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Announcement

CEO ADDRESS TO THE ANNUAL GENERAL MEETING

Melbourne, 19 October 2015

Thank you Hugh, and I would like to add my welcome to you all.

I am happy to report to you our commercial progress for this past very busy year. But before I do - this year also marked the sad loss of our long time director Don Brooks. Don contributed generously to the company with his time and advice based on his significant commercial experience. He is greatly missed.

Our focus continued on the LAIV and BDM-I programs as the closest revenue-generating prospects for BioDiem.

The LAIV Program Highlights were:

- Commencement of royalty income from sales of Nasovac-S™ in India, and income from milestone payments totaling $179,962 (2014: $93,398). Nasovac-S is a seasonal 'flu vaccine based on BioDiem's LAIV (live attenuated influenza virus) vaccine technology. Nasovac-S received WHO PQ this month: an important commercial milestone.

- Progress by our Chinese licensee, Changchun BCHT Biotechnology Co, who were granted approval to start clinical trials in China.

- Publication of the Phase II children's study on the safety of the LAIV intranasal 'flu vaccine (seasonal trivalent) conducted in Bangladesh in 2012 in children aged 2-5 years. 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.

- Publication of LAIV clinical trial and other research results supporting the value of the LAIV technology including for avian influenza (bird 'flu) including H5N1, H5N2, H7N3, H1N1, H2N2 and now H7N9 subtypes.

The Antimicrobial BDM-I Program highlights were:

- The formation of Opal Biosciences Ltd (Opal) in May 2015 for commercialization of BDM-I. Opal is a public company and a subsidiary of BioDiem Ltd. BioDiem shareholders approved the transfer of the BDM-I technology into Opal Biosciences in July.

- We saw a successful application by BioDiem's collaborator, Griffith University, to the Australian Federal government for an ARC Linkage grant for $241,564 to investigate the molecular targets for BDM-I's antimicrobial activity.

- Also we were awarded a new US patent for BDM-I 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 received notification of acceptance of European grants for the same claims.

- Assoc. Prof Slade Jensen's unit at the Western Sydney University investigated further how BDM-I works against resistant bacteria.

- And an article called "Opal Biosciences takes on the Superbugs" appeared in the Australian newspaper on 13 July 2015.

Corporate Activity Highlights were:

- We received more than $834,000 from exercise of 8c options and $128,000 from the R & D Tax Incentive program. This has been used to fund the additional commercial and development work on our LAIV and BDM-I programs, respectively.

Now in a little more detail.

The LAIV Program

BioDiem's LAIV Vaccine Licensing business involves licensing the company's platform technology to others for the production of intranasal LAIV vaccines for the prevention of seasonal and pandemic influenza.

BioDiem currently has two commercial partners:

- *Serum Institute of India (SII)(Pune, India), and*

- *Changchun BCHT Biotechnology Co.(BCHT) (Jilin, China).*

Our LAIV vaccine technology is also licensed to the World Health Organization (WHO) as part of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply.

- Looking first at progress in India: SII launched the swine 'flu vaccine in 2011 and this has now been followed by the launch of Nasovac-S, a seasonal influenza vaccine, last year. SII is one of the world's largest vaccine producers. We receive royalties on sales of this intranasal 'flu vaccine in the private market in India. The royalty flow was expected to be and is, modest initially.

  In May 2015 SII announced an exclusive marketing and distribution agreement with the pharmaceutical giant Cipla for Nasovac-S in India. This strategic partnership will leverage the strong Cipla sales presence already established in India and is expected to impact Nasovac-S sales favourably.

  Also this month Nasovac-S was granted WHO prequalification – this will allow SII to export to other developing country members of the United Nations.

  SII holds a licence to our LAIV technology for manufacture and commercialisation in India exclusively and non-exclusively for Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan, New Zealand, Myanmar and Sri Lanka. Additional territories are under discussion.

- Our Chinese licencee, Changchun BCHT Biotechnology Co. has made significant progress in the past year in line with their manufacturing and development plan and now have approval from the Chinese FDA to conduct clinical trials in China for LAIV which are expected to start in December this year.

The advantages of LAIV vaccines are well-known and continue to be recognised - the LAIV vaccines induce more comprehensive and protective immune responses giving a broader protection. This immunity can protect against virus strains which differ slightly from that used to prepare the vaccine (cross-protection).

- This year a seed grant was awarded to the University of Georgia and the Centers for Disease Control and Prevention (CDC) in the US for development and proof-of-concept (ferrets) studies of a thermostable dry powder LAIV. This is to develop a product with an extended shelf life.

- New publications continue to support the S and E of the vaccine. During the year we saw the publication of a Phase II LAIV 'flu vaccine safety study in 300 children (aged 24-59 months) conducted in Bangladesh showing the vaccine was safe and well-tolerated.

- Under an agreement with the WHO, Prof Rudenko's lab in the Institute of Experimental Medicine, in St Petersburg, prepares LAIV reassortant vaccine strains suitable for production of seasonal and also pandemic influenza vaccines. A range of pandemic strains has now been prepared and tested so that they could be available quickly to our licencees in the event of a pandemic. During the year further work was conducted and published from Prof Rudenko's lab on pandemic and potentially pandemic vaccine candidates including most recently, on an H7N9 vaccine candidate.

<u>The Antimicrobial BDM-I Program: Opal Biosciences ('Opal')</u>

BioDiem's antimicrobial compound BDM-I targets the treatment of antibiotic-resistant and hard-to-treat human infections. It is being commercialised through BioDiem's subsidiary, Opal Biosciences ("Opal") which was formed in May 2015. In July 2015, BioDiem shareholders approved the transfer of the BDM-I technology into Opal. A major focus of Opal has been to promote a capital raising of up to $4m to develop Opal-I, an injectable product, and Opal-T, which can be applied to the skin; and to support and continue existing collaborations.

Opal's technology has significant commercial potential.

- It has already shown activity against some serious disease-causing germs, as well as the more everyday infections which are not life-threatening.

- It could be formulated into many different product types so it could be used for many different types of infections

Because of BDM-I's results in the laboratory so far, we have been accepted into two US National Institutes of Health (NIH) programs (resistant tuberculosis and the fungal disease caused by Pneumocystis spp) and by the USAMRIID (biowarfare defense programs). This positions us well in our current US commercial discussions. In addition, BDM-I has been accepted into an updated program of the NIH[1] to screen for activity against strains of two vancomycin-resistant germs, vancomycin-resistant enterococci (VRE) and vancomycin-resistant *Staph aureus* (VRSA).

Infections can occur anywhere in the body and we see a wide product range potential for BDM-I based on the range of micro-organisms against which it has shown activity. We are developing an injection for serious infections like blood poisoning, and other life-threatening hospital infections, and next a gel to apply to the skin for infections in wounds, skin infections like impetigo, and even tinea. Additional products will follow for gut and lung infections.

Our capital raising is funding the development of these Opal antimicrobial products; an injectable (Opal-I) and a product for the skin (Opal-T). Our commercial objective is near term.

[1] http://www.niaid.nih.gov/LabsAndResources/resources/dmid/invitro/Pages/invitro.aspx

We have initiated the formulation development work for Opal-I and some laboratory safety screening studies. These are the first studies in a 12-18 month program ending in proof-of-concept studies in a model of infectious disease, that is, to show the product can work. Successful results will increase the value of the Opal technology significantly.

While we intend to float Opal Biosciences on a suitable stock exchange within 18mths to two years, we expect that we will have sold or outlicensed the Opal technology before reaching that stage.

The demonstrated market need for new anti-infective treatments is fuelling market growth, and driving high value merger and acquisition activity in the anti-infectives space. Recent high value transactions are reflecting this as multinationals move back into this sector.

The US is on the front foot in providing incentives for companies like Opal. These incentives get a product to market faster, with FDA assistance and longer market exclusivity. A faster development time will be reflected in a lower cost of development. Included in the FDA's list of "qualifying pathogens" are those which have shown susceptibility to BDM-I in the laboratory.

In addition to the benefits of the Generating Antibiotics Incentives Now (GAIN) Act, there are additional benefits related to Orphan Drug designation. In the US there is an additional 7 years of marketing exclusivity, bringing the total to 12 years for antibiotics targeting qualifying pathogens and diseases.

The opportunity to access US Incentives, particularly extended market exclusivity for one or more pathogens and fast track designation for expedited FDA review drives the attractiveness of the development plan for potential acquirers. The US is the market Opal is targeting.

Our development plan is being accomplished through an international network of experienced groups. In July this year Griffith University was successful in an ARC Linkage application for $241,000. This aims to identify the molecular targets of BDM-I. This together with the work being done in Assoc Prof Slade Jensen's lab at Western Sydney University is breaking new ground for us, and positioning us better to understand the best use of BDM-I to target treatment of superbugs and attract acquirers.

We look forward to keeping you up to date on developments with Opal.

Corporate activity:

Following our April 2014 rights issue, priced at 5.5c we were delighted with the exercise of 10.4 million 8c options by the end of January 2015 raising $834,400. We were also beneficiaries of the R & D Tax Incentive. We also continued to keep costs down.

Outlook

The outlook for the coming year is bright with growth in revenue prospects through sales and new territories. We will continue to support our licencees and engage in product innovation.

BioDiem holds a majority stake in Opal Biosciences and so BioDiem shareholders will be able to benefit from the successful development of the Opal technologies. Opal presentations have been given in Sydney, Hong Kong, Singapore and Philadelphia.

The market remains hot for technology such as ours and we intend to take the company to an IPO if the market is right, and a sale or licence prospect is not a more attractive option for shareholders.

Our cash requirement to support the 'flu technology and Opal Biosciences has led to the decision to undertake a small capital raising before the end of 2015. This will be done via a placement to the major shareholders and then an offer to other BioDiem shareholders with identical terms. We continue to pursue other sources of non-dilutionary funding. Importantly too, commercial discussions are underway and keeping us very busy.

In summary, we are focussed on what is necessary for success and believe BioDiem and our subsidiary Opal are well-positioned commercially and to the advantage of shareholders. This has been and continues to be cost-effectively managed.

Finally I would like to thank shareholders for their ongoing support, to all board members for their generosity of time and good advice, and particularly the chairman, and to our very small staff and service providers throughout the year. I will now hand you over to Prof. Rudenko for an overview of our international collaborations in the LAIV Program.

- 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.

About Opal Biosciences Ltd

Opal Biosciences is an 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 currently seeking funding to support the next stage of development of our products:

- Opal-I, an injectable product, and
- Opal-T, which can be applied to the skin.

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