

## PACIFIC EDGE RESULTS FOR SIX MONTHS ENDED 30 SEPTEMBER 2021

### Pacific Edge reports continued strong revenue growth despite continuing impact of Covid-19

#### Unaudited results for the six months ended 30 September 2021 (1H22)

Summary of performance for the period (% changes compared to prior comparative period (pcp)):

- Total revenue increased 66% to \$6.7m
- Operating revenue from test sales increased 62% to \$5.4m
- Total Laboratory Throughput increased 62% to 11,136 tests
- Commercial Test volumes increased 64% to 9,192 tests
- Cash Receipts from Customers increased 110% to \$5.4m
- Total operating expenses increased 41% on pcp to \$15.7m
- Net Loss After Tax increased 27% to \$9.0m
- Net cash, cash equivalents and short-term deposits were \$91.6m (which excludes the \$23.5m raised in the Retail Offer completed in October 2021)
- Growth in the US sales force from 16 to 28 (+75%) and the addition of two new sales territories
- Publication of clinical evidence key to supporting use of multiple Cxbladder products and Pacific Edge's Patient In-Home Sampling System (PIHSS)
- Conducted successful \$103.5m capital raise and dual listed on ASX
- Well positioned to capitalise on commercial milestones as Covid-19 restrictions ease, with a strong balance sheet and scaled up operations in the U.S.

Cancer diagnostics business, Pacific Edge Limited (NZX/ASX: PEB) has reported continuing growth for the six months ended 30 September 2021 (1H22), with key performance metrics significantly ahead of the same time last year, driven by reimbursement milestones, increasing insurance coverage and adoption by urologists and healthcare organisations.

CEO of Pacific Edge, David Darling, commented: "The momentum seen in 2H21 has continued with growth in test volumes, sales and cash receipts. This is particularly pleasing given the resurgence in Covid-19 restrictions due to the spread of the Delta variant, which further restricted access to clinics and urologists for both patients and for our sales people in both the U.S. and New Zealand. As Covid-19 restrictions are lifted and access improves, we expect to see a positive impact on our business.

"With a restructured balance sheet and significant cash resources now in hand, we continue to focus on scaling up our commercial operations to accelerate our growth in the U.S. and other targeted markets. We continue to make good progress as we position our Cxbladder suite of tests as the diagnostic product of choice for urologists and patients. The clinical evidence supporting the outperformance of our products, growing endorsement by key opinion leaders and our first mover advantage all serve to provide a strong competitive advantage for our business."

In particular, the recent clinical papers published in the leading Journal of Urology, highlight a pivotal shift in clinical utility from, firstly, an increase in clinical resolution from the combined use of multiple Cxbladder tests for each patient presenting with haematuria and, secondly, the gain in clinical utility from Pacific Edge's PIHSS for

management of patients outside the clinic. These publications are expected to provide added impetus to the adoption of Cxbladder by urologists and healthcare organisations.

### **1H FY22 Financial Result Summary**

Total Revenue increased 66% to \$6.7m and Operating Revenue from Cxbladder sales increased 62% on the prior comparative period (pcp) to \$5.4m. This record result reflects the continued positive impact from the commercial milestones achieved in 1H21, particularly LCD inclusion for Cxbladder Monitor and Cxbladder Triage from 1 July 2020 as well as growing adoption and use by urologists and healthcare organisations.

Total Laboratory Throughput (TLT) increased 62% on pcp and 24% on the prior six month period (2H FY21) to 11,136 tests.

Commercial test volumes increased 64% on pcp and 24% on the prior six month period (2H FY21) to 9,192 tests, and accounted for 83% of TLT (up from 82% in FY21).

The U.S. market accounted for 81% of TLT, 81% of commercial test volumes and 93% of operating revenue. CMS related tests (Medicare and Medicare Advantage) accounted for 65% of total U.S. commercial test volumes. Cxbladder Detect and Cxbladder Monitor (the two Cxbladder tests included in the LCD) accounted for 95% of total U.S. commercial test volumes.

Cash receipts from customers increased 110% on pcp to \$5.4m, reflecting the positive impact of cash reimbursement from the CMS and increased volumes.

Operating expenses increased 41% on pcp to \$15.7m as the company invested for growth, and particularly the sales and marketing efforts in the US.

For the six month period, Pacific Edge reported a Net Loss After Tax of \$9.0m, an increase of 27% on pcp.

The recent capital raise of \$103.5m has significantly strengthened the Company's balance sheet. As at 30 September 2021, net cash, cash equivalents and short term deposits were \$91.6m (which excludes the \$23.5m raised in the Retail Offer that was completed post-period end in October 2021).

### **Commercial Progress**

The company continues to achieve commercial milestones as it progresses its global growth strategy. In particular, in 1H22, Pacific Edge reported:

- Growth in the US sales force from 16 to 28 (75%) and the addition of two new sales territories
- Commercial adoption of second Cxbladder product (Cxbladder Triage) by Kaiser Permanente
- Expansion of coverage in New Zealand, with Northland and Taranaki public healthcare providers (DHBs) adopting Cxbladder into use taking the total coverage to more than 70% of New Zealand's population

- Acceptance of an important clinical paper outlining the significant increase in clinical resolution that can be achieved from using multiple Cxbladder products in the evaluation of a patient presenting to the clinic with haematuria
- Publication of real world lookback study in the U.S, highlighting the clinical utility of Cxbladder in a Covid19 setting for managing patients outside the clinic
- Analysis of results from Singapore study on-track for publication in early 2022. This will form the basis of Pacific Edge's planned commercial rollout in Southeast Asia, which is expected to become a market of scale for Cxbladder over time similar to the U.S
- Dual listing on the ASX in September 2021
- Completion of successful \$103.5 million capital raise to enable the company to capitalise on recent commercial milestones and to accelerate the execution of its global growth strategy in markets of scale
- In October 2021, announced the appointment of new CEO, Dr Peter Meintjes, who will commence in the role in January 2022.

## Outlook

Pacific Edge has a positive outlook for FY22 and beyond and is well positioned to capitalise on the opportunities available to the company.

The U.S. market remains the primary focus and continued growth is expected once Covid-19 restrictions ease. The scaled up U.S. commercial operations provide the capacity and resource to drive growth opportunities and positive results from this investment are now starting to be seen. The U.S. sales team grew to 28 experienced sales representatives over the last year, with 30 sales reps expected to be operating by end-November.

The focus for FY22 is on growing the commercial adoption of Cxbladder by Kaiser Permanente and other large healthcare organisations, further increasing reimbursement coverage from private payers, and achieving a positive shift in guideline inclusion language following the publication of new clinical evidence further supporting the clinical utility of Cxbladder.

Full integration into Kaiser's patient referral system and Electronic Medical Records has yet to be concluded and continues to constrain the growth rate expected from this important customer. Despite this, commercial test numbers continue to grow.

The recent clinical papers supporting the combined use of multiple Cxbladder products will further evolve how urothelial cancer is diagnosed and managed, with Cxbladder once again leading the way and delivering a greatly enriched clinical proposition for urologists. These papers also provide additional support in favour of inclusion in guidelines and national standards, which remains a key component that will drive widespread adoption of Cxbladder.

Pacific Edge's rest of world markets – New Zealand, Australia and Singapore – are markets of strategic importance, with tailored plans being executed dependent on each market's commercial maturity.

Chairman of Pacific Edge, Chris Gallaher, said: "Pacific Edge's growth momentum over the last six months, despite the ongoing headwinds from Covid19, confirms the validity of our global growth strategy and the way we go to market. We have a committed and experienced team, with significant funding in place to allow us to scale up and to deliver revenue growth and value creation for our shareholders in FY22 and beyond. We are confident in our

future and the actions we are taking now are positioning us to accelerate our growth trajectory once Covid-19 restrictions ease.”

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**OVERVIEW** [www.pacifiedge.co.nz](http://www.pacifiedge.co.nz) [www.pacifiedgedx.com](http://www.pacifiedgedx.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 Cxbladder suite of non-invasive, simple to use and accurate diagnostic tests provide actionable results, and better detection and management of urothelial cancer. The company is developing and commercialising its range of Cxbladder bladder cancer tests globally through its wholly owned central laboratories in New Zealand and the USA. The company's products have been tested and validated in international multi-centre clinical studies.

**ABOUT Cxbladder Triage** [www.cxbladder.com](http://www.cxbladder.com)

Cxbladder Triage combines the power of the genomic biomarkers with additional phenotypic and clinical risk factors to accurately identify 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 carcinoma.

**ABOUT Cxbladder Detect** [www.cxbladder.com](http://www.cxbladder.com)

Cxbladder Detect enables the non-invasive detection of bladder and other urinary tract cancers from a small volume of a patients' urine. Cxbladder Detect provides clinicians with a quick, cost effective and accurate measure of the presence of the cancer as an effective adjunct to cystoscopy.

**ABOUT Cxbladder Monitor** [www.cxbladder.com](http://www.cxbladder.com)

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 (UC) whose Cxbladder Monitor score shows that they have a low probability of recurrent urothelial carcinoma. 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** [www.cxbladder.com](http://www.cxbladder.com)

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](http://www.cxbladder.com) for more information.