BioDiem

BioDiem Ltd – Annual Report

ABN 20 096 845 993

2015

DEVELOPING COMMERCIAL OUTCOMES

WHO WE ARE

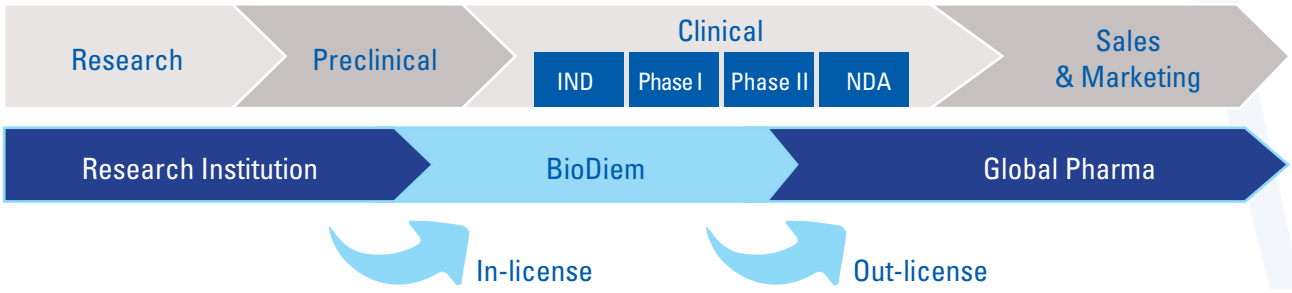
BioDiem is an Australian biopharmaceutical company based in Melbourne, Australia that is focussed on developing and commercialising vaccines and infectious disease therapies. BioDiem's business model is to generate income from partnerships including with other vaccine development companies through existing and new licences to its LAIV vaccine and other technologies. BioDiem has an established influenza vaccine licensing business. Its revenue comes from licence fees and royalties on sales.

BioDiem's lead technology, the LAIV (Live Attenuated Influenza Virus) vaccine, is 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 BDM-I is a synthetic antimicrobial compound targeting the treatment of serious human infections. BDM-I is active against a range of disease-causing micro-organisms. Key patents have been granted worldwide. BioDiem has benefited from work conducted by major research institutions in the United States that have undertaken studies of BDM-I.

BioDiem's antimicrobial technology, BDM-I, is being developed through its subsidiary, Opal Biosciences Ltd. Opal is currently raising capital to fund the next stage of development of its products:

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



"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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2015

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

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Highlights of FY2015

INFLUENZA VACCINE TECHNOLOGY (LAIV)

- Commencement of royalty income from sales of Nasovac-S™ in India, and income from milestone payments totalling $179,962 (2014: $93,398). 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.
- Results of the Phase II children's study on the safety of the LAIV intranasal 'flu vaccine (seasonal trivalent) conducted in Bangladesh in 2012 in children aged 2-5 years. The results support the safety of the vaccine in this young age group and found no statistical difference in reports of wheezing or other post-vaccination reactions between placebo and treatment arms.
- Publication of LAIV clinical trials and other research results supporting the value of the LAIV technology including for avian influenza (bird flu) including H5N1, H5N2, H7N3, H1N1 and H2N2 subtypes.
- Progress by our Chinese licensee, Changchun BCHT Biotechnology Co, in discussion with the Chinese FDA regarding the design of clinical trials in China as part of its development plan for the LAIV technology.
- Collaborating with the University of Georgia (UGA) and the Centers for Disease Control and Prevention (CDC) in a seed grant project for the development and proof-of-concept (ferrets) of a thermostable dry powder LAIV.

ANTIMICROBIAL BDM-I: OPAL BIOSCIENCES

- The formation of Opal Biosciences in May 2015 for commercialization of BDM-I, and commencement of fund-raising. Opal is a public company and subsidiary of BioDiem Ltd. Shareholder approval for the transfer of the BDM-I technology into Opal Biosciences in July 2015.
- The successful application by BioDiem's collaborator, Griffith University, to the Australian Federal government for an ARC Linkage grant for $241,564 to investigate the molecular targets for BDM-I's antimicrobial activity.
- The award of a new US patent for BDM-I for claims relating to infections of the gut, to add to those already granted for protozoal infections; vulvovaginitis; and skin and soft tissue infections. Also notification of acceptance of European grants for the same claims.
- Further investigation of how BDM-I works against "superbugs" by Associate Prof Slade Jensen's unit at the Ingham Institute for Applied Research and University of Western Sydney.
- "Opal Biosciences takes on the Superbugs" article in the Australian newspaper on 13 July 2015.

CORPORATE

- Receipt of more than $0.834m from exercise of our 8c options and $0.128m from the R&D Tax Incentive program. This has been used to fund the additional commercial and development work on our LAIV and BDM-I programs, respectively.

Image: In May 2015 Serum Institute announced a distribution deal with global pharmaceutical company Cipla for Nasovac-S in India

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. 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.

opal Biosciences

BioDiem Pipeline

Products & pipeline	Research	Preclinical	Phase I	Phase II	Phase III	Marketed
Influenza Seasonal and Pandemic						

Opal Biosciences' Pipeline

Antimicrobial BDM-I (Biological warfare agents, difficult-to-treat fungi and other serious pathogens)						
OPAL – I (injection) Serious infections						
OPAL – T (topical) Skin and wound infections						

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 our 2014-15 year.

Importantly this year we saw the beginnings of revenue from royalties from our LAIV flu vaccine technology licensing business, and the formation of Opal Biosciences.

Further information about the company's progress during the year is included later in this report, but in summary the highlights of the year were:

- Commencement of sales in India of Nasovac-S™. Nasovac-S is a seasonal influenza vaccine based on BioDiem's LAIV (live attenuated influenza virus) technology. A modest flow of royalty income to BioDiem has started from early sales of Nasovac-S. This will grow following export approval by the World Health Organisation for Nasovac-S and sales in additional territories. Export approval is expected before the end of 2015. In May 2015 Serum Institute announced a distribution deal with global pharmaceutical company Cipla for Nasovac-S in India. This will leverage the strong Cipla sales presence already established in India.
- The publication of the results from the Phase II children's study on the safety of the LAIV intranasal 'flu vaccine (seasonal trivalent) conducted in Bangladesh in 2012. The children were aged 2-5 years and the study was randomized, double-blind and placebo-controlled. The results support the safety of the vaccine in this young age group and found no statistical difference in reports of wheezing or other post-vaccination reactions between placebo and treatment arms. These results have been used to support a proposal for further studies in children less than 2 years where there is a need for safe, easy-to-administer vaccines. Standard "flu shots" are commonly associated with pain at the injection site both at the time of injection and afterwards. Young children can be more susceptible to serious complications from flu infections, and also act as a source of infection for adults. Because vaccination is recommended for children from 6 months of age, these studies supporting the safety of the pain-free LAIV influenza vaccine technology in younger children will further highlight its suitability for this underserved age group.
- Publication of LAIV clinical trials and other research results supporting the value of the LAIV technology including for avian influenza (bird flu) including H5N1, H5N2, H7N3, H1N1 and H2N2 subtypes.
- Progress by our Chinese licensee, Changchun BCHT Biotechnology Co, in discussion with the Chinese FDA regarding the design of clinical trials in China as part of its development plan for the LAIV technology.
- The successful application by BioDiem's collaborator, Griffith University, to the Australian Federal government for an ARC Linkage grant for $241,564 to investigate the molecular targets for BDM-I's antimicrobial activity.
- The award of a new US patent for BDM-I for claims relating to infections of the gut, to add to those already granted for protozoal infections; vulvovaginitis; and skin and soft tissue infections. Also notification of acceptance of European grants for the same claims.
- The formation of Opal Biosciences in May 2015 to permit external investment in the commercialization of BDM-I while allowing BioDiem shareholders to retain benefit from successful commercialisation.
- Shareholder approval for the transfer of the BDM-I technology into Opal Biosciences.
- Further investigation of how BDM-I works against "superbugs" by Associate Prof Slade Jensen's unit at the Ingham Institute for Applied Research and University of Western Sydney.
- "Opal Biosciences takes on the Superbugs" article in the Australian newspaper on 13 July 2015.
- Exercise of our 8c options in January 2015 contributing $834,400 in total.

On sad news however, in March this year our long-time director, Don Brooks passed away. Don had been involved with BioDiem from 2001. With his long experience in multinational companies, he was of immense value and instrumental in the company's negotiations and transactions with Merck, Nobilon, the World Health Organisation and our other LAIV licencees. We miss Don's enthusiasm and generosity and are grateful for his strong contribution.

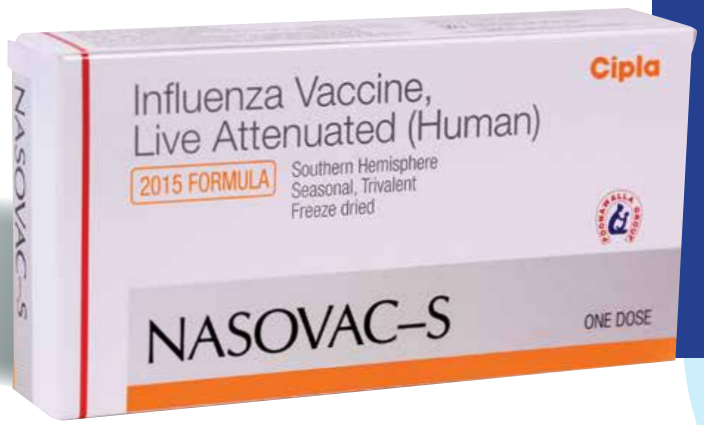
With the progress in commercialization of our lead asset, the LAIV flu vaccine technology, our company is in an increasingly better commercial position. I do recognize that as shareholders we have waited patiently for commercial success of our company. Our decision this year to incorporate Opal Biosciences as a vehicle for commercialization of the anti-infective technology BDM-I was deliberately to protect BioDiem shareholders from significant dilution on attracting the investment required to develop the BDM-I asset, but maintain a major stake in the technology. Our expenditure has been minimized and the Opal Biosciences fund-raising campaign is underway. While we are pleased with the developments of the flu vaccine and its prospects we will undertake a small capital raising into BioDiem to bridge us into being cash flow positive. This will be done by way of a placement to the three major shareholders followed by a pro-rata offer to all other shareholders at the same price.

There is nothing to diminish my positive outlook for the company and in fact the opposite. My thanks go to Professor Rudenko and our staff for their continued passion and achievements. We will update you through the coming year.

Yours sincerely,

Hugh Morgan AC
BioDiem Chairman

A modest flow of royalty income to BioDiem has started from early sales of **Nasovac-S**. This will grow following export approval by the World Health Organisation for Nasovac-S and sales in additional territories.



CEO letter

Dear Shareholders,

During the 2014-2015 year we have seen a number of significant commercial events in the company including

- the commencement of royalties from Serum Institute of India (SII) following the launch of its seasonal influenza vaccine, Nasovac-S in India last year; and
- the formation of Opal Biosciences as a vehicle for the commercialization of BioDiem's antimicrobial asset, BDM-I.

Nasovac-S is a seasonal influenza vaccine which is based on our LAIV influenza vaccine technology. SII is one of the world's biggest vaccine producers by volume and exports to more than 120 countries. 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 and as anticipated the royalty flow has been modest initially. Sales are expected to grow with increased Indian market growth and export to the other territories. There is raised concern about the impact of influenza in India following a wave of swine flu in the early months of 2015. India is now entering the usual peak flu season. The next key event will be the issue of export approval (prequalification) for Nasovac-S by the World Health Organisation (WHO). This is expected prior to the end of 2015.

In May 2015 SII announced an exclusive marketing and distribution agreement with the pharmaceutical giant Cipla for Nasovac-S in India. This strategic partnership will leverage the strong Cipla sales presence already established in India and is expected to favourably impact Nasovac-S sales.

The attractiveness of the LAIV technology for use in children continues to drive policymakers. The PATH organization is planning to expand the previous LAIV clinical trials which they have funded to include younger children. These trials will put our LAIV technology at the forefront of use in this age group.

Young children can be more susceptible to serious complications from flu infections and so vaccination is recommended for children older than 6 months of age.

The intranasal influenza vaccine technology is particularly suitable for children. A safety study conducted in Bangladesh in children 2-5 years has been published and supports the LAIV safety. Phase III efficacy studies designed to assess the effectiveness of the LAIV vaccine in children aged 2 to 8 against laboratory-confirmed influenza have been completed, funded by PATH, the CDC and the Bill and Melinda Gates Foundation. Publication of the results is awaited.

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

The other major asset in our company is our antimicrobial compound, BDM-I. The need for new antimicrobials and the opportunity for BDM-I is enormous. In May 2015 we incorporated Opal Biosciences as a public company to hold and commercialise our BDM-I technology. A capital raising for sophisticated investors is underway to raise $3.5m. This will fund the development of the Opal antimicrobial products; an injectable (Opal-I) and a product for the skin (Opal-T). This month we have initiated the formulation development work for Opal-I. In September we will commence some laboratory safety screening studies. These are the first studies in a 12-18 month program ending in proof-of-concept in a model of infectious disease, that is, to show the product can work. We expect that we will have sold or outlicensed the Opal technology before reaching clinical trial stage, however keep open the possibility of floating Opal Biosciences on a suitable stock exchange, depending on the best result for Opal shareholders.

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. Opal presentations have been given in Sydney, Hong Kong, Singapore and Philadelphia. Last month Griffith University was successful in an application for an ARC linkage award. This will fund work by Griffith to contribute to the identification of molecular targets of BDM-I. This together with the work being done in Associate Prof Slade Jensen's lab at the Ingham Research Institute is breaking new ground for us, and positioning us better to understand the best use of Opal technology to target treatment of superbugs and attract acquirers. Further information on Opal is included in this report.

Following our April 2014 rights issue, priced at 5.5c we were delighted with the exercise of 10.4 million 8c options by the end of January 2015 raising $834,400.

Our cash requirement to support the 'flu technology and Opal Biosciences has led to the decision to undertake a small capital raising before the end of 2015. This will be done via a placement to the major shareholders and then an offer to other Biodiem shareholders with the same terms. More details will follow shortly.

Shareholders would be aware through our announcements and website that we have arranged for DFS Equities to provide a comprehensive secondary market administration service for our shareholders and other interested parties wishing to invest in BioDiem. DFS Equities holds a register of interest of buyers and sellers of BioDiem equities. All enquiries about shares should be directed to our office.

This year also marked the sad loss of our long time director Don Brooks. Don contributed generously to the company with his time and advice based on his significant commercial experience. He is greatly missed.

I would like to thank the shareholders, board and staff for their ongoing support and enthusiasm, and look forward to keeping you informed of progress through our announcements and twitter.

Yours sincerely,

Julie Phillips
CEO

Review of operations

"Although the swine flu H1N1 pandemic which surfaced in 2009 had been declared ended in August 2010, there was a resurgence in India in the early part of this year. With about 33,000 cases and more than 1,900 deaths the outbreak is expected to reduce with increasing temperatures."

INFLUENZA VACCINE PROGRESS BY INTERNATIONAL PARTNERS

Influenza Vaccine (LAIV)

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

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 financial year include:

- BioDiem received income from royalties and milestone payments of $179,962 (2014: $93,398).
- Royalties from Serum Institute of India from the first launch in any country outside Russia of a seasonal influenza vaccine based on BioDiem's flu vaccine technology.
- Nasovac-S was launched in the Indian market in July 2014.
- Serum Institute announced an exclusive agreement with Indian drug maker, Cipla for marketing of Nasovac-S in India. The arrangement takes advantage of Cipla's strong countrywide sales force present in India.
- The WHO prequalification assessment has been undertaken for Nasovac-S, and the approval is awaited. WHO pre-qualification will allow SII to export to other developing countries of the United Nations. BioDiem would receive royalties on sales of Nasovac-S into the private markets of these countries.
- Publication of a Phase II LAIV flu vaccine safety study in 300 children (aged 24-59 months) in Bangladesh showing the vaccine was safe and well-tolerated.
- BioDiem received the third of its annual LAIV licensing payment from Chinese commercial partner Changchun BCHT Biotechnology Co.
- Collaboration with the University of Georgia (UGA) and the Centers for Disease Control and Prevention (CDC) in a seed grant project for the development and proof-of-concept (ferrets) of a thermostable dry powder LAIV.

About Influenza

Influenza is transmitted from person to person by virus-containing droplets from coughing and sneezing by infected people. Some infected people have few symptoms whereas others can be severely infected and require hospitalization, assisted ventilation and other life support.

In adults, symptoms of influenza may have an abrupt onset after a 1-3 day incubation period. They include feeling unwell, feverishness, chills, headache, muscle aches and pains and lack of appetite. A cough, runny nose and sneezing are often present.

Influenza in children and infants is similar although temperatures may be higher in children (even with convulsions), and ear infection and gastrointestinal problems may be more prominent.

The complications of influenza can be very serious, and even lead to death. In Australia it is estimated that there are more than 13,500 hospitalisations each year due to 'flu, and more than 3000 deaths just in those over 50 years of age.

TABLE A: SEASONAL INFLUENZA: THOSE MOST AT RISK FROM SEVERE INFLUENZA

Those most at risk from severe influenza	
Advanced age	Weakened immune system
Infancy	Severe obesity
Lack of immunity	Pregnancy
More potent virus	Smoking
Chronic conditions: heart, lung, kidney, neurological disease, diabetes	

The incidence of influenza fluctuates from year to year, and can be dependent on the seasons. The types of flu virus responsible for disease can also change from year to year. The World Health Organisation considers what flu virus strains are likely to be a problem each year and makes recommendations to flu vaccine manufacturers. This is done for the northern and southern hemispheres.

Pandemic influenza outbreaks are those where a new virus emerges and few people have immunity, that cause severe disease in humans, and spread easily and rapidly affecting large numbers of people around the world.

TABLE B: INFLUENZA PANDEMICS OVER THE PAST 100 YEARS

Year	Description	Virus SubType	Estimated Deaths
1918-19	The Spanish 'flu	H1N1	~ 50 million
1957-58	Asian 'flu	H2N2	~ 2 million
1968-69	Hong Kong 'flu	H3N2	~ 1 million
2009-10	Swine 'flu	H1N1	~ 0.28 million

Review of operations

ABOUT BIODIEM'S LAIV INFLUENZA VACCINES

Serum Institute of India marketed Nasovac™, the monovalent pandemic swine 'flu intranasal LAIV vaccine in 2009 and 2010, in India for that pandemic. In 2014, Serum Institute registered launched Nasovac-S™, the trivalent seasonal influenza vaccine. BioDiem receives royalties from sales on these products in the private market.

Although more drug treatments of influenza become available, prevention of 'flu by vaccination has demonstrated effectiveness[1]. Most influenza vaccines are inactivated viruses or virus parts. These produce an antibody protection related to that virus. The LAIV vaccines induce a more comprehensive and protective immune responses (antibody, T-cell and mucosal immunity) giving a broader protection. This immunity can protect against virus strains which differ slightly from that used for the vaccine (cross-protection).

This advantage is also especially relevant for avian (bird) flu vaccines, because the exact strain likely to cause a bird flu outbreak would not be known in advance. To avoid the long lag time needed to produce a strain-specific or targeted vaccine, a broadly protective vaccine could save many lives.

Periodic outbreaks of avian influenza continue to be of concern and are not uncommon in Asian and Middle Eastern countries. Human-to-human transmission of highly pathogenic viruses is the concern, because of the potentially high mortality rate[2], and it is known that little change is needed in the genetic make-up of existing viruses for this possibility to eventuate. Therefore the advance preparation and testing of vaccine candidates which could be effective in such a situation is an important public health initiative.

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

LAIV vaccine candidates have already been produced in order to be prepared for various pandemic scenarios. These candidates were found to be safe, immunogenic and protected animals from challenge with homologous (same) and heterologous (similar) 'flu viruses. Also clinical trials (Phase I) confirmed safety and immunogenicity in healthy adult volunteers.

The LAIV pandemic vaccines which have been prepared and used in clinical trials is shown in Table C.

WHAT IS PANDEMIC INFLUENZA[3] (FLU)?

An influenza pandemic can occur when a non-human (novel) influenza virus gains the ability for efficient and sustained human-to-human transmission and then spreads globally. Influenza viruses that have the potential to cause a pandemic are referred to as 'influenza viruses with pandemic potential.'

WHAT IS SEASONAL INFLUENZA[4] (FLU)?

Seasonal influenza, commonly called "the flu," is caused by influenza viruses, which infect the respiratory tract (i.e., the nose, throat, lungs). Unlike many other viral respiratory infections, such as the common cold, the flu can cause severe illness and life-threatening complications in many people. It is estimated that in the United States, each year on average 5% to 20% of the population gets the flu and more than 200,000 people are hospitalized from seasonal flu-related complications. Flu seasons are unpredictable and can be severe.

1 http://www.cdc.gov/flu/about/qa/benefit-publications.htm

2 According to the WHO "Influenza at the human-animal interface" summary, of the 667 lab-confirmed human cases of H5N1 (2003-2014), 393 have died (http://www.who.int/influenza/human_animal_interface/Influenza_Summary_IRA_HA_interface_27June14.pdf)

3 http://www.cdc.gov/flu/pandemic-resources/

4 http://www.cdc.gov/flu/about/qa/disease.htm

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

TABLE C: PANDEMIC LAIVs TESTED IN CLINICAL TRIALS

LAIV subtype	Wild-type parental virus	Designation	Reference
H1N1pdm	A/California/07/2009	H1N1pdm Len	Rudenko et al., 2011
H5N2	A/duck/Potsdam/1402-6/86	H5N2 Pot Len	Rudenko et al., 2008
H5N2	A/turkey/Turkey/1/2005	H5N2 Tur Len	Rudenko et al., 2015
H7N3	A/mallard/Netherlands/12/2000	H7N3 Len	Rudenko et al., 2014
H2N2	A/California/1/66	H2N2 Cal Len	Isakova-Sivak et al., 2015
H7N9	A/Anhui/1/2013	H7N9 Len	Publication pending

Advantages of the LAIV influenza vaccine technology:

- The vaccines are given by nose drop or spray. This makes the vaccine particularly useful for vaccination of children. The global disease burden associated with influenza in children less than 5 years of age is substantial. The rates of complications are highest in the youngest children. They also shed the virus longer and so can become a source of infection for longer than adults.
- Stimulation of both humoral (local and serum antibody) and cellular immune responses, whereas standard inactivated flu vaccines predominantly induce serum antibodies. In the case of a pandemic, the cross-reactive immune response induced by LAIV's would be beneficial to protect against a new pandemic, even if the pandemic strain is slightly different. In the case of a serious pandemic, such breadth of protection could be vitally important.
- High yield in egg and cell-based production. The virus multiplies in the eggs and cells meaning that more doses are recovered per production unit.
- Established safety and efficacy profile including in children from 2 years of age.

LAIV studies published in the last year are shown in Table D.

Review of operations

TABLE D: PUBLICATIONS ON BIODIEM'S LAIV INFLUENZA TECHNOLOGY:

IEM PUBLICATIONS LISTED.

Isakova-Sivak, I & Rudenko, L (2015)

Safety, immunogenicity and infectivity of new live attenuated influenza vaccines

Expert Rev. Vaccines Early online, 2015 1–17

Isakova-Sivak, I. Stukova, M. Erofeeva, M. Naykhin, A. Donina, S. Petukhova, G. Kuznetsova, V. Kiseleva, I. Smolonogina, T. Dubrovina, I. Pisareva, M. Nikiforova, A. Power, M. Flores, J. Rudenko, L (2015)

H2N2 live attenuated influenza vaccine is safe and immunogenic for healthy adult volunteers.

Hum Vaccin Immunother 2015 ;11(4):970-82

Desheva, YA. Smolonogina, TA. Donina, SA. Rudenko LG. (2015)

Serum strain-specific or cross-reactive neuraminidase inhibiting antibodies against pandemic / California/07/2009(H1N1) influenza in healthy volunteers.

BMC Res Notes 2015 10;8:136. Epub 2015 Apr 10.

Rudenko L, Isakova-Sivak, I. (2015)

Pandemic preparedness with live attenuated influenza vaccines based on A/Leningrad/134/17/57 master donor virus.

Expert Rev Vaccines 2015 Mar 2;14(3):395-412. Epub 2015 Jan 2.

Carter, DM. Bloom, CE. Kirchenbaum, GA. Tsvetnitsky, V. Isakova-Sivak, I. Rudenko, LG. Ross, TM. (2014)

Cross-protection against H7N9 influenza strains using a live-attenuated H7N3 virus vaccine.

Vaccine 2015 Jan 18;33(1):108-16. Epub 2014 Nov 18.

Kiseleva, I. Larionova, N. Fedorova, Bazhenova, E. Dubrovina, I. Isakova-Sivak, I. Rudenko, L. (2014)

Contribution of neuraminidase of influenza viruses to the sensitivity to sera inhibitors and reassortment efficiency.

Open Microbiol J 2014 11;8:59-70. Epub 2014 Jul 11.

Zang, Y. Du, D. Ge, P. Xu, Y. Liu, X. Zhang, Y. Su, W. Kiseleva, I. Rudenko, L. Xu, F. Kong, W. Jiang, C. (2014)

Development of one-step real-time PCR assay for titrating trivalent live attenuated influenza vaccines.

Hum Vaccin Immunother 2014 ;10(12):3642-8

Rekstin, A. Desheva, Y. Kiseleva, I. Ross, T. Swayne, D. Rudenko, D. (2014)

Live Attenuated Influenza H7N3 Vaccine is Safe, Immunogenic and Confers Protection in Animal Models.

Open Microbiol J 2014 31;8:154-62. Epub 2014 Dec 31.

Ortiz, JR. Goswami, D. Lewis, KD. Sharmeen, AT. Ahmed, M. Rahman, M. Rahman, MZ. Feser, J. Neuzil, KM. Brooks, WA.

Safety of Russian-backbone seasonal trivalent, live-attenuated influenza vaccine in a phase II randomized placebo-controlled clinical trial among children in urban Bangladesh

Vaccine 33 (2015) 3415–3421

BDM-I ANTIMICROBIAL

BioDiem's antimicrobial compound BDM-I targets the treatment of infections, including 'superbugs' and antibiotic-resistant serious human infections. It is being commercialised through BioDiem's subsidiary, Opal Biosciences ("Opal") which was formed in May 2015. In July 2015, BioDiem shareholders approved the transfer of the BDM-I technology into Opal.

A major focus of Opal has been to promote a capital raising of up to $4m to develop

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

and to support and continue existing collaborations.

Significant developments during the financial year include:

- In August 2015, the Opal-I development of a new injectable formulation was commenced. Laboratory safety screening will commence shortly. As capital is raised into Opal, the next development studies will be started.
- Griffith University was successful in the receipt of an ARC Linkage grant of $241,564 to investigate molecular targets of BDM-I. This work will help to explain how BDM-I works to kill germs.
- Mechanism of action studies are also being undertaken by PhD candidate Michael Radzieta under the supervision of Assoc Prof Slade Jensen, at the Ingham Institute for applied Medical Research and University of Western Sydney. Some interim results looking at superbugs VRE (vancomycin-resistant enterococci) and MRSA (methicillin-resistant Staph aureus) was presented as a poster at the Australian Society for Microbiology annual meeting in July 2015, where it won first prize.
- Additional patents were granted for BDM-I in Europe and the US to expand the claims covered.
- In addition to the investigation being undertaken in the resistant tuberculosis and fungal programs, BDM-I has been accepted into an updated program of the NIH[1] to screen for activity against strains of VRE and VRSA (vancomycin-resistant Staph aureus).

Opal is well positioned strategically in the anti-infective sector for the following reasons:

1 **Large and growing market**: The market for successful anti-infectives is large and growing due to the emergence of germs with resistance to many antibiotics.

2 **Few competitors**: The pipeline for potential competitor anti-infective drugs in development is weak compared to other diseases.

3 **Facilitated path to market:** incentives in place in the US and EU assist development of anti-infective products which can reduce risk and development costs.

4 **Work to date:** Opal's technology has already demonstrated significant activity against some of the highest threat germs where there is a need for new treatments. An extensive international team is already involved in the company's development program, including University of Western Sydney, Griffith University, various US and European specialist development companies and a number of US government-funded institutions.

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. The most significant transaction recently was the acquisition of Cubist Inc by Merck & Co in November 2014 in a deal reported as $US8.4bn.

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

Review of operations

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:

A **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.

B **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.

C **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.

D **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 (see Fig. 2).

The antibiotics we take for granted were only introduced in the 1940's. There are more reports of infections where antibiotics are not working like they used to. This includes common infections like children's middle ear infections, the sexually-transmitted infection, gonorrhea, tuberculosis, Golden Staph and many others.

Importantly, the large pharmaceutical companies are coming back to the sector and needing to buy in projects and products.

US Incentives

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[1].

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[2].

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.

Relevant US Incentives now in place include:

1 **The GAIN (Generating Antibiotic Incentives Now) Legislation**: Extends market exclusivity and gives assistance through the FDA.

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).

3 **Orphan Drug designation**: qualifies the sponsor of the drug for various development incentives, including tax credits and extended market exclusivity.

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.

RELEVANCE TO BDM-I

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.

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

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.

1 http://www.cdc.gov/drugresistance/threat-report-2013/

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

OPAL'S DEVELOPMENT AND COMMERCIALISATION PLAN

Opal technology has already shown activity against some superbugs, as well as the more everyday infections , and could be formulated into many different product types so it could be used for many different types of infections.

Initially we will develop two products (see Figure 1)

- an injection for serious infections like blood poisoning, and other serious hospital infections; and
- a cream or gel to apply to the skin for skin infections.

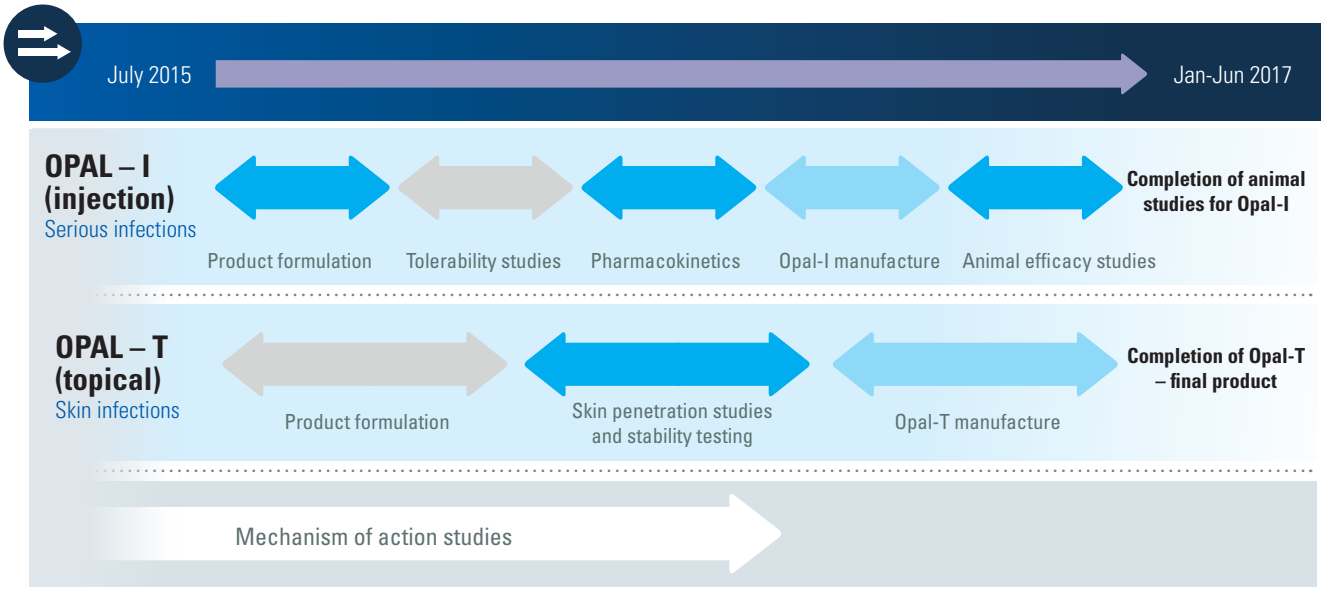
Opal development plan includes.

- 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.

The potential breadth of use, increases the value of the technology, increases potential sources of income for the company, and significantly reduces risk. Additional products can be developed for gut, lung and other sites of infection.

FIGURE 1: DEVELOPMENT PLAN SUMMARY (INDICATIVE)

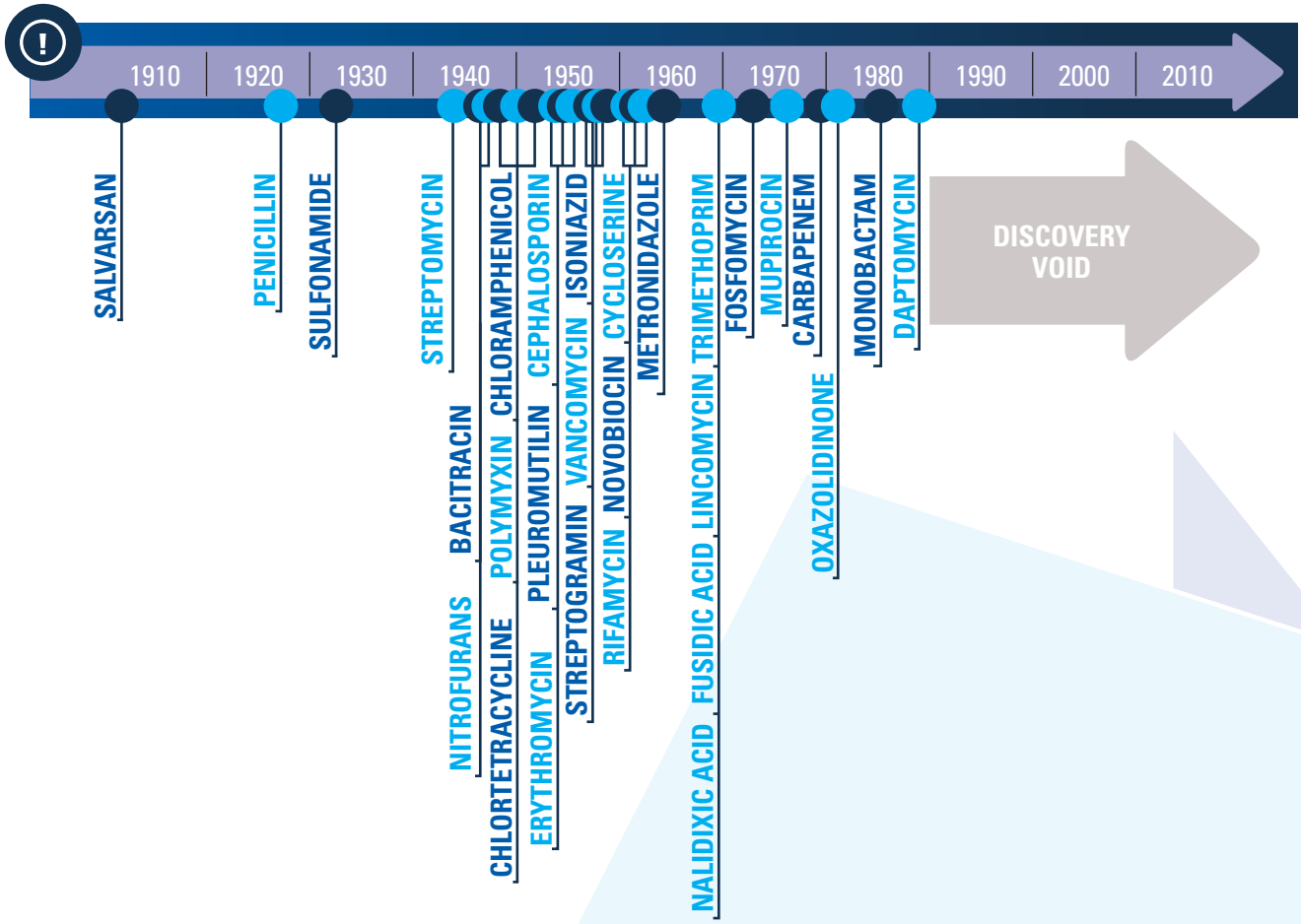


Review of operations

We are very excited about the prospects for Opal and have commenced the next stage of development work, being the new intravenous formulation. This will be undertaken by Pharmaterials Ltd in the UK. We are also preparing for additional studies including preliminary Safety Screening and Cytoxicity profiling. Additional work on the mechanism of action is underway at Ingham Research Institute/UWS with Associate Prof Slade Jensen.

As reported by Silver (2011)[1] about antibacterials at that time, ***"…there have been no successful discoveries of novel agents since 1987."*** There have however been drugs introduced which are "modifications" of other agents. The large pharmaceutical companies have not been developing new antibiotics, partly because the old ones were so highly effective and antibiotics became low-priced commodities (generics). With very few patented products currently available, the market is dominated by generic manufacturers. In December 2014, the Pew trust published its study[2] of the number of new antibiotics in development and found that ***"there are too few drugs in development to meet current and anticipated patient's needs".***

FIGURE TWO: ILLUSTRATION OF THE "DISCOVERY VOID"(BASED ON SILVER 2011[1]).
Dates indicated are those of reported initial discovery or patent.[1]



1 Silver, L. (2011) "Challenges of Antibacterial Discovery" Clinical Microbiology Reviews, Vol 24 (1) 71-109.

2 http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2014/03/12/tracking-the-pipeline-of-antibiotics-in-development

LATEST RESULTS

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 pre-clinical 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[1].

Under NIAID's preclinical services program[2], internationally recognised researchers, Professors Melanie Cushion and Thomas Patterson tested BDM-I's activity against a range of fungi which can cause serious human infection. This was expanded testing following on from an earlier assessment.

Nearly 70 different strains of opportunistic or hospital-acquired fungi have been assessed for sensitivity to BDM-I. These microorganisms can all cause illnesses which are difficult to treat. Examples include life-threatening bloodstream infections and pneumonia. In these bench-top studies, Opal's BDM-I demonstrated activity against several of the Cryptococcus species as well as endemic fungi such as *Blastomyces dermatitidis, Coccidioides immitis/posadasii* and *Histoplasma capsulatum*. Marked activity was also demonstrated by BDM-I against *Pneumocystis carinii* and *murina*. It was noted by the researchers Professors Cushion and Patterson that "further studies are warranted to determine the potential of this broad-spectrum antifungal agent". BDM-I has now been accepted for more screening by the NIAID against additional bacterial strains resistant to existing antibiotics.

SIGNIFICANT WORK HAS BEEN UNDERTAKEN TO DATE TO PRODUCE:

- Manufacture/synthesis of raw material (GLP) and stability testing (highly stable)
- Mechanism of action studies to investigate how BDM-I kills germs (University of Western Sydney and Griffith University)
- Pathogen (germ) screening to determine which germs and diseases are potential targets for commercial development (NIAID, USAMRIID, Monash University, QIMR, University of Sydney, UWS)
- Initial studies on propensity of pathogens to develop resistance upon repeated exposure to BDM-I at sub-lethal concentrations
- Physicochemical profiling and preliminary drug formulation studies so that BDM-I can be given by injection and by mouth (iv and oral administration)
- Pharmacokinetics, assay development (rat, mouse; oral, ip and iv) to show how BDM-I is absorbed into the body, where it goes, how long it takes, and how it is excreted
- Early stage toxicology studies (GLP and non-GLP, single and repeat dose, rat) to show dose-limiting effects

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

[2] http://www.niaid.nih.gov/LabsAndResources/resources/dmid/invitro/Pages/invitro.aspx
NIAID Contract Number * HHSN272201100018I

BioDiem

BioDiem FINANCIAL REPORT

2015

Mechanism of action studies are also being undertaken by PhD candidate Michael Radzieta (left image) under the supervision of Assoc Prof Slade Jensen, at the Ingham Institute for applied Medical Research and University of Western Sydney.

Financial Report
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Directors' report

The directors present their report, together with the financial statements, on the consolidated entity (referred to hereafter as the 'consolidated entity') consisting of BioDiem Limited (referred to hereafter as the 'company' or 'parent entity') and the entities it controlled at the end of, or during, the year ended 30 June 2015.

DIRECTORS

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

Mr Hugh M Morgan AC
Ms Julie Phillips
Mr Donald S Brooks (deceased 18 March 2015)
Dr Arthur Kwok Cheung Li (resigned 13 December 2014)
Dr Larisa Rudenko

PRINCIPAL ACTIVITIES

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

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

DIVIDENDS

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

REVIEW OF OPERATIONS

The loss for the consolidated entity after providing for income tax amounted to $1,146,481 (30 June 2014: $1,018,349).

Royalty and milestone revenues in 2015 were $0.180m compared to $0.093m in 2014, while interest income was $0.020m compared to $0.015m during the corresponding period in 2014. Research activity costs were $0.690m compared to $0.624m in 2014. Administration expenses were $0.902m as compared to $1.068m in the previous year. The Group commenced the financial year with cash reserves of $1.337m. Cash inflows from share issues totalled $0.342m compared to $1.308m in 2014 before costs. Cash outlays were $1.579m compared to $1.798m in the prior year for research and administration. Cash inflows were $0.180m from licensing agreements (2014: $0.093m from licensing agreements). Cash receipts from the R&D Tax Incentive was $0.128m compared to $0.583m in the previous year. Cash reserves at the end of the financial year totalled $0.446m. The Company holds its cash reserves mainly in Australian term deposits. In addition the Group holds funds in a US dollar account. This helps to provide a natural hedge against future overseas research expenditures. The Group has not entered into any forward contracts.

SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

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

MATTERS SUBSEQUENT TO THE END OF THE FINANCIAL YEAR

Subsequent to year end, Opal Biosciences Limited, the Company's new wholly-owned subsidiary, received funds from the first stage of the Opal Offer under the Information Memorandum dated 15 May 2015, following approval by BioDiem shareholders in July 2015 to transfer the BDM-I technology into Opal. The Opal capital raising is open to sophisticated investors until 15 May 2016.

No other matter or circumstance has arisen since 30 June 2015 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.

Name, qualifications and independence status	Experience and expertise
HUGH M MORGAN AC *LLB, BCom.* **Chairman** **Non-Executive Director**	Mr 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.
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

Directors' report

COMPANY SECRETARY

Melanie Leydin holds a Bachelor of Business majoring in Accounting and Corporate Law. She is a member of the Institute of Chartered Accountants 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. The practice provides outsourced company secretarial and accounting services to public and private companies specialising in the Resources, technology, bioscience and biotechnology sector. Melanie has over 23 years' experience in the accounting profession and has extensive experience in relation to public company responsibilities, including ASX and ASIC compliance, control and implementation of corporate governance, statutory financial reporting, reorganisation of Companies and shareholder relations.

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 2015, 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	10	11	2	2	–	–
Julie Phillips	11	11	–	–	–	–
Larisa Rudenko	11	11	1	1	–	–
Donald S Brooks	8	8	1	1	–	–
Arthur Kwok Cheung Li	6	6	1	1	–	–

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

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

The following ordinary shares of BioDiem Limited were issued during the year ended 30 June 2015 and up to the date of this report on the exercise of options granted:

Date options granted	Exercise price	Number of shares issued
12 November 2012	$0.080	4,273,844

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

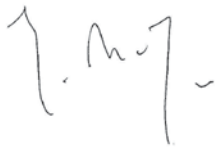
A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out on the following page.

AUDITOR

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

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

On behalf of the directors



H M Morgan AC
Director

31 August 2015
Melbourne

Auditor's independence declaration

Grant Thornton

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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 2015, I declare that, to the best of my knowledge and belief, there have been:

a no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the 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, 31 August 2015

Statement of profit or loss and other comprehensive income

	Note	Consolidated June 2015 $	Consolidated June 2014 $
Revenue	3	203,809	113,939
Other income	4	262,422	583,042
Expenses			
Licence fees and royalty expenses		(19,850)	(16,206)
Research and development expenses		(690,402)	(623,624)
Administration expenses		(902,460)	(1,068,606)
Net foreign exchange loss		–	(6,894)
Loss before income tax expense		(1,146,481)	(1,018,349)
Income tax expense	6	–	–
Loss after income tax expense for the year attributable to the owners of BioDiem Limited		(1,146,481)	(1,018,349)
Other comprehensive income for the year, net of tax		–	–
Total comprehensive income for the year attributable to the owners of BioDiem Limited		**(1,146,481)**	**(1,018,349)**

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

Statement of financial position

	Note	Consolidated June 2015 $	Consolidated June 2014 $
Assets			
Current assets			
Cash and cash equivalents	7	446,349	1,336,812
Trade and other receivables	8	13,978	11,965
Other	9	286,405	142,471
Total current assets		**746,732**	**1,491,248**
Total assets		**746,732**	**1,491,248**
Liabilities			
Current liabilities			
Trade and other payables	10	86,898	76,607
Employee benefits	11	52,691	26,044
Total current liabilities		**139,589**	**102,651**
Non-current liabilities			
Employee benefits	12	42,358	31,053
Total non-current liabilities		**42,358**	**31,053**
Total liabilities		**181,947**	**133,704**
Net assets		**564,785**	**1,357,544**
Equity			
Issued capital	13	30,429,799	30,087,862
Reserves	14	308,317	296,532
Accumulated losses		(30,173,331)	(29,026,850)
Total equity		**564,785**	**1,357,544**

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

Statement of changes in equity

Consolidated	Issued Capital $	Reserve $	Accumulated Losses $	Total equity $
Balance at 1 July 2013	28,812,349	263,598	(28,008,501)	1,067,446
Loss after income tax expense for the year	–	–	(1,018,349)	(1,018,349)
Other comprehensive income for the year, net of tax	–	–	–	–
Total comprehensive income for the year	–	–	(1,018,349)	(1,018,349)
Transactions with owners in their capacity as owners:				
Contributions of equity, net of transaction costs (note 13)	1,275,513	–	–	1,275,513
Share–based payments (note 25)	–	32,934	–	32,934
Balance at 30 June 2014	**30,087,862**	296,532	**(29,026,850)**	**1,357,544**

Consolidated	Issued Capital $	Reserve $	Accumulated Losses $	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 13)	341,937	–	–	341,937
Share–based payments (note 25)	–	11,785	–	11,785
Balance at 30 June 2015	**30,429,799**	**308,317**	**(30,173,331)**	**564,785**

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

Statement of cash flows

	Note	Consolidated June 2015 $	Consolidated June 2014 $
Cash flows from operating activities			
Cash receipts in course of operations		185,713	98,798
Cash payments in course of operations		(1,579,180)	(1,798,254)
		(1,393,467)	**(1,699,456)**
Interest received		17,011	15,344
Government grants received		3,300	–
R&D Tax Offset received		127,907	583,042
Net cash used in operating activities	24	**(1,245,249)**	**(1,101,070)**
Cash flows from investing activities			
Deposits supporting guarantees		–	(4,096)
Net cash used in investing activities		**–**	**(4,096)**
Cash flows from financing activities			
Proceeds from issue of shares	13	341,937	1,307,907
Net costs of issue of shares		–	(32,394)
Net cash from financing activities		**341,937**	**1,275,513**
Net increase/(decrease) in cash and cash equivalents		**(903,312)**	**170,347**
Cash and cash equivalents at the beginning of the financial year		1,336,812	1,171,738
Effects of exchange rate changes on cash and cash equivalents		12,849	(5,273)
Cash and cash equivalents at the end of the financial year	7	**446,349**	**1,336,812**

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

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 31 August 2015. 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 $1.147m (2014: $1.018m net loss after tax) for the financial year ended 30 June 2015. The net loss after tax is directly attributable to the expenditures incurred in ongoing research and development activities, as well as administration expenditure. Despite the net loss after tax incurred for the 2015 financial year, the Directors have prepared the annual financial statements on the going concern basis. The going concern basis is considered appropriate based on a combination of the existing net assets of the Group, which amount to $0.565m (2014: $1.358m), including cash and cash equivalent assets of $0.446m (2014: $1.337m), and the expectation of Group's ongoing ability to successfully secure additional sources of financing. In this regard, the Directors note the following:

- The Group has a marketing agreement with the Serum Institute of India ("Serum"), which entitles the Group to royalty income upon sales of LAIV influenza vaccine. Royalties from LAIV seasonal influenza vaccine commenced 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.
- The Group includes a subsidiary company, Opal Biosciences which was formed in May 2015 to commercialise the asset, BDM-I technology. This is currently undertaking a capital raising and will contribute to a reduction in ongoing expenses for BioDiem. 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.

Notes to the financial statements

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.

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 2015 and the results of all subsidiaries for the year then ended. BioDiem Limited and its subsidiaries together are referred to in these financial statements as the 'consolidated entity'.

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

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

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

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

Foreign currency translation

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

Foreign currency transactions

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

Revenue recognition

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

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.

Notes to the financial statements

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

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

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

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.

Employee benefits

Short-term employee benefits

Liabilities for wages and salaries, including non-monetary benefits, annual leave and long service leave expected to be settled within 12 months of the reporting date are 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.

Notes to the financial statements

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 2015. The consolidated entity has not yet assessed the impact of these new or amended Accounting Standards and Interpretations.

NOTE 3. REVENUE

	Consolidated June 2015 $	Consolidated June 2014 $
Royalty and milestone revenue	179,962	93,398
Grant income	3,300	5,000
	183,262	**98,398**
Other revenue		
Interest	20,097	15,141
Other revenue	450	400
	20,547	**15,541**
Revenue	**203,809**	**113,939**

NOTE 4. OTHER INCOME

	Consolidated June 2015 $	Consolidated June 2014 $
Net foreign exchange gain	5,101	–
Research & Development Tax Concession	257,321	583,042
Other income	**262,422**	**583,042**

NOTE 5. EXPENSES

	Consolidated June 2015 $	Consolidated June 2014 $
Loss before income tax includes the following specific expenses:		
Rental expense relating to operating leases		
Rental	36,000	43,624
Employee Benefits Expense		
Wages and salaries	714,270	750,464
Superannuation – defined contribution	42,689	33,618
Other associated personnel expenses	2,856	2,063
Increase in annual leave provision	26,647	14,716
Increase in long service leave provision	11,305	24,040
Share based payment (see note 25)	11,785	32,934
Total	**809,552**	**857,835**

Notes to the financial statements

NOTE 6. INCOME TAX EXPENSE

	Consolidated	
	June 2015 $	June 2014 $
Numerical reconciliation of income tax expense and tax at the statutory rate		
Loss before income tax expense	(1,146,481)	(1,018,349)
Tax at the statutory tax rate of 30%	(343,944)	(305,505)
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Share–based payments	3,535	9,880
Research & Development tax incentive – not assessable	(77,196)	(174,913)
	(417,605)	(470,538)
Current year tax losses not recognised	315,211	483,067
Current year temporary differences not recognised	102,394	(12,529)
Income tax expense	–	–

	Consolidated	
	June 2015 $	June 2014 $
Tax losses not recognised		
Unused tax losses for which no deferred tax asset has been recognised	29,025,977	27,975,272
Potential tax benefit @ 30%	8,707,793	8,392,582

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 2015 $	June 2014 $
Cash at bank	446,349	1,336,812

NOTE 8. CURRENT ASSETS – TRADE AND OTHER RECEIVABLES

	Consolidated	
	June 2015 $	June 2014 $
Trade receivables	1,868	1,868
Interest receivable	556	637
GST receivable	11,554	9,460
	13,978	**11,965**

NOTE 9. CURRENT ASSETS – OTHER

	Consolidated	
	June 2015 $	June 2014 $
Accrued revenue	129,414	–
Prepayments	41,511	30,158
Short term deposits supporting bank guarantees	115,480	112,313
	286,405	**142,471**

The company holds two short term deposits, one ($42,729) is a three month term deposit maturing on 10 September 2015. The other ($72,751) is a six month term deposit, maturing on 25 September 2015. The term deposits are earning 2.45% and 2.60% per annum respectively.

NOTE 10. CURRENT LIABILITIES – TRADE AND OTHER PAYABLES

	Consolidated	
	June 2015 $	June 2014 $
Trade payables	39,067	37,516
Other payables	47,831	39,091
	86,898	**76,607**

NOTE 11. CURRENT LIABILITIES – EMPLOYEE BENEFITS

	Consolidated	
	June 2015 $	June 2014 $
Annual leave	52,691	26,044

NOTE 12. NON–CURRENT LIABILITIES – EMPLOYEE BENEFITS

	Consolidated	
	June 2015 $	June 2014 $
Long service leave	42,358	31,053

Notes to the financial statements

NOTE 13. EQUITY – ISSUED CAPITAL

	Consolidated			
	June 2015 Shares	June 2014 Shares	June 2015 $	June 2014 $
Ordinary shares – fully paid	167,361,644	163,087,800	30,429,799	30,087,862

Movements in ordinary share capital

Details	Date	Shares	Issue price	$
Balance	**1 July 2013**	**142,105,934**		**28,812,349**
Exercise of options	28 February 2014	6,151,157	$0.080	492,093
Rights Issue	29 April 2014	14,825,709	$0.055	815,414
Exercise of options	23 June 2014	5,000	$0.080	400
Capital raising costs	–	$0.000	$0.000	(32,394)
Balance	30 June 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**

Ordinary shares

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

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

Capital risk management

The consolidated entity's objectives when managing capital is to safeguard its ability to continue as a going concern, so that it can provide returns for shareholders and benefits for other stakeholders and to maintain an optimum capital structure to reduce the cost of capital.

In order to maintain or adjust the capital structure, the consolidated entity may adjust the amount of dividends paid to shareholders, return capital to shareholders, issue new shares or sell assets to reduce debt.

The capital risk management policy remains unchanged from the 2014 Annual Report.

NOTE 14. EQUITY – RESERVES

	Consolidated	
	June 2015 $	June 2014 $
Share–based payments reserve	308,317	296,532

Share–based payments reserve

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

Movements in reserves

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

	Share based payments $	Total $
Consolidated		
Balance at 1 July 2013	263,598	263,598
Share based payment	32,934	32,934
Balance at 30 June 2014	296,532	296,532
Share based payment	11,785	11,785
Balance at 30 June 2015	**308,317**	**308,317**

NOTE 15. EQUITY - DIVIDENDS

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

NOTE 16. 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

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 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**

Consolidated - June 2014	Weighted average interest rate %	1 year or less $	Between 1 and 2 years $	Between 2 and 5 years $	Over 5 years $	Remaining contractual maturities $
Non-derivatives						
Non-interest bearing						
Trade payables	–%	76,607	–	–	–	76,607
Total non-derivatives		**76,607**	**–**	**–**	**–**	**76,607**

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 $72,751 and $42,729 respectively totalling $115,480 (2014: $112,313) in support of its undertakings under a guarantee for $60,000 on account of the Group's credit cards.

NOTE 17. 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 2015 $	June 2014 $
Audit services - Grant Thornton Audit Pty Ltd		
Audit or review of the financial statements	40,000	40,000

NOTE 18. CONTINGENT LIABILITIES

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

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

NOTE 19. 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 an rental agreement in place that enables cancellation with two months' notice.

NOTE 20. RELATED PARTY TRANSACTIONS

Parent entity

BioDiem Limited is the parent entity.

Subsidiaries

Interests in subsidiaries are set out in note 22.

Transactions with related parties

The following transactions occurred with related parties:

	Consolidated	
	June 2015 $	June 2014 $
Other transactions:		
Short-term employee benefits	553,427	600,703
Post-employee benefits	23,533	13,513
Share-based payment	11,784	32,934

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 $19,850 (2014: $16,206) to the Institute. In addition, research and development costs amounting to $45,000 (2014: $45,000) were also paid to the Institute.

Notes to the financial statements

Receivable from and payable to related parties

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

Loans to/from related parties

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

Terms and conditions

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

NOTE 21. PARENT ENTITY INFORMATION

In regards to the parent entity information, it is noted that there is no difference between the parent entity and the consolidated figures.

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:

Name	Principal place of business / Country of incorporation	Ownership interest June 2015 %	Ownership interest June 2014 %
Savine Therapeutics Pty Ltd	Australia	100.00%	100.00%
Opal Biosciences Limited	Australia	100.00%	–%

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

The purchase consideration comprised the issue of 111,111 ordinary shares (market value $10,000) and $10,000 in cash. The existing carrying value of the net assets of Savine at acquisition amounted to $nil. The $20,000 purchase consideration has been expensed in line with the Group's accounting policy for research and development, since, in substance, this investment was just another research and development project.

Opal Biosciences Limited ("Opal") was incorporated as a wholly owned subsidiary of BioDiem Limited on 4 May 2015. Opal has been incorporated during the financial year to transfer the BDM-I technology to Opal to raise capital to develop the BDM-I technology without diluting existing shareholders' interests in the Company while ensuring that shareholders keep access to the value of the BDM-I technology and potential future upside. Opal is currently completing a capital raising offer of up to $3.5 million by issuing 17.5 million fully paid ordinary shares at $0.20 (20 cents) per share, with the ability to accept over-subscriptions of up to a further $0.5 million through the issue of up to a further 2.5 million fully paid ordinary shares at $0.20 (20 cents) per share. The offer under Opal is open until 15 May 2016.

NOTE 23. EVENTS AFTER THE REPORTING PERIOD

Subsequent to year end, Opal Biosciences Limited, the Company's new wholly-owned subsidiary, received funds from the first stage of the Opal Offer under the Information Memorandum dated 15 May 2015, following approval by BioDiem shareholders in July 2015 to transfer the BDM-I technology into Opal. The Opal capital raising is opening to sophisticated investors until 15 May 2016.

No other matter or circumstance has arisen since 30 June 2015 that has significantly affected, or may significantly affect the consolidated entity's operations, the results of those operations, or the consolidated entity's state of affairs in future financial years.

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

	Consolidated	
	June 2014 $	June 2013 $
Loss after income tax expense for the year	(1,146,481)	(1,018,349)
Adjustments for:		
Depreciation and amortisation	–	2,926
Net loss on disposal of property, plant and equipment	–	4,068
Share–based payments	11,785	32,934
Foreign exchange differences	(12,849)	5,273
Change in operating assets and liabilities:		
Decrease/(increase) in trade and other receivables	(2,013)	36,153
Increase in prepayments	(11,353)	(9,674)
Increase in other current assets	(132,581)	–
Increase/(decrease) in trade and other payables	10,291	(193,157)
Increase in employee benefits	37,952	38,756
Net cash used in operating activities	**(1,245,249)**	**(1,101,070)**

NOTE 25. SHARE-BASED PAYMENTS

The Group has an Employees' and Officers' Incentive Option Scheme pursuant to which options may be issued to eligible persons, being directors', employees and consultants or their approved nominees. Eligible persons may receive options based on the achievement of specific performance hurdles, which are a blend of Group and personal objectives appropriate for the roles and responsibilities of each individual. Under the scheme signed in October 2006, the Group has the ability to issue options up to 5 percent of the issued capital. As at 30 June 2015 there were 163,087,800 shares on hand.

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

On 4 July 2007 the Group issued 539,635 options to directors and staff of which 497,250 were issued to key management personnel. The remaining 42,385 were issued to employees. These options were restricted until 4 July 2008 and lapsed on 4 July 2012. Each option had an exercise price of $0.36.

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

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

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

Notes to the financial statements

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

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

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

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

Grant date	Expiry date	2015 Number	2014 Number
27/07/2009	01/01/2010	–	100,000
08/10/2013	30/09/2023	1,333,334	666,667
		1,333,334	**766,667**

Directors' declaration

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:

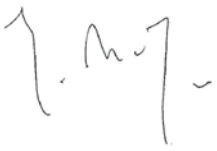
Grant date	Expiry date	Share price at grant date	Exercise price	Expected volatility	Dividend yield	Risk-free interest rate	Fair value at grant date
08/10/2013	30/09/2023	$0.030	$0.080	100.00%	–%	3.97%	$0.024
08/10/2013	30/09/2023	$0.030	$0.120	100.00%	–%	3.97%	$0.024
08/10/2013	30/09/2023	$0.030	$0.200	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 2015 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

31 August 2015
Melbourne

Independent auditor's report to the members of BioDiem Limited

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Independent Auditor's Report
To the Members of BioDiem Limited

We have audited the accompanying financial report of BioDiem Limited (the "Company"), which comprises the consolidated statement of financial position as at 30 June 2015, 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:

a 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 2015 and of its performance for the year ended on that date; and

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

b the financial report also complies with International Financial Reporting Standards as disclosed in the notes to the financial statements.

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 $1.147million during the year ended 30 June 2015. This condition, along with other matters as set forth in Note 2, indicate the existence of a material uncertainty which may cast significant doubt about the 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, 31 August 2015

Corporate directory

Directors
Mr Hugh M Morgan AC (Chairman, Non-Executive Director)
Ms Julie Phillips (Chief Executive Officer)
Dr Larisa Rudenko (Non-Executive Director)

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