ANNUAL REPORT 2013

PACIFIC EDGE LTD

## Vision...

To benefit global communities through delivery of innovative solutions for the early diagnosis and better treatment of cancer. Pacific Edge has its first product in the marketplace, Cxbladder, and four products in late stage development. Pacific Edge's products are based on proprietary genetic databases used to identify diagnostic biomarkers for cancers. The Company specialises in building commercial cancer tests from these proprietary biomarkers.

## Mission...

To improve patient outcomes, provide superior returns to our shareholders and benefits to other stakeholders by developing and commercialising innovative solutions for the early detection and management of cancer.

# Contents

Innovative solutions for the early detection and management of cancer.

# Company Directory

## Issued Capital

278,755,147 Ordinary Shares

152,500 Series A Convertible Shares

300,000 Redeemable Shares (Part Paid)

## Registered Office

Level 13, Otago House
481 Moray Place
Dunedin

## Directors

C. J. Swann — Chairman
D. C. Band
C. E. Dawson
A. G. H. Masfen

## Chief Executive Officer

D. Darling

## Auditors

PricewaterhouseCoopers
Dunedin

## Bankers

Bank of New Zealand
Dunedin

## Solicitors

Anderson Lloyd Lawyers
Otago House
481 Moray Place
Dunedin

## Securities Registrar

Link Market Services Limited
138 Tancred St
Ashburton

## Accountants

Deloitte
Otago House
481 Moray Place
Dunedin

## Company Number

119032

## Date of Incorporation

27 February 2001

## Nature of Business

Develop and commercialise new diagnostic and prognostic tools for the early detection and management of cancers.

# Company Directory
## (continued)

### Pacific Edge Scientific Advisory Board

Pacific Edge has a world class Scientific Advisory Board (see table below). The skills, experience and capability cover a range of disciplines from clinical medicine and pathology through to commercial biotechnology research and development.

Members of the Scientific Advisory Board advise on science, scientific progress and clinical opportunities. Visits to New Zealand by the international members also provide a strong linkage to international issues and opportunities while enabling us to keep abreast of the rapidly changing technology.

| Name | Position | Organisation | Country |
|---|---|---|---|
| P. Guilford | Chief Scientific Officer<br>Associate Professor | Pacific Edge<br>University of Otago | New Zealand |
| N. Kasabov | Head of Knowledge Engineering Discovery Research Institute (KEDRI) | Knowledge Engineering<br>School of Computer & Information Sciences, Auckland University of Technology | New Zealand |
| M. Sullivan | Senior Lecturer in Pediatrics | Department of Pediatrics, Christchurch School of Medicine<br>University of Otago | New Zealand |
| H. Seung Yoon | Professor of Pathology<br>Clinical Director of Anatomical Pathology | Department of Pathology, School of Medicine, University of Otago | New Zealand |
| M. Brennan | Physician<br>Vice President for International Programs | Memorial Sloan-Kettering Cancer Centre | USA |
| B. Williams | Director | Monash Institute of Medical Research, Monash University | Australia |
| O. Ogawa | Professor<br>Chairman | Department of Urology, Kyoto School of Medicine | Japan |
| P. Spence | Chief Scientific Officer | Spence Partners<br>Duga Healthcare Solutions | UK |

## Clinical Advisory Board

Pacific Edge has a Clinical Advisory Board to provide expert advice on global clinical needs and applications for the Cxbladder technology.

| Name | Position | Organisation | Country |
|---|---|---|---|
| R. Getzenberg | Director of Research<br>Professor of Urology | James Buchanan Brady Urological Institute<br>Johns Hopkins University School of Medicine | USA |
| S. Shariat | Surgeon and Specialist in Urologic Oncology | Department of Urology,<br>New York Presbyterian Hospital<br>Weill Medical College<br>Cornell University | USA |
| J. Raman | Urologist | Penn State Hershey Surgery Specialists<br>Hershey, Pennsylvania, USA | USA |
| P. Cozzi | Urologist | VMO at Hurstville Community Hospital<br>St George Public Hospital<br>Mater Private Hospital | Australia |
| P. Gilling | Consultant Urologist<br>Head of Urology Department | Tauranga Hospital<br>UROBop Ltd | New Zealand |
| M. Fraundorfer | Consultant Urologist | Tauranga Hospital<br>UROBop Ltd | New Zealand |
| P. Davidson | Consultant Urologist<br>Trustee of CURT | Urology Associates<br>Canterbury Urological Research Trust (CURT) | New Zealand |
| J. Masters | Urologist | Auckland City Hospital<br>Manukau Superclinic<br>Gilgit Road Specialists | New Zealand |

# Annual Report of Directors

The Directors present their Annual Report including Financial Statements of Pacific Edge Limited ("the Company") and Group for the year ended 31 March 2013. The Group consists of the Company and its subsidiaries Pacific Edge Diagnostics New Zealand Limited, Pacific Edge Diagnostics USA Limited, Pacific Edge Pty Limited and Pacific Edge Analytical Services Limited.

The business of the Company is developing and commercialising new diagnostic and prognostic tools for the early detection and management of cancers. The Company has wholly owned subsidiaries in New Zealand, Australia and the United States. The subsidiaries in New Zealand and the United States have been set up to manage and operate the commercial laboratories used for the detection of bladder cancer. The Australian subsidiary is a research and development company.

The nature of the Company's business has not changed during the year.

## AUDITORS

The Group's Auditors are PricewaterhouseCoopers. Audit fees payable for the year were $23,250. PricewaterhouseCoopers are willing to continue as the Group's Auditors.

## DIRECTORS' DISCLOSURES

The following disclosures were recorded in the interests register for the year ended 31 March 2013:

### Share Dealings

| Person/or Associated Persons | No. Sold | Class Sold | No. Purchased | Class Purchased |
|---|---|---|---|---|
| A. G. H. Masfen (Masfen Securities Limited) | 10,000,000 | Ordinary Shares | | Ordinary Shares |
| C. E. Dawson | | | 100,000 | Ordinary Shares |

Note: Mr A.G.H. Masfen is a director of the non-beneficial vendor of the above shares.

### Directors' Remuneration

Directors' remuneration paid was as follows:

| Directors' Fees | 2013 ($) | 2012 ($) |
|---|---|---|
| C. J. Swann (Chairman) | 27,500 | 27,500 |
| D. C. Band | 17,000 | 17,000 |
| A. G. H. Masfen | 17,000 | 17,000 |
| C. E. Dawson | 17,000 | 17,000 |
| J. P. Foster (Resigned (30/11/2012) | 9,917 | 17,000 |
| A. E. Reeve (Resigned 25/08/2011) | – | 8,500 |
| **Total** | **88,417** | **104,000** |

Note: D.C. Band Directors Fees were paid by the subsidiary Pacific Edge Diagnostics Pty Limited for the year ended 31 March 2013. All other fees were paid by Pacific Edge Limited.

## Transactions with Directors

The Company paid consultancy fees for accounting services to C J S Advisory Services Limited. C.J. Swann is a director and shareholder of this Company. The fees charged were on normal terms and conditions and totalled $40,467 (2012: $6,226). At balance date no fees were outstanding relative to these transactions (2012: $Nil).

A significant shareholder, the University of Otago, provides rental space and car parking to the Group costing $186,118 (2012: $144,725) and the Company costing $160,775 (2012: $122,356). As at 31 March 2013 the Group commitment is $147,360 (2012: $169,464) and the Company commitment is $125,760 (2012: $144,624). C.E. Dawson, a Director of the Company is also the Chief Executive Officer of Otago Innovation Limited, a wholly owned subsidiary of the University of Otago.

## The following Directors held office at 31 March 2013:

C. J. Swann (Chairman), D.C. Band, C. E. Dawson and A. G. H. Masfen.

J.P. Foster resigned as Director on 30 November 2012.

No other person was a Director at any time during the year.

The Board of Directors received no notices from Directors wishing to use Company information received in their capacity as Directors, which would not have ordinarily been available.

## Donations

The Group has made no donations during the year.

## Employee Remuneration

Employees of the Company receiving remuneration or benefits in excess of $100,000 were as follows:

| Remuneration | 2013 ($) | 2012 ($) |
|---|---|---|
| $100,000–$109,999 | – | 1 |
| $110,000–$119,999 | 2 | – |
| $180,000–$190,000 | 1 | – |
| $270,000–$279,999 | 1 | – |
| $290,000–$299,999 | – | 1 |

# Annual Report of Directors (continued)

## Pacific Edge Diagnostics New Zealand Limited

The Company has a wholly owned subsidiary called Pacific Edge Diagnostics New Zealand Limited which was incorporated on 15 April 2010 in New Zealand. This Company manages and operates a laboratory used for detection of bladder cancer in Dunedin. The Directors of the subsidiary are D. Darling (who is the CEO of the Company) and C. Swann (the Company's Chairman). No remuneration was paid by the subsidiary to these Directors.

There are no employees of Pacific Edge Diagnostics New Zealand Limited who received remuneration exceeding $100,000 in the year ended 31 March 2013. No donations have been made by the subsidiary. No amounts have been paid to the auditor by the subsidiary for the year ended 31 March 2013.

## Pacific Edge Analytical Services Limited

The Company has a wholly owned subsidiary called Pacific Edge Analytical Services Limited which was incorporated on 8 October 2010 in New Zealand. This Company is currently not trading. The sole director of the subsidiary is D. Darling. No remuneration was paid by the subsidiary to D. Darling for his role as Director.

There are no employees of Pacific Edge Analytical Services New Zealand Limited who received remuneration exceeding $100,000 in the year ended 31 March 2013. No donations have been made by the subsidiary. No amounts have been paid to the auditor by the subsidiary for the year ended 31 March 2013.

## Pacific Edge Diagnostics USA Limited

The Company has a wholly owned subsidiary called Pacific Edge Diagnostics USA Limited which was incorporated in the USA on 15 December 2011. This Company manages and operates a laboratory used for detection of bladder cancer in Hershey, Pennsylvania. The Directors of the subsidiary are B. Nogales, D. Darling, D. Band, C. Swann and J. Walker. No remuneration was paid directly by the subsidiary to D. Darling. However, D. Darling's salary as CEO has been apportioned to this subsidiary from the Company for work done in the United States of $117,903 for the year. B. Nogales was appointed on 11 March 2013. No remuneration was paid as at 31 March 2013. The annual remuneration fee for services is US$20,000 per annum.

The US subsidiary has one employee with remuneration between $270,000 and $279,999 for the year ended 31 March 2013. No donations have been made by the subsidiary. No amounts have been paid to the auditor by the subsidiary for the year ended 31 March 2013.

## Pacific Edge Pty Limited

The Company has a wholly owned subsidiary called Pacific Edge Pty Limited which was incorporated in Australia on 4 August 2008. This Company's purpose is to research and develop the Cxbladder product along with other diagnostic and prognostic tools for early detection and management of cancers. The Directors of the subsidiary are D. Darling, D. Band and B. Williams (who is a member of the Scientific Advisory Board for the Company). D. Band was paid Director's fees of $17,000 by the subsidiary.

There are no employees of Pacific Edge Pty Limited who received remuneration exceeding $100,000 in the year ended 31 March 2013. No donations have been made by the subsidiary. No audit fee was paid to the auditor by the subsidiary for the year ended 31 March 2013 (2012; $3,884).

For and on behalf of the Board of Directors,

Director Director

Dated the 27th day of June 2013.

Pacifc Edge Diagnostics USA, situated on the second floor of the HCAR building, Pennsylvania

Some of the Pacific Edge Diagnostics USA Team: Matthew Fountain (Laboratory Technician), Jackie Walker (CEO), Heather Carbaugh (Technical Supervisor).

# Chairman's and Chief Executive's Report

## Foreword from the Chief Executive Officer

2012 has been another significant year in the commercialisation of Pacific Edge. A number of great milestones have been achieved by the Pacific Edge people in New Zealand and the USA. Perhaps the most significant of these has been the initiation of our new business in the world's largest medical market, the USA. As a result, we have taken a major step towards realising the Company's vision of being a world leading cancer molecular diagnostic Company. In summary, in 2012 Pacific Edge has achieved all of our key commercial milestones that we set and raised funds for in 2011. A fantastic outcome.

On the market front, this year was all about building and substantiating the market acceptance of our products and understanding the adoption process for our innovative molecular diagnostic product Cxbladder by the clinicians. We have made great progress and we would expect to see this progress translate into commercial relationships during 2013.

A key part of this has been the building of the 'User Program'. This program has enabled us to put Cxbladder tests in the hands of a large number of clinicians over the last 12–18 months. Cxbladder has been under evaluation by physicians and clinicians in Australia, New Zealand, and the USA. One of the key learnings from the customer engagement through the User Programs is that Cxbladder is potentially needed and wanted by these clinicians for many more clinical endpoints than we had originally expected.

Looking forward to the financial year 2013–2014, we expect to see our initiatives in the 'User Program' translate into strong adoption in New Zealand and Australia as many of our 'User Programs' conclude and commercial arrangements are put in place with customers.

We have planned an aggressive sales program for the USA that will start in July 2013. We have put in place a number of new commercial systems and processes that will enable us to scale the business progressively and easily in response to the envisaged strong product demand. By the end of the 2013 financial year we expect Cxbladder to be selling well in our initial targeted sales territories in the USA and to have closed several commercial relationships with District Heath Boards (DHBs) or corporate entities in New Zealand.

2013 is expected to be a year of exciting growth for Pacific Edge as we push hard in the markets and grow our people in these new businesses.

## In summary

- We have entered the world's largest bio-medical market, the USA, and our laboratory is now commercially ready.
- We have recruited some outstanding people and will continue to recruit in 2013.
- We are looking to 2013 for a strong start to our revenue generation, particularly in the USA.

As we progress through 2013, we look forward to providing our shareholders and the wider market with our usual regular updates on the key events, the results of our work, and our business activities. We will also continue to review all market and other strategic opportunities that may help accelerate the commercialisation of our cancer diagnostics business.

We are grateful for the continued support of our employees, shareholders, customers, and partners in making this exciting business happen and we look forward to seeing our great products make a difference to healthcare globally and consequently delivering revenue to our business.

# Chairman and Chief Executive's Report (continued)

## PACIFIC EDGE MEETS ALL OF ITS COMMERCIAL GOALS IN 2012

Recruitment of the US subsidiary CEO Jackie Walker to lead the US Business.

Publication of the Cxbladder multicenter international study in the September 2012 edition of the prestigious Journal of Urology.

Build and fit-out of the new 260,000 test per annum laboratory in Hershey, Pennsylvania, on time, to specification and under budget.

Regulatory approval for the laboratory with registration by CLIA completed as planned in March 2013.

### Developing our business in the USA

Our primary goal in 2012 was to build, fit-out and gain regulatory approval for the new laboratory in Hershey, Pennsylvania. We achieved these objectives by firstly completing our laboratory in September 2012 on time, to plan, and within budget, a major achievement.

Secondly, in early 2013 we attained regulatory approval with the registration of the laboratory under the Clinical Laboratory Improvement Amendments (CLIA) in March 2013, on time, to plan, and within budget. This was another significant milestone for the Company as this then enabled us to start the many commercial processes that we had been developing in the background while awaiting the CLIA regulatory outcome, including the start of the recruitment and subsequent training of our sales and marketing team. This will roll out in 2013 and, as a result, we expect our sales activities to commence in July of 2013 and grow progressively during the year.

With the achievement of these major objectives, the Company's subsidiary, Pacific Edge Diagnostics USA, became commercially ready in late March of 2013.

Addressing the relevant clinical needs and challenges that clinicians face in their practices

# Chairman's and Chief Executive's Report (continued)

## Our Company has grown and developed significantly to deliver our commercial strategy

Pacific Edge is a cancer diagnostics Company. We develop and commercialise tests for the early detection and management of cancer.

Our first product that we have brought to the market, Cxbladder, is a bladder cancer detection test that requires a small sample of the patient's urine to be sent to one of our laboratories in New Zealand or the USA or one of our partner laboratories in Australia or Spain. The laboratory analyses the urine, measures the presence of five genes and determines, with a high degree of accuracy, whether the patient does or does not have bladder cancer.

We have successfully published our clinical trial results in the prestigious Journal of Urology in September 2012, consolidating for urologists the exciting performance of this test. Publication of peer-reviewed science papers is a key part of the awareness and validation of the Cxbladder product. However, it is not sufficient to just publish the results of the international, multicenter clinical study. We must also engage with the urologists to determine how this new and potentially market-disruptive product, can best work in their specific clinical practice. This awareness led to us putting in place our 'User Program' during the 2012 year.

For our laboratories and those of our selected partners, we have adopted a commercial operating strategy that enables us to take a technology platform agnostic approach. This means that we have been able to select for our laboratories world class operating platforms and equipment that can be purchased off the shelf, to analyse the expression of the proprietary RNA transcripts extracted from the patient urine. The laboratory equipment and consumables are specified as part of our 'Franchise-Like' systems and processes and as such are brought together with our standard operating procedures to ensure a high degree of repeatability in our laboratories. This ensures that we can deliver to clinicians a highly consistent user experience globally.

## Building our 'Cx' brand

Long-term value capture for Pacific Edge is based on us delivering on our brand 'Cx'. To enable the building and long-term development of our brand, we have wrapped up our bladder cancer technology as a set of 'Franchise-Like' systems and processes and made these available to our own subsidiaries and to our selected partners. By 'Franchise-Like' we mean a standardisation of the operating protocols, consumables and equipment used in the laboratory performing the Cxbladder test. These franchised processes are designed to give the urologist customer a fast turnaround time with highly repeatable results and a consistent customer experience.

Today as a Company we arrange and direct all of the key steps necessary to provide commercially successful molecular diagnostic tests. From the baseline of addressing the relevant clinical needs and challenges that the clinicians face in their practices, we develop, validate and provide commercial tests for these clinicians to meet these needs. Our business also now includes the marketing and sales of our products to the physicians and patients.

During the year we have reviewed and updated all of our marketing collateral including our website. This has been necessary for our rollout in the highly regulated USA operating environment but has also enabled us to take a global approach to these 'In-Market' assets. In 2013 we will consolidate and then grow our presence using the many social media technologies as a vital part of reaching the patient, who is the end user customer. Many patients are unaware of the presence of Cxbladder and the potential upside that such a non-invasive test can bring to their bladder cancer detection and management program.

## Rolling out the 'Franchise-Like' business model

The use of this 'Franchise-Like' model has enabled us to successfully run two parallel areas within our business model. The first of these consists of the ownership and management of our own laboratories in key selected markets such as New Zealand and the USA. The second is to identify other compelling markets and select partners with the appropriate skills, capability and desire to deliver Cxbladder to clinicians and physicians who are the targeted customers in those specific markets. On this basis we have started with the appointment of partners, Healthscope in Australia and Oryzon in Spain. We look forward to supporting our partners to perform and provide a significant contribution to our revenue in 2013. The first of our USA urologists to participate in the 'User Program' has now concluded in excess of one hundred Cxbladder tests where Cxbladder has successfully been evaluated in a large variety of challenging clinical cases and settings.

## The 'User Experience'

We have learnt in 2012 that we, Pacific Edge, are the best advocates of our diagnostic products and that we need to drive the in-market initiatives with our customers to gain awareness, evaluation and adoption of Cxbladder. As part of this drive for adoption, the Company has initiated and been running an extensive 'User Program' with urologists. The 'User Program' enables individual urologists to use Cxbladder in their own clinical setting to address their specific needs, generate performance data and to be able to compare this to their standard practice.

During 2012, and for the next few months into 2013, the Company has 'User Programs' in the USA, Australia, and New Zealand totaling in excess of 2000 tests. This has resulted in urologists identifying seven specific clinical needs that they wish to use Cxbladder to address. We have been delighted with this program to date and will be looking to shift these relationships from the 'User Program' into full commercial relationships that will add to our revenue in 2013 (Figure 1).

### **FIGURE 1:** Cxbladder: VALUE PROPOSITIONS TO THE CLINICIAN

**Triage micro-haematuria patients:** Identify and remove those patients who do not require a full clinical work-up.

**Replace Cytology:** Substitute Cxbladder for all cytologies in the clinical practice to enable greater accuracy of bladder cancer detection.

**Detect bladder cancer during BCG treatment:** Use Cxbladder when cystoscopy cannot be used by the clinician due to high inflammation.

**Replace NMP22:** NMP22 is used by some clinicians for the detection of bladder cancer. Cxbladder has a significantly greater accuracy.[1]

**Replace CT scans in primary work-up:** Cxbladder can be used in conjunction with Cystoscopy to lower the potential use of double contrast CT scans for the detection of upper urinary tract cancers.

**Adjunct to cystoscopy:** Cytology is currently the preferred adjunct to cystoscopy. Cxbladder is more accurate in all aspects and will become the preferred adjunct to cystoscopy.

**Replace some cystoscopies:** Lengthen cycle between cystoscopic examination, particularly in older patients.

Cxbladder is being used by clinicians in their 'User Programs' for an increasing number of different clinical end points in their clinical work-ups for haematuria and bladder cancer.

[1] J Urol. 2012 Sep;188(3):741-7
A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria.
O'Sullivan P, Sharples K, Dalphin M, Davidson P, Gilling P, Cambridge L, Harvey J, Toro T, Giles N, Luxmanan C, Alves CF, Yoon HS, Hinder V, Masters J, Kennedy-Smith A, Beaven T, Guilford PJ.
Pacific Edge Ltd, Dunedin, New Zealand.

# Chairman and Chief Executive's Report (continued)


## Our focus

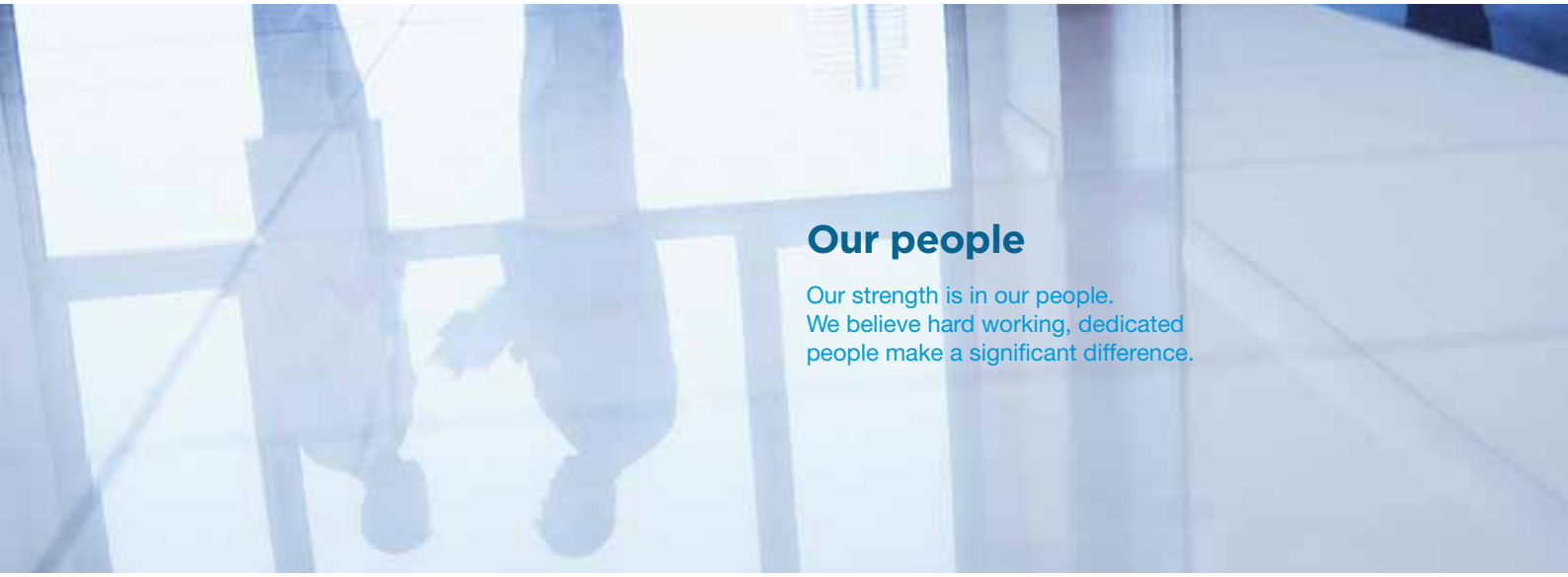
The development of state-of-the-art cancer diagnostics and prognostics.

## Our goal

To deliver actionable results that can contribute to a clinically meaningful difference in cancer treatment.

## Our motivation

To meet and exceed expectations.
Never stand still or accept second best.



## Our people

Our strength is in our people.
We believe hard working, dedicated
people make a significant difference.

# Chairman's and Chief Executive's Report (continued)

## The market for Cxbladder in the USA

There is an acute need in the USA for an effective clinical tool that will help the urologists and physicians detect and manage bladder cancer and the awareness of Cxbladder's capability in helping address those needs is growing. A number of our 'User Programs' are concluding in New Zealand and Australia and we hope to share these great results with you in 2013.

The USA biomedical market is the largest in the world and the population and demographics show a high bladder cancer incidence. Cxbladder has an opportunity to make a significant difference to how this cancer is detected and managed. Treatment of bladder cancer incurs the highest total medical costs of any cancer and in the USA this figure is approaching US $200,000 per patient from detection until death. In the USA there are expected to be up to two million people presenting to their healthcare provider this year with blood in their urine, haematuria, and it is anticipated that the USA healthcare system could spend over US $1.5 billion annually in investigating haematuria.

Bladder cancer is mostly an older person's disease. In the USA between 2006–2010 the median age at diagnosis was 73 years. However 58.5% of these people were between the ages of 65 and 84 years of age.

In the USA bladder cancer is four times more likely in men than in women and it is the 4th most common cancer for men, the 12th most common for women and 9th most common for both men and women. In 2013 there is estimated to be 72,570 new cases of bladder cancer in the USA, of which 54,610 will be in men and 17,960 in women.

Mortality is high for bladder cancer despite timely clinical intervention and possibly because of the suite of mostly poor tools at the disposal of the clinician to detect and manage this disease. In the USA the median age for death was 79 years of age during the period from 2006 to 2010 with 55.9% of these people aged between 65 & 84[1]. It is estimated that there will be 15,210 deaths from bladder cancer for both men and women in 2013[2].

Bladder cancer affects many age groups and all ethnicities despite the predominance of older people in this population. However, bladder cancer incidence is more common in the USA in white people than in any other racial and ethnic group (Figure 2).

The majority of these bladder cancer incidences are white men over the age of 60 years. White men are about two times more likely to develop bladder cancer than African American men.

[1] [2] Annual Report to the Nation on the status of cancer 1975–2007, Oxford University Press 2011.

[3] Source: Med Info Graphics.

**FIGURE 2:** USA BLADDER CANCER INCIDENCE RATES BY ETHNICITY[3]

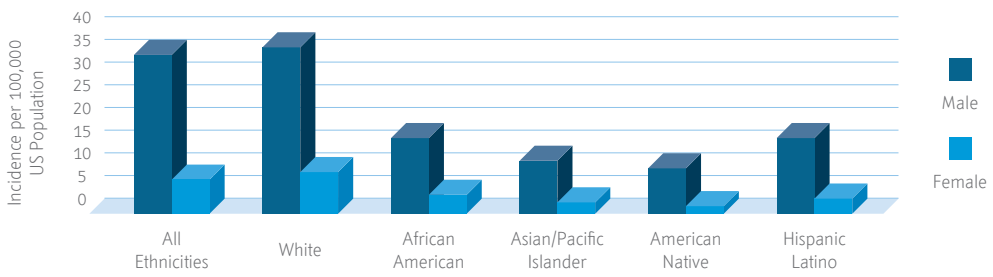



Figure 2 outlines the USA incidence rate for bladder cancer based on the 2007 figures.
The rates are per 100,000 people and are age adjusted to the USA standard population in 2000.

When we translate these bladder cancer incidence statistics into a financial model of the market for bladder cancer, we are able to define a maximum number of potential tests for this market in excess of two million tests per annum.

These incidence statistics are useful to understand the extent and breadth of the bladder cancer market. However, we need to note that Cxbladder is targeted to be used on people presenting to their physician or urologist with blood in their urine, haematuria, a potential symptom of bladder cancer. This market segment is many times greater than the incidence statistics, as approximately 12.5% of all gross haematuria (visible blood) will have bladder cancer compared with only 5% of those who present with non-visible blood in their urine (micro-haematuria) will have bladder cancer. Identifying and managing these patients who have bladder cancer from those who present with haematuria is the clinical proposition that we provide with the use of Cxbladder.

This number of potential tests, outlined in Figure 3, assumes that Cxbladder would or could be used as the test of preference to accompany the industry gold standard, cystoscopy, for all those people presenting with gross haematuria, but does not include those who present with micro haematuria. We believe that this is a conservative estimate of total market size.

When we look at a realistic penetration of this USA market by Cxbladder, we can quickly see that even conservative estimates have the potential to provide us with a significant business. We have estimated that this business could generate gross revenue for Pacific Edge in excess of $100 million by the end of our 5th year of trading in the USA. We look forward to reporting to you on our progress in attaining this goal.

**FIGURE 3:** THE EXPECTED NUMBERS FOR THE Cxbladder MARKET

| Market | Population (millions) | Patients presenting with Haematuria [1] | Potential total market (annual number of tests) [2] | Expected cost of Haematuria [1] evaluation on national health systems (US $) | Number of urologists (approximate) |
|---|---|---|---|---|---|
| NZ and Aust | 24 | 50,000 | 85,000 | 50 million | 300 |
| Spain | 42 | 200,000 | 300,000 | 200 million | 1,350 |
| USA | 327 | 1 million | 2,000,000 | 1 billion | 10,000 |

[1] Haematuria refers to blood in the patient's urine, a potential symptom of bladder cancer.
[2] Under current clinical guidelines, patients diagnosed with bladder cancer will require repeat testing over a period of years.

**FIGURE 4:** THE COMMERCIAL CENTRES FOR Cxbladder IN 2013

# Chairman and Chief Executive's Report (continued)

## BUSINESS OPPORTUNITIES AND RISKS

The market opportunities for Pacific Edge are large, particularly in the USA. In the USA there is expected to be approximately two million people presenting to clinicians and physicians with blood in their urine, either micro or macro haematuria, each year. Nearly all of these could be have one or more Cxbladder tests as part of their clinical regime.

While many of the risks for Pacific Edge decrease and fall away as a result of activities over the year, there remain a number of potential risks and some new ones that the Company has limited, if any, control over. Some of these have been identified here and we have attempted to outline how we expect to mitigate them.

Pacific Edge is a commercial entity operating in the field of molecular diagnostics in a number of international markets. We expect to grow these markets and add further new and exciting products and markets. By doing so, we limit Pacific Edge's and Cxbladder's exposure to any major market disruption.

We continue to own and manage the businesses in the key target markets and to license out the commercialisation of Cxbladder to selected partners where we seek the upside in having local skills, capability and knowledge. This further mitigates any risk that we may encounter in markets outside New Zealand.

The Company's products are diagnostic and prognostic gene tests, for the early detection and management of cancer. As such, Pacific Edge is subject to many industry-specific and Company-specific opportunities and risks. These could, individually or combined, dramatically affect our future revenue or earnings and have a negative impact on our future financial situation, as well as our share price.

### In-market opportunities and risks

We have launched Cxbladder now in the USA, Australia and New Zealand, with Spain expected to start in 2013. Whether we can bring in strong revenue from our bladder cancer diagnostic test will depend partly on how well we market and commercialise the test with clinicians and physicians and insurers. We have launched the products successfully in our diagnostic laboratories and now look to continue the work to gain broad acceptance by the medical community and third-party payers in each country. This is a herculean task and in 2012 we made significant advances in New Zealand and Australia. 2013 will be the year for the USA. The initiation of the 'User Program' in New Zealand and Australia has been a significant component in helping build and grow the acceptance and clinical utility of Cxbladder.

It is critical for us to get reimbursed for the tests by third parties and gain mass acceptance. We and our partners are acutely aware of the need to convince key private health organisations and guideline-issuing bodies to include our tests in their cancer-screening guidelines. Many of these processes have been initiated in New Zealand and Australia and will continue to be a feature in 2013.

Pacific Edge plans to take the Cxbladder test direct to the market in the USA through our own central laboratory in Hershey, Pennsylvania. Our current business model for this move involves offering Cxbladder to clinicians and physicians through a laboratory certified under the Clinical Laboratories Improvement Amendments (CLIA certified laboratory) as a 'Laboratory-Developed Test' (LDT). This approach does not currently require FDA approval. However, in the longer term it is anticipated that Pacific Edge may seek FDA approval and that the FDA may take a greater overview of all LDTs in the USA.


Cxbladder, the difference in cancer detection.

# Chairman's and Chief Executive's Report (continued)

Under this model, we will also depend on our partners to develop, commercialise, sell and distribute our products based on our licensed markers/technologies under the specific terms and conditions of our franchised-like processes.

Through partnering and licensing, we can leverage our marketing efforts to generate early revenue in the form of royalty income. Having launched Cxbladder in the Asia/Pacific region and with the expectation of launching in Europe in 2013, in collaboration with our partners Healthscope and Oryzon, we are now well underway with our own laboratory and commercial business in the strong USA market.

We are also subject to certain partnering-related risks. Our partnerships are still new and need to develop their full commercial potential in the future. We still intend to close additional non-exclusive licensing and partnering deals for Cxbladder so we can access the widest possible global market. We are currently in discussion with other new potential partners, but with no assurance that we will obtain favourable terms. Successful marketing by our existing partners will obviously play a big part. Changes in their corporate plans are beyond the influence and control of Pacific Edge.

By building an extensive clinical network for our Cxbladder clinical study as well as for the in-market cohort studies in Spain and Australia, we have partly mitigated the risk of getting timely access to enough high-quality patient samples. This clinical network in New Zealand, Australia and Spain allows us to tap into huge resources and to leverage our existing partnerships for gaining further partners in Europe and Asia. We have used these relationships to great effect in our 'User Program' in 2012.

The bladder cancer diagnostic field has yet to see any intense competition and we do not foresee any in the immediate future. However, it is very likely that there are some unknown competitors who could be expected to have made progress over the past year in developing other non-invasive bladder diagnostic tests. Our commercialisation partners and ourselves must strongly leverage the lead we have in clinical validation with Cxbladder and build a strong and loyal customer base. To this end Pacific Edge has in development other bladder cancer tests that address other specific bladder cancer needs. It is anticipated that the Company will bring these to market as Cxbladder builds a strong customer base for the first product Cxbladder $_{\text{DETECT}}$.

## IP-related opportunities and risks

Our business relies heavily on commercialising our intellectual property in the form of know-how, licenses to third-party patents and our patent applications. At risk are such things as:

- The scope, duration, depth and breadth of each single claim granted.
- The regional coverage.
- The competing IP that we could depend on.
- Our ability to enforce the protection.
- The potential for accidental infringment of other IP.
- Prevention of others from infringing our IP.
- Our ability to in-license key IP.

Any of these factors could affect our cost base, how we commercialise our products and close alliances, our revenue and ultimately our earnings and overall commercial success.

In some jurisdictions, we might face a challenge to the validity, ownership or legal enforceability of our patents. If a competitor were to successfully challenge our patents or even just limit the coverage of our patents, we could lose important patent protection of our technologies. We would also find it hard to prevent others from using those technologies without compensating us. Litigation is very costly, and any delay in commercialising our products could divert our management's attention and resources.

Since we have grown our business from developing new products to marketing and selling them, patent protection is now even more important in preventing competitors from launching competitive products based on our biomarkers. To that end, we have conducted analyses on intellectual property in these and related fields for our key markets. In some instances we have taken forward-looking licenses to hedge the event of others' IP impacting on us.

We have made great progress in expanding our IP portfolio and getting several key patents granted for cancer diagnosis and prognosis (such as our Cxbladder biomarkers in New Zealand). This puts Pacific Edge in a strong position to provide attractive licensing opportunities for the growing number of commercial parties who are commercially active in molecular diagnostics. Our recent licensing deals underscore this opportunity.

## Regulatory and reimbursement opportunities and risks

The regulatory environment in cancer molecular diagnostics has become more challenging, especially concerning laboratory-developed tests/homebrew assays in the USA market. This could affect our timing and cost as well as our ability to meet such regulatory standards. In part, the regulatory frameworks are not fully established or clarified, as evidenced by a number of warning letters sent by the FDA to a number of diagnostics companies and large reference laboratories. This could damage our ability to generate revenue and put a burden on our cost base and earnings, financial position and competitiveness.

To mitigate this risk and prepare for any potential issues, we have sought advice from experienced advisors and others who have traversed this regulatory landscape. Any change is likely to take some time, and lag behind any changes to healthcare systems. The FDA retains the right to review all processes, including CLIA and LDT.

By way of example, when the FDA mooted increasing regulatory process over 'In-Vitro Diagnostic Multi-Index Assays' (IVDMIAs), this drew a strong response from molecular diagnostic companies. As a result, the agency's suggested changes were taken back to the bench. For us, this means that any such changes could increase the cost or complexity of taking our products to the market should we need to or choose to market the technology with any commercialisation route that can be impacted on by the FDA.

The USA healthcare system is under severe duress and recent legislative changes in the 'Obama Care' initiative have begun to impact their market. Whilst generally these have an exciting upside opportunity to gain reimbursement recognition for a value-gain approach, these changes could slow up our progress and possibly cause us to change reimbursement tactics.

One recent change has been the removal of the CPT coding system by the CMS (Centre for Medicare and Medicaid). The CPT coding system enabled companies to 'Price-Out' their new technology using existing codes for the technology components and so gain revenue early before building 'In-Contract' relationships with the CMS and other insurance payers.

The CMS have implemented 'Interim' new codes and the impact of this change is largely unknown. However the longer-term effect is expected to be that companies will need to enter into 'In-Contract' negotiations with the CMS and other payers at an earlier stage in their commercialisation rollout than has been required under the old regime.

Pacific Edge has recognised this change and employed a dedicated specialist to oversee and manage the CMS relationship, with a recent appointment to the role of Director of National Accounts and Payer Relationships.

# Chairman's and Chief Executive's Report (continued)

## Financial opportunities and risks

As at 31 March 2013, our available liquidity (cash, cash equivalents and marketable securities) amounted to $NZ 10.676 million. This capital is the residual from the capital raised during the 2011 year. With the funds raised we planned in 2012 to build our new US business and start the generation of revenue. These funds were generated to provide the Company with enough liquidity for our medium-term operations, to enable us to take advantage of Cxbladder in the marketplace and in the USA in particular. With the expectation of receiving greater revenue in 2013, the Company's short to medium-term financial risks are reduced. Pacific Edge has been very successful in achieving its objectives in full, on time and within budget. The rate of adoption of Cxbladder in the USA market and corresponding sales will determine whether we have sufficient capital reserves to carry us through to a break-even and standalone position.

Should expansion opportunities occur for the existing product in a new geography or for one of the Company's pipeline products, the Company may seek to raise additional capital to expedite the market opportunity.

Our operating activities are still making a loss and therefore consuming cash. With our recently announced licensing partnerships, we would reasonably expect an increasing revenue stream from product royalties as we enter and gain momentum in Australia, New Zealand, Spain, Portugal and the USA. Successful entry, adoption of the product and rapid penetration in these markets, particularly the USA, will also further reduce any financial risks.

Commercially we are now located in New Zealand and Australia and plan on growing our presence in the USA as we move into our sales program for Cxbladder in July 2013 with the vision to operate globally with Cxbladder either through partnerships or wholly owned subsidiaries. We are therefore subject to foreign-exchange rate risks. At present, this is mainly limited to the AUD/NZD, USD/NZD and NZD/Euro relationships. In the future, our partners' and distributors' net sales may also be subject to foreign exchange risks and so our expected royalties may be indirectly exposed to additional price risks. We will monitor these risks regularly and evaluate, for individual instances, whether we can reduce exposure from a single risk or risk bundle by hedging transactions. We should also mention that foreign currency-related transactions always offer opportunities as well.

## Other opportunities and risks

We continuously monitor all applicable environmental, health-and-safety, operational and other statutory or industrial guidelines. At each of our business or laboratory locations, we have implemented functions and internal processes to comply with these. To lessen the impact from the many tax, corporate, employment, competition, IP and other legal frameworks, we consult external experts in our decision-making, policies and processes. Where appropriate, we set aside provisions to cover any potential liability.

There are particular risks associated with our shares, such as:

- The large holdings of a small number of private equity and/or institutional shareholders.
- Low levels of liquidity in the shares.
- Resulting high volatility in share price.
- External influences from global recession impacting on investor confidence.
- Negative perceptions of any share sale.

At the same time, the relatively small number of shareholders in Pacific Edge allows us to communicate to all on a regular basis.

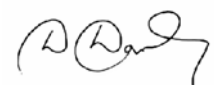
There may well be other risks and opportunities that we currently either consider insignificant or do not know about at the time of this annual report's preparation.

## Overall risk situation of Pacific Edge

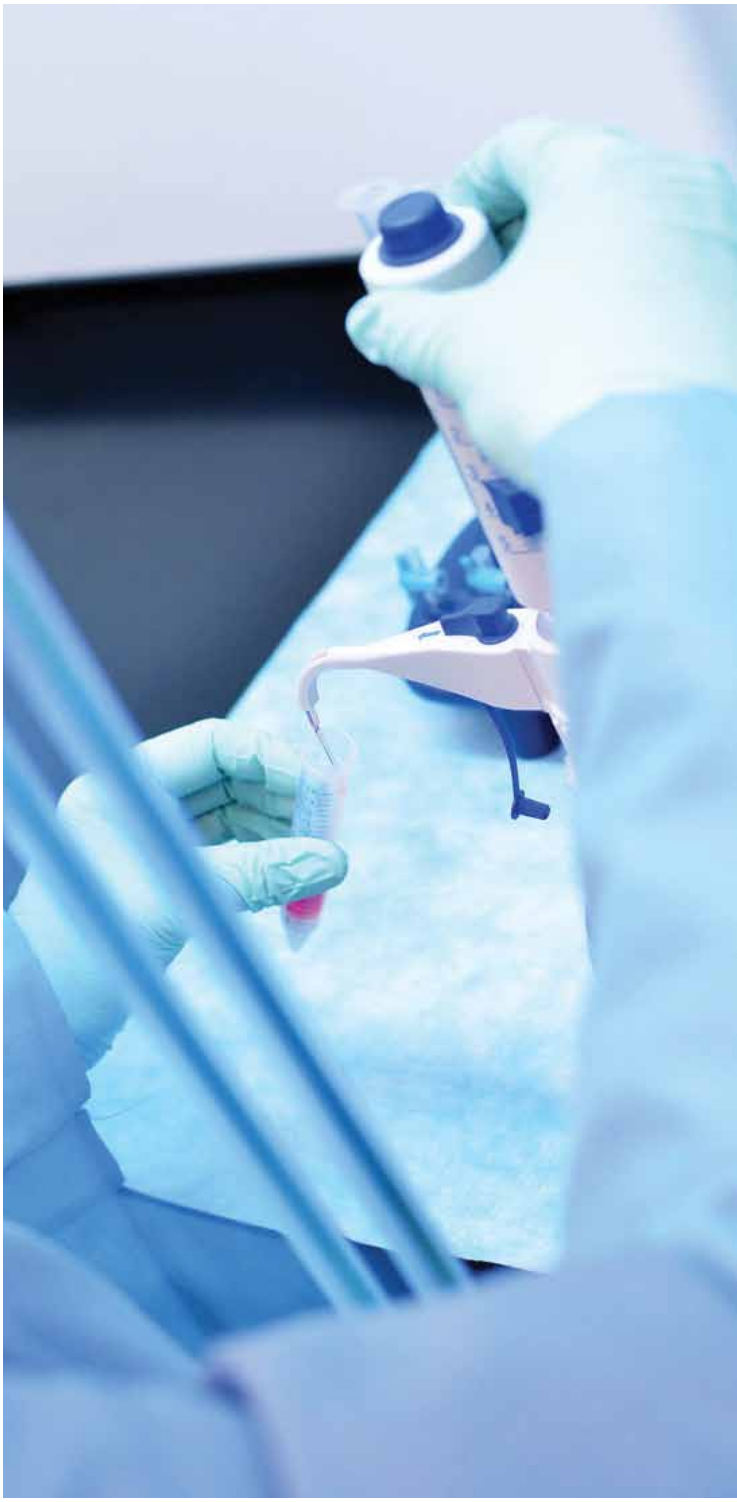
Pacific Edge holds significant capital received from the fund-raising completed in mid-2011 to continue with the commercialisation of the Cxbladder business in the USA as planned. The progress of sales that are achieved in our first six months of selling, beginning in July 2013, will determine whether we need further capital to grow our business in the USA and other new markets. The recent publication of the multicenter, international clinical study for Cxbladder, in September 2012, in the Journal of Urology, which consolidates for urologists that the successful Cxbladder clinical study met its primary aims; multiple commercial partners signed up in key markets and the launch of the roll-out of Cxbladder into the Australian market and the commercial start of the build-out of the business in the USA market means the Company has lowered or removed a number of the risks of the investment case.

With so much of the product development of Cxbladder completed, the logistics chain for the Urine Sample System (U.S.S.) completed, regulatory approvals for the U.S.S. for Cxbladder completed in some markets and underway in others, we see many of the clinical-development risks reduced. We continue to focus on managing our commercial execution risks. These include guideline inclusion and reimbursement in major markets; future product development; and regulatory approval in some markets and sustained reimbursement in the USA.

Chairman



Chief Executive Officer



# Directors' Responsibility Statement

The Directors are responsible for ensuring that the financial statements give a true and fair view of the financial position of the Company and Group as at 31 March 2013 and its financial performance and cash flows for the year ended on that date.

The Directors consider that the financial statements of the Company and Group have been prepared using appropriate accounting policies, consistently applied and supported by reasonable judgements and estimates and that all relevant financial reporting and accounting standards have been followed.

The Directors believe that proper accounting records have been kept which enable, with reasonable accuracy, the determination of the financial position of the Company and Group and facilitate compliance of the financial statements with the Financial Reporting Act 1993.

## CORPORATE GOVERNANCE

### Role of the Board of Directors

The Board of Directors of Pacific Edge Limited is elected by the shareholders to supervise the management of the Company. The Board establishes the Company's objectives, strategies for achieving these objectives, the overall policy framework within which the business of the Company is conducted, monitors management's performance and ensures that procedures are in place to provide effective internal financial control.

The day-to-day management responsibilities of the Company have been delegated to the Chief Executive Officer.

### Corporate Governance Practices in the Constitution

The Company's constitution sets out guidelines for Directors and management in carrying out their duties and responsibilities. The constitution requires that the Board comply with the Listing Rules and the Companies Act 1993. The provisions in the Second Schedule to the Company's constitution govern the proceedings of the Board. The Company's constitution covers matters such as:

- General corporate governance matters.
- Role of the Board.
- Composition of the Board.
- Directors' responsibilities.
- Appointment and removal of directors (including executive and alternate directors).
- Powers and rights of Directors.
- Remuneration of Directors.
- Confidentiality and protection of Company information.
- Compliance with laws and regulations.
- Shareholder participation, rights, and obligations.
- Company transactions.
- Conflicts of interest.
- Protection of Company assets.

The primary responsibilities of the Board include ensuring compliance with the Company's constitution, setting up clear goals for the Company and ensuring that there are appropriate strategies in place for achieving them, monitoring the performance of management, managing the Company's financial position and financial statements, ensuring that the Company follows high standards of ethical and corporate behaviour, and ensuring that the Company has appropriate risk management policies in place. Newly elected Directors are expected to be familiar with their obligations under the constitution. Training is also provided to new and existing Directors where this is required to enable Directors to fulfil their obligations under the constitution.

## Board Membership

The Board has been selected on their individual skills and contribution to the Company. The Board is comprised of 4 non-executive Directors including the Chairman Chris Swann, David Band, Colin Dawson and Anatole Masfen. The Chairman is a non-executive Director who is elected as Chairman by the Directors.

In accordance with the Company's constitution, one third, or the number nearest to one third, of the Board retire by rotation at each annual meeting. The Directors to retire are those who have been longest in office since the last election. Directors retiring by rotation may, if eligible, stand for re-election. A Director appointed since the previous annual meeting holds office only until the next annual meeting but is eligible for re-election at that meeting.

## Sub Committees

The Board forms subcommittees for designated tasks to be addressed. Such subcommittees include the Audit Subcommittee, the Nomination Subcommittee and the Remuneration Subcommittee.

## Internal Financial Control

The Board has overall responsibility for the Company's system of internal financial control. The Directors have established procedures and policies that are designed to provide effective internal financial control. Annual budgets and business plans are prepared, and agreed by the Board. Financial statements are prepared monthly and reviewed by the Board throughout the year to monitor performance against budget targets and objectives.

The Directors are responsible for presenting the financial statements for each financial year.

## Audit Committee

The Company's constitution requires it to have an Audit Committee comprised solely of Directors of the Company, with the majority of members being independent Directors. There must be at least three members in the Audit Committee and at least one member must have an accounting or financial background. Under the constitution the responsibilities of the Audit Committee include as a minimum:

- Ensuring that the processes are in place in monitoring those processes so that the Board is properly and regularly informed and updated on corporate financial matters.
- Recommending the appointment and removal of the independent auditor.
- Monitoring and reviewing the independent and internal auditing practices.
- Having direct communication with and unrestricted access to the independent auditors and any internal auditors or accountants.
- Reviewing the financial reports and advising all directors whether they comply with the appropriate laws and regulations.
- Ensuring that the external auditor or lead audit partner is changed at least every five years.
- The Audit Committee comprises 3 independent Directors, Chris Swann, David Band and Colin Dawson.

## Nominations Sub Committee

The Board has established a Nominations Committee to recommend Director appointments to the Board. The committee members are Colin Dawson, David Band and Chris Swann, who are all independent Directors.

# Directors' Responsibility Statement (continued)

## Remuneration Committee

The Board has a remuneration committee to recommend the remuneration for Directors to the shareholders. The members of this committee are Colin Dawson, David Band and Chris Swann.

## Conflicts of Interest

The constitution sets out a procedure to be followed where Directors are faced with a potential conflict of interest. At all times a Director must be able to act in the interests of the Company as a whole and in accordance with all relevant laws including the NZX Listing Rules and the Companies Act 1993.

The personal interests of a Director must not be allowed to prevail over those of the Company and its shareholders generally. The constitution requires a Director to disclose any personal interests to the Company which may conflict with the Company's interest.

The Company's constitution provides that a Director may:

- contract with the Company and be a party to any transaction with the Company.
- have any personal involvement or interest in any transaction or arrangement to which the Company is a party or is otherwise interested or involved.
- become a Director or other officer of, or otherwise be interested in, any corporation promoted by the Company or in which the Company may be directly or indirectly interested as a shareholder or otherwise.
- retain any remuneration profits or benefits in relation to any of these arrangements.

However a Director who is interested in a transaction that is entered into by the Company may not vote on a Board resolution in respect of any matter relating to the transaction unless that matter is one in which the Directors are either required to sign a certificate or where the matter relates to an indemnity.

## Compliance with NZX and Securities Commission Guidelines

The Company's governance policies are consistent with the NZX Corporate Governance Best Practice Code and meet the 9 Principles for Corporate Governance issued by the Securities Commission and set out on the Financial Markets Authority website.

In summary, the 9 principles are:

1. Ethical Standards – Directors should observe and foster high ethical standards.
2. Board Composition – There should be a balance of independence, skills, knowledge, experience, and perspectives among directors so that the board works effectively.
3. Board Committees – The Board should use committees where this would enhance its effectiveness in key areas while retaining board responsibility.
4. Reporting and Disclosure – The Board should demand integrity both in financial reporting and in the timeliness and balance of disclosures on entity affairs.
5. Remuneration – The remuneration of Directors and Executives should be transparent, fair, and reasonable.
6. Risk Management – The Board should regularly verify that the entity has appropriate processes that identify and manage potential and relevant risks.
7. Audits – The Board should ensure the quality and independence of the external audit process.
8. Shareholder Relations – The Board should foster constructive relationships with shareholders that encourage them to engage with the Company.
9. Stakeholder Interests – the Board should respect the interests of stakeholders within the context of a company structure and its fundamental purpose.

## Reporting and Disclosure

The Board focuses on providing accurate, adequate and timely information both to existing shareholders and to the market generally. This enables all investors to make informed decisions about the Company. All significant announcements made to NZX, and reports issued, are posted on the Company's website.

The Directors have pleasure in presenting the financial statements, set out on pages 30 to 62 for Pacific Edge Limited and the consolidated Group for the year ended 31 March 2013.

The Board of Pacific Edge Limited authorised these financial statements for issue on 27 June 2013.

For and on behalf of the Board of Directors,

Chairman

Director

Chief Executive Officer

Dated the 27th day of June 2013.

# Statements of Comprehensive Income

| | | Notes | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|---|---|
| **OPERATING REVENUE** | | | | | | |
| Cxbladder Sales | | | 15,022 | 9,615 | – | – |
| Grant Received | | **4** | 158,377 | 106,669 | 158,377 | 106,669 |
| Licence Fees | | | 4,530 | 163,502 | 115,992 | 163,502 |
| Interest Earned | | | 333,190 | 341,790 | 333,184 | 364,723 |
| Other Income | | | 4,419 | 24,926 | 210,728 | 159,250 |
| **Total Operating Revenue** | | | **515,538** | **646,502** | **818,281** | **794,144** |
| **LESS EXPENSES** | | | | | | |
| Audit Remuneration | Audit Fees | | 20,700 | 19,550 | 20,700 | 19,550 |
| | Other Assurance Services | | – | 7,194 | – | 3,310 |
| | | | **20,700** | **26,744** | **20,700** | **22,860** |
| Directors' Fees | | | 88,417 | 104,000 | 71,417 | 104,000 |
| Depreciation | | **5** | 195,213 | 177,907 | 66,133 | 82,465 |
| Currency Exchange Loss | | | 91,571 | 96,001 | 92,355 | 96,001 |
| Conference & Travel | | | 502,967 | 349,212 | 215,627 | 327,588 |
| Stock Exchange & Registry Fees | | | 147,187 | 105,892 | 147,187 | 105,892 |
| Leases | Rent of Premises | **6** | 365,037 | 144,725 | 134,502 | 122,356 |
| | Copier | | 11,553 | 11,974 | 11,553 | 11,974 |
| | | | **376,590** | **156,699** | **146,055** | **134,330** |
| Research | Employee Benefits | | 2,172,193 | 1,303,428 | 1,099,018 | 1,149,688 |
| | Consultants | | 420,609 | 869,871 | 71,946 | 307,565 |

*Note: These Statements are to be read in conjunction with the Notes to the Financial Statements.*

| | | Notes | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|---|---|
| Research | Clinical Trials | | 995,670 | 192,417 | 28,823 | 140,728 |
| | Consumables | | 141,913 | 89,165 | 85,491 | 7,797 |
| | Contract Services | | 143,647 | 121,703 | 70,512 | 121,703 |
| | Patents/ Trademarks | | 414,052 | 598,187 | 412,782 | 598,187 |
| | CX Bladder Development | | 733,193 | – | 100,201 | – |
| | | | **5,021,277** | **3,174,771** | **1,868,773** | **2,325,668** |
| Write down of investment and advance to subsidiaries | | **13** | – | – | 4,805,160 | 1,124,725 |
| Other Expenses | | | 984,980 | 563,518 | 330,273 | 369,457 |
| Interest Expense | | | 3,351 | 2,668 | 3,351 | 1,604 |
| **Total Expenses** | | | **7,432,253** | **4,757,412** | **7,767,031** | **4,694,590** |
| **NET (LOSS) BEFORE TAX** | | | **(6,916,715)** | **(4,110,910)** | **(6,948,750)** | **(3,900,446)** |
| Income Tax Expense | | **7** | – | – | – | -– |
| **(LOSS) FOR THE YEAR AFTER TAX** | | | **(6,916,715)** | **(4,110,910)** | **(6,948,750)** | **(3,900,446)** |
| Translation Foreign Operations | | **19** | (33,163) | 3,472 | – | 3,472 |
| **TOTAL COMPREHENSIVE INCOME/(LOSS)** | | | **(6,949,878)** | **(4,107,438)** | **(6,948,750)** | **(3,896,974)** |
| Earnings per share for profit attributable to the equity holders of the Company and Group during the year | | | | | | |
| Basic Earnings per share | | **3** | (0.025) | (0.018) | (0.025) | (0.017) |
| Diluted Earnings per share | | **3** | (0.025) | (0.018) | (0.025) | (0.017) |

*Note: These Statements are to be read in conjunction with the Notes to the Financial Statements.*

# Statements of Changes in Equity

| | Notes | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|---|
| **EQUITY AT START OF YEAR** | | | | | |
| As previously reported | | 17,677,922 | 2,690,644 | 17,677,922 | 2,690,644 |
| Prior year adjustment | **28** | (28,204) | – | 182,260 | – |
| **As restated** | | **17,649,718** | **2,690,644** | **17,860,182** | **2,690,644** |
| | | | | | |
| **(LOSS) FOR YEAR** | | **(6,916,715)** | **(4,110,910)** | **(6,948,750)** | **(3,900,446)** |
| Translation Foreign Operations difference | | (33,163) | 3,472 | – | 3,472 |
| **Total Comprehensive Loss** | | **(6,949,878)** | **(4,107,438)** | **(6,948,750)** | **(3,896,974)** |
| | | | | | |
| **TRANSACTION WITH OWNERS IN THEIR CAPACITY AS OWNERS** | | | | | |
| Owners Contribution | **17** | 445,363 | 20,128,024 | 445,363 | 20,128,024 |
| Issue Expenses | **17** | – | (1,061,512) | – | (1,061,512) |
| **Total** | | **445,363** | **19,066,512** | **445,363** | **19,066,512** |
| | | | | | |
| **EQUITY AT END OF YEAR** | | **11,145,203** | **17,649,718** | **11,356,795** | **17,860,182** |

## Equity Comprises:

| | Notes | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|---|
| **Share Capital** | | | | | |
| Opening Balance | | 46,153,930 | 27,087,418 | 46,153,930 | 27,087,418 |
| Shares Issued | | 445,363 | 19,066,512 | 445,363 | 19,066,512 |
| **Closing Balance** | **17** | **46,599,293** | **46,153,930** | **46,599,293** | **46,153,930** |
| | | | | | |
| **Accumulated Losses** | | | | | |
| Opening Balance — as restated | | (28,507,684) | (24,396,774) | (28,297,220) | (24,396,774) |
| Net (Loss) for the year | | (6,916,715) | (4,110,910) | (6,948,750) | (3,900,446) |
| **Closing Balance** | **18** | **(35,424,399)** | **(28,507,684)** | **(35,245,970)** | **(28,297,220)** |
| | | | | | |
| Reserves | | | | | |
| Translation Currency Reserve | **19** | (29,691) | 3,472 | 3,472 | 3,472 |
| | | | | | |
| **EQUITY AT END OF YEAR** | | **11,145,203** | **17,649,718** | **11,356,795** | **17,860,182** |

*Note: These Statements are to be read in conjunction with the Notes to the Financial Statements.*

# Balance Sheets

| | Notes | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|---|
| **CURRENT ASSETS** | | | | | |
| Cash and Cash Equivalents | **8** | 10,676,307 | 17,959,469 | 10,498,206 | 17,935,620 |
| Receivables | **9** | 132,206 | 207,380 | 198,373 | 346,155 |
| Other Assets | **10** | 204,282 | 83,553 | 27,094 | 1,417 |
| **Total Current Assets** | | **11,012,795** | **18,250,402** | **10,723,673** | **18,283,192** |
| **NON–CURRENT ASSETS** | | | | | |
| Work In Progress | **11** | 128,611 | – | 128,611 | – |
| Property, Plant & Equipment | **12** | 1,081,381 | 396,354 | 178,478 | 220,757 |
| Investment in and Advance to Subsidiaries | **13** | – | – | 1,154,895 | 244,551 |
| **Total Non–Current Assets** | | **1,209,992** | **396,354** | **1,461,984** | **465,308** |
| **TOTAL ASSETS** | | **12,222,787** | **18,646,756** | **12,185,657** | **18,748,500** |
| **CURRENT LIABILITIES** | | | | | |
| Payables and Accruals | **14** | 922,084 | 803,413 | 673,362 | 694,693 |
| Redeemable Shares (Part Paid) | **15** | 3,000 | 3,000 | 3,000 | 3,000 |
| Series A Convertible Preference Shares | **16** | 152,500 | 190,625 | 152,500 | 190,625 |
| **Total Current Liabilities** | | **1,077,584** | **997,038** | **828,862** | **888,318** |
| **TOTAL LIABILITIES** | | **1,077,584** | **997,038** | **828,862** | **888,318** |
| **NET ASSETS** | | **11,145,203** | **17,649,718** | **11,356,795** | **17,860,182** |
| Represented by: | | | | | |
| **EQUITY** | | | | | |
| Share Capital | **17** | 46,599,293 | 46,153,930 | 46,599,293 | 46,153,930 |
| Accumulated Losses | **18** | (35,424,399) | (28,507,684) | (35,245,970) | (28,297,220) |
| Reserves | **19** | (29,691) | 3,472 | 3,472 | 3,472 |
| **TOTAL EQUITY** | | **11,145,203** | **17,649,718** | **11,356,795** | **17,860,182** |

*Note: These Statements are to be read in conjunction with the Notes to the Financial Statements.*

# Statements of Cash Flows

| | Notes | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|---|
| **CASH FLOWS TO OPERATING ACTIVITIES** | | | | | |
| Cash was provided from: | | | | | |
| Receipts from Customers & Grants | | 291,676 | 374,632 | 278,225 | 362,249 |
| Net GST received | | – | 46,170 | – | 56,995 |
| Interest Received | | 316,119 | 320,108 | 526,844 | 320,031 |
| Income Tax Received | | – | 615 | – | 615 |
| | | **607,795** | **741,525** | **805,069** | **739,890** |
| Cash was disbursed to: | | | | | |
| Payments to Suppliers & Employees | | 7,313,100 | 4,346,266 | 2,975,939 | 3,270,243 |
| Interest Paid | | 3,351 | – | 3,351 | – |
| Net GST Paid | | 1,780 | – | 13,607 | – |
| | | **7,318,231** | **4,346,266** | **2,992,897** | **3,270,243** |
| **Net Cash Flows to Operating Activities** | **22** | **(6,710,436)** | **(3,604,741)** | **(2,187,828)** | **(2,530,353)** |
| **CASH FLOWS TO INVESTING ACTIVITIES** | | | | | |
| Cash was disbursed to | | | | | |
| Capital Expenditure on Plant and Equipment | **12** | 1,008,851 | 30,049 | 152,465 | 22,267 |
| Advances to subsidiaries | **13** | – | – | 5,533,247 | 1,105,458 |
| | | **1,008,851** | **30,049** | **5,685,712** | **1,127,725** |
| **Net Cash Flows to Investing Activities** | | **(1,008,851)** | **(30,049)** | **(5,685,712)** | **(1,127,725)** |

*Note: These Statements are to be read in conjunction with the Notes to the Financial Statements.*

| | Notes | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|---|
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | | | | |
| Cash was received from: | | | | | |
| Ordinary Shares Issued | **17** | 445,363 | 20,128,024 | 445,363 | 20,128,024 |
| Share funds in advance from shareholders | | – | 41,513 | – | 41,513 |
| | | **445,363** | **20,169,537** | **445,363** | **20,169,537** |
| Cash was disbursed to: | | | | | |
| Issue Expenses | **17** | – | 1,061,512 | – | 1,061,512 |
| Share funds in advance from shareholders | | 9,238 | – | 9,238 | – |
| | | **9,238** | **1,061,512** | **9,238** | **1,061,512** |
| **Net Cash Flows From Financing Activities** | | **436,125** | **19,108,025** | **436,125** | **1,061,512** |
| **Net (Decrease) / Increase in Cash Held** | | **(7,283,162)** | **15,473,235** | **(7,437,416)** | **15,449,947** |
| Add Opening Cash Brought Forward | | 17,959,469 | 2,486,234 | 17,935,620 | 2,485,674 |
| **Ending Cash Carried Forward** | | **25,242,631** | **17,959,469** | **25,373,036** | **17,935,620** |
| Comprised of: | | | | | |
| Bank of New Zealand Cheque Account | | 93,626 | 176,733 | 79,088 | 158,495 |
| Bank of New Zealand Call Accounts | | 2,212,092 | 8,767,088 | 2,212,092 | 8,767,088 |
| Bank of New Zealand US$ | | 3,963,723 | 5,865,702 | 3,963,723 | 5,865,702 |
| Bank of New Zealand AUD$ | | 20,946 | 51,656 | 20,946 | 51,656 |
| Bank of New Zealand EUR$ | | 27,137 | 29,063 | 27,137 | 29,063 |
| Bank of New Zealand Term Deposit | | 4,195,220 | 3,063,616 | 4,195,220 | 3,063,616 |
| Commonwealth Bank AUD$ Cheque Account | | 16,216 | 5,611 | – | – |
| Wells Fargo US$ Account | | 147,347 | – | – | – |
| **Ending Cash Carried Forward** | | **10,676,307** | **17,959,469** | **10,498,206** | **17,935,620** |

*Note: These Statements are to be read in conjunction with the Notes to the Financial Statements.*

# Notes to the Financial Statements

## 1. GENERAL INFORMATION

The financial statements presented for the "Parent" are for the entity Pacific Edge Limited ("the Company"), a company registered under the Companies Act 1993. The Company is registered and domiciled in New Zealand for the purpose of developing and commercialising new diagnostic and prognostic tools for the early detection and management of cancers. Pacific Edge Diagnostics New Zealand and Pacific Edge Diagnostics USA Limited manage and operate the laboratories used for the detection of bladder cancer.

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of Pacific Edge Limited as at 31 March 2013 and the results of all subsidiaries for the year then ended. Pacific Edge Limited and its subsidiaries together are referred to in these financial statements as the Group.

These consolidated financial statements have been approved for issue by the Board of Directors on 30 June 2013.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company is a reporting entity under the Financial Reporting Act 1993. The Company is an issuer for the purposes of the Financial Reporting Act 1993. These Financial Statements have been prepared in accordance with Generally Accepted Accounting Practice in New Zealand ("NZ GAAP"); and the Companies Act 1993. They comply with International Financial Reporting Standards, the New Zealand Equivalents to International Financial Reporting Standards ("NZ IFRS") and other applicable Financial Reporting Standards as appropriate for profit-oriented entities.

The Company and Group are designated as profit-oriented entities for financial reporting purposes.

The accounting policies set out below have been applied consistently to all periods presented in these financial statements.

The consolidated financial statements are presented in New Zealand dollars, which is the Company's functional currency and Group's presentation currency. All figures are rounded to the nearest dollar.

The accounting principles recognised as appropriate for the measurement and reporting of earnings, cash flows and financial position on an historical cost basis have been used.

### (a) Basis of Consolidation

The following entities and the basis of their inclusion for consolidation in these financial statements are as follows:

| Name of Subsidiary | Place of Incorporation (or registration) & Operation | Principal Activity | Ownership Interests & Voting Rights 2013 (%) | Ownership Interests & Voting Rights 2012 (%) |
|---|---|---|---|---|
| Pacific Edge Diagnostics New Zealand Limited | New Zealand | Commercial Laboratory Operation | 100 | 100 |
| Pacific Edge Pty Limited | Australia | Biotechnology Research & Development | 100 | 100 |
| Pacific Edge Diagnostics USA Limited | USA | Commercial Laboratory Operation | 100 | 100 |
| Pacific Edge Analytical Services Limited | New Zealand | Dormant Company | 100 | 100 |

Pacific Edge Limited is incorporated in New Zealand and is the parent entity of the Group.

Pacific Edge Diagnostics New Zealand Limited, Pacific Edge Diagnostics USA Limited, Pacific Edge Analytical Services Limited and Pacific Edge Pty Limited all have a balance date of 31 March which is the same as the Parent.

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of Pacific Edge Limited as at 31 March 2013 and the results of all subsidiaries for the year then ended. Pacific Edge Limited and its subsidiaries together are referred to in these financial statements as the Group.

Pacific Edge Limited consolidates as subsidiaries in the Group financial statements all entities where Pacific Edge Limited has the capacity to control their financing and operating polices, generally accompanying a shareholding of more than one-half of the voting rights so as to obtain benefits from the activities of the entity. The existence and effect of potential voting rights that are currently exercisable or convertible are considered when assessing whether the Company controls another entity. This power exists where Pacific Edge Limited controls the majority voting power on the governing body or where such policies have been irreversibly predetermined by Pacific Edge Limited or where the determination of such policies is unable to materially impact the level of potential ownership benefits that arise from the activities of the subsidiary.

Subsidiaries which form part of the Group are consolidated from the date on which control is transferred to the Company. They are de-consolidated from the date that control ceases.

The acquisition method of accounting is used to account for business combinations by the Group. The consideration transferred for the acquisition of a subsidiary is the fair value of the assets transferred, the liabilities incurred and the equity interest issued by the Group.

The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Acquisition-related costs are expensed as incurred. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. On an acquisition-by-acquisition basis, the Group recognises any non-controlling interest in the acquiree either at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets.

Inter-company transactions, balances and unrealised gains on transactions between Group companies are eliminated. Unrealised losses are also eliminated. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Investments in subsidiaries are accounted for at cost less impairment. Cost is adjusted to reflect changes in consideration arising from contingent consideration amendments. Cost includes direct attributable costs of investment.

## (b) Property, Plant and Equipment

Property, Plant and Equipment are those assets held by the Group for the purpose of carrying on its business activities on an ongoing basis. All Property, Plant and Equipment is stated at cost less subsequent accumulated depreciation and any accumulated impairment losses. The cost of purchased assets includes the original purchase consideration given to acquire the assets, and the value of other directly attributable costs that have been incurred in bringing the assets to the location and condition necessary for their intended service. This includes the laboratory equipment for the establishment of the laboratories.

# Notes to the Financial Statements (continued)

## (c) Depreciation

Depreciation of plant and equipment is based on writing off the assets over their useful lives, using the straight line and diminishing value basis.

Main rates used are:

- Laboratory Equipment 5% to 26.4%
- Office & Computer Equipment 5% to 60%
- Leasehold Improvements 10%
- Plant & Equipment 5% to 40%
- Furniture & Fittings 7% to 25%

## (d) Research and Development Costs

Research is the original and planned investigation undertaken with the prospect of gaining new scientific knowledge and understanding. This includes: direct and overhead expenses for diagnostic and prognostic biomarker discovery and research; pre-clinical trials; and costs associated with clinical trial activities. All research costs are expensed when incurred.

Development is the application of research findings to a plan or design for the production of new or substantially improved processes or products prior to the commencement of commercial production.

When a project reaches the stage where it is reasonably certain that future expenditure can be recovered through the process or products produced, expenditure that is directly attributed or reasonably allocated to that project is recognised as a development asset. The asset will be amortised from the date of commencement of commercial production of the product to which it relates on a straight-line basis over the period of expected benefit. Development assets are reviewed annually for any impairment in their carrying value. To date, all costs incurred have been considered to be research and have been expensed.

## (e) Intellectual Property

The costs of acquired Intellectual Property are recognised at cost and amortised on a straight-line basis over its anticipated useful life, which is currently assessed at four to five years. All Intellectual Property has a finite life. The carrying value of Intellectual Property is reviewed for impairment.

The following costs associated with Intellectual Property are expensed as incurred during the research phases of a project, and are only capitalised when incurred as part of the development phase of a process or product within development assets - Internal Intellectual Property costs including the costs of patents and patent application.

## (f) Goods & Services Tax

The Statements of Comprehensive Income and Statements of Cash Flows have been prepared so that all components are stated exclusive of GST. All items in the Balance Sheets are stated net of GST, with the exception of receivables and payables.

## (g) Share Capital

Ordinary shares are described as equity. Redeemable Shares (part paid) and Series A Convertible Preference Shares are classified as liabilities.

Issue expenses, including commission paid, relating to the issue of ordinary share capital, have been written off against the issued share price received and recorded in the Statements of Changes in Equity.

## (h) Financial Instruments

Financial instruments carried forward in the Balance Sheets include cash and bank balances, receivables, trade creditors, redeemable shares, convertible preference shares and advances to subsidiaries. The particular recognition methods adopted are disclosed in the individual policy statements associated with each item.

## (i) Receivables

Receivables are initially measured at fair value and subsequently measured at amortised cost using the effective interest method, less any provision for impairment. A provision for impairment of receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of receivables. Significant financial difficulties of the debtor, probability that the debtor will enter bankruptcy or financial reorganisation, and default or delinquency in payments (more than 30 days overdue) are considered indicators that the trade receivable is impaired. The amount of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted using the original effective interest rate.

## (j) Foreign Currency Translation

**Foreign Currency Transactions**

The individual financial statements of each group entity are presented in the currency of the primary economic environment in which the entity operates (its functional currency). For the purpose of the Group financial statements, the results and financial position of each group entity are expressed in New Zealand dollars ('NZ$'), which is the functional currency of the Company and the presentation currency for the Group financial statements.

In preparing the financial statements of the individual entities, transactions in currencies other than the entity's functional currency (foreign currencies) are recorded at the rates of exchange prevailing at the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at the end of the reporting period.

Non-monetary items carried at fair value that are denominated in foreign currencies are retranslated at the rates prevailing at the date when the fair value was determined. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Exchange differences are recognised in the statement of comprehensive income in the period in which they arise except for:

- Exchange differences on monetary items receivable from or payable to a foreign operation for which settlement is neither planned nor likely to occur, which form part of the net investment

# Notes to the Financial Statements (continued)

in a foreign operation, and which are recognised in other comprehensive income and accumulated as a separate component of equity in the Group's foreign currency translation reserve and reclassified from equity to profit or loss (as a reclassification adjustment) on disposal of the net investment.

**Foreign Operations**

For the purpose of presenting the Group financial statements, the assets and liabilities of the Group's foreign operations are expressed in New Zealand dollars using exchange rates prevailing at the end of the reporting period. Income and expense items are translated at the average exchange rates for the period, unless exchange rates fluctuated significantly during that period, in which case the exchange rates at the dates of the transactions are used. Exchange differences arising, if any, are recognised in other comprehensive income and accumulated as a separate component of equity in the Group's foreign currency translation reserve. Such exchange differences are reclassified from equity to profit or loss (as a reclassification adjustment) in the period in which the foreign operation is disposed of.

## (k) Cash and Cash Equivalents

Cash and cash equivalents includes cash in hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts.

Bank overdrafts are shown within borrowings in current liabilities in the balance sheet.

## (l) Revenue Recognition

Revenue is measured at the fair value of the consideration received or receivable. Amounts disclosed as revenue are net of returns, trade allowances, rebates and amounts collected on behalf of third parties.

The Group recognises revenue when the amount of revenue can be reliably measured, it is probable that future economic benefits will flow to the entity and specific criteria have been met for each of the Group's activities as described below.

Operating revenues represent the revenue from the sale of goods that is recognised when a group entity sells a product to the customer.

Consultancy fees are recognised in the accounting period in which the services are rendered. For fixed-price contracts, revenue is recognised under the percentage of completion method, based on the actual service provided as a proportion of the total services to be provided.

Grants from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received and the Group will comply with all attached conditions. Government grants relating to costs are deferred and recognised in the profit or loss over the period necessary to match them with the costs that they are intended to compensate. Grants are for reimbursement of laboratory costs.

Interest income is recognised using the effective interest method. When a receivable is impaired, the Group reduces the carrying amount to its recoverable amount, being the estimated future cash flow discounted at the original effective interest rate of the instrument, and continues unwinding the discount as interest income. Interest income on impaired loans is recognised using the original effective interest rate.

## (m) Borrowing Costs

Borrowing costs are recognised as an expense in the period in which they are incurred.

## (n) Operating Leases

Operating leases are charged to other expenses in the statements of comprehensive income on a straight-line basis over the term of the lease.

## (o) Employee Entitlements

Employee benefits are measured at nominal values based on accrued entitlements at current rates of pay. These include salaries and wages accrued up to balance date, annual leave earned to, but not yet taken at balance date, long service leave entitlements expected to be settled within 12 months.

## (p) Critical Accounting Estimates and Assumptions

In preparing these financial statements the Group made estimates and assumptions concerning the future. These estimates and assumptions may differ from the subsequent actual results. Estimates and assumptions are continually evaluated and are based on historical experience and other factors including expectations or future events that are believed to be reasonable under the circumstances. The main estimates and assumptions used are depreciation of property, plant and equipment, any impairment of subsidiaries and the going concern assumption. It is not expected that these estimates and assumptions will have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

## (q) Statements of Cash Flows

Cash means cash balances on hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts.

Operating activities include the cash received and cash paid for the principal revenue-producing activities of the Company and Group and other activities that are not investing or financing activities,

Investing activities are those activities relating to the acquisition and disposal of non-current assets.

Financing activities comprise the change in equity and debt capital structure of the Company and Group.

## (r) Income Tax

The tax expense for the period comprises current and deferred tax. Tax is recognised in profit or loss, except to the extent that it relates to items recognised in other comprehensive income or directly in equity. In this case, the tax is also recognised in other comprehensive income or directly in equity, respectively.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the countries where the company and its subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

# Notes to the Financial Statements (continued)

Deferred income tax is provided in full, using the liability method, on temporary difference arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements in accordance with NZ IAS 12. Deferred income tax assets are recognised to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilised. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realised or the deferred income tax liability is settled.

## (s) Employee Share Scheme

Employee share options under an employee share scheme are recorded at fair value of the employee services received in exchange for the grant of options and are recognised as an expense. The total amount to be recognised over the vesting period is determined by reference to the fair value of the options granted.

## (t) Impairment of Non-financial Assets

Non-financial assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment. Assets that have a finite useful life are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use.

The value in use for cash-generating assets is the present value of expected future cash flows.

The total impairment loss is recognised in the Statements of Comprehensive Income.

## (u) Segment Reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer who makes strategic decisions.

## (v) Standards or Interpretations not yet effective

Various standards, amendments and interpretations have been issued by the External Reporting Board (XRB) but not yet adopted by Pacific Edge Limited as they are not yet effective.

**NZ IFRS 9: Financial Instruments — Phase 1: Classification and Measurement**

NZ IFRS 9 Phase 1 was issued in November 2009 and is effective for the financial statements issued for the fiscal years beginning on or after 1 January 2015.

The new standard simplifies the classification criteria for financial assets, compared to the current requirements of NZ IAS 39, resulting in a reduced number of categories of financial assets and some consequential amendments to disclosures required by NZ IAS 1 "Presentation of Financial Statements" and NZ IFRS 7 "Financial Instruments: Disclosures". The Company and Group's financial assets and liabilities currently fall into the category of "Loans" and are receivables within the NZ IAS 39 classification. If NZ IFRS 9 was adopted, these assets would meet the definition of the category of "Financial

assets and liabilities measured at amortised cost". However, their measurement and disclosure would not be affected. The Company and Group would not have any transactions to disclose under the new NZ IAS 1 and NZ IFRS 7 disclosure requirements relating to gains or losses arising on derecognition of financial assets measured at amortised cost. This standard will be adopted when it is effective. There is no intention to adopt earlier.

**Financial statement presentation — presentation of other comprehensive income (amendment to IAS1)**

This amendment is effective for the financial statements issued for the fiscal years beginning on or after 1 January 2014.

The amendment requires profit or loss and other comprehensive income (OCI) to be presented, either in a single continuous statement or in two separate but consecutive statements. There is little noticeable change from the current requirements. However, the format of the OCI section is required to be changed to separate items that might be recycled from items that will not be recycled. The changes do not affect the measurement of net profit or earnings per share; however, they change the way items of OCI are presented.

This amendment has minimal effect on the Company and Group as they currently have only one immaterial other comprehensive income transaction. This standard will be adopted when it is effective. There is no intention to adopt earlier.

**NZ IFRS 10: Consolidated Financial Statements (amendment from May 2011)**

The amendment to NZ IFRS 10 from May 2012 is effective for the financial statements issued for the accounting periods beginning on or after 1 January 2013.

The amendment builds on existing principles by identifying the concept of control as the determining factor in whether an entity should be included within the consolidated financial statements. The standard provides additional guidance to assist in determining control where this is difficult to assess.

Application of this standard is not expected to have a material effect on the entities consolidated into the Pacific Edge Limited Group. This standard will be adopted when it is effective.

**NZ IFRS 13: Fair Value Measurement (amendment from May 2011)**

The amendment to NZ IFRS 13 from May 2011 is effective for the financial statements issued for the accounting periods beginning on or after 1 January 2013.

The standard provides guidance on how fair value should be applied where its use is already required or permitted by other standards within IFRS, including a precise definition of fair value and a single source of fair value measurement and disclosure requirements for use across IFRS.

Application of this standard is not expected to have a material effect on the Company or Group. This standard will be adopted when it is effective.

## (w) New and amended standards adopted by the Company and Group.

There are no other new NZ IFRSs or amendments to NZ IFRSs effective for periods beginning 1 April 2012 that are relevant to the Group.

# Notes to the Financial Statements (continued)

## 3. EARNINGS PER SHARE

### (a) Basic

Basic earnings per share is calculated by dividing the profit attributable to equity holders of the Company by the weighted average number of ordinary shares on issue during the year excluding ordinary shares purchased by the Company and held as treasury shares (note 17).

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Loss attributable to equity holders of the Company | (6,916,715) | (4,110,910) | (6,948,750) | (3,900,446) |
| Weighted average number of ordinary shares on issue | 275,351,207 | 231,982,797 | 275,351,207 | 231,982,797 |
| Earnings per share | (0.025) | (0.018) | (0.025) | (0.017) |

### (b) Diluted

Diluted earnings per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares.

The Company has two categories of dilutive potential ordinary shares: Redeemable shares and Series A Convertible Preference shares. Both categories are assumed to have been converted into ordinary shares. The number of shares calculated as above is compared with the number of shares that would have been issued assuming the exercise of the share option.

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Loss attributable to equity holders of the Company | (6,916,715) | (4,110,910) | (6,948,750) | (3,900,446) |
| Weighted average number of ordinary shares in issue | 275,351,207 | 231,982,797 | 275,351,207 | 231,982,797 |
| | | | | |
| Adjustments for: | | | | |
| Assumed redemption of redeemable shares | 201,000 | 60,000 | 201,000 | 60,000 |
| Assumed conversion of Series A convertible preference shares | 1,067,500 | 953,125 | 1,067,500 | 953,125 |
| Weighted average number of ordinary shares for diluted earnings per share | 276,619,707 | 232,995,922 | 276,619,707 | 232,995,922 |
| Earnings per share | (0.025) | (0.018) | (0.025) | (0.017) |

## 4. GRANT RECEIVED

During the 2013 financial year the Company submitted a claim for partial reimbursement of costs with New Zealand Trade & Enterprise in line their funding agreement (2012: Grant received from New Zealand Trade & Enterprise). A claim has also been submitted to the Ministry of Business, Innovation and Employment which relates to a postgraduate intern and summer student. This will be received in the 2014 year.

All conditions of the grants have been complied with.

## 5. DEPRECIATION

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Laboratory Equipment | | | | |
| General Laboratory | 80,546 | 38,064 | 28,636 | 38,064 |
| Storage | 2,362 | 2,945 | 2,362 | 2,945 |
| Tissue Preparation | 461 | 626 | 461 | 626 |
| Array | 3,668 | 4,984 | 3,668 | 4,984 |
| Cell Culture | 562 | 691 | 562 | 691 |
| Centrifuge | 1,769 | 2,302 | 1,769 | 2,302 |
| Electrophoresis | 440 | 598 | 440 | 598 |
| Multiplex Project Equipment | 4,912 | 6,675 | 4,912 | 6,675 |
| Computer/Office Equipment | 69,897 | 97,199 | 23,323 | 25,580 |
| Leasehold Property Improvements | 6,330 | 2,147 | – | – |
| Furniture & Fittings | 10,041 | 3,450 | – | – |
| Plant & Equipment | 14,225 | 18,226 | – | – |
| **Total Depreciation** | **195,213** | **177,907** | **66,133** | **82,465** |

# Notes to the Financial Statements (continued)

## 6. RELATED PARTIES

The Company paid consultancy fees for accounting services to C J S Advisory Services Limited. CJ Swann is a director and shareholder of this company. The fees charged were on normal terms and conditions and totalled $40,467 (2012: $6,226). At balance date no fees were outstanding relative to these transactions (2012: $Nil).

A significant shareholder, the University of Otago, provided rental space and car parking to the Group costing $365,037 (2012: $144,725) and the Company costing $134,502 (2012: $122,356). As at 31 March 2013 the Group commitment is $147,360 (2012: $169,464) and the Company commitment is $125,760 (2012: $144,624). Mr C E Dawson, a director of the Company is also the Chief Executive Officer of Otago Innovation Limited, a wholly owned subsidiary of the University of Otago.

Refer note 29 for an Incentive Plan that will also impact key management remuneration in future periods.

Director's fees and payments during the 2013 financial year are $88,417 (2012: $104,000). All members of the Group are considered to be related parties of Pacific Edge Limited (ultimate Parent). This includes the subsidiaries identified in Note 2(a).

During the 2013 financial year the Company advanced $913,808 (2012: $673,785) to Pacific Edge Diagnostics New Zealand Limited to fund laboratory work. $3,946,867 (2012: $431,705) was advanced by the Company to Pacific Edge Diagnostics USA Limited for plant and equipment and the setup of the Laboratory in Hershey. $691,013 (2012: $138,580) was advanced by the Company to Pacific Edge Pty Limited to fund continued research. No funds were advanced to Pacific Edge Analytical Services Limited. At the end of the 2012 year there was an intercompany receivable of $182,260 (Note 9) that relates to the interest charged on these advances and wages apportioned to the Pacific Edge Diagnostics USA Limited from Pacific Edge Limited. No interest has been charged on the funds advanced to subsidiaries from Pacific Edge Limited in 2013. These balances are recorded as an advance to the separate entities and are impaired per note 13 as they are not expected to be called for repayment within a year, until the subsidiaries have sufficient funds.

## 7. INCOME TAX

The Company and Group has incurred an operating loss for the 2013 financial year and no income tax is payable.

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Accounting profit | (6,916,715) | (4,110,910) | (6,948,750) | (3,900,446) |
| Permanent differences | 8,378 | – | 4,813,538 | 1,133,152 |
| **Net (Loss) before tax** | (6,908,335) | (4,082,706) | (2,135,210) | (2,949,554) |
| Tax at 28% (2012: 28%) | (1,934,334) | (1,143,158) | (597,859) | (1,143,158) |
| Less: not recognised as a deferred tax asset | 1,934,334 | 1,143,158 | 597,859 | 1,143,158 |
| **Income Tax Expense** | – | – | – | – |

There are tax losses that are available to be carried forward and offset against future taxable income, if various conditions required by income tax legislation are complied with. The group has losses to carry forward of approximately $11,065,802 (2012: $4,174,010) which is dependent on meeting requirements of New Zealand and foreign legislation. There is also deferred research and development expenditure totalling approximately $17,462,257 (2012:$13,589,000) to carry forward and claim for tax purposes in future years which equates to a potential benefit of $4,889,432. During the 2012 financial year losses of $5,530,528 were forfeited due to a breach in shareholder continuity from 2003 to 2012.

There is no income tax due for 2013 (2012 Nil). The Company had a certificate of exemption for RWT and as such no RWT was deducted from interest earned.

## 8. CASH & CASH EQUIVALENTS

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Bank of New Zealand Cheque Account | 93,626 | 176,732 | 79,088 | 158,495 |
| Bank of New Zealand Call Accounts | 2,212,092 | 8,767,088 | 2,212,092 | 8,767,088 |
| Bank of New Zealand US$ | 3,963,723 | 5,865,702 | 3,963,723 | 5,865,702 |
| Bank of New Zealand AUD$ | 20,946 | 51,656 | 20,946 | 51,656 |
| Bank of New Zealand EUR$ | 27,137 | 29,063 | 27,137 | 29,063 |
| Bank of New Zealand Term Deposit | 4,195,220 | 3,063,616 | 4,195,220 | 3,063,616 |
| Commonwealth Bank AUD$ Cheque Account | 16,216 | 5,612 | – | – |
| Wells Fargo US$ Account | 147,347 | – | – | – |
| **Total Cash & Cash Equivalents** | **10,676,307** | **17,959,469** | **10,498,206** | **17,935,620** |

Interest on the bank balances range from 0% to 4.20% (2012: 0% to 4.55%) per annum.

# Notes to the Financial Statements (continued)

## 9. RECEIVABLES

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Debtors | 38,266 | 147,595 | 118,236 | 122,669 |
| Amounts receivable from subsidiaries (note 6) | – | – | – | 182,260 |
| Accrued Interest | 38,754 | 21,682 | 38,754 | 21,682 |
| BAS Refund Due | 893 | 1,277 | – | – |
| GST Refund Due | 54,293 | 36,826 | 41,383 | 19,544 |
| **Total Receivables** | **132,206** | **207,380** | **198,373** | **346,155** |

## 10. OTHER ASSETS

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Prepayments | 110,417 | 1,417 | 27,094 | 1,417 |
| Other – Lease Security Deposit | 80,724 | 82,136 | – | – |
| Credit Card Collateral | 13,141 | – | – | – |
| **Total Other Assets** | **204,282** | **83,553** | **27,094** | **1,417** |

## 11. WORK IN PROGRESS

During the year there was there was $128,611 in expenditure on the NAV financial administration system, this is made up of intangible and tangible components. Once complete this asset this will be amortized and depreciated.

## 12. PROPERTY, PLANT & EQUIPMENT

### Group

| | Laboratory Equipment | Office & Computer Equipment | Leasehold Improvements | Plant & Equipment | Furniture & Fittings | Total |
|---|---|---|---|---|---|---|
| **COST** | | | | | | |
| Balance at 1 April 2011 | 1,335,023 | 527,423 | 21,825 | 88,618 | 15,601 | 1,988,490 |
| Additions | – | 27,221 | – | 1,703 | 2,749 | 31,673 |
| Disposals | – | – | – | (1,624) | – | (1,624) |
| **Balance at 31 March 2012** | **1,335,023** | **554,644** | **21,825** | **88,697** | **18,350** | **2,018,539** |
| | | | | | | |
| Balance at 1 April 2012 | 1,335,023 | 554,644 | 21,825 | 88,697 | 18,350 | 2,018,539 |
| Additions | 520,898 | 135,948 | 104,657 | 1,507 | 116,128 | 879,138 |
| Disposals | – | (95,257) | – | – | – | (95,257) |
| **Balance at 31 March 2013** | **1,855,921** | **595,335** | **126,482** | **90,204** | **134,478** | **2,802,420** |
| | | | | | | |
| **ACCUMULATED DEPRECIATION** | | | | | | |
| Balance at 1 April 2011 | 1,107,168 | 333,187 | 353 | 3,079 | 491 | 1,444,278 |
| Depreciation expense | 56,885 | 97,199 | 2,147 | 18,226 | 3,450 | 177,907 |
| **Balance at 31 March 2012** | **1,164,053** | **430,386** | **2,500** | **21,305** | **3,941** | **1,622,185** |
| | | | | | | |
| Balance at 1 April 2012 | 1,164,053 | 430,386 | 2,500 | 21,305 | 3,941 | 1,622,185 |
| Depreciation expense | 94,720 | 69,897 | 6,330 | 14,225 | 10,041 | 195,213 |
| Disposal | – | (94,360) | – | – | – | (94,360) |
| Foreign Translation difference | (1,420) | (256) | (120) | (201) | (2) | (1,999) |
| **Balance at 31 March 2013** | **1,257,353** | **405,667** | **8,710** | **35,329** | **13,980** | **1,721,039** |
| | | | | | | |
| **CARRYING AMOUNTS** | | | | | | |
| At 1 April 2011 | 227,855 | 194,236 | 21,472 | 85,539 | 15,110 | 544,212 |
| At 31 March 2012 & 1 April 2012 | 170,970 | 124,258 | 19,325 | 67,392 | 14,409 | 396,354 |
| At 31 March 2013 | 598,568 | 189,668 | 117,772 | 54,875 | 120,498 | 1,081,381 |

# Notes to the Financial Statements (continued)

## PROPERTY, PLANT & EQUIPMENT (CONTINUED)

### Parent

| | Laboratory Equipment | Office & Computer Equipment | Leasehold Improvements | Plant & Equipment | Furniture & Fittings | Total |
|---|---|---|---|---|---|---|
| **COST** | | | | | | |
| Balance at 1 April 2011 | 1,335,023 | 374,546 | – | – | – | 1,709,569 |
| Additions | – | 22,240 | – | – | – | 22,240 |
| Disposals | – | – | – | – | – | – |
| **Balance at 31 March 2012** | **1,335,023** | **396,786** | **–** | **–** | **–** | **1,731,809** |
| | | | | | | |
| Balance at 1 April 2012 | 1,335,023 | 396,786 | – | – | – | 1,731,809 |
| Additions | – | 24,781 | – | – | – | 24,781 |
| Disposals | – | (95,257) | – | – | – | (95,257) |
| **Balance at 31 March 2013** | **1,335,023** | **326,310** | **–** | **–** | **–** | **1,661,333** |
| | | | | | | |
| **ACCUMULATED DEPRECIATION** | | | | | | |
| Balance at 1 April 2011 | 1,107,168 | 321,449 | – | – | – | 1,428,617 |
| Depreciation expense | 56,885 | 25,580 | – | – | – | 82,465 |
| **Balance at 31 March 2012** | **1,164,053** | **347,029** | **–** | **–** | **–** | **1,511,082** |
| | | | | | | |
| Balance at 1 April 2012 | 1,164,053 | 347,029 | – | – | – | 1,511,082 |
| Depreciation expense | 42,557 | 23,576 | – | – | – | 66,133 |
| Disposals | – | (94,360) | – | – | – | (94,360) |
| **Balance at 31 March 2013** | **1,206,610** | **276,245** | **–** | **–** | **–** | **1,482,855** |
| | | | | | | |
| **CARRYING AMOUNTS** | | | | | | |
| At 1 April 2011 | 227,855 | 53,097 | – | – | – | 280,952 |
| At 31 March 2012 & 1 April 2012 | 170,970 | 49,757 | – | – | – | 220,727 |
| At 31 March 2013 | 128,413 | 50,065 | – | – | – | 178,478 |

## 13. INVESTMENT IN AND ADVANCE TO SUBSIDIARIES

| | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|
| Advances to subsidiaries | 5,959,055 | 1,368,276 |
| Shares in subsidiary | 1,000 | 1,000 |
| | 5,960,055 | 1,369,276 |
| Less Impairment loss for the year | (4,805,160) | (1,124,725) |
| | **1,154,895** | **244,551** |

The consolidated financial statements incorporate the assets, liabilities and results of Pacific Edge Diagnostics New Zealand Limited, Pacific Edge Diagnostics USA Limited, Pacific Edge Analytical Services Limited and Pacific Edge Pty Limited. They are all 100% owned by Pacific Edge Limited. The principal activity of the subsidiaries in NZ and USA is the management and operation of the laboratories used for the detection of bladder cancer. The Australian entity is a research and development company. Pacific Edge Analytical Services Limited is dormant so no funds have been advanced to it. The impairment loss in 2013 is a result of the effect of the investment and advances not being recoverable in full based on the total deficit in equity of the subsidiaries at 31 March 2013. Accordingly, the impairment loss reduces the value in the Parent's books to its fair value based on the recoverable amount at balance date.

## 14. PAYABLES AND ACCRUALS

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Trade Creditors | 535,263 | 456,109 | 296,541 | 347,389 |
| Accrued Expenses | 84,549 | 46,826 | 74,549 | 46,826 |
| Employee Entitlements (refer below) | 215,381 | 242,474 | 215,381 | 242,474 |
| Monies received in advance from shareholders | 86,891 | 58,004 | 86,891 | 58,004 |
| **Total Payables and Accruals** | **922,084** | **803,413** | **673,362** | **694,693** |

Payables and accruals are non-interest bearing and are normally settled on 30-day terms, therefore their carrying value approximates their fair value.

| Employee Entitlement | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| PAYE Tax | 39,906 | 29,281 | 39,906 | 29,281 |
| Holiday Pay | 111,319 | 97,119 | 111,319 | 97,119 |
| Accrued Wages | 64,156 | 116,074 | 64,156 | 116,074 |
| **Total Employee Entitlements** | **215,381** | **242,474** | **215,381** | **242,474** |

# Notes to the Financial Statements (continued)

## 15. REDEEMABLE SHARES

| Part Paid | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Redeemable shares (Part Paid) | 3,000 | 3,000 | 3,000 | 3,000 |
| **Total Redeemable Shares** | **3,000** | **3,000** | **3,000** | **3,000** |

These shares relate to an Employee Share Ownership Plan (ESOP). This is due to terminate after the 2013 financial year, once the two subscribers of the remaining 300,000 Redeemable Shares ($3,000 at 1 cent per share) have either converted their Redeemable Shares to Ordinary Shares or been repaid in cash. As these shares provide a right of redemption, they are included as a liability.

The Redeemable shares were originally issued in the ESOP on 26 August 2004. Following a subsequent reduction in the share price for Ordinary Shares, the Directors decided to cancel the scheme and offer all redeemable shareholders repayment in cash or the equivalent value in Ordinary Shares. The Scheme was cancelled on 31 July 2006. Consequently, the remaining value of the options to convert to Ordinary Shares in the ESOP, that had not been previously expensed, was expensed immediately.

## 16. SERIES A CONVERTIBLE PREFERENCE SHARES

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Opening Balance | 190,625 | 190,625 | 190,625 | 190,625 |
| Non-cash Conversion to ordinary shares | (38,125) | – | (38,125) | – |
| **Closing Balance** | **152,500** | **190,625** | **152,500** | **190,625** |

There are $152,500 (2012: 190,625) Series A Convertible Preference Shares on issue. The original agreement was for each Series A Convertible Preference shareholder having the right to convert, upon election, to five Ordinary Shares and then entitled to five votes. This was subsequently varied to seven Ordinary Shares and seven votes respectively.

On 19th November 2012 38,125 of Series A convertible Preference Shares were redeemed. This amounts to an issue of 266,875 ordinary shares.

These shares can be redeemed for cash at their purchase price of $1 per share; therefore they are classified as liabilities. There are no rights to any dividends (fixed or cumulative) attached to these preference shares. On liquidation, the holders of the Series A Convertible Preference Shares will be entitled to receive cash in preference to the holders of Ordinary Shares.

If all Series A Convertible Preference Shares on issue at balance date were converted to Ordinary Shares a total of 1,067,500 would be issued. (2012: 953,126).

## 17. SHARE CAPITAL

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Ordinary Shares | 46,599,293 | 46,153,930 | 46,599,293 | 46,153,930 |
| **Total Share Capital** | **46,599,293** | **46,153,930** | **46,599,293** | **46,153,930** |

There are 278,755,147 (2012: 274,463,410) Ordinary Shares on issue.

All fully paid shares in the Company have equal voting rights and equal rights to dividends. All Ordinary Shares are fully paid and have no par value.

| Share Capital Group & Parent | Shares | 2013 ($) | 2012 ($) |
|---|---|---|---|
| Opening Balance | 274,463,410 | 46,153,930 | 27,087,418 |
| New issues: Private Placement | – | – | 5,060,000 |
| New issues: Direct Offers | – | – | 15,048,024 |
| New issues: Conversion of Preference Shares | 266,875 | 38,125 | – |
| New Issues: Conversion of Options | 4,024,862 | 407,238 | – |
| | 278,755,147 | 46,599,293 | 47,195,442 |
| Less Issue Expenses | – | – | (1,061,512) |
| **Closing Balance** | **278,755,147** | **46,599,293** | **46,153,930** |

During the year ended 31 March 2013 4,024,862 ordinary shares were issued under existing options at $0.09 per share for $362,238. Also 500,000 ordinary shares were issued for $45,000 which related to an earlier conversion of options. 38,125 Series A Convertible preference shares were converted to 266,875 ordinary shares during the year.

## 18. ACCUMULATED LOSSES

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Opening Balance – as restated | (28,507,684) | (24,396,774) | (28,297,220) | (24,396,774) |
| Net (Loss) After Tax | (6,916,715) | (4,110,910) | (6,948,750) | (3,900,446) |
| **Closing Balance** | **(35,424,399)** | **(28,507,684)** | **(35,245,970)** | **(28,297,220)** |

# Notes to the Financial Statements (continued)

## 19. FOREIGN CURRENCY TRANSLATION RESERVE

Exchange differences relating to the translation from the functional currencies of the Group's foreign subsidiaries into New Zealand dollars are brought to account by entries made directly to the foreign currency translation reserve.

## 20. IMPUTATION CREDIT ACCOUNT

At balance date imputation credits available to the shareholders were:

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| **Opening Balance** | – | 615 | – | 615 |
| RWT Refund Received | – | (615) | | (615) |
| **Closing Balance** | **–** | **–** | **–** | **–** |

## 21. SEGMENT INFORMATION

The Chief Executive Officer has determined the operating segments based on reports reviewed by him that are used to make strategic decisions.

The Chief Executive Officer considers the business to be three operating segments at balance date. These segments being the research and development of diagnostic and prognostic products for human cancer and the operator of the laboratory used for the detection of bladder cancer; currently operating in the United States of America and New Zealand.

The segment information provided to the Chief Executive Officer for the reportable segment described above, for the year ended 31 March 2013, is shown below.

| 2013 | NZ Laboratory | US Laboratory | Research | Total |
|---|---|---|---|---|
| Total segment revenue | 82,465 | – | 485,096 | 567,561 |
| **Revenue from within the segment** | **63,019** | **–** | **322,189** | **385,208** |
| **Revenue from External Customers** | **19,440** | **–** | **162,907** | **182,347** |
| Adjusted EBITDA | (912,535) | (2,938,413) | (3,200,393) | (7,051,341) |
| Interest revenue | 5 | – | 333,185 | 333,190 |
| Interest expense | – | – | (3,351) | (3,351) |
| Depreciation & Amortisation | (56,084) | (72,996) | (66,133) | (195,213) |
| Income tax expense | – | – | – | – |
| **Total Loss Before Tax** | **(968,614)** | **(3,011,409)** | **(2,936,692)** | **(6,916,715)** |
| **Total Assets** | **160,212** | **1,104,192** | **10,958,383** | **12,222,787** |
| **Total Liabilities** | **40,086** | **208,636** | **828,862** | **1,077,584** |

## SEGMENT INFORMATION (CONTINUED)

| 2012 | NZ Laboratory | US Laboratory | Research | Total |
|---|---|---|---|---|
| Total segment revenue | 34,541 | – | 270,171 | 304,712 |
| **Revenue from External Customers** | **34,541** | **–** | **270,171** | **304,712** |
| Adjusted EBITDA | (457,991) | (431,705) | (3,382,409) | (4,272,105) |
| Interest revenue | 77 | – | 341,713 | 341,790 |
| Interest expense | (1,084) | – | (1,604) | (2,688) |
| Depreciation & Amortisation | (95,442) | – | (82,465) | (177,907) |
| Income tax expense | – | – | – | – |
| **Total Loss Before Tax** | **(554,440)** | **(431,705)** | **(3,124,765)** | **(4,110,910)** |
| **Total Assets** | **236,036** | **82,136** | **18,328,584** | **18,646,756** |
| **Total Liabilities** | **(61,103)** | **(12,215)** | **(923,720)** | **(997,038)** |

# Notes to the Financial Statements (continued)

## SEGMENT INFORMATION (CONTINUED)

Sales between segments are carried out at arm's length. The revenue from external parties reported to the Chief Executive Officer is measured in a manner consistent with that in the statement of comprehensive income.

The amounts provided to the Chief Executive Officer with respect to total assets are measured in a manner consistent with that of the financial statements. These assets are allocated based on the operation of the segment and the physical location of the asset. "Reportable segments" assets are reconciled to total assets as follows:

| | 2013 ($) | 2012 ($) |
|---|---|---|
| Segment assets for reportable segments | 12,222,787 | 18,646,756 |
| Unallocated | – | – |
| **Total Assets per the Balance Sheet** | **12,222,787** | **18,646,756** |

The amounts provided to the Chief Executive Officer with respect to total liabilities are measured in a manner consistent with that of the financial statements. These liabilities are allocated based on the operations of the segment. "Reportable segments" liabilities are reconciled to total liabilities as follows:

| | 2013 ($) | 2012 ($) |
|---|---|---|
| Segment liabilities for reportable segment | 1,077,584 | 997,038 |
| Unallocated | – | – |
| **Total Liabilities per the Balance Sheet** | **1,077,584** | **997,038** |

The reportable operating segment derives their revenue primarily from grant income and the reportable operating segment laboratories derive their revenue primarily of sales of Cx bladder kits. The Chief Executive Officer assesses the performance of the operating segment based on net profit/(loss) for the period.

## 22. RECONCILIATION OF CASH USED FROM OPERATING ACTIVITIES WITH OPERATING NET LOSS

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Net Loss for the Period | (6,949,878) | (4,107,438) | (6,948,750) | (3,896,974) |
| | | | | |
| **Add Non Cash Items:** | | | | |
| Depreciation | 195,213 | 177,907 | 66,133 | 82,465 |
| Write down of investment in and advance to subsidiary | – | – | 4,805,160 | 1,124,725 |
| **Total Non Cash Items** | **195,213** | **177,907** | **4,871,293** | **1,207,190** |
| | | | | |
| **Add Movements in Other Working Capital items:** | | | | |
| Decrease in Tax Refund Due | – | 615 | – | 615 |
| Increase in GST Receivable | – | – | – | – |
| (Increase)/Decrease in Receivables and Other Assets | (73,766) | (27,004) | (60,153) | (83,643) |
| Increase in Payables and Accruals | 117,995 | 322,975 | (50,218) | 242,459 |
| **Total Movement in Other Working Capital** | **44,229** | **296,586** | **(110,371)** | **159,431** |
| | | | | |
| **Other:** | | | | |
| Gain (Loss) on Sale included in Investing Activities | – | – | – | – |
| **Net Cash Flows to Operating Activities** | **(6,710,436)** | **(3,604,741)** | **(2,187,828)** | **(2,530,353)** |

# Notes to the Financial Statements (continued)

## 23. FINANCIAL INSTRUMENTS

### Managing financial risk

The Company and Group's activities expose it to the financial risks of changes in interest rate risk, credit risk, liquidity risk and foreign currency risk.

- **Interest Rate Risk:** Bank overdrafts at variable interest rates expose the Company and Group to interest rate risk. The Company manages its interest rate risk by arranging share capital to provide available funds to meet commitments as they fall due.
- **Credit Risk:** In the normal course of business the Company and Group incurs credit risk from trade receivables and other assets. Regular monitoring of receivables and other assets is undertaken to ensure that the credit exposure remains within the Company and Group's normal terms of trade.
- **Liquidity Risk:** Prudent liquidity risk management implies maintaining sufficient cash and marketable securities, and the availability of funding through an adequate amount of committed credit facilities. The Company and Group aims to maintain flexibility in funding by keeping committed credit lines available.
- **Foreign Currency Risk:** The Company and Group purchase goods from overseas suppliers. It also operates Pacific Edge Diagnostics USA Limited in the USA. This exposes the Company and Group to foreign currency risk. The Company manages foreign currency risk by only purchasing foreign currency when the exchange rate is favourable and hold until required.

### Interest Rate Risk

The Company and Group's bank deposits are at floating interest rates, which mitigates the risk of interest rates being less than market rates.

### Credit Risk

The Company and Group incur credit risk from bank balances, receivables in the normal course of its business and other assets. The Group's cash and short term deposits are placed with high credit quality financial institutions. Accordingly, the Company and Group have no significant concentration of credit risk other than bank deposits with 87.11% of total assets at the Bank of New Zealand. The carrying values of financial assets represent maximum exposure to credit risk. At balance date there were no impaired or past due receivables.

### Liquidity Risk

Liquidity risk is the risk that the Company and Group may encounter difficulty in raising funds at short notice to meet its commitments as they fall due. Management maintains sufficient cash and the availability of funding through an adequate amount of committed credit facilities if required.

### Foreign Currency Risk

The Group undertakes certain transactions and now operates in USA which will be denominated in foreign currencies. Hence, exposures to exchange rate fluctuations arise. Exchange rate exposures are managed within approved policy parameters before a foreign currency transaction is approved. The Company hedges foreign currency risk by operating foreign currency bank accounts.

## Fair Values

In the opinion of the directors, the carrying amount of current assets and current liabilities approximate their fair values at balance date.

## Unrecognised Financial Instruments

There are no unrecognised financial instruments, hedges or forward exchange contracts at 31 March 2013 (2012 Nil).

## Market Risk

Management is of the opinion that the Company and Group's exposure to market risk at balance date is defined as:

| Risk Factor | Description | Sensitivity |
|---|---|---|
| Currency risk | Assets and liabilities are denominated in NZD, USD, AUD, and EUR currencies | As below |
| Interest rate risk | Exposure to changes in Bank interest rates | As below |
| Other price risk | No securities are bought, sold or traded | Nil |

Balances in AUD and EUR currencies are not significant. A 1% increase or decrease in USD will reduce/increase the loss reported by approximately $46,000 (2012: $30,000) respectively and increase/reduce equity by the same amount.

A 1% increase or decrease in Bank deposit interest rates will reduce/increase the loss reported by approximately $2,500 (based on normal levels of bank deposits) and increase/reduce equity by the same amount (2012: $180,000).

# Notes to the Financial Statements (continued)

## Liquidity / maturity profile of liabilities at 31 March 2013:

| Group Liabilities | 0–3 Months ($) | 3–6 Months ($) | 6–12 Months ($) | 1–2 Years ($) | 2+ Years ($) | Total ($) |
|---|---|---|---|---|---|---|
| Payables & Accruals | 922,084 | – | – | – | – | 922,084 |
| Redeemable Shares (Part Paid) | 3,000 | – | – | – | – | 3,000 |
| Series A Convertible Preference Shares | 152,500 | – | – | – | – | 152,500 |
| | **1,077,584** | – | – | – | – | **1,077,584** |

| Parent Liabilities | 0–3 Months ($) | 3–6 Months ($) | 6–12 Months ($) | 1–2 Years ($) | 2+ Years ($) | Total ($) |
|---|---|---|---|---|---|---|
| Payables & Accruals | 673,362 | – | – | – | – | 673,362 |
| Redeemable Shares (Part Paid) | 3,000 | – | – | – | – | 3,000 |
| Series A Convertible Preference Shares | 152,500 | – | – | – | – | 152,500 |
| | **828,862** | – | – | – | – | **828,862** |

This profile recognises the earliest time band of share conversions or redemptions (as there is no fixed conversion or redemption date).

## Liquidity / maturity profile of liabilities at 31 March 2012:

| Group and Parent Liabilities | 0–3 Months ($) | 3–6 Months ($) | 6–12 Months ($) | 1–2 Years ($) | 2+ Years ($) | Total ($) |
|---|---|---|---|---|---|---|
| Payables & Accruals | 803,413 | – | – | – | – | 803,413 |
| Redeemable Shares (Part Paid) | 3,000 | – | – | – | – | 3,000 |
| Series A Convertible Preference Shares | 190,625 | – | – | – | – | 190,625 |
| | **997,038** | – | – | – | – | **997,038** |

| Parent Liabilities | 0–3 Months ($) | 3–6 Months ($) | 6–12 Months ($) | 1–2 Years ($) | 2+ Years ($) | Total ($) |
|---|---|---|---|---|---|---|
| Payables & Accruals | 694,693 | – | – | – | – | 694,693 |
| Redeemable Shares (Part Paid) | 3,000 | – | – | – | – | 3,000 |
| Series A Convertible Preference Shares | 190,625 | – | – | – | – | 190,625 |
| | **888,318** | – | – | – | – | **888,318** |

## 24. CONTINGENT LIABILITIES

There were no known contingent liabilities at 31 March 2013 (2012 Nil). The Company and Group have not granted any securities in respect of liabilities payable by any other party whatsoever.

## 25. BANK SECURITIES

The Company has provided a debenture to the Bank of New Zealand to secure borrowings. There were no net bank borrowings at balance date.

## 26. CAPITAL COMMITMENTS

There are no capital commitments for the Company or Group at 31 March 2013 (2012 Nil).

## 27. LEASE COMMITMENTS

The Company has the following lease commitment for buildings.

| | Group 2013 ($) | Group 2012 ($) | Parent 2013 ($) | Parent 2012 ($) |
|---|---|---|---|---|
| Non cancellable operating lease commitments within one year | 346,131 | 377,498 | 125,760 | 125,760 |
| Later than one year, not later than two years | 330,414 | 377,498 | 125,760 | 125,760 |
| Later than two years, not later than five years | 925,119 | 690,414 | 125,760 | – |
| **Total Lease Commitments** | **1,601,664** | **1,445,410** | **377,280** | **251,520** |

The lease of premises (in the Centre for Innovation) with the University of Otago was renewed on 26 May 2013 for further two years at $125,760 per annum, the rental in the 2013 year remains unchanged from 2012. The Pacific Edge Diagnostics Limited's lease of premises is $21,600 a year. Pacific Edge Diagnostics USA Limited has a 5 year lease which expires on 30 November 2017. The total financial commitment remaining for this lease is $1,577,104 (2012: $1,150,691).

## 28. PRIOR YEAR ADJUSTMENT

During 2013 Pacific Edge Limited charged Pacific Edge Diagnostics USA Limited $171,336 and Pacific Edge Pty Limited $10,924 for services by the parent company and interest on funding advances for the 2012 year. This was previously not recognised in 2012 financial statements. The interest income profit and loss account line is impacted by an increase of $23,010 for interest charged on intercompany receivables and other income increased by $159,250 for the on charge of services of Pacific Edge Limited to Pacific Edge Diagnostics USA Limited. Both items equal the amounts receivable from subsidiaries balance in Note 9. The basic and diluted EPS has been updated in Note 3 for the parent from ($0.018) to ($0.017) per share. On consolidation the entries are eliminated between the Group.

Pacific Edge Diagnostics USA Limited paid expenses of $28,204 during the year which actually related to the 2012 financial year. This is due to an invoice being billed late by a supplier. The other expenses profit and loss account line is impacted along with the trade payables balance, both items increase $28,204. This was previously not recognised in 2012 financial statements. The basic and diluted EPS (Note 3) does not change.

# Notes to the Financial Statements (continued)

## 29. SUBSEQUENT EVENTS

There were no events subsequent to balance date.

## 30. MANAGEMENT OF CAPITAL

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and benefit for other stakeholders and to maintain an optimal capital structure to support the development of its business. The Company meets these objectives through managing their liquidity position with available funds by reducing costs, issue new shares or sell assets.

## 31. PACIFIC EDGE INCENTIVE PLAN (PEIP)

In March 2011 the Company developed an "Incentive Plan" as a means of providing Key Persons with the opportunity to participate in the potential increasing profitability of the Group. The Plan is an Equity Equivalent (EE) Scheme that provides EE Units on the following terms:

- EE Units are vested to the Participant over a period of 4 years but cannot be redeemed during the first two years from the date of their issue.
- Each EE Unit has the equivalent value of an ordinary share in the Company.
- Redemption is in cash for the difference between the value of the EE Units at the time of allocation and their value at the time of redemption.
- The Company must be trading in a cash flow positive condition and the Company's share price on the NZX must be at a minimum price of $1.00 per share.
- A maximum of 25% of a Participant's vested EE Units can be redeemed in any one year.
- The Company commenced issuing the EE Units in late March 2011. At balance date 6,449,000 EE units had been vested. The fair value of these EE Units has been determined as $Nil at 31 March 2013 (2012: $Nil) because the conditions above are assessed as unlikely to be met and, accordingly, no expense or liability have been recorded in these financial statements.

**Holding of EE units by current Directors and Officers**

| | |
|---|---|
| Chris Swann | 412,500 |
| Colin Dawson | 330,000 |
| David Darling | 1,800,000 |

# Additional Stock Exchange Information

The total number of issued voting securities is 278,907,647 comprised of 278,755,147 Ordinary Shares and 152,500 Series A Convertible Preference Shares.

The Company's Ordinary Shares are listed on the NZSX.

The Company's Series A Convertible Preference Shares and Redeemable Shares (Part Paid) are not listed on the NZSX.

The Company currently does not have a credit rating.

## 1. SUBSTANTIAL SECURITY HOLDERS

The Company's register of substantial security holders, prepared in accordance with section 26 of the Securities Markets Act 1988, recorded the following information as at 31 March 2013. These shareholders have a relevant interest of 5% or more in all classes of securities.

| Name | Number of Ordinary Voting Securities | Number of Series A Convertible Preference Share Voting Securities | Part paid Redeemable Shares |
|---|---|---|---|
| Masfen Securities Limited | 15,057,641 (5.40%) | – | – |
| K One W One Limited | 20,021,739 (7.18%) | – | – |
| M J Sullivan | – | – | 200,000 (66.67%) |
| S H Morgan | – | – | 100,000 (33.33%) |

## 2. SPREAD OF SECURITY HOLDERS AT 30 APRIL 2013

| | No. of Ordinary Security Holders | Percentage of Issued Ordinary Equity | No. of Series A Security Holders | Percentage of Issued Series A Equity | No. of Part Paid Redeemable Share Holders | Percentage of Issued Part Paid Redeemable Shares |
|---|---|---|---|---|---|---|
| 1 – 1,000 | 83 | 4.04% | | | | |
| 1,001 – 5,000 | 420 | 20.46% | | | | |
| 5,001 – 10,000 | 364 | 17.73% | 2 | 28.57% | | |
| 10,001 – 100,000 | 939 | 45.74% | 5 | 71.43% | 1 | 33.33% |
| 100,001 – 500,000 | 196 | 9.55% | | | 1 | 66.67% |
| 500,001 – 1,000,000 | 16 | 0.78% | | | | |
| 1,000,001 – 2,500,000 | 19 | 0.93% | | | | |
| 2,500,001 – 13,000,000 | 13 | 0.63% | | | | |
| 13,000,001 and Over | 3 | 0.15% | | | | |
| **Total Security Holders** | **2,053** | **100.00%** | **7** | **100.00%** | **2** | **100.00%** |

# Additional Stock Exchange Information (continued)

## 3. TWENTY LARGEST EQUITY SECURITY SHAREHOLDERS AS AT 30 APRIL 2013

Ordinary Shares

| | |
|---|---|
| New Zealand Central Securities Depository Ltd | 52,434,706 |
| K One W One Limited | 20,021,739 |
| Masfen Securities Limited | 15,057,641 |
| Superlife Trustee Nominees Limited | 12,794,446 |
| Christopher & Banks Private Equity I Limited | 9,424,146 |
| Hypertech Medical Limited | 8,029,197 |
| FNZ Custodians Limited | 7,733,175 |
| Sinclair Long Term Holdings Limited | 6,000,000 |
| Carol Anne Edwards & Graeme Brent Ramsey | 3,370,000 |
| David Darling & Yvonne McCallum Independent Trustees (Tauranga) Limited | 2,949,862 |
| University of Otago | 2,925,000 |
| Peter Karl Christopher Huljich / Christopher Peter Huljich / Elizabeth Anne Ferguson | 2,806,041 |
| Custodial Services Limited | 2,797,494 |
| Christopher Peter Huljich / Colin Gordon Powell | 2,769,813 |
| Superlife Trustees Nominees | 2,316,722 |
| Ewan John Bennie | 2,261,540 |
| Steven Cyril Hancock/ Bronwyn Hilda Hancock | 2,250,000 |
| Forsyth Barr Custodians Limited | 2,141.659 |
| Michael Walter Daniel/ Nigel Geoffrey Burton/ Michael Murray Benjamin | 2,000,000 |
| Lewis Holdings Limited | 1,907,577 |

Part Paid Redeemable Shares

| | |
|---|---|
| Michael James Sullivan | 200,000 |
| Shannon Henry Morgan | 100,000 |

## 4. DIRECTORS' SHAREHOLDINGS

Listed below, equity securities in which each director, and associated person of each Director, holds a relevant interest at balance date:

| | 2013 ($) | 2012 ($) |
|---|---|---|
| **NUMBER OF ORDINARY SHARES** | | |
| C E Dawson | 1,034,580 | 934,580 |
| C J Swann | 1,055,556 | 1,055,566 |

## 5. WAIVERS GRANTED BY NZSX

NZX granted the following waiver in the 12 month period from 1 May 2012 to 30 April 2013:

- Listing Rule 3.3.1 (c) and 3.6.2 (c) which prescribes the Board must include a minimum of two Independent Directors; and for the Audit Committee to be comprised of a minimum of three Directors, of which a majority must be Independent Directors. This was applied for on 27th of August 2012. However subsequently it was determined at the time both Chris Swann and Colin Dawson were also independent directors. Therefore the waiver was not required. There has been no further change to directors during the 12 month period therefore the Company complies with the Listing Rules.

## 6. EXERCISE OF NZSX POWERS (LISTING RULE 5.4.2)

NZSX placed a halt on the trading of the Company's ordinary shares on 21st September 2012 at 2.13pm for a price enquiry. The trading halt was lifted at 4.46pm that day after a response to the enquiry by Pacific Edge Limited.

## 7. DIVERSITY

As at 31 March 2013 all four directors of the Company were male. The Chief Executive Officer was also male. The Company does not have a gender diversity policy as at 31 March 2013.

## 8. INDEPENDENCE

- The following directors are considered by the Board to be Independent (as defined under the NZSX Listing Rules): C.J. Swann, C.E.Dawson and D.C Band.
- The following directors are considered by the Board to not be independent: A.G.H Masfen.

# *Independent Auditors' Report*

to the shareholders of Pacific Edge Limited

## Report on the Financial Statements

We have audited the financial statements of Pacific Edge Limited on pages 30 to 62, which comprise the balance sheets as at 31 March 2013, the statements of comprehensive income, statements of changes in equity, statements of cash flows for the year then ended and the notes to the financial statements that include a summary of significant accounting policies and other explanatory information for both the Company and the Group. The Group comprises the Company and the subsidiaries it controlled at 31 March 2013 or from time to time during the financial year.

### *Directors' Responsibility for the Financial Statements*

The Directors are responsible for the preparation of these financial statements in accordance with generally accepted accounting practice in New Zealand and that give a true and fair view of the matters to which they relate and for such internal controls as the Directors determine are necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

### *Auditors' Responsibility*

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing (New Zealand) and International Standards on Auditing. These standards require that we comply with relevant ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditors consider the internal controls relevant to the Company and Group's preparation of financial statements that give a true and fair view of the matters to which they relate, in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company and Group's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

We have no relationship with, or interests in, Pacific Edge Limited or its subsidiaries other than in our capacities as auditors and providing tax services. These services have not impaired our independence as auditors of the Company and Group.

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pwc

# *Independent Auditors' Report*

Pacific Edge Limited

***Opinion***

In our opinion, the financial statements on pages 30 to 62:

(i) comply with generally accepted accounting practice in New Zealand;

(ii) comply with International Financial Reporting Standards; and

(iii) give a true and fair view of the financial position of the Company and the Group as at 31 March 2013, and their financial performance and cash flows for the year then ended.

## *Report on Other Legal and Regulatory Requirements*

We also report in accordance with Sections 16(1)(d) and 16(1)(e) of the Financial Reporting Act 1993. In relation to our audit of the financial statements for the year ended 31 March 2013:

(i) we have obtained all the information and explanations that we have required; and

(ii) in our opinion, proper accounting records have been kept by the Company as far as appears from an examination of those records.

## *Restriction on Distribution or Use*

This report is made solely to the Company's shareholders, as a body, in accordance with Section 205(1) of the Companies Act 1993. Our audit work has been undertaken so that we might state to the Company's shareholders those matters which we are required to state to them in an auditors' report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's shareholders, as a body, for our audit work, for this report or for the opinions we have formed.

PricewaterhouseCoopers

Chartered Accountants Dunedin

27 June 2013

# Glossary

Assay. Chemical reactions that allow detection or quantification of substances or biomarkers in samples.

Biomarker. A characteristic that is objectively measured and evaluated as an indicator of normal biologic or pathogenic processes or pharmacological responses to a therapeutic intervention.

Biopsy. Sample of tissue from a living body extracted for diagnostic purposes.

Classification. The division of a disease into medically relevant subtypes, such as aggressive and nonaggressive subclasses of tumours in oncology.

CLIA. Clinical Laboratory Improvement Ammendment. Regulatory ammendment that enables laboratories to offer Laboratory Developed Tests (LDTs).

Clinical Trial. A single statistically significant trial for patients with disease. The results of the trial provide performance statistics for the test and are written up and published in a peer reviewed journal.

Colonoscopy. Invasive endoscopic examination of the large colon and the end section of the small bowel with a CCD camera or a fibre optic camera on a flexible tube passed through the anus. Frequently used to diagnose colorectal cancer and other colon diseases.

DNA. Deoxyribonucleic acid. The carrier of genetic information for all complex organisms. DNA consists of four different bases bound to a sugar phosphate backbone: adenine (A), cytosine (C), guanine (G), thymine (T). The genetic information is encoded in the sequence of four bases.

Endoscope. Optical device for the inspection of body cavities and minimally invasive surgery. See also colonoscopy.

Endoscopy. Visual inspection of body cavities by use of an endoscope.

False-positive rate. Percentage of healthy individuals, falsely identified as sick due to the imprecision of a diagnostic procedure.

FDA. Food and Drug Administration. U.S. government agency responsible for the approval of drugs and medical devices (e.g. IVD tests)

Incidence. Number of new cases per year in a specific disease indication.

Indication. A valid reason to use a certain test, medication, procedure or surgery.

In vitro. In a test tube.

IVD. In vitro diagnostic.

Milestone payment. One-time payment between contractual parties upon reaching important goals with collaboration.

Molecular classification test. Diagnostic test that, based on the analysis of DNA or RNA allows the more precise classification of a disease in clinically or pathologically relevant subgroups.

Molecular Diagnostics. Diagnostics based on genetic and epigenetic information.

Monitoring. The tracing of potential recurrence or assessment of progression of a disease.

NMP22. Nuclear Matrix Protein 22, a single protein biomarker test used to detect bladder cancer.

Non exclusive licensing model. Strategy for the commercialisation of patents by which several licensees in a geographic region obtain the rights to use one or more patents for the same application.

Nonexclusive partnerships. Business partnerships of a company with several other companies in which each of the collaborations [pursues the same or similar goals.

Oncology. The branch of medicine that studies tumours (cancer) and seeks to understand their development, diagnosis, treatment and prevention.

PCR. Polymerase chain reaction. Method to multiply a section of the DNA in a test tube.

Prognosis. Prediction of how a patient's disease will progress, and the chance of recovery.

Prototype assay. Prototype of a test procedure as a starting point for the development of diagnostic products.

Reagents. Chemical substances needed for the performance of an assay.

Relapse. Disease return following treatment to the primary or distant organ.

Recurrence. Disease return following medical intervention (see relapse)

Research market. Market for laboratory equipment and supplies not intended for therapeutic or diagnostic use in humans or animals.

RNA. Ribonucleic acid. Molecule build of similar components as DNA that mainly as an information carrier is involved in the use of genetic information to direct the synthesis of proteins. Compared to DNA, RNA is chemically and biologically considerably less stable.

RT PCR. Real-time PCR. PCR in which the amplification of a DNA segment is continuously measured.

RUO. Research-Use-Only. Label for products only intended for research applications.

Screening. The systematic and preventative mass screening of an asymptomatic population for early detection of disease.

Sensitivity. The measure of a test's ability to accurately detect the presence of a disease. For example, a sensitivity of 90% means that out of 100 patients which actually have the disease, on average 90 are correctly diagnosed.

Specificity. The measure for a test's ability to exclude a disease if it is truly not present. For example, a specificity of 90% means that out of 100 healthy people ten are falsely identified as having the disease.

Surveillance. Tight surveillance of individuals at high risk of developing a disease by using diagnostic procedure.

Test kit. Test reagent kit. A set of reagents, consumables and processing instructions necessary to perform a diagnostic laboratory test.

Test panel. Combination of different biomarkers in a diagnostic test.

Tumour. A mass of excess tissue that results from abnormal cell division.

Urologist. Specialist clinicians for urological diseases and disorders.

Validation. Establishing documented evidence that a process or system, when operated within established parameters, can perform effectively and reproducibly and meet its predetermined specifications and quality attributes.

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