

opal

Biosciences

Opal Biosciences Limited

ABN 97 605 631 963

ANNUAL REPORT 2016



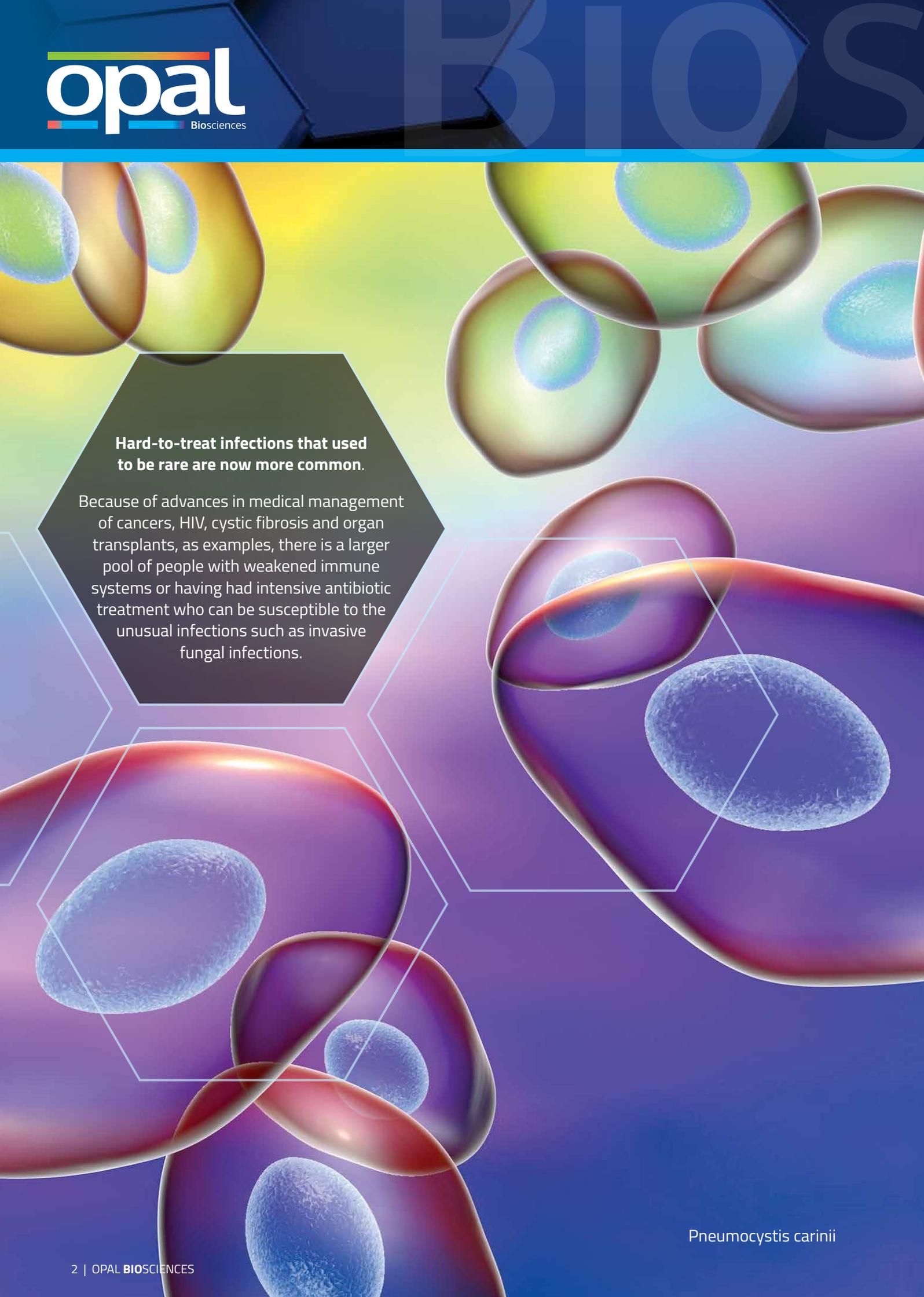




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A microscopic view of several cells, likely yeast or fungi, with blue nuclei and reddish-brown cytoplasm. The cells are arranged in a cluster, and the background is a gradient of yellow, green, and blue. A dark grey hexagonal box is overlaid on the left side of the image, containing text.

Hard-to-treat infections that used to be rare are now more common.

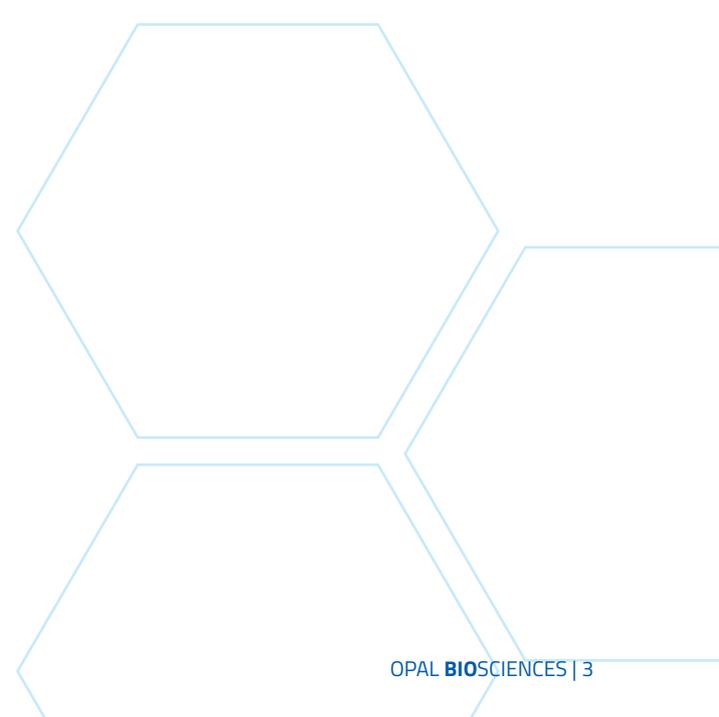
Because of advances in medical management of cancers, HIV, cystic fibrosis and organ transplants, as examples, there is a larger pool of people with weakened immune systems or having had intensive antibiotic treatment who can be susceptible to the unusual infections such as invasive fungal infections.

Pneumocystis carinii



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Highlights of 2016:

Corporate

- In July/August 2016 the parent company, BioDiem Ltd, completed a successful capital raising of \$1.149m through a nonrenounceable entitlement offer of convertible preference shares.

The proceeds of the Offer are being applied to BioDiem's flu vaccine operations as well as providing support for Opal Biosciences, to conduct further studies for a data package for licensing of its antimicrobial:

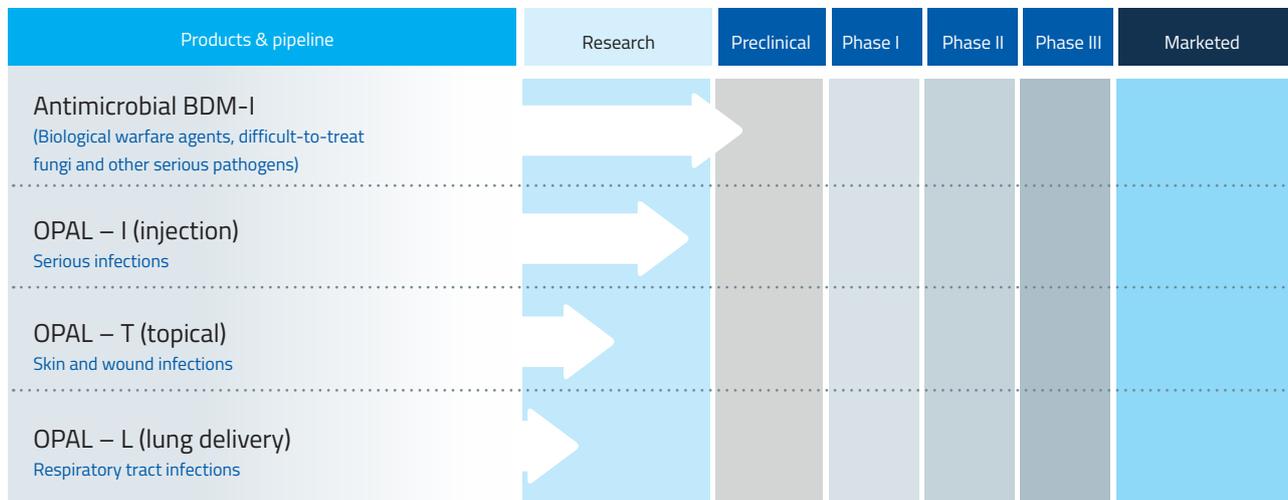
- Studies in preparation for efficacy testing in infectious disease models; and
- Proof-of-concept studies in relevant infectious disease models; and
- Continue mechanism of action studies at Western Sydney University.

A microscopic image showing numerous small, purple-stained, spherical organisms, identified as Pneumocystis Carinii, against a light pink background. The organisms are clustered and some show internal structures. Three semi-transparent hexagonal shapes are overlaid on the image: a dark grey one on the left containing text, and two lighter grey ones on the right and bottom left.

BioDiem currently is in U.S. programs in which BDM-I has progressed to preclinical animal studies to assess its potential as a treatment for the fungal disease, pneumocystosis.

Pneumocystis Carinii

Opal Biosciences' Pipeline



Antimicrobial BDM-I

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

Chairman's Letter

Dear shareholders,

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

This last year has seen some highlights and some disappointments. Our fundraising during 2015-16 for Opal Biosciences was disappointing, although we believe the prospect for the technology is enormous. The majority of the development program cost is being borne by BioDiem which owns 95.1% of Opal Biosciences.

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

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

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

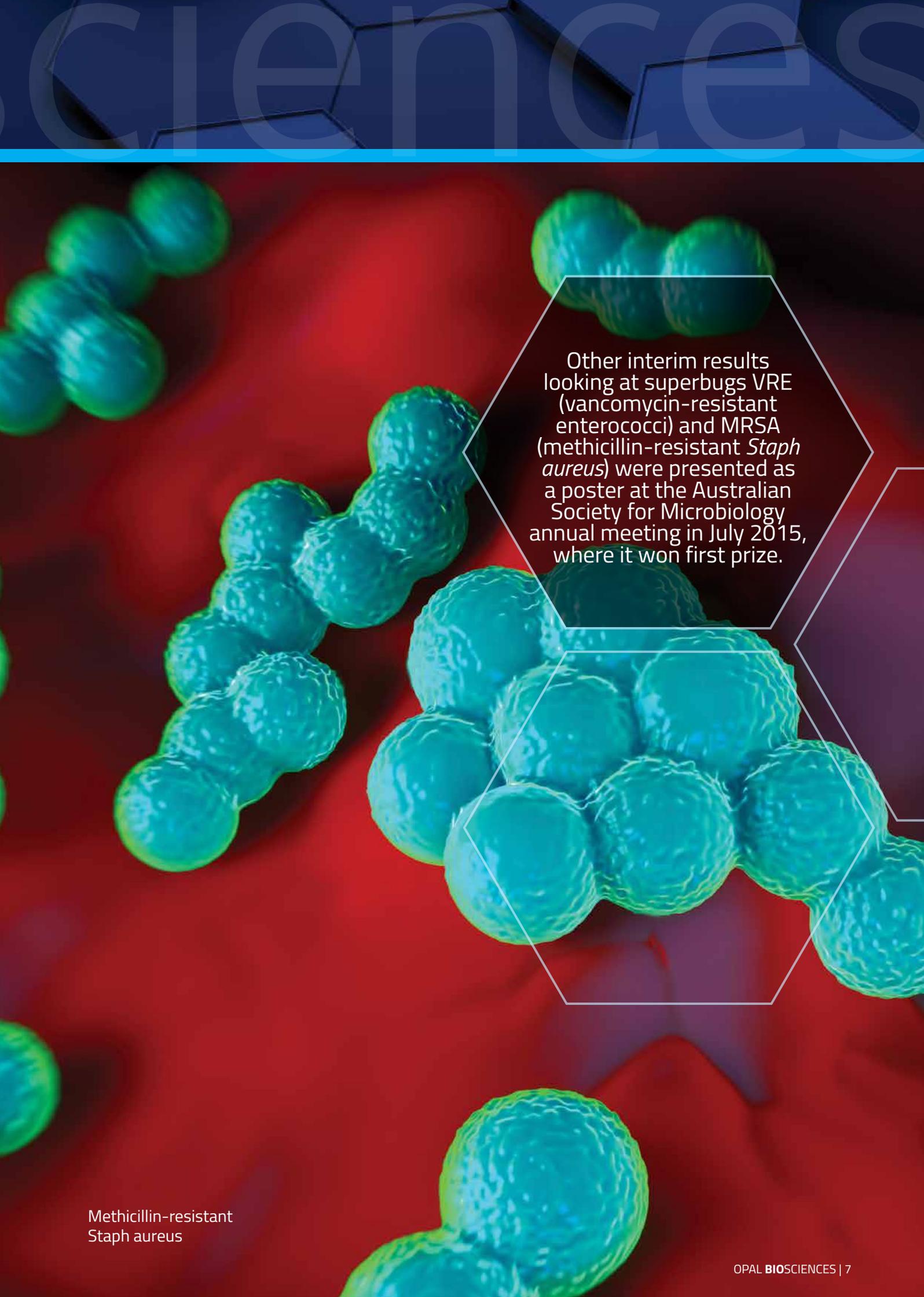
So we have a lot of work planned and are doing our best to access Australian and international grants to extend our program and leverage our limited resources. Expenditure is managed very tightly and we will continue to seek external investment to accelerate development. Nevertheless we are pleased with our progress in the circumstances and Opal's commercial potential particularly in the US where the financial incentives for antimicrobial developers are unequalled. We look forward to relating our progress through the coming year.

I thank you for your support.

Yours faithfully,

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

Hugh Morgan
Chairman



Other interim results looking at superbugs VRE (vancomycin-resistant enterococci) and MRSA (methicillin-resistant *Staph aureus*) were presented as a poster at the Australian Society for Microbiology annual meeting in July 2015, where it won first prize.

Methicillin-resistant
Staph aureus

A scanning electron micrograph (SEM) of Mycobacterium tuberculosis bacteria. The bacteria are rod-shaped and have a highly textured, wavy surface. They are arranged in a dense, overlapping cluster. The image is rendered in shades of yellow and green against a black background. Several white hexagonal outlines are overlaid on the image, framing the text and other elements.

BioDiem currently is in U.S. programs in which BDM-I has progressed to preclinical animal studies to assess its potential as a treatment for resistant tuberculosis (TB).

Mycobacterium
tuberculosis

Managing Director Letter

Fellow Shareholders,

The 2015-2016 year has seen progress with BDM-I, our antimicrobial being developed through BioDiem's subsidiary, Opal Biosciences Ltd.

Our Opal capital raising which commenced in May 2015 fell well short of our \$3.5m target, however notwithstanding this, with the support of BioDiem, we are pleased to have been able to progress the various forms of the antimicrobial:

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

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

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

Many Opal shareholders are also BioDiem shareholders. We were delighted with the recent BioDiem capital raising which saw the issue of preference shares and raised \$1.15m and my thanks go to those who participated.

BioDiem and Opal Biosciences are public unlisted companies. We have retained the Leydin Freyer group to provide a matching service for those wishing to buy and sell shares. Please contact our company secretary for more information on how to trade.

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

Yours sincerely,



Julie Phillips
Managing Director

Review of Operations

Antimicrobial BDM-I: Opal Biosciences ("Opal")

- Opals' preclinical antimicrobial compound BDM-I is being developed and commercialised to target the treatment of infections, including 'superbugs' that cause antibiotic-resistant serious human infections. The formation of Opal Biosciences in May 2015 as a subsidiary of BioDiem Limited, was undertaken to permit external investment in the development of BDM-I while allowing BioDiem shareholders to retain benefit from successful commercialisation.

Significant developments during the past year include:

- BioDiem Shareholder approval for the transfer of the BDM-I technology into Opal Biosciences was obtained in July 2015.
- Additional European and US patent claims granted for Opal Biosciences, targeting serious and treatment-resistant infections.
- BDM-I presented at the prestigious European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Amsterdam in April 2016. Western Sydney University (WSU) PhD candidate Michael Radzieta, presented "Investigating the Mechanism of Action of the Novel Antimicrobial BDM-I" and was part of the session "Discovery and novel developments in antibacterial drugs and drug potentiators".
- Mr Radzieta's PhD research arises from the collaboration between BioDiem and Western Sydney University's Antibiotic Resistance and Mobile Elements Group (ARMEG) led by Associate Professor Slade Jensen and located at the Ingham Institute for Applied Medical Research and Western Sydney University. This research focuses on BDM-I's activity against hospital pathogens such as MRSA (methicillin-resistant *Staphylococcus aureus* or "Golden Staph") and other superbugs. Results to date indicate that BDM-I's cellular target is novel and therefore BDM-I represents a next-generation anti-infective.
- Other interim results looking at superbugs VRE (vancomycin-resistant enterococci) and MRSA (methicillin-resistant *Staph aureus*) were presented as a poster at the Australian Society for Microbiology annual meeting in July 2015, where it won first prize.
- Opal-I (injectable) formulation development work has been initiated by an overseas specialist company to develop a suitable intravenous injection for the next stages of studies in animal models.
- Preliminary safety pharmacology and cytotoxicity studies continue to support the potential for Opal technologies to be used as future therapeutics.

- Commencement of early stage formulation development studies for Opal-T (the topical application of BDM-I). Opal-T could be used for superficial infections of the mucous membranes and skin infections such as tinea (athlete's foot) and candida (thrush).
- Commencement of early stage research studies for Opal-L (the lung delivery of BDM-I). Early feasibility studies of nanoparticle formation of BDM-I have led to discussions of a program for lung delivery of BDM-I with Prof Kim Chan, Professor of Pharmaceutics (Advanced Drug Delivery), University of Sydney. Grant funding for this program will be sought. Possible disease targets include life-threatening respiratory tract infections.
- In addition to the investigation being undertaken in the resistant tuberculosis and fungal programs, BDM-I was accepted into an updated program of the NIH¹ and showed activity against strains of VRE (vancomycin-resistant enterococci) and VRSA (vancomycin-resistant *Staph aureus*).

Commercial objective

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

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

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

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

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

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

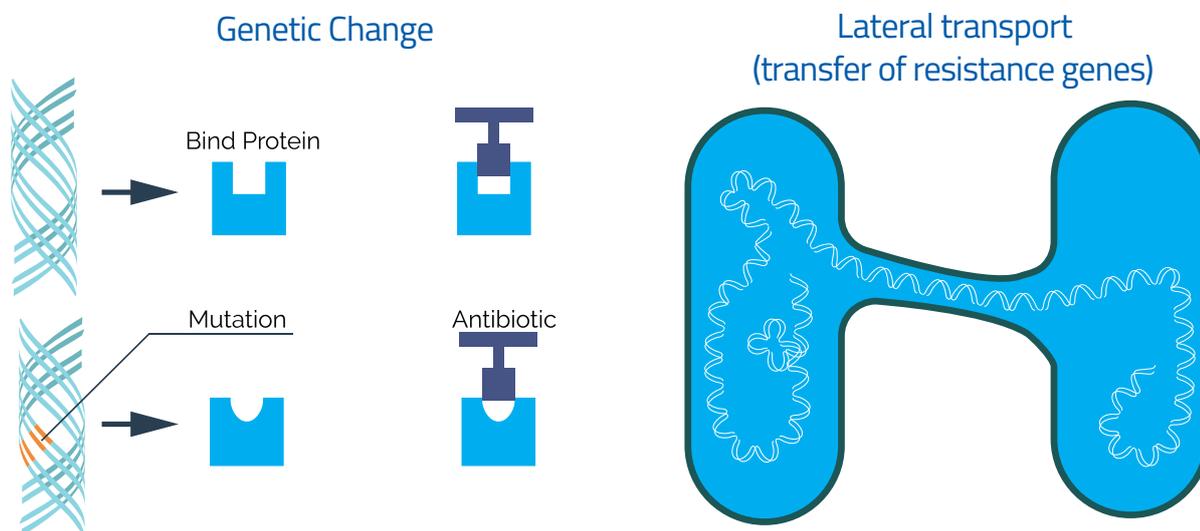
4 Few new treatments are in development. The lead time to develop any new drug is long, generally 12 or more years, and few new anti-infective drugs have been brought to market in the last 25 years.

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

² <http://www.cdc.gov/drugresistance/threat-report-2013/>

³ http://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

Acquired antibiotic resistance



OPAL's Development and Commercialisation Plan

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

US Incentives

The US is a key commercial target territory for Opal Biosciences to seek a partner. The US has instigated a series of incentives which would contribute significantly to the potential commercial success of an antimicrobial development program. As in the UK and Europe, the US recognizes the seriousness of the rise in antibiotic resistance. Already, 23,000 people die yearly directly from antibiotic-resistant bacterial infections in the U.S. and more than 2 million fall ill, according to the Centers for Disease Control².

But as many as 10 million people a year could die from antimicrobial-resistant infections worldwide by 2050 if there is a continued rise in resistance and new treatments are not discovered, according to a recent report from the Review on Antimicrobial Resistance³.

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

Relevant US Incentives now in place include:

1 The GAIN (Generating Antibiotic Incentives Now) Legislation: was passed in 2012 to help to stimulate the development of new antimicrobials. The law allows the FDA to designate certain antimicrobials as “Qualified Infectious Disease Products” (QIDPs), which allows for priority review and possible fast-track status. The designation also provides sponsors with an extra 5 years of market exclusivity. To date, FDA has granted 107 QIDP designations for 63 different unique molecules⁴.

2 FDA’s Priority Review: A Priority Review designation means FDA’s goal is to take action on an application within 6 months (compared to 10 months under standard review). The FDA has approved five new antibacterial drugs and one new antifungal since the GAIN Act’s passage. Three of the five antibacterials are for acute skin and skin-structure infections caused by methicillin-resistant *Staphylococcus aureus* and certain other pathogens; the other two are for complicated urinary tract and intra-abdominal infections⁴.

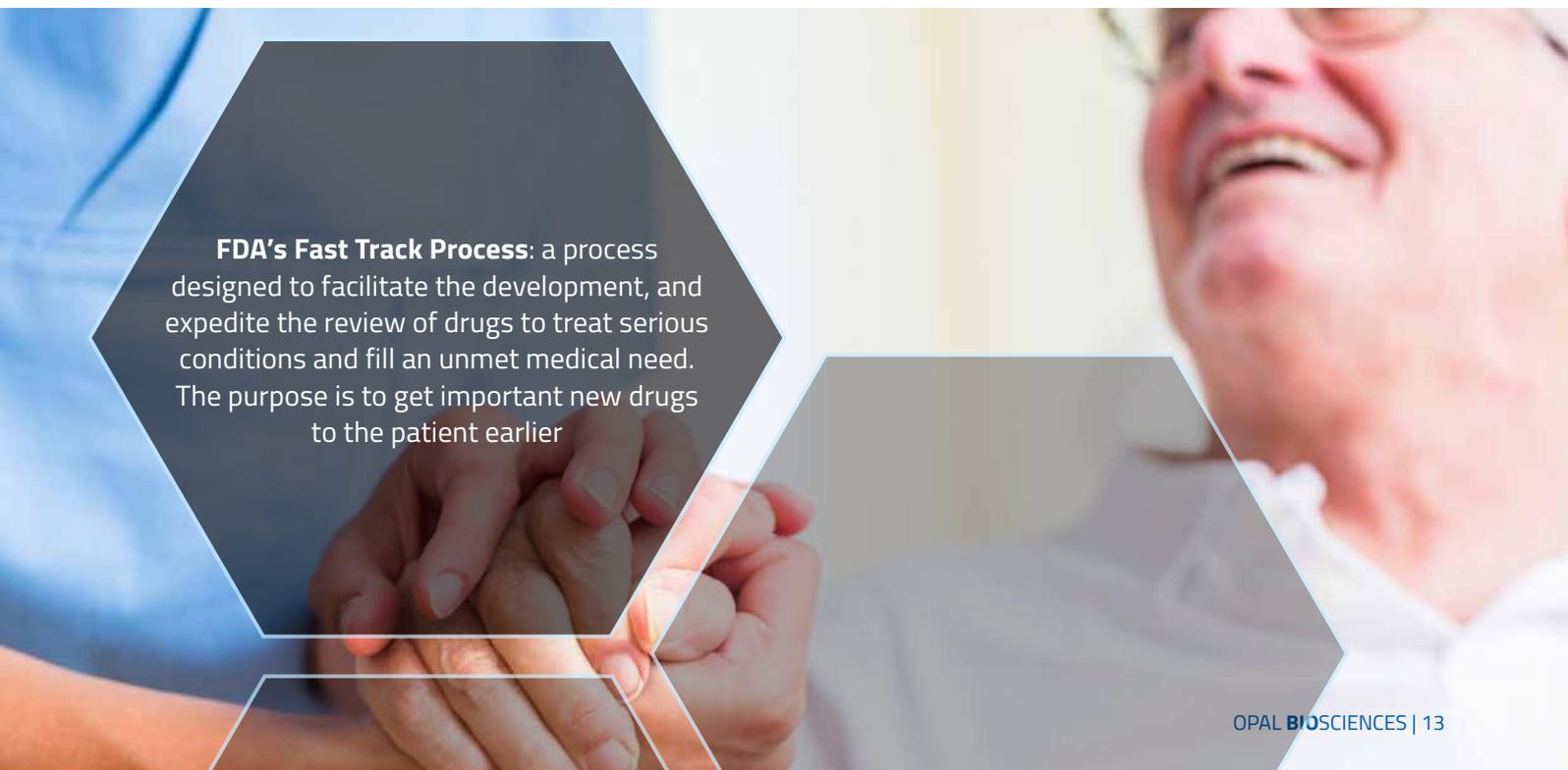
3 Orphan Drug designation: qualifies the sponsor of the drug for various development incentives, including tax credits and extended market exclusivity. This would apply to rare life-threatening infections such as respiratory infection by *Scedosporium* or other fungal species.

4 FDA’s Fast Track Process: a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. There are opportunities for frequent interactions with the review team for a fast track product. These include meetings with FDA, including pre-IND meetings, end-of-phase 1 meetings, and end-of-phase 2 meetings to discuss study design, extent of safety data required to support approval, dose-response concerns, and use of biomarkers. Other meetings may be scheduled as appropriate (e.g., to discuss accelerated approval, the structure and content of an NDA, and other critical issues).⁵

⁴<http://www.cidrap.umn.edu/news-perspective/2016/06/feds-detail-range-steps-limit-antibiotic-resistance>

⁵ <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>

⁶ <http://www.niaid.nih.gov/labsandresources/resources/dmid/animalmodels/Pages/default.aspx>



FDA’s Fast Track Process: a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier



Mr Radzieta's PhD research arises from the collaboration between BioDiem and Western Sydney University's Antibiotic Resistance and Mobile Elements Group (ARMEG) led by Associate Professor Slade Jensen and located at the Ingham Institute for Applied Medical Research and Western Sydney University.

Relevance to BDM-I

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

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

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

BioDiem currently has agreements with the U.S. Army Medical Research Institute of Infectious Diseases (*USAMRIID*) to assess its potential as a biological weapons counter-measure, and with the U.S. National Institute of Allergy and Infectious Diseases (NIAID) in which BDM-I has progressed to preclinical animal studies to assess its potential as a treatment for the fungal disease, pneumocystosis and tuberculosis infection. The later studies are conducted under the U.S. National Institute of Allergy and Infectious Diseases' (NIAID's) preclinical services program Animal Models of Infectious Disease Service⁶. Our intravenous formulation work and other necessary precursor studies are intended to lead to conduct of the proof of concept studies.

Opal development plan includes

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

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

United Nations high-level meeting on antimicrobial resistance



Antimicrobial resistance (AMR) has become one of the biggest threats to global health and endangers other major priorities, such as human development. All around the world, many common infections are becoming resistant to the antimicrobial medicines used to treat them, resulting in longer illnesses

and more deaths. At the same time, not enough new antimicrobial drugs, especially antibiotics, are being developed to replace older and increasingly ineffective ones.

Global leaders will meet at the United Nations General Assembly in New York in September 2016 to commit to fighting antimicrobial resistance together. This is only the fourth time in the history of the UN that a health topic is discussed at the General Assembly (HIV, noncommunicable diseases, and Ebola were the others). Heads of State and Heads of Delegations are expected to address the seriousness and scope of the situation and to agree on sustainable, multisectoral approaches to addressing antimicrobial resistance.

Financial Report – Table of Contents

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Directors' Report

The directors present their report, together with the financial statements, on the company for the period ended 30 June 2016.

Directors

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

Mr Hugh M Morgan AC (appointed 4 May 2015)

Ms Julie Phillips (appointed 4 May 2015)

Prof Larisa Rudenko (appointed 4 May 2015)

Principal activities

During the financial period the principal activity of the company consisted of the development and commercialisation of pharmaceutical and biomedical research.

Dividends

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

Review of operations

The loss for the company after providing for income tax amounted to \$24,591.

Significant changes in the state of affairs

During the period Opal Biosciences issued 10,000,000 ordinary shares to BioDiem Limited in accordance with the resolution proposed at the BioDiem General Meeting on 6 July 2015, in which shareholders approved the assignment of the BDM-I technology to Opal.

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

There were no other significant changes in the state of affairs of the company during the financial period.

Matters subsequent to the end of the financial period

No matter or circumstance has arisen since 30 June 2016 that has significantly affected, or may significantly affect the company's operations, the results of those operations, or the company's state of affairs in future financial years.

Likely developments and expected results of operations

Information on likely developments in the operations of the company and the expected results of operations have not been included in this report because the directors believe it would be likely to result in unreasonable prejudice to the company.

Environmental regulation

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

Meetings of directors

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

| | Full Board | |
|---------------------|------------|------|
| | Attended | Held |
| Mr Hugh M Morgan AC | 2 | 2 |
| Ms Julie Phillips | 2 | 2 |
| Prof Larisa Rudenko | 2 | 2 |

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

Shares under option

There were no unissued ordinary shares of the company under option outstanding at the date of this report.

Shares issued on the exercise of options

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

Indemnity and insurance of officers

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

During the financial period, 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 period, indemnified or agreed to indemnify the auditor of the company or any related entity against a liability incurred by the auditor.

During the financial period, the company has not paid a premium in respect of a contract to insure the auditor of the company or any related entity.

Proceedings on behalf of the company

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

Auditor's independence declaration

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

Auditor

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



Mr Hugh M Morgan AC

Director

28 September 2016

Auditor's independence declaration



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Auditor's Independence Declaration To the Directors of Opal Biosciences Limited

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the audit of Opal Biosciences Limited for the period ended 30 June 2016, I declare that, to the best of my knowledge and belief, there have been:

- a no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the audit; and
- b no contraventions of any applicable code of professional conduct in relation to the audit.

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

M. A. Cunningham
Partner - Audit & Assurance

Melbourne, 28 September 2016

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Statement of profit or loss and other comprehensive income

For the period ended 30 June 2016

| | Note | 30 June 2016 \$ |
|--|------|--------------------|
| Expenses | | |
| Administration | | (165) |
| Research and development | | (24,426) |
| Loss before income tax expense | | (24,591) |
| Income tax expense | 4 | - |
| Loss after income tax expense for the period attributable to the owners of Opal Biosciences Limited | | (24,591) |
| Other comprehensive income for the period, net of tax | | - |
| Total comprehensive income for the period attributable to the owners of Opal Biosciences Limited | | (24,591) |

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

Statement of financial position

For the period ended 30 June 2016

| | Note | 30 June 2016 \$ |
|-----------------------------|------|--------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | 5 | 78,421 |
| Total current assets | | 78,421 |
| Total assets | | 78,421 |
| Liabilities | | |
| Total liabilities | | - |
| Net assets | | 78,421 |
| Equity | | |
| Issued capital | 6 | 103,012 |
| Accumulated losses | | (24,591) |
| Total equity | | 78,421 |

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

Statement of changes in equity

For the period ended 30 June 2016

| | Issued capital \$ | Accumulated losses \$ | Total equity \$ |
|--|-------------------------|-----------------------------|-----------------------|
| Balance at 4 May 2015 | - | - | - |
| Loss after income tax expense for the period | - | (24,591) | (24,591) |
| Other comprehensive income for the period, net of tax | - | - | - |
| Total comprehensive income for the period | - | (24,591) | (24,591) |
| <i>Transactions with owners in their capacity as owners:</i> | | | |
| Contributions of equity, net of transaction costs (note 7) | 103,012 | - | 103,012 |
| Balance at 30 June 2016 | 103,012 | (24,591) | 78,421 |

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

Statement of cash flows

For the period ended 30 June 2016

| | Note | 30 June 2016 \$ |
|--|------|--------------------|
| Cash flows from operating activities | | |
| Payments to suppliers and employees (inclusive of GST) | | (24,591) |
| Net cash used in operating activities | 11 | (24,591) |
| Cash flows from investing activities | | |
| Net cash from investing activities | | - |
| Cash flows from financing activities | | |
| Proceeds from issue of shares | 6 | 103,012 |
| Net cash from financing activities | | 103,012 |
| Net increase in cash and cash equivalents | | 78,421 |
| Cash and cash equivalents at the beginning of the financial period | | - |
| Cash and cash equivalents at the end of the financial period | 5 | 78,421 |

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

Notes to the financial statements

Note 1. General information

The financial statements cover Opal Biosciences Limited as an individual entity. The financial statements are presented in Australian dollars, which is Opal Biosciences Limited's functional and presentation currency.

Opal Biosciences 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 company's operations and its principal activities are included in the directors' report, which is not part of the financial statements.

Opal Biosciences Limited was incorporated on 4 May 2015. These financial statements are included all the financial results from the date of incorporation to balance date which is a period of greater than twelve months.

The financial statements were authorised for issue, in accordance with a resolution of directors, on 28 September 2016. The directors have the power to amend and reissue the financial statements.

Note 2. Significant accounting policies

The principal accounting policies adopted in the preparation of the financial statements are set out below.

New, revised or amending Accounting Standards and Interpretations adopted

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

Any new, revised or amending Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

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.

Critical accounting estimates

The preparation of the financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the company's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed in note 3.

Income tax

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

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

- When the deferred income tax asset or liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting nor taxable profits; or
- When the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, and the timing of the reversal can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

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

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

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

Current and non-current classification

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

An asset is classified as current when: it is either expected to be realised or intended to be sold or consumed in the company'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 company'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.

Fair value measurement

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

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

Issued capital

Ordinary shares are classified as equity.

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

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

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

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

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

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

New Accounting Standards and Interpretations not yet mandatory or early adopted

Australian Accounting Standards and Interpretations that have recently been issued or amended but are not yet mandatory, have not been early adopted by the company for the annual reporting period ended 30 June 2016. The company has assessed the impact of these new or amended Accounting Standards and Interpretations, and determined that none are likely to have a material impact on the financial statements.

Note 3. Critical accounting judgements, estimates and assumptions

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements, estimates and assumptions on historical experience and on other various factors, including expectations of future events, management believes to be reasonable under the circumstances. There are no critical accounting judgements, estimates and assumptions that are likely to affect the current or future financial years.

Note 4. Income tax expense

| | 30 June 2016 |
|--|--------------|
| | \$ |
| Numerical reconciliation of income tax expense and tax at the statutory rate | |
| Loss before income tax expense | (24,591) |
| Tax at the statutory tax rate of 30% | (7,377) |
| Current period temporary differences not recognised | 7,377 |
| Income tax expense | - |

Note 5. Current assets - cash and cash equivalents

| | 30 June 2016 |
|--------------|--------------|
| | \$ |
| Cash at bank | 78,421 |

Note 6. Equity - issued capital

| | 30 June 2016 | |
|------------------------------|--------------|-----------|
| | Shares | \$ |
| Ordinary shares - fully paid | 10,515,012 | 2,103,012 |

Movements in ordinary share capital

| Details | Date | Shares | Issue price | \$ |
|-----------------|-------------------|------------|-------------|---------|
| Issue of shares | 4 May 2015 | 12 | \$1.00 | 12 |
| Issue of shares | 6 July 2015 | 10,000,000 | \$0.00 | - |
| Issue of shares | 22 July 2015 | 477,500 | \$0.20 | 95,500 |
| Issue of shares | 23 September 2015 | 37,500 | \$0.20 | 7,500 |
| Balance | 30 June 2016 | 10,515,012 | | 103,012 |

Ordinary shares

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

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

Capital risk management

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

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

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

Note 7. Equity - dividends

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

Note 8. Financial instruments

Financial risk management objectives

The company's activities expose it to a variety of financial risks: market risk (including foreign currency risk, price risk and interest rate risk), credit risk and liquidity risk. The Company's overall risk management program focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the financial performance of the Company. The Company uses different methods to measure different types of risk to which it is exposed. These methods include sensitivity analysis in the case of interest rate, foreign exchange and other price risks, ageing analysis for credit risk and beta analysis in respect of investment portfolios to determine market risk.

Risk management is carried out by the Board. The policies employed to mitigate risk include identification and analysis of the risk exposure of the Company and appropriate procedures, controls and risk limits. The Board identifies risk and evaluates the effectiveness of its responses.

The company is not subject to any significant financial risks as at balance date.

Note 9. Related party transactions

Parent entity

BioDiem Limited is the parent entity.

Transactions with related parties

Other than the issue of shares to the parent entity as detailed in Note 6, there were no transactions with related parties during the financial period.

Receivable from and payable to related parties

Refer to Note 6 for details of receivable from related parties.

Loans to/from related parties

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

Note 10. Events after the reporting period

No matter or circumstance has arisen since 30 June 2016 that has significantly affected, or may significantly affect the company's operations, the results of those operations, or the company's state of affairs in future financial years.

Note 11. Reconciliation of loss after income tax to net cash used in operating activities

| | 30 June 2016 |
|--|--------------|
| | \$ |
| Loss after income tax expense for the period | (24,591) |
| Net cash used in operating activities | (24,591) |

Directors' declaration

For the period ended 30 June 2016

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 company's financial position as at 30 June 2016 and of its performance for the financial period 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



Mr Hugh M Morgan AC
Director

28 September 2016

Independent auditor's report

to the members of Opal Biosciences Limited



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INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF OPAL BIOSCIENCES LIMITED

We have audited the accompanying financial report of Opal Biosciences Limited (the Company), which comprises the statement of financial position as at 30 June 2016, the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, notes comprising a summary of significant accounting policies and other explanatory information and the directors' declaration of the Company.

Directors' Responsibility for the Financial Report

The Directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001*. The Directors' responsibility also includes such internal control as the Directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error. The Directors also state, in the notes to the financial report, in accordance with Accounting Standard AASB 101 *Presentation of Financial Statements*, the financial statements comply with International Financial Reporting Standards.

Auditor's Responsibility

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

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

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Independent auditor's report to the members of Opal Biosciences Limited



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

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

Independence

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

Auditor's Opinion

In our opinion:

- a the financial report of Opal Biosciences Limited is in accordance with the *Corporations Act 2001*, including:
 - i giving a true and fair view of the Company's financial position as at 30 June 2016 and of its performance for the year ended on that date; and
 - ii complying with Australian Accounting Standards and the *Corporations Regulations 2001*; and
- b the financial report also complies with International Financial Reporting Standards as disclosed in the notes to the financial statements.



GRANT THORNTON AUDIT PTY LTD
Chartered Accountants



M.A. Cunningham
Partner - Audit & Assurance

Melbourne, 28 September 2016

Corporate directory

Directors

Mr Hugh M Morgan AC
Ms Julie Phillips
Prof Larisa Rudenko

Company secretary

Melanie Leydin

Registered office

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

Principal place of business

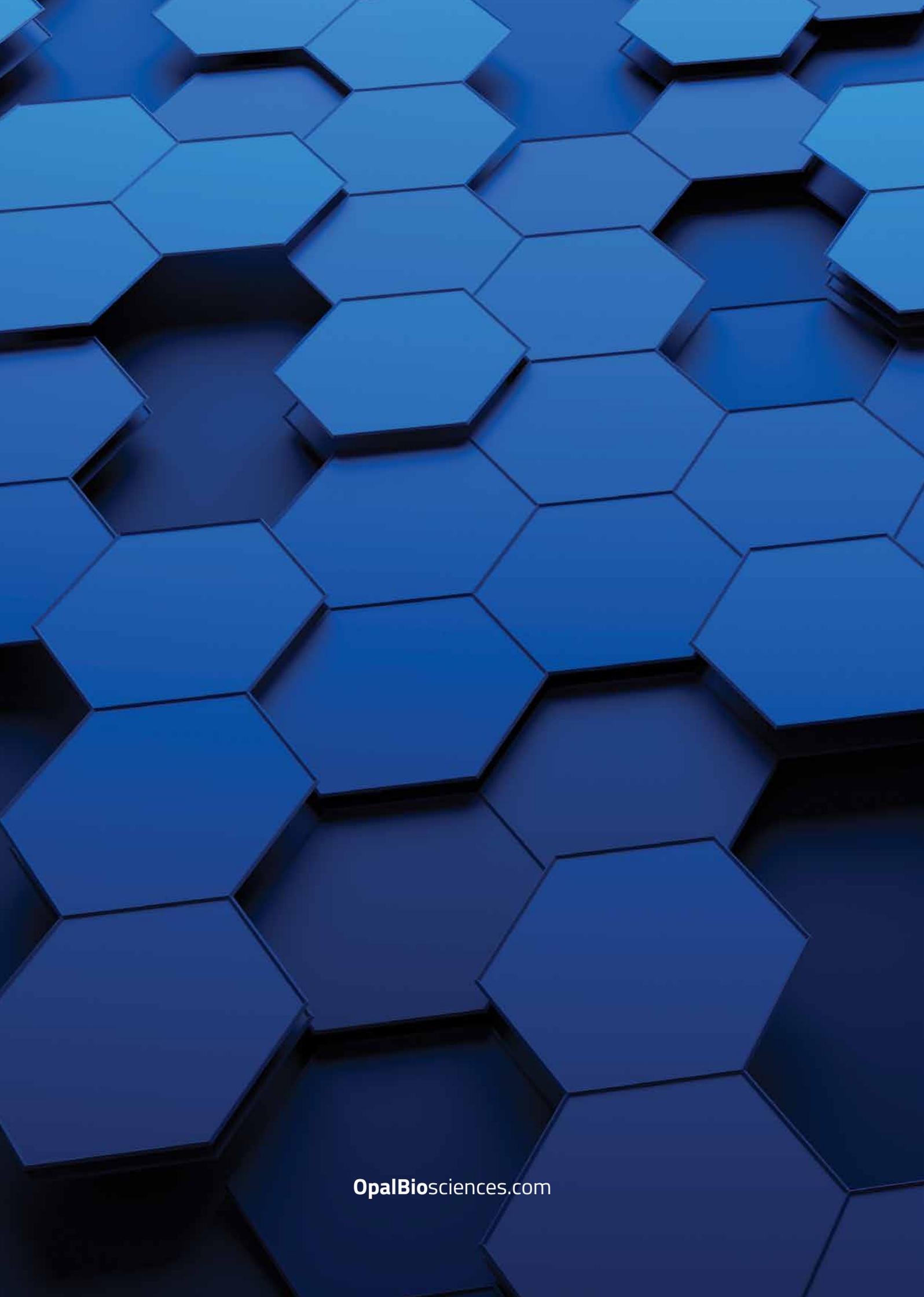
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