Opal Biosciences Limited | ABN 97 605 631 963

INFORMATION MEMORANDUM 2018

For the capital raising of $1.5m through the issue of 6,000,000 shares at $0.25 (25 cents) per share (with the possible issue of a further 4,000,000 shares at $0.25 (25 cents) per share to raise up to a further $1.0m to satisfy over-subscriptions) and the issue of up to 10,000,000 options with an exercise price of $0.25 (25 cents), expiring on 2nd October 2020. The Opal Biosciences Information Memorandum is issued by Opal Biosciences Ltd ACN 605 631 963.

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Important Notice

This information memorandum is dated 19 July 2018.

This information Memorandum has been prepared by Opal Biosciences Limited ("Opal") for the purpose of providing certain financial and business information to potential investors on a private and confidential basis for use solely in connection with their consideration of investing in 6,000,000 fully paid ordinary shares in Opal Biosciences Limited at an issue price of $0.25 (25 cents) per share to raise $1,500,000 with the possibility of a further issue of up to 4,000,000 fully paid ordinary shares at an issue price of $0.25 (25 cents) per share to satisfy over-subscriptions. Opal will also issue 1 option for every 1 share subscribed, to applicants whose valid application forms together with all application money are received on or prior to 2nd October 2018, and prior to the offer closing. The maximum number of options Opal will issue assuming the maximum over-subscription amount is also achieved and all applications are received prior to 2nd October 2018 is 10,000,000. The option exercise price is $0.25 (25 cents) and the option expiry date is 2nd October 2020.

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This Information Memorandum does not purport to be all inclusive or contain all of the information which its recipients may require in order to make an informed assessment of whether to invest in Opal. Accordingly, this Information Memorandum does not take into account the investment objectives, financial situation and particular needs of the individual investor. Before making an investment in Opal, the investor, or prospective investor, should consider whether such an investment is appropriate to their particular investment needs, objectives and financial circumstances and consult an investment, tax or legal adviser if necessary.

This Information Memorandum contains forward looking statements. Statements about Opal's future operations, projections and forecasts are based on assumptions about future events and management actions which may not necessarily take place and are subject to uncertainties which may be outside the control of Opal. Opal makes no guarantees, representations or warranties regarding whether projections or forecasts will be achieved or whether they represent the most likely outcomes.

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Antibiotic resistance
leads to longer hospital stays, higher medical costs and increased mortality

http://www.who.int/mediacentre/factsheets/antibiotic-resistance/en/

1 Executive Summary

Under this Offer, Opal Biosciences Limited ("Opal") seeks to raise A$1,500,000 by the issue of 6,000,000 fully paid ordinary shares ("Shares") to support the next stage of development of its technology. Opal reserves the right to accept over-subscriptions for up to a further 4,000,000 Shares at an issue price of $0.25 (25 cents) per share to raise up to a further $1,000,000. Opal will also issue 1 option for every 1 Share subscribed (including over subscriptions), to applicants whose valid application forms together with all application money are received on or prior to 2nd October 2018, and prior to the offer closing. The maximum number of options Opal will issue assuming the maximum over-subscription amount is also achieved and all applications are received prior to 2nd October 2018 is 10,000,000. The option exercise price is A$0.25 (25 cents) and the option expiry date is 2nd October 2020.

Opal was formed to develop and commercialise the BDM-I technology which targets the treatment of infections, primarily serious human infections.

Its main asset is the intellectual property and know-how relating to its patented proprietary anti-infective molecule, BDM-I. BDM-I has shown activity against many micro-organisms responsible for causing serious human infections, including those which are resistant to commonly used antibiotics[1]. Antibiotic resistance is creating many problems worldwide[2].

Since the introduction of penicillin more than 20 new classes of antibiotics have been introduced, however since 1962, only two new classes have reached the market[3]. Opal's BDM-I is the first in a new class: it is novel and is patented.

Opal's approach is to target infections

- where antibiotics are becoming less effective
- which are of greatest concern internationally; and
- where BDM-I has shown activity[1] against known resistant bacteria and infections.

To date, BDM-I has been screened against many disease-causing micro-organisms and activity has been found for some bacteria which are resistant to currently used antibiotics[1].

Recent news of the spread of an antibiotic-resistant strain of the sexually-transmitted infection (STI) gonorrhoea[4], and the successful screening of BDM-I against a panel of antibiotic-resistant strains of *Neisseria gonorrhoea* has led Opal to prioritise this STI as a target disease for BDM-I's development.

The CDC in Atlanta has rated the "Threat Level" of drug-resistant *Neisseria gonorrhoea* as URGENT. This is the highest level in the "Current Antibiotic resistance Threats in the US" report[5]. Drug-resistant gonorrhoea is also one of 12 bacteria on the WHO Priority Pathogens List for R&D of New Antibiotics (2017)[6].

1. Data on file from work commissioned from independent laboratories including Ingham Institute for Medical Research, Centre for Infectious Diseases and Microbiology, National Institutes of Health (NIAID) and Eurofins Cerep Panlabs (Taiwan).
2. https://www.cdc.gov/antibiotic-use/community/about/antibiotic-resistance-faqs.html
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3085877/pdf/bph0163-0184.pdf
4. http://www.health.gov.au/internet/main/publishing.nsf/Content/mr-yr18-dept-dept004.htm
5. https://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf#page=49
6. http://www.who.int/medicines/publications/WHO-PPL-Short_Summary_25Feb-ET_NM_WHO.pdf?ua=1

To further this development work, Opal is raising funds to continue development of BDM-I as

- an injectable (Opal-I) product candidate; and also
- a topical (Opal-T) product candidate.

The BDM-I anti-infective is in a high growth commercially attractive market segment due to the recognised need for new antibiotics and antibiotic alternatives. The global infectious disease therapeutics market size was valued at USD 46.88 billion in 2016 and is projected to grow at a CAGR of 6.6% during the 2018-2025 period[7], with the gonorrhoea therapeutics market predicted to reach USD 5.6bn by 2021[8].

Opal is well positioned to provide investors with potential returns for the following reasons:

- **Large and growing market**

  The market for successful anti-infectives is large and growing due to the emergence of germs with resistance to many antibiotics, and the recognition of the need to curb use of antibiotics where possible[7].

- **Few competitors**

  The pipeline for potential competitor anti-infective drugs in development is weak compared to other diseases[14]. Following the success of the introduction of antibiotics in the last century, investment in new research declined and antibiotics research teams were wound back in favour of those focused on non-communicable diseases[15].

- **Development incentives and government policy (see**

  International incentives (see page 17) are aimed at assisting companies who are developing anti-infective products to reduce risk, time and development costs.

- **Opal technology's potential**

  Opal's BDM-I technology has already demonstrated significant activity against some of the highest threat bacteria where there is a need for new treatments. Product development of injectable and topical presentations has already commenced. An extensive Australian and international team is already involved in Opal's development program, including Western Sydney University; Griffith University; University of Technology Sydney; formulation expert company, Formulytica Pty Ltd; various US and European specialist development companies; and a number of US government-funded institutions.

The BDM-I technology (Opal-I and Opal-T) is in a high growth commercially attractive market segment of much needed new anti-infectives. The development path of the BDM-I based products assumes progress towards FDA approval and product launch. This will allow marketing by Opal Biosciences Ltd or through distributors or licencees. Opal would also consider sale, co-development or outlicence of the technology to a larger partner.

This Offer represents an opportunity for investors to acquire a shareholding at a pivotal stage of Opal's growth.

7. https://www.grandviewresearch.com/industry-analysis/infectious-disease-therapeutics-market
8. https://www.technavio.com/report/global-gonorrhea-therapeutics-market

Opal technology has the potential to provide a range of treatments for serious infections, some of which could be life-saving. The team behind the development of this technology is dedicated to making this a reality for future patients and to reward investors by the development of a successful Opal technology franchise.

Table One: Summary of the offer, key features and dates

Profile	
Company name	Opal BioSciences Ltd ACN 605 631 963.
Share Issue Price	A$0.25 (25 cents)
Investment amount	A$1,500,000
Maximum oversubscription amount	A$1,000,000
Options to be issued	1 option for every 1 Share subscribed to be issued to applicants whose valid application forms together with all application money are received on or prior to 2nd October 2018. The maximum number of options Opal will issue (including over subscriptions) is 10,000,000. The option exercise price is A$0.25 (25 cents) and the option expiry date is 2nd October 2020.
Maximum Total shares on issue	39,075,012 post capital raising on a fully diluted basis (assuming the maximum oversubscription amount is also achieved and all applications are received prior to 2nd October 2018)
Indicative Offer Timetable	
Opens	19th July 2018
Closes	2nd October 2018 or earlier if subscriptions are received up to the maximum oversubscription amount

Figure 1: International Incentives for Antibiotic R&D

- World Health Organisation's Global Antibiotic R&D Partnership (**GARDP**)
- Re-investment in R&D and Responsible Antibiotic Use **DRIVE-AB**
- Joint Programming Initiative On Antimicrobial Resistance (**JPIAMR**)
- Innovative Medicine's Initiative (**IMI's**) New Drugs for Bad Bugs (**ND4BB**)
- Transatlantic Task Force on Antimicrobial Resistance (**TATFAR**)
- US Generating Antibiotic Incentives Now Act (**GAIN Act**)
- Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (**CARB-X**)
- US Biomedical Advanced Research and Development Authority's (**BARDA's**) Broad Spectrum Antimicrobials program

2 Key Features of This Offer

2.1 Overview

This summary is not intended to provide full information on the Shares described in this Information Memorandum. Before deciding to apply for Shares this Information Memorandum and the Constitution of Opal should be read in their entirety.

Opal is a public company focused on development of products targeting treatment of serious human infections. Its main asset is the intellectual property and know-how relating to its novel proprietary anti-infective molecule, BDM-I. BDM-I has shown activity against many micro-organisms responsible for causing serious human infections, including those which are resistant to commonly used antibiotics.

Opal was incorporated in May 2015 and is based in Melbourne, Australia. Opal is a subsidiary of BioDiem Limited and owns intellectual property rights to a novel anti-infective compound, BDM-I. Opal seeks to raise $1.5m in equity funding to continue development BDM-I.

Emergence of micro-organisms which are resistant to antibiotic treatment is creating many problems worldwide. It is highlighting the need for new treatments for infections.

Between 1940 and 1962, more than 20 new classes of antibiotics were introduced, however since then, only two new classes have reached the market[9]. Opal's BDM-I is novel and is patent-protected.

Opal's approach is to target infections

- where antibiotics are becoming less effective
- which are of greatest concern internationally (see Figure 2); and
- where BDM-I has shown activity[1] (see Figure 3) against known resistant bacteria and infections.

To date, BDM-I has been screened against many disease-causing micro-organisms and activity has been shown against some responsible for infections of the bloodstream, genitourinary tract, respiratory tract, skin and gastrointestinal tract (see Figure 3). BDM-I activity has been found for some bacteria which are resistant to currently used antibiotics.

Recent news[5] of the spread of an antibiotic-resistant strain of the sexually-transmitted infection (STI) gonorrhoea, and the successful screening of BDM-I against a panel of antibiotic-resistant strains of *Neisseria gonorrhoea* has led Opal to prioritise this STI as a target disease for BDM-I's development.

The CDC in Atlanta has rated the "Threat Level" of drug-resistant Neisseria gonorrhoea as URGENT. This is the highest level in the "Current Antibiotic resistance Threats in the US" report[10]. Drug-resistant gonorrhoea is also one of 12 bacteria on the WHO Priority Pathogens List for R&D of New Antibiotics (2017)[11].

Figure 2: Antibiotic Resistance Threats in the US 2013

Antibiotic Resistance Threats per CDC Report 2013†

⚠ 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 β-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*

†Antibiotic Resistance Threats in the US 2013, US DHHS CDC, April 2013
**BDM-I has shown activity against (some strains of) Fluconazole-resistant Candida*

New anti-infectives

⚠ The current market needs new anti-infectives. There are few <u>new</u> 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

BDM-I shows activity against other micro-organsims affecting the urogenital tract including *Trichomonas vaginalis*, *Candida albicans* and *Candida glabrata*. Screening for activity against chlamydia is currently being undertaken.

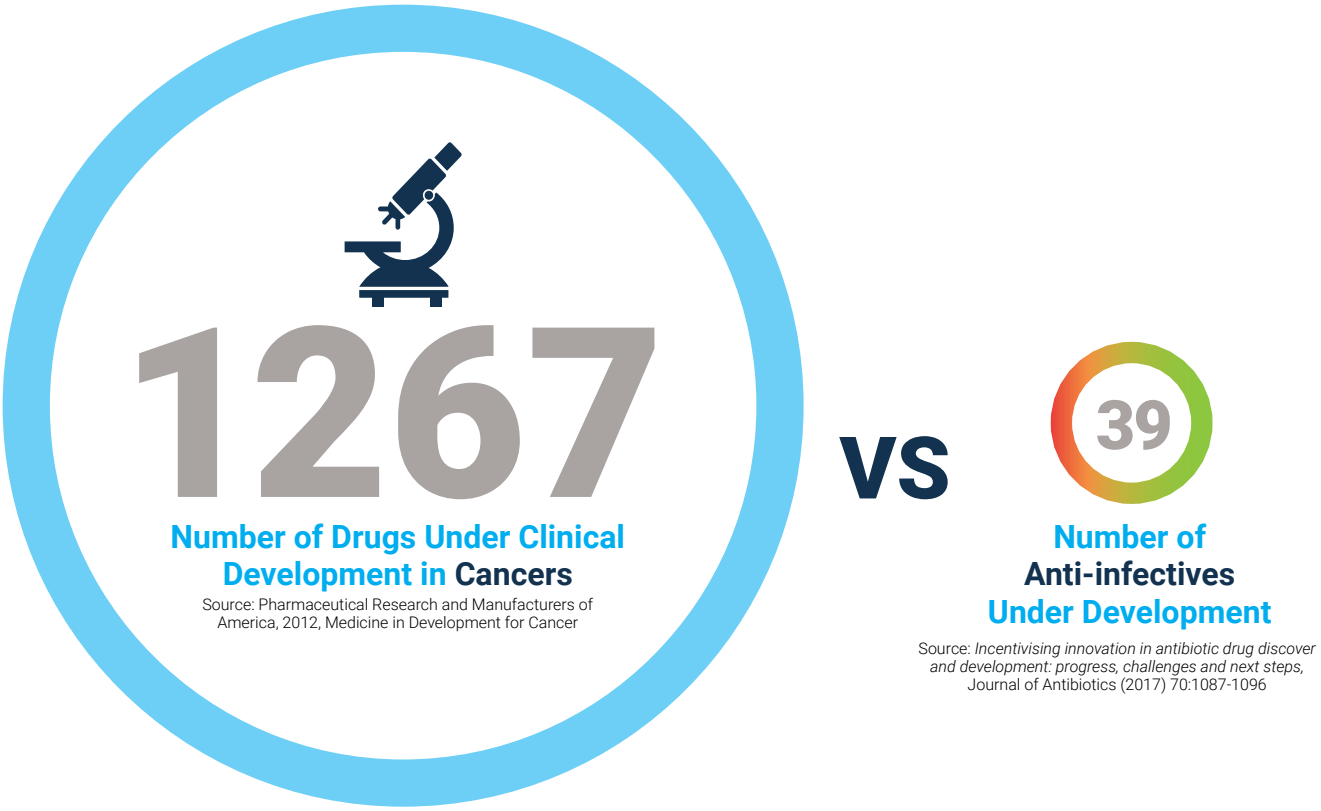
To further this work, Opal is raising funds to continue development of BDM-I as

- an injectable (Opal-I) product development candidate; and also
- a topical (Opal-T) product development candidate.

Because of the high level of threat from resistant infections, international development assistance programs exist for the development of new classes of anti-infective medicines. These public health and government-subsidised programs result from the recognised importance of developing new treatments for antibiotic-resistant infections. Opal is seeking access to these programs where appropriate.

The BDM-I anti-infective is in a high growth commercially attractive market segment due to the recognised need for new antibiotics and antibiotic alternatives. The global infectious disease therapeutics market size was valued at USD 46.88 billion in 2016 and is projected to grow at a CAGR of 6.6% during the 2018-2025 period[12], with the gonorrhoea therapeutics market predicted to reach US$5.6bn by 2021[13].

The development path of Opal's BDM-I-based products assumes development progress towards FDA approval and product launch. This would allow marketing by Opal or through distributors or licencees. Opal would also consider sale, co-development or outlicence of the technology to a larger partner.



[12] https://www.grandviewresearch.com/industry-analysis/infectious-disease-therapeutics-market
[13] https://www.technavio.com/report/global-gonorrhea-therapeutics-market

Figure 3: Examples of Opal's Infection Targets (where BDMI has shown activity *in vitro* studies including in antibiotic-resistant strains)

Infection	Cause (Microorganism)	BDM-I activity (*in vitro*)
Fungal (serious) infection	*Scedosporium prolificans, Aspergillus fumigatus, Cryptococcus spp and others*	✔
Tuberculosis	*Mycobacterium tuberculosis (including resistant TB)*	✔
Upper & lower respiratory tract infection	*Pneumocystis (carinii), Haemophilus influenza*	✔
Sexually transmitted infection	*Neisseria gonorrhoea, Candida spp, Trichomonas vaginalis*	✔
Gastrointestinal infection	*Campylobacter jejunii*	✔
Invasive, urogenital infection	*Candida glabrata*	✔
Wound infection	*Staph aureus (MRSA)*	✔

2.2 Offer Under This Information Memorandum

This Offer is for the subscription of Shares and the issue of Options in Opal.

If the investment amount of $1.5million is raised prior to 2nd October 2018, the new shareholders will own 38.62% of the fully diluted capital of Opal, with BioDiem owning 40.23%. If the maximum oversubscription amount of $1.0m is also raised prior to 2nd October 2018, the new shareholders will own 51.18% of the fully diluted capital of Opal, with BioDiem owning 31.99%.

The Offer is open from 19th July 2018 and will close on 2nd October 2018 or earlier if the maximum oversubscription amount has been fully subscribed. These dates are indicative only and Opal reserves the right to change the dates, including to close the Offer early without prior notice or to accept applications after the closing date.

Terms of Options

Opal will issue 1 Option for every 1 Share subscribed, to applicants whose valid application forms together with all application money are received on or prior to 2nd October 2018, and prior to the offer closing. The maximum number of Options Opal will issue assuming the maximum over-subscription amount is also achieved and all applications are received prior to 2nd October 2018 is 10,000,000.

Each Option entitles the holder to be issued one Share in Opal if the optionholder exercises the Option and pays the Option exercise price to Opal before the Option expiry date.

The Option exercise price is A$0.25 (25 cents) per Option and the Option expiry date is 2nd October 2020.

2.3 Investment Potential

Any investment in this emerging sector must be considered speculative. Returns on this investment are not likely to correlate with returns on the overall stock market.

Opal is well positioned to provide investors with potential returns for the following reasons:

- **Large and growing market:** The market for successful anti-infectives is large and growing due to the emergence of micro-organisms with resistance to many antibiotics.
- **Few competitors:** The pipeline for potential competitor anti-infective drugs in development is weak and there is a serious lack of new antibiotics under development[14]. Following the success of the introduction of antibiotics in the last century, investment in new research declined and antibiotics research teams were wound back in favour of those focused on non-communicable diseases[15].
- **Development incentives and government policy:** International incentives, such as the US Generating Antibotics Incentives Now (GAIN) legislation, are aimed at assisting companies who are developing anti-infective products to reduce risk, time and development costs (see page 17).
- **Opal technology's potential:** Opal's BDM-I technology has already demonstrated significant activity against some of the highest threat bacteria where there is a need for new treatments (see Figures 2 & 3). Product development of novel injectable and topical products has already commenced. An extensive Australian and international team is already involved in the Opal's development program, including Western Sydney University; Griffith University; University of Technology Sydney; formulation expert company, Formulytica Pty Ltd; various US and European specialist development companies; and a number of US government-funded institutions.

The BDM-I technology (Opal-I and Opal-T) is in a high growth commercially attractive market segment of new anti-infectives. The development path of the BDM-I based products assumes progress towards FDA approval and product launch. This will allow marketing by Opal Biosciences Ltd or through distributors or licencees. Opal would also consider sale, co- development or outlicence of the technology to a larger partner.

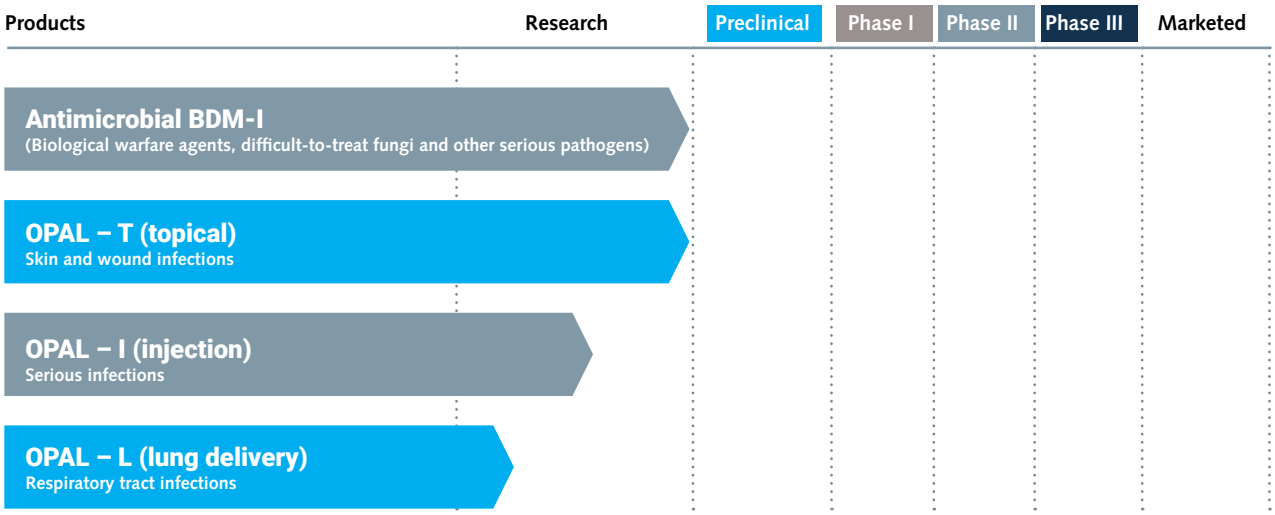
This Offer represents an opportunity for investors to acquire a shareholding at a pivotal stage of Opal's value growth. As significant amounts of expenditure will occur in the development of novel BDM-I-based products, the Options being issued as part of this capital raising will allow further investment by current investors at an attractive price once more data is gained on the progress of this technology.

Opal technology has the potential to provide a wide range of treatments for serious infections, many of which could be life-saving, as well as for less serious infections. The team behind the development of this technology is dedicated to making this a reality for future patients and endeavours to reward investors by seeking to develop a successful Opal technology franchise.

14 http://www.who.int/news-room/detail/20-09-2017-the-world-is-running-out-of-antibiotics-who-report-confirms
15 Fernandes and Martens (2017) *Antibiotics in late clinical development*, Biochemical Pharmacology 133:152-163

Figure 4: Pipeline

Opal Biosciences' Pipeline



There are a number of possible methods of valuing a technology portfolio. One such method, by way of example only, is to consider the value of the potential market for the technology and to make assumptions in relation to the market share which may be obtained by the new technology. Comparison to recent deals of similar technologies at a similar stage of development can also assist in the value assessment.

As Opal's technology has not yet reached the commercialization stage, the board of Opal cannot definitively value Opal or its technology at this time. For the purposes of this Offer, the Opal board considers that the pre-money valuation of Opal is A$4.0m. However, investors should reach their own conclusions as to the value of Opal and its technologies.

3 The Global Market Opportunity

3.1 Market Overview

The Medical Need

Antimicrobial resistance (AMR) is a globally recognised public health issue with deaths now recorded that are caused by infections which are resistant to all known antibiotics being recorded increasingly[16 17]. This problem is starting to impact society generally, and is not just confined to hospitals[18 19].

> *Staphylococcus aureus* (commonly known as staph) are common bacteria. Staph are usually harmless and many healthy people carry these bacteria on their skin or in their nose. However, sometimes **they can cause infection and serious illness**. Some strains of staph are resistant to the antibiotic called methicillin, and to other antibiotics. These staph are known as methicillin resistant *Staphylococcus aureus* (MRSA). Some people call MRSA infection "**golden staph**".
>
> Community acquired MRSA (CaMRSA) can cause skin and other more serious infections. It can spread from person to person via direct contact, hands, towels and personal grooming items. Avoid sharing items and wash hands thoroughly, especially after touching skin infections.
>
> *(from http://www.health.nsw.gov.au/Infectious/factsheets/Pages/methicillin-resistant.aspx)*

> **Growing numbers of people are dying from "flesh-eating" microbes;** from infections picked up in hospital and nursing homes; and from strains of pneumonia, tuberculosis, gonorrhea and other diseases that are impervious to most drugs. Such infections kill about 23,000 Americans a year, the Centers for Disease Control and Prevention estimates.
>
> *https://www.nytimes.com/2018/01/23/health/antibiotic-resistence-glaxo-johnson.html?action=click&contentCollection=Health&module=RelatedCoverage&region=Marginalia&pgtype=article*

This is creating many problems. Doctors are being urged to curb their use of antibiotics and there are few new antibiotics being developed[20 21].

As AMR increases, there is a pressing need for novel products to be developed to replace ineffective treatment options. In addition to the medical need, there is a price to pay for increasing antimicrobial resistance.

16. Migliori, G. "First tuberculosis cases in Italy resistant to all tested drugs", Euro Surveill. 2007 www.eurosurveillance.org
17. Morbidity and Mortality Weekly Report (MMWR) ***Notes from the Field***: Pan-Resistant New Delhi Metallo-Beta-Lactamase-Producing Klebsiella pneumoniae — Washoe County, Nevada, 2016. *Weekly* / January 13, 2017 / 66(1);33
18. http://www.health.gov.au/internet/main/publishing.nsf/content/cda-mrsa-anrep.htm
19. First case of super-resistant gonorrhea reported, https://edition.cnn.com/2018/03/28/health/uk-man-multidrug-resistant-gonorrhoea-intl/index.html
20. http://www.who.int/news-room/detail/20-09-2017-the-world-is-running-out-of-antibiotics-who-report-confirms
21. https://www.theguardian.com/society/2014/oct/10/doctors-antibiotics-prescriptions
22. WHO Fact Sheets on Sustainable Development Goals: Health Targets: Antimicrobial Resistance http://www.euro.who.int/__data/assets/pdf_file/0005/348224/Fact-sheet-SDG-AMR-FINAL-07-09-2017.pdf
23. O 'Neill J. Tackling drug-resistant infections globally: final report and recommendations. London: The Review on Antimicrobial Resistance; 2016 (https://amrreview.org/sites/default/files/160518_Final%20paper_with%20cover.pdf, accessed 19 August 2017).
24. Drug-resistant infections: a threat to our economic future. Washington (DC): World Bank; 2016 (http://pubdocs.worldbank.org/ en/527731474225046104/AMR-Discussion-Draft-Sept18updated.pdf, accessed 19 August 2017).
25. Data on file from work commissioned from independent laboratories including Ingham Institute for Medical Research, Centre for Infectious Diseases and Microbiology, National Institutes of Health (NIAID) and Eurofins Cerep Panlabs (Taiwan).`

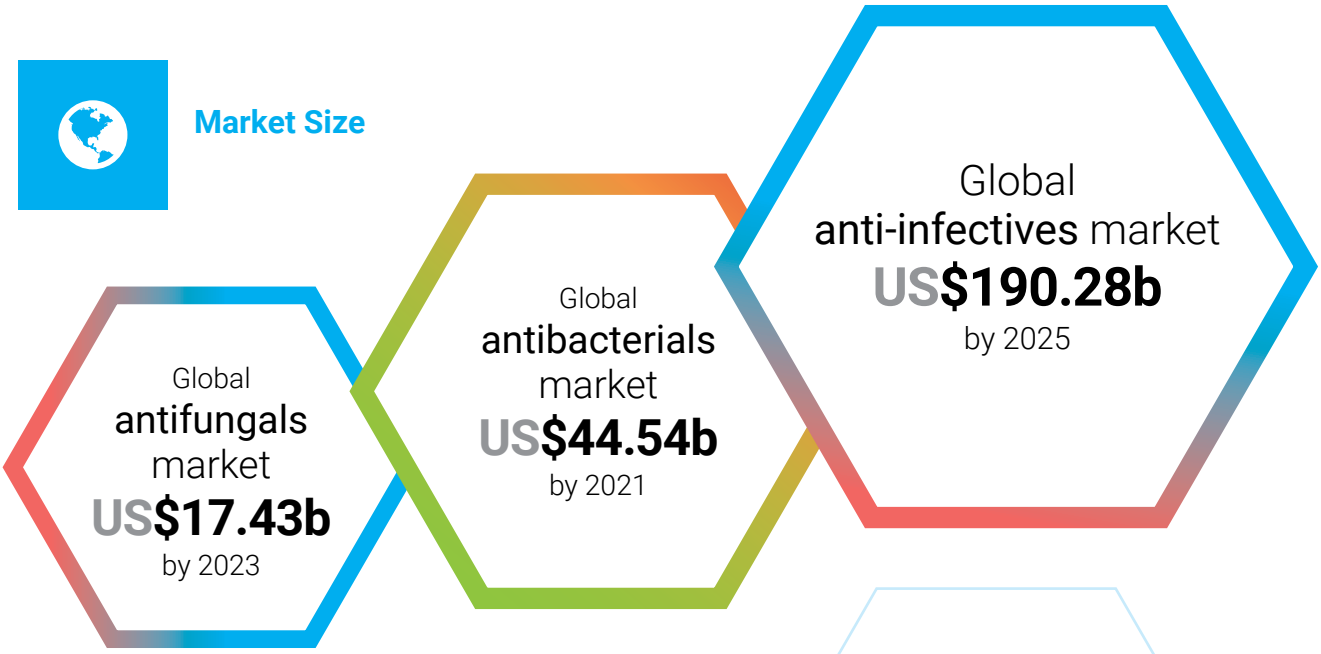
If no action is taken to contain AMR, the economic cost in terms of lost global production between now and 2050 would be USD 100 trillion. Low- and middle-income countries would be more negatively impacted and a widening of the inequity gap within countries is expected[22 23 24].

The indirect costs of drug-resistant infections to the individual and society from morbidity, disability, premature deaths and reduced effective labour supply are estimated to cause a decrease in the global economic output of 1–3% by 2030, with estimated losses ranging from USD 1 trillion to USD 3.4 trillion annually if no action is taken [23 24].

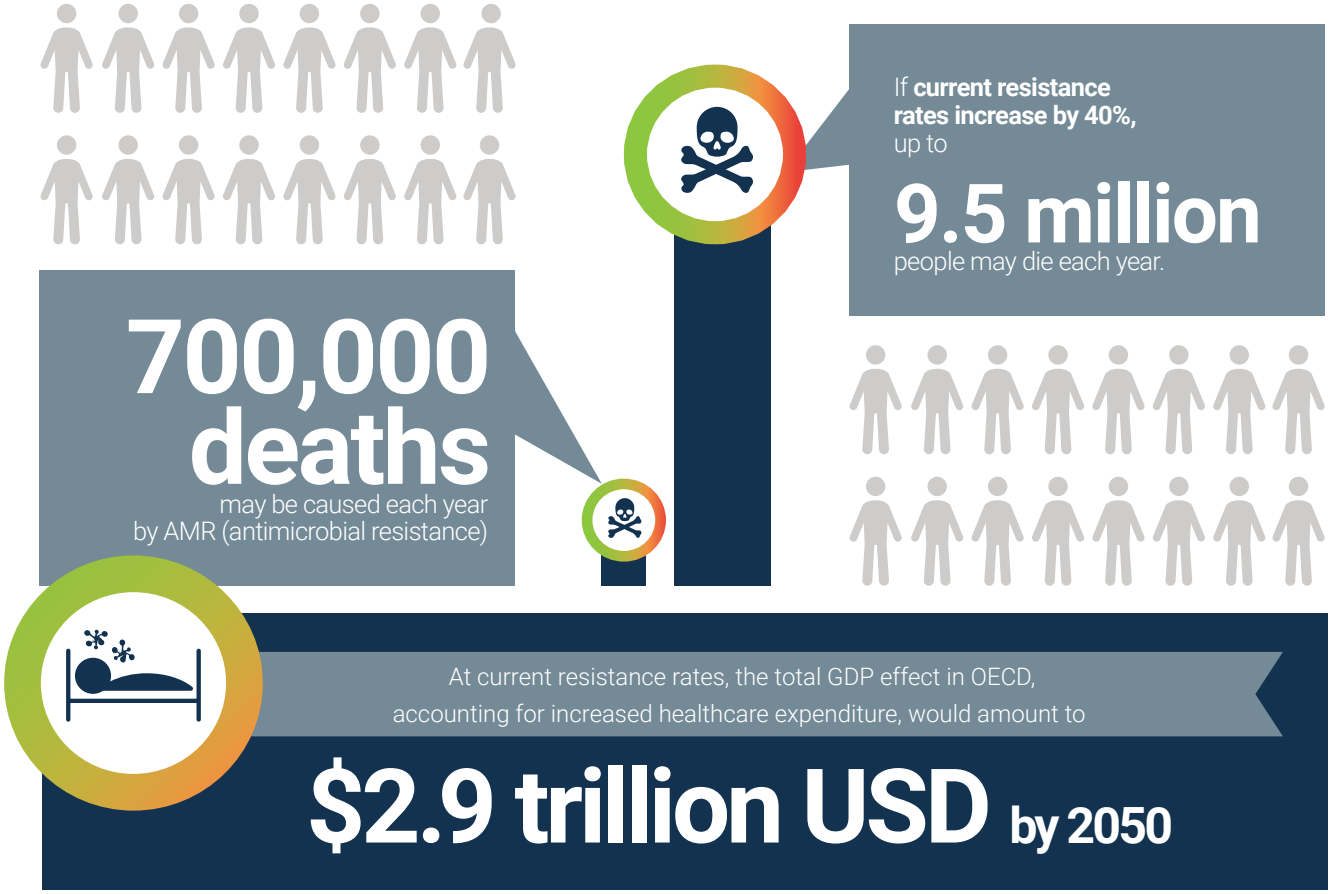
Opal's main asset is the novel drug, BDM-I. BDM-I has been shown to work against many micro-organisms (bacteria and fungi) which cause serious infections. In the lab BDM-I has shown effect against some strains of bacteria where mainstream antibiotics do not work[25]. This includes Staphylococcus aureus "Golden Staph" (MRSA, VISA, VRSA) and drug-resistant *Neisseria gonorrhoea* (which causes the sexually transmitted infection, gonorrhoea).

Opal is running two primary development programs:

- Opal-I, a novel product to treat bloodstream and serious infections; and
- Opal-T, a novel product to treat skin and mucous membrane infections.



Patients infected with resistant infections



Economic burden

From the OECD report[26]:

Patients infected with resistant infections:

- show increased risk of complication and death. Globally, about 700 000 deaths may be caused each year by AMR (antimicrobial resistance). If current resistance rates increase by 40%, up to 9.5 million people may die each year.
- require more intensive and expensive care and are more likely to be admitted to hospital. Hospitals spend, on average, an additional USD 10 000 to 40 000 to treat a patient infected by resistant bacteria in OECD.
- suffer from a loss of productivity and income due to ill-health and additional time away from work. At current resistance rates, the total GDP effect in OECD, accounting for increased healthcare expenditure, would amount to 2.9 trillion USD by 2050.

26. https://www.oecd.org/health/health-systems/AMR-Policy-Insights-November2016.pdf

The Pharmaceutical Market

The anti-infectives market is growing in value – estimated at a CAGR of around 6.3% over the next decade to reach approximately USD 190.28 billion by 2025[27] - due to recognition of the dire global public health consequences of antibiotic resistance. The term "anti-infectives" includes both antibiotics and non-antibiotics.

Antibacterials global market

The global antibacterial drugs market was estimated at USD 41.76 billion in 2016 and is expected to grow at a compound annual growth rate (CAGR) of 1.3-3.1% from 2013 to 2019, to reach an estimated value of USD 44.54 billion in 2021[28].

Antifungal market size:

The global antifungal therapeutics market reached USD 12.6 billion in 2016 and is expected to reach USD 17.7 billion by 2023 with a CAGR of 3.7% over the five-year period from 2017 to 2025[29 30].

Sexually Transmitted Infection (STI) Market

The STI therapeutics drug market (which includes chlamydia, gonorrhea, syphilis, genital herpes, HPV, HIV/AIDS and others) was valued at USD 32.8 billion in 2016 and is projected to expand at a CAGR of 11.2% to 2025 to reach USD 83 billion by 2025[31], with the gonorrhoea therapeutics market predicted to reach USD 5.6bn by 2021[32].

International and Government Policies

New antibiotic development

International governments and public health agencies are introducing measures (see Figure 1) to encourage the development of new antibiotics. New policies are driving the market growth for the Opal business by attracting players back into antibiotic development.

In September 2017 the WHO's Global Antibiotic R&D Partnership (GARDP) announced a Eur 56m fund to develop new drugs to fight antibiotic resistance. The European Commission has established a program to counter antimicrobial resistance called New Drugs 4 Bad Bugs. The DRIVE-AB government and industry alliance is part of this and the program is developing incentives for new antibiotic development. In the US, BARDA has awarded a contract for up to USD 62 million to assist the Phase III development of the UK company, Summit Therapeutic's new antibiotic. The US' "Generating Antibiotics Incentives Now" (GAIN) legislation was passed in an attempt to incentivise the development of new antibiotics. In recognising the medical need for new antibiotics, the legislation

27. Anti-Infectives Market Analysis & Trends - Product (Antibacterials, Antifungals and Antivirals) - Forecast to 2025 (Report October 2016 Accuray Research LLP)
28. Global Antibacterial Drugs Market 2017 – 2027, Visiongain 13th May 2017.
29. Global Antifungal Agents: (Drugs Therapies and Applications) Market Forecast 2017 – 2025 Inkwood Research, 2 May 2017.
30. Antifungal Drugs Market by Drug Type - Global Opportunity Analysis and Industry Forecast, 2017-2023 Allied Market Research June 2017
31. Sexually Transmitted Diseases (STDs) Drug Market (Disease Type - Chlamydia, Gonorrhoea, Syphilis, Genital herpes, HPV, and HIV / AIDS; Therapy Class- Antibiotics, Antiviral / Antiretrovirals, and Vaccines) - Global Industry Analysis, Size, Share, Growth, Trends, and Forecast 2017 – 2025,Transparency Market Research and https://www.finanznachrichten.de/nachrichten-2017-11/42222364-sexually-transmitted-diseases-drug-market-to-reach-us-dollar-83-04-billion-by-2025-transparency-market-research-008.htm
32. Global Gonorrhoea Therapeutics Market 2017-2021, Technavio Research Report Oct 2017 and https://www.businesswire.com/news/home/20171109006393/en/Top-3-Drivers-Global-Gonorrhea-Therapeutics-Market

- extends market exclusivity for certain life-saving antibiotics
- speeds development and review of new antibiotics through the FDA by fast track and priority status
- requires the FDA to issue guidance and advice on the necessary development pathway, and
- requires the FDA to develop a list of “qualifying pathogens” that have the potential to threaten public health[33].

One of the GAIN Act's main provisions is Section 505E, which grants companies an additional five years of market exclusivity if they develop an antibiotic intended for a "qualified infectious disease”[34]. Opal products are targeting at least six of the pathogens on the “Qualified Infectious Disease Pathogen” list[35].

3.2 Key Industry Players

The **traditional anti-infectives market** is dominated by antibiotics but there are not enough new antibiotics or anti-infective agents in development to fill the increasing need caused by antibiotic resistance. The development of new anti-infectives includes many small companies, with only five of the top 50 pharmaceutical companies in the Pew Charitable Trust’s May 2017 edition of “Antibiotics Currently in Clinical Development”. The Trust notes that “drug-resistant bacteria, or superbugs present a serious and worsening threat to human health.” However when referring to the list of new antibiotics in clinical development, it says “it is clear that there are too few drugs in development to meet current and anticipated patient needs”.

With respect to the major pharmaceutical companies, according to the 2018 Antimicrobial Resistance Benchmark[36] produced by the Access to Medicine Foundation in Amsterdam and launched at the World Economic Forum in Davos in 2018, GlaxoSmithKline (GSK) has been ranked as doing the most to combat the global antimicrobial resistance (AMR) crisis, followed by Johnson & Johnson. A separate ranking of manufacturers of generic antibiotics ranks Mylan, Cipla, and Fresenius Kabi Global highest, with Entasis Therapeutics, a US company developing new treatments for resistant gram-negative infections ranks first among biotech companies.

New antibiotic developments can be “block-busters”: Cubicin sales of 2016 USD 1.087m[37] met market forecasts following the acquisition of Cubist Inc by Merck & Co in November 2014 in a deal reported as USD 8.4bn. The sector is active with Pfizer acquiring a small range of late stage antibiotics and marketed products from Astra Zeneca in August 2016 in a USD 1.6b deal.

These companies and many others are seeking new opportunities from in-licensing.

33. http://thehill.com/images/stories/blogs/healthwatch/gainact.pdf
34. http://www.raps.org/regulatory-focus/news/2014/06/19395/FDA-Final-Rule-On-Qualifying-GAIN-Act-Pathogens/
35. ***Aspergillus*** spp, ***Candida*** spp., ***Enterococcus*** species., ***Coccidioides*** spp., ***Mycobacterium tuberculosis*** complex, ***Neisseria gonorrhoeae, Staphylococcus aureus.***
36. https://amrbenchmark.org/wp-content/uploads/2018/04/Antimicrobial-Resistance-Benchmark-2018.pdf
37. per Merck release 2 Feb 2017

4 The Company

4.1 Establishment of Opal Biosciences Limited

Opal, a subsidiary of BioDiem Ltd, is a public company established on 4 May 2015. Opal was formed to develop and commercialise the BDM-I technology which targets the treatment of infections, primarily serious human infections.

The BDM-I technology which is the main asset of Opal, was assigned from Biodiem to Opal with the approval of BioDiem shareholders and the Institute of Experimental Medicine. Consideration for the assignment included the issue of 10m fully paid ordinary shares to BioDiem which occurred on 6 July 2015. Shareholders of Opal and BioDiem approved the issue of a further 2.5m Shares to BioDiem in lieu of the final $500,000 component of the consideration which was originally to be paid in cash. This was completed in November 2017.

In March 2018, Opal announced the closure of a share placement of 3,030,000 fully paid ordinary shares raising approximately $606,000.

4.2 Opal Biosciences' Business

Since its incorporation in 2015, Opal has progressed the development of its injectable (Opal-I) and topical (Opal-T) product candidates, and explored delivery of BDM-I to the lung (Opal-L). In parallel, studies at Western Sydney University have continued to focus on the way BDM-I kills bacteria, in particular antibiotic-resistant strains of Staphylococcus aureus and Enterococci. On the basis of these research results a new provisional patent *BDM-I Therapy* was lodged in August 2017.

Under an Australian Federal Government Innovation Connection grant, work recommenced in May 2018 on the formulation of BDM-I for intravenous administration. This formulation will be used for *in vivo* testing and potential demonstration of efficacy in a disease model and also for tolerability studies. This complements the Opal-T formulation development work already conducted by Melbourne-based topical formulation expert company, Formulytica Pty Ltd.

A gel form of Opal-T has shown antibacterial activity against *Staph aureus* and *Neisseria gonorrhoea*, the bacterium responsible for the sexually transmitted infection gonorrhoea.

38. Data on file from work commissioned from independent laboratories at Eurofins Cerep Panlabs (Taiwan).

Opal-T development: Demonstration of BDM-I activity *in vitro* in a topical formulation[38]

Many studies in different laboratories have shown that the active ingredient BDM-I is active against many micro-organisms which can cause serious human infections including strains of *Staphylococcus aureus* (wound infections and others) and *Neisseria gonorrhoea* (gonorrhea). However it could not be assumed that BDM-I mixed into an ointment, gel or cream would retain its antimicrobial activity, so a testing program was conducted in April 2017:

***In vitro* activity shown against *Staphylococcus aureus* and *Neisseria gonorrhoea*.**

A topical formulation program for BDM-I (Opal-T) was conducted in partnership with Formulytica Pty Ltd, a specialist topical formulation company based in Melbourne

- Three prototype formulations passed 3 months stability testing
- These three prototypes were tested in laboratory experiments (*in vitro*) under placebo-controlled conditions in a validated study against
    - A strain of methicillin-resistant *Staph aureus*, a multidrug resistant (MDR) bacteria which is responsible for community-associated Golden Staph infections e.g. skin infections, and which is also resistant to many other commonly used antibiotics including mupirocin, quinolones, macrolides and all classes of beta-lactam antibiotics. It has emerged as an epidemic strain which causes rapidly progressive and fatal disease; and
    - A strain of *Neisseria gonorrhoea* which is responsible for causing the sexually transmitted infection, gonorrhoea.
- The results of this testing showed
    - All three prototype formulations were more active against the *Staph aureus* strain than their matching placebos
    - The gel prototype formulation was the most active of all prototypes tested against the strain of *Neisseria gonorrhoea*.

***In vivo* testing – proof of concept**

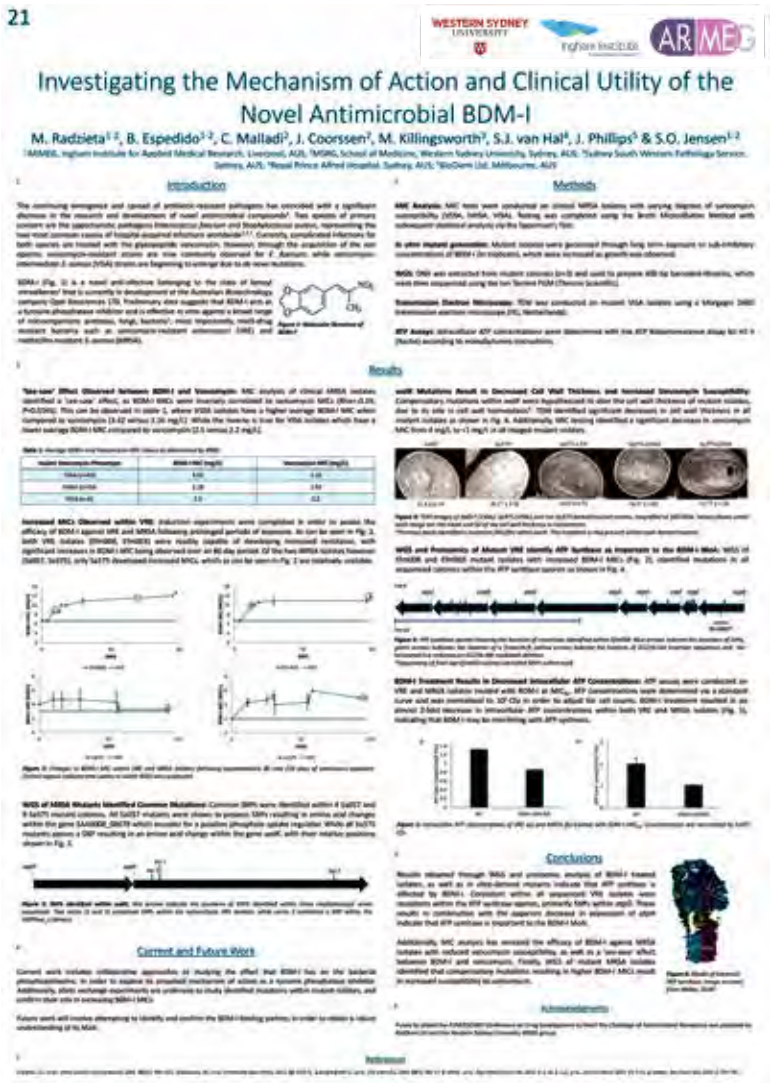
The next step was to conduct testing in a model of infectious disease.

- The gel prototype formulation was tested in a pilot study against the same virulent resistant strain of *Staph aureus* in an *in vivo* model. While the gel did show antimicrobial activity it was deemed not sufficient to proceed with this prototype formulation against this virulent strain of *Staph aureus*. Opal is seeking alternative infectious disease models and non-dilutionary funding to continue this work including against other microorganisms, and with other prototype formulations.

Mechanism of action against bacteria – Ingham Institute for Applied Medical Research, Western Sydney University:

Under the supervision of Associate Professor Slade Jensen, PhD candidate Michael Radzieta has continued studies to understand how BDM-I kills bacteria.

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


21

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

M. Radzieta[1,2], B. Espedido[1,2], C. Malladi[2], J. Coorssen[2], M. Killingsworth[3], S.J. van Hal[4], J. Phillips[5] & S.O. Jensen[1,2]

Figure 5
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;.

This research focuses on BDM-I's activity against hospital pathogens such as MRSA (methicillin-resistant *Staphylococcus aureus* or "Golden Staph") and other superbugs such a vancomycin-resistant enterococci (VRE). Results to date indicate that BDM-I's cellular target is novel and therefore BDM-I represents a next-generation anti-infective.

Michael Radzieta presented a poster (see figure 5) 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; and based on the discoveries made in this research a new patent was filed in August 2017 entitled BDM-I Therapy.

Whereas the focus of Opal is the progression of development of injectable (Opal-I) and topical (Opal-T) forms of BDM-I, opportunities for development and funding of oral and lung delivery forms will also be explored.

5 Opal's Intellectual Property and Opportunities

5.1 Intellectual Property

Opal has finalised the acquisition of all global rights to BDM-I from BioDiem Ltd following shareholder approval of the issue of $500,000 value of Opal shares to BioDiem in November 2017. Opal's intellectual property management is undertaken by patent attorney firm, Davies Collison Cave in Melbourne.

The intellectual property of BDM-I covers three patent families and considerable know-how from research and development work which has been conducted over recent years. The three patent families are:

- The parent patent Antimicrobial and Radioprotective Compounds covers the method of treatment and/or prophylaxis of a microbial infection using BDM-I.
- The second patent Method of treating Scedosporium spp. Infection is specifically directed at the invasive fungal condition caused by Scedosporium spp.
- The third provisional patent, BDM-I Therapy, covers the use of BDM-I and related compounds in the treatment of vancomycin-resistant infections.

The following Table Two shows the patent status for Opal's BDM-I technology.

Title	Granted	Pending
Antimicrobial and radioprotective compounds	Australia, Canada, France, Germany, Great Britain, Japan, USA, Russia	
Method of treating Scedosporium spp. infection	Australia, Europe, USA	Canada, HK
BDM-I Therapy		(PCT lodged August 2017)

5.2 Opportunities for Opal's Products

Opal was formed to develop and commercialise the BDM-I technology which targets the treatment of infections, primarily serious human infections. Antibiotic resistance is creating many problems worldwide.

Its main asset is the intellectual property and know-how relating to its novel proprietary anti-infective molecule, BDM-I. BDM-I has shown activity against many micro-organisms responsible for causing serious human infections, including those which are resistant to commonly used antibiotics.

Since the introduction of penicillin more than 20 new classes of antibiotics have been introduced, however since 1962, only two new classes have reached the market[39]. Opal's BDM-I is in a new class: it is novel and is patented.

Opal's approach is to target infections

- where antibiotics are becoming less effective
- which are of greatest concern internationally; and
- where BDM-I has shown activity against known resistant bacteria and infections.

Recent news of the spread of an antibiotic-resistant strain of the sexually-transmitted infection (STI) gonorrhoea, and the successful screening of BDM-I against a panel of antibiotic-resistant strains of *Neisseria gonorrhoea* has led Opal to prioritise this STI as a target disease for BDM-I's development.

The CDC in Atlanta has rated the "Threat Level" of drug-resistant Neisseria gonorrhoea as URGENT. This is the highest level in the "Current Antibiotic resistance Threats in the US" report[40]. Drug-resistant gonorrhoea is also one of 12 bacteria on the WHO Priority Pathogens List for R&D of New Antibiotics (2017)[41].

To further this development work, Opal is raising funds to continue development of BDM-I as

- an injectable (Opal-I) product candidate; and also
- a topical (Opal-T) product candidate.

5.3 Opal's Existing Products in Development

Opal's research program is developing new products based on the novel molecule BDM-I. BDM-I has shown anti-infective activity in *in vitro* studies.

5.3.1 Intravenous Use (Injection) "Opal-I"

Systemic bacterial infection (injection)

Bacteria can cause blood poisoning, urinary tract infections, pneumonia, deep tissue and many other infections. Antibiotic-resistance is a major problem with these serious infections and increases the risk of joint replacement, heart and other surgeries as well as cancer therapies which can increase a patient's risk of infection[42].

Invasive fungal infections

Devastating life threatening infections can be caused by fungi that invade the bloodstream, lungs and other body cavities e.g. the sinuses.

Opal-I, an injectable formulation of BDM-I, will be aimed at these hard-to-treat bacterial and fungal infections which may occur in patients with weakened immune systems such as after cancer treatment.

5.3.2 Topical Use (gel, cream, spray, dusting powder, varnish) "Opal –T"

Opal-T gel has shown activity in the laboratory against the micro-organism causing the sexually transmitted infection, gonorrhoea, and also against antibiotic-resistant Golden Staph. Opal–T development is directed against micro-organisms associated with skin, soft tissue and mucous membrane infections, such as those that cause tinea, conjunctivitis, thrush and external ear infections. There is an opportunity for a wide range of topical products which would be aimed at treatment of these infections, including use for wounds and burns.

39. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3085877/pdf/bph0163-0184.pdf
40. https://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf#page=49
41. http://www.who.int/medicines/publications/WHO-PPL-Short_Summary_25Feb-ET_NM_WHO.pdf?ua=1
42. https://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf#page=49

5.4 Future Potential Products

The product development programs for Opal-O and Opal-L could be pursued with funding partners.

5.4.1 Oral Use (tablets, capsules, syrup, mouthwash) "Opal –O"

A range of micro-organisms can infect the human gut causing problems such as gastroenteritis. While some resolve on their own, other infections are more troublesome and make people very sick. BDM-I has shown activity against a number of micro-organisms which cause gut problems. Opal-O, oral formulations of BDM-I, would be directed towards use in such infections. The product development program for Opal-O has not commenced, and could be pursued with a funding partner.

5.4.2 Lung (inhalation) "Opal –L"

In chronic diseases such as cystic fibrosis, antibiotic treatment has had an important role and has significantly improved life expectancy of patients with this disease. The emerging increase in resistance to antibiotics is of major concern for these patients where lung infection is a major cause of illness and death. The development of an inhalation formulation of BDM-I, Opal-L, would be directed towards use in such patients as well as for other lung infections. A number of the problem germs in cystic fibrosis have been shown to be sensitive to BDM-I in laboratory studies.

Nanoparticle delivery of BDM-I to the lungs may be possible following pilot work undertaken by Prof Kim Chan of University of Sydney. The product development program for Opal-L has not progressed further, and could be pursued with a funding partner.

NIH NIAID* ICAAC** poster

Antifungal and Antipneumocystis Activity of the Investigational Antimicrobial BDM-I

A.W. Fothergill[1], **M.T. Cushion[2]**, M.S. Collins[2], W.R. Kirkpatrick[1,3], L.K. Najvar[1,3], **T. F. Patterson[1,3]**, N.P. Wiederhold[1]

The University of Texas Health Science Center at San Antonio[1],
Cincinnati Foundation for Biomedical Research and Education[2]
South Texas Veterans Health Care System[3]

"BDM-I demonstrated potent activity against endemic fungi, including *B. dermatitidis*, *Coccidioides* species, and *H. capsulatum* (MIC90 range 0.25 – 0.5 µg/ml at 100% growth inhibition). Similarly, activity was also observed against *C. neoformans* and *C. gattii* (MIC90 2 µg/ml at 100% growth inhibition) as well as *C. glabrata* (MIC90 2 µg/ml). BDM-I also had marked activity against *P. carinii* and *P. murina* (IC50 on day 3 of exposure <0.1 and 0.174 µg/ml, respectively)."

It was noted by the researchers Professors Cushion and Patterson that "further studies are warranted to determine the potential of this broad-spectrum antifungal agent".

*Work funded by NIH/NIAID/DMID Contract No. HHSN272201100018I
**ICAAC is the annual Interscience Conference on Antimicrobial Agents and Chemotherapy, run by the American Society of Microbiology, in Denver, Colorado.

Antifungal study results relating to Opal's novel antimicrobial BDM-I presented at the 2013 annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Denver, Colorado.

6 Opal's R&D and Commercialisation Strategy

6.1 Research and Development

The funds raised under this Information Memorandum will be used to

- Continue development of two BDM-I-based products towards clinical trials to explore BDM-I's potential as a treatment for antibiotic-resistant infections
  - Opal-I (injection formulation) and
  - Opal-T (topical product)
- Strengthen and expand the intellectual property portfolio, by increasing the territories protected and lodging new patents.

Novel products (Opal-I and Opal-T) based on BDM-I

- Manufacture and test injectable BDM-I and analogues to optimize Opal-I formulation. Then commence dose-ranging, efficacy, pharmacokinetic and toxicology studies to move towards clinical trials.
- Manufacture and test topical Opal-T in new models of infectious disease e.g. gonorrhoea and chlamydia, before completing the additional studies necessary to move into human trials.
- Continue studies into how Opal Technology (BDM-I) works as an anti-infective and use to increase further the Opal intellectual property portfolio.
- Screening for additional potential indications e.g. chlamydia.

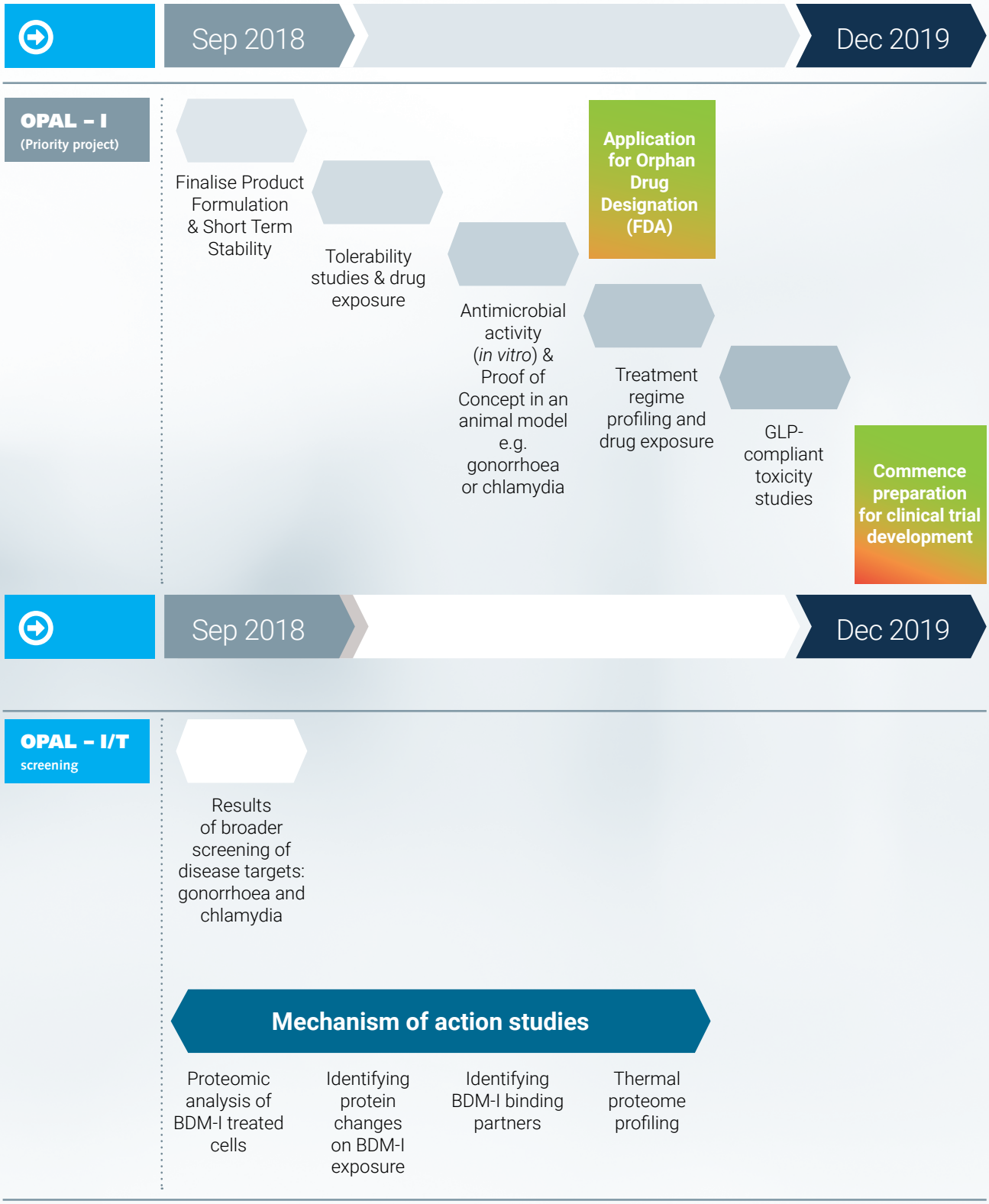
Following the successful completion of this stage (by mid to late 2019) it is expected that

- Two novel BDM-I-related product candidates (Opal-I and Opal-T) will have shown efficacy in studies to support an application for Orphan Drug Designation from the FDA. It is expected that there will be a significant value uplift once Orphan Drug Designation is obtained; and
- The mechanism of action of BDM-I will be described.

6.2 Expected Exit

The BDM-I technology (Opal-I and Opal-T) is in a high growth commercially attractive market segment of new anti-infectives. The development path of the BDM-I based products assumes progress towards FDA approval and product launch. This will allow marketing by Opal Biosciences Ltd or through distributors or licencees. Opal would also consider sale, co- development or outlicence of the technology to a larger partner.

Indicative development plan summary



7 Reasons For This Offer

7.1 Major Goals for 2018-2020

Opal's goals for the next two years are:

- Continued development of two BDM-I-based products towards clinical trials to explore BDM-I's potential as a treatment for antibiotic-resistant infections
  - Opal-I (injection formulation) and
  - Opal-T (topical product)
- Strengthen and expand the intellectual property portfolio, by increasing the territories protected and lodging new patents.

7.2 Use of Funds Raised Under This Offer

The use of funds is categorised below in **Table Five**:

Table Five: Use of funds

	2018 - 2019 $
Research and Development - Opal products (IV priority)	744,000
Patents (approx.)	165,000
Insurances, legal and IT	90,000
Other costs (management & corp services, facilities & admin)	501,000
Total	**$1,500,000**

7.3 Company Management

The management, facilities and services used by Opal are supplied by BioDiem under a services agreement. This minimizes costs and ensures efficient development under an existing commercialisation plan (see Section 8).

8 Board, Management and Corporate Governance

8.1 Board of Directors

Mr Hugh Morgan AC

Non-Executive Chairman – LLB, BCom

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. Hugh is Chairman of BioDiem.

Ms Julie Phillips

Executive Director – BPharm, DHP, MSc, MBA

Ms Julie Phillips 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 was appointed Chairman of AusBiotech Ltd in October 2014, the peak biotechnology industry association in Australia. Julie is a Director of MTPConnect, the Medtech and Pharma Industry Growth Centre, and sits on Innovation and Science Australia's R&D Incentives Committee.

Ken Windle

Non-Executive Director – BPharm, DipEc, MPS

Ken has a successful career in the Australian and international pharmaceutical industry and more recently with smaller Australian companies.

Ken is currently Executive Chairman of Advent Pharmaceuticals Pty Ltd, a director of AusBio Ltd, and Chair of R&D , and Chairman of RMIT University's Program Advisory Committee. Ken has served on ASX-listed company boards and state and federal government committees including two terms as a Member of the Innovation Australia Board. Ken has previously served as Consultant to the (Australian) Prime Minister's Science Council on Industry Development, a Director of the (Singapore) Economic Development Board EDB, and (Singapore's) Committee on Competitiveness. He has been Chairman of the APMA (now Medicines Australia) and has been twice a winner of the Governor of Victoria's Export Prize.

Ken is a Pharmacy and Economics graduate and spent the latter 20 years of his 30 years with Glaxo/Glaxo Wellcome (now GSK) in senior International positions including as a member of the Group's Executive Committee, as Head of Global Commercialisation based in London, and managing subsidiaries in UK, Australia, and as Regional President, Asia Pacific, based in Singapore overseeing operations in 20 countries.

8.2 Management

A services agreement is in place with BioDiem Ltd whereby management and services will be provided by BioDiem to Opal. Additional key staff include:

Ms Melanie Leydin CA
Company Secretary – BBus, CA

Melanie Leydin CA was appointed to the position of Company Secretary of BioDiem Ltd in November 2012. Ms Leydin has 24 years' experience in the accounting profession and is a director and company secretary for a number of oil and gas, junior mining and exploration entities listed on the Australian Securities Exchange. She is a Chartered Accountant and a Registered Company Auditor. She graduated from Swinburne University in 1997, became a Chartered Accountant in 1999 and since February 2000 has been the principal of chartered accounting firm, Leydin Freyer specialising in outsourced company secretarial and financial duties for resources and biotechnology sectors.

8.3 Expert Advisors

Professor Tania Sorrell AM, University of Sydney

Professor Tania Sorrell, AM is Director of the Marie Bashir Institute for Infectious Diseases and Biosecurity (MBI) and recently chaired the NHMRC's Research Translation Faculty Steering Group on New and Emerging Health Threats. She is an internationally renowned infectious diseases physician and medical mycologist whose research focuses on invasive fungal infections. She has a long-standing interest in the prevention, diagnosis and treatment of infectious diseases, especially in immunocompromised individuals. As a leading international researcher on Cryptococcus, she has made major contributions toward understanding the mechanisms by which these fungi cause invasive infections. Professor Sorrell's research on virulence determinants in C neoformans aims to develop new fungal diagnostic tests and new treatments. Her work has resulted in the development of clinically-useful rapid diagnostic tests (e.g. for brain infections). Professor Sorrell's leadership was instrumental in establishing the MBI, a multi-faculty, multidisciplinary institute devoted to reducing the risks from and global impact of emerging and re-emerging infectious diseases, especially in the Asia-Pacific Region. She has successfully created multidisciplinary research networks including medical and veterinary sciences, biological sciences, and humanities and social sciences, in an effort to improve capacity in Australia and abroad, in diagnostics, surveillance, infection control and infectious disease prevention. She leads the MBI's functioning as an expert resource in infectious diseases and biosecurity for government and professional bodies.

Professor Sorrell is a regular expert contributor to international policy-forming bodies including the WHO and is a Senior Adviser at GAFFI (Global Action Fund for Fungal Infections). In 2014, she was awarded Member of the Order of Australia (AM), for significant service to medicine and the community as an infectious diseases researcher and adviser.

Professor Kim Chan, University of Sydney

Hak-Kim Chan, Professor in Pharmaceutics, is leading the Advanced Drug Delivery Group at the School of Pharmacy, University of Sydney, Australia. He previously worked in Genentech Inc as a scientist developing inhalable therapeutic proteins such as Pulmozyme. His research focuses on inhalation drug delivery, ranging from aerosol formulation and inhaler device to scintigraphic imaging of lung deposition and clinical outcome. He played a pivotal role in the product development of Pharmaxis' Aridol and Bronchitol (inhaled mannitol for bronchoprovocation and mucus clearance). His research on pulmonary drug delivery has led to >400 scientific publications (with >10,000 citations) and seven patents. He is an executive editor of Advanced Drug Delivery Reviews, a Fellow of the American Association of Pharmaceutical Scientists and Fellow of Royal Australian Chemical Institute. He served as Vice President of the Asian Federation for Pharmaceutical Sciences.

Associate Professor Sharon Chen, University of Sydney

Dr. Sharon Chen is a research physician and microbiologist with a PhD in Mycology.
Dr. Sharon Chen is a research physician and microbiologist with a PhD in Mycology.
She is the Director of the Centre for Infectious Diseases Laboratory Services, NSW South Wales Health Pathology, which incorporates the Clinical Mycology reference Laboratory, She is also a member of the Molecular Mycology Research Laboratory, Marie Bashir Institute for Emerging infections and Biosecurity, University of Sydney. She is the current co-chair (2014 -) of the the Australia and New Zealand Mycoses Interest Group (ANZMIG), a national body devoted to the study of fungal infections and mycological–related diseases and to education in mycology. She is internationally recognised for her role as convenor/co-convenor of numerous epidemiological and applied clinical studies. These include a multicentre trial using serological and molecular tools for diagnosing invasive aspergillosis in haematology patients, the Australian Candidemia Study, Australian Scedosporium Study and a Cryptococcus gattii study in collaboration with the Mycoses Study Group, USA and British Columbia Centre for Diseases Control (2008-2017). She is principal site investigator of international antifungal drug trials and actively contributed to the writing of Australian guidelines for use of antifungal agents. Research interests include clinical and molecular epidemiology of fungal infections and of *Clostridium difficile* infections, evaluation of novel antifungal and antibacterial agents and innovative diagnostics in medical microbiology including whole genome sequencing

Associate Professor Slade Jensen, Western Sydney University

Dr Slade Jensen is an Associate Professor in the School of Medicine, Western Sydney University and Head of the Antibiotic Resistance and Mobile Elements Group based at the Ingham Institute for Applied Medical Research. He is a Fellow of the Australian Society for Microbiology (ASM) and a past president of the ASM NSW Branch, and has made significant contributions in the areas of microbial evolution and the study of multi-resistant staphylococci. His expertise spans biochemistry, cell biology, molecular microbiology, genomics and plasmid biology, and in recent years his research has centred on antibiotic development and the evolution of antibiotic resistance in ESKAPE pathogens, particularly Staphylococcus aureus and Enterococcus faecium; he has national and international collaborations focused on these pathogens.

Dr Richard Buchta

Managing Director of Formulytica Pty Ltd, (est 2015), an expert formulation and analytical method development company, developing innovative formulations for pharma, OTC and cosmetic products. Worked in senior R&D roles with pharma companies leading and designing research programmes:, including Stiefel Research Australia for 14 years and the development of over 30 products which resulted in launch of 14 aerosol foam products in the US market. Prior to that he worked in Business Development at Wyeth Australia, Astra Zeneca (sterile injectables) and Arthur Webster Pty Ltd, where he developed the SingVac range of veterinary vaccines. Dr Buchta has a PhD, Master of Science and Bachelor of Science (Hons) and an MBA.

9 Risk Factors

Opal's future value is reliant on the success of its existing and future intellectual property and its ability to protect that intellectual property.

This section outlines the risks associated with investing in Opal. There are a number of risks, both specific to Opal and of a general nature, which may either individually or in combination, materially and adversely affect the future operating and financial performance of Opal and the value of the Shares.

While Opal seeks to manage the risks to prevent adverse outcomes to shareholders, many of these risks are outside the control of Opal, its Directors and management.

Applicants should be aware that this is not an exhaustive list of the risks associated with an investment in Opal. Applicants should consider these risk factors in conjunction with other information disclosed in this Information Memorandum and consult their stockbroker, accountant, lawyer or other professional advisor before deciding whether to invest in Opal and apply for Shares.

9.1 Uncertainty of Research: Project Risks

The success of Opal is dependent on the quality of the research it has under development, its results and its acceptance in the market. There are risks related to the successful research and development of any technology and ensuing commercialisation. Product development involves lengthy processes and is subject to evaluations by external groups such as the United States Food and Drug Administration ("FDA") and Australian Therapeutic Goods Administration ("TGA"). There is a risk inherent in activities of this nature that obtaining approvals may be affected by factors outside the control of Opal and its partners, including but not only that government agencies may not process applications in a timely manner or that their activities may be interrupted or delayed due to government policy changes or funding not being available.

Additionally, new products must also find acceptance in a competitive marketplace. Market acceptance will depend on many factors, including convincing potential customers and alliance partners that Opal's product is more attractive than other alternative products and the ability to manufacture products in sufficient quantities with acceptable quality at an acceptable cost. Because of these and other factors, our products may not gain market acceptance and will mean that it is unlikely that Opal will become profitable.

In order to continue Opal's research and development of its projects and investments, Opal may from time to time enter into new business initiatives. Such arrangements will expose Opal to risks commonly associated with such ventures including amongst others assimilation of the new operations and personnel into Opal. There can be no assurance that any potential venture will not have a material adverse effect on Opal's business, financial conditions and operations.

9.2 Intellectual Property

Obtaining, securing and maintaining rights to technology and patents are an integral part of securing potential product value in Opal's activities. Competition in retaining and sustaining protection of technology and the complex nature of technologies can lead to patent disputes. Opal's success

depends, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. Additionally, success may depend on Opal enforcing and defending its intellectual property against third-party challengers. Because the patent positions of biotechnology and pharmaceutical companies can be highly uncertain and frequently involve complex legal and factual questions, neither the breadth of claims allowed in biotechnology and pharmaceutical patents nor their enforceability can be predicted. There can be no assurance that any patents which Opal may own, access or control will afford Opal commercially significant protection of its technology or its products or have commercial application, or that access to these patents will mean that Opal will be free to commercialise its technology.

9.3 Dependence on Key Personnel

Opal is dependent on the principal members of its scientific and management team, the loss of whose services could materially and adversely affect Opal and might impede the achievements of its research and development objectives. Because of the specialised nature of Opal's business, Opal's ability to maintain its program effectively will depend in part on its ability to attract and retain qualified research personnel either within Opal or via its contracted activities. There can be no assurance that Opal will be able to retain sufficient qualified personnel on a timely basis, retain its key scientific and management personnel or maintain its relationships with its collaborators. The failure to retain such personnel and develop such expertise could materially adversely affect Opal's prospects for success. The ability of Opal to maintain and develop the competence and skills of its key responsible managers is affected by its size. Extensive ongoing training opportunities are not feasible for small biotechnology companies such as Opal.

9.4 Competition

The biotechnology and medical technology industries are characterised by rapid and continuous technology innovation. Opal faces high competition as new and existing companies enter the market and advances in research and new technologies become available. Opal's technology, services and expertise may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by Opal or one or more of its competitors.

Opal's success will depend on strategic partnering and the extent to which these partners are interested in pursuing licensing and further development of Opal's research outputs. The number of Opal's potential strategic partners is diminishing as the current trend towards consolidation continues. Accordingly, Opal expects that an increasingly small number of partners will account for a substantial portion of our licensing and partnering opportunities with third parties.

9.5 Commercialisation

The commercialisation of technology developed by Opal could require the licensing of technology to or from other entities. Opal cannot give an assurance that such licences will be obtained or, if obtainable, will be on commercially acceptable terms. Furthermore there is always the risk that licensing arrangements, once negotiated, could be terminated for reasons that may be beyond Opal's control.

Commercialisation may also depend on obtaining and/or maintaining government approvals for production, marketing and sales. Opal and its partners are dependent on government agencies having funding for their functions, and being able to perform their roles without undue delay. A delay in an application being processed may result in a product not being able to be marketed or distributed, or to obtain or maximise sales, in a particular market.

9.6 International Agreements

Opal has contractual relations with parties that are domiciled in foreign jurisdictions. There is scope for change in the areas of contract law, property and in particular intellectual property in developing foreign jurisdictions which is outside Opal's control. Where possible, Opal will seek to have contracts that are entered into with foreign entities governed by the laws of Western jurisdictions such as Australia, the United States of America or European countries in order to attempt to minimise any risks in this regard.

9.7 Funding Requirements

Operating costs and net losses and negative cash flow from Company operations may increase for the foreseeable future, due primarily to increases in expenses for research and product development, should the research prove successful. The time required for Opal to reach or sustain profitability is highly uncertain and Opal may not be able to achieve or maintain profitability. Also, if Opal does achieve profitability, the level of any profitability cannot be predicted and may vary significantly. Opal may need additional funds in the future to continue to develop and fund its business. However, to the extent that Opal's capital resources are insufficient to meet future capital requirements, Opal may have to raise additional funds to continue the development of its technology.

Opal may not be able to raise funds on favourable terms or at all. Opal's current operating plan could change as a result of many factors and Opal may require additional funding sooner than anticipated. Opal's requirements for additional capital may be substantial and will depend on many factors, some of which are beyond Opal's control, including:

- Slower than anticipated progress in research;
- Requirement to undertake additional research;
- Competing technological and market developments;
- • The cost of protection of patent and other intellectual property rights;
- Progress with commercialisation.

Technology development is inherently high risk and the above risks are not exhaustive. Other risks may become evident with further development of the technology and commercial relationships. Opal can give no assurance that all of Opal's objectives can be satisfactorily achieved.

9.8 Unlisted, illiquid Shares

Opal and its Shares and Options are not listed or quoted on ASX or any other securities exchange. Accordingly there is no liquid market for Opal's Shares, Options or other securities, and shareholders would be entirely reliant on off-market buyers being able to be identified and private arrangements for sales to be made if they wish to trade their Shares or Options.

Prospective investors should be aware that the price (if any) they may be able to sell Shares at may be less than the Offer price. There is no guarantee that Shares will be able to be traded or in respect of profitability, dividends, return of capital or the price at which the Shares may be able to be traded.

External factors such as general economic outlook, movements in interest or inflation rates, currency fluctuations, commodity prices, investor confidence and other factors, may affect whether, and if so what, Share prices may be able to be obtained.

Other Risks

9.9 General Economic Climate

Factors such as inflation, currency fluctuations, interest rates, legislative changes, political decisions and industrial disruption have an impact on Opal's operating costs. Opal's future income, asset values and Share price can be affected by these factors and, in particular, by the market price for any services or products that Opal may sell.

9.10 Market Conditions

The price of Opal's Shares and Options may be subject to a variety of unpredictable market influences in general and relating to biotechnology and life sciences stocks in particular. These market conditions may affect the value of Opal's Shares and Options regardless of Opal's performance.

9.11 Government Policy Changes

Any material adverse changes in government policies or legislation of any countries in which Opal operates or may operate in may affect the viability and profitability of Opal.

9.12 Foreign Currency and Exchange Rate Fluctuations

Revenue and expenditure of Opal may be domiciled in currencies other than Australian dollars and as such expose Opal to foreign exchange movements, which may have a positive or negative influence on the Australian dollar equivalent of such revenue and expenditure.

Opal will appropriately monitor and assess such risks and may from time to time implement measures, such as foreign exchange currency hedging, to assist managing these risks. However the implementation of such measures may not eliminate all such risks and the measures themselves may expose Opal to related risks.

9.13 Future Performance of Business Activities

The value of Opal's business activities is subject to the various and unpredictable influences of the market it operates in and the economy in general. Accordingly, adverse economic and market conditions may be experienced by Opal which are outside of its control and may have an adverse effect on Opal.

General

The above list of risk factors should not be taken as exhaustive of the risks faced by Opal or by investors in Opal. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of Opal and the value of Shares offered under this Information Memorandum.

Therefore, the Shares to be issued pursuant to this Information Memorandum carry no guarantee with respect to the payment of dividends, returns of capital or the market or other value of the Shares. Potential investors should consider that the investment in Opal is speculative and should consult their professional advisors before deciding whether to apply for Shares in Opal.

Glossary

Anti-infectives means something that is capable of acting against infection and includes both antibiotics and non antibiotics.

BARDA means the Biomedical Advanced Research and Development Authority which is part of the US Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response.

BDM-I Technology means the anti-microbial technology (which targets the treatment of infections) assigned to BioDiem by the Institute of Experimental Medicine, St Petersburg, pursuant to a Commercialisation Agreement dated 1 November 2001 and assigned by BioDiem to Opal in July 2015.

BioDiem means BioDiem Limited ACN 096 845 993

FDA means the United States Food and Drug Administration.

Offer means the offer of Shares and Options set out in this Information Memorandum.

Opal means Opal Biosciences Limited ACN 605 631 963.

Option means an option to subscribe for a Share at an exercise price per option of A$0.25, with an expiry date of 2nd October 2020.

Share means a fully paid ordinary share in Opal.

TGA means the Australian Therapeutic Goods Administration.