BioDiem

Annual General Meeting

20 October 2011

Agenda

- Chairman's Overview
- Review of Operations
- Questions
- AGM Resolutions

Review of Operations

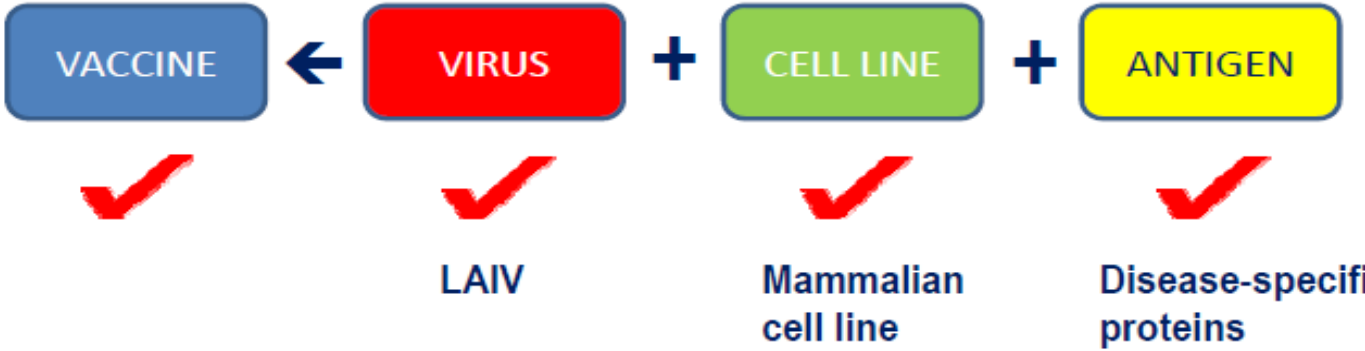
Julie Phillips

Chief Executive Officer

Key Developments

- LAIV vaccine for pandemic H1N1 influenza launched in India as Nasovac™.
  - First royalty income received for LAIV influenza vaccine.
- Regained rights to LAIV technology (worldwide, excluding Russia and CIS).
  - Received valuable GMP materials.
  - Received documentation relating to the Proof of Concept (Phase II) Clinical Trial program for cell-based manufactured LAIV vaccine.
  - Cell-based manufacturing technology – added value driver – expands scope of vaccines that can be manufactured including avian influenza vaccines.
- LAIV Viral Vector project – opportunity opened into $23.5b vaccine market.
  - Accelerated commercial positioning using GMP materials.
- Re-focus as a vaccine and vaccine technology developer.

Corporate Strategy



- BioDiem has become a vaccine franchise.
- Access to a virus and mammalian cell lines.
- Variation of antigen component creates new vaccines for different diseases.
- Acquisition of proprietary antigen IP under discussion.
- Multiple revenue streams possible from licences to any combinations of the three proprietary technologies LAIV, cell line and antigen components.

Corporate Strategy

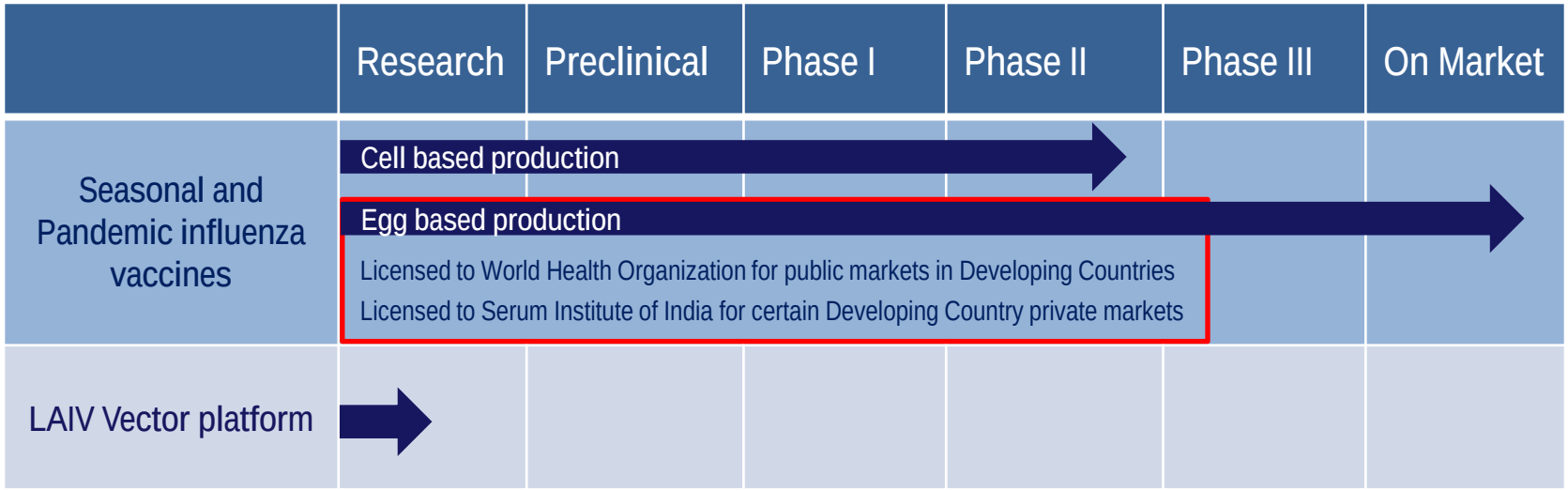
BioDiem

Vaccines markets are attractive:

- Global market size in 2010: US$23.5b *(US$36.5b in 2013).*
- High growth market: CAGR 2008–2013: 13%.
- High level of unmet medical need.
  (>40 human disease pathogens without effective vaccines)
- Therapeutic and prophylactic vaccine applications.
- High barriers to entry with little generic competition.

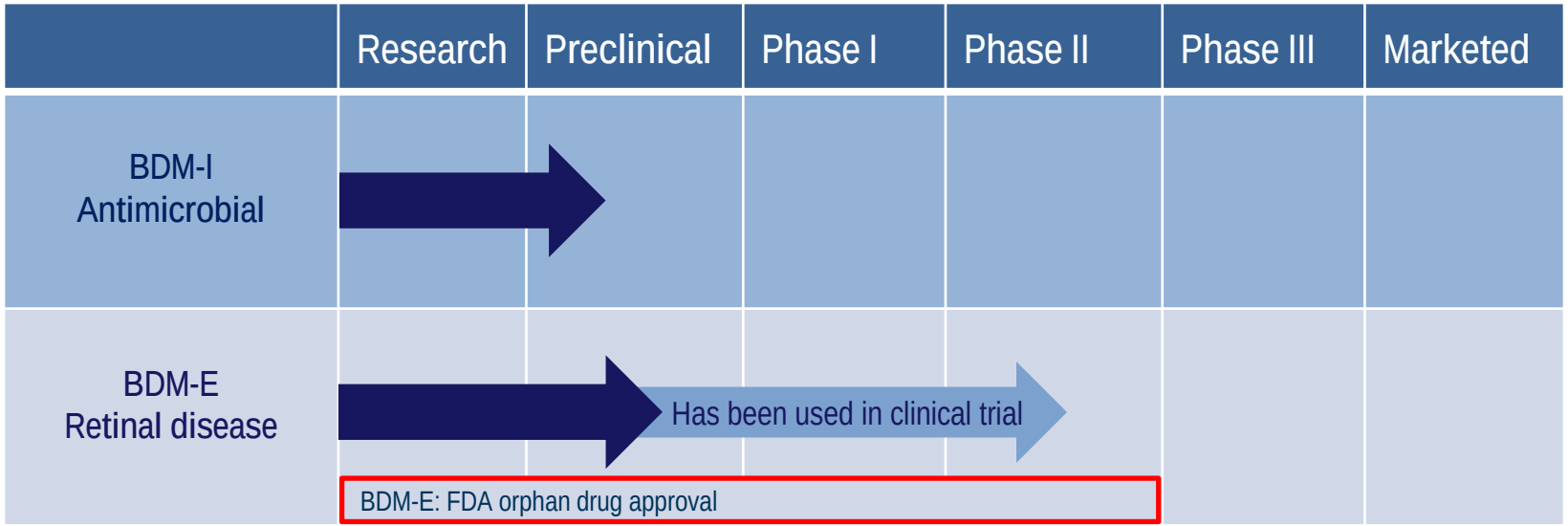
Source: Kalorama Information

Vaccine Development Pipeline



Non-core Development Pipeline

These projects are to be out-licensed



BioDiem's LAIV

A Live Attenuated Influenza Virus vaccine for the prevention of seasonal and pandemic influenza.

- Cold-adapted, temperature-sensitive, live attenuated influenza virus (LAIV).
- Proprietary Master Donor Virus (MDV) strains.
- Established safety and efficacy profile through use as 'flu vaccine (>100 million doses distributed).
- Intranasal delivery (Needle-free = no trained personnel, blood/sharps precautions necessary).
- Induces broad immune response – mucosal, systemic, cell-mediated response, similar to natural infection.
- High yield in egg & cell-based production to meet pandemic need.

Egg-based LAIV vaccine

LAIV made available to WHO as part of Global Pandemic Influenza Action Plan

- WHO has signed sub-licences with the Government Pharmaceutical Office of Thailand and the Serum Institute of India Ltd (SII).
- H1N1 (pandemic) influenza vaccine launched in India by SII in July 2010 (Nasovac™).
- Exclusive licence signed with Serum Institute of India for private sector sales in India.
- Non-exclusive license signed with Serum Institute for Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan and Sri Lanka.
- US$0.8m paid under licence agreement.

Pandemic H5N1 (avian flu) development at the CDC

The H5N1 threat remains – estimated fatality rate 60%

Aim of the project

- Is LAIV H5N1 influenza vaccine a more efficacious pandemic vaccine than inactivated H5N1 vaccines in development?

Results

- Using a cell-based (not egg-based) manufactured LAIV vaccine product, LAIV provided greater protection compared to the inactivated influenza vaccine against heterologous variants of influenza viruses (cross-protection).

PATH Vaccine Solutions Collaboration

‘Program for Appropriate Technology in Health:
an international non-profit organization whose aim is to improve the health of people around the world and break long standing cycles of poor health’

Aim: To develop an affordable and accessible pandemic LAIV influenza vaccine for distribution in developing countries.

- Nonclinical studies of LAIV vaccine against H5N1 (avian) and H7N3 (avian) strains completed.
- H5N1 LAIV vaccine scheduled to enter early stage clinical trials in 2012.

LAIV Vaccine Program – Next Steps

- Continue preparation of seasonal & pandemic strains for WHO licencees.
- Negotiate further licences for sale of egg-based product into private markets per WHO agreement.
- Pursue H5N1 & other pandemic vaccine early registration in developing countries.
- Conduct clinical studies of H5N1 and H7N3 under PATH collaboration.
- Pursue licences for cell-based manufacture of LAIV influenza vaccine.

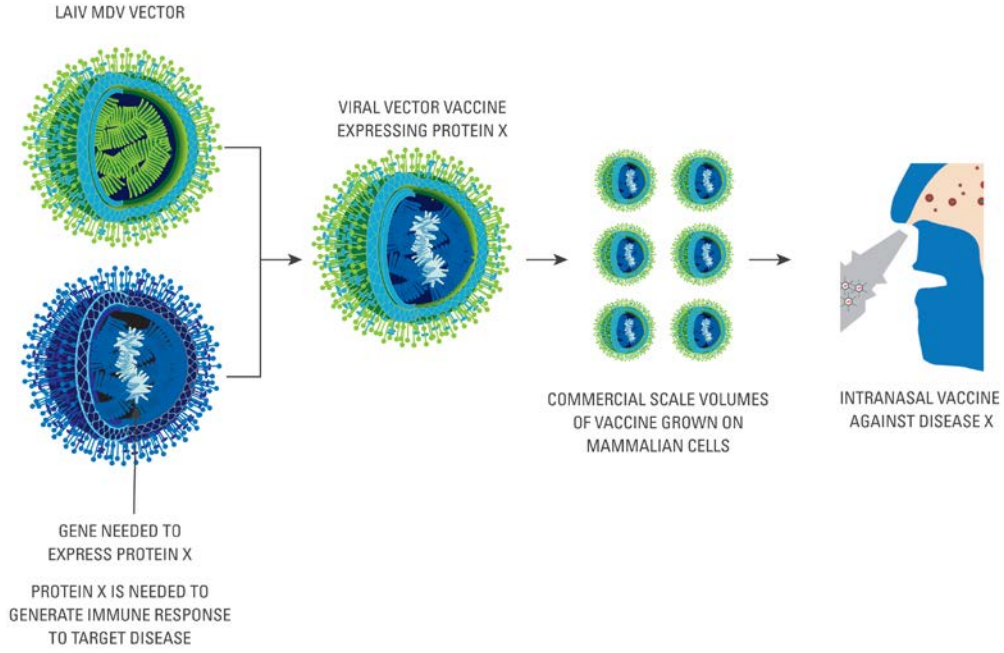
LAIV Vector Platform

‘Opportunity to create a proprietary and versatile platform technology to generate income from sales of licences to other vaccine developers’

- Viruses are like mini protein factories, pumping out proteins they are programmed to manufacture.
- In the case of a vaccine, the virus can be used to produce a desirable protein which, in the host, can trigger a helpful immune response.
- By choosing the right protein or antigen to be produced by the virus, the immune response obtained can:
  - ❖ protect against a disease e.g. the infection caused by Respiratory Syncytial Virus (RSV) or
  - ❖ bolster the immune system to help fight against a disease e.g. cancer.

The LAIV virus has important potential advantages compared to other viruses used as vector systems.

Using the LAIV as a Vector to Design New Vaccines



Viral Vectors:

- Many viruses in use as vectors are too weak and do not generate strong immune responses.

Potential Advantages of LAIV as a viral vector:

- Established safety profile
  (Use in Russia and European clinical trials).
- Intranasal administration;
  broader immune response.
- Shown to induce strong immune response when used in a flu vaccine.

LAIV Vector Program – Next Steps

- Import starting materials (cell bank and master virus stock).
- Co-development/partnering exploration.
- Confirm feasibility.
- Demonstrate usability in disease-specific vaccine examples:
  - ❖ nasopharyngeal carcinoma (Epstein Barr Virus-related cancer)
  - ❖ infectious disease target (Respiratory Syncytial Virus)
- Proof of concept testing.
- Revenue from research and commercialisation licenses.

Other Projects

Julie Phillips, CEO

BDM-E

- BioDiem's studies show BDM-E has biological effect in:
  - *In vitro* studies of cell proliferation & apoptosis; inflammation.
  - Several animal models of human retinal diseases, including genetic models of retinitis pigmentosa.
- Safety shown in the doses tested in clinical trials.
- FDA granted Orphan Drug status for *retinitis pigmentosa.*
- Expanded studies have generated new intellectual property and shown possibility of benefit in other diseases of ageing.

BDM-E – Next steps

- Finalisation of new Intellectual Property.
- Complete outlicensing package.
- Publication of studies.
- Pursue sale or outlicence to company with ophthalmic expertise for further commercial development.

BDM-I

- Novel synthetic compound active against a broad range of pathogenic micro-organisms.
- Target indications: *Serious bacterial and invasive fungal disease* (*high value niche).*
- Attractive target markets:
  - ❖ Antifungal market estimated to reach US$11.3 billion in 2014
  - ❖ Antibacterial market expected to exceed $100 billion by 2015
- BDM-I substance has been manufactured to GLP (Good Laboratory Practice) standards to undertake testing.
- Preparatory physicochemical studies have provided formulations that can be used for both *in vitro* and *in vivo* assessment in disease models.
- Pharmacokinetic studies to date have improved and better characterised the profile of BDM-I.

BDM-I – Work in Progress

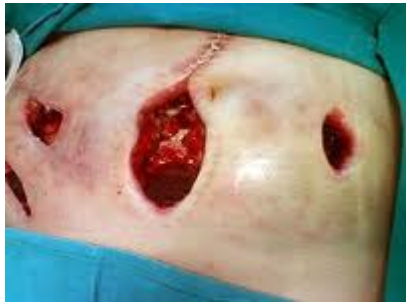
MIC Testing Results from NIH NIAID's[1] In Vitro Assessment for Antimicrobial Activity Service[2]

Pathogen	MIC (µg/mL)
E. faecalis (drug resistant)	8
C. jejuni	0.5
S. aureus	4
MRSA	8
A. fumigatus	8

The results are encouraging and BioDiem will discuss with NIAID the potential to use NIAID's Animal Models of Infectious Disease Service[3] to further evaluate BDM-I's activity.

[1] (NIAID) is the National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health (NIH).
[2] http://www.niaid.nih.gov/LabsAndResources/resources/dmid/invitro/Pages/invitro.aspx
[3] http://www.niaid.nih.gov/labsandresources/resources/dmid/animalmodels/Pages/default.aspx

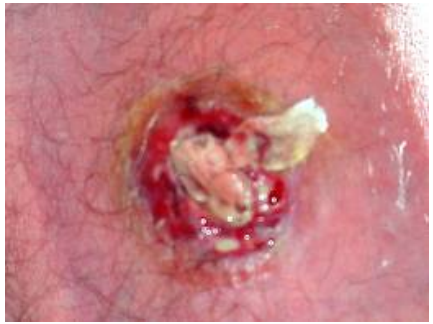
BDM-I – Work in Progress



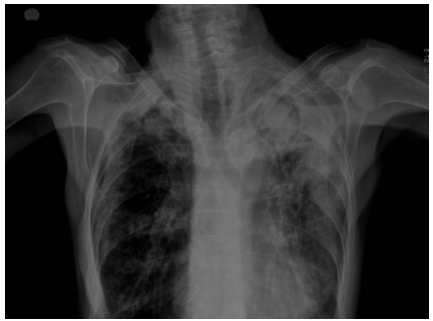
Enterococcus faecalis (antibiotic resistant); Gram-positive bacteria that can cause life-threatening illnesses, particularly when antibiotic resistance is involved. Associated with endocarditis, bacteremia, urinary tract infections (UTI), meningitis and other infections particularly related to surgical or intrusive procedures in a hospital situation.
Enterococci are part of the normal intestinal flora of humans but are also responsible for serious infections. Isolation of enterococci resistant to multiple antibiotics, including vancomycin, has become increasingly common in the hospital setting. This can leave clinicians treating these infections with limited therapeutic options.

Campylobacter jejuni; Gram-negative bacteria causing gastroenteritis. It is the leading cause of bacterial diarrheal illness in the United States. It is often isolated from healthy cattle, chickens, birds and even flies.
It can cause severely debilitating gastro which can be treated in approximately 90% of cases, however, relapses are not uncommon (approximately 25%).

BDM-I – Work in Progress



Staphylococcus aureus; Gram –positive bacteria frequently found in the nose and on skin. *Staphylococcus aureus* can cause a range of illnesses from minor skin infections, such as pimples, impetigo, boils (furuncles) and abscesses, to life-threatening diseases such as pneumonia, meningitis, osteomyelitis, endocarditis, bacteremia, and sepsis. It is one of the dominant causes of lung infection of children with cystic fibrosis.
MRSA; Methicillin resistant *Staphylococcus aureus;* such strains of *S. aureus* have become resistant to most antibiotics. MRSA strains are most often found associated with institutions such as hospitals, but are becoming increasingly prevalent in community-acquired (CA) infections.
MRSA is responsible for 15–20% of all *S. aureus* infections in Australia (Ref: MJAInsight, 17 January 2011).



Asperigillus fumigatus; is a fungus and one of the most common *Aspergillus* species to cause disease in individuals with an immunodeficiency. The fungus is widespread in nature, and is typically found in soil and decaying organic matter. In immunocompromised individuals, such as organ transplant recipients and people with AIDS or leukemia, the fungus is more likely to become pathogenic, over-running the host's weakened defenses and causing a range of diseases generally termed aspergillosis. This species is the most common invasive mold infection in immuno-compromised patients and mortality rates exceed 50% in high risk groups such as leukemia. It is also found in Cystic Fibrosis patients on a frequent basis.

BDM-I – Work in Progress

In Vitro Assessment for Antimicrobial Effectiveness of BDM-I on Schistosomes

Schistosomes are flatworm parasites responsible for severe human disease schistosomiasis (Bilharzia) in tropical developing nations.

Approximately 200 million people affected, 600 million at risk.

Current need for therapeutic and prophylactic treatments for disease.

Low mortality but chronic illness that can damage internal organs and in children impair growth.

- Studies conducted at Queensland Institute of Medical Research (QIMR) by Professor Don McManus & Assoc. Professor Malcolm Jones.
- *Schistosoma japonicum* adult parasites (schistosome stage of parasitic infection schistosomiasis).
- Results are encouraging.
- Further and broader testing is envisaged.

BDM-I – Next Steps

- Testing in other specific disease models.
- Secure grant funding.
- Proof of concept studies.
- Co-development / partnering exploration.
  - ❖ collaboration with drug development / delivery technology companies to expand routes of administration
- Outlicence for one or more indications or sale of technology.

Outlook

- Non-core assets (BDM-E & BDM-I) to be divested.
- Core focus on vaccine business.
- BioDiem is well-positioned to grow as a vaccine franchise company in attractive growing market.
  - ❖ Proprietary LAIV is already marketed as an influenza vaccine – well established safety profile.
  - ❖ Vector project may provide access to a range of vaccines for wider group of diseases.
  - ❖ Access to high quality biomaterials: virus and cell bank manufactured in compliance with Good Manufacturing Practice (GMP) requirements – accelerates commercialisation of new vaccines.
  - ❖ Acquisition of complementary antigen technologies.
  - ❖ Continued licence fees and royalties from LAIV technology to be supplemented by income from the development of our additional vaccine technology.

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