

BIODIEM LTD

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Australia

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#### **BioDiem Releases Half Year Results**

Melbourne, 31 March 2016: Australian infectious disease therapy and vaccine development company BioDiem Ltd today announced its financial results for the half year ended 31 December 2015.

The Company's focus for the half year was on the commercial influenza vaccine licensing business, and on its subsidiary, Opal Biosciences, with its novel antimicrobial, BDM-I, and its development for treatment of antibiotic-resistant infections.

# Highlights

- Royalties and milestone payments from the licencees of BioDiem's LAIV technology of \$126,255 for the period, compared to \$103,732 for the previous corresponding period. Growth in sales and royalties is expected with new sales into expanded territories following relevant regulatory approvals.
- World Health Organisation Prequalification for Nasovac-S in October 2015 which will allow SII to export to other
  developing countries of the United Nations. BioDiem will gain income from royalties on sales of Nasovac-S in the
  private sector of these export markets.
- Chinese FDA approval for commencement of clinical trials by BioDiem's licencee, Changchun BCHT Biotechnology
  Co.'s (BCHT). These trials will be used in support of an application for marketing by BCHT of their influenza vaccine
  based on BioDiem's LAIV influenza technology. BioDiem will gain income from royalties on sales of BCHT's LAIV
  vaccine in the private sector in China.
- Ongoing discussions with new parties for additional licences to BioDiem's LAIV technology.
- Continuation of the development program of BDM-I, through Opal Biosciences. Work included commencement of new formulation development, safety pharmacology and cytotoxicity studies (*in vitro*) and ongoing mechanism of action studies at Western Sydney University.
- Continued expenditure control management.

# **Key Results Summary**

		% change from previous corresponding period	A\$'000
Revenue from ordinary activities	Up	6.34	\$128,272
Loss from ordinary activities	Up	25.46%	(596,927)
Net loss for the half year attributable to Non- controlling interest	Up	100%	(1,201)
Net loss for the half year attributable to Owners of BioDiem Limited	Up	25.21%	(595,726)

### Other Information

No dividends have been declared or are expected to be declared in the remainder of the year.

- ENDS -

# About BioDiem Ltd

BioDiem is an Australian biopharmaceutical company that is focused on developing and commercialising vaccines and infectious disease therapies. BioDiem's business model is to generate income from partnerships including with other vaccine and infectious disease treatment companies through existing and new licences to its LAIV vaccine and other technologies. Income comes from licence fees and royalties on sales.

BioDiem's lead technology is the LAIV (Live Attenuated Influenza Virus) vaccine technology used for production of seasonal and pandemic influenza vaccines and is given intranasally. This technology is licensed currently to two commercial partners, in India and China, and is licenced to the World Health Organisation as part of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply. Serum Institute of India's Nasovac-S™ is based on BioDiem's technology and is already marketed in India.

BioDiem's antimicrobial technology, BDM-I, is being developed through its subsidiary, Opal Biosciences Ltd. For additional information, please visit <a href="https://www.biodiem.com">www.biodiem.com</a>.

# **About Opal Biosciences Ltd**

Opal Biosciences is an Australian biotechnology company and an innovative player in infectious disease treatment. The unmet need for new anti-infectives is due to increasing resistance to existing antibiotics, more widespread and common difficult-to-treat infections, and the paucity of upcoming new treatments. This need has spurred the EU and US to introduce significant financial incentives to encourage development of new anti-infectives. Opal is currently seeking funding to support the next stage of development of our products:

- Opal-I, an injectable product, and
- Opal-T, which can be applied to the skin.

For more information, please visit <a href="https://www.opalbiosciences.com">www.opalbiosciences.com</a>.

#### **Further information**

Julie Phillips, Chief Executive Officer

BioDiem Ltd

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# **BioDiem Limited**

ABN 20 096 845 993

Half-year Financial Report - 31 December 2015

# BioDiem Limited Contents 31 December 2015

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# BioDiem Limited Corporate directory 31 December 2015

Directors Mr Hugh M Morgan AC (Chairman, Non-Executive Director)

Ms Julie Phillips (Chief Executive Officer)
Prof Larisa Rudenko (Non-Executive Director)

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Investor Queries (within Australia): 1300 850 505

Company secretary Melanie Leydin

Registered office Level 4

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Principal place of business Level 4

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Auditor Grant Thornton Audit Pty Ltd

The Rialto, Level 30 525 Collins Street Melbourne VIC 3000

Website www.biodiem.com

## BioDiem Limited Directors' report 31 December 2015

The directors present their report, together with the financial statements, on the consolidated entity (referred to hereafter as the 'Group') consisting of BioDiem Limited (referred to hereafter as the 'Company' or 'parent entity') and the entities it controlled at the end of, or during, the half-year ended 31 December 2015.

#### **Directors**

The following persons were directors of BioDiem Limited during the whole of the financial half-year and up to the date of this report, unless otherwise stated:

Mr Hugh M Morgan AC Ms Julie Phillips Prof Larisa Rudenko

### **Principal activities**

During the financial half-year the principal continuing activities of the Group consisted of:

- The development and commercialisation of pharmaceutical and biomedical research.
- Securing licences for its range of biopharmaceutical products currently under development.

#### **Review of operations**

The loss for the Group after providing for income tax and non-controlling interest amounted to \$596,927 (31 December 2014: \$475,782).

During the six months ended 31 December 2015, significant progress has been made on all key development programs towards commercial milestones.

Revenue from licensing activities for the half year was \$0.126m compared to \$0.104m in 2014, whilst interest income was \$0.002m compared to \$0.013m in 2014. Research activity costs were \$0.372m compared to \$0.326m in 2014. Administration expenses were \$0.471m as compared to \$0.441m in 2014.

The Group commenced the period with cash reserves of \$0.446m. Cash outlays for research and administration were \$0.745m compared to \$0.692m in the comparative period. Cash inflows were \$0.128m from royalties and licensing agreements (2014: \$0.104m). Cash received from Research and Development Tax Offset in the current period was \$0.178 (2014 \$Nil). Cash reserves at the end of the financial half-year totalled \$0.547m.

#### Significant changes in the state of affairs

On 6 July 2015 the Company received approval from its shareholders at a General Meeting to assign the BDM-I technology into Opal Biosciences Limited. Consideration payable by Opal for this assignment comprised the following:

- (i) the issue by Opal to BioDiem of 10 million fully paid ordinary shares:
- (ii) the issue by Opal to BioDiem of 5 million options; and
- (iii) \$500,000 cash consideration

The reason BioDiem assigned the BDM-I technology to Opal was to raise capital to develop the BDM-I technology without diluting existing shareholders' interest in the Company while ensuring that shareholders keep access to the value of the BDM-I technology and potential future upside.

During the period Opal Biosciences raised a total of \$103,000 via the issue of 515,000 ordinary shares and the grant of 248,125 options in accordance with the information memorandum dated 15 May 2015.

On 1 October 2015 the Company issued 3,735,250 ordinary shares via a private placement to two of the Company's major shareholders at \$0.08 (8 cents) per share raising \$298,820.

On 21 December 2015 the Company issued 471,844 ordinary shares via a non-renounceable pro-rata entitlement offer at \$0.08 (8 cents) per share raising \$37,748.

There were no other significant changes in the state of affairs of the Group during the financial half-year.

## Auditor's independence declaration

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out on page 5.

# BioDiem Limited Directors' report 31 December 2015

This report is made in accordance with a resolution of directors, pursuant to section 306(3)(a) of the Corporations Act 2001.

On behalf of the directors

H M Morgan AC

Director

22 March 2016 Melbourne



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# Auditor's Independence Declaration To The Directors of BioDiem Limited

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the review of BioDiem Limited for the half-year ended 31 December 2015, I declare that, to the best of my knowledge and belief, there have been:

- a No contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- b No contraventions of any applicable code of professional conduct in relation to the review.

GRANT THORNTON AUDIT PTY LTD

I want Thompson

Chartered Accountants

M. A. Cunningham

Partner - Audit & Assurance

Melbourne, 22 March 2016

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# BioDiem Limited Statement of profit or loss and other comprehensive income For the half-year ended 31 December 2015

	Note	Consolid 31 December 3 2015 \$	
Revenue	3	128,272	120,623
Other income		152,754	192,614
Expenses Licence fees and royalty expenses Research and development expenses Administration expenses Net foreign exchange loss		(34,447) (372,175) (471,331)	(20,000) (326,411) (440,533) (2,075)
Loss before income tax expense		(596,927)	(475,782)
Income tax expense			<u>-</u>
Loss after income tax expense for the half-year		(596,927)	(475,782)
Other comprehensive income for the half-year, net of tax			
Total comprehensive income for the half-year		(596,927)	(475,782)
Loss for the half-year is attributable to: Non-controlling interest Owners of BioDiem Limited		(1,201) (595,726) (596,927)	(475,782) (475,782)
Total comprehensive income for the half-year is attributable to: Non-controlling interest Owners of BioDiem Limited		(1,201) (595,726) (596,927)	(475,782) (475,782)

		Conso	lidated
		31 December	
	Note	2015	30 June 2015
		\$	\$
Assets			
Current assets			
Cash and cash equivalents		547,416	446,349
Trade and other receivables		16,357	13,978
Other		219,416	286,405
Total current assets		783,189	746,732
Total assets		783,189	746,732
Liabilities			
Current liabilities			
Trade and other payables		160,206	86,898
Employee benefits		64,985	52,691
Other	4	100,000	
Total current liabilities		325,191	139,589
Non-current liabilities			
Employee benefits		48,534	42,358
Total non-current liabilities		48,534	42,358
Total Pakilisia		070 705	404.047
Total liabilities		373,725	181,947
Net assets		400.464	EGA 70E
Net assets		409,464	564,785
F Mar.			
Equity	_	00 700 000	00 400 700
Issued capital	5	30,766,366	30,429,799
Reserves	6	310,356	308,317
Accumulated losses		(30,769,057)	
Equity attributable to the owners of BioDiem Limited		307,665	564,785
Non-controlling interest		101,799	
Total amilia		400 404	F04 70F
Total equity		409,464	564,785

# BioDiem Limited Statement of changes in equity For the half-year ended 31 December 2015

Consolidated	Issued Capital \$	Reserves	Accumulated losses \$	Non- controlling interest \$	Total equity \$
Balance at 1 July 2014	30,087,862	296,532	(29,026,850)	-	1,357,544
Loss after income tax expense for the half-year Other comprehensive income for the half-year, net of tax	- -	-	(475,782)	- 	(475,782)
Total comprehensive income for the half-year	-	-	(475,782)	-	(475,782)
Transactions with owners in their capacity as owners: Share-based payments		8,131			8,131
Share-based payments	<u>-</u>	0,131	·		0,131
Balance at 31 December 2014	30,087,862	304,663	(29,502,632)		889,893
				Non-	
Consolidated	Issued Capital \$	Reserves \$	Accumulated losses \$	controlling interest \$	Total equity \$
Consolidated Balance at 1 July 2015			losses	controlling interest	equity
	Capital \$	\$	losses \$	controlling interest	equity \$
Balance at 1 July 2015  Loss after income tax expense for the half-year Other comprehensive income for the half-year,	Capital \$	\$	losses \$ (30,173,331)	controlling interest \$	<b>equity</b> \$ 564,785
Balance at 1 July 2015  Loss after income tax expense for the half-year Other comprehensive income for the half-year, net of tax	Capital \$	\$	(30,173,331) (595,726)	controlling interest \$ - (1,201)	equity \$ 564,785 (596,927)

# **BioDiem Limited** Statement of cash flows For the half-year ended 31 December 2015

	Consolidated		dated
	Note	31 December 3 2015	1 December 2014
	Note	2015 \$	2014 \$
		•	
Cash flows from operating activities		120 022	102 022
Cash receipts in course of operations Cash payments in course of operations		128,022 (744,954)	103,932 (692,233)
Interest received		473	11,620
Government grants received		-	3,300
R&D Tax Offset received		177,959	
Net cash used in operating activities		(438,500)	(573,381)
Cash flows from investing activities			
Net cash from investing activities			
Cash flows from financing activities			
Proceeds from issue of shares	5	439,567	-
Proceeds received in advance of share issue		100,000	119,941
Net cash from financing activities		539,567	119,941
Net increase/(decrease) in cash and cash equivalents		101,067	(453,440)
Cash and cash equivalents at the beginning of the financial half-year		446,349	1,336,812
Cash and cash equivalents at the end of the financial half-year		547,416	883,372
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#### Note 1. General information

The financial statements cover BioDiem Limited as a Group consisting of BioDiem Limited and the entities it controlled at the end of, or during, the half-year. The financial statements are presented in Australian dollars, which is BioDiem Limited's functional and presentation currency.

BioDiem Limited is a listed public company limited by shares, incorporated and domiciled in Australia. Its registered office and principal place of business is:

Level 4 100 Albert Road South Melbourne VIC 3205

A description of the nature of the Group's operations and its principal activities are included in the directors' report, which is not part of the financial statements.

The financial statements were authorised for issue, in accordance with a resolution of directors, on 22 March 2016. The directors have the power to amend and reissue the financial statements.

#### Note 2. Significant accounting policies

These general purpose financial statements for the interim half-year reporting period ended 31 December 2015 have been prepared in accordance with Australian Accounting Standard AASB 134 'Interim Financial Reporting' and the Corporations Act 2001, as appropriate for for-profit oriented entities. Compliance with AASB 134 ensures compliance with International Financial Reporting Standard IAS 34 'Interim Financial Reporting'.

These general purpose financial statements do not include all the notes of the type normally included in annual financial statements. Accordingly, these financial statements are to be read in conjunction with the annual report for the year ended 30 June 2015 and any public announcements made by the Company during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations Act 2001.

The principal accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period, unless otherwise stated.

# New, revised or amending Accounting Standards and Interpretations adopted

The Group has adopted all of the new, revised or amending Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting period.

Any new, revised or amending Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

#### Going concern

The financial report has been prepared on the going concern basis, which assumes continuity of normal business activities and the realisation of assets and the settlement of liabilities in the ordinary course of business.

The Group reported a net loss after tax of \$0.597m (2014: \$0.476m net loss after tax) for the half-year ended 31 December 2015. The net loss after tax is directly attributable to the expenditures incurred in ongoing research and development activities, as well as administration expenditure. Despite the net loss after tax incurred for the period, the Directors have prepared the financial statements on the going concern basis. The going concern basis is considered appropriate based on a combination of the existing net assets of the Group, which amount to \$0.409m (30 June 2015: \$.565m), including cash and cash equivalent assets of \$0.547m (30 June 2015: \$0.446m), and the expectation of Group's ongoing ability to successfully secure additional sources of financing. In this regard, the Directors note the following:

## Note 2. Significant accounting policies (continued)

- The Group has a licence agreement with the Serum Institute of India ("Serum"), which entitles the Group to royalty income upon the sale of LAIV seasonal influenza vaccine in the private market in the territories covered by the agreement. Royalty income has commenced from this licence agreement and the Group expects this to strengthen within the next 12 months.
- The Group has a LAIV licensing agreement with Changchun BCHT Biotechnology Co., where the vaccine subject to the LAIV licensing agreement is currently under development. If the development and commercialisation of the vaccine in the private market in the territories covered by the agreement is successful, the LAIV licensing agreement is expected to provide further royalty income streams in the future. Annual milestone payments apply until sales occur.
- The Group is considering other alternative sources of cash inflows from sale of technologies. The Directors have the discretion to initiate financing initiatives, such as capital raisings.
- Directors have the ability to curtail discretionary expenditures, which form a significant part of the Group's total expenditure, enabling the Group to fund its operating expenditures within its available cash reserves.

For these reasons, the Directors believe the Group has positive future prospects and are satisfied the going concern basis of preparation of these financial statements is appropriate.

Whilst the directors are confident in the Group's ability to continue as a going concern, in the event the commercial opportunities and potential sources of financing described above do not eventuate as planned, there is uncertainty as to whether the Group will be able to generate sufficient net operating cash inflows or execute alternative funding arrangements to enable it to continue as a going concern.

Consequently, material uncertainty exists as to whether the Group will continue as a going concern and it may therefore be required to realise assets, extinguish liabilities at amounts different to those recorded in the statement of financial position and settle liabilities other than in the ordinary course of business.

#### Note 3. Revenue

		lidated
		31 December
	2015	2014
	\$	\$
Royalty and milestone revenue	126,255	103,732
Grant income		3,300
	126,255	107,032
Other revenue		
Interest	2,005	13,391
Other revenue	12	200
	2,017	13,591
Revenue	128,272	120,623
Note 4. Current liabilities - Other		
	Consc	lidated
	31 December	
	2015	30 June 2015
	\$	\$
Funds received in advance	100,000	-

Funds totalling \$100,000 received as at 31 December 2015 relate to amounts received for participation in the rights issue shortfall, which were allotted into ordinary shares subsequent to period end.

### Note 5. Equity - issued capital

	Consolidated				
	31 December		31 December	,	
	2015 Shares	30 June 2015 Shares	2015 \$	30 June 2015 \$	
Ordinary shares - fully paid	171,568,738	167,361,644	30,766,366	30,429,799	

# Movements in ordinary share capital

Details	Date	Shares	Issue price	\$
Balance Placement Non-renounceable pro-rata entitlement offer	1 July 2015 1 October 2015 21 December 2015	167,361,644 3,735,250 471,844	\$0.08 \$0.08	30,429,799 298,820 37,747
Balance	31 December 2015	171,568,738		30,766,366

### Ordinary shares

Ordinary shares entitle the holder to participate in dividends and the proceeds on the winding up of the Company in proportion to the number of and amounts paid on the shares held. The fully paid ordinary shares have no par value and the Company does not have a limited amount of authorised capital.

On a show of hands every member present at a meeting in person or by proxy shall have one vote and upon a poll each share shall have one vote.

## Note 6. Equity - reserves

	Consolidated 31 December		
	2015 \$	30 June 2015 \$	
Share-based payments reserve	310,356	308,317	

## Share-based payments reserve

The share based payments reserve represents the cumulative value (based on grant date fair value) of outstanding and lapsed awards. No gain or loss is recognised in profit or loss on the purchase, sale, issue or cancellation of the Company's own equity instruments.

#### Movements in reserves

Movements in each class of reserve during the current financial half-year are set out below:

	Share based	
Consolidated	payments \$	Total \$
Balance at 1 July 2015 Share based payments	308,317 2,039	308,317 2,039
Balance at 31 December 2015	310,356	310,356

# Note 7. Equity - dividends

There were no dividends paid, recommended or declared during the current or previous financial half-year.

### Note 8. Contingent liabilities

The Group has acquired a licence to commercialise influenza vaccine technologies from the Institute of Experimental Medicine. Under this agreement the Group is obliged to pay the Institute of Experimental Medicine twenty percent of all payments received from any Licensee and twenty percent of any royalties arising from net income.

#### Note 9. Commitments

The Group has no lease commitments at 31 December 2015.

# Note 10. Interests in subsidiaries

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiary in accordance with the accounting policy described in note 2 of the 30 June 2015 annual financial report:

		nip interest r	
Name	Principal place of business / Country of incorporation	<b>2015</b> %	30 June 2015 %
Savine Therapeutics Pty Ltd	Australia	100.00%	100.00%
Opal Biosciences Limited *	Australia	95.10%	-

<sup>\*</sup> On 6 July 2015 the Company received approval from its shareholders at a General Meeting to assign the BDM-I technology into Opal Biosciences Limited. Consideration payable by Opal for this assignment comprised the following:

- (i) the issue by Opal to BioDiem of 10 million fully paid ordinary shares;
- (ii) the issue by Opal to BioDiem of 5 million options; and
- (iii) \$500,000 cash consideration

The reason BioDiem assigned the BDM-I technology to Opal was to raise capital to develop the BDM-I technology without diluting existing shareholders' interest in the Company while ensuring that shareholders keep access to the value of the BDM-I technology and potential future upside.

During the period Opal Biosciences raised a total of \$103,000 via the issue of 515,000 ordinary shares and the grant of 248,125 options in accordance with the information memorandum dated 15 May 2015.

### Note 11. Events after the reporting period

No matter or circumstance has arisen since 31 December 2015 that has significantly affected, or may significantly affect the Group's operations, the results of those operations, or the Group's state of affairs in future financial years.

## BioDiem Limited Directors' declaration 31 December 2015

In the directors' opinion:

- the attached financial statements and notes comply with the Corporations Act 2001, Australian Accounting Standard AASB 134 'Interim Financial Reporting', the Corporations Regulations 2001 and other mandatory professional reporting requirements;
- the attached financial statements and notes give a true and fair view of the Group's financial position as at 31 December 2015 and of its performance for the financial half-year ended on that date; and
- there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of directors made pursuant to section 303(5)(a) of the Corporations Act 2001.

On behalf of the directors

H M Morgan AC Director

22 March 2016 Melbourne



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# Independent Auditor's Review Report To the Members of BioDiem Limited

We have reviewed the accompanying half-year financial report of BioDiem Limited ("Company"), which comprises the consolidated financial statements being the statement of financial position as at 31 December 2015, and the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, notes comprising a statement or description of accounting policies, other explanatory information and the directors' declaration of the consolidated entity, comprising both the Company and the entities it controlled at the half-year's end or from time to time during the half-year.

## Directors' responsibility for the half-year financial report

The directors of BioDiem Limited are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 and for such controls as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement, whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to express a conclusion on the consolidated half-year financial report based on our review. We conducted our review in accordance with the Auditing Standard on Review Engagements ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Company, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the Corporations Act 2001 including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001. As the auditor of BioDiem Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

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A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Independence

In conducting our review, we complied with the independence requirements of the Corporations Act 2001.

#### Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of BioDiem Limited is not in accordance with the Corporations Act 2001, including:

- a giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and of its performance for the half-year ended on that date; and
- b complying with Accounting Standard AASB 134 Interim Financial Reporting and Corporations Regulations 2001.

#### Significant uncertainty regarding going concern

Without qualifying our opinion, we draw attention to Note 2 in the financial report which indicates that the consolidated entity incurred a net loss of \$596,927 during the half-year ended 31 December 2015. This condition, along with other matters as set forth in Note 2, indicate the existence of a material uncertainty which may cast significant doubt about the consolidated entity's ability to continue as a going concern and therefore, the consolidated entity may be unable to realise its assets and discharge its liabilities in the normal course of business, and at the amounts stated in the financial report

GRANT THORNTON AUDIT PTY LTD

Chartered Accountants

M. A. Cunningham

Partner - Audit & Assurance

Melbourne, 22 March 2016