

PEB: FULL YEAR RESULTS TO 31 MARCH 2016

Pacific Edge Reports Another Year of Commercial Progress and Growth

Cancer diagnostics company Pacific Edge Limited (NZX: PEB) has reported another year of commercial progress and growth as it continues to gain traction for its bladder cancer diagnostic products in the United States and other targeted markets.

The US remains the company's main opportunity for growth. Several significant commercial initiatives were achieved in the 2016 financial year including an expanded US sales force and access to the Veterans Administration. In addition, the company launched its third Cxbladder test and established a new commercial partnership in Australia.

Pacific Edge today reported its financial results for the year ended 31 March 2016.

Operating revenue increased by 162% to \$4.98 million, with a corresponding 114% year on year uplift in annual laboratory test throughput, which includes both commercial sales and User Programmes.

Total revenue grew 74% to \$7.19 million and includes grants and other income. The majority of FY16 year's revenue was generated in the US and was impacted by the NZ:US exchange rate.

Expenses for the year increased in line with expectations as the company continued to invest in People, Product Development, Market Expansion and the protection of Intellectual Property. In particular, Pacific Edge has increased its investment in the rollout of its US growth strategy, with an expanded sales and marketing team and the development and launch of new products.

The full year loss increased to \$15.45 million as planned (FY15: \$12.32m), with cash on hand at year-end of \$24.16 million, from which Pacific Edge will continue to fund its growth strategy.

	FY16	FY15	% Change
	(\$NZ'000)	(\$NZ'000)	
Operating Revenue	4,976	1,900	162%
Other Revenue	2,218	2,232	
Total Revenue/Income	7,193	4,132	74%
Total Comprehensive (Loss)	(15,453)	(12,322)	-25%
Cash on hand as at 31 March 2016	24,160	7,819	

MANAGEMENT COMMENT David Darling, CEO and Executive Director

Positive evidence of Pacific Edge's commercial progress is starting to emerge with the company ticking off a number of significant milestones in the 2016 financial year, particularly in our key market, the United States.

Our primary focus has been on building awareness and access for our products in the US, the world's largest healthcare market with over 10,500 urologists and millions of potential clinical opportunities for our Cxbladder technology.

During FY16, we expanded our sales force to 18 executives targeting 19 sales regions, which we have identified as covering the majority of our potential market in the US.



We also signed a Federal Supply Schedule agreement, allowing us to market our Cxbladder technology to the Veterans Administration (VA), the United States' largest integrated healthcare system. This is something we have been working towards for some time and the VA could eventually become one of Pacific Edge's largest customers.

We are well down the track to completing a significant User Programme with Kaiser Permanente, one of the US' largest not-for-profit health insurers and providers. We are also continuing to progress our discussions with the Centre for Medicare and Medicaid Services. Along with the VA, these organisations could be transformational for our company.

We are also making good progress in other markets, with a new commercial partnership in Australia with Tolmar Australia Pty Ltd and continuing investigations into the opportunity in South East Asia, with the start of the first User Programme with a leading Singapore hospital.

We continue to work closely with urologists in New Zealand. In March 2016, we signed an agreement with the Canterbury District Health Board to provide our Cxbladder technology for primary care referral in the evaluation of haematuria (blood in the urine). This is the first time a health organisation has entered into a process to replace cytology, the incumbent urine test, with Cxbladder.

Clinical validation of our technology continues and, in 2015, research was published demonstrating that Cxbladder outperforms other non-invasive bladder cancer diagnostics, including the UroVysion® FISH assay that is widely used in the United States.

We are constantly innovating and now have three products in market and a fourth in the pipeline. We are the only company in the world to offer multiple molecular tests for the detection and management of bladder cancer. This 'one stop shop' provides urologists and their patients with access to a growing suite of simple, non-invasive and effective diagnostic tests for bladder cancer.

OUTLOOK

Our commercial journey is still in its infancy and we are firmly focused on growth and gaining traction in the US and our other targeted markets.

We have mobilised our expanded US sales force and are working hard to secure further opportunities including the Centre for Medicaid and Medicare Services and the completion of the Kaiser Permanente User Programme.

We are continuing to build traction in other markets, particularly in Australia through our new commercial relationship with Tolmar Australia. Investigations continue into South East Asia and we are in discussions with several Singaporean healthcare providers to allow them to evaluate Cxbladder products in their own clinical settings.

The opportunity for our Cxbladder technology is significant and we anticipate another year of growing returns as we work towards our goal of providing a 'one stop shop' of high performance Cxbladder products for urologists.

FY16 BUSINESS HIGHLIGHTS:

- Successful \$35.3 million capital raising completed in July 2015, providing funds to accelerate the growth strategy in the US and investigate the market opportunity in South East Asia
- Expanded the US sales force to 18 sales executives and added to the commercial, marketing and product development teams in New Zealand



- Signed Federal Supply Schedule agreement with the Veterans Administration in the US in February 2016
- Progressed the Kaiser Permanente Southern California User Programme which is on track to complete in 2016
- Publication of research demonstrating that Cxbladder outperforms other non-invasive bladder cancer diagnostics, including the UroVysion® FISH assay that is widely used in the United States
- Commenced first User Programme in South East Asia, with a leading hospital in Singapore
- Announced a new commercial relationship with Tolmar in Australia to market and distribute Pacific Edge's Cxbladder tests
- Signed an agreement with one of New Zealand's largest healthcare providers, Canterbury District Health Board (CDHB), to enter into a process to replace cytology, the incumbent urine test, with Cxbladder
- Announced sponsorship of online patient community, bladdercancer.me, providing on-line resources for bladder cancer patients and their families
- Launch of third product, Cxbladder Monitor, in New Zealand, with progressive rollout into other markets over 2016
- Appointment of US-based director, David Levison, to the Pacific Edge Board.

(All currency is in New Zealand dollars and the full year results are released together with this commentary)

ENDS

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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 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. Pacific Edge has three proprietary, novel, accurate, molecular diagnostic products in-market providing actionable results, and better detection and management of urothelial cancer. Cxbladder Detect is available through the company's dedicated CLIA certified laboratories for customers in New Zealand, Australia and the USA. Cxbladder Triage is available in New Zealand and Australia. Cxbladder Monitor launched in New Zealand in December 2015 and is anticipated being available in the US in 2016.

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 hematuria 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 was launched in 2013 in the USA and is commercially available in New Zealand, Australia and the USA as a Laboratory Developed Test (LDT) from the company's CLIA certified laboratories. Cxbladder

26 May 2016 Company Announcement



Detect provides physicians and clinicians with a quick, cost effective and accurate measure of the presence of the cancer as an effective adjunct to cystoscopy.

ABOUT Cxbladder Monitor <u>www.cxbladder.com</u>

Cxbladder Monitor, the third test in the Cxbladder portfolio for urologists, is a proprietary, non-invasive, molecular diagnostic test that combines genomic biomarkers measured from a small quantity of a patient's urine, with patient specific clinical factors to better monitor bladder cancer patients for recurrence. 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.

Refer to www.cxbladder.com for more information.