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## Announcement

### CHAIRMAN'S ADDRESS TO THE ANNUAL GENERAL MEETING

#### Melbourne, 19 October 2015:

Welcome to the BioDiem Annual General Meeting. It is a pleasure to address you this afternoon as the Chairman of BioDiem Ltd and also of our new subsidiary, Opal Biosciences Ltd. Today I will give you a brief overview of the many highlights of the 2014-2015 year and some more recent news before handing over to our CEO Julie Phillips.

Since I addressed you last year, a number of important events have occurred which are very encouraging for us, and most welcome, given our expectations over the past several years. Despite previous delays I am pleased to report that we are now engaged in a series of activities which reveal that our outlook is most sound.

The two key events of this year were

- the beginnings of revenue from royalties however modest from our LAIV 'flu vaccine technology licensing business, and
- the strategic demerger of our promising antimicrobial compound, BDM-I, into Opal Biosciences ("Opal").

Let me explain in more detail:

Firstly, the progress of the licence holders of our main asset, the LAIV flu vaccine technology:

- In July 2014 Nasovac-S™, the Serum Institute of India's seasonal influenza vaccine was launched in India. Serum Institute is a licensee of BioDiem and previously successfully marketed the pandemic swine flu vaccine, Nasovac™, in 2011. The launch and commencement of sales of their new seasonal vaccine product marks the first such product launch based on our technology outside of Russia and the CIS. BioDiem has begun to receive modest royalties from sales of this product in the private sector market in India.
- Importantly, this month, the SII formally received WHO prequalification certification of this vaccine, Nasovac-S. What does WHO prequalification mean? WHO Prequalification aims to ensure that health-related products, including vaccines, for high burden diseases, meet global standards of quality, safety and efficacy. The WHO prequalification process comprises a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers. This information, in conjunction with other procurement criteria, is used by UN and

other procurement agencies to make purchasing decisions regarding these health-related products or vaccines.

- Therefore with the WHO PQ approval for Nasovac-S SII can prepare for export to markets outside India. Sales in the private sector of export markets will strengthen the royalty stream to BioDiem. Regulatory approval will be needed in many of the new export jurisdictions, with expected approval times generally 1-2 years before sales can commence. We understand, in other markets such as some South American PAHO (the Pan American Health Organisation) members, WHO prequalification is sufficient for marketing approval.
- In May 2015 Serum Institute announced a distribution deal with global pharmaceutical company Cipla for Nasovac-S in India. Under the arrangement SII will manufacture the vaccine and it will be distributed in India by Cipla exclusively. Cipla is India's fourth largest drug maker by sales and has more than 60% of its sales outside India. Cipla's turnover in FY2015 was USD 1.7 billion. It has a strong presence in India, and is also in Europe, North America and South Africa. The Nasovac-S distribution arrangement will leverage the strong Cipla sales presence already established in India.
- In addition, this month Serum Institute and Cipla announced an exclusive agreement for supply of SII's vaccines for the South African market where Cipla's subsidiary, Cipla Medpro P/L, is the third largest pharmaceutical manufacturer. This follows the Cipla and SII announcement in November 2014, where Cipla will seek to market SII's vaccines in Europe to complement Cipla's pharmaceutical product range.
- These announcements coincide with opportunities opening for the LAIV technology in other markets, both developed and developing countries.
- In China, our licensee, Changchun BCHO Biotechnology Co has last month received approval to conduct clinical trials from the Chinese FDA. This is an important milestone for BCHO and also for BioDiem: clinical trials are the necessary precursors to marketing approval for product launch. Similarly here in China, BioDiem will receive royalties on the eventual sales of the LAIV vaccine in the private sector.
- Over the 2015 year, we have also seen the publication of the results from the Phase II children's study on the safety of the LAIV intranasal 'flu vaccine (seasonal trivalent) conducted in Bangladesh in 2012. The study enrolled children aged 2-5 years and was randomized, double-blind and placebo-controlled. The results support the safety of the vaccine in this young age group and found no statistical difference in reports of wheezing or other post-vaccination reactions between placebo and treatment arms. These results have been used to support a proposal for further studies in children less than 2 years where there is a need for safe, easy-to-administer vaccines. Young children can be more susceptible to serious complications from flu infections, and also act as a source of infection for adults. Because vaccination is recommended for children from 6 months of age, these studies supporting the safety of the pain-free LAIV influenza vaccine technology in younger children will further highlight its suitability for this underserved age group.
- Additionally, there has been publication of further LAIV clinical trials and other research results supporting the value of the LAIV technology including for avian influenza (bird flu) including H5N1, H5N2, H7N3, H1N1 and H2N2 subtypes. Very recently Prof Rudenko's group were co-authors on a

paper for their completed H7N9 (bird flu) LAIV vaccine Phase I clinical trial. The paper has been accepted for publication in the prestigious Lancet Infectious Diseases.

Secondly, the strategic demerger of our promising antimicrobial compound, BDM-I, into Opal Biosciences (“Opal”) Limited:

- The formation of Opal Biosciences in May 2015 was undertaken to permit external investment in the commercialization of BDM-I while allowing BioDiem shareholders to retain benefit from successful commercialisation.
- Shareholder approval for the transfer of the BDM-I technology into Opal Biosciences was obtained in July 2015.
- BioDiem’s collaborator, Griffith University, applied successfully to the Australian Federal Government for an ARC Linkage grant for \$241,564 to investigate the molecular targets for BDM-I’s antimicrobial activity.
- A new US patent for BDM-I was awarded for claims relating to infections of the gut, to add to those already granted for protozoal infections; vulvovaginitis, and skin and soft tissue infections. We also received notification of acceptance of European grants for the same claims.
- Further investigation of how BDM-I works against “superbugs” was performed by Associate Prof Slade Jensen’s unit at the Ingham Institute for Applied Research and Western Sydney University, and is ongoing.
- The “Opal Biosciences takes on the Superbugs” article appeared in the Australian newspaper on 13 July 2015.
- Also we saw exercise of our 8c options in January 2015 contributing \$834,400 in total.

On sad news however, in March this year our long-time director, Don Brooks passed away. Don had been involved with BioDiem from 2001. With his long experience in multinational companies, he was of immense value and instrumental in the company’s negotiations and transactions with Merck, Nobilon, the World Health Organisation and our other LAIV licencees. We miss Don’s enthusiasm and generosity and are grateful for the strong contribution.

With the commercialization of our lead asset, the LAIV flu vaccine technology, we are now in an increasingly better commercial position. I do recognize that as shareholders we have been very patient for the commercial success of our company. Our decision this year to incorporate Opal Biosciences as a vehicle for commercialization of the anti-infective technology BDM-I was deliberately to protect BioDiem shareholders from significant dilution on attracting the investment required to develop the BDM-I asset, while maintaining a major stake in the technology. Our expenditure has been minimized and the Opal fund-raising campaign is underway. It is our present intention to proceed to an IPO for Opal within 18months to two years, subject to any alternate arrangement before then. While we are pleased with the developments and improved commercial prospects of the ‘flu vaccine and the contribution that Opal will make to BioDiem, we will undertake a small capital raising into BioDiem to bridge us into being cash flow positive. This will be done as a rights issue entitlement preceded by a placement to the major shareholders at the same price.

The board has approved a placement to its major shareholders which is being undertaken now and expected to be completed in several weeks. Thereafter there will be an issue to remaining shareholders in the same terms in order to ensure there is no dilution of shareholders who subscribe. This will be preceded by the issue of a prospectus.

The fund-raising will be at 8c/share, equivalent to the option exercise price from the end of last year. Provisions will be made for the allocation of any shortfall in entitlement at the discretion of the board.

In summary, I am very pleased with the outlook for both BioDiem and its subsidiary, Opal Biosciences. I

congratulate Professor Rudenko on her many successes this year and thank her, her staff and ours for their continued passion and achievements. Any my appreciation to our CEO Julie Phillips for her tireless commitment to the company throughout the year. We will continue to update you through the coming year.

- ENDS -

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### **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 already 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](http://www.biodiem.com).