

# PRELIMINARY FULL-YEAR DISCLOSURE: PACIFIC EDGE LIMITED FINANCIAL YEAR ENDED 31 MARCH 2014 RESULTS FOR ANNOUNCEMENT TO THE MARKET

**Reporting Period:** 12 months to 31 March 2014.

**Previous Reporting Period:** 12 months to 31 March 2013.

|   | Current Full Year<br>(\$NZ'000) | Previous<br>Corresponding<br>Year (\$NZ'000) | % Change     |
|---|---------------------------------|--|--------------|
| Trading Revenue   | 523                             | 182  | 187.4%       |
| Other Revenue   | 315                             | 333  | (5.4%)       |
| <b>Total Revenue from Ordinary Activities</b>                                     | <b>838</b>                      | <b>515</b>                                   | <b>62.7%</b> |
| Profit (Loss) from ordinary activities after tax attributable to Security Holders | (9,951)                         | (6,917)                                      | 43.9%        |
| Translation Foreign Operations  | 571                             | (33)   | (1,831.8%)   |
| <b>Total Comprehensive Income/(Loss)</b>  | <b>(9,380)</b>                  | <b>(6,950)</b>                               | <b>35%</b>   |

**Interim/Final Dividend:** The Company does not propose to pay dividends to Shareholders.

## FY14 MARKS SIGNIFICANT COMMERCIAL MILESTONE FOR PACIFIC EDGE

The 2014 Financial Year marked a significant commercial milestone for Pacific Edge as the Company celebrated the start of revenue generation in its primary market, the USA, alongside a strong year of market development and customer capture.

Pacific Edge, which develops and markets molecular diagnostic tests, primarily for the detection of bladder cancer, commercially launched its first bladder cancer product, Cxbladder, in the US market in July 2013. This diagnostic test allows urologists to evaluate patients who present to their clinic with hematuria (blood in the urine) for bladder cancer.

The USA is the world's largest biomedical market, and has 10,500 urologists evaluating in excess of 1 million people with hematuria and investing in excess of US\$1 billion in the evaluation of those patients annually. Pacific Edge has conservatively estimated that this market could provide the Company with the opportunity to develop \$100 million in gross revenue at the completion of its fifth full year of trading.

Over the last 18 months, Pacific Edge has made a significant investment in the growth of the business and its entry into the American market. The Company has achieved a very rapid commercial rollout of Cxbladder

in the USA, building its own laboratory, gaining regulatory approval, establishing a sales force and launching Cxbladder. All of these steps were completed on time, to specification and within budget.

For the 2014 Financial Year Ended 31 March 2014, Pacific Edge recorded a Total Comprehensive Loss after tax of \$9.38 million (FY13: \$6.95 million), in line with budgeted expectations. The Company reported its first substantial trading revenue and whilst still only a small number, this is a strong lift despite the short period of selling in the American market. The majority of the Net Loss is the significant investment the Company has made in the growth of the business; setting up and roll out of business in the USA, clinical trials and User Program's with new customers, further product development and management of intellectual property<sup>1</sup>.

Chairman of Pacific Edge, Chris Swann, said: "During the year it has been affirmed to us that our product, Cxbladder, is in strong demand as an accurate tool for the detection of bladder cancer.

"Evaluating hematuria in American patients for bladder cancer is a significant market of scale and could be worth up to \$100 million in gross revenue for our Company in five years' time. It takes time to develop competency and

<sup>1</sup> As a matter of policy, the Company continues to write off all research and development expenditure until the point at which products or projects provide reasonable certainty of cost recovery. Over this period, the Company has made further significant investment in market development, intellectual property protection, and product development and in the adoption process 'User Program' for the Company's bladder cancer test.

recognition in the market and to begin establishing the relationships with our customers at a commercial level. We have been delighted to see the first steps of our revenue generation since the appointment of sales staff in the USA in July 2013 and we are confident the momentum of the extensive commercialisation program, to familiarise the urology clinicians in the US health system with the significant benefits of Cxbladder, will accelerate sales in FY15.”

“Whilst the New Zealand and Australian markets are important to us from a product development and commercialisation process perspective, it is the scale and accessibility of the American market that is paramount to the success of the Company.”

### Pacific Edge delivered on a number of key elements in FY14

- Contracted commercial relationships with three National Network Providers in the USA—FedMed, ACPN and Stratos. These National Provider Networks provide patients with access to healthcare services and technology by contracting with providers and payers on a national basis. The agreements signed give millions of Americans access to Cxbladder and its positive benefits as a quick, cost effective, non-invasive and highly accurate cancer detection test.
- The US Laboratory achieved CAP accreditation to add to the CLIA accreditation. CAP accreditation elevates the status of the laboratory in the eyes of the clinicians, healthcare specialists and payers.
- Started revenue from US customers. The first person in the Company’s US direct sales force started in July 2013 following an extensive training program. The sales force has increased in number over 2013 and is being aggressively increased in 2014. Reimbursement for Cxbladder is now underway in the US and the revenue is growing.
- Successful completion of \$20 million capital raising in October 2013 that will drive an acceleration of the Pacific Edge salesforce rollout in the USA in 2014 and beyond and aid continued research and development of new products for urologist customers.
- Progress on delivery of the next new product to the market over the coming 2015 Financial Year. The fastest way for Pacific Edge to grow revenue is to deliver another test to existing urology customers down the same channel to market. Progress has been made on developing the next product, Cxbladder<sub>triage</sub>, and the collection of the clinical performance data has begun, with a New Zealand launch expected late in 2014.

- A steady increase in the growth of the adoption of Cxbladder in our markets of New Zealand, Australia and the USA. The focus in all of these markets is on providing a consistent and highly repeatable clinical experience for both the patient and the clinicians when using Cxbladder, delivered from one of Pacific Edge’s specialist laboratories in New Zealand, Australia and now the USA. We have identified high volume segments in these markets and have signed a number of valuable contracts and agreements over the past year. These provide us with access to a market with a scale in excess of two million tests, per annum, in the US and tens of thousands in New Zealand and Australia.

### Looking forward in FY15

The market roll out in the USA has been a dominant component of our commercialisation program this year, and our focus remains firmly fixed on delivering Cxbladder<sub>detect</sub> to the US market and building scale. As part of this, we will be rapidly growing our US sales team and ramping up our sales efforts in the USA, after our initial launch in the second half of 2013.

The Company will continue to invest significant funds this year in customer capture in the USA, particularly with high volume user groups. We continue our focus and efforts with key organisations that facilitate reimbursement, such as the National Provider Networks, where we are involved in ongoing negotiations. We will also continue to invest in the set-up and roll out of the franchised business model in the targeted markets of New Zealand, Australia, USA and Spain, and the further development of the Company’s bladder cancer product portfolio.

We will continue to accelerate the adoption of Cxbladder through our successful ‘User Program’, which provides urologists with the opportunity to evaluate and use our tests in their practice at scale. As well as gaining their validation of our product and providing further independent performance data, the feedback from these urologists enables us to develop new products to meet the needs of clinicians and patients.

We have identified a number of different potential uses of the Cxbladder technology, which provides us with new product opportunities. This remains the fastest and surest way for our Company to grow its product base and total revenue. Therefore, the short to medium term is all about developing the portfolio of new products that we can take to the urologist customers with whom we have been working with so diligently with over the last few years.

To that end, we will continue to maintain our portfolio of intellectual property in the areas of gastric, colorectal and endometrial cancers and melanoma. These will provide us with further options in the future.

Our goal of attaining a business with a Gross Revenue of \$100 million remains our target and continues to be readily attainable.



**Chris Swann**  
Chairman



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## About Pacific Edge

Pacific Edge Limited (NZX: PEB) is a New Zealand based cancer diagnostic company specialising in the discovery and commercialisation of diagnostic and prognostic technology for the early detection and monitoring of cancer. Products in development and in clinical trials are accurate and simple to use genomic and proteomic tools for the earlier detection, improved characterisation and better management of gastric, bladder, colorectal cancers and melanoma. The Company has recently completed and released its first product for the detection of bladder cancer, Cxbladder, and is actively marketing the product to urologists in New Zealand, Australia and the USA. [www.pacificedge.co.nz](http://www.pacificedge.co.nz)

## About Pacific Edge Diagnostics

Pacific Edge takes its exciting cancer detection tests to market through its wholly owned subsidiaries, Pacific Edge Diagnostics NZ Limited and Pacific Edge Diagnostics USA Limited, and selected commercial partners in Australia and Spain, Healthscope Pathology and Oryzon respectively. [www.pacificedgedx.com](http://www.pacificedgedx.com)

## About Cxbladder

Cxbladder is a non-invasive, accurate test that enables the early detection of bladder cancer from a small volume of urine. It provides general practitioners and urologists with a quick, cost effective and accurate measure of the presence of the cancer and provides urologists with the opportunity to reduce their reliance on the need for invasive tests such as cystoscopy. The recently published, Journal of Urology in September 2012, multi-centre international clinical study recruited 485 patients from Australia and New Zealand. Results show that Cxbladder out-performed all other benchmark technologies in the clinical trial and detected nearly all of the tumours of concern to a urologist; At 85% specificity the test sees 100% of T1, T2, T3, Tis and greater than 95% of high grade tumours. [www.cxbladder.com](http://www.cxbladder.com)

## About Bladder Cancer

Globally, bladder cancer has the ninth highest incidence and the fourth highest incidence for men. One of the early symptoms of bladder cancer is the presence of blood in the urine, called haematuria. People with haematuria often present to their general practitioner before being referred on to a urologist.

There are a number of 'At Risk' occupations that have shown a much higher incidence of bladder cancer. Fire fighters and fire control officers have shown in a US study to have a twice the incidence of bladder cancer over non fire fighters. Smoking is a significant contributing factor (over 50% in males and 33% in females, and approximately one of every two new incidences of bladder cancer is linked to smoking). Exposure to certain industrial chemicals or carcinogens increases risks for some occupations e.g. hairdressers, painters, printers, fire fighters, metal workers and chemical engineers. Incidence increases with age so the older you are, the greater the potential for bladder cancer.

Bladder cancer has a very high recurrence rate of approximately 50%-70% with up to 30% of these recurring as later stage tumours. This is a higher recurrence than for skin cancer. However, bladder cancers are highly treatable, especially if detected in the early stages. If diagnosed early, there is a much higher probability of survival for early stage tumours relative to later stage tumours. This makes timely and regular surveillance and monitoring of this cancer a key element of the clinical process and of the individual's annual healthcare plan.