



PACIFIC EDGE

Cancer Diagnostic Company

Annual Meeting of Shareholders

13 August 2015

# CHAIRMAN

Chris Swann



# BOARD OF DIRECTORS

Experienced Board With A Range Of Complementary Skills Which Add Value To Pacific Edge

Chris Swann	Chairman
David Band	Independent Director
Anatole Masfen	Non-Executive Director
Charles Sitch	Independent Director
Bryan Williams	Independent Director
David Darling	Managing Director and Chief Executive Officer

## GOVERNANCE

### Board of Directors

Experience in governance, finance, cancer research, biotechnology and life sciences, investment and business advisory. Two new independent directors appointed in past two years.

### Subsidiary Board Directors

In-country commercial experience and scientific expertise.

### Scientific and Clinical Advisory Boards

Expert advice on global clinical needs and product applications; and scientific progress and clinical opportunities.

# MANAGEMENT

Providing The Experience and Capability to Deliver on Pacific Edge's Growth Strategy

<b>David Darling</b>	<b>Chief Executive Officer</b>
Jimmy Suttie	Chief Operating Officer
Parry Guilford	Chief Scientific Officer
Kate Rankin	Chief Financial Officer
Jackie Walker	CEO Pacific Edge Diagnostics USA
Brent Pownall	Commercial Director Pacific Edge Diagnostics New Zealand

## MANAGEMENT TEAM

**Experienced and knowledgeable in the following areas:**

Development and international commercialisation of biomedical and biotech businesses

Leadership

New product development

Research and development

Commercial experience including in-market knowledge.

# MEETING AGENDA

- Presentations:
  - Address from the Chair, Chris Swann
  - Address from the Chief Executive Officer, David Darling
- Shareholder Discussion
- Resolutions as per Notice of Meeting
  - Re-election of Anatole Masfen as a director
  - Re-election of Bryan Williams as a director
  - Authorise the directors to fix the auditor's remuneration
- General Business
- Close of Annual Meeting

# OUR STRATEGY

Growth Strategy, Primarily Focused On The USA Market

## OUR OFFER

Delivering innovative solutions for the early detection and better management of cancer

Current focus on building a suite of Cxbladder tests, to increase detection and better management of bladder cancer

Our tests are non-invasive, accurate, fast, easy to use and cost effective

## OUR MARKETS

Primary market is the USA, one of the world's biggest healthcare markets

Pacific Edge tests are also sold commercially in Australia and New Zealand

Continuing to investigate new global market opportunities – identified opportunity in South East Asia

## INVESTING FOR GROWTH


Four main areas of investment: People, Intellectual Property, Market Expansion and Product Development



POTENTIAL FOR  
**MILLIONS** OF TESTS  
IN OUR KEY MARKETS

BLADDER CANCER  
IS THE WORLD'S  
**NINTH**  
MOST PREVALENT CANCER

ESTIMATED MEDICAL  
COST PER BLADDER  
CANCER PATIENT  
**\$240,000**

  
**MORE THAN 1 MILLION** TESTED FOR  
BLADDER  
CANCER  
EVERY YEAR  
IN THE USA

**EXCITING** OPPORTUNITIES  
IN  
SOUTH  
EAST  
ASIA 

  
PARTNERSHIPS IN **USA,**  
**NEW ZEALAND, SPAIN**  
AND **AUSTRALIA**

**2** CERTIFIED  
LABORATORIES  
IN USA & NZ 

**2** **Cxbladder™**  
**PRODUCTS**  
PLUS TWO MORE IN THE PIPELINE

# SHAREHOLDER COMPENSATION UPDATE

- In May 2015, Pacific Edge announced a settlement with FMA in regards to what FMA considered to be breaches of continuous disclosure obligations
- Delay of the announcements in question was not made with an intent to breach continuous disclosure but rather to meet the specific needs of the US contractual counterparties
- Agreed to compensate shareholders who sold PEB shares during the period of delay and the announcement to the NZX
- Compensation has now closed with a total of NZ\$365,000 being paid out to valid claims

# FUNDING FOR GROWTH

Our Goal Is To Attain \$100 Million Of Gross Revenue By Our Fifth Full Year Of Trading

Cash and cash equivalents \$7.82 million as at 31 March 2015

Debt free with funding from capital and technology grants for new product development, commercialisation and USA rollout

Successful capital raising with a total of \$35.3 million raised through a fully underwritten rights offer completed in July 2015

Total of 67% of rights taken up by existing shareholders and the balance being taken up by the underwriters

Funds will be invested into expanding the commercial programme in the US, launch of new Cxbladder products, evaluation of South East Asia opportunity and subsequent commercial programme in SE Asia



# CHIEF EXECUTIVE OFFICER

David Darling



# FY15 HIGHLIGHTS

Primary Focus On Execution Of USA Market Strategy

## **Strong Uplift in Commercial Revenue**

Reflects rollout of USA sales and marketing strategy since initial launch in mid-2013

## **Launch of Second Product, Cxbladder Triage**

Launched in NZ in late 2014, with USA launch planned for 2015

## **Strong Commercial Progress in USA**

Increasing awareness, trial and adoption by targeted urologists

User Programme with Kaiser Permanente

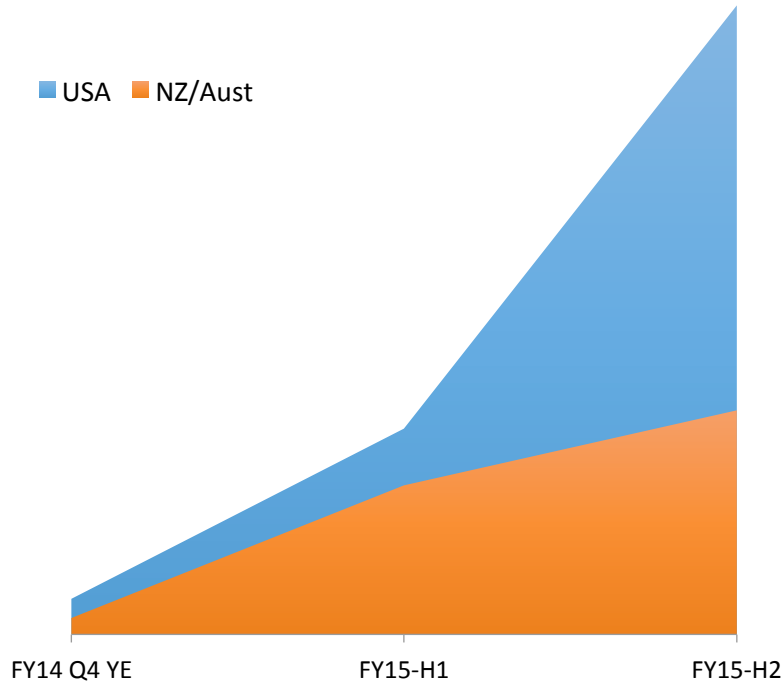
## **Continued Investment into Growth**

People, Intellectual Property, Market Expansion, Product Development

# OUR GOALS AND PROGRESS IN FY15

Expand Our USA Sales Presence And Drive Global Revenue

## Laboratory Throughput



- Sales team expanded from four to twelve sales specialists in the USA
- Strong growth in New Zealand and Australia
- Continuing increase in laboratory throughput with 278% increase in the first half and 140% increase for the second half year.

Laboratory throughput is a measure of total commercial activity and includes tests in User Programmes

# OUR GOALS AND PROGRESS IN FY15

Continue To Rollout User Programmes

## Continue To Rollout User Programmes, Driving Adoption In Our Key Markets, Particularly In The USA

- Increase in number of User Programmes in NZ, Australia and the USA
- Announced large scale User Programme for 2,000 patients in partnership with Southern California Permanente Medical Group (SCPMG), part of Kaiser Permanente

Kaiser Permanente is one of the United States largest not-for-profit health plans, serving more than 10 million members.

More than 17,000 physicians are employed across 38 hospitals and more than 600 medical offices and other facilities



# OUR GOALS AND PROGRESS IN FY15

## Continue To Negotiate Agreements With Payers And NPNs

Continue To Negotiate Agreements With Payers And National And Regional Provider Networks (NPNs) In The USA



- Signed agreement with Multiplan. Pacific Edge now has agreements with the four largest NPNs including FedMed, ACPN and Stratose
- Progressed discussions with Centre for Medicare & Medicaid Services
- Progressed commercial access to the Veteran's Administration through negotiations to gain access to the Federal Supply Schedule

Medicaid and Medicare are two governmental programs that provide medical and health-related services to tens of millions of low income and elderly people in the USA.

The Veteran's Administration provides patient care and other services to USA veterans and their families. There are approx. 2.4 million veterans in the USA.

# OUR GOALS AND PROGRESS IN FY15

Continue To Invest Into R&D and Protection of IP

Continue To Invest Into Research And Development of New Products And Protection of Our Intellectual Property

- Completion of two large validation studies for Cxbladder with results supporting clinical study findings
- Two new bladder cancer diagnostic products currently being developed
- Granted multiple patents for Pacific Edge diagnostic technologies
  - Cxbladder in India and in 38 countries in Europe
  - Prognosis of melanoma in the USA
  - Prognosis of colorectal cancer in Japan and in Europe
  - Detection of gastric cancer in China and in Europe

Investment into clinical performance validation studies, research and peer reviewed science papers

- Completion of two large validation studies for Cxbladder with results supporting clinical study findings
- Four peer-reviewed clinical and science papers published to date with further papers pending
- Completion and of large study demonstrating outperformance of Cxbladder compared to other widely used non-invasive bladder cancer diagnostics, including the UroVysion® FISH assay that is widely used in the United States

# OUR GOALS AND PROGRESS IN FY15

Successfully Launch Second Cxbladder Product, Cxbladder Triage

- Launch of Cxbladder Triage in New Zealand in December 2014 on plan and to schedule
- Cxbladder Triage performance published in peer reviewed science paper in the prestigious international medical journal, BMC Urology, in April 2015



# OUR GOALS AND PROGRESS IN FY15

## Build Presence In Targeted Markets

Ongoing focus on building presence in other targeted markets



- Launch of e-commerce site in New Zealand, making Cxbladder test easily accessible by New Zealand urologists, physicians and patients
- Signed agreements with urologists servicing the Bay of Plenty and Lakes District Health Boards in New Zealand
- Continuing to work with the National Health Committee to put Cxbladder into the Standard of Care in New Zealand
- Evaluation of opportunities in South East Asia



# INVESTING IN PEOPLE

Our success is founded on the expertise, experience and commitment of the clinical, management and sales professionals who work for Pacific Edge



- Refreshed Board of Directors with three new directors in past two years PLUS new director for US subsidiary Board
- Strengthened corporate team with appointment of new CFO in FY15
- Expanded US sales team from four to twelve people in FY15
- Expanded bio-informatics and data management team with three new personnel

# FY15 SUMMARY FINANCIAL PERFORMANCE

Result Reflects Ongoing Investment into Growth Strategy

Strong uplift in sales revenue reflecting growing traction in USA market and strong increase in commercial customer numbers

Second year of funding from a \$4.5 million Callaghan Innovation Grant spread over three years

Other revenue includes interest and foreign exchange gains

Expenses include investment into research and product development including clinical trials and User Programmes

Net Loss After Tax \$11.2 million (Total Comprehensive Loss \$11.1 million)

Cash, cash equivalents and short term deposits on hand at 31 March 2015 \$7.8 million

	FY15 \$NZ'000	FY14 \$NZ'000
Sales Revenue	1,900	145
Grant Income and Research Rebate	1,446	378
Other Revenue	786	315
TOTAL INCOME	4,132	838
TOTAL EXPENSES	14,861	10,789
NET PROFIT/ LOSS BEFORE TAX	(10,729)	(9,951)
Income Tax Expense	-	-
NET PROFIT/LOSS AFTER TAX	(10,729)	(9,951)
Foreign Exchange Translation	145	571
COMPREHENSIVE LOSS AFTER TAX	(10,575)	(9,380)
Earnings Per Share	(0.033)	(0.032)

# OUR GOALS FOR FY16 AND PROGRESS TO DATE



# USA HEALTHCARE MARKET

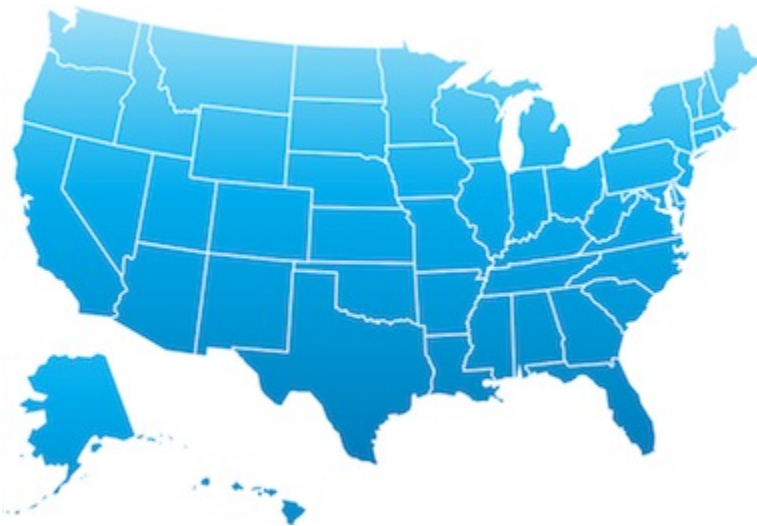
Primary focus on USA healthcare market

## TARGETING THE USA, ONE OF THE WORLD'S LARGEST HEALTHCARE MARKETS

Primary focus for Pacific Edge in the short to medium term

Over 10,000 urologists and millions of potential clinical opportunities for use of Cxbladder products

Growing knowledge base and understanding of the USA market over the past two years



## OTHER MARKETS

Established commercial partnerships in New Zealand and Australia

Continuing to investigate other market opportunities, particularly South East Asia (SEA)

Other Markets: Ongoing discussions and activity to tailor solution to population/clinical requirements

# USA HEALTHCARE MARKET: INFRASTRUCTURE

## Build Infrastructure for Growth

Expand to 18 sales executives covering 19 targeted major metropolitan regions, and increase the number of User Programmes



- Planned recruitment of additional six sales executives
- Two recruited to date and expected to start in their sales territories in September 2015
- Further four sales executives expected to be recruited and in place by November 2015
- Total dedicated sales force of 18 specialists targeting 19 sales regions

# USA HEALTHCARE MARKET: CUSTOMERS

## **Capture Transformational Customers**

Complete the VA and CMS processes to allow access to these patient groups and initiate commercial relationship

Complete the Kaiser Permanente User Programme and transition to commercial relationship



CENTRE FOR MEDICARE & MEDICAID SERVICES (CMS)

Progressing discussions

VETERAN'S ADMINISTRATION

Progressing commercial access to the Veteran's Administration (VA) - have now submitted dossier to gain access to the Federal Supply Schedule (FSS) and expect this process to be completed this calendar year

KAISER PERMANENTE

User Programme underway. Recruitment of patients commenced in June 2015

# USER PROGRAMMES: CONTINUED ROLLOUT

## Enhance Awareness and Foster Strong Adoption

Continue to roll out User Programmes to targeted urologists and clinical groups, particularly in the USA

Complete the Kaiser Permanente User Programme and transition this into commercial sales in the following year

## KAISER PERMANENTE

User Programme underway for Cxbladder Triage. Recruitment of patients commenced in July 2015

- 2000 patient target for recruitment
- Expected completion of recruitment end of FY



# SOUTH EAST ASIA: MARKET ENTRY

## Grow Our International Presence

Finalise business case for entry into the market and look to establish operations in Singapore



- Continuing investigation into market opportunities
- Two distinct markets segments of interest:
  - Patients requiring testing for bladder cancer
  - Medical tourists coming to SEA for regular wellness medical checks
- Launched User Programme with the prestigious Tan Tock Seng (TTSH) hospital in Singapore
- First tests have arrived in Dunedin, enabling us to trial the supply chain logistics
- Targeting further three sites for User Programmes this year



# DELIVER A ONE STOP SHOP OF CXBLADDER PRODUCTS

Our aim is to provide urologists with a 'one stop shop' by offering a suite of Cxbladder products designed to meet the specific clinical needs of the different patient groups

Cxbladder Triage  
In-Market 2014/15

To be used by clinicians and physicians responsible for the primary detection of bladder cancer as a frontline tool in the early evaluation of haematuria (blood in the urine)

Cxbladder Detect  
In-Market 2013/14

Designed for use by urologists, for patients who have been referred for a full work up

Cxbladder Monitor  
Expected Launch 2015

Help physicians monitor bladder cancer in patients

Cxbladder Predict  
Expected Launch 2016

Help segregate low grade tumours from high grade tumours

# CXBLADDER TRIAGE: USA LAUNCH

## Launch Cxbladder Triage in the USA



- Launch programme for Cxbladder Triage in the USA underway early July 2015 with commercial go-live expected in October 2015
- Received CLIA approval for Dunedin laboratory in August 2015
- Expect to have CLIA approval for Hershey laboratory by October 2015

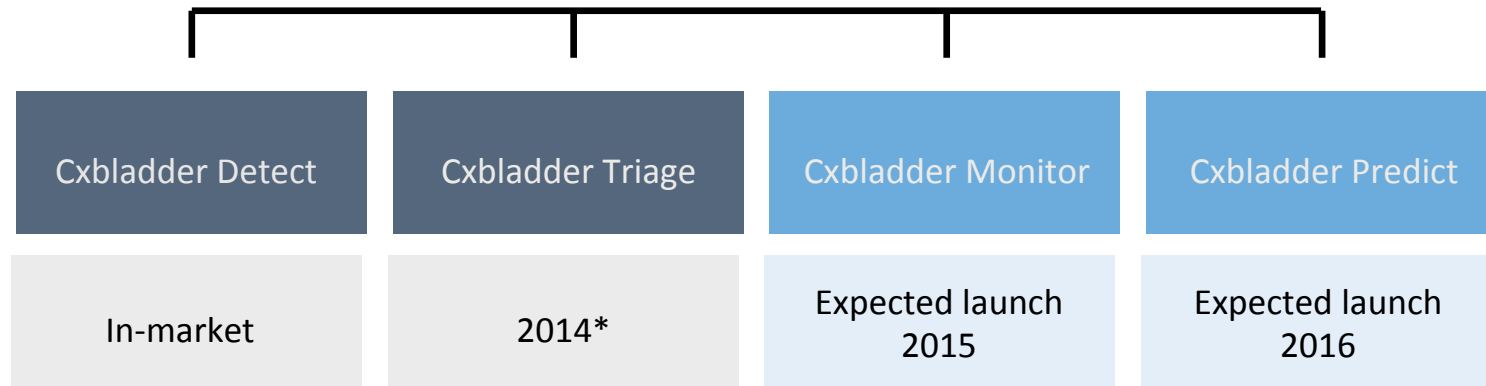


# CXBLADDER PIPELINE: PRODUCT DEVELOPMENT

Bring into commercialisation Cxbladder Monitor and Predict, with initial launch in New Zealand and a fast follow up in the USA

- Continuing development of third Cxbladder product – Cxbladder Monitor
- On track for launch in late-2015 in New Zealand
- Continuing development of fourth Cxbladder product - Cxbladder Predict

## Cxbladder Product Suite



\*Launched in New Zealand

# ENGAGEMENT: PATIENT COMMUNITY

## Engage With The People Who Matter

Launch online patient community for bladder cancer patients and their families

Pacific Edge is the leading sponsor of bladdercancer.me, developed and empowered by Melon Health



Login [Join now](#)

## Welcome to Bladdercancer.me

An online community where people affected by bladder cancer can connect with one another, share experiences and support each other in a safe, secure environment.

[How it works](#)

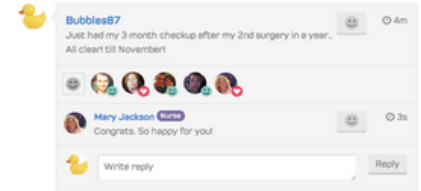
# Bladdercancer.me

- Provides online, relevant resources for bladder cancer patients
  - Peer support
  - Access to appropriate healthcare providers
  - Symptom tracking

Referral site to enable patients to seek the most appropriate healthcare providers and solutions

## Private social network

A safe, supportive online community that allows members to share their experiences, with the freedom to do so anonymously and remotely.



## Clinical support

Specialist nurses interact within the community, monitoring patients progress and providing real time clinical support.

## Video meetings

Users can book a video chat with the nurses through the community, reducing the number of visits to their doctor.

## Welcome to your meeting with Pene

Your meeting is scheduled on September 30, 2014, at 12:00pm



## How do you feel today?



## Health tracking

Users can track their progress from Mood, Pain & Fatigue through to Weight, Bleeding / haematuria events and Frequency of urination. Results are displayed on an easy to read graph and users have the option of adding open text content to support that data.

## Reporting

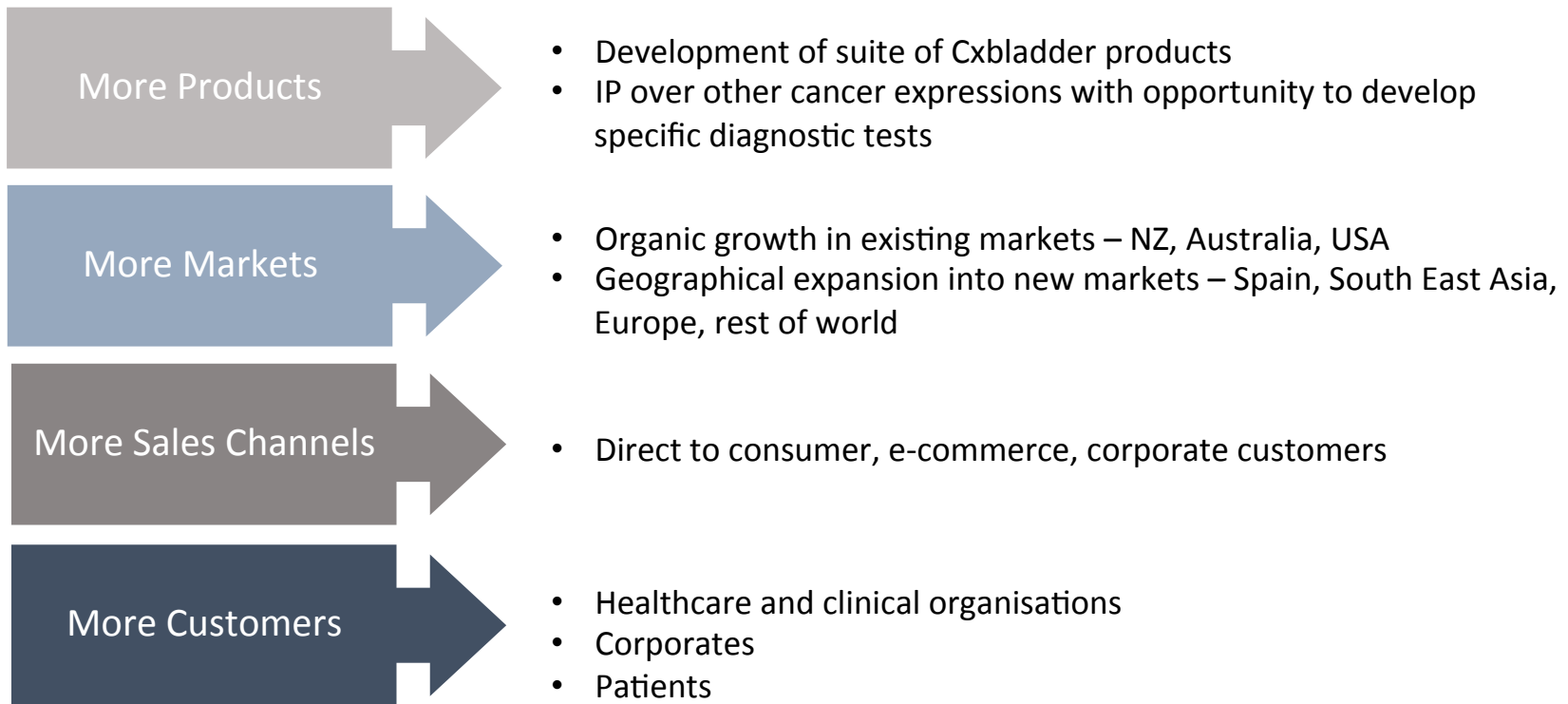
Users can export their tracking data in easy to read formats that they can then share with their caregivers or doctor.

# LOOKING FORWARD



# STRATEGIC OPPORTUNITIES FOR GROWTH

Targeting High Growth Over The Medium Term by Creating More Products and Building Sales in an Increasing Number of Markets



# AN EXCITING FUTURE FOR OUR COMPANY

*We are excited about the opportunities ahead of us and expect our laboratory through-put and commercial revenue to continue growing strongly as we add more exciting Cxbladder products and as more clinicians and patients use our innovative cancer diagnostic products.*





# SHAREHOLDER DISCUSSION

# RESOLUTION: Re-election of Anatole Masfen

That Anatole Masfen, who retires by rotation and is eligible for re-election, be re-elected as a Director of the Company

# RESOLUTION: Re-election of Bryan Williams

That Bryan Williams, who retires by rotation and is eligible for re-election, be re-elected as a Director of the Company

# RESOLUTION: Auditor's Remuneration

That the Directors of the Company be authorised to fix the auditor's remuneration for the ensuing year

# PROXIES

We have received the following valid votes and proxies:

## PROXIES AND POSTAL VOTES

	FOR	AGAINST	DISCRETIONARY	VALID VOTES/ PROXIES RECEIVED	% OF TOTAL ISSUED CAPITAL
Re-election of Anatole Masfen (Resolution 1)	98.75%	0.53%	0.72%	141,106,519	37.47%
Re-election of Bryan Willams (Resolution 2)	99.26%	0.02%	0.72%	141,099,019	37.47%
Authorisation to fix the auditors' remuneration (Resolution 3)	99.26%	0.02%	0.72%	141,085,089	37.47%

# OTHER BUSINESS

# CLOSE OF THE MEETING

Presentations are available at [www.pacificedgedx.com](http://www.pacificedgedx.com)

[www.pacifedge.co.nz](http://www.pacifedge.co.nz)  
[www.cxbladder.com](http://www.cxbladder.com)  
[www.pacifedgedx.com](http://www.pacifedgedx.com)

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