolment and site monitoring to drive the studies more rapidly towards completion.

In the closing months of the financial year, we were pleased to gain Medicare coverage for Cxbladder Triage. This followed the test's inclusion in the Local Coverage Article (LCA 58917) that Pacific Edge currently relies upon for Medicare coverage of all our tests in the US.

As signalled in April, we expect the development to lead to modest increases in rates of payment from Medicare and Medicare Advantage payors for Triage. We also see coding and listing in LCA 58917 as a faster tangible path for Cxbladder Detect+ to gain coverage, should the current approach to reimbursement of our tests in the US continue.

Finally, we are now working to supplement our evidence generation program with investigator-initiated trials and the establishment of a Cxbladder registry, where clinicians can record a wide range of patient data, including follow up and outcomes. The registry, as it grows, becomes a multi-site, real-world evidence clinical trial. While clinical utility trials are the gold standard for guidelines inclusion, and we expect many private payors to cover Cxbladder after inclusion in guidelines, real-world evidence is frequently required by many private payors to drive medical policy and subsequent contracting.

RESEARCH AND INNOVATION

The key success of our innovation team in FY 23 was the publication of evidence supporting the analytical validity of Cxbladder Detect+ in the prestigious Journal of Urology, which demonstrated significant improvements in test performance. A key focus in the coming year will be to investigate the potential for a Monitor+ product for surveillance based on similar DNA SNPs. Our R&D team continue to evaluate product concepts to address unmet

[2] For definitions of analytical and clinical validity and clinical utility please refer to page 45 of the investor presentation released to the NZX and ASX today.

clinical needs in urology diagnostics, for example, our MONSTER study is aimed at identifying additional markers of residual disease in surveillance patients.

OUTLOOK

Pacific Edge is building on the steady growth we have achieved in FY 23. We continue to invest prudently to improve the effectiveness and efficiency of the team we now have in place, Dr Meintjes said. "The lack of clarity over continued Medicare coverage continues to represent a headwind for the company, but we remain confident and optimistic about our outlook. We have world-leading technology, a strong balance sheet and we are building momentum in the US and establishing footholds in new markets.

"We also see the potential for several catalysts to drive our success in the coming year, including a positive Medicare determination, the 'go live' of the Kaiser EMR integration, the growing maturity of our sales force and, locally, a national contract with *Te Whatu Ora*. Longer-term we are looking to the publication of clinical utility evidence from our studies and those conducted independently of Pacific Edge," Dr Meintjes said.

"The entire Pacific Edge team is working hard to bring all of these catalysts to fruition, and we look forward to providing an update to our shareholders at our annual meeting in Auckland at the end of July."

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

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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.