BioDiem

BioDiem Ltd – Annual Report

ABN 20 096 845 993

2016

DEVELOPING COMMERCIAL OUTCOMES

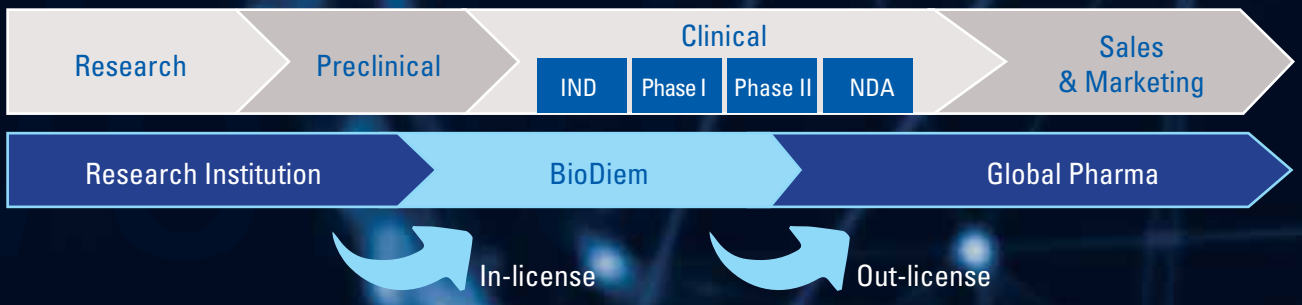
WHO WE ARE

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

BioDiem's lead technology is the LAIV (Live Attenuated Influenza Virus) vaccine technology used for production of seasonal and pandemic influenza vaccines and is given intranasally.

This technology is licensed currently to two commercial partners, in India and China, and is licenced to the World Health Organisation as part of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply. Serum Institute of India's Nasovac-S™ is based on BioDiem's technology and is already marketed in India.

BioDiem's antimicrobial technology, BDM-I, is being developed through its subsidiary, Opal Biosciences Ltd. OPAL is progressing the development of its anti-infective for injectable (Opal-I); topical use (Opal-T) and lung delivery (Opal-L).



"BioDiem uses a licensing model…

…we take early stage technologies, mostly from universities and research institutes, and them work them up through to preparation for clinical trial….

…. To accelerate full development, we then licence them out to larger companies for clinical trials and marketing …."

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2016

Forging a position as an innovative player in infectious disease vaccines and therapies

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Highlights of FY2016

CORPORATE

- Successful capital raising of $1.149m through a nonrenounceable entitlement offer of convertible preference shares was completed in July/August of 2016. The proceeds of the Offer are being applied to:
  - Developing existing and new commercial licensing opportunities for the influenza vaccine (LAIV) technology;
  - Providing support for BioDiem's subsidiary, Opal Biosciences, to conduct further studies for a data package for licensing:
    - Studies in preparation for efficacy testing in infectious disease models; and
    - Proof-of-concept studies in relevant infectious disease models; and
    - Continue mechanism of action studies at Western Sydney University.
  - Supporting the Institute of Experimental Medicine (IEM), in St Petersburg, Russia, which provides necessary materials and expertise to our LAIV 'flu vaccine technology licensees; including the World Health Organisation (WHO), Serum Institute of India (SII) and Changchun BCHT Biotechnology Co (BCHT).

INFLUENZA VACCINE TECHNOLOGY (LAIV)

- Royalty income from sales of Nasovac-S in India, and income from milestone payments totaling $136,604.
- Expansion of market access:
  - SII's Nasovac-S product received WHO prequalification (WHO PQ) in October 2015. WHO's list of prequalified medicinal products is used by international procurement agencies and increasingly by countries to guide bulk purchasing of medicines.
  - In October 2015, SII and Cipla announced an exclusive agreement for supply of SII's vaccines for the South African market.
- BCHT, BioDiem's licencee in China, commenced clinical trials in March 2016 following Chinese FDA approval. Further trials will follow and will be used in support of an application for marketing by BCHT of their influenza vaccine.
- On-going pandemic and avian 'flu vaccine development program through our partnership with the IEM. This program is designed to prepare possible influenza vaccine candidates that could be needed in a serious influenza outbreak (pandemic).
- Publication in the Lancet by IEM's Rudenko et al[1] reports that a H7N9 LAIV vaccine (i.e. using BioDiem's technology and MDV) was well tolerated and safe and showed good immunogenicity. An independent review[2] of this work, also published in the Lancet, describe this work as "possibly the most promising LAIV immunogenicity data so far".
- Completion and commissioning of a facility at the IEM in St Petersburg to handle highly pathogenic viruses (such as avian influenza viruses). This work was supported by the WHO and the US Biomedical Advanced Research and Development Authority (BARDA).
- Continued product enhancement programs including
  - liquid formulation intranasal delivery
  - thermostable powder intranasal delivery
  - universal vaccine

[1] Rudenko LG, Isakova-Sivak I, Naykhin A, Kiseleva I, Stukova M, Erofeeva M, Korenkov D, Matyushenko V, Sparrow E, Kieny M-P,. H7N9 live attenuated influenza vaccine in healthy adults: a randomised, double-blind, placebo-controlled, phase 1 trial. Lancet Infect Dis 2016; 16: 303–10

[2] Zanin M, Webby R. Live-attenuated H7N9 influenza vaccine is weak, yet strong. Lancet Infect Dis 2015 Published online December 7, 2015 http://dx.doi.org/10.1016/S1473-3099(15)00425-9

ANTIMICROBIAL BDM-I: OPAL BIOSCIENCES

- Shareholder approval for the transfer of the BDM-I technology into Opal Biosciences was obtained in July 2015.
- Additional European and US patent claims granted for Opal Biosciences, targeting serious and treatment-resistant infections.
- BDM-I presented at the prestigious European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Amsterdam in April 2016. Western Sydney University (WSU) PhD candidate Michael Radzieta, presented "Investigating the Mechanism of Action of the Novel Antimicrobial BDM-I" This research focuses on BDM-I's activity against hospital pathogens such as MRSA (methicillin-resistant Staphylococcus aureus or "Golden Staph"). Results to date indicate that BDM-I's cellular target is novel and therefore BDM-I represents a next-generation anti-infective.
- Other interim results looking at superbugs VRE (vancomycin-resistant enterococci) and MRSA (methicillin-resistant Staph aureus) were presented as a poster at the Australian Society for Microbiology annual meeting in July 2015, where it won first prize.
- Opal-I (injectable) formulation development work has been initiated by an overseas specialist company to develop a suitable intravenous injection.
- Preliminary safety pharmacology and cytotoxicity studies continue to support the potential for Opal technologies to be used as future therapeutics.
- Commencement of early stage formulation development studies for Opal-T (the topical application of BDM-I).
- Commencement of early stage research feasibility studies for Opal-L (the lung delivery of BDM-I).
- In addition to the investigation being undertaken in the resistant tuberculosis and fungal programs, BDM-I was accepted into an updated program of the NIH and showed activity against strains of VRE (vancomycin-resistant enterococci) and VRSA (vancomycin-resistant *Staph aureus*).

BIODIEM FOCUS

BioDiem is focused on reduced-risk co-development of promising assets with internationally recognised partners. Each program is focused on targets with near-term potential for revenue generation. As a small adaptable company with a diverse portfolio, BioDiem stands to rapidly gain value from a successful licensing deal or acquisition of an asset, complementing the existing revenues from LAIV vaccine licensing.

BIODIEM'S SUBSIDIARY: OPAL BIOSCIENCES

Opal Biosciences is an innovative player in infectious disease treatment. Opal is committed to tackling a serious global health threat: treatment-resistant infectious diseases caused by bacteria and fungi. Opal's technologies target human infection: a high growth, commercially attractive market segment.

The unmet need for new anti-infectives is due to increasing resistance to existing antibiotics, more widespread and common difficult-to-treat infections, and the paucity of upcoming new treatments.

Chairman's report

Fellow shareholders,

On behalf of the Board and Management of BioDiem, and also our subsidiary, Opal Biosciences, I am pleased to report to you for the 2016 financial year.

This last year has seen some highlights and some disappointments. With revenue from our LAIV technology licence for influenza vaccines for the year being lower than expected, we needed to undertake a capital raising to exploit our technologies commercially. I do note that royalty revenue has already started to pick up in the first half of this calendar year.

Our recent capital raising secured $1.15m from the issue of convertible preference shares (CPS). Each CPS holder is entitled to receive a priority amount equal to eight times the issue price of that share, before the holders of ordinary shares receive any amount by way of dividend, return of capital or otherwise. Once the CPS holders have received the priority amount, the CPS will convert automatically into ordinary shares, ranking equally with all other ordinary shares of the Company.

The decision to undertake this raising was based on our belief in the value of our technologies, the need to fund the commercial exploitation of our technologies and our commercial discussions and continue Opal Biosciences' development program for our antimicrobial technology.

Previous capital raisings have been supported primarily by the top three shareholders who prior to the CPS issue, had contributed more than $3m out of the $4m raised over the past four years. The Board also realised that we cannot ask you to contribute endlessly and therefore we included a minimum subscription of $800,000 for this last raising. We were pleased that this was easily exceeded, including $59K from our CEO Julie Phillips.

We are using these funds to develop existing and new commercial licensing opportunities for the influenza vaccine (LAIV) technology. We are also providing support for our subsidiary, Opal Biosciences, which is developing BDM-I, our antimicrobial being targeted at the treatment of hard-to-treat infections.

One surprising event in June this year was the report of the recommendation from the US CDC's Advisory Committee on Immunization Practices (ACIP) that in the US LAIV should not be used in the 2016-2017 season.

The ACIP reports that the decision was based on data on the quadrivalent (four strain) LAIV product available in the US (not BioDiem's product) which showed poor and/or lower protection from influenza than expected. As far as I am aware, the reason for this poor protection is unknown and is complicated by conflicting results showing efficacy in some studies and lack of efficacy in others. The cause is being investigated by international public health agencies as well as the companies involved. I hasten to add that BioDiem's LAIV intranasal vaccine is not marketed in the US, however we are tracking this situation, to understand any potential for impact on our technology and our commercial discussions. The appeal of an intranasal influenza vaccine is well-recognised and we are confident an understanding will be forthcoming.

In the meantime we continue to support development of new dosage forms of the LAIV including US studies using an intranasal temperature-stable powder form (instead of liquid), and a universal vaccine candidate i.e. one which would not require annual vaccinations.

Our review of operations in this annual report will outline the progress by our commercial partners. Our Chinese licencee commenced LAIV clinical trials in March 2016 on the path to registration in China, and our Indian licencee announced new distribution arrangements with global pharma giant, Cipla. We are very pleased with the progress by these companies and the commercial prospects in India and China. Additional interest has been shown by new parties in our technology and these discussions continue. Special interest is shown in the pandemic applications and the work already done in ferrets (the animal model for influenza) and in Phase I human studies.

The media continues to report emergence of micro-organisms resistant to treatment: this is in the news almost every day. This month a bacteria (E.coli) was discovered in the US which is resistant to the two last resort antibiotics. In line with this, high value acquisition activity in the antimicrobial sector continues with the most recent being Pfizer's bid for AstraZeneca's small molecule antibiotics business for US$1.5 billion.

Opal Biosciences' development of BDM-I is aiming at use in treatment-resistant infections. These are infections where existing therapies are ineffective meaning that the infections can become life-threatening. Our fundraising during 2015-16 for Opal Biosciences was disappointing, although we believe the prospect for the technology is enormous. The majority of the development program cost is being borne by BioDiem which owns 95.1% of Opal Biosciences. We are commencing the studies necessary as the prelude to efficacy testing of an injectable formulation in animals (Opal-I), and in addition, are very excited to have started the formulation of a topical gel (Opal-T) with Formulytica, a Melbourne-based specialist formulation company (www.formulytica.com). Opal-T will target treatment of skin, mucous membrane and wound infections caused by Golden Staph, fungi and other disease-causing germs. We are also pleased to have opened discussions with the University of Sydney's Professor Kim Chan who is an expert in drug delivery to the lung. If successful, a product derived from this development program (Opal-L) could be used to fight life-threatening fungal infections of the lung and respiratory tract, such as Scedosporium infections. Such infections are often life-threatening and are notoriously difficult to treat with existing therapies.

The aim of this work, in combination with the studies being continued at Western Sydney University by Prof Slade Jensen, is to provide the data necessary to attract an acquirer of the technology for final development, clinical trials and registration.

So we have a lot of work underway and have limited resources. We manage expenditure tightly and are pleased with opportunity presented by the program ahead. We expect the coming one-two years to be the most significant for the Company.

I thank you for your support.

Yours faithfully,

Hugh Morgan AC
BioDiem Chairman

CEO letter

Fellow Shareholders,

The 2015-2016 year has seen progress with our company's commercial position with more interest shown in our technologies, the LAIV influenza vaccine program and BDM-I, our antimicrobial being developed through our subsidiary, Opal Biosciences Ltd.

Significant events being:

- the commencement of LAIV vaccine clinical trials in China by our licencee, Changchun BCHT Biotechnology Co;
- WHO Prequalification of Nasovac-S (India) and progress towards export sales in territories BioDiem has already granted to SII; and
- and progress of precursor studies through Opal Biosciences of BioDiem's antimicrobial asset, BDM-I.

Nasovac-S is a seasonal influenza vaccine which is based on our LAIV influenza vaccine technology. SII holds a licence to our LAIV technology for manufacture and commercialisation in India and non-exclusively for Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan, New Zealand, Myanmar and Sri Lanka. Sales of Nasovac-S commenced in 2014 the royalty flow has been modest initially, however we expect the issue of export approval (prequalification) for Nasovac-S by the World Health Organisation (WHO) in October 2015 will lead to preparation for export to SII's granted territories. SII is one of the world's biggest vaccine producers by volume and exports to more than 120 countries and its new marketing and distribution relationship with pharmaceutical giant Cipla for Nasovac-S in India and other territories will leverage the strong Cipla sales presence and is expected to favourably impact Nasovac-S sales.

More details on the LAIV program will be provided later in this report.

The Opal Biosciences' capital raising commenced in May 2015 fell well short of our $3.5m target, however we are pleased to have been able to progress the various forms of the antimicrobial:

- Opal I (injectable for serious infections): formulation work continuing and in vivo testing due to commence in 2017; some laboratory safety screening studies have been completed successfully;
- Opal –T (topical for wound, mucous membrane and skin infections); formulation work commenced in August 2016; and
- Opal-L (lung and respiratory tract infections) early stage research work commenced looking at nanoparticle formation.

We have used shareholder funds sparingly to access government grants to progress this program which could deliver life-saving treatments.

BioDiem holds a majority stake in Opal Biosciences and so BioDiem shareholders will be able to benefit from the successful development of the Opal technologies.

Prof Slade Jensen's lab at the Ingham Institute for Applied Research at Western Sydney University continues to investigate how Opal technology works to target treatment of superbugs. Further information on Opal is included in this report.

We were delighted with the recent BioDiem capital raising which saw the issue of preference shares and raised $1.15m. My thanks go to those shareholders, new and pre-existing who supported us.

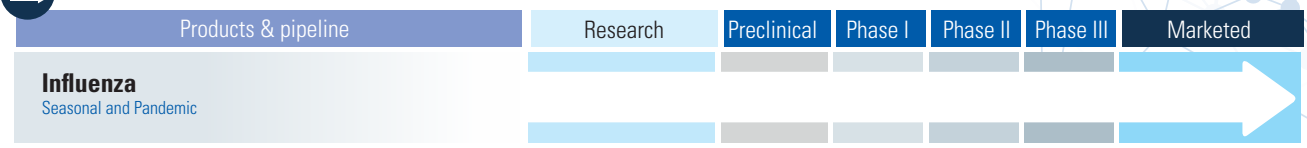
BioDiem and Opal Biosciences are public unlisted companies. We have retained the Leydin Freyer Corp. Pty Ltd to provide a matching service for those wishing to buy and sell shares. Please contact our company secretary for more information on how to trade. Also please ensure your details are up-to-date at our share registry, Computershare.

I would like to thank the shareholders, board and staff for their ongoing support through the year. Please do not hesitate to contact me should you have any questions about your company; and please follow us by joining our email list, via our websites (www.biodiem.com and www.opalbiosciences.com) and twitter (@biodiem and @opalbiosciences).

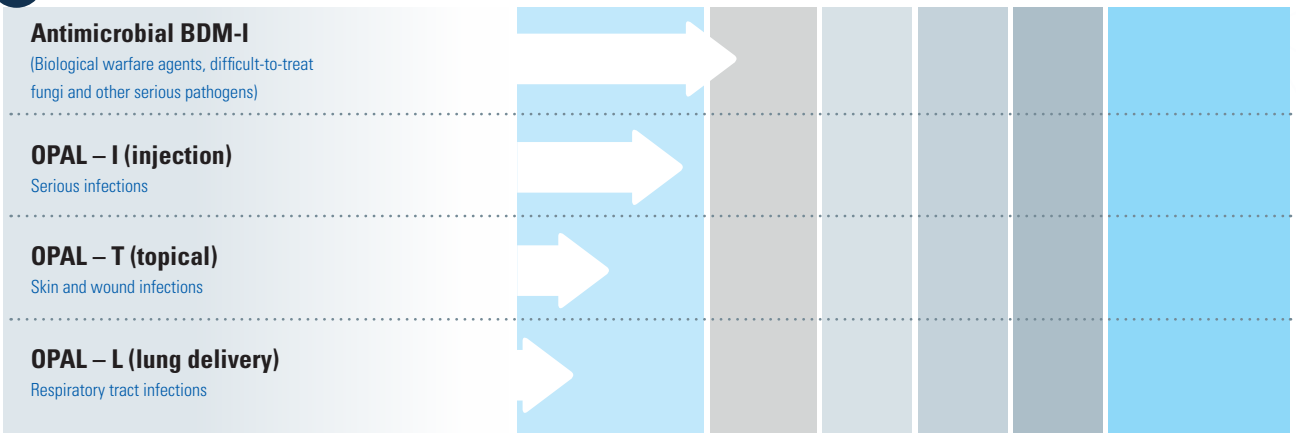
Yours sincerely,

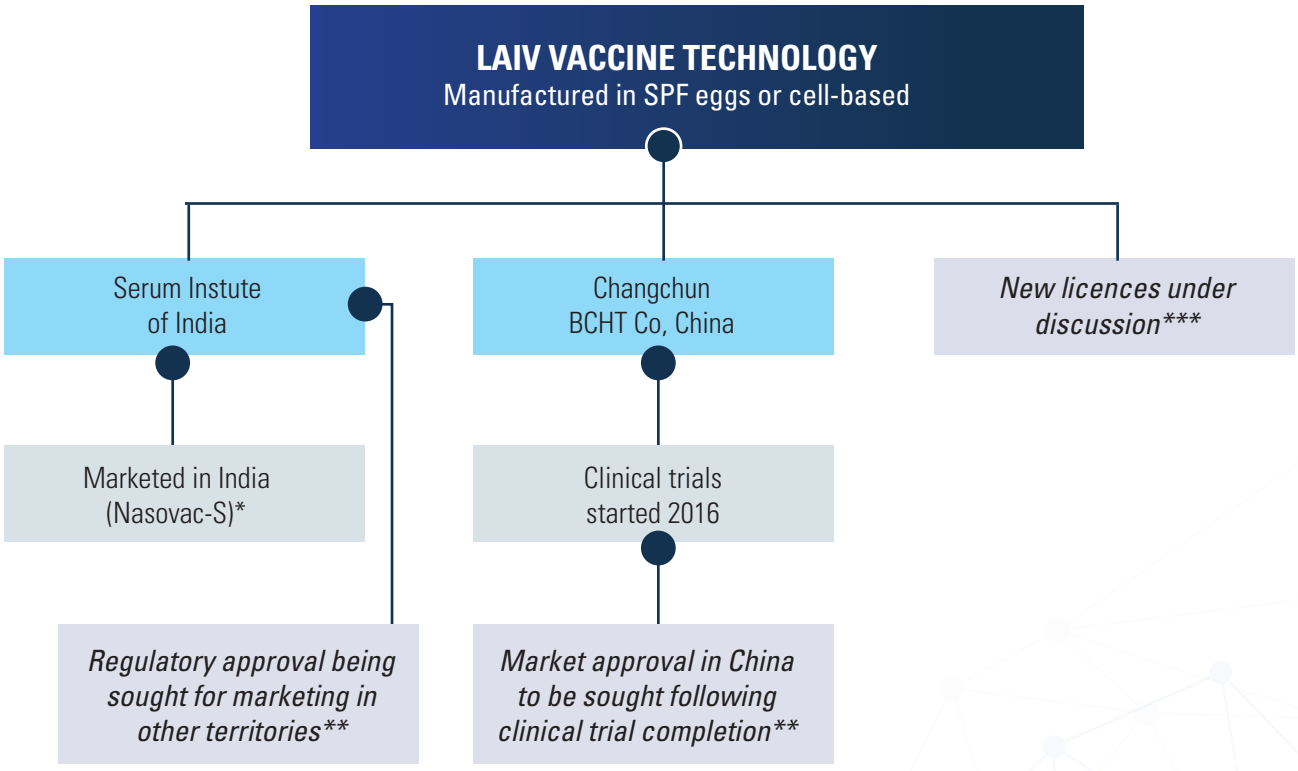
Julie Phillips
CEO

BIODIEM PIPELINE



OPAL BIOSCIENCES' PIPELINE





*Royalties from sales flow to BioDiem (private market)
**Royalties from sales will flow to BioDiem (private market)
***Licence fees/royalties etc will flow to BioDiem.

Review of operations

BioDiem's main development programs are:

- **Influenza vaccine program:** expansion of the revenue-generating LAIV-based influenza vaccine technology licensing business including next generation products; and
- **BDM-I antimicrobial:** development and commercialisation of BioDiem's BDM-I for the treatment of important infectious diseases through our subsidiary Opal Biosciences.

INFLUENZA VACCINE

BioDiem's LAIV Vaccine business involves licensing our platform technology to others for the production of intranasal vaccines for the prevention of seasonal and pandemic influenza. BioDiem receives payment from licence fees and royalties on sales.

BioDiem currently has two commercial partners:

- Serum Institute of India (Pune, India), and
- Changchun BCHT Biotechnology Co. (Jilin, China).

Our 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 past year include:

- Royalty and milestone income from sales of Nasovac-S™ in India, and income from milestone payments totaling $136,604. Nasovac-S is a seasonal influenza vaccine based on BioDiem's LAIV (live attenuated influenza virus) vaccine technology. BioDiem receives royalties from sales of this product into the private market in India.
- Potential new markets:
  - Nasovac-S received WHO prequalification (WHO PQ) in October 2015. Nasovac-S received WHO prequalification in October 2015: an important commercial milestone as this permits vaccine export to other developing countries of the United Nations. BioDiem will gain income from royalties on sales of Nasovac-S in the private sector of these export markets. The WHO prequalification process comprises a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers. This information, in conjunction with other procurement criteria, is used by UN and other procurement agencies to make purchasing decisions regarding these health-related products or vaccines. WHO PQ of Nasovac-S is an important commercial milestone.
  - Therefore with the WHO prequalification approval for Nasovac-S, SII can prepare for export to markets outside India. Sales in the private sector of export markets will strengthen the royalty stream to BioDiem. Regulatory approval will be needed in many of the new export jurisdictions, with expected approval times generally 1-2 years before sales can commence. We understand, in other markets such as some South American PAHO (the Pan American Health Organisation) members, the current WHO prequalification approval is sufficient for marketing approval.

...possibly the most promising LAIV immunogenicity data so far

2 Zanin M, Webby R. Live-attenuated H7N9 influenza vaccine is weak, yet strong. Lancet Infect Dis 2015 Published online December 7, 2015 http://dx.doi.org/10.1016/S1473-3099(15)00425-9

  - In October 2015, SII and Cipla announced an exclusive agreement for supply of SII's vaccines for the South African market where Cipla's subsidiary, Cipla Medpro P/L, is the third largest pharmaceutical manufacturer. This follows the Cipla and SII announcement in November 2014, where Cipla will seek to market SII's vaccines in Europe to complement Cipla's pharmaceutical product range; and in May 2015, SII announced a distribution deal with global pharmaceutical company Cipla for Nasovac-S in India. Under the arrangement SII will manufacture the vaccine and it will be distributed in India by Cipla exclusively. The Nasovac-S distribution arrangement will leverage the strong Cipla sales presence already established in India. Cipla is India's fourth largest drug maker by sales and has more than 60% of its sales outside India. Cipla's turnover in FY2015 was USD 1.7 billion. It has a strong presence in India, and is also in Europe, North America and South Africa.

- Changchun BCHT Biotechnology Co. (BCHT), BioDiem's licencee in China, commenced a clinical trial in March 2016 following Chinese FDA approval. Clinical trials will continue into 2017. The results of these clinical trials will be used in support of an application for marketing by BCHT of their influenza vaccine. BioDiem will gain income from royalties on sales of BCHT's LAIV vaccine in the private sector in China.

- BioDiem has an on-going pandemic and avian 'flu vaccine development program through its partnership with the IEM. This program is designed to prepare possible influenza vaccine candidates that could be needed in a serious influenza outbreak (pandemic). The candidate vaccines would be already tested for efficacy and safety and be ready to be used. Successful Phase I clinical trials have been conducted with the candidate vaccine strains. A recent publication in the Lancet by IEM's Rudenko et al[3] reports that a H7N9 LAIV vaccine (i.e. using BioDiem's technology and MDV) was well tolerated and safe and showed good immunogenicity. An independent review[4] of this work, also published in the Lancet, describe this work as "possibly the most promising LAIV immunogenicity data so far".

- Completion and commissioning of a facility at the IEM in St Petersburg to handle highly pathogenic viruses (such as avian influenza viruses). This work was supported by the WHO and the US Biomedical Advanced Research and Development Authority (BARDA).

- Continued product enhancement programs including
  - liquid formulation intranasal delivery
  - thermostable powder intranasal delivery
  - universal vaccine

- Additional publications to support the use of the LAIV vaccine shown overleaf.

[3]Rudenko LG, Isakova-Sivak I, Naykhin A, Kiseleva I, Stukova M, Erofeeva M, Korenkov D, Matyushenko V, Sparrow E, Kieny M-P,. H7N9 live attenuated influenza vaccine in healthy adults: a randomised, double-blind, placebo-controlled, phase 1 trial. Lancet Infect Dis 2016; 16: 303–10

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Review of operations

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Potentially Pandemic Live Influenza Vaccines Based on Russian Master Donor Virus are Genetically Stable after Replication in Humans//

Journal of Vaccines & Vaccination. 2016. T7. T3.

Desheva YA, Smolonogina TA, Doroshenko EM, Rudenko LG.

[Development of the quadrivalent live attenuated influenza vaccine including two influenza B lineages--Victoria and Yamagata]

Vopr Virusol. 2016;61(1):16-20. Russian.

PRESENTATIONS

7th Orthomyxovirus Research Conference,

Toulouse, France 16-18 September 2015
http://eventegg.com/orthomyxovirus-2015/

1. I Isakova-Sivak, D Korenkov, V Kuznetsova, T Smolonogina, T Tretiak, A Rekstin, A Naykhin, and L Rudenko

A Rationale for Incorporation of Nucleoprotein from Wild-Type Influenza Viruses into Genome of Live Attenuated Influenza Vaccine Reassortants. Abstract book 7th Orthomyxovirus Research Conference, Toulouse, France 16-18 September 2015. 2015; Oral presentation, O28. Page 43.

2. D. Korenkov, G. Petukhova, S. Donina, I. Losev, L. Rudenko, A.Naykhin.

The integrated approach in the Immunogenicity studies of pandemic Live Attenuated Influenza Vaccines. Abstract book 7th Orthomyxovirus Research Conference, Toulouse, France 16-18 September 2015. 2015; Posters, P18. Page 50

Options IX for the Control of Influenza

Chicago, 24-28 August, 2016

http://2016.isirv.org/

1. Iu.Desheva, G. Leontieva, T. Kramskaya, T. Smolonogina, K. Grabovskaya, A. Rekstin, A.r Suvorov, L. Rudenko

Prevention of mixed influenza and bacterial infections using combined vaccine based on attenuated influenza virus and the group B Streptococcus proteins.

2. Iu. Desheva, T. Smolonogina, I.Sychev, L. Rudenko

Study of cross-reactive anti-neuraminidase serum antibodies following past influenza infections or LAIV vaccination

3. D. Korenkov, I. Isakova-Sivak, A. Naykhin, L. Rudenko

Theoretical and experimental assessment of CTL epitopes renewal in NP of Live Attenuated Influenza Vaccine viruses

4. I. Isakova-Sivak, D. Korenkov, I. Kiseleva, A. Rekstin, A. Naykhin, T. Smolonogina, T. Tretiak, Sv. Donina, G. Petukhova, I. Losev, Sv. Shcherbik, T. Bousse, L. Rudenko

Approaches to enhance immunogenicity and crossreactivity of live attenuated influenza vaccine

H5N1 (VN/1203) or H9N2 (Quail/HK/1997) virus

5. I. Kiseleva, E. Bazhenova, E. Fedorova, I. Dubrovina, V. Matyushenko, T. Smolonogina, I. Isakova-Sivak, L. Rudenko

Optimization of wild type influenza virus selection for the development of live attenuated reassortant vaccine

6. T. Tretiak, I. Isakova-Sivak, D. Korenkov, E. Fedorova, T. Smolonogina, L. Rudenko

Development of live attenuated influenza vaccine expressing several epitopes of respiratory syncytial virus

Review of operations

REVIEW OF OPERATIONS (CONTINUED)

Antimicrobial BDM-I: Opal Biosciences

- BioDiem's preclinical antimicrobial compound BDM-I targets the treatment of infections, including 'superbugs' that cause antibiotic-resistant serious human infections. It is being developed and commercialised through our subsidiary, Opal Biosciences ("Opal"). The formation of Opal Biosciences in May 2015 was undertaken to permit external investment in the development of BDM-I while allowing BioDiem shareholders to retain benefit from successful commercialisation.

Significant developments during the past year include:

- Shareholder approval for the transfer of the BDM-I technology into Opal Biosciences was obtained in July 2015.
- Additional European and US patent claims granted for Opal Biosciences, targeting serious and treatment-resistant infections.
- BDM-I presented at the prestigious European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Amsterdam in April 2016. Western Sydney University (WSU) PhD candidate Michael Radzieta, presented "Investigating the Mechanism of Action of the Novel Antimicrobial BDM-I" and was part of the session "Discovery and novel developments in antibacterial drugs and drug potentiators".
- Mr Radzieta's research arises from the collaboration between BioDiem and Western Sydney University's Antibiotic Resistance and Mobile Elements Group (ARMEG) led by Associate Professor Slade Jensen and located at the Ingham Institute for Applied Medical Research and Western Sydney University. This research focuses on BDM-I's activity against hospital pathogens such as MRSA (methicillin-resistant Staphylococcus aureus or "Golden Staph") and other superbugs. Results to date indicate that BDM-I's cellular target is novel and therefore BDM-I represents a next-generation anti-infective.
- Other interim results looking at superbugs VRE (vancomycin-resistant enterococci) and MRSA (methicillin-resistant *Staph aureus*) were presented as a poster at the Australian Society for Microbiology annual meeting in July 2015, where it won first prize.
- Opal-I (injectable) formulation development work has been initiated by an overseas specialist company to develop a suitable intravenous injection for the next stages of studies in animal models.
- Preliminary safety pharmacology and cytotoxicity studies continue to support the potential for Opal technologies to be used as future therapeutics.
- Commencement of early stage formulation development studies for Opal-T (the topical application of BDM-I). Opal-T could be used for superficial infections of the mucous membranes and skin. Infections such as tinea (athlete's foot) and candida (thrush).
- Commencement of early stage research studies for Opal-L (the lung delivery of BDM-I). Early feasible studies of nanoparticle formation of BDM-I has led to discussions of a program for lung delivery of BDM-I with Prof Kim Chan, Professor of Pharmaceutics (Advanced Drug Delivery), University of Sydney. Grant funding for this program will be sought. Possible disease targets include life-threatening respiratory tract infections.
- In addition to the investigation being undertaken in the resistant tuberculosis and fungal programs, BDM-I was accepted into an updated program of the NIH[5] and showed activity against strains of VRE (vancomycin-resistant enterococci) and VRSA (vancomycin-resistant *Staph aureus*).

[5]http://www.niaid.nih.gov/LabsAndResources/resources/dmid/invitro/Pages/invitro.aspx

COMMERCIAL OBJECTIVE

Opal's commercial objective is to outlicence or sell the technologies to a larger pharmaceutical company for clinical trials and marketing. The growth in number and value of acquisitions of anti-infective technologies internationally is driven by larger companies being drawn back to the anti-infectives market segment by its growing attractiveness, and the need to buy innovation with R&D pipelines dry.

What do we do when current antibiotics don't work anymore?

The medical need for **new** effective anti-infective agents is growing. This is due to a number of well-established factors:

1 **The increasing resistance seen to existing antibiotics.** This is giving rise to "super bugs" which are no longer as responsive or are completely resistant to existing treatments. For example, this has been seen with the germs that cause infections such as tuberculosis, gonorrhea and also blood and wound infections.

2 **Hard-to-treat infections that used to be rare are now more common**. Because of advances in medical management of cancers, HIV, cystic fibrosis and organ transplants, as examples, there is a larger pool of people with weakened immune systems or having had intensive antibiotic treatment who can be susceptible to the unusual infections such as invasive fungal infections.

3 **Resistant disease is more widespread**. There is a rise in resistance among the germs that cause common infections such a urinary tract infections, bloodstream infections and pneumonia. Similarly, resistant germs are an increasing problem in tuberculosis and malaria.

4 **Few new treatments are in development.** The lead time to develop any new drug is long, generally 12 or more years, and few new anti-infective drugs have been brought to market in the last 25 years.

OPAL'S DEVELOPMENT AND COMMERCIALISATION PLAN

Since formation Opal Biosciences has sought external funding for its development plan. The fund-raising has been slower than expected which has extended the time frame for work to be completed. In view of this, the prospect of topical development (Opal-T) and lung delivery (Opal-L) are pleasing. The progress of the injectable formulation development work has been impeded by the speed in accessing Australian sites to perform formulation and animal testing. Hence some of this work has been performed overseas and at greater cost. Where possible we prefer to access Australian sites where Australian development capability exists and to access the important federal government R&D tax incentive program which returns 45c in the dollar for eligible R&D conducted in Australia. We continue to seek grant funding to leverage shareholder funds for this antimicrobial development work.

US INCENTIVES

The US is a key commercial target territory for Opal Biosciences to seek a partner. The US has instigated a series of incentives which would contribute significantly to the potential commercial success of an antimicrobial development program. As in the UK and Europe, the US recognizes the seriousness of the rise in antibiotic resistance. Already, 23,000 people die yearly directly from antibiotic-resistant bacterial infections in the U.S. and more than 2 million fall ill, according to the Centers for Disease Control[6].

But as many as 10 million people a year could die from antimicrobial-resistant infections worldwide by 2050 if there is a continued rise in resistance and new treatments are not discovered, according to a recent report from the Review on Antimicrobial Resistance[7].

In 2014, President Barack Obama committed $1.2 billion in his annual budget proposal to a five year plan to fight life-threatening infections caused by antibiotic-resistant bacteria – a doubling of the existing federal funding allocation.

[6]http://www.cdc.gov/drugresistance/threat-report-2013/

[7]http://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

Review of operations

Relevant US Incentives now in place include:

1 **The GAIN (Generating Antibiotic Incentives Now) Legislation:** was passed in 2012 to help to stimulate the development of new antimicrobials. The law allows the FDA to designate certain antimicrobials as "Qualified Infectious Disease Products" (QIDPs), which allows for priority review and possible fast-track status. The designation also provides sponsors with an extra 5 years of market exclusivity. To date, FDA has granted 107 QIDP designations for 63 different unique molecules[8].

2 **FDA's Priority Review**: A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review). The FDA has approved five new antibacterial drugs and one new antifungal since the GAIN Act's passage. Three of the five antibacterials are for acute skin and skin-structure infections caused by methicillin-resistant *Staphylococcus aureus* and certain other pathogens; the other two are for complicated urinary tract and intra-abdominal infections[8].

3 **Orphan Drug designation**: qualifies the sponsor of the drug for various development incentives, including tax credits and extended market exclusivity. This would apply to rare life-threatening infections such as respiratory infection by Scedosporium or other fungal species.

4 **FDA's Fast Track Process**: a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. There are opportunities for frequent interactions with the review team for a fast track product. These include meetings with FDA, including pre-IND meetings, end-of-phase 1 meetings, and end-of-phase 2 meetings to discuss study design, extent of safety data required to support approval, dose-response concerns, and use of biomarkers. Other meetings may be scheduled as appropriate (e.g., to discuss accelerated approval, the structure and content of an NDA, and other critical issues).[9]

Relevance to BDM-I

Included in the FDA's list of "qualifying pathogens" are those germs which have shown susceptibility to BDM-I e.g. *Mycobacterium tuberculosis, Neisseria gonorrhoeae, Streptococcus pneumoniae, Streptococcus pyogenes, Staphylococcus aureus,* Candida species, Coccidioides species, Cryptococcus species, Enterococcus species etc, in the laboratory.

In addition to the benefits of the GAIN Act, there are additional benefits related to Orphan Drug designation. The benefit for the Orphan Drug designation varies between markets. In the US there is 7 years of marketing exclusivity, bringing the total to 12 years for antibiotics targeting qualifying pathogens and diseases.

The opportunity to access US Incentives, particularly **extended market exclusivity** for one or more pathogens and **fast track designation for expedited FDA review** will drive the attractiveness of the development plan for potential acquirers.

BioDiem currently has agreements with the U.S. Army Medical Research Institute of Infectious Diseases (*USAMRIID*) to assess its potential as a biological weapons counter-measure, and with the U.S. National Institute of Allergy and Infectious Diseases' (NIAID's) in which BDM-I has progressed to preclinical animal studies to assess its potential as a treatment for the fungal disease, pneumocystosis and tuberculosis infection. The later studies are conducted under the U.S. National Institute of Allergy and Infectious Diseases' (NIAID's) preclinical services program Animal Models of Infectious Disease Service[10]. Our intravenous formulation work and other necessary precursor studies are intended to lead to conduct of the proof of concept studies by the NIH.

[8] http://www.cidrap.umn.edu/news-perspective/2016/06/feds-detail-range-steps-limit-antibiotic-resistance

[9] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf

[10] http://www.niaid.nih.gov/labsandresources/resources/dmid/animalmodels/Pages/default.aspx

Opal development plan includes.

- Additional formulation studies (including topical products) to deliver BDM-I by different routes of administration
- Dose-range finding pilot tolerability studies (to assist dose choice and treatment schedule and point to future toxicology studies needed)
- Pharmacokinetics studies using additional formulations
- *In vivo* preclinical efficacy studies to show the effect of BDM-I on actual infections in an animal model.

Successful results will increase the value of the Opal technology significantly and will be used to seek Orphan Drug Designation from the FDA. The development plan will be pursued so that Opal will have the option of continuing development to IND submission and Phase I clinical trial in the absence of a suitably profitable deal beforehand.

UNITED NATIONS HIGH-LEVEL MEETING ON ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) has become one of the biggest threats to global health and endangers other major priorities, such as human development. All around the world, many common infections are becoming resistant to the antimicrobial medicines used to treat them, resulting in longer illnesses and more deaths. At the same time, not enough new antimicrobial drugs, especially antibiotics, are being developed to replace older and increasingly ineffective ones.

Global leaders will meet at the United Nations General Assembly in New York in September 2016 to commit to fighting antimicrobial resistance together. This is only the fourth time in the history of the UN that a health topic is discussed at the General Assembly (HIV, noncommunicable diseases, and Ebola were the others). Heads of State and

Heads of Delegations are expected to address the seriousness and scope of the situation and to agree on sustainable, multisectoral approaches to addressing antimicrobial resistance.

Per http://www.who.int/antimicrobial-resistance/events/UNGA-meeting-amr-sept2016/en/

BioDiem

FINANCIAL REPORT

2016

Financial Report

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development

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 2016.

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
Prof Larisa Rudenko
Prof Arthur Kwok Cheung Li (appointed 20 January 2016)

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 and non-controlling interest amounted to $1,161,711 (30 June 2015: $1,146,481).

During the financial year ended 30 June 2016, significant progress has been made on all key development programs towards commercial milestones. Royalty and milestone revenues in 2016 were $0.137m compared to $0.180m in 2015, while interest income was $0.003m compared to $0.020m during the corresponding period in 2015. Research activity costs were $0.661m compared to $0.690m in 2015. Administration expenses were $0.811m as compared to $0.902m in the previous year. The Group commenced the financial year with cash reserves of $0.446m. Cash inflows from share issues totalled $0.693m compared to $0.342m in 2015 before costs. Cash outlays were $1.433m compared to $1.579m in the prior year for research and administration. Cash inflows were $0.137m from licensing agreements (2015: $0.180m from licensing agreements). Cash receipts from the R&D Tax Incentive was $0.216m compared to $0.128m in the previous year. Cash reserves at the end of the financial year totalled $0.260m.

SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

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

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

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

During the year Opal Biosciences raised a total of $103,000 via the issue of 515,000 ordinary shares and the grant of 248,125 options in accordance with the information memorandum dated 15 May 2015. The Opal Biosciences capital raising closed on 15 May 2016. BioDiem retains the majority shareholding of Opal Biosciences due to its equity holding and continues to support the development of Opal Biosciences' asset, BDM-I. As at 30 June 2016 the assignment of the BDM-I technology has not taken place, as Opal Biosciences has not yet completed all of the conditions precedent for the assignment of the BDM-I technology, which includes payment to BioDiem of $500,000 cash consideration.

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

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

On 19 January 2016 the Company issued 3,165,322 ordinary shares in relation to the shortfall facility at $0.08 (8 cents) per share raising $253,225.

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

In August 2016 the Company announced that it had completed the issue and allotment of entitlement and shortfall convertible preference shares under the shortfall facility of its recent Non-Renounceable pro-rata Entitlement Offer. The Company confirmed that it raised a total of $948,940.24 under the Entitlement Offer.

No other matter or circumstance has arisen since 30 June 2016 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 and expertise
HUGH M MORGAN AC *LLB, BCom.* **Chairman** **Non-Executive Director**	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. Special responsibilities Chairman of Audit Committee, Chairman of Remuneration and Nomination Committee
JULIE PHILLIPS *BPharm, DHP, MSc, MBA.* **Chief Executive Officer**	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 Chairman of AusBiotech Ltd, the peak biotechnology industry association in Australia, and a Director of the Medtech and Pharma Growth Centre, MTP Connect. Julie has also been appointed to the University of Newcastle Council. Special responsibilities None
LARISA RUDENKO *MD, PhD, DSc.* **Director of Russian Projects,** **Non-Executive Director**	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. Special responsibilities Member of Audit Committee, Member of Remuneration and Nomination Committee

Name, qualifications and independence status	Experience and expertise

ARTHUR KWOK CHEUNG LI

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, HonFRCS(I), HonFACS, HnFRCP(Lon), HonFCSHK, HonFAS

Non-Executive Director

Professor Arthur Li was appointed a Director of the Company for the first time on 27 May 2010. He then resigned as a Director on 13 December 2014, and was recently re-appointed as a Director on 20 January 2016. 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; an Independent Non-Executive Director of Shangri-La Asia Ltd. He is Emeritus Professor of Surgery of The Chinese University of Hong Kong and Council Chairman of The University of Hong Kong. He is a member of the Executive Council of the Hong Kong Special Administrative Region and also Chairman of the Council for Sustainable Development of the Government of the Hong Kong special Administrative Region. He was 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.

Special responsibilities

Member of Audit Committee, Member of Remuneration and Nomination Committee

COMPANY SECRETARY

Melanie Leydin is the company secretary and has 24 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 is 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, and Director of Leydin Freyer Corp Pty Ltd, specialising in outsourced company secretarial and financial duties for resources and biotechnology sectors.

MEETINGS OF DIRECTORS

The number of meetings of the company's Board of Directors ('the Board') and of each Board committee held during the year ended 30 June 2016, and the number of meetings attended by each director were:

	Full Board		Audit and Risk Committee		Nomination and Remuneration Committee	
	Attended	Held	Attended	Held	Attended	Held
Hugh M Morgan	11	11	1	1	–	–
Julie Phillips	11	11	–	–	–	–
Larisa Rudenko	11	11	1	1	–	–
Arthur Kwok Cheung Li	3	4	–	–	–	–

Held: represents the number of meetings held during the time the director held office or was a member of the relevant committee.

Directors' report

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
8 October 2013	30 September 2023	$0.080	666,667
8 October 2013	30 September 2023	$0.120	666,667
8 October 2013	30 September 2023	$0.200	666,666
			2,000,000

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

There were no ordinary shares of BioDiem Limited issued on the exercise of options during the year ended 30 June 2016 and up to the date of this report.

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 the 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 immediately after this directors' report.

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

9 September 2016
Melbourne

Auditor's independence declaration

The Rialto, Level 30
525 Collins St
Melbourne Victoria 3000

Correspondence to:
GPO Box 4736
Melbourne Victoria 3001

T +61 3 8320 2222
F +61 3 8320 2200
E info.vic@au.gt.com
W www.grantthornton.com.au

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 2016, 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, 9 September 2016

Statement of profit or loss and other comprehensive income

For the year ended 30 June 2016

	Note	Consolidated June 2016 $	Consolidated June 2015 $
Revenue	3	139,815	203,809
Other income	4	205,667	262,422
Expenses			
Licence fees and royalty expenses		(36,265)	(19,850)
Research and development expenses		(661,499)	(690,402)
Administration expenses		(810,633)	(902,460)
Loss before income tax expense		**(1,162,915)**	**(1,146,481)**
Income tax expense	6	–	–
Loss after income tax expense for the year		**(1,162,915)**	**(1,146,481)**
Other comprehensive income for the year, net of tax		–	–
Total comprehensive income for the year		**(1,162,915)**	**(1,146,481)**
Loss for the year is attributable to:			
Non-controlling interest		(1,204)	–
Owners of BioDiem Limited		(1,161,711)	(1,146,481)
		(1,162,915)	**(1,146,481)**
Total comprehensive income for the year is attributable to:			
Non-controlling interest		(1,204)	–
Owners of BioDiem Limited		(1,161,711)	(1,146,481)
		(1,162,915)	**(1,146,481)**

Statement of financial position

For the year ended 30 June 2016

	Note	Consolidated June 2016 $	Consolidated June 2015 $
Assets			
Current assets			
Cash and cash equivalents	7	259,540	446,349
Trade and other receivables	8	14,374	13,978
Other	9	278,128	286,405
Total current assets		552,042	746,732
Total assets		**552,042**	**746,732**
Liabilities			
Current liabilities			
Trade and other payables	10	112,927	86,898
Borrowings	11	228,378	–
Employee benefits	12	94,560	52,691
Total current liabilities		**435,865**	**139,589**
Non-current liabilities			
Employee benefits	13	19,475	42,358
Total non-current liabilities		**19,475**	**42,358**
Total liabilities		**455,340**	**181,947**
Net assets		**96,702**	**564,785**
Equity			
Issued capital	14	31,019,592	30,429,799
Reserves	15	46,757	308,317
Accumulated losses		(31,071,443)	(30,173,331)
Equity/(deficiency) attributable to the owners of BioDiem Limited		(5,094)	564,785
Non-controlling interest		101,796	–
Total equity		**96,702**	**564,785**

Statement of changes in equity

For the year ended 30 June 2016

Consolidated	Issued Capital $	Reserves $	Accumulated Losses $	Non–controlling interest $	Total equity $
Balance at 1 July 2014	30,087,862	296,532	(29,026,850)	–	1,357,544
Loss after income tax expense for the year	–	–	(1,146,481)	–	(1,146,481)
Other comprehensive income for the year, net of tax	–	–	–	–	–
Total comprehensive income for the year	**–**	**–**	**(1,146,481)**	**–**	**(1,146,481)**
Transactions with owners in their capacity as owners:					
Contributions of equity, net of transaction costs (note 14)	341,937	–	–	–	341,937
Share–based payments (note 26)	–	11,785	–	–	11,785
Balance at 30 June 2015	**30,429,799**	**308,317**	**(30,173,331)**	**–**	**564,785**

Consolidated	Issued Capital $	Reserves $	Accumulated Losses $	Non–controlling interest $	Total equity $
Balance at 1 July 2015	30,429,799	308,317	(30,173,331)	–	564,785
Loss after income tax expense for the year	–	–	(1,161,711)	(1,204)	(1,162,915)
Other comprehensive income for the year, net of tax	–	–	–	–	–
Total comprehensive income for the year	**–**	**–**	**(1,161,711)**	**(1,204)**	**(1,162,915)**
Transactions with owners in their capacity as owners:					
Contributions of equity, net of transaction costs (note 14)	589,793	–	–	103,000	692,793
Share–based payments (note 26)	–	2,039	–	–	2,039
Transfer to retained earnings (note 26)	–	(263,599)	263,599	–	–
Balance at 30 June 2016	**31,019,592**	**46,757**	**(31,071,443)**	**101,796**	**96,702**

Statement of cash flows

For the year ended 30 June 2016

	Note	Consolidated June 2016 $	Consolidated June 2015 $
Cash flows from operating activities			
Cash receipts in course of operations		136,604	185,713
Cash payments in course of operations		(1,433,370)	(1,579,180)
		(1,296,766)	(1,393,467)
Interest received		713	17,011
Government grants received		–	3,300
R&D Tax Offset received		215,707	127,907
Net cash used in operating activities	25	(1,080,346)	(1,245,249)
Cash flows from investing activities			
Net cash from investing activities		–	–
Cash flows from financing activities			
Proceeds from issue of shares	14	589,793	341,937
Proceeds from issue of shares in Opal Biosciences Limited		103,000	–
Proceeds from borrowings		200,000	–
Net cash from financing activities		892,793	341,937
Net decrease in cash and cash equivalents		(187,553)	(903,312)
Cash and cash equivalents at the beginning of the financial year		446,349	1,336,812
Effects of exchange rate changes on cash and cash equivalents		744	12,849
Cash and cash equivalents at the end of the financial year	7	259,540	446,349

Notes to the financial statements

NOTE 1. GENERAL INFORMATION

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

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 9 September 2016. 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 $1.163m (2015: $1.146m net loss after tax) for the financial year ended 30 June 2016. The net loss after tax is directly attributable to the expenditures incurred in ongoing research and development activities, as well as administration expenditure. Despite the net loss after tax incurred for the period, the Directors have prepared the financial statements on the going concern basis. The going concern basis is considered appropriate based on a combination of the existing net assets of the Group, which amount to $0.097m (30 June 2015: $.565m), including cash and cash equivalent assets of $0.260m (30 June 2015: $0.446m), and the expectation of Group's ongoing ability to successfully secure additional sources of financing. In this regard, the Directors note the following:

- The Group has a licensing agreement with the Serum Institute of India ("Serum"), which entitles the Group to royalty income upon sales of LAIV influenza vaccine. WHO prequalification certification was received in the reporting period.
- The Group has a LAIV licensing agreement with the Changchun BCHT Biotechnology Co., where the vaccine subject to the LAIV licensing agreement is currently under development. If the development and commercialisation of the vaccine is successful, the LAIV licensing agreement is expected to provide further royalty income streams over the next two years. Clinical trials in China commenced in the reporting period.
- The Group completed a Non-Renounceable pro-rata Entitlement Offer in August 2016, via the issuance of Convertible Preference Shares in the Group raising approximately $0.949m before costs.
- The Group includes a subsidiary company, Opal Biosciences which was formed in May 2015 to commercialise the asset, BDM-I technology. Opal recently completed a capital raising of $103,000 under its Information Memorandum which closed during the financial year. 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.

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.

Parent entity information

In accordance with the Corporations Act 2001, these financial statements present the results of the consolidated entity only. Supplementary information about the parent entity is disclosed in note 22.

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 2016 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.

Non-controlling interest in the results and equity of subsidiaries are shown separately in the statement of profit or loss and other comprehensive income, statement of financial position and statement of changes in equity of the consolidated entity. Losses incurred by the consolidated entity are attributed to the non-controlling interest in full, even if that results in a deficit balance.

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.

Notes to the financial statements

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.

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 and milestone revenue

Royalty and milestone revenues 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 the 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 be applied 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 at 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 classified as current when: it is either expected to be realised or intended to be sold or consumed in the consolidated entity's 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 classified as current when: it is either expected to be settled in the consolidated entity's 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.

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.

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.

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.

Notes to the financial statements

Borrowings

Loans and borrowings are initially recognised at the fair value of the consideration received, net of transaction costs. They are subsequently measured at amortised cost using the effective interest method.

Where there is an unconditional right to defer settlement of the liability for at least 12 months after the reporting date, the loans or borrowings are classified as non-current.

Finance costs

Finance costs attributable to qualifying assets are capitalised as part of the asset. All other finance costs are expensed in the period in which they are incurred.

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 wholly within 12 months of the reporting date 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 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:

- 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 interests. 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 2016. The consolidated entity's assessment of the impact of these new or amended Accounting Standards and Interpretations, most relevant to the consolidated entity, are set out below.

Notes to the financial statements

AASB 9 Financial Instruments

This standard is applicable to annual reporting periods beginning on or after 1 January 2018. The standard replaces all previous versions of AASB 9 and completes the project to replace IAS 39 'Financial Instruments: Recognition and Measurement'. AASB 9 introduces new classification and measurement models for financial assets. A financial asset shall be measured at amortised cost, if it is held within a business model whose objective is to hold assets in order to collect contractual cash flows, which arise on specified dates and solely principal and interest. All other financial instrument assets are to be classified and measured at fair value through profit or loss unless the entity makes an irrevocable election on initial recognition to present gains and losses on equity instruments (that are not held-for-trading) in other comprehensive income ('OCI'). For financial liabilities, the standard requires the portion of the change in fair value that relates to the entity's own credit risk to be presented in OCI (unless it would create an accounting mismatch). New simpler hedge accounting requirements are intended to more closely align the accounting treatment with the risk management activities of the entity. New impairment requirements will use an 'expected credit loss' ('ECL') model to recognise an allowance. Impairment will be measured under a 12-month ECL method unless the credit risk on a financial instrument has increased significantly since initial recognition in which case the lifetime ECL method is adopted. The standard introduces additional new disclosures. The consolidated entity will adopt this standard from 1 January 2018 but the impact of its adoption is yet to be assessed by the consolidated entity.

AASB 15 Revenue from Contracts with Customers

This standard is applicable to annual reporting periods beginning on or after 1 January 2018. The standard provides a single standard for revenue recognition. The core principle of the standard is that an entity will recognise revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard will require: contracts (either written, verbal or implied) to be identified, together with the separate performance obligations within the contract; determine the transaction price, adjusted for the time value of money excluding credit risk; allocation of the transaction price to the separate performance obligations on a basis of relative stand-alone selling price of each distinct good or service, or estimation approach if no distinct observable prices exist; and recognition of revenue when each performance obligation is satisfied. Credit risk will be presented separately as an expense rather than adjusted to revenue. For goods, the performance obligation would be satisfied when the customer obtains control of the goods. For services, the performance obligation is satisfied when the service has been provided, typically for promises to transfer services to customers. For performance obligations satisfied over time, an entity would select an appropriate measure of progress to determine how much revenue should be recognised as the performance obligation is satisfied. Contracts with customers will be presented in an entity's statement of financial position as a contract liability, a contract asset, or a receivable, depending on the relationship between the entity's performance and the customer's payment. Sufficient quantitative and qualitative disclosure is required to enable users to understand the contracts with customers; the significant judgements made in applying the guidance to those contracts; and any assets recognised from the costs to obtain or fulfil a contract with a customer. The consolidated entity will adopt this standard from 1 January 2018 but the impact of its adoption is yet to be assessed by the consolidated entity.

NOTE 3. REVENUE

	Consolidated	
	June 2016 $	June 2015 $
Royalty and milestone revenue	136,604	179,962
Grant income	-	3,300
	136,604	**183,262**
Other revenue		
Interest	3,199	20,097
Other revenue	12	450
	3,211	**20,547**
Revenue	**139,815**	**203,809**

NOTE 4. OTHER INCOME

	Consolidated	
	June 2016 $	June 2015 $
Net foreign exchange gain	744	5,101
Research & Development Tax Concession	204,923	257,321
Other income	**205,667**	**262,422**

NOTE 5. EXPENSES

	Consolidated	
	June 2016 $	June 2015 $
Loss before income tax includes the following specific expenses:		
Rental expense relating to operating leases		
Rental	26,000	36,000
Employee Benefits Expense		
Wages and salaries	606,057	714,270
Superannuation - defined contribution	39,501	42,689
Other associated personnel expenses	3,119	2,856
Increase in annual leave provision	10,234	26,647
Increase in long service leave provision	8,752	11,305
Share based payment (see note 26)	2,039	11,785
Total	**669,702**	**809,552**

Notes to the financial statements

For the year ended 30 June 2016

NOTE 6. INCOME TAX BENEFIT

	Consolidated	
	June 2016 $	June 2015 $
Numerical reconciliation of income tax benefit and tax at the statutory rate		
Loss before income tax expense	(1,162,915)	(1,146,481)
Tax at the statutory tax rate of 30%	(348,875)	(343,944)
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Share-based payments	611	3,535
Research & Development tax incentive – not assessable	(61,477)	(77,196)
	(409,741)	**(417,605)**
Current year tax losses not recognised	343,727	315,211
Current year temporary differences not recognised	66,014	102,394
Income tax benefit	–	–

	Consolidated	
	June 2016 $	June 2015 $
Tax losses not recognised		
Unused tax losses for which no deferred tax asset has been recognised	29,988,214	29,025,977
Potential tax benefit @ 30%	8,996,464	8,707,793

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 2016 $	June 2015 $
Cash at bank	259,540	446,349

NOTE 8. CURRENT ASSETS – TRADE AND OTHER RECEIVABLES

	Consolidated	
	June 2016 $	June 2015 $
Trade receivables	1,868	1,868
Interest receivable	532	556
GST receivable	11,974	11,554
	14,374	**13,978**

NOTE 9. CURRENT ASSETS – OTHER

	Consolidated	
	June 2016 $	June 2015 $
Accrued revenue	118,630	129,414
Prepayments	41,508	41,511
Short term deposits supporting bank guarantees	117,990	115,480
	278,128	**286,405**

The company holds two short term deposits, one ($43,257) is a three month term deposit maturing on 4 September 2016. The other ($74,733) is a six month term deposit, maturing on 25 September 2016. The term deposits are earning 2.25% and 2.35% per annum respectively.

NOTE 10. CURRENT LIABILITIES – TRADE AND OTHER PAYABLES

	Consolidated	
	June 2016 $	June 2015 $
Trade payables	54,455	39,067
Other payables	58,472	47,831
	112,927	**86,898**

Refer to note 17 for further information on financial instruments.

NOTE 11. CURRENT LIABILITIES – BORROWINGS

	Consolidated	
	June 2016 $	June 2015 $
Unsecured Loan	200,000	–
Insurance funding	28,378	–
	228,378	**–**

Refer to note 17 for further information on financial instruments.
Two of BioDiem's major shareholders contributed $200,000 through an unsecured loan prior to the opening of the Entitlement Offer Prospectus which closed subsequent to 30 June 2016. Under the terms of the Prospectus, following conclusion of a successful capital raising under the Prospectus (i.e. subscription funds of $800,000 or more) the loan will convert to Convertible Preference Shares at the same price and with the same terms and conditions as those offered under the Prospectus.

NOTE 12. CURRENT LIABILITIES – EMPLOYEE BENEFITS

	Consolidated	
	June 2016 $	June 2015 $
Annual leave	**94,560**	**52,691**

Notes to the financial statements

For the year ended 30 June 2016

NOTE 13. NON–CURRENT LIABILITIES – EMPLOYEE BENEFITS

	Consolidated	
	June 2016 $	June 2015 $
Long service leave	19,475	42,358

NOTE 14. EQUITY – ISSUED CAPITAL

	Consolidated			
	June 2016 Shares	June 2015 Shares	June 2016 $	June 2015 $
Ordinary shares - fully paid	174,734,060	167,361,644	31,019,592	30,429,799

Movements in ordinary share capital

Details	Date	Shares	Issue price	$
Balance	**1 July 2014**	**163,087,800**		**30,087,862**
Exercise of options	23 January 2015	1,368,828	$0.080	109,506
Exercise of options	29 January 2015	140,462	$0.080	11,237
Exercise of options	13 February 2015	2,764,554	$0.080	221,194
Balance	30 June 2015	167,361,644		30,429,799
Placement	1 October 2015	3,735,250	$0.080	298,820
Non-renounceable pro-rata entitlement offer	21 December 2015	471,844	$0.080	37,748
Shortfall share issue	19 January 2016	3,165,322	$0.080	253,225
Balance	**30 June 2016**	**174,734,060**		**31,019,592**

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.

Capital is regarded as total equity, as recognised in the statement of financial position, plus net debt. Net debt is calculated as total borrowings less cash and cash equivalents.

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.

The capital risk management policy remains unchanged from the 2015 Annual Report.

NOTE 15. EQUITY – RESERVES

	Consolidated	
	June 2016 $	June 2015 $
Share–based payments reserve	46,757	308,317

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:

Consolidated	Share based payments $	Total $
Balance at 1 July 2014	296,532	296,532
Share based payment	11,785	11,785
Balance at 30 June 2015	308,317	308,317
Share based payment	2,039	2,039
Transfer to retained earnings	(263,599)	(263,599)
Balance at 30 June 2016	**46,757**	**46,757**

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.

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.

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.

Notes to the financial statements

For the year ended 30 June 2016

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 2016	Weighted average interest rate %	1 year or less $	Between 1 and 2 years $	Between 2 and 5 years $	Over 5 years $	Remaining contractual maturities $
Non-derivatives						
Non-interest bearing						
Trade payables		112,927	–	–	–	112,927
Total non-derivatives		**112,927**	**–**	**–**	**–**	**112,927**

Consolidated - June 2015	Weighted average interest rate %	1 year or less $	Between 1 and 2 years $	Between 2 and 5 years $	Over 5 years $	Remaining contractual maturities $
Non-derivatives						
Non-interest bearing						
Trade payables		86,898	–	–	–	86,898
Total non-derivatives		**86,898**	**–**	**–**	**–**	**86,898**

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 $74,733 and $43,257 respectively totalling $117,990 (2015: $115,480) in support of its undertakings under a guarantee for $60,000 on account of the Group's credit cards.

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 2016 $	June 2015 $
Audit services - Grant Thornton Audit Pty Ltd		
Audit or review of the financial statements	42,073	40,000

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 holds a licence to commercialise the BDM-I antimicrobial technology from the Institute of Experimental Medicine. Under this agreement the consolidated entity is obliged to pay the Institute of Experimental Medicine 10% of all payments received from any Licensee and 10% of any royalties arising from net sales (or 5% in each case, where the commercialisation is done by the consolidated entity). One raising at least $1.5m into Opal Biosciences a one-off payment will be made by Opal Biosciences to the IEM in consideration of the assignment of the BDM-I technology into Opal Biosciences. The consolidated entity is also obliged to pay Formulytica Pty Ltd the final payment of $95,200 on successful completion of the BDM-I topical development work currently being undertaken.

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 23.

Transactions with related parties

The following transactions occurred with related parties:

	Consolidated	
	June 2016 $	June 2015 $
Other transactions:		
Short-term employee benefits	385,197	553,427
Post-employee benefits	20,345	23,533
Share-based payment	2,039	11,784

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 $36,265 (2015: $19,850) to the Institute. In addition, research and development costs amounting to $45,000 (2015: $45,000) were also paid to the Institute.

Notes to the financial statements

For the year ended 30 June 2016

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

The Company received a $100,000 unsecured loan from Hugh Morgan (who is a related party by virtue of being a director of the Company) during the financial year, which formed part of the $200,000 unsecured loan received prior to the commencement of the Entitlement Offer Prospectus. Under the terms of the Prospectus, the loan would convert into Convertible Preference Shares upon the minimum of $800,000 being reached under the Offer, which occurred subsequent to year end.

Terms and conditions

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

NOTE 22. PARENT ENTITY INFORMATION

Set out below is the supplementary information about the parent entity.

Statement of profit or loss and other comprehensive income

NOTE 22. INTERESTS IN SUBSIDIARIES

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiaries in accordance with the accounting policy described in note 2:

	Parent June 2016 $	June 2015 $
Loss after income tax	(1,138,324)	(1,146,481)
Total comprehensive income	**(1,138,324)**	**(1,146,481)**

	Parent June 2016 $	June 2015 $
Total current assets	**473,803**	**746,732**
Total assets	**473,803**	**746,732**
Total current liabilities	**435,865**	**139,589**
Total liabilities	**455,340**	**181,947**
Equity		
Issued capital	31,019,592	30,429,798
Share-based payments reserve	46,757	308,317
Accumulated losses	(31,047,886)	(30,173,330)
Total equity	**18,463**	**564,785**

Guarantees entered into by the parent entity in relation to the debts of its subsidiaries

The parent entity had no guarantees in relation to the debts of its subsidiaries as at 30 June 2016 and 30 June 2015.

Contingent liabilities

The parent entity had no contingent liabilities as at 30 June 2016 and 30 June 2015, other than as mentioned below.

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 holds a licence to commercialise the BDM-I antimicrobial technology from the Institute of Experimental Medicine. Under this agreement the consolidated entity is obliged to pay the Institute of Experimental Medicine 10% of all payments received from any Licensee and 10% of any royalties arising from net sales (or 5% in each case, where the commercialisation is done by the consolidated entity). One raising at least $1.5m into Opal Biosciences a one-off payment will be made by Opal Biosciences to the IEM in consideration of the assignment of the BDM-I technology into Opal Biosciences. The consolidated entity is also obliged to pay Formulytica Pty Ltd the final payment of $95,200 on successful completion of the BDM-I topical development work currently being undertaken.

Capital commitments - Property, plant and equipment

The parent entity had no capital commitments for property, plant and equipment as at 30 June 2016 and 30 June 2015.

Significant accounting policies

The accounting policies of the parent entity are consistent with those of the consolidated entity, as disclosed in note 2, except for the following:

- Investments in subsidiaries are accounted for at cost, less any impairment, in the parent entity.

NOTE 23. INTERESTS IN SUBSIDIARIES

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiaries in accordance with the accounting policy described in note 2:

		Ownership interest	
Name	Principal place of business / Country of incorporation	June 2016 %	June 2015 %
Savine Therapeutics Pty Ltd	Australia	100.00%	100.00%
Opal Biosciences Limited*	Australia	95.10%	–%

Notes to the financial statements

For the year ended 30 June 2016

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

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

The reason BioDiem proposed to assign the BDM-I technology to Opal was to raise capital to develop the BDM-I technology without diluting existing shareholders' interest in the Company while ensuring that shareholders keep access to the value of the BDM-I technology and potential future upside. As at 30 June 2016 the assignment of the BDM-I technology has not taken place, as Opal Biosciences has not yet completed all of the conditions precedent for the assignment of the BDM-I technology, which includes payment to BioDiem of $500,000 cash consideration.

During the year Opal Biosciences raised a total of $103,000 via the issue of 515,000 ordinary shares and the grant of 248,125 options in accordance with the information memorandum dated 15 May 2015. The Opal Biosciences capital raising closed on 15 May 2016. BioDiem retains the majority shareholding of Opal Biosciences due to its equity holding and continues to support the development of Opal Biosciences' asset, BDM-I.

NOTE 24. EVENTS AFTER THE REPORTING PERIOD

In August 2016 the Company announced that it had completed the issue and allotment of entitlement and shortfall convertible preference shares under the shortfall facility of its recent Non-Renounceable pro-rata Entitlement Offer. The Company confirmed that it raised a total of $948,940.24 under the Entitlement Offer.

No other matter or circumstance has arisen since 30 June 2016 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 25. RECONCILIATION OF LOSS AFTER INCOME TAX TO NET CASH USED IN OPERATING ACTIVITIES

	Consolidated	
	June 2016 $	June 2015 $
Loss after income tax expense for the year	(1,162,915)	(1,146,481)
Adjustments for:		
Share-based payments	2,039	11,785
Foreign exchange differences	15,810	(12,849)
Change in operating assets and liabilities:		
Increase in trade and other receivables	(396)	(2,013)
Increase in prepayments	(3)	(11,353)
Increase in other current assets	(8,274)	(132,581)
Increase in trade and other payables	26,029	10,291
Increase in employee benefits	18,986	37,952
Increase in other provisions	28,378	-
Net cash used in operating activities	**(1,080,346)**	**(1,245,249)**

NOTE 26. 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 2016 there were 174,734,060 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 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.

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

2016 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
08/10/2013	30/09/2023	$0.000	666,667	–	–	–	666,667
08/10/2013	30/09/2023	$0.000	666,667	–	–	–	666,667
08/10/2013	30/09/2023	$0.000	666,666	–	–	–	666,666
			2,000,000	**–**	**–**	**–**	**2,000,000**
Weighted average exercise price			$0.133	$0.000	$0.000	$0.000	$0.133

2015 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
27/07/2009	27/07/2014	$0.136	100,000	-	-	(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
			2,100,000	**-**	**-**	**(100,000)**	**2,000,000**
Weighted average exercise price			$0.133	$0.000	$0.000	$0.136	$0.133

Directors' declaration

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

Grant date	Expiry date		2016 Number	2015 Number
08/10/2013	30/09/2023		2,000,000	1,333,334
			2,000,000	**1,333,334**

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:

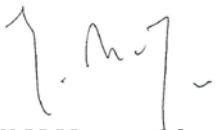
Grant date	Expiry date	Share price at grant date	Exercise price	Expected volatility	Dividend yield	Risk-free interest rate	Fair value at grant date
08/10/2013	30/09/2023	$0.030	$0.080	100.00%	-	3.97%	$0.024
08/10/2013	30/09/2023	$0.030	$0.120	100.00%	-	3.97%	$0.024
08/10/2013	30/09/2023	$0.030	$0.200	100.00%	-	3.97%	$0.022

In the directors' opinion:

- the attached financial statements and notes 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 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 give a true and fair view of the consolidated entity's financial position as at 30 June 2016 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

9 September 2016
Melbourne

Independent auditor's report to the members of BioDiem Limited

The Rialto, Level 30
525 Collins St
Melbourne Victoria 3000

Correspondence to:
GPO Box 4736
Melbourne Victoria 3001

T +61 3 8320 2222
F +61 3 8320 2200
E info.vic@au.gt.com
W www.grantthornton.com.au

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 2016, 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.

Independent auditor's report to the members of BioDiem Limited

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 2016 and of its performance for the year ended on that date; and

ii complying with Australian Accounting Standards and the Corporations Regulations 2001.

Emphasis of matter

Without qualifying our opinion, we draw attention to Note 2 in the financial report which indicates that the company incurred a net loss of $1.163 million during the year ended 30 June 2016. 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.

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

M.A. Cunningham
Partner - Audit & Assurance

Melbourne, 9 September 2016

Corporate directory

Directors
Mr Hugh M Morgan AC (Chairman, Non-Executive Director)
Ms Julie Phillips (Chief Executive Officer)
Prof Larisa Rudenko (Non-Executive Director)
Prof Arthur Kwok Cheung Li (Non-Executive Director)

Share Registry
Computershare Investor Services Pty Ltd
Yarra Falls, 452 Johnston Street
Abbotsford Victoria 3067
PH: + 61 3 9415 5000
Investor Queries (within Australia): 1300 850 505

Company Secretary
Melanie Leydin

Registered Office
Level 4
100 Albert Road
South Melbourne VIC 3205
PH: + 61 3 9692 7240

Principal place of business
Level 4
100 Albert Road
South Melbourne VIC 3205
PH: + 61 3 9692 7240

Auditor
Grant Thornton Audit Pty Ltd
The Rialto
Level 30, 525 Collins Street
Melbourne VIC 3000

Website
www.biodiem.com