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Announcement

Company Update and EOFY 2019 Information

Highlights:

- **Progress in research study program**
- **Grant funding and R&D Tax rebate**
- **ESIC eligibility**
- **EOFY 2019 valuation for tax purposes**

Melbourne, 12 July 2019: Australian infectious disease therapy company Opal Biosciences Limited ("Opal") is pleased to provide the following update.

Our aim for 2019 has been to complete key studies showing the value of our antimicrobial drug, BDM-I, in treating infections including those resistant to currently available antibiotics.

Study Program Update:

Tolerability study: the first mouse study was conducted earlier this year in Taiwan by a specialist contract research company, Eurofins PanLabs Discovery Services (Eurofins). The study compared six different doses of BDM-I to understand how much BDM-I could be given to mice without side affects. Of the six doses, three different amounts were given straight into the bloodstream (intravenously) and three doses were given by mouth (orally). We received the results at the end of March and they showed that the mice tolerated all the dosages in the range given both intravenously and orally.

Pharmacokinetic (PK) study: Subsequent to the tolerability study results we are now utilising the US National Institute of Allergy and Infectious Diseases (NIAID)'s suite of preclinical services to test BDM-I in a mouse model. The study currently underway is comparing the concentrations of BDM-I which are obtained in the blood (of a mouse) after doses given orally with those by injection (intraperitoneally). We anticipate receiving the results of this study within the next month. This study is also being conducted in Taiwan by Eurofins and is at no charge to Opal.

Next steps: Proof-of-concept study: The results of the tolerability and PK studies will assist us choose a dose range of BDM-I which can be given to mice to try to cure an infection (a "Proof of Concept" study). The dose range is important as it should not to be too high as to cause side effects but high enough to give sufficient levels in the bloodstream to kill an infection. The plan is to target initially the treatment of invasive fungal infections.

Invasive fungal infections are often life-threatening infections in humans and few new therapies are available: only three classes of antifungal drugs have been developed and in use for these infections in the last 50 years[1]. Resistance to treatment is also a growing problem for fungal infections exemplified by the recent emergence of multi-drug resistant *Candida glabrata* and *Candida auris*[2]. In the laboratory, BDM-I has already shown the ability to kill some resistant strains of *Candida glabrata* and strains of *Candida auris*, and also some moulds which are naturally resistant to treatment e.g. *Scedosporium prolificans*[3].

A successful result from a proof-of-concept study will be a key event for us and will allow us to apply for an internationally recognised status: "*FDA Orphan Drug Designation*". The FDA Orphan Drug Designation Program 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.

All being well we would expect to have the result of the proof-of-concept study within four to six months. We would then be seeking meetings with regulatory authorities to plan an appropriate pathway to take this candidate drug into studies in humans.

Grant and R&D Tax Refund

An R&D tax refund of $53,469 was received relating to the research work conducted in FY2018. A further $25,000 refund was also received from the Innovations Connection grant. On current forecast, Opal will require a small amount of additional funding before the end of 2019 and shareholders will be advised of the plan for this shortly.

Early Stage Innovation Company ("ESIC") qualification

Australian-based Opal shareholders who participated in the 2015 and 2018 fund-raising may be eligible for certain tax benefits. Those investors will be contacted by Opal to assist in determining their eligibility.

EOFY Share Price information

The EOFY 2019 valuation of Opal Biosciences ordinary shares is 25 cents ($0.25).

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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

[1] Krysan, DJ, *The unmet clinical need of novel antifungal drugs, VIRULENCE 2017, VOL. 8, NO. 2, 135–137*

[2] Centers of Disease Prevention and Control. Antifungal Resistance, https://www.cdc.gov/fungal/antifungal-resistance.html

[3] Data on file.

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

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