

Announcement

Company Update and EOFY 2019 Information

Highlights:

- **Chinese LAIV progress**
- **Progress in Opal research study program**
- **Grant funding and R&D Tax rebate**
- **EOFY 2019 valuation for tax purposes**

Melbourne, 12 July 2019: Infectious disease therapy and vaccine development company BioDiem Ltd and its subsidiary company Opal Biosciences Ltd (“Opal”) are pleased to provide the following update.

Live attenuated flu virus (LAIV) vaccine licensee progress in China

BioDiem’s LAIV licensee in China, Changchun BCHT Biotechnology Co, has advised that it is undergoing regulatory review by the Chinese FDA for marketing approval of its LAIV vaccine. The timeline for regulatory review is uncertain. Shareholders will be advised when a further update is available.

Opal Biosciences Ltd (“Opal”)

Opal’s aim for 2019 has been to complete key studies showing the value of Opal’s 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 effects. Of the six doses, three different amounts were given straight into the bloodstream (intravenously) and three doses were given by mouth (orally). The results were received 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 Opal is now 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). The receipt of the results of this study is anticipated 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 choice of 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 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 years¹. 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 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 Opal and will allow Opal to apply for an internationally recognised status for BDM-I: “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 the results of the proof-of-concept study would be expected within four to six months. Opal 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

BioDiem has received a R&D tax refund rebate of \$42,059 and Opal received \$53,469 relating to the research work conducted in FY2018. Opal also received a further \$25,000 refund from the Innovations Connection grant. On current forecast, Opal will require a small amount of additional funding before the end of 2019 and Opal shareholders will be advised of the plan for this shortly.

EOFY Share Price information

For EOFY 2019 valuation purposes, the last sale price of

- BioDiem ordinary shares = \$0.08 (8 cents)
- BioDiem preference shares = \$0.08 (8 cents)

For those BioDiem shareholders who also separately hold shares in Opal, the EOFY 2019 valuation of Opal Biosciences ordinary shares = \$0.25.

Shareholder Information at Share Registry, Computershare.

Shareholders are asked to ensure their contact details/email addresses are up-to-date at Computershare. This can be done online via the Computershare Investor Centre (www.computershare.com.au).

- ENDS -

About BioDiem Ltd

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

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

BioDiem’s antimicrobial technology, BDM-I, is being developed through its subsidiary, Opal Biosciences Ltd. For additional information, please visit www.biodiem.com.

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.

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, Chief Executive Officer, BioDiem Ltd

Phone +61 3 9692 7222

Email jphillips@biodiem.com

Twitter @biodiem @opalbiosciences