

# BioDiem

BioDiem Ltd – Annual Report

ABN 20 096 845 993



# 2014

DEVELOPING COMMERCIAL OUTCOMES

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World-class development and commercialisation  
of vaccines and infectious disease therapies



## Highlights of FY2014

### CORPORATE

- Successful completion and oversubscription to our 2014 rights issue raising \$0.815m after scale-back.
- De-listing of the Company from the Australian Stock Exchange. Following shareholder approval, this action was commenced to reduce the compliance burden on the Company and the associated costs. BioDiem's historical low liquidity was also contributing to a low company valuation which could impede commercial negotiations.
- Receipt of \$0.583m from the R&D Tax Incentive program and more than \$0.492m from exercise of our 8c options. This has been used to fund the additional commercial and development work on our LAIV and BDM-I programs, respectively.



### INFLUENZA VACCINE TECHNOLOGY (LAIV)

- Marketing approval granted for Serum Institute of India's Nasovac-S™ in India. Nasovac-S is a seasonal influenza vaccine based on BioDiem's LAIV (live attenuated influenza virus) technology. BioDiem will receive royalties from sales of this product into the private market.
- Announcement by the US Centers for Disease Control (CDC) in June 2014 that the US Advisory Committee on Immunisation Practices (ACIP) voted to recommend a preference for the LAIV nasal 'flu spray instead of 'flu injection in healthy children 2-8 years of age.
- Publication of further LAIV research and clinical trial results which support the immunogenicity and safety of BioDiem's LAIV manufactured using tissue culture.

- Preclinical and clinical evaluation of pandemic live attenuated influenza vaccines of H5N1, H5N2, H7N3, H1N1 and H2N2 subtypes which were shown to be safe and immunogenic, and showed protection from challenge with homologous (similar) and heterologous (different) 'flu viruses in animal models.
- Submission by our Chinese licensee, Changchun BCHO Biotech, of its application to conduct clinical trials of LAIV in China as part of its development plan for BioDiem's LAIV technology.

### ANTIMICROBIAL BDM-I

- The presentation at the American Society of Microbiology's Denver ICAAC<sup>1</sup> conference by world class specialist antifungal researchers exploring BDM-I's activity against micro-organisms responsible for difficult-to-treat fungal diseases.
- The award of a new US patent for BDM-I for claims relating to skin and soft tissue infections, to add to those already granted for protozoal infections and vulvovaginitis.
- Commencement of two new Australian studies of BDM-I looking at the drug's mechanism of action and resistance. The results of these will be used to profile BDM-I's novelty and potential value as a human therapeutic and will be used for commercial discussions.



<sup>1</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy

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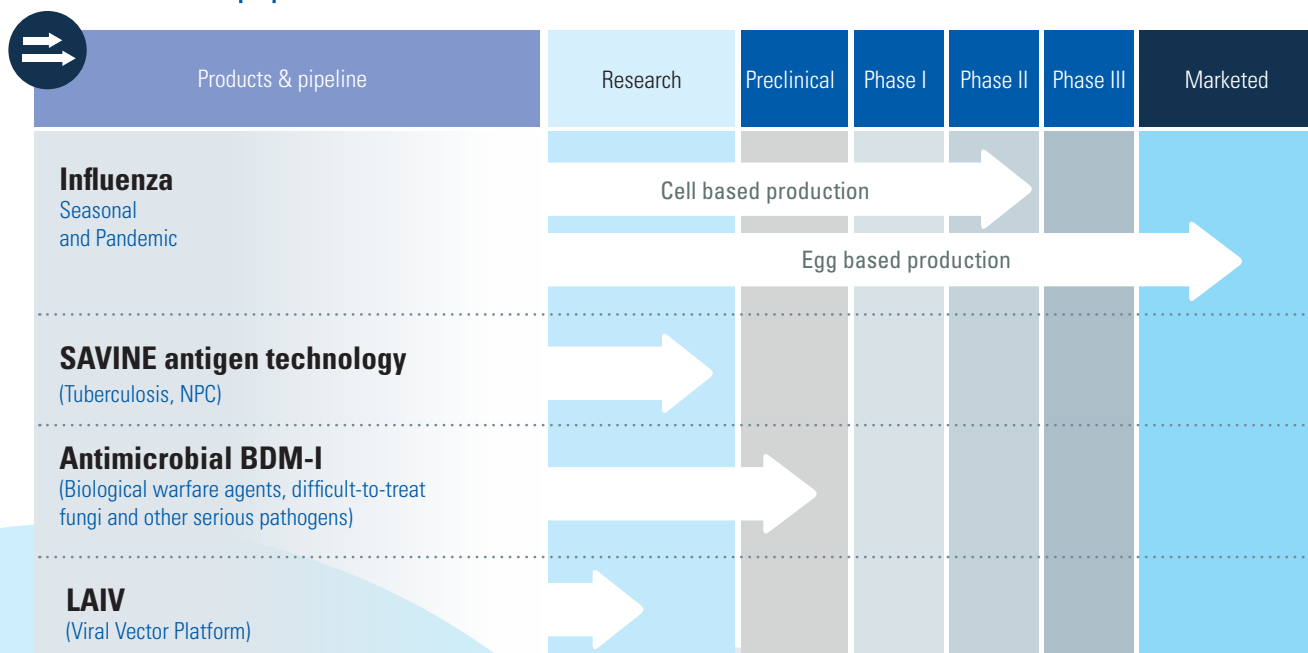
*“We have now received approval from the Indian regulatory authorities for seasonal influenza LAIV vaccine following our application made last year. We are delighted to have achieved this important approval and have our new product, Nasovac-S™, in the market for our winter influenza season. Having previously launched Nasovac for the prevention of swine flu, we appreciate the growing recognition by the government and also the public about the benefit of a needle-free alternative in India for prevention of influenza. Our peak influenza occurrence is in the rainy season which generally lasts from June to August. The trivalent seasonal flu vaccine is a new product to the Indian market however with the awareness generated by the successful use of the pandemic flu vaccine for swine flu, we expect the product will get a good response. The market for influenza vaccines in India currently is small but is growing.”*



**Dr Rajeev Dhere** – Executive director, Serum Institute of India Ltd, Pune, India

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## Products & pipeline





## Chairman's report

### Fellow shareholders,

On behalf of the Board and Management of BioDiem, I am pleased to present the 2013-14 annual report for your review.

A number of significant events in this period made it an important year for BioDiem:

- Marketing approval for Nasovac-S™. The regulatory dossier for Nasovac-S was lodged in India by our licensee, Serum Institute of India (SII). Nasovac-S is a seasonal influenza vaccine based on BioDiem's LAIV (live attenuated influenza virus) technology. The Indian regulatory authorities, the Drug Controller General of India (DCGI), approved SII's application for marketing of the trivalent seasonal influenza vaccine in January 2014. This heralds the commencement of a royalty stream to BioDiem from the sale of the seasonal influenza vaccine in the private market in India.
- Increased support for the value of the LAIV nasal 'flu vaccine especially for children: on 25 June 2014 the US Centers for Disease Control (CDC) announced that the US Advisory Committee on Immunisation Practices (ACIP) voted to recommend a preference for the LAIV nasal 'flu spray instead of 'flu injection in healthy children 2-8 years of age.
- Completion of the Institute of Experimental Medicine's new multimillion dollar laboratory facility in St Petersburg designed to manufacture seasonal and pandemic influenza vaccine candidates. This facility was funded by the World Health Organisation (WHO) and PATH.
- The completion of efficacy trials for LAIV in children 2-5 years (randomized, double-blind placebo-controlled design, n=1761) in Bangladesh and Senegal funded by the PATH organization, CDC, and the Bill and Melinda Gates Foundation. The results are due before the end of this year or early next year.
- Publication of further LAIV research and clinical trial results which support the immunogenicity and safety of LAIV manufactured using tissue culture.
- Finalisation of the preparation and testing of a collection of pandemic LAIV candidates using cold-adapted master donor (MDV) virus A/Leningrad/134/17/57 (Len/17) as a backbone. Preclinical studies demonstrated safety, immunogenicity and efficacy of these candidates in various animal models (mice, ferrets, monkeys). Preclinical and clinical evaluation of pandemic live attenuated influenza vaccines of H5N1, H5N2, H7N3, H1N1 and H2N2 subtypes were shown to be safe, immunogenic and protected animals from challenge with homologous and heterologous viruses.
- Submission by our Chinese licensee, Changchun BCHT Biotechnology Co., of its application to conduct clinical trials of LAIV in China as part of its development plan for the LAIV technology.
- The presentation of the results of BioDiem's antimicrobial, BDM-I, at the American Society of Microbiology's Denver ICAAC conference by world class specialist antifungal researchers exploring BDM-I's activity against micro-organisms responsible for difficult-to-treat fungal diseases. These results warrant further exploration of BDM-I as a potential fungal disease treatment.
- The award of a new US patent for BDM-I for claims relating to skin and soft tissue infections, to add to those already granted for protozoal infections and vulvovaginitis.
- Commencement of two new Australian studies of BDM-I looking at the drug's mechanism of action and resistance. The results of these will be used to profile BDM-I's novelty and potential value as a human therapeutic and will be used for commercial discussions.
- De-listing of the Company from the Australian Stock Exchange. Following shareholder approval, this action was commenced to reduce the compliance burden on the Company and the associated costs. BioDiem's historical low liquidity was also contributing to a low company valuation which could impede commercial negotiations.

- Successful completion and oversubscription to our 2014 rights issue raising \$815,414 after scale-back. Also the Company received \$0.583m from the R&D Tax Incentive program and more than \$0.492m from exercise of our 8c options. This has been used to fund the additional commercial and development work on our LAIV and BDM-I programs, respectively.

The Board is delighted with the progress of our commercial influenza vaccine program and the efforts of our licensees to drive the development and regulatory approvals of our LAIV technology. Special thanks go to our Board member, Prof Larisa Rudenko who works tirelessly behind the scenes to support these efforts. She in turn has close relationships with the international public health organisations who research, regulate, advise and fund influenza vaccine programs to meet world needs.

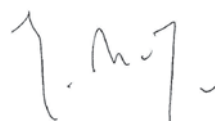
The Board is conscious that our patient shareholders have long awaited on the delivery of the commercial prospects from our Company. Our deliberate strategy has been to focus on this, as much as it is in our hands, and to reduce our cash expenditure while maintaining our other assets. In line with this we have wound back the liver-targeting and LAIV vector programs to concentrate our efforts and resources on LAIV and BDM-I.

BDM-I, our antimicrobial, remains an important asset of the Company. Just as the gap in medical need for new antimicrobials has widened, so has the opportunity for us increased. The US government has legislated incentives for companies developing new antimicrobials and the market interest is growing. The Generating Antibiotics Incentives Now 2012 Act ("GAIN" Act) means an extra 5 years of market exclusivity. Relatively new companies such as Cubist Inc, have had recent successes and attracted investors back towards the anti-infectives space. To ensure we obtain the best value for our shareholders with BDM-I we are reviewing

the alternatives open to us to ensure this. While interest in BDM-I is keen, potential acquirers are interested in "proof of concept" (POC) data. In the last year we had expected to receive some *in vivo* test results for use of BDM-I however those POC studies were hampered by a technical problem with the formulation. This requires that we prepare a new formulation development plan, and this comes at additional cost. Given our proximity to being able to assemble a data package to attract licencees and especially given the possible broad application of a compound such as BDM-I, we believe it is worth accelerating BDM-I's development to complete the formulation and POC work to raise the value of the data package.

I emphasise that while the Company's developments represent important progress of the Company to a commercially advantageous position, the Board and management are acutely aware that the Company has limited financial resources, hence we maintain a tight control on expenditure. The Board believes we are in a good position and have achieved much over the past year to bring us to this point. My thanks go to the other Board members and also to the staff for their enthusiasm and dedication. My thanks also go to my fellow shareholders with whom I look forward to sharing our ongoing progress.

Yours sincerely,



**Hugh Morgan AC**  
Chairman

## CEO letter

### Dear Shareholders,

Our 2013-2014 year has been action-packed and the highlight was the exciting news of the marketing approval of Nasovac-S in India in January and its very recent launch into the Indian market. Nasovac-S is a seasonal influenza vaccine which is based on our LAIV technology and manufactured by our licensee, Serum Institute of India (SII), one of the world's biggest vaccine producers. This event is significant for us because we will receive royalties on sales of this intranasal 'flu vaccine in the private market in India. The royalty flow is expected to be modest initially and is expected to commence in early 2015.

This good news comes at a time when the benefits of the LAIV vaccine technology are becoming of much higher profile. It is acknowledged that the benefits of LAIV are particularly relevant to children. Recently large Phase III clinical trials have been conducted in Bangladesh and Senegal using SII's Nasovac-S. These trials were designed to assess the efficacy of the LAIV vaccine in children aged 2 to 8 against laboratory-confirmed influenza and were funded by PATH, the CDC and the Bill and Melinda Gates Foundation. The results of these studies are expected towards the end of this year or early next year.

Also importantly in June this year the US Advisory Committee on Immunisation Practices (ACIP) to the CDC voted unanimously to recommend a preference for the LAIV intranasal 'flu vaccine for healthy children aged 2 – 8 years compared to inactivated flu virus injections. The committee's recommendation was based on its review of studies suggesting the nasal spray flu vaccine can provide better protection than the ordinary 'flu injection in this age group.

We are delighted with the progress of our LAIV vaccine franchise including that by licensee, Changchun BCHO Biotechnology Co. in China. In March we participated in the Developing Country Vaccine Manufacturers network meeting in Dubai where international public health organisations interested in promoting influenza prevention gathered to discuss their progress. This impressive network has instigated and pursued successfully a co-ordinated effort to address the need for better influenza prevention around the world. I will expand on this and the progress of our licensees later in this report.

Our antimicrobial compound BDM-I continues to generate considerable interest due to its spectrum of activity *in vitro* and its wide possible applications as a treatment for infections. The results of studies conducted so far have been encouraging including the poster presentation in the US we announced last year of BDM-I's activity against deadly Pneumocystis and other fungal pathogens. Additional patents have also been granted. In April this year we initiated studies of BDM-I's mechanism of action and resistance with both Griffith University and the University of Western Sydney. As the world becomes more aware of "superbugs" the importance and potential market attractiveness of BDM-I is enhanced. More information about BDM-I is provided later in this report.

We had expected to be able to report to you results of *in vivo* testing of BDM-I however these "proof of concept" studies require preliminary reformulation work to be undertaken. Costing for this and the next stages of the development plan are being collated now. We are focused on positioning BDM-I for outlicence and so will seek to undertake this necessary development work to complete the data package to attract larger partners. The best funding strategy to accelerate this is being determined now.

Following the Company's de-listing from the Australian Stock Exchange last November we have continued to control expenditure tightly. Our focus has been on supporting our LAIV licensees and also on the development path of BDM-I, our antimicrobial.

Under the Australian federal government's R&D tax incentive program we have received \$0.583m this financial year. The amount is based on our local R&D expenditure and allows us to stretch our R&D dollars. This is crucial to support our further commercialisation efforts.

In April 2014 with the strong support of our major shareholders we completed a capital raising which successfully met our target of \$0.815m. The rights issue was priced at 5.5c per share.

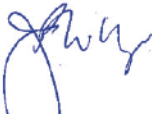
## CEO letter

So far this year more than 6 million (6,156,157) of our 8c options have been exercised contributing \$0.492m to our bank balance. The remaining 8c BioDiem options expire on 31st December 2014. These options formed part of the entitlement in the 2012 rights issue. Following our de-listing last November, option holders would have received an Issuer Sponsored Statement to show the number of options which they hold and the SRN required for trading. These options can be traded similarly to our shares. Option holders can choose to exercise these options prior to 31st December 2014 or let them lapse. We have arranged for DFS Equities to provide a comprehensive secondary market administration service for our shareholders and other interested parties wishing to invest in BioDiem. DFS Equities can assist with information about this and holds

a register of interest of buyers and sellers of BioDiem equities. Further information can be found on our website ([www.biodiem.com](http://www.biodiem.com)).

I encourage shareholders to keep in touch with us and add their details to our email list (on our website) and to contact us with any questions. We look forward to updating you with our progress over the coming year.

Yours sincerely,



**Julie Phillips**  
CEO



## Review of operations

### INFLUENZA FLU VACCINE PROGRESS BY INTERNATIONAL PARTNERS

BioDiem's LAIV Vaccine Licensing business involves out-licensing of the company's platform technology for the production of intranasal vaccines for the prevention of seasonal and pandemic influenza.

BioDiem currently has two commercial partners, in China and India, and its LAIV vaccine technology is also licensed to the World Health Organization (WHO) as part of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply.

#### Significant developments during the financial year include:

- SII received licences from the Indian regulatory authority to market the seasonal influenza (trivalent) intranasal vaccine, Nasovac-S, for both southern and northern hemispheres.
- Nasovac-S was launched in the Indian market in July 2014.
- SII has applied for WHO prequalification for Nasovac-S which when granted will allow SII to export to other developing countries of the United Nations. BioDiem would receive royalties on sales of Nasovac-S into the private markets of these countries. SII previously successfully registered and marketed Nasovac for swine flu (pandemic A/California/2009 [H1N1]).

- Completion of large LAIV vaccine safety and efficacy studies in children in Bangladesh and Senegal (results expected towards the end of 2014, early 2015).
- Completion of the new laboratory at the Institute of Experimental Medicine in St Petersburg dedicated to the preparation of reassortants LAIV vaccine strains for seasonal and pandemic influenza. This facility was funded primarily by the World Health and PATH organizations.
- BioDiem received the second of its annual LAIV licensing payments from Chinese commercial partner Changchun BCCT Biotechnology Co.

The influenza field is constantly being researched to understand more about the influenza virus, evolution of new strains, the transmission and the risk to human health. This informs vaccine development and also assists identification of the best parameters to measure in preclinical and clinical studies to judge vaccine effectiveness. In addition, clinical trials are conducted to support registration dossiers and also for post-marketing surveillance.

A snapshot of some relevant publications can be seen in Table 1.



**Nasovac-S**  
was launched in the  
Indian market in July 2014.

**TABLE 1: STUDIES ON SEASONAL TRIVALENT LAIV**

Design (product)	Location	Number of subjects, age of subjects, randomization ratio	Outcomes measured	Sponsor/ Funder	Completion of study visits
Randomized, double-blind, active-controlled	India	n=110 each; children >2 years of age, adults >18 to <50, adults >50, 1:1 (lower dose: higher dose)	Safety, Immunogenicity	SIIL	Completed June 25, 2012
Randomized, double-blind, placebo-controlled	Bangladesh	N=300, children 2-5 years of age, 1:1 (standard dose: placebo)	Safety, Immunogenicity, Shedding	PATH/BMGF	Completed February 2, 2013
Randomized, double-blind, placebo-controlled	Bangladesh	N=1761, children 2-5 years of age, 2:1 (standard dose: placebo)	Safety, Efficacy against laboratory-confirmed influenza	PATH/BMGF	Completed December 2013 Safety follow-up extended 1 year
Randomized, double-blind, placebo-controlled	Senegal	N=1761, children 2-6 years of age, 2:1 (standard dose: placebo)	Safety, Efficacy against laboratory-confirmed influenza, Shedding	PATH /US Centers for Disease Control and Prevention/ BMGF	Completed December 2013

Source: Presentation by John Boslego, Director, Vaccine Development Global Program, PATH presentation at 7th Meeting with International Partners on Prospects for Influenza Vaccine Technology Transfer to Developing Country Vaccine Manufacturers, 25-26 March 2014, Hyatt Regency Hotel, Dubai. ([http://www.who.int/phi/Agenda\\_7thPartners\\_mtg.pdf](http://www.who.int/phi/Agenda_7thPartners_mtg.pdf)).

SIIL: Serum Institute of India Ltd; BMGF: Bill and Melinda Gates Foundation.

## PRESTIGIOUS RUSSIAN AWARD TO BIODIEM DIRECTOR



Prof Larisa Rudenko is a director of our company and leads our international LAIV influenza vaccine program. She connects into the WHO, CDC, PATH and other organisations to promote the use of LAIV around the world. Prof Rudenko has been recognized with many awards during her career and in February 2014 was notified she would receive the Order of Friendship Award. The Order of Friendship is awarded to Russian and foreign nationals for special merit in strengthening peace, friendship,

cooperation and understanding between nations, for fruitful work on the convergence and mutual enrichment of cultures of nations and peoples; for the active conservation, development and promotion of the cultural and historical heritage of Russia; for great contribution to the implementation of joint ventures with the Russian Federation, major economic projects and attracting investments into the economy of the Russian Federation; for broad charitable activities.

We are very proud that Prof Rudenko has been recognised in this way and congratulate her sincerely.

## Review of operations

### CHANGCHUN BCHT BIOTECHNOLOGY CO. UPDATE



*Photograph of the manufacturing facility building for the manufacture of seasonal influenza vaccine based on in-licensed LAIV technology from BioDiem.*



*"We have filed an application with the Chinese FDA for conduct of clinical trials and completed necessary preclinical work. We are happy with our progress to date and know how important it is to have a needle-free vaccine available in China for prevention of influenza. In China, while vaccination is not mandatory, there is growing government/public awareness of the importance of this public health measure."*

**Dr Jinchang Wu** – Director, R&D and International Affairs at Changchun BCHT Biotechnology Co.





### BioDiem's LAIV technology in the fight to prepare for influenza pandemics

Outbreaks of influenza remain a serious concern to the global community as evidenced by the recent examples of H7N9 in China and occasional cases of H5N1 in other countries. Human-to-human transmission of highly pathogenic viruses is the concern, because of the potentially high mortality rate, and it is known that little change is needed in the genetic make-up of existing viruses for this possibility to eventuate. Therefore the advance preparation and testing of vaccine candidates which could be effective in such a situation is an important public health initiative.

Under an agreement with the World Health Organisation (WHO), the Institute of Experimental Medicine, St Petersburg, Russia prepares LAIV reassortant vaccine strains suitable for production of seasonal and also pandemic influenza vaccines. A range of pandemic LAIV strains based on BioDiem's LAIV technology has now been prepared and tested so that they could be available quickly in the event of an influenza pandemic (see Table 2).

LAIV vaccine candidates have already been produced in order to be prepared for various pandemic scenarios. The candidates include subtypes of H5N1, H5N2, H7N3, H1N1 and H2N2. Preparatory studies in ferrets (the animal model of choice for influenza) showed the candidates were safe, immunogenic and protected animals from challenge with homologous (same) and heterologous (similar) 'flu viruses. Also clinical trials (Phase I) showed safety and immunogenicity in healthy adult volunteers.

The advantages of LAIV vaccines includes stimulation of both humoral (local and serum antibody) and cellular immune responses, whereas standard inactivated flu vaccines predominantly induce serum antibodies. In the case of a pandemic, the cross-reactive immune response induced by LAIV's would be beneficial to protect against a new pandemic, even if the pandemic strain is slightly different. In the case of a serious pandemic, such breadth of protection could be vitally important.

### SEASONAL INFLUENZA

Young children are at higher risk from the consequences of infection with influenza. In well-designed clinical trials, the LAIV has shown superiority over standard inactivated influenza vaccines in children, and has the advantage of being given intranasally rather than by injection.

The PATH organization has co-sponsored large clinical trials of LAIV in young children to assess safety and efficacy. These are summarized in Table 1. The LAIV vaccine used for the trials was Nasovac-S, prepared by BioDiem's licensee, Serum Institute of India. These studies are now completed and the final reports are expected towards the end of 2014, early 2015.

### TISSUE CULTURE PRODUCTION: CLINICAL TRIAL PUBLICATION

The Phase I clinical trial demonstrating the safety in healthy adults of cell culture-based production of LAIV seasonal vaccine was published earlier in 2014. This study was conducted by BioDiem's previous licensee, Nobilon and the authors concluded that the intranasal LAIV vaccine was immunogenic and safe.

**TABLE 2. LIST OF PANDEMIC LAIVS PREPARED ON A/LENINGRAD/134/17/57 (H2N2) BACKBONE**

Vaccine strain	Subtype	Wild-type parental virus	The stage of the study
A/17/California/2009/38	H1N1	A/California/07/2009 (H1N1)*	Phase I-II clinical trials completed. The vaccine is registered in Russia
A/17/duck/Potsdam/86/92	H5N2	A/duck/Potsdam/1402-6/86 (H5N2)**	Phase I-II clinical trials completed. The vaccine is registered in Russia
A/17/turkey/Turkey/05/133	H5N2	A/turkey/Turkey/1/2005 (H5N1)**; clade 2.2	Phase I clinical trial completed
A/17/Vietnam/04/65107	H5N2	A/Vietnam/1203/2004 (H5N1)**; clade 1	Studied in animal models
caVN1203-Len17rg	H5N1	A/Vietnam/1203/2004 (H5N1)*; clade 1	Studied in animal models
caEG321-Len17rg	H5N1	A/Egypt/321/2007 (H5N1)*; clade 2.2	Studied in animal models
A/17/mallard/Netherlands/00/95	H7N3	A/mallard/Netherlands/12/2000 (H7N3)*	Phase I clinical trial completed
A/17/California/66/395	H2N2	A/California/1/66 (H2N2)*	Phase I clinical trial completed
A/17/Tokyo/67/326	H2N2	A/Tokyo/3/67 (H2N2)*	Studied in animal models
A/17/Anhui/2013/61	H7N9	A/Anhui/1/2013 (H7N9)*	Phase I clinical trial scheduled for 2014

\* vaccine strain inherited HA and NA genes from wild-type parental virus and remaining 6 genes – from master donor virus, i.e. 6:2 genetic formula;

\*\* vaccine strain inherited only HA gene from wild-type parental virus and remaining 7 genes – from master donor virus, i.e. 7:1 genetic formula.

## Review of operations

### PUBLICATIONS ON BIODIEM'S LAIV INFLUENZA TECHNOLOGY:

- Heldens J, Hulskotte E, Voeten T, Breedveld B, Verweij P, van Duijnhoven W, Rudenko L, van Damme P, van den Bosch H. (2014)

*Safety and immunogenicity in man of a cell culture derived trivalent live attenuated seasonal influenza vaccine: A Phase I dose escalating study in healthy volunteers.*

Vaccine 32(39):5118-24. Epub 2014 May 23
- Rudenko L, Kiseleva I, Naykhin AN, Erofeeva M, Stukova M, et al. (2014)

*Assessment of Human Immune Responses to H7 Avian Influenza Virus of Pandemic Potential: Results from a Placebo-Controlled, Randomized Double-Blind Phase I Study of Live Attenuated H7N3 Influenza Vaccine.*

PLoS ONE 9(2): e87962.
- Isakova-Sivak I, Chen LM, Bourgeois M, Matsuoka Y, Voeten JT, Heldens JG, van den Bosch H, Klimov A, Rudenko L, Cox NJ, Donis RO. (2014)

*Characterization of Reverse Genetics-Derived Cold-Adapted Master Donor Virus A/Leningrad/134/17/57 (H2N2) and Reassortants with H5N1 Surface Genes in a Mouse Model.*

Clin Vaccine Immunol. 21(5):722-31. Epub 2014 Mar 19.
- Larionova N, Kiseleva I, Isakova-Sivak I, Rekstin A, Dubrovina I, et al. (2013)

*Live Attenuated Influenza Vaccines against Highly Pathogenic H5N1avian Influenza: Development and Preclinical Characterization.*

J Vaccines Vaccin 4: 208.
- Isakova-Sivak I, de Jonge J, Smolnogina T, Rekstin A, van Amerongen G, van Dijken H, Mouthaan J, Roholl P, Kuznetsova V, Doroshenko E, Tsvetnitsky V, Rudenko L. (2014)

*Development and Pre-Clinical Evaluation of Two LAIV Strains against Potentially Pandemic H2N2 Influenza Virus.*

PLoS One. 24;9(7):e102339. eCollection 2014.
- Smolnogina TA, Desheva IuA, Rekstin AR, Mironov AN, Rudenko LG. (2013)

*[Evaluation of the anti-neuraminidase antibodies in clinical trials of the live influenza vaccine of the A(H5N2) subtype]*

58(6):31-5. Russian.
- Kiseleva IV, Bazhenova EA, Larionova NV, Fedorova EA, Dubrovina IA, Isakova-Sivak IN, Rudenko LG. (2013)

*[Peculiarity of reassortment of current wild type influenza viruses with master donor viruses for live influenza vaccine].*

Vopr Virusol. 58(5):26-31. Russian.
- Rudenko L, Isakova-Sivak I, Rekstin A. (2013)

*H7N9: can H7N3 live-attenuated influenza vaccine be used at the early stage of the pandemic?*

Expert Rev Vaccines. 13(1):1-4. Epub 2013 Nov 28.
- Rudenko L, Isakova-Sivak I, Donina S. (2013)

*H7N3 live attenuated influenza vaccine has a potential to protect against new H7N9 avian influenza virus.*

Vaccine. 31(42):4702-5. Epub 2013 Aug 26.
- Donina SA, Petukhova GD, Koren'kov DA, Grigor'eva EP, Kuznetsova SA, Losev IV, Rudenko LG, Na khin AN. (2013)

*[Local antibody immune responses in influenza patients and persons vaccinated with seasonal, pre-pandemic, and pandemic live attenuated influenza vaccines].*

Vopr Virusol. 58(3):37-42. Russian.
- Shembekar N, Mallajosyula VV, Mishra A, Yeolekar L, Dhere R, Kapre S, Varadarajan R, Gupta SK. (2013)

*Isolation of a high affinity neutralizing monoclonal antibody against 2009 pandemic H1N1 virus that binds at the 'Sa' antigenic site.*

PLoS One. 8(1):e55516. Epub 2013 Jan 31.
- Yeolekar LR, Dhere RM. (2012)

*Development and validation of an egg-based potency assay for a trivalent live attenuated influenza vaccine.*

Biologicals. 40(2):146-50. Epub 2012 Jan 23.
- Dhere R, Yeolekar L, Kulkarni P, Menon R, Vaidya V, Ganguly M, Tyagi P, Barde P, Jadhav S. (2011)

*A pandemic influenza vaccine in India: from strain to sale within 12 months. Vaccine. 1;29 Suppl 1:A16-21. Review.*
- Kulkarni PS, Raut SK, Dhere RM. (2013)

*A post-marketing surveillance study of a human live-virus pandemic influenza A (H1N1) vaccine (Nasovac (®) ) in India.*

Hum Vaccin Immunother. 9(1):122-4.
- Kulkarni PS, Jadhav SS, Dhere RM. (2013)

*Horizontal transmission of live vaccines.*

Hum Vaccin Immunother. 9(1):197.
- Stittelaar KJ, Veldhuis Kroeze EJ, Rudenko L, Dhere R, Thirapakpoomanunt S, Kieny MP, Osterhaus AD. (2011)

*Efficacy of live attenuated vaccines against 2009 pandemic H1N1 influenza in ferrets.*

Vaccine. 29(49):9265-70. Epub 2011 Sep 22.
- Kulkarni PS, Agarkhedkar S, Lalwani S, Bavdekar AR, Jog S, Raut SK, Parulekar V, Agarkhedkar SS, Palkar S, Mangrulkar S. (2014)

*Effectiveness of an Indian-made Attenuated influenza A(H1N1)pdm 2009 vaccine: A case control study.*

Hum Vaccin Immunother. 10(3). pii: 27490. Epub 2014 Jan 9.



### BDM-I ANTIMICROBIAL

BioDiem's antimicrobial compound BDM-I has demonstrated broad-spectrum activity against a wide range of disease-causing microbes such as bacteria, fungi, and parasites. It is currently being researched as a treatment against 'superbugs' or antibiotic-resistant bacteria and fungi. These organisms are of major concern to international healthcare agencies as the number of available treatments for these infections shrinks.

The diseases currently covered by BDM-I's collective patents are:

- **A variety of bacterial infections:** BDM-I's broad spectrum activity suggests the capacity for wide usage against infection of wounds, mucosal membranes, enteric (intestinal) infections and sepsis (blood infection).
- **Serious fungal infections:** in immunocompromised patients such as those undergoing cancer treatment or following organ transplantation or in certain infections such as HIV, susceptibility to fungal infections can increase and become serious and life-threatening. New effective treatments are urgently needed.
- **Common sexually transmitted infections:** common infections such as gonorrhoea, trichomoniasis and candidiasis which may develop from bacterial or fungal infections leading to common female complaints such as vaginal inflammation or the increased likelihood of HIV infections and reproductive issues.
- **Malaria:** a parasitic disease carried by mosquitoes which affects hundreds of millions of people worldwide each year. Malaria caused an estimated 627,000 deaths in 2012. Current treatments are meeting increasing resistance and often have undesirable side effects.
- **MRSA:** a high-profile strain of antibiotic-resistant "Golden Staph" of major concern to global healthcare systems, contributing a significant burden of illness made more costly by resistant infections and the disease's increased spread.
- **Tuberculosis:** A bacterial infection that predominantly attacks the lungs. TB is second only to HIV/AIDS as the greatest cause of deaths worldwide attributable to a single infectious agent.

BDM-I studies continue to deliver encouraging results. The broad-spectrum activity it has displayed suggests considerable value, as multiple potential therapeutic indications can be out-licensed, providing multiple revenue streams to BioDiem.

### Significant developments during the financial year include:

- The presentation of study results at the American Society of Microbiology's Denver ICAAC conference by world class specialist antifungal researchers exploring BDM-I's activity against micro-organisms responsible for difficult-to-treat fungal diseases. These results warrant further exploration of BDM-I as a potential fungal disease treatment. The researchers were affiliated with the University of Cincinnati College of Medicine, the University of Texas Health Science Center at San Antonio, and South Texas Veterans Health Care System. (The project was funded with US Federal funds from the NIH/NIAID/DMID under contract No. HHSN2722011000181.)
- The award of a new US patent for BDM-I for claims relating to skin and soft tissue infections, to add to those already granted for protozoal infections and vulvovaginitis.
- Commencement of two new Australian studies of BDM-I looking at mechanism of action and resistance. The results of these will be used to profile BDM-I's novelty and potential value as a human therapeutic and will be used for commercial discussions.

### COLLABORATION WITH GRIFFITH UNIVERSITY

In May 2014 BioDiem announced a collaboration with Griffith University's Institute of Glycomics under the Griffith University Industry Collaborative Scheme (GUICS) co-funded by Griffith University's Industry Fund.

This co-funded project is designed to

- screen candidate proteins that potentially interact with BDM-I; and thereafter
- explore predicted binding interactions between BDM-I and the candidate proteins.

## Review of operations

This work will identify the possible chemical candidates which are structurally related to BDM-I from the protein database bank. This database already contains all currently known structures between protein targets and their ligands. BDM-I will then be verified against the identified targets and the results will feed into a growing information package about how BDM-I works as an antimicrobial. This information could also assist to identify what testing might be required to support the safety profile of BDM-I in its development.

This collaborative project is led by Professor Yaoqi Zhou and Dr. Joe Tiralongo. Professor Zhou is an established world leader in computational screening and structure-based prediction of protein interactions with more than 130 publications. Dr Tiralongo is an internationally recognised glycobiologist, with over 50 publications and extensive experience in analysing small molecule-protein interactions. The Institute for Glycomics is the only one of its kind in the southern hemisphere and only one of a few multi-disciplinary glycoscience research centres in the world.

### COLLABORATION WITH UNIVERSITY OF WESTERN SYDNEY (UWS)

In April 2014 BioDiem announced a collaboration with the University of Western Sydney's Antibiotic Resistance and Mobile Elements Group (ARMEG) led by Dr. Slade Jensen to investigate the mechanism of action of BioDiem's BDM-I. The research focuses on BDM-I's activity against hospital pathogens such as MRSA (methicillin-resistant *Staphylococcus aureus* or "Golden Staph"). The ARMEG group's core research projects are centred on the evolution of antibiotic resistance in ESKAPE pathogens, particularly MRSA and VRE, but also has projects that examine the role of biofilms in hospital-acquired infections and the clinical utility of whole genome sequencing in an infectious disease context. Key members of the group are Dr. Slade Jensen, Dr. Björn Espedido, Dr. Sebastiaan van Hal and Prof. Iain Gosbell.

Strains of MRSA are not only a major cause of healthcare-associated infections around the world, but are an emerging cause of infections in the wider community. In Australia, MRSA accounts for approximately 24% of *S. aureus* bloodstream infections and is associated with increased health-care costs, morbidity and mortality. Despite the entry of a small number of new therapies for MRSA, the old antibiotic, vancomycin, is considered the mainstay of therapy for invasive MRSA infections i.e. infections that spread in the body. However, intermediate

vancomycin resistance has emerged, which can be associated with treatment failure, and there are concerns about the toxicity and effectiveness of alternative antimicrobial treatments.

At present, the BDM-I mechanism of action (MOA) is unknown but previous studies indicate that its cellular target is novel and therefore it represents a next-generation anti-infective.

The UWS investigations are at the cutting edge of bacterial genomics research into bacterial evolution and mechanisms of antibiotic resistance. Due to the lack of available options for the treatment of infections caused by MRSA (and other bacterial pathogens), development of new antimicrobial drugs such as BDM-I are urgently needed in order to combat the ever-growing threat that antimicrobial resistance represents. It is therefore important to elucidate the MOA of this next-generation anti-infective, in order to facilitate its future development.

### Growing concern about antibiotic resistance

Early this year the WHO Report "Antimicrobial Resistance: Global Report on Surveillance" was released. In its opening pages it states *"Antimicrobial resistance (AMR) within a wide range of infectious agents is a growing public health threat of broad concern to countries and multiple sectors. Increasingly, governments around the world are beginning to pay attention to a problem so serious that it threatens the achievements of modern medicine. A post-antibiotic era – in which common infections and minor injuries can kill – far from being an apocalyptic fantasy, is instead a very real possibility for the 21st century."*

The foreword to CDC's "Antibiotic Resistance Threats in the United States, 2013" states *"Antimicrobial resistance is one of our most serious health threats. Infections from resistant bacteria are now too common, and some pathogens have even become resistant to multiple types or classes of antibiotics (antimicrobials used to treat bacterial infections). The loss of effective antibiotics will undermine our ability to fight infectious diseases and manage the infectious complications common in vulnerable patients undergoing chemotherapy for cancer, dialysis for renal failure, and surgery, especially organ transplantation, for which the ability to treat secondary infections is crucial."*

*When first-line and then second-line antibiotic treatment options are limited by resistance or are unavailable, healthcare providers are forced to use antibiotics that may*

*be more toxic to the patient and frequently more expensive and less effective. Even when alternative treatments exist, research has shown that patients with resistant infections are often much more likely to die, and survivors have significantly longer hospital stays, delayed recuperation, and long-term disability. Efforts to prevent such threats build on the foundation of proven public health strategies: immunization, infection control, protecting the food supply, antibiotic stewardship, and reducing person-to-person spread through screening, treatment and education."*

### **"GAIN" legislation in the USA**

On 9 July 2012 the US government passed the "Generating Antibiotics Incentives Now" (GAIN) legislation.

In recognising the medical need for new antibiotics, the legislation

- extends market exclusivity for certain life-saving antibiotics
- speeds development and review of new antibiotics through the FDA by fast track and priority status
- requires the FDA to issue guidance and advice on the necessary development pathway, and
- requires the FDA to develop a list of "qualifying pathogens" that have the potential to threaten public health.

Included in the FDA's draft list of "qualifying pathogens" are those which show susceptibility to BDM-I in in vitro experiments e.g. *Mycobacterium tuberculosis*, *Neisseria gonorrhoea*, *Strep pneumoniae*, *Strep pyogenes*, *Staph aureus*, *Candida* species, etc.

### **OUTLOOK FOR BDM-I**

During the past year several proof-of-concept studies were planned for demonstration of BDM-I's activity in an infectious disease model. To conduct these studies re-formulation of BDM-I is required and companies with suitable formulation expertise have been approached.

Because of the interest in BDM-I and the clear need for more effective antimicrobial agents, BioDiem is considering alternatives to continue development of BDM-I to increase the value of the data package before outlicensing and to accelerate its development as an antimicrobial therapy for serious human infections.

### **BDM-L: LIVER-TARGETING VACCINE PROGRAM**

In June 2012 BioDiem announced the acquisition of a licence to a novel hepatitis vaccine technology from the University of Canberra, and the commencement of a collaborative research program. In July 2013, BioDiem announced that this hepatitis vaccine program had successfully achieved an important milestone towards developing treatments for liver diseases.

The researchers at the University of Canberra have developed a system designed to target the liver specifically to deliver therapies directly there. This would be relevant for hepatitis and liver cancer, for example. Due to this targeting, smaller dosages of currently used therapies could be given to liver disease patients such as those with hepatitis or liver cancer.

This project will continue at the University of Canberra in a program to achieve the development milestones which will assist in commercialization of the technology.

### **OUTLOOK**

During the last financial year the focus has been on the commercialization path for BDM-I and targeting expenditure carefully towards particularly the LAIV program and BDM-I. Early commercial conversations have continued with a number of larger pharma companies interested in our projects, and also some groups with complementary technologies.

The approval of Serum Institute's LAIV seasonal influenza vaccine, Nasovac-S, in India and the progress by our Chinese partner, Changchun BCBT Biotech Co. have been very pleasing and demonstrate the growth of this program. Further progress is expected in 2014-15 including clinical trial approval in China.

The commercial potential for BDM-I's development has become clearer and the focus currently for the coming period for this program is to complete the work identified to finalise the data package to assist outlicensing this technology.

# research

development



## Financial Report

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development  
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## Directors' report

The directors present their report, together with the financial statements, on the consolidated entity (referred to hereafter as the 'consolidated entity') 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 year ended 30 June 2014.

### DIRECTORS

The following persons were directors of BioDiem Limited during the whole of the financial 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 Arthur Kwok Cheung Li
- Dr Larisa Rudenko

### PRINCIPAL ACTIVITIES

During the financial year the principal continuing activities of the consolidated entity consisted of:

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

### DIVIDENDS

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

### REVIEW OF OPERATIONS

The loss for the consolidated entity after providing for income tax amounted to \$1,018,349 (30 June 2013: \$2,316,160).

Royalty and milestone revenues in 2014 were \$0.093m compared to \$0.075m in 2013, while interest income was \$0.015m compared to \$0.021m during the corresponding period in 2013. Research activity costs were \$0.624m compared to \$1.170m in 2013. Administration expenses were \$1.068m as compared to \$1.231m in the previous year.

The Group commenced the financial year with cash reserves of \$1.172m. Cash inflows from share issues totalled \$1.308m compared to \$2.000m in 2013 before costs. Cash outlays were \$1.798m compared to \$2.404m in the prior year for research and administration. Cash inflows were \$0.093m from licensing agreements (2013: \$0.75m from milestone payments). Cash receipts from the R&D Tax Incentive were \$0.583m compared to \$0.317m in the previous year. Cash reserves at the end of the financial year totalled \$1.337m. The Company holds its cash reserves mainly in Australian term deposits. In addition the Group holds funds in a US dollar account. This helps to provide a natural hedge against future overseas research expenditures. The Group has not entered into any forward contracts.

### REVIEW OF RESEARCH

The focus of the Group during the year was to continue development of its assets towards commercialisation and outlicensing.

### VACCINE TECHNOLOGIES

#### Live attenuated influenza virus technology

BioDiem's licensee, the Serum Institute of India (SII) announced the marketing approval given by the Indian regulatory authority for their LAIV seasonal influenza vaccine, Nasovac-S. The product is now on the market in India and modest royalties will flow to BioDiem from sales of Nasovac-S in the private market. SII will now seek WHO prequalification which will allow it to export the vaccine to other developing countries. Changchun BCHT Biotechnology Co (BCHT) continues progress of the development of its LAIV seasonal vaccine under licence. BCHT submitted an application to conduct clinical trials to the Chinese FDA in October 2013. BioDiem continues to seek new licencees for this technology to gain income from milestone and royalty payments.

A new laboratory facility has been completed at the Institute for Experimental Medicine (IEM), Biodiem's licensor, which will allow it to continue to prepare and supply LAIV reassortants viruses for the WHO. This facility was funded by the WHO and PATH organisations. Efficacy trials for LAIV seasonal influenza vaccine in children 2-5 years (randomized, double-blind placebo-controlled design, n=1761) in Bangladesh and Senegal which were funded by the PATH organization, CDC, and the Bill and Melinda Gates Foundation were completed during the year. The final report is expected to be completed within the next six months.

## *LAIV Vector technology*

The project at the RMIT under Professor Peter Smooker continued to explore novel options for LAIV vector development as a basis for new non-influenza vaccines. New research work is planned to be conducted at the IEM.

## *SAVINE technology*

SAVINE Therapeutics Pty Ltd was acquired in December 2011 to access proprietary technologies for targeting tuberculosis, Epstein Barr virus, HIV and other diseases. Commercial discussions continue with a view to development of the technology with external funding for outlicence.

## *Dengue fever vaccine technology*

In June 2012 BioDiem acquired a licence for a flavivirus vaccine technology from the Australian National University with the first disease target being dengue fever. This project has been returned to the ANU for further development.

## *Liver targeting technology*

In June 2012 BioDiem acquired a licence for a hepatitis vaccine technology from the University of Canberra. Additional research work is required to develop a commercial data package and this will be undertaken by the University of Canberra.

## **INFECTIOUS DISEASE TECHNOLOGY**

### **BDM-I**

Continued development of BDM-I as a treatment against a broad range of serious pathogens occurred through the year. Pilot proof-of-concept in vivo studies were hampered by a technical problem with the BDM-I formulation chosen. This requires that we prepare a new formulation development plan.

- The NIH fungal program was presented as a poster at the American Society of Microbiology's Denver ICAAC conference
- A new US patent for BDM-I for claims relating to skin and soft tissue infections was granted to add to those already granted for protozoal infections and vulvovaginitis
- Two new Australian studies of BDM-I looking at mechanism of action and resistance were commenced. The results of these will be used to profile BDM-I's novelty and potential value as a human therapeutic and will be used for commercial discussions.

## **OTHER TECHNOLOGIES**

### **BDM-E**

Commercial discussions were initiated to outlicence the BDM-E technology for further development.

## **SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS**

On 14 November 2013 the company was delisted from the Official List of the ASX, after receiving approval from shareholders at the Annual General Meeting on 8 October 2013.

In February 2014 6,151,157 fully paid ordinary shares were issued upon exercise of options at \$0.08 (8 cents) raising \$492,093. A further \$400 was raised from the exercise of 5,000 options in June 2014.

In April 2014 the company completed a Rights Issue, issuing 11,758,890 fully paid ordinary shares, with the shortfall of 3,066,819 allocated to shareholders applying for additional shares above their allocation, raising a total of \$815,414 before costs.

There were no other significant changes in the state of affairs of the consolidated entity during the financial year.

### **Matters subsequent to the end of the financial year**

No matter or circumstance has arisen since 30 June 2014 that has significantly affected, or may significantly affect the consolidated entity's operations, the results of those operations, or the consolidated entity's state of affairs in future financial years.

### **Likely developments and expected results of operations**

The Company will continue to implement its existing strategy by focusing on the development of its various technologies in an economically efficient manner.

### **Environmental regulation**

The consolidated entity is not subject to any significant environmental regulation under Australian Commonwealth or State law.

## Directors' report

Name, qualifications and independence status	Experience, special responsibilities and other directorships
<p><b>HUGH M MORGAN AC</b> <i>LLB, BCom.</i></p> <p><b>Chairman</b> <b>Non-Executive Director</b></p>	<p>Hugh Morgan is Principal of First Charnock Pty Ltd. Hugh was appointed Chief Executive Officer of Western Mining Corporation (1990-2003) and prior to that served as an Executive Officer (1976-1986) and then Managing Director (from June 1986). Hugh has served as a Director of Alcoa of Australia Limited (1977-1998 and 2002-2003); Director of Alcoa Inc. (1998-2001); Member of the Board of the Reserve Bank of Australia (1981-1984 and 1996-2007); President of the Australian Japan Business Co-Operation Committee (1999-2006); Joint Chair of the Commonwealth Business Council (2003-2005) and now Emeritus Director; President of the Business Council of Australia (2003-2005) and now an Honorary Member; Member of the Anglo American plc Australian Advisory Board (2006-2014). Hugh is a Member of the Lafarge International Advisory Board; Chairman of the Order of Australia Association Foundation Limited; Trustee Emeritus of The Asia Society New York; Chairman Emeritus of the Asia Society AustralAsia Centre; Member of the Asia Society Australia Advisory Council; President of the National Gallery of Victoria Foundation. Hugh is a graduate in Law and Commerce from the University of Melbourne.</p> <p><i>Chairman of Audit Committee, Chairman of Remuneration and Nomination Committee</i></p>
<p><b>JULIE PHILLIPS</b> <i>BPharm, DHP, MSc, MBA.</i></p> <p><b>Chief Executive Officer</b></p>	<p>Ms Julie Phillips was appointed to the position of Chief Executive Officer on July 14, 2009 and was appointed a Director on May 7, 2010. She has a strong background in the biotech and pharmaceutical industry, having worked as the CEO and Director of start-up Australian biotechnology companies operating in the life sciences sector. Her technical background in clinical trials, regulatory affairs and pharmacoeconomic assessment/pricing of therapeutics was gained in multinational pharmaceutical companies with responsibility for market entry of new products in Australia and New Zealand. She is a Director of AusBiotech Ltd, the peak biotechnology industry association in Australia.</p>
<p><b>LARISA RUDENKO</b> <i>MD, PhD, DSc.</i></p> <p><b>Director of Russian Projects,</b> <b>Non-Executive Director</b></p>	<p>Professor Larisa Rudenko is Head of the Virology Department in the Institute of Experimental Medicine, St. Petersburg, Russia. Professor Rudenko worked with Academician Smorodintsev and has been responsible for the development and clinical trials of the live attenuated influenza vaccines in Russia. She is recognised as one of the world's leading experts in live attenuated influenza vaccines and as such has worked closely over the past 20 years with scientists at the Centers for Disease Control and Prevention, Atlanta, USA in developing effective influenza prophylaxis programs for use in children and in the elderly. She has published in excess of 225 scientific papers and 42 patents. Under her supervision, 11 PhD and 2 DSc theses have been prepared. In 1999 her contribution to medical science was recognised with the award of the title of Honoured Scientist of the Russian Federation. Professor Rudenko is currently leading the WHO and PATH programs, developing a new pandemic LAIV.</p> <p><i>Member, Remuneration and Nomination Committee</i></p>

## Directors' report

Name, qualifications and independence status	Experience, special responsibilities and other directorships
<b>DONALD S BROOKS</b> <i>BA, JD.</i> <b>Non-Executive Director</b>	<p>Mr Don Brooks, a graduate of Columbia University School of Law, is a US-based lawyer, who for many years was Senior Counsel-Licensing at Merck &amp; Co., Inc. and was formerly its Counsel for U.S. pharmaceutical operations and Counsel for its research operations. He retired from Merck in 1993 and since that time has served as Counsel to a U.S. law firm representing clients in the biotechnology industry, as well as serving as an advisor to firms in the biotechnology and the pharmaceutical industry in general. He has been general counsel of Maryland-based biotech company, EntreMed Inc.</p>

[Member Audit Committee, Member of Remuneration and Nomination Committee](#)

<b>ARTHUR KWOK CHEUNG LI GBS JP</b> <i>BA, MA, MB BChir, MD, HonDSc (Hull), HonDLitt (HKUST), HonDoc (Soka), HonLLD (CUHK), HonDSc(Med) (UCL), HonLLD (UWE), FRCS, FRCSEd, FRACS, FCSHK, FHKAM (Surgery), HonFPCS, HonFRCGlas, HonFRSM, HonFRCGS(I), HonFACS, HnFRCPLon, HonFCSHK, HonFASA, Emeritus Professor of Surgery (CUHK)</i>	<p>Professor Arthur Li was appointed a Director on May 7, 2010. Professor Li was awarded the degree of Doctor of Medicine by University of Cambridge, UK. He is a well-credentialed and respected educator and surgeon who is currently Deputy Chairman of The Bank of East Asia and is Emeritus Professor of Surgery of The Chinese University of Hong Kong. He is a member of the Executive Council of the Hong Kong Special Administrative Region. He is also a Director of AFFIN Holdings Berhad. Among his many previous appointments and associations, he has been a Council Fellow of the University of Melbourne, Dean of the Faculty of Medicine and Vice-Chancellor of The Chinese University of Hong Kong. Professor Li was the Secretary for Education and Manpower of the Government of HKSAR. He was also a member of the Board of Glaxo Wellcome plc. He is a member of the National Committee of the Chinese People's Political Consultative Conference.</p>
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**Non-Executive Director**

[Member Audit Committee](#)

### COMPANY SECRETARY

Melanie Leydin is company secretary and has 23 years' experience in the accounting profession and is a director and company secretary for a number of oil and gas, junior mining and exploration entities listed on the Australian Securities Exchange. She is a Chartered Accountant and a Registered Company Auditor. She graduated from Swinburne University in 1997, became a Chartered Accountant in 1999 and since February 2000 has been the principal of chartered accounting firm, Leydin Freyer specialising in outsourced company secretarial and financial duties for resources and biotechnology sectors.

## Directors' report

### MEETINGS OF DIRECTORS

The number of meetings of the company's Board of Directors ('the Board') held during the year ended 30 June 2014, and the number of meetings attended by each director were:

	Full Board		Nomination and Remuneration Committee			Audit and Risk Committee	
	Attended	Held	Attended	Held		Attended	Held
Hugh M Morgan	13	13	—	—		2	2
Julie Phillips	13	13	—	—		—	—
Larisa Rudenko	13	13	—	—		—	—
Donald S Brooks	13	13	—	—		2	2
Arthur Kwok Cheung Li	10	13	—	—		—	—

*Held: represents the number of meetings held during the time the director held office.*

### SHARES UNDER OPTION

Unissued ordinary shares of BioDiem Limited under option at the date of this report are as follows:

Grant date	Expiry date	Exercise price	Number under option
5 December 2012	31 December 2014	\$0.080	18,482,417

No person entitled to exercise the options had or has any right by virtue of the option to participate in any share issue of the company or of any other body corporate.

### SHARES ISSUED ON THE EXERCISE OF OPTIONS

The following ordinary shares of BioDiem Limited were issued during the year ended 30 June 2014 and up to the date of this report on the exercise of options granted:

Date options granted	Exercise price	Number shares issued
5 December 2012 - Options issued as part of Rights Issue	\$0.080	6,151,157

### INDEMNITY AND INSURANCE OF OFFICERS

The company has indemnified the directors and executives of the company for costs incurred, in their capacity as a director or executive, for which they may be held personally liable, except where there is a lack of good faith.

During the financial year, the company paid a premium in respect of a contract to insure the directors and executives of the company against a liability to the extent permitted by the Corporations Act 2001. The contract of insurance prohibits disclosure of the nature of liability and the amount of the premium.



### INDEMNITY AND INSURANCE OF AUDITOR

The company has not, during or since the end of the financial year, indemnified or agreed to indemnify the auditor of the company or any related entity against a liability incurred by the auditor.

### PROCEEDINGS ON BEHALF OF THE COMPANY

No person has applied to the Court under section 237 of the Corporations Act 2001 for leave to bring proceedings on behalf of the company, or to intervene in any proceedings to which the company is a party for the purpose of taking responsibility on behalf of the company for all or part of those proceedings.

### AUDITOR'S INDEPENDENCE DECLARATION

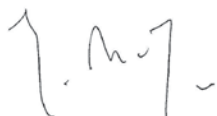
A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out on the following page.

### AUDITOR

Grant Thornton Audit Pty Ltd continues in office in accordance with section 327 of the Corporations Act 2001.

This report is made in accordance with a resolution of directors, pursuant to section 298(2)(a) of the Corporations Act 2001.

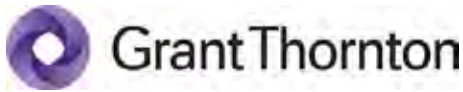
On behalf of the directors



**H M Morgan AC**  
Director

4 September 2014  
Melbourne

## Auditor's independence declaration



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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 audit of BioDiem Limited for the year ended 30 June 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 audit; and
- b no contraventions of any applicable code of professional conduct in relation to the audit.



GRANT THORNTON AUDIT PTY LTD  
Chartered Accountants



M.A. Cunningham  
Partner - Audit & Assurance

Melbourne, 4 September 2014

Grant Thornton Audit Pty Ltd ACN 130 913 594  
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## Statement of profit or loss and other comprehensive income

		Consolidated	
	Note	June 2014	June 2013
		\$	\$
<b>Revenue</b>			
	3	113,939	101,615
Other income	4	583,042	16,338
<b>Expenses</b>			
Licence fees and royalty expenses		(16,206)	(33,768)
Research and development expenses		(623,624)	(1,169,662)
Administration expenses		(1,068,606)	(1,230,683)
Net foreign exchange loss		(6,894)	-
Loss before income tax expense		(1,018,349)	(2,316,160)
Income tax expense	6	-	-
Loss after income tax expense for the year attributable to the owners of BioDiem Limited		(1,018,349)	(2,316,160)
Other comprehensive income for the year, net of tax		-	-
<b>Total comprehensive income for the year attributable to the owners of BioDiem Limited</b>		<b>(1,018,349)</b>	<b>(2,316,160)</b>

*The above statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes*

## Statement of financial position

	Note	Consolidated June 2014 \$	June 2013 \$
<b>Assets</b>			
Current assets			
Cash and cash equivalents	7	1,336,812	1,171,738
Trade and other receivables	8	11,965	48,118
Other	9	142,471	128,701
<b>Total current assets</b>		<b>1,491,248</b>	<b>1,348,557</b>
<b>Non-current assets</b>			
Property, plant and equipment	10	-	6,994
<b>Total non-current assets</b>		<b>-</b>	<b>6,994</b>
<b>Total assets</b>		<b>1,491,248</b>	<b>1,355,551</b>
<b>Liabilities</b>			
Current liabilities			
Trade and other payables	11	76,607	269,764
Employee benefits	12	26,044	11,328
<b>Total current liabilities</b>		<b>102,651</b>	<b>281,092</b>
<b>Non-current liabilities</b>			
Employee benefits	13	31,053	7,013
<b>Total non-current liabilities</b>		<b>31,053</b>	<b>7,013</b>
<b>Total liabilities</b>		<b>133,704</b>	<b>288,105</b>
<b>Net assets</b>		<b>1,357,544</b>	<b>1,067,446</b>
<b>Equity</b>			
Issued capital	14	30,087,862	28,812,349
Reserves	15	296,532	263,598
Accumulated losses		(29,026,850)	(28,008,501)
<b>Total equity</b>		<b>1,357,544</b>	<b>1,067,446</b>

The above statement of financial position should be read in conjunction with the accompanying notes

## Statement of changes in equity

	Issued Capital	Share based Compensation Reserve	Accumulated Losses	Total equity
Consolidated	\$	\$	\$	\$
Balance at 1 July 2012	26,929,511	263,598	(25,692,341)	1,500,768
Loss after income tax expense for the year	-	-	(2,316,160)	(2,316,160)
Other comprehensive income for the year, net of tax	-	-	-	-
Total comprehensive income for the year	-	-	(2,316,160)	(2,316,160)
<i>Transactions with owners in their capacity as owners:</i>				
Contributions of equity, net of transaction costs (note 14)	1,882,838	-	-	1,882,838
Balance at 30 June 2013	28,812,349	263,598	(28,008,501)	1,067,446

	Issued Capital	Share based Compensation Reserve	Accumulated Losses	Total equity
Consolidated	\$	\$	\$	\$
Balance at 1 July 2013	28,812,349	263,598	(28,008,501)	1,067,446
Loss after income tax expense for the year	-	-	(1,018,349)	(1,018,349)
Other comprehensive income for the year, net of tax	-	-	-	-
Total comprehensive income for the year	-	-	(1,018,349)	(1,018,349)
<i>Transactions with owners in their capacity as owners:</i>				
Contributions of equity, net of transaction costs (note 14)	1,275,513	-	-	1,275,513
Share-based payments (note 25)	-	32,934	-	32,934
Balance at 30 June 2014	30,087,862	296,532	(29,026,850)	1,357,544

*The above statement of changes in equity should be read in conjunction with the accompanying notes*



## Statement of cash flows

	Note	Consolidated June 2014 \$	June 2013 \$
<b>Cash flows from operating activities</b>			
Cash receipts in course of operations		98,798	82,515
Cash payments in course of operations		(1,798,254)	(2,404,678)
		(1,699,456)	(2,322,163)
Interest received		15,344	20,525
R&D Tax Offset received		583,042	317,000
<b>Net cash used in operating activities</b>	<b>24</b>	<b>(1,101,070)</b>	<b>(1,984,638)</b>
<b>Cash flows from investing activities</b>			
Payments for property, plant and equipment	10	-	(5,243)
Deposits supporting guarantees		(4,096)	(6,081)
<b>Net cash used in investing activities</b>		<b>(4,096)</b>	<b>(11,324)</b>
<b>Cash flows from financing activities</b>			
Proceeds from issue of shares	14	1,307,907	2,000,000
Net costs of issue of shares		(32,394)	(119,054)
<b>Net cash from financing activities</b>		<b>1,275,513</b>	<b>1,880,946</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>170,347</b>	<b>(115,016)</b>
Cash and cash equivalents at the beginning of the financial year		1,171,738	1,267,211
Effects of exchange rate changes on cash and cash equivalents		(5,273)	19,543
<b>Cash and cash equivalents at the end of the financial year</b>	<b>7</b>	<b>1,336,812</b>	<b>1,171,738</b>

The above statement of cash flows should be read in conjunction with the accompanying notes

# Notes to the financial statements

## NOTE 1. GENERAL INFORMATION.

The financial statements cover BioDiem Limited as a consolidated entity 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 consolidated entity'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 4 September 2014. The directors have the power to amend and reissue the financial statements.

## NOTE 2. SIGNIFICANT ACCOUNTING POLICIES.

The principal accounting policies adopted in the preparation of the financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

### New, revised or amending Accounting Standards and Interpretations adopted

The consolidated entity 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 \$1.018m (2013: \$2.316m net loss after tax) for the financial year ended 30 June 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 2014 financial year, the Directors have prepared the annual 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 \$1.358m (2013: \$1.067m), including cash and cash equivalent assets of \$1.337m (2012: \$1.171m), and the expectation of Group's ongoing ability to successfully secure additional sources of financing. In this regard, the Directors note the following:

- The Group has a marketing agreement with the Serum Institute of India ("Serum"), which will entitle the Group to royalty income upon the commencement of sales of LAIV seasonal influenza vaccine. The Group anticipates royalty income will be generated from this license agreement within the next 12 months.
- The Group has a LAIV licensing agreement with the Changchun BCBT Biotechnology Co., where the vaccine subject to the LAIV licensing agreement is currently under development. If the development and commercialisation of the vaccine successful, the LAIV licensing agreement is expected to provide further royalty income streams over the next two years.
- The Group is considering other alternative sources of cash inflows from 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 annual 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.

## Notes to the financial statements

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.

### BASIS OF PREPARATION

These general purpose financial statements have been prepared in accordance with Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') and the Corporations Act 2001, as appropriate for for-profit oriented entities. These financial statements also comply with International Financial Reporting Standards as issued by the International Accounting Standards Board ('IASB').

#### *Historical cost convention*

The financial statements have been prepared under the historical cost convention, except for, where applicable, the revaluation of available-for-sale financial assets, financial assets and liabilities at fair value through profit or loss, investment properties, certain classes of property, plant and equipment and derivative financial instruments.

### PRINCIPLES OF CONSOLIDATION

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of BioDiem Limited ('company' or 'parent entity') as at 30 June 2014 and the results of all subsidiaries for the year then ended. BioDiem Limited and its subsidiaries together are referred to in these financial statements as the 'consolidated entity'.

Subsidiaries are all those entities over which the consolidated entity has control. The consolidated entity controls an entity when the consolidated entity is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the consolidated entity. They are de-consolidated from the date that control ceases.

Intercompany transactions, balances and unrealised gains on transactions between entities in the consolidated entity are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of the impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the consolidated entity.

The acquisition of subsidiaries is accounted for using the acquisition method of accounting. A change in ownership interest, without the loss of control, is accounted for as an equity transaction, where the difference between the consideration transferred and the book value of the share of the non-controlling interest acquired is recognised directly in equity attributable to the parent.

Where the consolidated entity loses control over a subsidiary, it derecognises the assets including goodwill, liabilities and non-controlling interest in the subsidiary together with any cumulative translation differences recognised in equity. The consolidated entity recognises the fair value of the consideration received and the fair value of any investment retained together with any gain or loss in profit or loss.

### FOREIGN CURRENCY TRANSLATION

The financial statements are presented in Australian dollars, which is BioDiem Limited's functional and presentation currency.

### FOREIGN CURRENCY TRANSACTIONS

Foreign currency transactions are translated into Australian dollars using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at financial year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in profit or loss.

### REVENUE RECOGNITION

Revenue is recognised when it is probable that the economic benefit will flow to the consolidated entity and the revenue can be reliably measured. Revenue is measured at the fair value of the consideration received or receivable.

## Notes to the financial statements

### *Licensing fees*

Licensing fees derived from the grant of rights to exploit certain master donor strains are recognised by reference to the stage of completion at the transaction date. This is expected to be when the milestone events outlined in the contract have occurred.

No revenue is recognised unless the outcome of a transaction can be estimated reliably, it is probable that the economic benefits associated with the transaction will flow to the entity, the stage of completion can be measured reliably, and costs incurred for the transaction and costs to complete the transaction can be measured reliably.

### *Royalty revenue*

Royalties are recognised in the period in which the right to receive the royalty has been established.

### *Grant revenue*

Unconditional government grants are recognised in profit or loss as other income when the grant becomes receivable. Any other government grant is recognised in the balance sheet initially as deferred income when received and when there is reasonable assurance that the entity will comply with the conditions attaching to it. Grants that compensate the entity for expenses incurred are recognised as revenue in profit or loss on a systematic basis in the same periods in which the expenses are incurred.

### *Interest*

Interest revenue is recognised as interest accrues using the effective interest method.

## INCOME TAX

The income tax expense or benefit for the period is the tax payable on that period's taxable income based on the applicable income tax rate for each jurisdiction, adjusted by changes in deferred tax assets and liabilities attributable to temporary differences, unused tax losses and the adjustment recognised for prior periods, where applicable.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to apply when the assets are recovered or liabilities are settled, based on those tax rates that are enacted or substantively enacted, except for:

- When the deferred income tax asset or liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting nor taxable profits; or

- When the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, and the timing of the reversal can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax assets are recognised for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

The carrying amount of recognised and unrecognised deferred tax assets are reviewed each reporting date. Deferred tax assets recognised are reduced to the extent that it is no longer probable that future taxable profits will be available for the carrying amount to be recovered. Previously unrecognised deferred tax assets are recognised to the extent that it is probable that there are future taxable profits available to recover the asset.

Deferred tax assets and liabilities are offset only where there is a legally enforceable right to offset current tax assets against current tax liabilities and deferred tax assets against deferred tax liabilities; and they relate to the same taxable authority on either the same taxable entity or different taxable entities which intend to settle simultaneously.

## CURRENT AND NON-CURRENT CLASSIFICATION

Assets and liabilities are presented in the statement of financial position based on current and non-current classification.

An asset is current when: it is expected to be realised or intended to be sold or consumed in normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realised within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is current when: it is expected to be settled in normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current.

Deferred tax assets and liabilities are always classified as non-current.

# Notes to the financial statements

## CASH AND CASH EQUIVALENTS

Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

## TRADE AND OTHER RECEIVABLES

Trade receivables are initially recognised at fair value and subsequently measured at amortised cost using the effective interest method, less any provision for impairment. Trade receivables are generally due for settlement within 30 days.

Other receivables are recognised at amortised cost, less any provision for impairment.

## PROPERTY, PLANT AND EQUIPMENT

Land and buildings are shown at fair value, based on periodic, at least every 3 years, valuations by external independent valuers, less subsequent depreciation and impairment for buildings. The valuations are undertaken more frequently if there is a material change in the fair value relative to the carrying amount. Any accumulated depreciation at the date of revaluation is eliminated against the gross carrying amount of the asset and the net amount is restated to the revalued amount of the asset. Increases in the carrying amounts arising on revaluation of land and buildings are credited in other comprehensive income through to the revaluation surplus reserve in equity. Any revaluation decrements are initially taken in other comprehensive income through to the revaluation surplus reserve to the extent of any previous revaluation surplus of the same asset. Thereafter the decrements are taken to profit or loss.

Plant and equipment is stated at historical cost less accumulated depreciation and impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Depreciation is calculated on a straight-line basis to write off the net cost of each item of property, plant and equipment (excluding land) over their expected useful lives as follows:

Plant and equipment	33%
Furniture and fittings	33%

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each reporting date.

Leasehold improvements and plant and equipment under lease are depreciated over the unexpired period of the lease or the estimated useful life of the assets, whichever is shorter.

An item of property, plant and equipment is derecognised upon disposal or when there is no future economic benefit to the consolidated entity. Gains and losses between the carrying amount and the disposal proceeds are taken to profit or loss. Any revaluation surplus reserve relating to the item disposed of is transferred directly to retained profits.

## RESEARCH AND DEVELOPMENT

Expenditure on research activities undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is recognised in profit or loss as an expense as incurred.

Expenditure on any development activities, whereby research findings are applied to a plan or design for the production of new or substantially improved products and processes, is capitalised if the product is technically feasible and the Group has sufficient resources to complete development. The expenditure capitalised includes the cost of materials, direct labour and overhead costs that are directly attributable to preparing the asset for its intended use.

Other development expenditure is recognised in the profit or loss as an expense as incurred. Capitalised development expenditure is stated at cost less accumulated amortisation and impairment losses.



## Notes to the financial statements

### IMPAIRMENT OF NON-FINANCIAL ASSETS

Goodwill and other intangible assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other non-financial assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount.

Recoverable amount is the higher of an asset's fair value less costs of disposal and value-in-use. The value-in-use is the present value of the estimated future cash flows relating to the asset using a pre-tax discount rate specific to the asset or cash-generating unit to which the asset belongs. Assets that do not have independent cash flows are grouped together to form a cash-generating unit.

### TRADE AND OTHER PAYABLES

These amounts represent liabilities for goods and services provided to the consolidated entity prior to the end of the financial year and which are unpaid. Due to their short-term nature they are measured at amortised cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

### EMPLOYEE BENEFITS

#### Short-term employee benefits

Liabilities for wages and salaries, including non-monetary benefits, annual leave and long service leave expected to be settled within 12 months of the reporting date are recognised in current liabilities in respect of employees' services up to the reporting date and are measured at the amounts expected to be paid when the liabilities are settled.

#### Other long-term employee benefits

The liability for annual leave and long service leave not expected to be settled within 12 months of the reporting date are recognised in non-current liabilities, provided there is an unconditional right to defer settlement of the liability. The liability is measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting date

using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on national government bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

### SHARE-BASED PAYMENTS

Equity-settled and cash-settled share-based compensation benefits are provided to employees.

Equity-settled transactions are awards of shares, or options over shares, that are provided to employees in exchange for the rendering of services. Cash-settled transactions are awards of cash for the exchange of services, where the amount of cash is determined by reference to the share price.

The cost of equity-settled transactions are measured at fair value on grant date. Fair value is independently determined using either the Binomial or Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk free interest rate for the term of the option, together with non-vesting conditions that do not determine whether the consolidated entity receives the services that entitle the employees to receive payment. No account is taken of any other vesting conditions.

The cost of equity-settled transactions are recognised as an expense with a corresponding increase in equity over the vesting period. The cumulative charge to profit or loss is calculated based on the grant date fair value of the award, the best estimate of the number of awards that are likely to vest and the expired portion of the vesting period. The amount recognised in profit or loss for the period is the cumulative amount calculated at each reporting date less amounts already recognised in previous periods.

The cost of cash-settled transactions is initially, and at each reporting date until vested, determined by applying either the Binomial or Black-Scholes option pricing model, taking into consideration the terms and conditions on which the award was granted. The cumulative charge to profit or loss until settlement of the liability is calculated as follows:

## Notes to the financial statements

- during the vesting period, the liability at each reporting date is the fair value of the award at that date multiplied by the expired portion of the vesting period.
- from the end of the vesting period until settlement of the award, the liability is the full fair value of the liability at the reporting date.

All changes in the liability are recognised in profit or loss. The ultimate cost of cash-settled transactions is the cash paid to settle the liability.

Market conditions are taken into consideration in determining fair value. Therefore any awards subject to market conditions are considered to vest irrespective of whether or not that market condition has been met, provided all other conditions are satisfied.

If equity-settled awards are modified, as a minimum an expense is recognised as if the modification has not been made. An additional expense is recognised, over the remaining vesting period, for any modification that increases the total fair value of the share-based compensation benefit as at the date of modification.

If the non-vesting condition is within the control of the consolidated entity or employee, the failure to satisfy the condition is treated as a cancellation. If the condition is not within the control of the consolidated entity or employee and is not satisfied during the vesting period, any remaining expense for the award is recognised over the remaining vesting period, unless the award is forfeited.

If equity-settled awards are cancelled, it is treated as if it has vested on the date of cancellation, and any remaining expense is recognised immediately. If a new replacement award is substituted for the cancelled award, the cancelled and new award is treated as if they were a modification.

### FAIR VALUE MEASUREMENT

When an asset or liability, financial or non-financial, is measured at fair value for recognition or disclosure purposes, the fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date; and assumes that the transaction will take place either: in the principal market; or in the absence of a principal market, in the most advantageous market.

Fair value is measured using the assumptions that market participants would use when pricing the asset or liability, assuming they act in their economic best interest. For non-financial assets, the fair value measurement is based on its highest and best use. Valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, are used, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

### ISSUED CAPITAL

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

### GOODS AND SERVICES TAX ('GST') AND OTHER SIMILAR TAXES

Revenues, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the tax authority. In this case it is recognised as part of the cost of the acquisition of the asset or as part of the expense.

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the tax authority is included in other receivables or other payables in the statement of financial position.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the tax authority, are presented as operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the tax authority.

### NEW ACCOUNTING STANDARDS AND INTERPRETATIONS NOT YET MANDATORY OR EARLY ADOPTED

Australian Accounting Standards and Interpretations that have recently been issued or amended but are not yet mandatory, have not been early adopted by the consolidated entity for the annual reporting period ended 30 June 2014. The consolidated entity has not yet assessed the impact of these new or amended Accounting Standards and Interpretations.

## Notes to the financial statements

### NOTE 3. REVENUE

	Consolidated	
	June 2014	June 2013
	\$	\$
Royalty and milestone revenue	93,398	75,251
Grant income	5,000	5,000
	98,398	80,251
Other revenue		
Interest	15,141	21,364
Other revenue	400	-
	15,541	21,364
Revenue	113,939	101,615

### NOTE 4. OTHER INCOME

	Consolidated	
	June 2014	June 2013
	\$	\$
Net foreign exchange gain	-	16,338
Research & Development Tax Concession	583,042	-
Other income	583,042	16,338

### NOTE 5. EXPENSES

	Consolidated	
	June 2014	June 2013
	\$	\$
Loss before income tax includes the following specific expenses:		
<i>Employee Benefits Expense</i>		
Wages and salaries	750,464	777,928
Superannuation - defined contribution	33,618	24,423
Other associated personnel expenses	2,063	20,545
(Decrease)/Increase in annual leave provision	14,716	(21,420)
(Decrease)/Increase in long service leave provision	24,040	(15,027)
Share based payment (see note 25)	32,934	-
<b>Total</b>	<b>857,835</b>	<b>786,449</b>

## Notes to the financial statements

### NOTE 6. INCOME TAX BENEFIT

	Consolidated	
	June 2014	June 2013
	\$	\$
Numerical reconciliation of income tax expense and tax at the statutory rate		
Loss before income tax expense	(1,018,349)	(2,316,160)
Tax at the statutory tax rate of 30%	(305,505)	(694,848)
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Share-based payments	9,880	-
Research & Development tax incentive - not assessable	(174,913)	-
	(470,538)	(694,848)
Current year tax losses not recognised	483,067	688,651
Current year temporary differences not recognised	(12,529)	6,197
Income tax expense	-	-

	Consolidated	
	June 2014	June 2013
	\$	\$
Tax losses not recognised		
Unused tax losses for which no deferred tax asset has been recognised	28,355,486	26,745,261
Potential tax benefit @ 30%	8,506,646	8,023,578

The above potential tax benefit for tax losses has not been recognised in the statement of financial position. These tax losses can only be utilised in the future if the continuity of ownership test is passed, or failing that, the same business test is passed.

### NOTE 7. CURRENT ASSETS - CASH AND CASH EQUIVALENTS

	Consolidated	
	June 2014	June 2013
	\$	\$
Cash at bank	1,336,812	1,171,738

### NOTE 8. CURRENT ASSETS - TRADE AND OTHER RECEIVABLES

	Consolidated	
	June 2014	June 2013
	\$	\$
Trade receivables	1,868	1,868
Interest receivable	637	840
GST receivable	9,460	45,410
	11,965	48,118

## Notes to the financial statements

### NOTE 9. CURRENT ASSETS - OTHER

	Consolidated	
	June 2014	June 2013
	\$	\$
Prepayments	30,158	20,484
Short term deposits supporting bank guarantees	112,313	108,217
	142,471	128,701

The company holds two short term deposits, one (\$41,784) is a three month term deposit maturing on 15 September 2014. The other (\$70,529) is a six month term deposit, maturing on 25 September 2014. Both term deposits are earning 3.15% per annum.

### NOTE 10. NON-CURRENT ASSETS - PROPERTY, PLANT AND EQUIPMENT

	Consolidated	
	June 2014	June 2013
	\$	\$
Plant and equipment - at cost	140,230	185,590
Less: Accumulated depreciation	(140,230)	(178,596)
	-	6,994

#### Reconciliations

Reconciliations of the written down values at the beginning and end of the current and previous financial year are set out below:

	Plant and equipment	Total
Consolidated	\$	\$
Balance at 1 July 2012	6,127	6,127
Additions	5,243	5,243
Depreciation expense	(4,376)	(4,376)
Balance at 30 June 2013	6,994	6,994
Disposals	(4,068)	(4,068)
Depreciation expense	(2,926)	(2,926)
Balance at 30 June 2014	-	-

### NOTE 11. CURRENT LIABILITIES - TRADE AND OTHER PAYABLES

	Consolidated	
	June 2014	June 2013
	\$	\$
Trade payables	37,516	207,561
Other payables	39,091	62,203
	76,607	269,764

Refer to note 17 for further information on financial instruments.



## Notes to the financial statements

### NOTE 12. CURRENT LIABILITIES - EMPLOYEE BENEFITS

	Consolidated	
	June 2014	June 2013
	\$	\$
Annual leave	26,044	11,328

### NOTE 13. NON-CURRENT LIABILITIES - EMPLOYEE BENEFITS

	Consolidated	
	June 2014	June 2013
	\$	\$
Long service leave	31,053	7,013
	31,053	7,013

### NOTE 14. EQUITY - ISSUED CAPITAL

	Consolidated			
	June 2014	June 2013	June 2014	June 2013
	Shares	Shares	\$	\$
Ordinary shares - fully paid	163,087,800	142,105,934	30,087,862	28,812,349

#### Movements in ordinary share capital

Details	Date	Shares	Issue price	\$
Balance	1 July 2012	102,095,554		26,929,511
NED Purchase		10,380	\$0.180	1,868
Rights Issue		40,000,000	\$0.050	2,000,000
Capital raising costs		-	\$0.000	(119,030)
Balance	30 June 2013	142,105,934		28,812,349
Exercise of options	28 February 2014	6,151,157	\$0.080	492,093
Rights issue	29 April 2014	14,825,709	\$0.055	815,414
Exercise of options	23 June 2014	5,000	\$0.080	400
Capital raising costs		-	\$0.000	(32,394)
Balance	30 June 2014	163,087,800		30,087,862

#### 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.

#### Capital risk management

The consolidated entity's objectives when managing capital is to safeguard its ability to continue as a going concern, so that it can provide returns for shareholders and benefits for other stakeholders and to maintain an optimum capital structure to reduce the cost of capital. In order to maintain or adjust the capital structure, the consolidated entity may adjust the amount of dividends paid to shareholders, return capital to shareholders, issue new shares or sell assets to reduce debt.

## Notes to the financial statements

The consolidated entity is subject to certain financing arrangements covenants and meeting these is given priority in all capital risk management decisions. There have been no events of default on the financing arrangements during the financial year.

The capital risk management policy remains unchanged from the 2013 Annual Report.

### NOTE 15. EQUITY - RESERVES

	Consolidated	
	June 2014	June 2013
	\$	\$
Share-based payments reserve	296,532	263,598

#### *Share-based payments reserve*

The reserve is used to recognise the value of equity benefits provided to employees and directors as part of their remuneration, and other parties as part of their compensation for services.

Movements in reserves

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

	Share based payments	Total
	\$	\$
<b>Consolidated</b>		
Balance at 1 July 2012	263,598	263,598
Balance at 30 June 2013	263,598	263,598
Share based payment	32,934	32,934
Balance at 30 June 2014	296,532	296,532

### NOTE 16. EQUITY - DIVIDENDS

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

### NOTE 17. FINANCIAL INSTRUMENTS

#### *Financial risk management objectives*

Exposure to liquidity, credit and currency risks arise in the normal course of the company's business.

#### MARKET RISK

##### *Foreign currency risk*

The consolidated entity undertakes certain transactions denominated in foreign currency and is exposed to foreign currency risk through foreign exchange rate fluctuations.

Foreign exchange risk arises from future commercial transactions and recognised financial assets and financial liabilities denominated in a currency that is not the entity's functional currency. The risk is measured using sensitivity analysis and cash flow forecasting. The exposure to foreign exchange risk is not material at year end.

##### *Price risk*

The consolidated entity is not exposed to any significant price risk.

##### *Interest rate risk*

The company is not exposed to significant interest rate risk.

## Notes to the financial statements

### *Credit risk*

Management has a credit policy in place and the exposure to credit risk is monitored on an ongoing basis. Credit risk is minimised, as counterparties are recognised financial intermediaries, with acceptable credit ratings determined by recognised credit agencies. The maximum exposure to credit risk is represented by the carrying amounts of the financial assets in the Statement of Financial Position. None of the company's receivables are past their due date.

### *Liquidity risk*

The consolidated entity manages liquidity risk by maintaining adequate cash reserves and available borrowing facilities by continuously monitoring actual and forecast cash flows and matching the maturity profiles of financial assets and liabilities.

### *Remaining contractual maturities*

The following tables detail the consolidated entity's remaining contractual maturity for its financial instrument liabilities. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the financial liabilities are required to be paid. The tables include both interest and principal cash flows disclosed as remaining contractual maturities and therefore these totals may differ from their carrying amount in the statement of financial position.

Consolidated - June 2014	Weighted average interest rate %	1 year or less \$	Between 1 and 2 years \$	Between 2 and 5 years \$	Over 5 years \$	Remaining contractual maturities \$
<b>Non-derivatives</b>						
<i>Non-interest bearing</i>						
Trade payables	%	76,607	-	-	-	76,607
<b>Total non-derivatives</b>		<b>76,607</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>76,607</b>
Consolidated - June 2013	Weighted average interest rate %	1 year or less \$	Between 1 and 2 years \$	Between 2 and 5 years \$	Over 5 years \$	Remaining contractual maturities \$
<b>Non-derivatives</b>						
<i>Non-interest bearing</i>						
Trade payables	%	269,764	-	-	-	269,764
<b>Total non-derivatives</b>		<b>269,764</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>269,764</b>

The cash flows in the maturity analysis above are not expected to occur significantly earlier than contractually disclosed above.

### *Fair value of financial instruments*

Unless otherwise stated, the carrying amounts of financial instruments reflect their fair value.

### *Guarantees*

The Group has in place two term deposits for periods of six months and three months amounting to \$70,529 and \$41,784 respectively totalling \$112,313 (2013: \$108,217) in support of its undertakings under a guarantee for \$60,000 on account of the Group's credit cards.

# Notes to the financial statements

## NOTE 18. REMUNERATION OF AUDITORS

During the financial year the following fees were paid or payable for services provided by Grant Thornton Audit Pty Ltd, the auditor of the company:

	Consolidated	
	June 2014 \$	June 2013 \$
Audit services - Grant Thornton Audit Pty Ltd (June 2013: KPMG)	40,000	60,000
Audit or review of the financial statements		

## NOTE 19. CONTINGENT LIABILITIES

The consolidated entity holds a licence to commercialise influenza vaccine technologies from the Institute of Experimental Medicine. Under this agreement the consolidated entity is obliged to pay the Institute of Experimental Medicine 20% of all payments received from any Licensee and 20% of any royalties arising from net sales.

The consolidated entity also holds a licence to commercialise certain technologies from the 000 Klinika Instituta Bioregulyastii I Gerontologii ("the Clinic"). The licence is in relation to retinal eye disease. The consolidated entity is obliged to pay the Clinic 20% of all payments received from any Licensee and 20% of any royalties arising from net sales.

## NOTE 20. COMMITMENTS

The company entered into a non-cancellable operating lease on 7 January 2013 in respect of its previous office. The twelve month lease expired on 6 January 2014 with an option to extend for a further twelve month period. The company chose not to extend the lease. The company currently occupies office premises with a rental agreement in place that enables cancellation with two months' notice.

## NOTE 21. RELATED PARTY TRANSACTIONS

### *Parent entity*

BioDiem Limited is the parent entity.

### *Subsidiaries*

Interests in subsidiaries are set out in note 22.

### *Transactions with related parties*

Prof Rudenko is the Head of the Virology Department at the Institute of Experimental Medicine ("the Institute"). During the course of the year the Group paid licence fees and royalties amounting to \$16,206 (2013: \$16,875) to the Institute. In addition, research and development costs amounting to \$45,000 (2013: \$45,000) were also paid to the Institute. The company also made a donation to the Institute of \$50,000 during 2013 to assist in the construction of the WHO laboratory facility in St Petersburg, Russia.

### *Receivable from and payable to related parties*

There were no trade receivables from or trade payables to related parties at the current and previous reporting date.

### *Loans to/from related parties*

There were no loans to or from related parties at the current and previous reporting date.

### *Terms and conditions*

All transactions were made on normal commercial terms and conditions and at market rates.

## Notes to the financial statements

### NOTE 22. 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:

Name	Principal place of business / Country of incorporation	Ownership interest	June 2013
		June 2014 %	%
Savine Therapeutics Pty Ltd	Australia	100.00%	100.00%

On 14 December 2011, the Company acquired control of Savine Therapeutics Pty Ltd a company that has developed a proprietary method for designing synthetic vaccines that are expected to stimulate and enhance the body's immune system. The Company acquired all Savine's issued shares and Savine's directors resigned on that date with the exception of Julie Phillips.

The purchase consideration comprised the issue of 111,111 ordinary shares (market value \$10,000) and \$10,000 in cash. The existing carrying value of the net assets of Savine at acquisition amounted to \$nil. The \$20,000 purchase consideration has been expensed in

line with the Group's accounting policy for research and development, since, in substance, this investment was just another research and development project.

### NOTE 23. EVENTS AFTER THE REPORTING PERIOD

No matter or circumstance has arisen since 30 June 2014 that has significantly affected, or may significantly affect the consolidated entity's operations, the results of those operations, or the consolidated entity's state of affairs in future financial years.

### NOTE 24. RECONCILIATION OF LOSS AFTER INCOME TAX TO NET CASH USED IN OPERATING ACTIVITIES

	Consolidated	
	June 2014 \$	June 2013 \$
Loss after income tax expense for the year	(1,018,349)	(2,316,160)
Adjustments for:		
Depreciation and amortisation	2,926	4,376
Net loss on disposal of property, plant and equipment	4,068	-
Share-based payments	32,934	-
Foreign exchange differences	5,273	(16,338)
Change in operating assets and liabilities:		
Decrease in trade and other receivables	36,153	319,848
Increase in prepayments	(9,674)	(3,296)
Increase/(decrease) in trade and other payables	(193,157)	63,378
Increase/(decrease) in employee benefits	38,756	(36,446)
Net cash used in operating activities	(1,101,070)	(1,984,638)



## Notes to the financial statements

### NOTE 25. SHARE-BASED PAYMENTS

The Group has an Employees' and Officers' Incentive Option Scheme pursuant to which options may be issued to eligible persons, being directors', employees and consultants or their approved nominees. Eligible persons may receive options based on the achievement of specific performance hurdles, which are a blend of Group and personal objectives appropriate for the roles and responsibilities of each individual. Under the scheme signed in October 2006, the Group has the ability to issue options up to 5 percent of the issued capital. As at 30 June 2014 there were 163,087,800 shares on hand.

When issued, the options will have an exercise price of not less than the average closing trading price of the Group's ordinary listed shares on the five days prior to issuing invitations to accept options under the scheme, will have an expiry date not later than five years after the date of issue, and will vest at such times as the Board with the advice from the Remuneration Committee may specify in the applicable invitation to accept the options.

On 4 July 2007 the Group issued 539,635 options to directors and staff of which 497,250 were issued to key management personnel. The remaining 42,385 were

issued to employees. These options were restricted until 4 July 2008 and lapsed on 4 July 2012. Each option had an exercise price of \$0.36.

On 1 July 2008 the Group issued 80,000 options to employees. These options were restricted until 1 July 2009 and lapsed on 4 July 2013. Each option had an exercise price of \$0.14. On 27 July 2009 the Group issued 160,000 options under the ESOP. These options were restricted until 27 July 2010 and lapsed on 27 July 2014. The exercise price was set at \$0.136.

At the Annual General Meeting, held on 8 October 2013, 2 million options were granted to the CEO under the scheme. The options vested in accordance with the Scheme rules and lapse after 30 September 2023.

All options vest on the basis of one third per annum after the year of issue. There are no voting rights or dividend rights attached to these options. All these options expire on the earlier of the expiry date or the date of the employee termination, unless otherwise agreed. No shares issued on exercise of options granted under the scheme during the year or in the previous year.

## Notes to the financial statements

Set out below are summaries of options granted under the plan:

June 2014							
Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Expired/ forfeited/ other	Balance at the end of the year
01/07/2008	04/07/2013	\$0.140	80,000	-	-	(80,000)	-
27/07/2009	27/07/2014	\$0.136	160,000	-	-	(60,000)	100,000
08/10/2013	30/09/2023	\$0.080	-	666,667	-	-	666,667
08/10/2013	30/09/2023	\$0.120	-	666,667	-	-	666,667
08/10/2013	30/09/2023	\$0.200	-	666,666	-	-	666,666
			240,000	2,000,000	-	(140,000)	2,100,000
Weighted average exercise price			\$0.137	\$0.133	\$0.000	\$0.138	\$0.133

Set out below are the options exercisable at the end of the financial year:

Grant date	Expiry date	June 2014 Number	June 2013 Number
27/07/2009	01/01/2010	100,000	240,000
08/10/2013	30/09/2023	666,667	-
		766,667	240,000

\*These options lapsed unexercised on 27 July 2014.

The weighted average remaining contractual life of options outstanding at the end of the financial year was 8 years and 8 months (2013: 9 months).

For the options granted during the current financial year, the valuation model inputs used to determine the fair value at the grant date, are as follows:

Grant date	Expiry date	Share price at grant date	Exercise price	Expected volatility	Dividend yield	Risk-free interest rate	Fair value at grant date
08/10/2013	30/09/2013	\$0.030	\$0.080	100.00%	-%	3.97%	\$0.025
08/10/2013	30/09/2013	\$0.030	\$0.120	100.00%	-%	3.97%	\$0.025
08/10/2013	30/09/2013	\$0.030	\$0.200	100.00%	-%	3.97%	\$0.023

## Directors' declaration

In the directors' opinion:

- the attached financial statements and notes thereto comply with the Corporations Act 2001, the Accounting Standards, the Corporations Regulations 2001 and other mandatory professional reporting requirements;
- the attached financial statements and notes thereto comply with International Financial Reporting Standards as issued by the International Accounting Standards Board as described in note 2 to the financial statements;
- the attached financial statements and notes thereto give a true and fair view of the consolidated entity's financial position as at 30 June 2014 and of its performance for the financial 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 295(5)(a) of the Corporations Act 2001.

On behalf of the directors



**H M Morgan AC**

Director

4 September 2014

Melbourne

# Independent auditor's report to the members of BioDiem Limited



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

We have audited the accompanying financial report of BioDiem Limited (the "Company"), which comprises the consolidated statement of financial position as at 30 June 2014, the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, notes comprising a summary of significant accounting policies and other explanatory information and the directors' declaration of the consolidated entity comprising the Company and the entities it controlled at the year's end or from time to time during the financial year.

### Directors' responsibility for the financial report

The Directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001. The Directors' responsibility also includes such internal control as the Directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

### Auditor's responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. Those standards require us to comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error.

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# Independent auditor's report to the members of BioDiem Limited



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In making those risk assessments, the auditor considers internal control relevant to the Company's preparation of the financial report that gives a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Directors, as well as evaluating the overall presentation of the financial report.

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

## **Independence**

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

## **Auditor's opinion**

In our opinion the financial report of BioDiem Limited is in accordance with the Corporations Act 2001, including:

- i giving a true and fair view of the consolidated entity's financial position as at 30 June 2014 and of its performance for the year ended on that date; and
- ii complying with Australian Accounting Standards and the 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 company incurred a net loss of \$1,018,349 during the year ended 30 June 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.

A stylized, handwritten signature in black ink that reads "Grant Thornton".

GRANT THORNTON AUDIT PTY LTD  
Chartered Accountants

A stylized, handwritten signature in black ink, likely belonging to M.A. Cunningham.

M.A. Cunningham  
Partner - Audit & Assurance

Melbourne, 4 September 2014



## Corporate directory

### **BioDiem Ltd**

ABN 20 096 845 993

### **Directors**

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

Ms Julie Phillips (Chief Executive Officer)

Mr Donald S Brooks (Non-Executive Director)

Dr Arthur Kwok Cheung Li (Non-Executive Director)

Dr Larisa Rudenko (Non-Executive Director)

### **Share Registry**

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**Investor Queries (within Australia):** 1300 850 505

### **Company Secretary**

Melanie Leydin

### **Registered Office**

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### **Principal place of business**

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### **Auditor**

Grant Thornton Audit Pty Ltd

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### **Website**

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For more information, please visit: [www.biodiem.com](http://www.biodiem.com)