# PACIFIC EDGE LIMITED INTERIM REPORT 2015

FOR THE SIX MONTHS TO 30 SEPTEMBER 2015



Issued Capital 376,543,478 Ordinary Shares

Registered Office Anderson Lloyd Level 10, Otago House Cnr Moray Place and Princes Street Dunedin

Directors C J Swann - Chairman D C Band C Sitch A G H Masfen D Darling - Chief Executive Officer B R G Williams

**Chief Executive Officer** David Darling Auditors PricewaterhouseCoopers Dunedin

**Bankers** Bank of New Zealand Dunedin

Solicitors Anderson Lloyd Otago House 481 Moray Place Dunedin

Securities Registrar Link Market Services Limited 138 Tancred St Ashburton

Company Number 1119032

**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.

The Board of Directors of Pacific Edge Limited are pleased to present the Interim Report for the six months ended 30 September 2015.

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Chris Swann Chairman

David Darling Managing Director and Chief Executive

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# **BUSINESS SNAPSHOT**

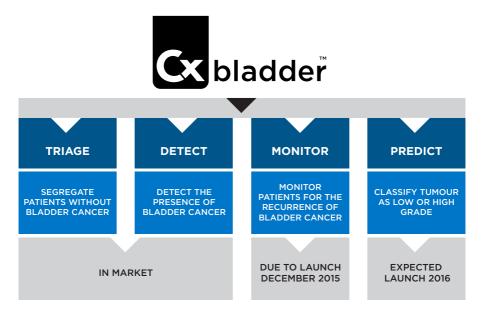
Pacific Edge is a young company, delivering exciting medical products, into a large, complex and changing international healthcare market.

Our novel cancer diagnostic products challenge traditional physician behaviour and offer a new, more effective and less invasive way to test for bladder cancer.

We are currently focused on providing a 'one stop shop' of Cxbladder tests for bladder cancer. Our primary opportunity is in the United States and we also have partnerships in other key markets around the world.

We are in the early stages of our journey and the potential for our company is significant.

# ONE STOP SHOP OF CXBLADDER PRODUCTS



# **FINANCIAL HIGHLIGHTS**

### TOTAL REVENUE \$2.69 MILLION, UP 68% ON HY15

#### **PRODUCT SALES \$1.80 MILLION**

Up 238% on previous first half year and almost equal to full year sales in FY15

### NET LOSS \$6.42 MILLION

Reflects continuing rollout of USA sales strategy and continued investment into people and protection of intellectual property

### SUFFICIENT FUNDING FOR INVESTMENT INTO GROWTH

Cash on hand, cash equivalents and short term deposits of \$32.72 million, as at 30 September 2015, including proceeds from the successful \$35.3 million capital raising completed in July 2015

# **KEY EVENTS**

- Further investment into people including expanding the USA sales team and increasing the commercial and product development teams in New Zealand
- Publication of research demonstrating that Cxbladder out performs other non-invasive bladder cancer diagnostics, including the UroVysion<sup>®</sup> FISH assay that is widely used in the United States
- Successful \$35.3 million capital raising completed in July 2015, providing funds to accelerate the growth strategy in the USA and investigate the market opportunity in South East Asia
- Announced first User Programme in South East Asia, with a leading hospital in Singapore
- Commenced recruitment of patients for the Kaiser Permanente Southern California User Programme, with a target of 2,000 patients
- Pacific Edge's New Zealand laboratory received CLIA regulatory approval to process Cxbladder Triage tests for USA patients
- Announced the termination of the commercial arrangement with Healthscope in Australia, with a new commercial partner currently being finalised
- Announced sponsorship of online patient community, bladdercancer.me, providing resources for bladder cancer patients and their families, due to go live by the end of December 2015
- Finalisation of third product, Cxbladder Monitor, with New Zealand launch planned for December 2015

# FY16 OPERATING OBJECTIVES

## **USA HEALTHCARE MARKET**

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

#### Capture Transformational Customers

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

#### **USER PROGRAMMES**

# 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

## SOUTH EAST ASIA

Grow Our International Presence Finalise business case for entry into the market and look to establish operations in Singapore

#### DELIVER A 'ONE STOP SHOP' OF CXBLADDER PRODUCTS

Launch Cxbladder Triage in the USA

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

# ENGAGE WITH THE PEOPLE WHO MATTER

Launch online patient community for bladder cancer patients

# CHAIRMAN AND CEO REVIEW

Pacific Edge is a young company, with ambitious growth plans. We are making good traction in our commercial journey and have set ourselves a number of milestones to complete in the 2016 financial year. We are pleased to report that we are progressing well towards achieving these goals.

### USA HEALTHCARE MARKET

North America remains our primary growth opportunity, with more than 10,000 urologists and the potential for millions of clinical opportunities for our Cxbladder tests. An additional four out of a planned six sales people were recruited in the half year period. This saw the sales team grow to 16 specialists targeting 19 sales regions, which we have identified as covering 60% of our potential market in the USA.

Progress is also being made in discussions to gain registration on the Federal Supply Schedule (FSS), which will then enable Pacific Edge to sell directly to the Veterans Administration (VA). Completion of this will provide us with access to market and sell our Cxbladder products to the VA's clinicians and health providers who provide care for 8.8 million USA veterans and their families.

We are also looking to conclude the process with the Centre for Medicaid and Medicare Services (CMS) in the near future. This will allow Pacific Edge to claim reimbursement for Cxbladder tests used by the elderly and low income people who are covered under Medicare and Medicaid. Both the VA and the CMS are federal programmes and, as such, they work to their own timetable. The FSS registration with the VA is highly prescribed. It takes some significant time to complete. The CMS is an iterative process and will eventually run its course.

#### USER PROGRAMMES

We are in the early stages of our commercial journey and User Programmes are an essential part of building awareness and acceptance of Cxbladder tests. Lab throughput is expected to increase as momentum builds.

One of our largest User Programmes to date is with Kaiser Permanente, one of America's leading health care providers, which provides services to 9.5 million people. The recent introduction of a new electronic recruiting platform is expected to boost the number of patients recruited, after a slower than anticipated start following the commencement of the Programme in late June 2015. Once the User Programme is completed, we will be working to transition Kaiser Permanente into a large scale commercial customer.

Kaiser Permanente, the VA and the CMS offer access to very large target populations and revenue potential, which could be transformational for our company.

### SOUTH EAST ASIA AND OTHER MARKETS

We have also been investigating the opportunity in South East Asia, where we have identified two distinct potential markets. Firstly, patients requiring testing and management for bladder cancer, and secondly, and more unique to South East Asia, the rapidly growing number of medical tourists who come to the region for regular wellness and medical checkups.

A leading hospital in Singapore signed up to a User Programme earlier in the half year, and we are continuing discussions with several other Singaporean healthcare providers to allow them to evaluate Cxbladder products in their own clinical settings.

We are also continuing to build our other markets. Australia is an important market, albeit much smaller than the USA. We are looking to build traction in this market and are currently finalising discussions with a new commercial partner to market and sell our Cxbladder tests. In New Zealand, sales remain steady, as early adopters transition from User Programmes into commercial customers. It is a real advantage for us to be able to service our Singaporean customers from our New Zealand base.

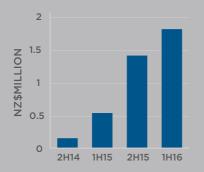
#### BUILDING A 'ONE STOP SHOP' OF CXBLADDER TESTS

We are continuing to develop our new product pipeline as we build a 'one stop shop' of bladder cancer diagnostic tests. The USA launch of the second product in the suite, Cxbladder Triage, started in July and is due to be completed in December 2015, with a number of leading urologists currently trialling Cxbladder Triage in their clinical settings. This product will be commercially available in the USA from January 2016.

A third product, Cxbladder Monitor, is due to launch in New Zealand by the end of 2015 and into the USA in 2016. This test provides urologists with a 'Rule-Out' diagnosis for patients who are being monitored for the recurrence of bladder cancer. In line with our normal USA launch process, this product will be made available for trial by clinicians while we gain CLIA laboratory approval, and then will be made commercially available.

## PRODUCT SALES

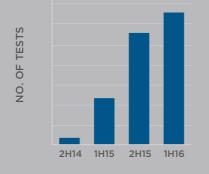
238% increase in product sales compared to the same six months last year



## LABORATORY THROUGHPUT

Includes User Programmes and commercial tests

185% increase in test throughput compared to the same six months last year



# ENGAGE WITH THE PEOPLE WHO MATTER

We are proud to be the leading sponsor of an online patient community bladdercancer.me which has been developed by Melon Health, and is expected to launch by the end of December 2015.

There is a need for support and resources for people affected by bladder cancer and their families including access to a urologist nurse. This community site provides relevant, online resources for bladder cancer patients including peer support, access to appropriate healthcare providers and symptom tracking.

## SIX MONTH FINANCIAL REVIEW

We reported growth in commercial sales as our USA strategy continues to rollout and we build customer numbers in North America and other markets. Sales revenue for the six months was \$1.80 million (HY15: \$0.53m), up 238% on the previous first half year, and almost equal to full year sales achieved in FY15 (FY15:\$1.90m).

Total revenue grew 68% to \$2.69 million (HY15: \$1.60m) and includes grants and other income.

Investment into People, Product Development, Market Expansion and the protection of Intellectual Property remain the largest areas of expenditure for Pacific Edge, and along with the rollout in the USA, formed the majority of \$6.42 million loss for the six month period (HY15: \$4.73m).

Following the successful \$35.3 million capital raising, which was completed in July 2015, we are in a strong position to continue the rollout of our commercial strategy. At 30 September 2015, we had cash on hand, cash equivalents and short term deposits of \$32.72 million (HY15: \$14.71m).

We are continuing to record good growth in the number of Cxbladder tests processed through Pacific Edge laboratories. In the six months to 30 September 2015, numbers were up 19% on the previous six months and 185% up on the same six months in the previous year.

The first half laboratory throughput reflects the transition of User Programmes to commercial use in New Zealand, and the seasonal summer downturn in the USA in July and August. Lab throughput stepped up again in September and October 2015, and we expect to see numbers continuing to grow.

# OUTLOOK

We are firmly focused on growth and providing urologists with high performance tests that provide the potential to significantly improve patient treatment and outcomes.

We are working towards completing a number of milestones in the second half of the financial year, including commencing the commercial launch of Cxbladder Triage into the United States and the launch of our third product, Cxbladder Monitor, in New Zealand.

We will continue to build our presence in the USA market, and are looking to recruit a further two sales executives as planned.

The Veterans Administration and the Centre for Medicaid and Medicare Services offer significant opportunities and we are working hard to finalise discussions with them. Along with Kaiser Permanente, these organisations could be transformational for our company.

We are continuing our investigations into South East Asian markets and also looking to build traction in our other existing markets, particularly in Australia where we hope to soon announce a new commercial partnership to market and sell our tests.

We are focused on driving growth in the second half of the 2016 financial year and expect commercial revenue to continue to rise as we execute our growth strategy, particularly in the USA.

# CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS TO 30 SEPTEMBER 2015





FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2015

# STATEMENT OF COMPREHENSIVE INCOME

	UNAUDITED SEPT 2015 6 MONTHS (\$000)	UNAUDITED SEPT 2014 6 MONTHS (\$000)	AUDITED MARCH 2015 12 MONTHS (\$000)
Product Sales	1,797	531	1,900
Grant Received and Research Rebate	575	480	1,446
Other Revenue (Includes interest and foreign exchange gains)	320	587	786
Total Income	2,692	1,598	4,132
Total Expenses	9,702	6,457	15,361
Net (Loss) for the period	(7,010)	(4,859)	(11,229)
Other Comprehensive Income - Foreign Translation	588	125	154
Total Comprehensive (Loss) attributable to equity holders	(6,422)	(4,734)	(11,075)

The following items are included in the Statement of Comprehensive Income:

Interest Earned	282	305	510
Rent Expense	460	365	750
Depreciation	166	144	308
Amortisation	75	44	151

# STATEMENT OF CHANGES IN EQUITY

	UNAUDITED SEPT 2015 6 MONTHS (\$000)	UNAUDITED SEPT 2014 6 MONTHS (\$000)	AUDITED MARCH 2015 12 MONTHS (\$000)
Net (Loss) for the period	(7,010)	(4,859)	(11,229)
Equity at beginning of the period	10,703	21,778	21,778
Currency translation difference	588	125	154
Contributions by owners	33,400	-	-
Equity at end of period	37,681	17,044	10,703

AS AT 30 SEPTEMBER 2015

## STATEMENT OF FINANCIAL POSITION

	UNAUDITED SEPT 2015 6 MONTHS (\$000)	UNAUDITED SEPT 2014 6 MONTHS (\$000)	AUDITED MARCH 2015 12 MONTHS (\$000)
Cash and Cash Equivalents	3,721	4,707	2,819
Short Term Deposits	29,000	10,000	5,000
Trade Receivables	4,188	1,404	2,584
Inventory	846	443	623
Other Current Assets	374	245	245
Total Current Assets	38,129	16,799	11,271
Property, Plant and Equipment	1,157	1,120	1,118
Intangible Assets	253	275	244
Total Non-Current Assets	1,410	1,395	1,362
Total Assets	39,539	18,194	12,633
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Trade Creditors and Accruals	1,858	1,150	1,930
Total Current Liabilities	1,858	1,150	1,930
Non Current Liabilities	-	-	-
Total Liabilities	1,858	1,150	1,930
Net Assets	37,681	17,044	10,703
Share Capital	100,011	66,612	66,612
Other Reserves	1,284	667	695
Retained Profit (Accumulated Losses)	(63,614)	(50,235)	(56,604)
Shareholders' Equity	37,681	17,044	10,703
Return on Assets (%)	(16%)	(26%)	(88%)
Return on Equity (%)	(17%)	(28%)	(103%)
Debt to Equity Ratio (%)	5%	7%	18%
Earnings per share (basic and diluted) (\$)	(0.017)	(0.015)	(0.035)
Net Tangible Assets per share (\$)	0.100	0.053	0.034

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2015

# STATEMENT OF CASH FLOWS

	UNAUDITED SEPT 2015 6 MONTHS (\$000)	UNAUDITED SEPT 2014 6 MONTHS (\$000)	AUDITED MARCH 2015 12 MONTHS (\$000)
Receipts from Customers	821	370	1,184
Interest Received	194	112	602
Payments to Suppliers/Employees	(9,850)	(6,350)	(14,325)
Net Operating Cash Flows	(8,835)	(5,868)	(12,539)
Cash paid for Purchases of Plant, Property and Equipment	(106)	(85)	(227)
Cash paid for Intangible Assets	(82)	(123)	(199)
Cash (transfers to) proceeds from Short Term Deposits	(24,000)	5,500	10,500
Net Investing Cash Flows	(24,188)	5,292	10,074
Cash proceeds from the Issue of Shares	35,336	-	-
Cash paid for Share Issue expenses	(1,936)	-	-
Net Financing Cash Flows	33,400	-	-
Net Movement in Cash Held	377	(576)	(2,465)
Cash at beginning of period	2,819	4,944	4,944
Effect of exchange rate changes on net cash	525	339	340
Cash at end of period	3,721	4,707	2,819
Comprised of:			
On call accounts	3,721	4,707	2,819
Ending Cash Carried Forward	3,721	4,707	2,819
ANZ Term Deposit	29,000	10,000	5,000
Total Short Term Deposits	29,000	10,000	5,000
Total Cash, Cash Equivalents and Short Term Deposits	32,721	14,707	7,819

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2015

## RECONCILIATION OF (LOSS) WITH NET OPERATING CASH FLOWS

	UNAUDITED SEPT 2015 6 MONTHS (\$000)	UNAUDITED SEPT 2014 6 MONTHS (\$000)	AUDITED MARCH 2015 12 MONTHS (\$000)
Net (Loss) for the period	(7,010)	(4,859)	(11,229)
Add: Non Cash Items			
Depreciation and Amortisation	242	188	459
Add: Movements in Other Working Capital Items:			
(Increase) in Receivables and Other Current Assets	(1,732)	(911)	(2,089)
(Increase) in Inventory on hand	(224)	(201)	(381)
(Decrease)/Increase in Payables	(73)	197	978
Effect of: Currency Translation	(38)	(282)	(277)
Net Operating Cash Flows (Outflows)	(8,835)	(5,868)	(12,539)

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2015

## 1. SUMMARY OF ACCOUNTING POLICIES

The unaudited preliminary financial statements (the "financial statements") presented are those of Pacific Edge Limited ("Company") and its subsidiaries ("Group"). 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 Limited and Pacific Edge Diagnostics USA Ltd manage and operate the laboratories used for the detection of bladder cancer. The Company is a profit oriented entity, registered in New Zealand under the Companies Act 1993. The Company is a Financial Markets Conduct reporting entity for the purposes of the Financial Reporting Act 2013, it is a Financial Markets Conduct Tier 1 reporting entity and its annual financial statements comply with that Act. The unaudited preliminary financial statements are prepared in accordance with Generally Accepted Accounting Practice (NZ GAAP) and comply with the New Zealand Equivalents to International Financial Reporting Standards (NZ IFRS).

## (a) Basis of Preparation of Financial Statements

These general purpose financial statements for the six months ended 30 September 2015 have been prepared in accordance with NZ IAS 34, Interim Financial Reporting. In complying with NZ IAS 34, these consolidated interim financial statements also comply with IAS 34.

These consolidated interim financial statements do not include all the notes of the type normally included in an annual financial report. Accordingly, this report should be read in conjunction with the audited financial statements of Pacific Edge Limited for the year ended 31 March 2015 which have been prepared in accordance with the New Zealand equivalents to International Financial Reporting Standards (NZ IFRS) and International Financial Reporting Standards as a profit-oriented entity for financial reporting purposes.

## (b) Accounting Policies

All significant accounting policies have been applied on a basis consistent with those used in the audited financial statements of Pacific Edge Limited for the year ended 31 March 2015.

## (c) Basis of Consolidation

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

### FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2015

				o Interests g Rights
Name of Subsidiary	Place of Incorporation (or registration) and Operation	Principal Activity	30 Sept 2015 (%)	30 Sept 2014 (%)
Pacific Edge Diagnostics New Zealand Limited	New Zealand	Commercial Laboratory Operation	100	100
Pacific Edge Pty Ltd	Australia	Biotechnology Research & Development	100	100
Pacific Edge Diagnostics USA Ltd	USA	Commercial Laboratory Operation	100	100
Pacific Edge Analytical Services Limited	New Zealand	Dormant Company	100	100
Pacific Edge Diagnostics Singapore Pte Ltd	Singapore	Dormant Company	100	-

## 2. INVESTMENT AND ADVANCES IN SUBSIDIARIES

The consolidated financial statements incorporate the assets and liabilities and result of Pacific Edge Diagnostics New Zealand Limited, Pacific Edge Diagnostics USA Ltd, Pacific Edge Diagnostics Singapore Pte Ltd, Pacific Edge Analytical Services Limited and Pacific Edge Pty Ltd, all of which are 100% owned. Subsidiaries have a 31 March balance date. The investment and advance in subsidiaries are eliminated on consolidation in the Group financial statements.

## 3. DIVIDENDS

The company does not propose to pay dividends to shareholders similar to previous years. This policy continues.

## 4. SEGMENT INFORMATION

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

The Chief Executive Officer considers the business to be three operating segments at balance date.

These segments are:

- Research and development of diagnostic and prognostic products for human cancer (Pacific Edge Limited and Pacific Edge Pty Ltd).
- The operator of the laboratories in New Zealand (Pacific Edge Diagnostics New Zealand Limited).

- The operator of the commercial laboratory in the United States (Pacific Edge Diagnostics USA Ltd).

## FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2015

The segment revenue and assets information provided to the Chief Executive Officer for the reportable segments described above, for the six months ended 30 September 2015, are shown below.

Unaudited - 6 Months 30 September 2015	NZ Laboratory (\$000)	US Laboratory (\$000)	Research NZ & Australia (\$000)	Less: Eliminations (\$000)	Total External Income (\$000)
Income					
Product Sales	30	1,766	1	-	1,797
Grant Revenue and Research Rebate	-	-	575	-	575
Other Income	145	75	360	(260)	320
Total Income	175	1,841	936	(260)	2,692
Expenses					
Expenses	587	5,146	3,988	(260)	9,461
Depreciation & Amortisation	8	105	128	-	241
Total Operating Expenses	595	5,251	4,116	(260)	9,702
Loss Before Tax	(420)	(3,410)	(3,180)	-	(7,010)
Unaudited - 6 Months 30 September 2014	NZ Laboratory (\$000)	US Laboratory (\$000)	Research NZ & Australia (\$000)	Less: Eliminations (\$000)	Total External Income (\$000)
Income					
Product Sales	71	460	-	-	531
Grant Revenue and Research Rebate	-	-	480	-	480
Other Income	169	14	585	(181)	587
Total Income	240	474	1,065	(181)	1,598
Expenses					
Expenses	447	2,521	3,482	(181)	6,269
Depreciation & Amortisation	12	83	93	-	188
Total Operating Expenses	459	2,604	3,575	(181)	6,457
Loss Before Tax	(219)	(2,130)	(2,510)	-	(4,859)

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2015

Pacific Edge Diagnostics New Zealand Limited and Pacific Edge Diagnostics USA Ltd have carried out the analysis of Cxbladder tests for Pacific Edge Limited as part of the Company's user programmes with customers in New Zealand, Australia and the USA respectively. User Programmes are an important component of the adoption process for Cxbladder.

The revenue from intercompany transactions has been eliminated on consolidation of Group results.

### 4. SEGMENT INFORMATION CONTINUED

Segment assets and liabilities information:

Unaudited - 6 Months 30 September 2015	NZ Laboratory (\$000)	US Laboratory (\$000)	Research NZ & Australia (\$000)	Total (\$000)
Total Assets	185	4,608	34,746	39,539
Total Liabilities	50	684	1,124	1,858

Unaudited - 6 Months 30 September 2014	NZ Laboratory (\$000)	US Laboratory (\$000)	Research NZ & Australia (\$000)	Total (\$000)
Total Assets	237	1,671	16,286	18,194
Total Liabilities	85	224	841	1,150

### 5. SHARE CAPITAL

	Shares (000)	Unaudited Sept 2015 6 Months (\$000)	Unaudited Sept 2014 6 months (\$000)	Audited March 2015 12 months (\$000)
Opening Balance	318,616	66,611	66,611	66,611
New Issues: Direct Offers	57,928	35,336	-	-
Share capital before issue expenses	376,544	101,947	66,611	66,611
Less: Issue Expenses	-	(1,936)	-	-
Closing Balance	376,544	100,011	66,611	66,611

There are 376,543,478 (March 2015: 318,615,921 and September 2014: 318,615,921) 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.

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2015

## 6. CONTINGENT LIABILITIES

There were no known contingent liabilities at 30 September 2015 (March 2015: Nil and September 2014: Nil). The Company and Group have not granted any securities in respect of liabilities payable by any other party whatsoever.

## 7. CAPITAL COMMITMENTS

There are no capital commitments at 30 September 2015 (March 2015 Nil: and September 2014: Nil).

## 8. SUBSEQUENT EVENTS

There were no events subsequent to balance date.



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