



OPAL BIOSCIENCES LIMITED

ABN 97 605 631 963

Level 4,

100 Albert Road,

South Melbourne, Victoria, 3205

Australia

Phone: +613 9692 7240

Web: www.opalbiosciences.com

Announcement

Funds from Opal option exercise fuel antimicrobial development plan

Melbourne, 16 September 2019: Australian infectious disease therapy company Opal Biosciences Limited (“Opal”) is pleased to announce the early exercise of share options by Opal shareholders raising \$280,000.

Highlights:

- Early exercise of options raises \$280,000.
- New study results (single dose in mice) showing good blood levels and without adverse effects.
- Mouse blood levels after injection exceed concentrations needed in screening to kill important human pathogens.

Options to acquire shares in Opal at A\$0.20 per share were issued in February 2018 and formed part of a \$606,000 share placement at that time. The options expire on 1st February 2020 and can be exercised at any time up until 5.00pm (AEDT) on 1 February 2020. Exercise of the remaining options would raise \$326,000.

With the funds raised from the early exercise of the options Opal can defer external fund-raising and the consequent dilution of existing shareholders.

This follows the recent results of a pharmacokinetic study which showed that Opal’s antimicrobial, BDM-I, given by injection can achieve blood levels in mice which both exceed those needed in lab bench testing to kill dangerous micro-organisms and which have no ill effects in the mice. The study compared the concentrations of BDM-I obtained in the blood (of a mouse) after a single dose.

The next six to nine months will be a critical period for Opal, specifically to:

- demonstrate proof-of-concept,
- achieve Orphan Drug Designation (FDA), and
- form the basis for what we hope will be further commercial interest in the BDM-I technology.

Since the placement in February 2018 Opal has followed the BDM-I development plan that was indicated to potential shareholders at that time, and has done so successfully and within a tight budget. Achievements include:

- European grant of Opal's second patent: *Method of Treatment of Scedosporium spp infections*, which had also been granted in the US. *Scedosporium* species are associated with deadly difficult-to-treat fungal infections in patients whose immune systems are compromised.
- The addition to the Opal board of Ken Windle, a seasoned pharmaceutical executive with international experience.
- Study results showing that BDM-I shows activity (on the lab bench = *in vitro*) against a range of antibiotic-resistant strains of *Neisseria gonorrhoea*. This is responsible for causing the infection gonorrhoea. The spread of gonorrhoea around the world is causing concern in major public health agencies such as the World Health Organisation.
- The transfer of all BDM-I property rights from BioDiem to Opal Biosciences.
- The award of a A\$50,000 Innovation Connections grant and conduct of studies to explore further the way BDM-I kills bacteria; and further development of an intravenous injection formulation which could be used in animal studies.
- The appointment to the Opal board of Mr Peter Snowball, an experienced financial markets executive and biotechnology company investor.
- International filing of a new patent describing how BDM-I works to reverse resistance to the important antibiotic, vancomycin.
- Discussion with the US National Institutes of Health (NIH) branch that deals with infectious diseases, National Institute of Allergy and Infectious Diseases (NIAID), about utilising its suite of preclinical services.
- Opal joined the US CDC's Antimicrobial Challenge becoming the first Australian company to do so.
- Results from an antifungal screening *in vitro* program which showed the concentration of BDM-I needed was far lower in six out of eight instances including where the other drugs did not work at all. New drugs are desperately needed for treatment of the infections that these fungi cause, and in one case, *Candida auris*, the marketed drugs are almost totally ineffective, but the concentration of BDM-I needed to be effective was low. The problem posed by *Candida auris* is described by the US CDC <https://www.cdc.gov/fungal/candida-auris/candida-auris-qanda.html>. Invasive fungal infections, unlike those that occur on the skin or mucous membrane, are serious infections that can affect the blood, heart, brain, eyes, bones, and other parts of the body. They are often difficult to treat and can be deadly.
- The results of a BDM-I tolerability study were received in March 2019 and showed that BDM-I was tolerated at all doses tested in a mouse study when injected and when given by mouth at different doses. The study was critical to understand the dose range which could be used in future mouse studies e.g. to determine effectiveness.
- The results of a BDM-I pharmacokinetic study described above.

Opal's next steps

Proof-of-concept: It has always been Opal's goal to undertake a "proof-of-concept" study. We expect that the results in one infection area, if successful, can be extrapolated to other therapeutic infection areas and assist us (or an acquirer) move towards clinical trials, especially for infections where choices for treatment are scarce.

FDA Orphan Drug Designation: The results would also be used to apply for US FDA Orphan Drug Designation which provides a number of incentives including research grants, tax credits for clinical research, and protocol assistance for the development of drugs for rare diseases and disorders. It also provides marketing exclusivity for approved orphan drug products.

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About Opal Biosciences Ltd

Opal Biosciences is a preclinical stage Australian biotechnology company and an innovative player in infectious disease treatment. The unmet need for new anti-infectives is due to increasing resistance to existing antibiotics, more widespread and common difficult-to-treat infections, and the paucity of upcoming new treatments. This need has spurred the EU and US to introduce significant financial incentives to encourage development of new anti-infectives.

Opal is developing a small molecule, BDM-I, as a therapeutic to treat serious human infections including those resistant to antibiotics. BDM-I is in the preclinical stage of development and has obtained development assistance from international agencies.

BDM-I has shown activity against select bacterial and fungal pathogens, responsible for serious infections. These include methicillin-resistant *Staph aureus* (MRSA) and resistant strains of *Neisseria gonorrhoea*. Rising reports of antibiotic resistance to gonorrhoea are concerning health authorities worldwide.

For more information, please visit www.opalbiosciences.com.

Further information

Julie Phillips, Managing Director, Opal Biosciences Ltd

Phone +61 3 9692 7222

Email jphillips@opalbiosciences.com

Twitter @opalbiosciences