

BIODIEM LTD ABN 20 096 845 993

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# **BioDiem Releases Half Year Results**

Melbourne, 16 March 2015: Australian infectious disease therapy and vaccine development company BioDiem Ltd today announced its financial results for the half year ended 31 December 2014.

The Company's focus for the half year was on the commercial influenza vaccine licensing business, and BDM-I, BioDiem's antimicrobial development program.

# Highlights

- Launch of Nasovac-S<sup>™</sup> in India by commercial partner Serum Institute of India (SII). Nasovac-S is SII's seasonal
  influenza vaccine product based on BioDiem's technology. A major advantage of Nasovac-S is that it is given by
  nose drop rather than injected. Royalties from sales of Nasovac-S into the private market are expected to flow to
  BioDiem before the end of financial year 2015. Currently India is experiencing a swine flu outbreak and more than
  1700 deaths have been reported to date.
- Progress of Serum Institute of India's application to the World Health Organisation for prequalification of Nasovac-S. Prequalification, when granted, 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.
- Progress of our Chinese licencee, Changchun BCHT Biotechnology Co.'s (BCHT) application to conduct clinical trials in China. These trials will be used in support of an application for marketing by BCHT of their influenza vaccine based BioDiem's LAIV influenza technology.
- Exploration of new commercial opportunities in developed world markets for the LAIV technology.
- Development of a plan to take antimicrobial, BDM-I, to proof-of-concept stage in nonclinical models to assist discussions with potential partners. The plan includes expanded formulation presentation.
- Continued expenditure control management.

		% change from previous corresponding period	A\$
Revenue from ordinary activities	Up	15.5%	\$120,623
Loss from ordinary activities	Down	16.5%	(475,782)
Net loss for the half year attributable to equity holders	Down	16.5%	(475,782)

# Key Results Summary

# Other Information

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

Commenting on the results, BioDiem's CEO Julie Phillips said: "With the launch the first seasonal influenza vaccine product based on our technology outside of Russia, the Company is in a new position. The royalty flow to BioDiem is expected to strengthen once the product becomes established in current and new markets. Also the recent transactions in the antimicrobial market supports our view of the attractiveness of BDM-I. Our focus for this asset is to complete the path to proof-of-concept and then commercialise through outlicensing."

- ENDS -

# About BioDiem Ltd

BioDiem is an Australian biopharmaceutical company that is focussed 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<sup>™</sup> is based on BioDiem's technology and is already marketed in India. For additional information, please visit <u>www.biodiem.com</u>

# Further information

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# **BioDiem Limited**

ABN 20 096 845 993

Half-year Financial Report - 31 December 2014

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# BioDiem Limited Corporate directory 31 December 2014

Directors	Mr Hugh M Morgan AC (Chairman, Non-Executive Director) Ms Julie Phillips (Chief Executive Officer) Mr Donald S Brooks (Non-Executive Director) Dr Larisa Rudenko (Non-Executive Director)
Share Registry	Computershare Investor Services Pty Ltd Yarra Falls, 452 Johnston Street Abbotsford Victoria 3067 Telephone: + 61 3 9415 5000 Investor Queries (within Australia): 1300 850 505
Company secretary	Melanie Leydin
Registered office	Level 4 100 Albert Road South Melbourne VIC 3205 Ph: +61 3 9692 7240
Principal place of business	Level 4 100 Albert Road South Melbourne VIC 3205 Ph: +61 3 9692 7240
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 2014

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 2014.

#### 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 Mr Donald S Brooks Dr Larisa Rudenko Dr Arthur Kwok Cheung Li (resigned 13 December 2014)

# **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 amounted to \$475,782 (31 December 2013: \$570,085).

During the six months ended 31 December 2014, significant progress has been made on all key development programs towards commercial milestones.

Revenue from licensing activities for the half year was \$0.104m compared to \$0.093m in 2013, whilst interest income was \$0.013m compared to \$0.005m in 2013. Research activity costs were \$0.326m compared to \$0.303m in 2013. Administration expenses were \$0.441m as compared to \$0.543m in 2013.

The Group commenced the period with cash reserves of \$1.337m. Cash outlays for research and administration were \$0.692m compared to \$0.954m in the comparative period. Cash inflows were \$0.104m from royalties and licensing agreements (2013: \$0.093m). Cash received from Research and Development Tax Offset in the current period was \$Nil (2013 \$0.224m). The Company expects to receive approximately \$0.128m in relation to its FY2014 Research and Development Tax Offset in the coming months. Cash reserves at the end of the financial half-year totalled \$0.883m.

#### Significant changes in the state of affairs

There were no 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 the following page.

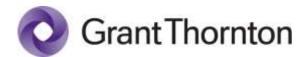
This report is made in accordance with a resolution of directors, pursuant to section 306(3)(a) of the Corporations Act 2001.

On behalf of the directors

J. M.J.-

H M Morgan AC Director

13 March 2015 Melbourne



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

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the review of BioDiem Ltd for the half-year ended 31 December 2014, 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.

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GRANT THORNTON AUDIT PTY LTD Chartered Accountants

M.A Cunningham Partner - Audit & Assurance

Melbourne, 13 March 2015

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# BioDiem Limited Statement of profit or loss and other comprehensive income For the half-year ended 31 December 2014

	Note	Consolic 31 December 3 2014 \$	
Revenue	3	120,623	104,402
Other income		-	5,374
Expenses Licence fees and royalty expenses Research and development expenses Administration expenses Net foreign exchange loss		(20,000) (326,411) (440,533) (2,075)	(57,563) (303,006) (543,312)
Loss before income tax benefit		(668,396)	(794,105)
Income tax benefit		192,614	224,020
Loss after income tax benefit for the half-year attributable to the owners of BioDiem Limited		(475,782)	(570,085)
Other comprehensive income for the half-year, net of tax		-	-
Total comprehensive income for the half-year attributable to the owners of BioDiem Limited		(475,782)	(570,085)

# BioDiem Limited Statement of financial position As at 31 December 2014

		Consolidated 31 December	
Να	ote	2014 \$	30 June 2014 \$
Assets			
Current assets Cash and cash equivalents Trade and other receivables Other Total current assets		883,372 14,204 <u>317,024</u> 1,214,600	1,336,812 11,965 142,471 1,491,248
Total assets		1,214,600	1,491,248
Liabilities			
Current liabilities Trade and other payables Employee benefits Other Total current liabilities	4	126,725 39,425 119,941 286,091	76,607 26,044 - 102,651
<b>Non-current liabilities</b> Employee benefits Total non-current liabilities		<u>38,616</u> 38,616	<u>31,053</u> 31,053
Total liabilities		324,707	133,704
Net assets		889,893	1,357,544
Equity Issued capital Reserves Accumulated losses	5	30,087,862 304,663 (29,502,632)	30,087,862 296,532 (29,026,850)
Total equity		889,893	1,357,544

## BioDiem Limited Statement of changes in equity For the half-year ended 31 December 2014

Consolidated	Issued Capital \$	Accumulated losses \$	Reserves \$	Total equity \$
Balance at 1 July 2013	28,812,349	(28,008,501)	263,598	1,067,446
Loss after income tax benefit for the half-year Other comprehensive income for the half-year, net of tax	-	(570,085)	-	(570,085) -
Total comprehensive income for the half-year		(570,085)	-	(570,085)
Balance at 31 December 2013	28,812,349	(28,578,586)	263,598	497,361
Consolidated	lssued Capital \$	Accumulated losses \$	Reserves \$	Total equity \$
Balance at 1 July 2014	30,087,862	(29,026,850)	296,532	1,357,544
Loss after income tax benefit 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)
<i>Transactions with owners in their capacity as owners:</i> Share-based payments			8,131	8,131
Balance at 31 December 2014	30,087,862	(29,502,632)	304,663	889,893

## **BioDiem Limited** Statement of cash flows For the half-year ended 31 December 2014

	Consolid 31 December 3 2014 \$	
Cash flows from operating activities Cash receipts in course of operations Cash payments in course of operations Interest received Government grants received R&D Tax Offset received	103,932 (692,233) 11,620 3,300	91,048 (954,381) 3,848 5,000 224,020
Net cash used in operating activities	(573,381)	(630,465)
Cash flows from investing activities		
Net cash from investing activities		
Cash flows from financing activities Proceeds received in advance of share issue	119,941	<u> </u>
Net cash from financing activities	119,941	-
Net decrease in cash and cash equivalents Cash and cash equivalents at the beginning of the financial half-year	(453,440) 1,336,812	(630,465) 1,171,738
Cash and cash equivalents at the end of the financial half-year	883,372	541,273

#### BioDiem Limited Notes to the financial statements 31 December 2014

# Note 1. General information

The financial statements cover BioDiem Limited as a Group consisting of BioDiem Limited and its subsidiaries. The financial statements are presented in Australian dollars, which is BioDiem Limited's functional and presentation currency.

BioDiem Limited is an unlisted 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 13 March 2015. 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 2014 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 2014 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 \$0.476m (2013: \$0.570m net loss after tax) for the half-year ended 31 December 2014. 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 \$0.890m (30 June 2014: \$1.358m), including cash and cash equivalent assets of \$0.883m (30 June 2014: \$1.337m), 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 will entitle 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

	Consolic 31 December 3 2014 \$	
Royalty and milestone revenue	103,732	93,398
Grant income	3,300	5,000
	107,032	98,398
Other revenue Interest Other revenue	13,391 200 13,591	5,604 400 6,004
Revenue	120,623	104,402
Note 4. Current liabilities - Other	Consolic	lated

	31 December		
	2014 \$	30 June 2014 \$	
Funds received in advance	119,941		

Funds totaling \$119,941 received as at 31 December 2014 relate to amounts received for the exercise of options, which were allotted and converted into ordinary shares subsequent to period end.

#### Note 5. Equity - reserves

	Consolidated 31 December		
	2014 \$	30 June 2014 \$	
Share-based payments reserve	304,663	296,532	

#### 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:

Consolidated	Share based payments \$	Total \$
Balance at 1 July 2014 Share based payments	296,532 8,131	296,532 8,131
Balance at 31 December 2014	304,663	304,663

#### Note 6. Equity - dividends

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

#### Note 7. 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.

The Group has a licence to commercialise certain technologies from the OOO Klinika Instituta Bioregulyatsii I Gerontologii ("the Clinic"). The licence is in relation to retinal eye disease. The Group is obliged to pay the Clinic twenty percent of all payments received from any Licensee and twenty percent of any royalties arising from net sales.

#### Note 8. Commitments

The Group has no lease commitments at 31 December 2014.

#### Note 9. 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 2014 annual financial report:

	Ownership inter 31 December		
Name	Principal place of business / Country of incorporation	2014 %	30 June 2014 %
Savine Therapeutics Pty Ltd	Australia	100.00%	100.00%

### BioDiem Limited Notes to the financial statements 31 December 2014

# Note 10. Events after the reporting period

During January and February 2015, 4,273,844 options were exercised in the Company at an exercise price of \$0.08 (8 cents) each raising \$341,908.

No other matter or circumstance has arisen since 31 December 2014 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 2014

In the directors' opinion:

- the attached financial statements and notes thereto 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 thereto give a true and fair view of the Group's financial position as at 31 December 2014 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

1. M-7-

H M Morgan AC Director

13 March 2015 Melbourne



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

We have reviewed the accompanying half-year financial report of BioDiem Ltd ("Company"), which comprises the consolidated financial statements being the statement of financial position as at 31 December 2014, 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 Ltd 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 Entity, 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 BioDiem Ltd consolidated entity's financial position as at 31 December 2014 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 Ltd , 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 Ltd 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 2014 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.

#### Material uncertainty regarding going concern

Without qualifying our opinion, we draw attention to Note 2 in the financial report which indicates that the company incurred a net loss of \$475,782 during the half-year ended 31 December 2014. 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 company's ability to continue as a going concern and therefore, the company 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.

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GRANT THORNTON AUDIT PTY LTD Chartered Accountants

M.A Cunningham *V* Partner - Audit & Assurance

Melbourne, 13 March 2015