

# PACIFIC EDGE REPORTS CONTINUED GROWTH IN FY19

# Audited Financial results for the year ended 31 March 2019

- Adoption of Cxbladder continues and sales are increasing, with accelerating commercial progress being noted, particularly in Q419.
- Operating revenue from test sales was up 12% to \$3.8m, with total revenue for the period of \$5.1m.
- Total laboratory throughput (which includes commercial sales as well as tests from User Programmes) grew to 15,697 tests in FY19, a 9% increase on FY18.
- Total billable tests grew to 12,744 tests in FY19, a 7% increase on FY18.
- Total operating expenses reduced to \$(23.0)m for the year, a 7% improvement on FY18.
- Net operating cash outflow reduced to \$(17.5)m for the year, a 3% improvement on FY18.
- Overall, the Company reported a net loss of \$(17.9)m for the year, an improvement of 9% on FY18.
- Pacific Edge had cash, cash equivalents and short term deposits of \$12.9m as at 31 March 2019.

Cancer diagnostics company, Pacific Edge (NZX: PEB) has today released its audited financial results for the year ended 31 March 2019, reporting accelerating demand from new and existing customers in the second half of the financial year, particularly from New Zealand customers in the final quarter of the year.

The majority of New Zealand's national healthcare providers (District Health Boards, DHBs) have now added Cxbladder into the standard of care and, in some cases, into clinical guidelines with Cxbladder replacing the gold standard cystoscopy in both the evaluation of haematuria (blood in the urine) and in the monitoring for recurrence.

More than 3 million people (over 60% of New Zealand's population) are now covered under contract with these DHBs. Demand and commercial sales are exceeding the company's expectations, with strong growth in Q419 in particular. Based on current sales and projected demand, the New Zealand business is expected to reach a cashflow positive position in FY20.

Given the success in New Zealand with the commercial contracting of public healthcare providers, Pacific Edge has increased its focus on large institutional healthcare organisations in its USA, South East Asia and Australasian markets. While these institutional customers can take longer to bring to completion, once commercial agreement is reached, they provide significant volume, require lower sales maintenance and deliver more sustainable, longer term growth opportunities with shorter cash conversion cycles.

The USA market remains the priority for Pacific Edge. Management is focused on completing agreements and building sales from the large institutional accounts and payers it is targeting, including Kaiser Permanente, Johns Hopkins Medicine, the Veterans Administration and Tricare, the Centers for Medicare and Medicaid Services (CMS) and other blue chip institutions.

Two of the three milestones required for USA national public reimbursement were completed during FY19, being (1) receipt of product specific CPT codes for Cxbladder Detect and Cxbladder Monitor in March 2018 and (2) the notification of a national price for all Cxbladder tests (US\$760 per test) in October 2018. These have allowed the Company to initiate negotiations for contract terms with private payers. Successful completion of these contracts will enable a shortening of the overall commercial transaction time and provide a positive reduction in the time to

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receipt of cash. The introduction of the national product specific CPT codes from 1 January 2019 has started to have a positive impact on cash collection rates in Q419 and this positive trend is expected to continue going forward.

Progress continues to be made with the third and final reimbursement milestone, which is to have Cxbladder included in a Local Coverage Determination (LCD). This will allow for reimbursement of tests used by patients covered by the Centers for Medicare and Medicaid Services (CMS). The CMS currently account for approximately 50% of the Company's total laboratory throughput in the US.

South East Asia remains an exciting opportunity for Pacific Edge. User Programmes with the five largest hospitals in Singapore are nearing completion and the focus is on transitioning these to commercial customers and growing the adoption of Cxbladder by other large healthcare organisations in the region. In Australia, Pacific Edge has taken over the sales and distribution of Cxbladder, building on the successful practices developed in the New Zealand market.

## **Outlook for FY20**

Pacific Edge's Cxbladder tests continue to provide a compelling value proposition for healthcare providers, patients and clinicians alike. Test adoption, coverage and reimbursement is expected to grow in FY20 as clinical evidence continues to accumulate in favour of Cxbladder.

Demand from public healthcare providers in New Zealand is expected to continue to grow strongly and positively impact commercial test throughput volumes. The New Zealand business is expected to reach a cashflow positive position in FY20 and onwards.

Demand from the USA is expected to be positively impacted from having the national product specific CPT codes for Cxbladder Detect and Cxbladder Monitor and a national CMS reimbursement price (effective 1 January 2019) in place. The focus remains on gaining the LCD and accelerating the commercial adoption of all Cxbladder tests.

Pacific Edge has a prudent approach to its investment into the growth of the Company while operating with a net negative cash position. Total operating expenses are expected to remain in line with FY19.

CEO of Pacific Edge, David Darling, said: "Many of the foundations for commercial success have now been completed. We have a proven business model and a growing list of compelling clinical evidence published in top-tier international journals. This published evidence is the key ingredient in driving widespread reimbursement and adoption of Cxbladder with customers globally.

"Adoption of Cxbladder is growing and commercial sales are increasing. We remain focused on further accelerating the adoption of Cxbladder by large healthcare organisations in New Zealand and internationally. Gaining inclusion in the Local Coverage Determination remains a priority."

Chairman Chris Gallaher said that the Board remained committed to the Company's strategy and to achieving the key milestone of cashflow breakeven for the Group. "We are now seeing steadily increasing traction from our commercial strategies, particularly in New Zealand and the USA. The barriers to entry for medical devices are high and Pacific Edge remains the only company in the world to have bought a new diagnostic for urothelial cancer to market in the last 17 years. Clinical evidence published in top-tier journals is facilitating test adoption, coverage and



reimbursement and we expect to see a continued uplift in adoption and sales in FY20. We remain focused on the USA market which offers enormous potential for our company."

The Company's key objectives for FY20 are as follows:

- **GLOBAL REACH**: Grow the number of large institutional healthcare customers globally and build on initial sales to these organisations.
- USA: Successfully achieve the third and final USA reimbursement milestone to gain inclusion in the LCD, upsell additional Cxbladder tests to contracted customers, and build on initial sales to the VA and other organisations.
- **NEW ZEALAND**: Further accelerate the roll out of Cxbladder in New Zealand to obtain widespread contract coverage with public health care providers (DHBs), upsell additional Cxbladder tests to each of the contracted DHBs, and bringing Pacific Edge's New Zealand business to a cashflow positive position.
- **AUSTRALIA**: Replicate the successful NZ sales and marketing model in Australia to drive sales.
- **SE ASIA**: transition User Programmes in Singapore into commercial customers, and progress discussions with potential strategic partners in South East Asia.
- **TEST ADOPTION**: Increase the commercial adoption of Cxbladder in the USA, Australia and South East Asia by leveraging the clinical validation and commercial success of Cxbladder in New Zealand.
- **CLINICAL EVIDENCE**: Continue to build out the evidence portfolio to drive further positive reimbursement decisions.

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## For more information contact:

David Darling Chief Executive Officer Pacific Edge Ltd P: +64 (3) 479 5800

## **OVERVIEW** www.pacificedge.co.nz www.pacificedgedx.com

Pacific Edge Limited (NZX: PEB) is a New Zealand publicly listed, cancer diagnostic company specialising in the discovery and commercialisation of diagnostic and prognostic tests for better detection and management of cancer. Its non-invasive, simple to use and accurate Cxbladder tests enable the detection of bladder and other urinary tract cancers from a small volume of a patients' urine. Cxbladder provides actionable results and better detection and management of urothelial cancer. The company is developing and commercialising its range of Cxbladder tests globally and has two wholly owned accredited laboratories in New Zealand and the USA. The company's products have been tested and validated in multiple international clinical studies.

## ABOUT Cxbladder Triage

Cxbladder Triage accurately identifies patients with haematuria who have a low probability of bladder cancer and may not require a more extensive urological evaluation. Cxbladder Triage is a tool for use by clinicians and physicians in primary evaluation of patients with haematuria and is intended to reduce the need for an expensive and invasive work-up in patients who have a low probability of having urothelial cancer.

ABOUT Cxbladder Detect

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Cxbladder Detect provides clinicians with a quick, cost effective and accurate measure of the presence of the cancer as an effective adjunct to cystoscopy. Is often used in conjunction with Cxbladder Triage to provide greater rule-out and resolution of patients who have UC.

#### **ABOUT Cxbladder Monitor**

Cxbladder Monitor allows urologists to monitor bladder cancer patients for recurrence of the disease. Bladder cancer has a recurrence rate of 50-80% and requires life-long surveillance. Cxbladder Monitor accurately identifies patients with a prior history of urothelial cancer whose Cxbladder Monitor score shows that they have a low probability of recurrent urothelial cancer. Cxbladder Monitor is designed to be used as the preferred adjunct test to cystoscopy in the management of patients for ongoing evaluation of recurrent bladder cancer.

#### **ABOUT Cxbladder Resolve**

Cxbladder Resolve identifies those patients who are likely to have aggressive or more advanced bladder cancer. Cxbladder Resolve, when used as part of the primary evaluation of haematuria and/or in conjunction with other Cxbladder tests (Triage, Detect), is designed to assist clinicians by accurately identifying patients with a high probability of having high grade or late stage bladder cancer, for whom alternative or expedited treatment options may be warranted, or who can be prioritised for further investigation in high throughput settings.

Refer to www.cxbladder.com for more information.