29 May 2020

PACIFIC EDGE ANNOUNCES FY20 RESULTS

Results for the 12 months ended 31 March 2020

Cancer diagnostics company, Pacific Edge Limited (NZX: PEB) has today released its audited financial results for the 12 months ended 31 March 2020 (FY20).

$M	FY20	FY19	% change
Operating Revenue	4.4	3.8	14%
Total Revenue	5.2	5.1	1%
Operating Expenses	24.1	23.0	5%
Net Loss After Tax	(18.9)	(17.9)	5%
Cash Receipts from Customers	4.4	3.7	19%
Net Operating Cashflow	(15.4)	(17.5)	(12%)
Cash, cash equivalents and short term deposits	14.8	12.8	15%
Share Capital	165.4	146.4	13%

The company has reported continuing growth and achievement of commercial milestones, with growing adoption and use of its Cxbladder bladder cancer diagnostics tests.

Highlights for the period include the publication of three additional peer reviewed papers in support of Cxbladder; inclusion in the National Comprehensive Cancer Network (NCCN) guidelines in the US; increased adoption and commercial use by New Zealand's public healthcare providers (DHBs); and growing recognition and adoption by urologists in the US and New Zealand.

Total Laboratory Throughput[1] increased 7% to 16,861 tests, with 81% of those tests being Commercial Tests[2]. Since commencing commercial sales in 2015, Total Laboratory Throughput has grown at a compound annual growth rate (5-year CAGR) of 34%.

Operating revenue from test sales was $4.4m, up 14% on the prior comparative period (pcp), with cash receipts from customers up 19% year on year. US operating revenue increased 15% on pcp (+9% in USD terms) and accounted for 86% of group operating revenue in FY20.

The US remains the company's largest market, providing 79% of Total Laboratory Throughput in FY20. The company's commercial focus remains on achieving inclusion in the Local Coverage Determination (LCD) for the Centers for Medicare and Medicaid (CMS); and integration and scale adoption of Cxbladder with targeted large US institutional customers. A successful LCD decision will allow Pacific Edge to start recognising revenue for approximately 43% of its current commercial sales in the US. A growing number of organisations and urologists in the US are now using Cxbladder, which was reflected in a 6% increase in US Laboratory Throughput for the full year and a 14% year on year increase in Q420.

[1] Total Laboratory Throughput means total commercial and non-commercial tests processed through Pacific Edge's laboratories in the USA and New Zealand, including tests for User Programmes.
[2] Commercial Tests means tests that have been analysed by Pacific Edge, for a specific customer, including the User Programmes run by customers as part of their adoption process but excluding any tests run for clinical studies.

Commercial test numbers include tests performed for CMS patients that have been invoiced but for which no cash payments have been received or revenue recognised. CMS-related tests accounted for approximately 43% of US Commercial Tests in FY20 and cumulatively totalled 21,789 tests as at 31 March 2020. Pacific Edge is continuing to progress its application to achieve inclusion in the LCD with an updated dossier of clinical evidence accepted by the CMS's Medicare Administrative Contractor (Novitas), for formal review in August 2019. In February 2020, Pacific Edge successfully added its latest peer-reviewed publication to that clinical evidence dossier, which provided further real world evidence of significant gains in clinical utility from the commercial adoption of Cxbladder Monitor (CxbM) by three different public healthcare providers in New Zealand.

Under NZ IFRS 15, a successful LCD decision would allow Pacific Edge to start recognising revenue for all the tests that are performed on CMS patients in the US (FY20: 4,774 tests) at the already determined national CMS price for Cxbladder of US$760 per test. A successful LCD decision would also have a significant positive impact on operating cashflow and would allow the company to seek reimbursement from the CMS for the tests that have previously been completed and invoiced, but for which no revenue has been recognised.

While the New Zealand market is small relative to the US, New Zealand's public healthcare providers continue to lead the global adoption of Cxbladder. New Zealand Laboratory Throughput increased 12% year on year, with operating revenue increasing 11%. The majority of New Zealand's public healthcare providers have adopted Cxbladder into their standard of care and in some instances, replaced the gold standard cystoscopy. In Q420, two New Zealand DHBs added an additional Cxbladder test to their mainstream commercial use, and three DHBs started using Cxbladder for in-home testing as a solution for their patients. More than 65% of New Zealand's population is now covered by contracts with public healthcare providers.

Operating expenses were $24.1m, up 5% on the prior year, primarily due to the foreign exchange impact of a weaker NZD compared to USD. US operating expenses account for 60% of total operating expenses and were down 2% in local currency terms (up 3% in NZD). In Q420, the US business increased the number of sales representatives selling Cxbladder to 16 (compared to 11 at the start of the financial year).

As at 31 March 2020, Pacific Edge had $14.8m in cash, cash equivalents and short term deposits, following a successful $20.1m capital raising completed during the year. Cash receipts from customers increased 19% year on year and net operating cash outflow reduced to $(15.4)m, a 12% improvement on pcp. The company reported a Net Loss After Tax of $(18.9)m. The Board and management continue to carefully manage cash resources and achieving a cashflow breakeven position remains a priority.

COVID-19 Impact and Response

Pacific Edge continued to operate as an essential business during the COVID-19 restrictions in both New Zealand and the US. While Q420 Laboratory Throughput remained strong (US Total Laboratory Throughput +14% y/y), the negative impact from the stay-at-home restrictions was felt in the first half of April 2020 with urologists balancing the conflicting demands of COVID-19 restrictions and managing at-risk patients. This resulted in reduced Laboratory Throughput in April 2020, with US and New Zealand Laboratory Throughput averaging 51% of April 2019 levels. Test demand recovered in New Zealand during the second half of April 2020 following the easing of COVID-19 restrictions. Test demand is also expected to recover in the US as restrictions ease.

Pacific Edge has been able to reduce costs to offset income reductions and has also received financial support in the form of COVID-19 relief packages from Governments in New Zealand, Australia and the US.

Helping to offset the reduced Laboratory Throughput from patients visiting clinics has been the increased adoption of Cxbladder's unique in-home sampling system which allows patients to collect a sample at home for delivery to a Pacific Edge laboratory. Three DHBs commenced in-home sample collection in New Zealand during April 2020, and Pacific Edge has also seen increased sales activity with healthcare institutions as they seek alternative methods to treat their patients remotely.

The COVID-19 pandemic has highlighted the need for novel ways to detect cancer early and guide treatment Following the rapid increased use of telehealth in the US during this time, Pacific Edge expects tele-consultations to become more common practise going forward. A leading US healthcare provider has recently stated that their use of tele-consultations has increased from 15% of all appointments pre-COVID-19 to 80% currently. In line with this growing trend, in-home diagnostic testing for cancer is also expected to become an accepted option for patients and physicians, both during the COVID-19 pandemic and beyond.

CEO of Pacific Edge, David Darling, commented: "Our business continues to progress, with particularly strong growth in our domestic market. We have achieved some significant milestones that drive reimbursement and, combined with the strong clinical evidence portfolio underpinning the commercialisation of Cxbladder, we are seeing increased adoption and commercial use of our tests.

"We remain focused on continuing to build scale in the US, through the signing of commercial agreements with large scale healthcare organisations, as well as achieving inclusion in the CMS's LCD. Upon completion, these will provide a significant positive impact on the company's financial position.

"The deployment of telehealth as a main stream component of patient health management has been accelerated globally by the COVID-19 pandemic and we expect to see Cxbladder continue to benefit as in-home sampling becomes a more integrated and valued alternative for many patients and physicians around the world."

Outlook

Pacific Edge is in a unique global position, with a first mover advantage, a large addressable market and a proven model and products with compelling and repeatable performance. Cxbladder provides the only commercially available, non-invasive, accurate, clinically validated diagnostic solution across the bladder cancer pathway. Cxbladder products deliver better care for patients, better utility for urologists and savings for the payers.

Scale adoption by large healthcare institutions remains the commercial objective for Pacific Edge in all markets, particularly the US. The recent Inclusion in the NCCN bladder cancer guidelines (July 2019) and the publication of additional compelling, peer reviewed clinical utility evidence (February 2020) is expected to facilitate greater test adoption, reimbursement and additional guideline inclusion. Two of the three milestones required for reimbursement from the CMS have been achieved and progress is being made to conclude the third milestone, being inclusion in the LCD. A successful LCD decision would allow Pacific Edge to start recognising revenue for all the tests that are performed on CMS patients in the US and would also have a significant positive impact on operating cashflow. It remains a priority focus for the company.

In New Zealand, demand from public healthcare providers continues to grow and the focus is now on upselling additional tests to existing customers and gaining adoption from the remaining DHBs.

Continuing progress is being made in Southeast Asia with clinical trials in Singapore nearing completion. The published results from these will form the basis for a proposed Singapore-wide commercial rollout. In Australia, Pacific Edge is replicating its New Zealand-proven sales and marketing model to drive sales growth.

The company remains focused on achieving its key strategic objectives and commercial momentum is increasing. Operating cashflow is expected to improve further, whilst operating expenses will be maintained at current levels or lower.

Chair of Pacific Edge, Chris Gallaher, said: "The company has continued to make progress on the commercialisation of Cxbladder and milestones continue to be achieved. We have added substantially to our body of peer reviewed publications during the year and now have a compelling body of independent evidence supporting the accuracy and clinical utility of our bladder cancer tests.

"While good progress has been made in our domestic market, the largest market opportunity, and the largest investment of our capital and resources continues to be the USA. To the extent that we can control the pace of progress in the USA, we are doing all that we can to achieve the remaining milestones achievement of which will be transformative for the company.

"Covid-19 has given rise to both challenges and opportunities for the company. We may well see permanent changes to the way the health professionals interact with patients and we are proving our logistics capabilities through the delivery of in-home testing in both New Zealand and the USA."

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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. The company's suite of non-invasive, simple to use and accurate Cxbladder diagnostic tests provide actionable results, and better detection and management of urothelial cancer. The company is developing and commercialising its range of Cxbladder 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
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
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
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
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.