BIODIEM LTD
ABN 20 096 845 993

Level 4,
100 Albert Road
South Melbourne
Victoria, 3205
Australia

Phone: +61 3 9692 7240

Annual General Meeting
19th October 2016

Chairman's Address

Today I will give you a brief overview of the 2015-2016 year for BioDiem Ltd and also for our subsidiary, Opal Biosciences Ltd.

The key events of this year were

- commercial interest in developed world markets for our LAIV 'flu vaccine technology,
- progress with the development of BDM-I programs, Opal-I, Opal-T and now Opal-L, and
- the successful nonrenounceable entitlement offer of convertible preference shares to raise $1.149m
- there have also been very recent events since the year end, which are important for the company.

Let me take you back to this time last year and recap events since then. At the AGM we had early revenues from our LAIV licences and we were looking forward to those growing. Also we had launched Opal Biosciences and a capital raising for it to allow external investment in that promising antimicrobial asset. This was to prevent the dilution of BioDiem shareholders' position with the LAIV vaccine licensing business. We announced an entitlement issue to BioDiem shareholders which closed in December 2015 raising $590,000. Those funds were used to support the LAIV business and Opal Biosciences' development.

By June 2016 we were presented with both lower than expected royalty revenues from the LAIV business and also the conclusion of an unsuccessful capital raising into Opal Biosciences. This required us to undertake a further capital raising in BioDiem which closed successfully two months ago in August. The situation in June was that we had had several approaches by external parties interested in licences to the LAIV technology. Given the company's need for capital and the potential value to shareholders from a successful new licence issue and, in recognition of this second impost on shareholders following so quickly on the last, the board decided to issue an entitlement offer for preference shares. The intention of this last raising, capped at $1.25m and raising $1.15m, was to support the company through potential LAIV licensing discussions, including soliciting wider interest in new licences, and to progress the development work within Opal Biosciences. The amount raised was expected to be sufficient to take us through this period to do this.

Then last month the World Health Organisation convened a meeting in Geneva, Switzerland held on 20-21 September to discuss LAIV vaccines' performance data from different sources and settings. There are currently two different LAIVs: FluMist/Fluenz (the Ann-Arbor backbone LAIV) which is manufactured by AstraZeneca and mainly used in North America and Europe; and BioDiem's LAIV (the Russian backbone) which is produced or under development by a number of developing country vaccine manufacturers. There have been some observational studies reported in the US suggesting LAIVs have been less effective than inactivated flu vaccines in recent years. These data were surprising, because there is much evidence including recently from randomized controlled trials and other observational data to show LAIV vaccines to be efficacious especially in children. At the Geneva meeting various factors were raised by the participants as contributing to these mixed results. This phenomenon may be associated with one or more changes that have been introduced into the vaccines over the last few years. One outcome of the meeting was a recommendation for a course of further evaluation to understand the possible LAIV performance limitations better. The report and presentations from this Geneva meeting can be found on the WHO website:
http://www.who.int/immunization/research/meetings_workshops/live_attenuated_influenza_vaccine_effectiveness_sept_2016/en/

This recent event has led to uncertainty around all LAIV vaccine technologies. For example in the US, it is now not recommended to be used for the 2016-17 season, but this is not the case elsewhere to our knowledge.

So what does this mean for us? While our vaccine is not marketed in the US, these events have impacted on our planned outreach to new licencees and held up the current commercial discussions. Until the cause of these curious results are explored further and clarified, progress is outside our control.

The LAIV licensing opportunities were the major reason for going to shareholders with the last capital raising, and therefore the board is resolved to reduce our expenditure to maintain our LAIV licence and optimise our position for when commercial discussions can re-open to invigorate the program's expansion.

Before explaining further what we intend to do, let me take you through some of the other events and highlights of the year

- In Oct 2015 our licencee SII formally received WHO prequalification certification of Nasovac-S. WHO Prequalification (PQ). This certification forms part of what is used by UN and other procurement agencies to make purchasing decisions regarding these health-related products or vaccines.
- With the WHO PQ approval for Nasovac-S SII can prepare for export to markets outside India.
- In October 2015 Serum Institute and Cipla announced an exclusive agreement for supply of SII's vaccines for the South African market through its subsidiary Cipla Medpro P/L. This follows the announcement that Cipla will seek to market SII's vaccines in Europe to complement Cipla's pharmaceutical product range. South Africa's population is ~54 million and represents about 0.73% of the world pharma market.

- In China, our licencee, Changchun BCHT Biotechnology Co has completed a Phase I study of their seasonal LAIV vaccine. A Phase II study has started and is due to be completed next year. Also a large Phase III study is due to start at the end of this month. The results of these will be used to support BCHT's marketing application for their seasonal LAIV vaccine in China. BioDiem will receive royalties on the eventual sales of BCHT's LAIV vaccine in the private sector in China.

- There have been many further publications regarding BioDiem's LAIV technology during the year and these are detailed in the annual report. Of particular note was Prof Rudenko's group's paper published in the prestigious Lancet Infectious Diseases Journal. The paper reported the results of a Phase I H7N9 (avian flu) clinical trial. An independent review of this work also published in the Lancet described it as "possibly the promising LAIV immunogenicity data so far".

Opal Biosciences ("Opal") which, since shareholder approval in July last year, houses the development work for BDM-I, BioDiem's antimicrobial asset, continues to expand the opportunities open to it:

- Additional patents have been granted in Europe and the US with claims directed at serious and treatment-resistant infections.

- Studies on how BDM-I works to kill germs and superbugs continued at Western Sydney University's Antibiotic Resistance and Mobile Elements Group (ARMEG) led by Associate Professor Slade Jensen, who is with you today and who will be presenting some of his work to you. This research focuses on BDM-I's activity against hospital pathogens such as MRSA (methicillin-resistant Staphylococcus aureus or "Golden Staph") and other superbugs. Results to date indicate that BDM-I's cellular target is novel and therefore BDM-I represents a next-generation anti-infective.

- *On product development*,

    - we continued to prepare for *in vivo* proof-of-concept testing. BDM-I is very insoluble and to develop an injectable (Opal-I) formulation for use in the next studies in animal models we commissioned work by a UK specialist company. This injectable formulation development is ongoing;

    - we explored early feasibility studies of nanoparticle formation of BDM-I which has led to discussions of a program for lung delivery of BDM-I (Opal-L) with Prof Kim Chan, Professor of Pharmaceutics (Advanced Drug Delivery), University of Sydney. Grant funding for this program will be sought. Possible disease targets include life-threatening respiratory tract fungal infections and tuberculosis;

    - subsequent to the year end, we also started early stage formulation development for Opal-T (the topical application of BDM-I) with Formulytica, a Melbourne-based specialist formulation company. Opal-T could be used for superficial infections of the mucous membranes and skin: such as tinea (athlete's foot) and candida (thrush);

- Preliminary safety pharmacology and cytotoxicity studies were performed during the year.

- In addition to the investigation being undertaken in the resistant tuberculosis and fungal programs, BDM-I was accepted into an updated program of the NIH and showed activity against strains of VRE (vancomycin-resistant enterococci) and VRSA (vancomycin-resistant *Staph aureus*).

In closing and in summary, firstly, our further commercialisation plans for our LAIV technology are suspended temporarily while we await clarification of the LAIV vaccine performance issues reported, so in the meantime we are significantly reducing expenditure in this program. Secondly, the commercial opportunities with Opal Biosciences appear only limited by the amount of funding we are able to devote to the technology development. We have been the recipient of modest Australian federal government grants for which we are grateful and are also the beneficiaries of US government programs. We are therefore seeking a cornerstone investor to fund the necessary next work to take the antimicrobial candidates towards clinical trials and to configure the board of Opal with the requisite expertise to ensure this.

The introduction of a cornerstone investor for Opal will reduce cost borne by BioDiem for this program. Further expenditure reduction will also be undertaken immediately. This will include:

- a reduction in financial support for the LAIV program including the IEM,
- further reductions in director payments; and
- reduction in staff costs.

This will be undertaken to stretch our existing cash reserves out into 2018.

On behalf of the BioDiem board I would like to thank shareholders for their patience and support. I thank the other directors for their important contributions and our also our staff who have worked tirelessly through the year. We will post updates on our website and email them to shareholders so they can follow the company in its much reduced format, and monitor progress as our position clarifies.

ENDS

For more information please contact:

Julie Phillips
Chief Executive Officer
Email jphillips@biodiem.com