



BioDiem Ltd | ABN 20 096 845 993

## Annual Report 30 June 2018

 DEVELOPING COMMERCIAL OUTCOMES



## Who We Are

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

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

BioDiem's licensee in China, Changchun BCHT Biotechnology Co, has submitted a marketing application to the Chinese FDA and awaits approval. BioDiem's antimicrobial technology, BDM-I, is being developed through its subsidiary, Opal Biosciences Ltd. Opal is progressing the development of its anti-infective for injection (Opal-I); topical use (Opal-T) and lung delivery (Opal-L).

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



### BioDiem uses a licensing model

- We take early stage technologies, mostly from universities and research institutes, and then 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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“10 year effort on flu vaccine shows progress but pandemic influenza remains a global threat

World Health Organisation

Reference: [http://www.who.int/influenza\\_vaccines\\_plan/news/gap3\\_Nov16/en/](http://www.who.int/influenza_vaccines_plan/news/gap3_Nov16/en/)



# Highlights of 2017-18



# Highlights of 2018

## Corporate

- Finalisation of de-merger of subsidiary Opal Biosciences Ltd ("Opal") following shareholder approval in November 2017.
- Completion of assignment of all BDM-I intellectual property rights into Opal in March 2018.
- Successful placement of \$0.6m into Opal by sophisticated investors in February 2018.
- Appointment of Mr Ken Windle, a well-known and experienced pharma executive, to the Opal board of directors in March 2018.
- Subsequent to year end, the appointment to the Opal board of Mr Peter Snowball, an experienced financial markets executive and biotechnology company investor.
- Award of an Innovation Connection grant of \$50,000 in April 2018 to support studies being undertaken in Opal.

## Influenza Vaccine Technology (LAIV)

- Royalty income from sales of Nasovac-S in India, and income from milestone payments totalling \$119,397.
- In 2017 Changchun BCHT Biotechnology Co. ("BCHT") China, completed Phase III clinical trials of their LAIV intranasal influenza vaccine made under licence from BioDiem. Subsequently BCHT has advised that it has submitted an application for marketing approval of its LAIV vaccine to the Chinese FDA. BioDiem will gain income from royalties on sales of BCHT's LAIV vaccine in the private sector in China.
- Reinstatement in the US by the CDC's Advisory Committee on Immunization Practices (ACIP) of the inclusion of the Live Attenuated Influenza Vaccine (LAIV) among those eligible for use in the 2018-19 influenza season. While this recommendation specifically referred to FluMist manufactured by Medimmune, which is marketed in the US, the reinstatement impacts the development and marketing of the LAIV technology generally.



### Antimicrobial BDM-I: Opal Biosciences Ltd

- Demonstration that Opal-T gel in a mouse model showed effect against a highly antibiotic-resistant strain of *Staphylococcus aureus*; bacteria responsible for causing serious and life-threatening infections.
- Demonstration of effect of Opal's BDM-I against highly antibiotic-resistant strains of *Neisseria gonorrhoea*, which is responsible for causing the sexually transmitted infection, gonorrhoea.
- Under an Innovation Connections grant, completed formulation revision of Opal-I (injectable) in preparation for proof-of-concept and development studies.
- Completion of proteomics studies describing how BDM-I targets bacteria to cause their death.
- Grant of the "Method of Treatment of Scedosporium spp. Infection" patent in Europe and the US.
- International filing of new PCT patent "Treatment of staphylococcal and enterococcal infections using substituted nitrostyrene compounds" in July 2018.

## Chairman's letter

### Fellow Shareholders,

We are pleased to bring you this report on the activity and achievements of BioDiem Ltd and its subsidiary, Opal Biosciences Ltd.

Our focus for the past year has been to maintain the cash in BioDiem until the LAIV royalty income begins to increase, and to unlock the value to BioDiem shareholders of our subsidiary, Opal Biosciences Ltd ("Opal"). We have achieved both well.

In this past year we have seen in China the finalisation of BCHT's successful clinical trial program of their LAIV vaccine and lodgement of their application for marketing approval to their regulatory agency. We await news of the regulators review in the coming year. Also in the US there has been significant work carried out to illuminate the LAIV efficacy issues found in the US so that now the US now has restored the LAIV vaccine option to its list of eligible influenza vaccines for use in the coming US influenza season. While products made under licence from us are not available in the US, this change should have positive benefit to our royalty flow, for example, in India where the Indian vaccination guidelines take the US recommendations into consideration.

During the year the Board explored the sale of BioDiem's LAIV technology licence and this continues.

Our greatest activity this past year has been in our subsidiary, Opal. News of the growing international problem of resistance of infections to our current antibiotics continues to proliferate. At our AGM in 2017 the BioDiem shareholders approved the finalisation of the transfer of BDM-I assets into Opal for the issue of shares. This was to allow raising of funds into Opal without dilution of BioDiem shareholders. In February 2018 Opal then completed a placement of shares to sophisticated investors raising \$606,000. These funds were used to kick-start the BDM-I development plans in early 2018.

We started 2018 with results from a study done in Taiwan, that Opal's drug BDM-I shows potential as a treatment against a particularly worrisome infection which is making a high profile come-back, gonorrhoea. On the back of these results Opal has been given access to a major US research centre for further investigation of BDM-I's potential. This access is at no cost to Opal. We will report these results over the coming year.

Significant progress in preparation of an injectable form of BDM-I suitable for ongoing research was completed under a Federal government Innovation Connection grant of \$50,000. Together with Opal's gel form, for application to the skin, Opal can now explore treatment of a variety of infectious conditions. These formulations have provided Opal new intellectual property to add to the existing granted and pending patent portfolio.

During the year, Prof Larisa Rudenko stepped down from the Opal board, and we welcomed Messrs Ken Windle and Peter Snowball. The BioDiem board remains unchanged and I chair both Opal and BioDiem.

We have continued to carefully manage our resources and the cash requirement of BioDiem has been reduced further as a result the efficiencies gained in sharing services with Opal. While BioDiem maintains a majority ownership of Opal, currently at 77%, this efficiency is maintained. Last November, BioDiem also received \$205,621 from the R&D tax incentive rebate. Opal is undertaking a capital raising under an Information Memorandum which is open to sophisticated investors. Depending on the funds raised, this will reduce BioDiem's shareholding in Opal, but, by providing funds for the Opal development work, should increase Opal's value to BioDiem.

The coming year will see us with news of progress of the regulatory review of the LAIV vaccine and its progress towards marketing in China and further advances towards commercialisation in Opal's antimicrobial program.

I look forward to advising you of these events. Yours faithfully,

A handwritten signature in black ink, appearing to read "H. Morgan".

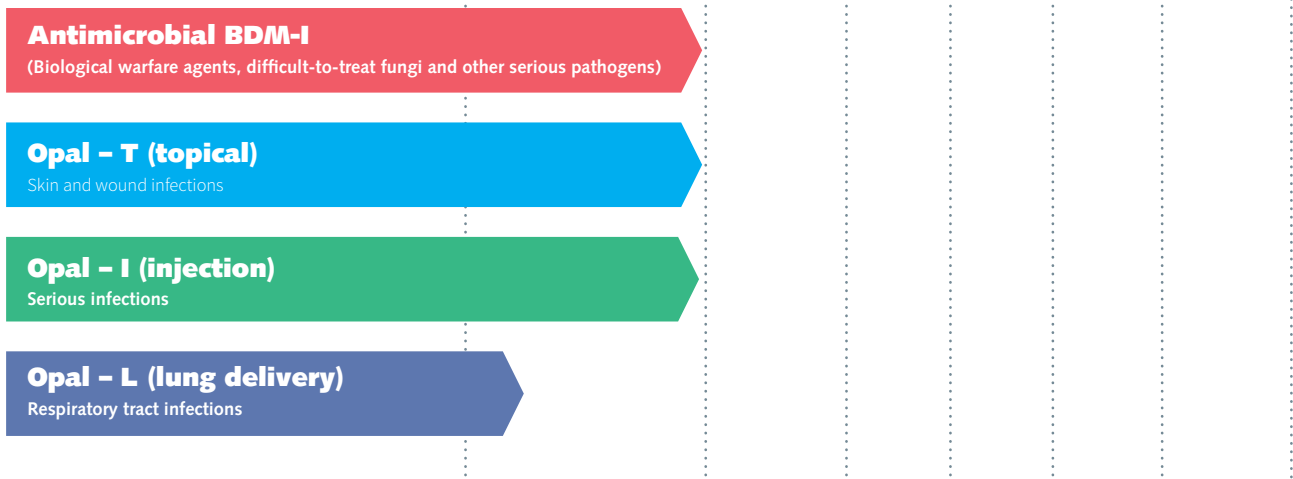
**Hugh Morgan**  
Chairman

“  
 The coming year will see us with news of progress of the regulatory review of the LAIV vaccine and its progress towards marketing in China and further advances towards commercialisation in Opal’s antimicrobial program.  
 ”

### BioDiem Pipeline



### Opal Biosciences’ Pipeline



## CEO's letter

### Fellow Shareholders,

We were pleased this past year to see developments in both our major programs: the intranasal influenza vaccine (LAIV) technology, and the antimicrobial program in our subsidiary, Opal Biosciences ("Opal").

In February 2018, it was announced that the Centers of Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices voted to recommend the return of the intranasal LAIV influenza vaccine to the list of recommended vaccines for the 2018-2019 influenza season in the US. We do not manufacture the LAIV influenza vaccine ourselves but have two commercial licences: Serum Institute of India and Changchun BCHT Biotechnology Co (BCHT), China. Neither one of our licences has their LAIV vaccine on the market in the US, but the news was heartening because other markets heed the US recommendations. We are yet to see if this will increase sales in India where despite the high number of influenza infections and deaths each year, there is still no national influenza immunisation policy in place and our royalties have remained low.

In China, BCHT completed its clinical trial program at the end of last year and compiled and filed a submission to the Chinese FDA for marketing approval of their LAIV vaccine. The regulatory approval review timelines in China are uncertain however would be expected to take between 12 and 24 months. Overall vaccination coverage in China is estimated to be less than 2% but there is interest in increasing awareness about the value of vaccination especially amongst high risk groups i.e. young children, older adults and pregnant women, and where this is undertaken, vaccination coverage increases.

Progress within Opal Biosciences has been outstanding and a capital raising is underway to raise \$1.5 million to continue the development work. Opal's preclinical stage antimicrobial compound, BDM-I, has shown promising activity against a range of human disease-causing microbes. Earlier this year we tested BDM-I in a laboratory setting against a panel of strains of gonorrhoea bacteria which are highly resistant to treatment. Gonorrhoea is a sexually transmitted infection which has come to world attention recently due to reports of strains being multi-drug resistant. In our study BDM-I successfully blocked the growth of all the drug-resistant gonorrhoea bacteria strains tested and at concentrations which we would expect to be able to achieve in the bloodstream. This result has led us to prioritise gonorrhoea as a target disease indication for BDM-I development. The US CDC has rated antibiotic-resistant gonorrhoea in its highest threat category. Despite the threat internationally there are very few new treatments in development for it. Newspaper headlines heralded two "superbug" cases in Australia early in 2018. Untreated gonorrhoea can cause serious and permanent health problems in both women and men and can increase a person's risk of acquiring or transmitting HIV, the virus that causes AIDS.

The next important development for Opal this year was the successful completion of an injectable form of BDM-I, funded with the assistance of a Federal government Entrepreneur's Program Innovation Connection grant. The formulation work was performed by Formulytica, the same expert group that had developed the gel formulation ("Opal-T") of BDM-I for Opal. The injectable form of BDM-I, which we have termed Opal-I, can be used in the development of a product for treatment of serious infections.

Opal's next step will be to characterise the BDM-I dosage that can be used in non-clinical testing. Once the dosage range is known this can be applied in studies of effectiveness. This will provide "proof of concept" and will provide part of the data package we are aiming to compile in the coming year to attract partners and acquirers of our technology. The capital-raising announced in July 2018 will fund these non-clinical stages.

Recently we had news of our ability to use the US National Institute of Allergy and Infectious Diseases (NIAID) non-clinical and pre-clinical services. This will allow us to access these services at minimal cost and to gain benefit from this group's expertise. In parallel we are working with Australian research groups to accelerate Opal's progress.

Also completed in this past year has been investigation into BDM-I's mechanism of action using proteomics. This work was undertaken through the University of Western Sydney, under Assoc. Prof Slade Jensen and conducted by PhD candidate Michael Radzieta. The investigation looked at the effect BDM-I has on bacteria and used a strain of Staph aureus (Golden Staph) as an example. The results showed that BDM-I can disrupt some essential mechanisms in the bacterial cell hence causing its death. The results are consistent with earlier studies undertaken by Assoc. Prof Jensen's team and are the subject of further investigation currently underway. This new work will assist identify the area on the bacteria where BDM-I binds and is expected to generate some new intellectual property.

Opal has the prospect of a commercial transaction within about 12-18 months if the next stages of work are successful. In a similar timeframe news of the Chinese FDA review of BCHT's dossier could coincide. We look forward to appraising shareholders of developments.

Yours faithfully,



**Julie Phillips**  
CEO



## New anti-infectives



The current market needs new anti-infectives. There are few new treatments available.

**Opal's business addresses this need by:** Development of novel products, Opal-I and Opal-T, based on BDM-I technology, to treat bloodstream and skin infections respectively

**opal**  
Biosciences

Opal-I



Opal-T



Overall [flu] vaccination coverage in China is estimated to be less than 2% but there is interest in increasing awareness about the value of vaccination especially amongst high risk groups i.e. young children, older adults and pregnant women, and where this is undertaken, vaccination coverage increases.



### LAIIV vaccine technology

Manufactured in SPF eggs or cell-based



\*Royalties from sales flow to BioDiem (private market)  
 \*\*Royalties from sales will flow to BioDiem (private market)

# Review of operations

BioDiem owns

- an **influenza vaccine licensing business:**
  - this is based on BioDiem’s proprietary live attenuated influenza virus (LAIV) technology.
- a **majority shareholding in Opal Biosciences Ltd:**
  - developing the antimicrobial drug, BDM-I, for the treatment of serious infectious diseases.

## Influenza Vaccine Licensing Business

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

### **BioDiem currently has two commercial partners:**

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

Our LAIV vaccine technology is also licensed to the World Health Organization (WHO) as part of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply.

### **Significant developments during the past year include:**

- Royalty and milestone income from sales of Nasovac-S in India, and income from milestone payments totalling \$119,397. Nasovac-S is a seasonal influenza vaccine manufactured by Serum Institute of India based on BioDiem’s LAIV (live attenuated influenza virus) vaccine technology. BioDiem receives royalties from sales of this product into the private market in India.

- In August 2017 Changchun BCHAT Biotechnology Co. (“BCHAT”) China, advised that it has submitted an application for marketing approval of its LAIV vaccine to the Chinese FDA. This followed completion of Phase III clinical trials of their LAIV intranasal influenza vaccine made under licence from BioDiem. The Phase III trial was a multicentre randomised double-blind placebo-controlled study investigating the safety, efficacy and immunogenicity of BCHAT’s LAIV. It involved 9000 participants aged between 3 and 17 years. BioDiem will gain income from royalties on sales of BCHAT’s LAIV vaccine in the private sector in China.

The regulatory approval timelines in China are uncertain however would be expected to be between 12 and 24 months. Currently Influenza vaccination is not prioritised in public health and is not included in the National Expanded Program on Immunisation in China so the market is mainly private. The Chinese Center for Disease Control and Prevention (China CDC) recommends children aged 6 to 59 months as a priority group for seasonal influenza immunisation and this is consistent with the World Health Organisation recommendation for annual vaccination, however it has been estimated that the coverage rate for this group in China was only about 26% in the 2009-2012 period. In older individuals, the coverage has been reported at only about 5%, but among unvaccinated individuals lack of awareness of the vaccine was reported as the most common reason for lack of vaccination (48%), and the cost of vaccination cited by only 10% in another study. Overall vaccination coverage in China is estimated to be less than 2% but there is interest in increasing awareness about the value of vaccination amongst high risk groups in China i.e. young children, older adults and pregnant women).

# Review of operations

The seasonal influenza vaccine across the Asia-Pacific is forecast to grow to \$1.7 billion by 2022 at an annual compound growth rate of 4.7%. The growth is expected to be driven by increasing affordability of healthcare and increased healthcare access in China and India.

- In February 2018 the US Centers for Disease Control and Prevention (CDC) Vaccine Advisory Committee on Immunization Practices (ACIP) voted to include Medimmune's Live Attenuated Influenza Vaccine (LAIV) among those eligible for use in the 2018-19 influenza

season in the US i.e. the ACIP have now reviewed updated information from Medimmune and so Flumist is now again included in the list of recommended seasonal 'flu vaccines in the US. The ACIP is the key committee in the US which advises on seasonal influenza vaccines to be recommended for use in the US each influenza season.

While this recommendation specifically refers to FluMist manufactured by Medimmune, which is marketed in the US, the reinstatement has wider implications for LAIV technology generally.



## Additional publications supporting the safety and effectiveness of the LAIV vaccine include:

Nigwekar PV, Kumar A, Padbidri VV, Choudhury A, Chaudhari AB, Kulkarni PS.

*Safety of Russian-Backbone Trivalent, Live Attenuated Seasonal Influenza Vaccine in Healthy Subjects: Open-Label, Non-randomized Phase 4 Study.*

Drug Safety 2018 Feb;41(2):171-177. doi: 10.1007/s40264-017-0605-3.

Armitage EP, Camaraa J, Sulayman B, Forster AS, Clarke E, Kampmann B and de Silva TI.

*Acceptability of intranasal live attenuated influenza vaccine, influenza knowledge and vaccine intent in The Gambia*  
Vaccine 2018 Mar; 36(13):1772-1780

Victoria Matyushenko V, Isakova-Sivak I, Smolonogina T, Dubrovina I, Tretiak T, and Rudenko L

*Genotyping assay for differentiation of wild-type and vaccine viruses in subjects immunized with live attenuated influenza vaccine*  
PLoS One. 2017; 12(7): e0180497. Published online 2017 Jul 7. doi: 10.1371/journal.pone.0180497

Isakova-Sivak I, Korenkov D, Smolonogina T, Kotomina T, Donina S, Matyushenko V, Mezhenkaya D, Krammer F, Rudenko L.

*Broadly protective anti-hemagglutinin stalk antibodies induced by live attenuated influenza vaccine expressing chimeric hemagglutinin.*  
Virology. 2018 May;518:313-323. doi: 10.1016/j.virol.2018.03.013. Epub 2018 Mar 22.

Kiseleva I, Krutikova E, Stepanova E, Donina S, Pisareva M, Krivitskaya V, Rekestin A, Sparrow E, Torelli G, and Rudenko L.

*Cross-Protective Efficacy of Monovalent Live Influenza B Vaccines against Genetically Different Lineages of B/Victoria and B/Yamagata in Ferrets*

BioMed Research International 2018, Article ID 9695628, 11 pages  
<https://doi.org/10.1155/2018/9695628>

Desheva YA, Leontieva GF, Kramskaya TA, Smolonogina TA, Grabovskaya KB, Landgraf GO, Karev VE, Suvorov AN, Rudenko LG.

*Prevention of Influenza A(H7N9) and Bacterial Infections in Mice Using Intranasal Immunization With Live Influenza Vaccine and the Group B Streptococcus Recombinant Polypeptides*

Virology: Research and Treatment 2017, Volume 8: 1–10  
<https://doi.org/10.1177/1178122X17710949>

Bazhenova E, Kiseleva I, Isakova-Sivak I and Kotomina T.

*Two Alternative Approaches to Generate Live Attenuated Influenza Vaccine Candidates against Potentially Pandemic Avian Influenza H7N9 Virus*

Biomedical <http://dx.doi.org/10.26717/BJSTR.2018.03.000925>

Kiseleva I, Larionova N and Rudenko L.

*Live Attenuated Reassortant Vaccines Based on A/Leningrad/134/17/57 Master Donor Virus Against H5 Avian Influenza*  
The Open Microbiology Journal 2017 Volume 12, 2018  
DOI:10.2174/1874285801711010316

# Review of operations

## Antimicrobial BDM-I: Opal Biosciences Ltd (“Opal”)

- Opal’s preclinical-stage antimicrobial compound BDM-I is being developed and commercialised to target the treatment of antibiotic-resistant and hard-to-treat human infections including ‘superbugs’.
- Opal was formed in May 2015 as a subsidiary of BioDiem Ltd. This was undertaken to permit external investment in the commercialisation of BDM-I while allowing BioDiem shareholders to retain benefit from successful commercialisation.
- In November 2017 following shareholder approval by both Opal and BioDiem shareholders, the de-merger of the subsidiary was completed.
- In March 2018 the assignment of all BDM-I intellectual property rights into Opal was completed, following a successful placement of \$0.6m by sophisticated investors in February 2018.
- Mr Ken Windle was appointed to the Opal board in March 2018. Mr Windle is a well-known and experienced pharma executive.
- The Opal board was additionally strengthened following year-end by the appointment of Mr Peter Snowball, an experienced financial markets executive and biotechnology company investor, and a shareholder in both BioDiem and Opal.

## Significant developments during the past year include:

### Re-focus on Gonorrhoea

- *Neisseria gonorrhoea* is the bacteria responsible for causing the sexually transmitted infection, gonorrhoea. It is highly infectious, easily spread through sexual contact and kissing, and untreated gonorrhoea can cause serious and permanent health problems in both women and men.
- Gonorrhoea infections are increasing around the world and many strains are becoming resistant to treatment with antibiotics. The Centers of Disease Control and Prevention (CDC) in the US rates antibiotic-resistant gonorrhoea in the “Urgent Threat” category.

*Neisseria gonorrhoea* now has strains which are resistant to multiple antibiotics. In Australia gonorrhoea incidence rates are reportedly up 63% (from 62 to 101 infections per 100,000 people). In major cities, infection rates rose 99% between 2012 and 2016, with US rates higher than in Australia.

In March 2018, BDM-I was tested against the 14 reference strains of gonorrhoea identified by World Health Organisation. These strains represent different levels of antibiotic resistance. In this laboratory test, conducted by Eurofins, Taiwan,

BDM-I successfully blocked the growth of all the gonorrhoea bacterial strains at concentrations which Opal would expect to achieve in the bloodstream. This screening result has led us to prioritise development of BDM-I towards gonorrhoea as a target disease indication.

### In this testing, not only was BDM-I potent against all strains of gonorrhoea included in the panel, it was effective against

- nine strains classed as resistant or highly resistant to the comparator ciprofloxacin, and
- strains which are highly resistant to the currently recommended treatments, azithromycin and ceftriaxone.

It is Opal’s intention to expand the breadth of this screening work and then publish these data.

Following these pleasing results, Opal approached the US National Institute of Allergy and Infectious Diseases (NIAID) at the US National Institutes of Health (NIH), to seek admission to their program which is focussed on gonorrhoea and assisting companies such as Opal to develop new potential treatments. Opal has now had news of its ability to use their non-clinical and pre-clinical services. It will allow us to access these NIAID services at minimal cost and to gain further benefit from this group’s expertise.

Whereas BDM-I has shown similar potency to block growth of other disease-causing micro-organisms, antibiotic-resistant gonorrhoea has been raised in profile recently. Newspaper headlines heralded two multidrug resistant cases in Australia and one in the UK in early in 2018. Internationally there are very few new treatments in development for gonorrhoea and resistance is spreading.

### Injectable formulation (Opal-I) program

In the laboratory, BDM-I shows that it can inhibit or kill many disease-causing micro-organisms (pathogens). To demonstrate that BDM-I can also work in animal experiments, the BDM-I drug substance must be made into a liquid formulation that can be given in the preclinical studies.

#### Step 1: Formulate an injectable form of BDM-I:

During the year one of the most important developments for Opal was the successful formulation of an injectable form of BDM-I. This work was funded with the assistance of a federal government Entrepreneur’s Program Innovation Connection grant. The formulation work was performed by Formulytica, the same expert group that had developed the gel formulation of BDM-I (Opal-T) for Opal. Formulytica’s work included stability testing to ensure that the preparation would remain stable through preclinical experiments.

The injectable form of BDM-I, which has been termed Opal-I, can now be used in further testing towards the development of a product for treatment of infections.

# Review of operations

## Step 2: Tolerability studies of BDM-I.

The development plan aim is to demonstrate that BDM-I can cure an infection in an animal model experiment (preclinical efficacy testing). To understand what range of dosage or amount of BDM-I that should be used and for how long it should be given, tolerability studies are to be conducted. The preparation for these studies is underway.

## Step 3: Preclinical efficacy studies:

Previously Opal-T gel in a mouse model showed effect against a highly antibiotic-resistant strain of *Staphylococcus aureus*; bacteria responsible for causing serious and life-threatening infections. Additional *in vivo* testing will provide “proof of concept” and form part of the data package Opal is aiming to compile in the coming year.

## Mechanism of action against bacteria (i.e. how does BDM-I kill bacteria?)

Under the supervision of Associate Professor Slade Jensen at the Ingham Institute for Applied Medical Research, Western Sydney University, PhD candidate Michael Radzieta continued studies to understand how BDM-I kills bacteria. Included in these studies were proteomics studies which examined the effect BDM-I has on bacteria.

A strain of *Staph aureus* (Golden Staph) was used as an example. The results showed that BDM-I can disrupt some essential mechanisms in the bacterial cell hence causing the death of the bacterium. The results are consistent with earlier studies undertaken by Assoc. Prof Jensen’s team and are the subject of further investigation currently underway. This new thermoprofiling work will assist identify the area on the bacteria where BDM-I binds.

## Antibiotic Resistance Threats in the US 2013

### Antibiotic Resistance Threats per CDC Report 2013<sup>†</sup>

#### ⚠ Threats where BDM-I has shown activity

##### Urgent Threats

- Clostridium difficile
- Carbapenem-resistant Enterobacteriaceae (CRE)

#### ⚠ Drug-resistant *Neisseria gonorrhoeae*

##### Serious Threats

- Multidrug-resistant *Acinetobacter*
- Drug-resistant *Campylobacter*

#### ⚠ Fluconazole-resistant *Candida* (a fungus)\*

- Extended spectrum  $\beta$ -lactamase producing Enterobacteriaceae (ESBLs)

#### ⚠ Vancomycin-resistant *Enterococcus* (VRE)

- Multidrug-resistant *Pseudomonas aeruginosa*
- Drug-resistant Non-typhoidal *Salmonella*
- Drug-resistant *Salmonella* Typhi
- Drug-resistant *Shigella*

#### ⚠ Methicillin-resistant *Staphylococcus aureus* (MRSA)

- Drug-resistant *Streptococcus pneumoniae*

#### ⚠ Drug-resistant tuberculosis

##### Concerning Threats

#### ⚠ Vancomycin-resistant *Staphylococcus aureus* (VRSA)

- Erythromycin-resistant Group A *Streptococcus*
- Clindamycin-resistant Group B *Streptococcus*

<sup>†</sup>Antibiotic Resistance Threats in the US 2013, US DHHS CDC, April 2013

\*BDM-I has shown activity against (some strains of) Fluconazole-resistant *Candida*

This work was funded with the assistance of a federal government Entrepreneur's Program Innovation Connection grant.

Results to date indicate that BDM-I's cellular target is novel and therefore BDM-I represents a next-generation anti-infective.

PhD candidate Michael Radzieta presented a poster at the prestigious ASM/ESCMID Conference on "Drug Development to Meet the Challenge of Antimicrobial Resistance" in Boston, MA, USA on the 6-8 September 2017.

### Intellectual property strengthening:

- In January 2018 the patent entitled "Method of Treatment of Scedosporium spp. Infection" was granted in the US.
- In April 2018 the patent entitled "Method of Treatment of Scedosporium spp. Infection" was granted in Europe.
- In July 2018 based on the discoveries made in the research undertaken at the Ingham Institute, Western Sydney University, an International filing of a new PCT patent was made entitled "Treatment of staphylococcal and enterococcal infections using substituted nitrostyrene compounds".

### Capital raising

In late July 2018, Opal released an Information Memorandum to raise up to \$1.5m (accepting up to \$2.5m). These funds will be used for the next stages of development of BDM-I including tolerability studies and preclinical efficacy testing.

### Other studies

- In July 2018, BDM-I was screened for effect against *Chlamydia trachomatis* which is responsible for causing chlamydia infections, however BDM-I was not active against this micro-organism and so no further work will be undertaken against chlamydia.

## Investigating the Mechanism of Action and Clinical Utility of the Novel Antimicrobial BDM-I

M. Radzieta<sup>1,2</sup>, B. Espedido<sup>1,2</sup>, C. Malladi<sup>1</sup>, J. Coorsen<sup>2</sup>, M. Killingsworth<sup>2</sup>, S.J. van Halbeek<sup>3</sup>, J. Phillips<sup>3</sup> & S.O. Jensen<sup>1,2</sup>  
<sup>1</sup>ARMEG, Ingham Institute for Applied Medical Research, Liverpool, NSW; <sup>2</sup>NSMG, School of Medicine, Western Sydney University, Sydney, NSW; <sup>3</sup>Typhoid South Division Pathology Service, Sydney, NSW; <sup>4</sup>Royal Prince Alfred Hospital, Sydney, NSW; <sup>5</sup>Westmead Hospital, Westmead, NSW

**Introduction**

The continuing emergence and spread of antibiotic-resistant pathogens has correlated with a significant increase in the research and development of novel antimicrobial compounds. Two species of primary concern are the opportunistic pathogens *Pseudomonas* (Pseudo) and *Scedosporium* (Scedo), representing the two most common causes of hospital-acquired infections worldwide<sup>1,2</sup>. Currently, consolidated infections for both species are treated with glycopeptide intravenous treatment, through the acquisition of the vanA gene, substituted nitrostyrene classes are more commonly observed for *S. falciforme*, with substituted nitrostyrene I versus (NSI) classes being proposed to emerge due to its novel mechanism.

**Methods**

NSI Analysis: MIC tests were conducted on clinical NSI isolates with varying degrees of vancomycin susceptibility (VISA, VRSA, VISA). Testing was completed using the broth microdilution method with subsequent statistical analysis via the Spearman's Rank.

**Results**

**Vancomycin Effect Observed Between BDM-I and Vancomycin MIC Analysis of Clinical NSI Isolates**

Species	Vancomycin MIC (μg/L)	BDM-I MIC (μg/L)	Correlation (p-value)
VISA (n=10)	1.00	1.00	0.001
VRSA (n=10)	1.00	1.00	0.001
VISA (n=10)	1.00	1.00	0.001

**NSI and Elements of NSI MIC Identify ATP Synthase as Important to the BDM-I Mode of Action**

**Conclusions**

Results obtained through MIC and proteomic analysis of BDM-I treated isolates, as well as an effect-based analysis, indicate that ATP synthase is affected by BDM-I. Consistent with this, treatment with BDM-I isolates were resistant within the ATP synthase system, primarily NSI, within NSI. These results in combination with the apparent increase in resistance of NSI isolates that ATP synthase is important to the BDM-I mode of action.

**Current and Future Work**

Current work includes collaborative approaches to studying the effect that BDM-I has on the bacterial phosphotransferase system, in order to explore its proposed mechanism of action as a tyrosine phosphorylation inhibitor. Additionally, effect-based approaches are underway to study identified molecules within NSI isolates, and confirm their role in increasing BDM-I MIC.

**References**

1. van Halbeek HJ, et al. (2017) Antimicrobial resistance in the hospital-acquired infection setting. *Journal of Antimicrobial Chemotherapy*, 79(12), 2101-2110. doi:10.1093/acq/kqz011

Michael Radzieta presented a poster at the prestigious ASM/ESCMID Conference on "Drug Development to Meet the Challenge of Antimicrobial Resistance" in Boston, MA, USA on the 6-8 September 2017;

# 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 2018.

### Directors

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

- Mr Hugh M Morgan AC
- Ms Julie Phillips
- Prof Larisa Rudenko
- Prof Arthur Kwok Cheung Li

### Principal activities

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

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

### Dividends

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

### Review of operations

The loss for the consolidated entity after providing for income tax and non-controlling interest amounted to \$367,419 (30 June 2017: \$487,395).

During the financial year ended 30 June 2018, significant progress has been made on all key development programs towards commercial milestones. Royalty and milestone revenues in 2018 were \$119,397 compared to \$132,165 in 2017, while interest income was \$4,724 compared to \$11,291 during the corresponding period in 2017. Research activity costs were \$194,995 compared to \$354,731 in 2017. Administration expenses were \$518,524 as compared to \$542,280 in the previous year.

The Group commenced the financial year with cash reserves of \$475,871. Cash inflows from its subsidiary Opal Biosciences Limited ("Opal") from the issue of 3,030,000 ordinary shares at \$0.20 (20 cents) per share raised \$606,000 compared to \$948,940 raised in

2017 in BioDiem. Cash outlays were \$323,590 compared to \$732,609 in the prior year for research and administration. Cash inflows were \$345,729 from licensing fees and management fees (2017: \$132,165 from licensing fees). Cash receipts from the R&D Tax Incentive were \$125,937 compared to \$207,493 in the previous year. Cash reserves at the end of the financial year totalled \$758,281.

### Significant changes in the state of affairs

The deed of assignment between Opal Biosciences and BioDiem was finalised during the financial year by Opal issuing 2,500,000 shares to BioDiem in lieu of \$500,000 cash consideration.

In addition to this Opal also completed a placement of 3,030,000 ordinary shares at \$0.20 (20 cents) per share, raising \$606,000 in February 2018 with one free attaching option for every one share subscribed for was issued with an exercise price of \$0.20 (20 cents) per option, expiring on 1 February 2020, diluting BioDiem's controlling interest in Opal from 95.10% to 77.91%.

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

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

Subsequent to year end, Opal Biosciences has commenced a capital raise of up to \$1,500,000 via an Information Memorandum. As at 26 October 2018, Opal had received applications amounting to \$91,000. Opal continues to seek investor interest in the fundraising, with the offer currently scheduled to close on the 31 October 2018. Opal has the ability to extend the Offer at its discretion.

No other matter or circumstance has arisen since 30 June 2018 that has significantly affected, or may significantly affect the consolidated entity's operations, the results of those operations, or the consolidated entity's state of affairs in future financial years.

### Likely developments and expected results of operations

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

### Environmental regulation

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



# Directors' report

Name, title, qualifications	Experience and expertise
<p><b>Hugh M Morgan AC</b> <i>LLB, BCom.</i></p> <p><b>Chairman</b> <b>Non-Executive Director</b></p>	<p>Hugh Morgan is Principal of First Charnock Pty Ltd. Hugh was appointed Chief Executive Officer of Western Mining Corporation (1990-2003) and prior to that served as an Executive Officer (1976-1986) and then Managing Director (from June 1986). Hugh has served as a Director of Alcoa of Australia Limited (1977-1998 and 2002-2003); Director of Alcoa Inc. (1998-2001); Member of the Board of the Reserve Bank of Australia (1981-1984 and 1996-2007); President of the Australian Japan Business Co-Operation Committee (1999-2006); Joint Chair of the Commonwealth Business Council (2003-2005) and now Emeritus Director; President of the Business Council of Australia (2003-2005) and now an Honorary Member; Member of the Anglo American plc Australian Advisory Board (2006-2014). Hugh is a Member of the Lafarge International Advisory Board; Chairman of the Order of Australia Association Foundation Limited; Trustee Emeritus of The Asia Society New York; Chairman Emeritus of the Asia Society AustralAsia Centre; Member of the Asia Society Australia Advisory Council; President of the National Gallery of Victoria Foundation. Hugh is a graduate in Law and Commerce from the University of Melbourne.</p> <p><b>Special responsibilities</b> Chairman of Audit Committee, Chairman of Remuneration and Nomination Committee</p>
<p><b>Julie Phillips</b> <i>BPharm, DHP, MSc, MBA.</i></p> <p><b>Chief Executive Officer</b></p>	<p>Ms Julie Phillips was appointed to the position of Chief Executive Officer on July 14, 2009 and was appointed a Director on May 7, 2010. She has a strong background in the biotech and pharmaceutical industry, having worked as the CEO and Director of start-up Australian biotechnology companies operating in the life sciences sector. Her technical background in clinical trials, regulatory affairs and pharmacoeconomic assessment/pricing of therapeutics was gained in multinational pharmaceutical companies with responsibility for market entry of new products in Australia and New Zealand. She is Chairman of AusBiotech Ltd, the peak biotechnology industry association in Australia, and a Director of the Medtech and Pharma Growth Centre, MTP Connect. Julie has also been appointed to the University of Newcastle Council and sits on a number of government advisory committees.</p> <p><b>Special responsibilities</b> None</p>
<p><b>Larisa Rudenko</b> <i>MD, PhD, DSc.</i></p> <p><b>Director of Russian Projects,</b> <b>Non-Executive Director</b></p>	<p>Professor Larisa Rudenko is Head of the Virology Department in the Institute of Experimental Medicine, St. Petersburg, Russia. Professor Rudenko worked with Academician Smorodintsev and has been responsible for the development and clinical trials of the live attenuated influenza vaccines in Russia. She is recognised as one of the world's leading experts in live attenuated influenza vaccines and as such has worked closely over the past 20 years with scientists at the Centers for Disease Control and Prevention, Atlanta, USA in developing effective influenza prophylaxis programs for use in children and in the elderly. She has published in excess of 225 scientific papers and 42 patents. Under her supervision, 11 PhD and 2 DSc theses have been prepared. In 1999 her contribution to medical science was recognised with the award of the title of Honoured Scientist of the Russian Federation. Professor Rudenko is currently leading the WHO and PATH programs, developing a new pandemic LAIV.</p> <p><b>Special responsibilities</b> Member of Audit Committee, Member of Remuneration and Nomination Committee</p>

## Directors' report

Name, title, qualifications	Experience and expertise
<p><b>Arthur Kwok Cheung Li</b>  <i>BA, MA, MB BChir, MD, HonDSc (Hull), HonDLitt (HKUST), HonDoc (Soka), HonLLD (CUHK), HonDSc(Med) (UCL), HonLLD (UWE), FRCS, FRCSEd, FRACS, FCSHK, FHKAM (Surgery), HonFPCS, HonFRCGlas, HonFRSM, HonFRCS(I), HonFACS, HnFRCP(Lon), HonFCSHK, HonFAS</i></p> <p><b>Non-Executive Director</b></p>	<p>Professor Arthur Li was appointed a Director of the Company for the first time on 27 May 2010. He then resigned as a Director on 13 December 2014, and was recently re-appointed as a Director on 20 January 2016. Professor Li was awarded the degree of Doctor of Medicine by University of Cambridge, UK. He is a well-credentialed and respected educator and surgeon who is currently Deputy Chairman of The Bank of East Asia; an Independent Non-Executive Director of Shangri-La Asia Ltd. He is Emeritus Professor of Surgery of The Chinese University of Hong Kong and Council Chairman of The University of Hong Kong. He is a member of the Executive Council of the Hong Kong Special Administrative Region and also Chairman of the Council for Sustainable Development of the Government of the Hong Kong special Administrative Region. He was also a Director of AFFIN Holdings Berhad. Among his many previous appointments and associations, he has been a Council Fellow of the University of Melbourne, Dean of the Faculty of Medicine and Vice-Chancellor of The Chinese University of Hong Kong. Professor Li was the Secretary for Education and Manpower of the Government of HKSAR. He was also a member of the Board of Glaxo Wellcome plc. He is a member of the National Committee of the Chinese People's Political Consultative Conference. He was appointed as Council Member of the Executive Council of HKSAR on 1 July 2017, and was awarded the Grand Bauhinia Medal by the Chief Executive of HKSAR Government on 30 June 2017.</p> <p><a href="#">Special responsibilities</a>            Member of Audit Committee, Member of Remuneration and Nomination Committee</p>

### Company Secretary

Ms Leydin has 25 years' experience in the accounting profession including 13 years in the Corporate Secretarial professions and is a company secretary and finance officer for a number of entities listed on the Australian Securities Exchange. She is a Chartered Accountant and a Registered Company Auditor. Since February 2000, she has been the principal of Leydin Freyer, specialising in outsourced company secretarial and financial duties.

### Meetings of directors

The number of meetings of the company's Board of Directors ('the Board') held during the year ended 30 June 2018, and the number of meetings attended by each director were:

	Full Board		Audit and Risk Committee	
	Attended	Held	Attended	Held
Hugh M Morgan	9	10	1	1
Julie Phillips	10	10	-	-
Larisa Rudenko	10	10	-	1
Arthur Kwok Cheung Li	3	10	-	1

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

# Directors' report

## Shares under option

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

Grant date	Expiry date	Exercise price	Number under option
8 October 2013	30 September 2023	\$0.080	666,667
8 October 2013	30 September 2023	\$0.120	666,667
8 October 2013	30 September 2023	\$0.200	666,666
			2,000,000

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

## Shares issued on the exercise of options

There were no ordinary shares of BioDiem Limited issued on the exercise of options during the year ended 30 June 2018 and up to the date of this report.

## Indemnity and insurance of officers

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

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

## Indemnity and insurance of auditor

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

## Proceedings on behalf of the company

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

## Auditor's independence declaration

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out immediately after this directors' report.

## Auditor

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

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

On behalf of the directors



**H M Morgan AC**  
Director

29 October 2018  
Melbourne

# Auditor's independence declaration



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727 Collins Street  
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Melbourne VIC 3001

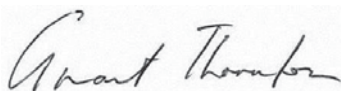
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## Auditor's Independence Declaration

To the Directors of BioDiem Limited

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the audit of BioDiem Limited for the year ended 30 June 2018, 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, 29 October 2018

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## Statement of profit or loss and other comprehensive income

For the year ended 30 June 2018

	Note	Consolidated	
		2018	2017
		\$	\$
<b>Revenue</b>	3	124,121	143,456
Other income	4	83,810	292,236
<b>Expenses</b>			
Licence fees and royalty expenses		(18,251)	(26,085)
Research and development expenses		(194,995)	(354,731)
Administration expenses		(518,524)	(542,280)
<b>Loss before income tax expense</b>		(523,839)	(487,404)
Income tax expense	6	-	-
<b>Loss after income tax expense for the year</b>		(523,839)	(487,404)
Other comprehensive income for the year, net of tax		-	-
<b>Total comprehensive income for the year</b>		(523,839)	(487,404)
Loss for the year is attributable to:			
Non-controlling interest		(156,420)	(9)
Owners of BioDiem Limited		(367,419)	(487,395)
		(523,839)	(487,404)
Total comprehensive income for the year is attributable to:			
Non-controlling interest		(156,420)	(9)
Owners of BioDiem Limited		(367,419)	(487,395)
		(523,839)	(487,404)

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

# Statement of financial position

As at 30 June 2018

	Note	Consolidated	
		2018	2017
		\$	\$
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents	7	758,281	475,871
Trade and other receivables	8	17,459	23,975
Other assets	9	258,752	380,542
Total current assets		1,034,492	880,388
<b>Total assets</b>		1,034,492	880,388
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	10	85,106	50,928
Employee benefits	11	108,987	71,222
Total current liabilities		194,093	122,150
<b>Total liabilities</b>		194,093	122,150
<b>Net assets</b>		840,399	758,238
<b>Equity</b>			
Issued capital	12	32,168,532	32,168,532
Reserves	13	46,757	46,757
Accumulated losses		(31,926,257)	(31,558,838)
Equity attributable to the owners of BioDiem Limited		289,032	656,451
Non-controlling interest	14	551,367	101,787
<b>Total equity</b>		840,399	758,238

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

# Statement of changes in equity

For the year ended 30 June 2018

	Issued Capital	Reserves	Accumulated Losses	Non- controlling interest	Total equity
Consolidated	\$	\$	\$	\$	\$
Balance at 1 July 2016	31,019,592	46,757	(31,071,443)	101,796	96,702
Loss after income tax expense for the year	-	-	(487,395)	(9)	(487,404)
Other comprehensive income for the year, net of tax	-	-	-	-	-
Total comprehensive income for the year	-	-	(487,395)	(9)	(487,404)
<i>Transactions with owners in their capacity as owners:</i>					
Issue of convertible preference shares	1,148,940	-	-	-	1,148,940
Balance at 30 June 2017	32,168,532	46,757	(31,558,838)	101,787	758,238

	Issued Capital	Reserves	Accumulated Losses	Non- controlling interest	Total equity
Consolidated	\$	\$	\$	\$	\$
Balance at 1 July 2017	32,168,532	46,757	(31,558,838)	101,787	758,238
Loss after income tax expense for the year	-	-	(367,419)	(156,420)	(523,839)
Other comprehensive income for the year, net of tax	-	-	-	-	-
Total comprehensive income for the year	-	-	(367,419)	(156,420)	(523,839)
<i>Transactions with owners in their capacity as owners:</i>					
Contributions of equity, net of transaction costs (note 16)	-	-	-	606,000	606,000
Balance at 30 June 2018	32,168,532	46,757	(31,926,257)	551,367	840,399

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

# Statement of cash flows

For the year ended 30 June 2018

	Note	Consolidated	
		2018	2017
		\$	\$
<b>Cash flows from operating activities</b>			
Cash receipts in course of operations		345,729	132,165
Cash payments in course of operations		(798,019)	(1,079,566)
		(452,290)	(947,401)
Interest received		2,763	7,299
R&D Tax Offset received		125,937	207,493
Net cash used in operating activities	24	(323,590)	(732,609)
<b>Cash flows from investing activities</b>			
Net cash from investing activities		-	-
<b>Cash flows from financing activities</b>			
Proceeds from issue of shares of subsidiary		606,000	-
Proceeds from issue of shares of parent entity		-	948,940
Net cash from financing activities		606,000	948,940
Net increase/(decrease) in cash and cash equivalents		282,410	216,331
Cash and cash equivalents at the beginning of the financial year		475,871	259,540
Effects of exchange rate changes on cash and cash equivalents		-	-
Cash and cash equivalents at the end of the financial year	7	758,281	475,871

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



# Notes to the financial statements

30 June 2018

## 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 ended 30 June 2018. 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 29 October 2018. 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 or amended Accounting Standards and Interpretations adopted

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

Any new or amended 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 \$523,839 (2017: \$487,404 net loss after tax) for the financial year ended 30 June 2018.

The net loss after tax is directly attributable to the expenditures incurred in ongoing research and development activities, as well as administration expenditure. Despite the net loss after tax incurred for the period, the Directors have prepared the financial statements on the going concern basis. The going concern basis is considered appropriate based on a combination of the existing net assets of the Group, which amount to \$840,399 (30 June 2017: \$758,238), including cash and cash equivalent assets of \$758,281 (30 June 2017: \$475,871), and the expectation of Group's ongoing ability to successfully secure additional sources of financing. In this regard, the Directors note the following:

- The Group has a licensing agreement with the Serum Institute of India ("Serum"), which entitles the Group to royalty income upon sales of LAIV influenza vaccine.
- The Group has a LAIV licensing agreement with the Changchun BCHO Biotechnology Co., where the vaccine subject to the LAIV licensing agreement is currently under development. If the development and commercialisation of the vaccine is successful, the LAIV licensing agreement is expected to provide further royalty income streams over the next two years. Clinical trials in China have concluded in the reporting period.
- The Group includes a subsidiary company, Opal Biosciences which was formed in May 2015 to commercialise the asset, BDM-I technology. Opal Biosciences has issued \$606,000 shares in February 2018 and the Group is considering other alternative sources of cash inflows from financing initiatives, such as capital raisings, including the Information Memorandum which is currently open.
- 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. During the reporting period significant cost reductions continued to be implemented.

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.

# Notes to the financial statements

30 June 2018

Should the Company be unable to continue as a going concern it may be required to realise its assets and extinguish its liabilities other than in the normal course of business and at amounts different to those stated in the financial statements. The financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or to the amount and classification of liabilities that might result should the Company be unable to continue as a going concern and meet its debts as and when they fall due.

## **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.

## **Parent entity information**

In accordance with the Corporations Act 2001, these financial statements present the results of the consolidated entity only. Supplementary information about the parent entity is disclosed in note 21.

## **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 2018 and the results of all subsidiaries for the year then ended. BioDiem Limited and its subsidiaries together are referred to in these financial statements as the 'consolidated entity'.

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

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

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

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

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

# Notes to the financial statements

30 June 2018

## 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 and concession 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.

Other grants or concessions, including the Research and Development Tax concessions, 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, and as a receivable over the same period.

### 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.

# Notes to the financial statements

30 June 2018

## Current and non-current classification

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

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

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

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

## Cash and cash equivalents

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

## Trade and other receivables

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

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

## Research and development

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

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

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

## 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 wholly within 12 months of the reporting date are measured at the amounts expected to be paid when the liabilities are settled.

### *Other long-term employee benefits*

The liability for annual leave and long service leave not expected to be settled within 12 months of the reporting date are measured at 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.

# Notes to the financial statements

30 June 2018

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

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

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

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

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

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

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

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

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

## Fair value measurement

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

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

## Issued capital

Ordinary shares are classified as equity.

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

## Goods and Services Tax ('GST') and other similar taxes

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

# Notes to the financial statements

30 June 2018

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 2018. The consolidated entity's assessment of the impact of these new or amended Accounting Standards and Interpretations, most relevant to the consolidated entity, are set out below.

### *AASB 9 Financial Instruments*

This standard is applicable to annual reporting periods beginning on or after 1 January 2018. The standard replaces all previous versions of AASB 9 and completes the project to replace IAS 39 'Financial Instruments: Recognition and Measurement'. AASB 9 introduces new classification and measurement models for financial assets. A financial asset shall be measured at amortised cost, if it is held within a business model whose objective is to hold assets in order to collect contractual cash flows, which arise on specified dates and solely principal and interest. All other financial instrument assets are to be classified and measured at fair value through profit or loss unless the entity makes an irrevocable election on initial recognition to present gains and losses on equity instruments (that are not held-for-trading) in other comprehensive income ('OCI'). For financial liabilities, the standard requires the portion of the change in fair value that relates to the entity's own credit risk to be presented in OCI (unless it would create an accounting mismatch). New simpler hedge accounting requirements are intended to more closely align the accounting treatment with the risk management activities of the entity. New impairment requirements will use an 'expected credit loss' ('ECL') model to recognise an allowance. Impairment will be measured under a 12-month ECL method unless the credit risk on a financial instrument has increased significantly since initial recognition in which case the lifetime ECL method is adopted. The standard introduces additional new disclosures. The consolidated entity has adopted this standard and amendments from 1 July 2018, with no impact on accounting processes or balances.

### *AASB 15 Revenue from Contracts with Customers*

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

# Notes to the financial statements

30 June 2018

## Note 3. Revenue

	Consolidated	
	2018	2017
	\$	\$
Royalty and milestone revenue	119,397	132,165
<i>Other revenue</i>		
Interest	4,724	11,291
Revenue	124,121	143,456

## Note 4. Other income

	Consolidated	
	2018	2017
	\$	\$
Net foreign exchange gain/ (loss)	6,745	(8,938)
Research & Development Tax Concession	77,065	301,174
Other income	83,810	292,236

## Note 5. Expenses

	Consolidated	
	2018	2017
	\$	\$
Loss before income tax includes the following specific expenses:		
<i>Rental expense relating to operating leases</i>		
Rental	-	12,000
<i>Employee Benefits Expense</i>		
Wages and salaries	196,195	403,280
Superannuation - defined contribution	18,358	27,323
Other associated personnel expenses	-	3,030
(Decrease)/Increase in annual leave provision	26,170	(19,648)
(Decrease)/Increase in long service leave provision	11,595	(23,165)
Total	252,318	390,820

# Notes to the financial statements

30 June 2018

## Note 6. Income tax expense

	Consolidated	
	2018	2017
	\$	\$
<i>Numerical reconciliation of income tax expense and tax at the statutory rate</i>		
Loss before income tax expense	(\$523,839)	(487,404)
Tax at the statutory tax rate of 27.5%	(144,056)	(134,036)
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Research & Development tax incentive - not assessable	(21,193)	(82,823)
Research & Development expenditure - not deductible	48,718	-
	(116,531)	(216,859)
Current year tax losses not recognised	125,073	133,694
Current year temporary differences not recognised	(8,542)	83,165
Income tax expense	-	-

	Consolidated	
	2018	2017
	\$	\$
<i>Tax losses not recognised</i>		
Unused tax losses for which no deferred tax asset has been recognised	30,777,963	30,259,076
Potential tax benefit @ 27.5%	8,463,940	8,321,246

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	
	2018	2017
	\$	\$
Cash at bank	656,813	275,871
Cash on deposit	101,468	200,000
	758,281	475,871

## Note 8. Current assets – trade and other receivables

	Consolidated	
	2018	2017
	\$	\$
Trade receivables	10,540	8,201
Other receivables	-	2,339
Interest receivable	606	1,173
GST receivable	6,313	12,262
	17,459	23,975



# Notes to the financial statements

30 June 2018

## Note 9. Current assets – other assets

	Consolidated	
	2018	2017
	\$	\$
Accrued revenue	83,755	212,312
Prepayments	51,128	46,889
Short term deposits supporting bank guarantees	123,869	121,341
	<u>258,752</u>	<u>380,542</u>

The company holds two short term deposits, one (\$45,831) is a three month term deposit maturing on 25 August 2018. The other (\$78,038) is a six month term deposit, maturing on 25 September 2018. The term deposits are earning 2.00% and 2.05% per annum respectively

## Note 10. Current liabilities – trade and other payables

	Consolidated	
	2018	2017
	\$	\$
Trade payables	48,281	12,284
Other payables	36,825	38,644
	<u>85,106</u>	<u>50,928</u>

Refer to note 16 for further information on financial instruments.

## Note 11. Current liabilities – employee benefits

	Consolidated	
	2018	2017
	\$	\$
Annual leave	69,447	43,277
Long service leave	39,540	27,945
	<u>108,987</u>	<u>71,222</u>

*Amounts not expected to be settled within the next 12 months*

The current provision for employee benefits includes all unconditional entitlements where employees have completed the required period of service and also those where employees are entitled to pro-rata payments in certain circumstances. The entire amount is presented as current, since the consolidated entity does not have an unconditional right to defer settlement. However, based on past experience, the consolidated entity does not expect all employees to take the full amount of accrued leave or require payment within the next 12 months.

The following amounts reflect leave that is not expected to be taken within the next 12 months:

	Consolidated	
	2018	2017
	\$	\$
Long service leave	<u>39,540</u>	<u>27,945</u>

# Notes to the financial statements

30 June 2018

## Note 12. Equity – issued capital

	Consolidated			
	2018	2017	2018	2017
	Shares	Shares	\$	\$
Ordinary shares - fully paid	174,734,060	174,734,060	31,019,592	31,019,592
Convertible Preference shares - fully paid	14,392,433	14,392,433	1,148,940	1,148,940
	<u>189,126,493</u>	<u>189,126,493</u>	<u>32,168,532</u>	<u>32,168,532</u>

### Movements in Convertible preference share capital

Details	Date	Shares	Issue price	\$
Balance	1 July 2016	-	-	-
Convertible preference shares	8 August 2016	14,392,433	\$0.080	1,151,395
Capital raising costs		-	\$0.000	(2,455)
Balance	30 June 2017	14,392,433		1,148,940
Balance	30 June 2018	<u>14,392,433</u>		<u>1,148,940</u>

### 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.

### Convertible Preference shares

Preference 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, with priority over ordinary shareholders.

### Capital risk management

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

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

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

The capital risk management policy remains unchanged from the 2017 Annual Report.

# Notes to the financial statements

30 June 2018

## Note 13. Equity – reserves

	Consolidated	
	2018	2017
	\$	\$
Share-based payments reserve	46,757	46,757

### 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.

## Note 14. Equity – non-controlling interest

	Consolidated	
	2018	2017
Issued capital	709,007	103,007
Accumulated losses	(157,640)	(1,220)
	551,367	101,787

Details	Date	Shares	Issue Price	\$
Opening Balance	01/07/2016	515,000	\$0.20	103,007
Issue of Shares to external investors	23/02/2018	3,030,000	\$0.20	606,000
Closing Balance as 30 June 2018		3,545,000		709,007

## Note 15. Equity - dividends

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

### 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.

## 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.

### Credit risk

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

### Liquidity risk

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

# Notes to the financial statements

30 June 2018

## 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.

	Weighted average interest rate	1 year or less	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Remaining contractual maturities
<b>Consolidated - 2018</b>	<b>%</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Non-derivatives</b>						
<i>Non-interest bearing</i>						
Trade payables	-	85,106	-	-	-	85,106
Total non-derivatives		85,106	-	-	-	85,106

	Weighted average interest rate	1 year or less	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Remaining contractual maturities
<b>Consolidated - 2017</b>	<b>%</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Non-derivatives</b>						
<i>Non-interest bearing</i>						
Trade payables	-	50,928	-	-	-	50,928
Total non-derivatives		50,928	-	-	-	50,928

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 \$78,038 and \$45,831 respectively totalling \$123,869 (2017: \$121,341) 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	
	2018	2017
	\$	\$
Audit services - Grant Thornton Audit Pty Ltd		
Audit or review of the financial statements	35,750	41,000

# Notes to the financial statements

30 June 2018

## 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 holds a licence to commercialise the BDM-I antimicrobial technology from the Institute of Experimental Medicine. Under this agreement the consolidated entity is obliged to pay the Institute of Experimental Medicine 10% of all payments received from any Licensee and 10% of any royalties arising from net sales (or 5% in each case, where the commercialisation is done by the consolidated entity).

	Consolidated	
	2018	2017
	\$	\$
Bank guarantees	13,750	13,750

The guarantee above is related to the credit card facility operated by BioDiem.

## Note 19. Commitments

There are no commitments for 2018 (2017: Nil).

## 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	
	2018	2017
	\$	\$
Key management personnel compensation:		
Short-term employee benefits	196,195	253,836
Post-employee benefits	18,358	16,831

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 \$18,251 (2017: \$26,085) to the Institute. In addition, research and development costs amounting to \$nil (2017: \$15,000) were also paid to the Institute.

### 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.

### Terms and conditions

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

# Notes to the financial statements

30 June 2018

## Note 21. Parent entity information

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

### Statement of profit or loss and other comprehensive income

	Parent	
	2018	2017
	\$	\$
Loss after income tax	(315,737)	(487,214)
Total comprehensive income	(315,737)	(487,214)

### Statement of financial position

	Parent	
	2018	2017
	\$	\$
Total current assets	530,279	802,340
Total assets	530,279	802,340
Total current liabilities	165,822	122,150
Total liabilities	165,822	122,150
Equity		
Issued capital	32,168,532	32,168,532
Share-based payments reserve	46,757	46,757
Accumulated losses	(31,850,832)	(31,535,099)
Total equity	364,457	680,190

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

The parent entity had no guarantees in relation to the debts of its subsidiaries as at 30 June 2018 and 30 June 2017.

### Contingent liabilities

The parent entity had no contingent liabilities as at 30 June 2018 and 30 June 2017, other than as mentioned below.

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

The consolidated entity holds a licence to commercialise the BDM-I antimicrobial technology from the Institute of Experimental Medicine. Under this agreement the consolidated entity is obliged to pay the Institute of Experimental Medicine 10% of all payments received from any Licensee and 10% of any royalties arising from net sales (or 5% in each case, where the commercialisation is done by the consolidated entity).

# Notes to the financial statements

30 June 2018

## Capital commitments - Property, plant and equipment

The parent entity had no capital commitments for property, plant and equipment as at 30 June 2018 and 30 June 2017.

## Significant accounting policies

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

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

## Note 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	
		2018 %	2017 %
Savine Therapeutics Pty Ltd	Australia	100.00%	100.00%
Opal Biosciences Limited*	Australia	77.91%	95.10%

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

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

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

During financial year 2016, Opal raised a total of \$103,000 via the issue of 10,515,000 ordinary shares and the grant of 248,125 options in accordance with the information memorandum dated 15 May 2015. The Opal capital raising closed on 15 May 2016.

Part (iii) above completed Opal's acquisition of the BDM-I technology from BioDiem Limited by the issue by Opal of 2,500,000 fully paid ordinary shares to BioDiem Limited in lieu of \$500,000 cash consideration noted above.

On 23 February 2018, Opal successfully completed a placement, issuing 3,030,000 ordinary shares at \$0.20 per share raising \$606,000. In addition, one free attaching option for every one share subscribed for was issued with an exercise price of \$0.20 (20 cents) per option, expiring on 1 February 2020.

BioDiem retains the majority shareholding of Opal due to its equity holding and continues to support the development of Opal's asset, BDM-I.

## Note 23. Events after the reporting period

Subsequent to year end, Opal Biosciences has commenced a capital raise of up to \$1,500,000 via an Information Memorandum. As at 26 October 2018, Opal had received applications amounting to \$91,000. Opal continues to seek investor interest in the fundraising, with the offer currently scheduled to close on the 31 October 2018. Opal has the ability to extend the Offer at its discretion.

No other matter or circumstance has arisen since 30 June 2018 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.

# Notes to the financial statements

30 June 2018

## Note 24. Reconciliation of loss after income tax to net cash used in operating activities

	Consolidated	
	2018	2017
	\$	\$
Loss after income tax expense for the year	(523,839)	(487,404)
Change in operating assets and liabilities:		
Decrease/(increase) in trade and other receivables	6,516	(7,264)
Increase in prepayments	(4,239)	(5,381)
Increase in other current assets	126,029	(97,032)
Increase/(decrease) in trade and other payables	34,178	(92,715)
Increase/(decrease) in employee benefits	37,765	(42,813)
Net cash used in operating activities	(323,590)	(732,609)

## 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 2018 there were 174,734,060 shares on hand.

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

On 27 July 2009 the Group issued 160,000 options under the ESOP. These options were restricted until 27 July 2010 and lapsed on 27 July 2014. The exercise price was set at \$0.136.

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

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

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

2018							
Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Expired/forfeited/other	Balance at the end of the year
08/10/2013	30/09/2023	\$0.080	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
			2,000,000	-	-	-	2,000,000



# Notes to the financial statements

30 June 2018

2017							
Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Expired/forfeited/other	Balance at the end of the year
08/10/2013	30/09/2023	\$0.080	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
			2,000,000	-	-	-	2,000,000
Weighted average exercise price			\$0.133	\$0.000	\$0.000	\$0.000	\$0.133

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

		2018	2017
Grant date	Expiry date	Number	Number
08/10/2013	30/09/2023	2,000,000	2,000,000
		2,000,000	2,000,000

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

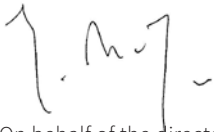
## Directors' declaration

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 2018 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

A handwritten signature in black ink, appearing to be "H. Morgan".

On behalf of the directors

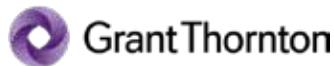
**H M Morgan AC**

Director

29 October 2018

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

Report on the audit of the financial report

### Opinion

We have audited the financial report of BioDiem Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 30 June 2018, 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, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion, the accompanying financial report of the Group is in accordance with the *Corporations Act 2001*, including:

- a giving a true and fair view of the Group's financial position as at 30 June 2018 and of its performance for the year ended on that date; and
- b complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

### Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Group in accordance with the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

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

### Information Other than the Financial Report and Auditor's Report Thereon

The Directors are responsible for the other information. The other information comprises the information included in the Group's annual report for the year ended 30 June 2018, but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and accordingly we do not express any form of assurance conclusion thereon.

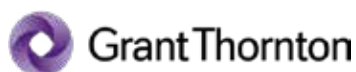
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## Independent auditor's report to the members of BioDiem Limited



In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

### Responsibilities of the Directors 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* and for 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.

In preparing the financial report, the Directors are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

### Auditor's Responsibilities for the Audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: [http://www.auasb.gov.au/auditors\\_responsibilities/ar3.pdf](http://www.auasb.gov.au/auditors_responsibilities/ar3.pdf). This description forms part of our auditor's report.



Grant Thornton Audit Pty Ltd  
Chartered Accountants



M A Cunningham  
Partner – Audit & Assurance

Melbourne, 29 October 2018

# Corporate directory

## Directors

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

## Share Registry

Computershare Investor Services Pty Ltd  
Yarra Falls, 452 Johnston Street  
Abbotsford Victoria 3067

**PH:** + 61 3 9415 5000

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

## Company Secretary

Melanie Leydin

## Registered Office

Level 4  
100 Albert Road  
South Melbourne VIC 3205

**PH:** + 61 3 9692 7240

## Principal place of business

Level 4  
100 Albert Road  
South Melbourne VIC 3205

**PH:** + 61 3 9692 7240

## Auditor

Grant Thornton Audit Pty Ltd  
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Melbourne VIC 3000

## Website

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