

Announcement

CHAIRMAN'S ADDRESS TO ANNUAL GENERAL MEETING

Melbourne, 23 October 2014:

Welcome to the BioDiem Annual General Meeting. It is a pleasure to address you this afternoon as your Chairman. Since our meeting last year there have been key events within our company and I will give you a brief overview of these now before handing over to our CEO Julie Phillips.

I am pleased to report to you:

- Firstly, the progress of the licence holders of our LAIV flu vaccine technology:
 - In India, the approval of a marketing application by Serum Institute of India, by their regulatory authorities, for their seasonal influenza vaccine. This was launched as Nasovac-S in July 2014. BioDiem will receive royalties from sales of this product into the private sector in India;
 - In China, the further progress in the building of a manufacturing facility by our licensee, Changchun BCHO Biotech; and submission of a clinical trial application to the Chinese FDA for the LAIV seasonal vaccine product as part of its development plan for the LAIV technology. Clinical trials are the precursors to marketing approval. Similarly here, BioDiem will receive royalties on the eventual sales of the LAIV vaccine in the private sector;
- Secondly, there have been developments with our licensor, the Institute of Experimental Medicine in St Petersburg:
 - where its new multimillion dollar laboratory facility has been completed and commissioned. It is designed to manufacture seasonal and pandemic influenza vaccine candidates. This facility was funded by the World Health Organisation (WHO) and PATH.
- Internationally, there has been a rise of support and interest in the live viral vaccine for flu especially for children:
 - on 25 June 2014 the US Centers for Disease Control and Prevention (CDC) announced that the US Advisory Committee on Immunisation Practices (ACIP) voted to recommend a preference for the LAIV nasal 'flu spray instead of 'flu injection in healthy children 2-8 years of age.
 - In recently completed clinical trials funded by the PATH organization, CDC, and the Bill and Melinda Gates Foundation the LAIV flu vaccine efficacy was studied in children 2-5 years. The

- study was of randomized, double-blind and placebo-controlled design, involving 1761 children. This work was conducted in Bangladesh and Senegal. The results are due before the end of this year or early next year.
- Further research and clinical trial results have been published which support the immunogenicity and safety of LAIV flu vaccine manufactured using tissue culture.
- An international collaboration involving IEM, WHO, CDC, PATH and BioDiem was finalised. This involved the preparation and testing of a collection of pandemic LAIV candidates using cold-adapted master donor (MDV) virus A/Leningrad/134/17/57 (Len/17) as a backbone. Preclinical studies demonstrated safety, immunogenicity and efficacy of these candidates in various animal models (mice, ferrets, monkeys). Preclinical and clinical evaluation of pandemic live attenuated influenza vaccines of H5N1, H5N2, H7N3, H1N1 and H2N2 subtypes were shown to be safe, immunogenic and protected animals from challenge with homologous and heterologous viruses.
- Turning to our antimicrobial asset, BDM-I:
 - We saw the presentation of the results of BioDiem's antimicrobial, BDM-I, at the American Society of Microbiology's Denver ICAAC¹ conference by world class specialist antifungal researchers exploring BDM-I's activity against micro-organisms responsible for difficult-to-treat fungal diseases. These results warrant further exploration of BDM-I as a potential fungal disease treatment.
 - Also the award of a new US patent for BDM-I for claims relating to skin and soft tissue infections, to add to those already granted for protozoal infections and vulvovaginitis.
 - Two new Australian studies of BDM-I have commenced which are looking at the drug's mechanism of action and resistance. The results of these will be used to profile BDM-I's novelty and potential value as a human therapeutic and will be used for commercial discussions.
- On corporate activities the last year has seen:
 - De-listing of the Company from the Australian Stock Exchange. Following shareholder approval, this action was commenced to reduce the compliance burden on the Company and the associated costs. BioDiem's historical low liquidity was also contributing to a low company valuation which could impede commercial negotiations.
 - Also earlier in 2014, we saw successful completion and oversubscription to our entitlement issue raising \$815,414 after scale-back. Also the Company received \$0.583m from the R&D Tax Incentive program and more than \$0.492m from exercise of our 8c options. This has been used to fund the additional commercial and development work on our LAIV and BDM-I programs, respectively.

Our successful de-listing from the Australian Stock Exchange in November last year along with continued streamlining has assisted in further reducing the cost of running the company as we move towards a commercial position. In April/May this year we asked shareholders for further funds which we saw as bridging us to a possible

¹ Interscience Conference on Antimicrobial Agents and Chemotherapy

commercial outlook. As chairman as well as a major shareholder of the company I can now update you on BioDiem's current positioning in this regard.

While the company's lead asset is our LAIV flu vaccine technology, we have sought over time to provide a pipeline of technologies to back up the LAIV. This has been a two-edged sword for us, for although the technology pipeline assembled is interesting, it is early-stage and would require additional funding to get to a commercial data package for sale.

On the revenue side, receipts from the LAIV technology from royalties will be lower than we had expected initially and we will therefore cut our cloth to match our resources. Doing this we will seek to ensure we maximise benefits to the company from our pipeline projects, but we will from now focus expenditure on the LAIV and continue to explore ways to boost income from this technology from both existing and new commercial opportunities.

We already know the significant benefits of the LAIV flu technology over other flu vaccines on the market, and these benefits are increasingly recognised by others, and nothing has diminished, in our view, the commercial prospects for this technology, other than the delays inherent in the regulatory approval and drug development processes which are outside our control. In fact there have been enhancements in the prospects of the technology and interest from a number of international groups to collaborate on commercially attractive new product development for the developed world markets. I can share more information with you when these collaborations are secured.

Importantly this year we recognise the significant commercial milestone achieved through the approval of the first seasonal vaccine product based on our LAIV technology in our licensed territory since the formation of the company. This is the approval and launch of Nasovac-S by our licensee, Serum Institute of India. We are also delighted with the news of the IND application to the Chinese FDA of our second licensee, Changchun BCHO Biotech, for commencement of clinical trials in China as part of the process towards approval of the vaccine in that territory.

We have all confidence in the processes underway for development and marketing of our LAIV technology in developing countries and now are turning our attention to opportunities for LAIV in the developed world. You would have seen my reference in the Annual Report to the recent release from the US CDC's Advisory Committee on Immunisation Practices as to the general preference for choice of the LAIV flu vaccine for immunisation of children.

Two years ago we thought that in calendar year 2015 there would be all hope of significant revenue from LAIV royalty income by this stage, but this now appears to be thin. Hence we will focus on ensuring sufficient resources to complete calendar year 2015 with the expectation of a more prospective 2016.

Our Company's other major technology is the antimicrobial BDM-I. The concern internationally about antibiotic resistance and the lack of new treatments to meet the medical need has inspired introduction of incentives, especially in the US, for new antimicrobial development. We view the potential of the BDM-I asset as significant, however further funding is required to move the technology towards preparation for proof-of-concept studies and eventual clinical trials. To this end, management is focussed on the BDM-I development plan and the opportunities open to us to promote the development of BDM-I cost-effectively. As we develop these plans, shareholders will be informed.

And finally, before I pass over to our CEO, I would like to thank our shareholders, including our two major shareholders, for their ongoing support of the company.

I wish to acknowledge the contribution of all our board members for their hard work over the year, and particularly the dedicated work of our CEO Julie Phillips and Professor Larisa Rudenko. In addition to this I would also like to acknowledge the assistance of our service team, Melanie Leydin as Company Secretary, and Stefan Ross as Company Accountant.

Last year I placed on the screen a photo of the then latest progress of the construction of the BCHT building within which the LAIV is to be produced. Today I can show you this and the more recent photograph to show the progress and the enormity of the investment. Also here is a photo of the finished product marketed by Serum Institute of India now.

As I said to you all last year, the timing of further income flows from both India and China is dependent on the respective regulatory authorities of those countries and market conditions. We can see progress and this is built on a foundation of hard work by our licencees and also Prof Rudenko's team at the IEM and international partners.

Our CEO's presentation will outline more information about progress with BioDiem's projects. The company continues to be very active and I am appreciative of the support of the staff, board and shareholders alike. I look forward to reporting further progress over the coming year.

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About BioDiem Ltd

BioDiem is an Australian biopharmaceutical company based in Melbourne, that is focussed on developing and commercialising vaccines and infectious disease therapies. BioDiem's business model is to generate income from partnerships including with other vaccine development companies through existing and new licences to its LAIV vaccine and other technologies. BioDiem has an established influenza vaccine licensing business. Its revenue comes from licence fees and royalties on sales.

BioDiem's lead technology, the LAIV (Live Attenuated Influenza Virus) vaccine, is 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 BDM-I is a synthetic antimicrobial compound targeting the treatment of serious human infections. BDM-I is active against a range of disease-causing microorganisms. Key patents have been granted worldwide. BioDiem has benefited from work conducted by major research institutions in the United States that have undertaken studies of BDM-I. BDM-I is in the preclinical stage of development and BioDiem seeks co-development and co-investment partners for this technology.

For additional information, please visit www.biodiem.com

Further information

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