Annual General Meeting

23 October 2014

Agenda

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

Product launch: India – Nasovac-S™

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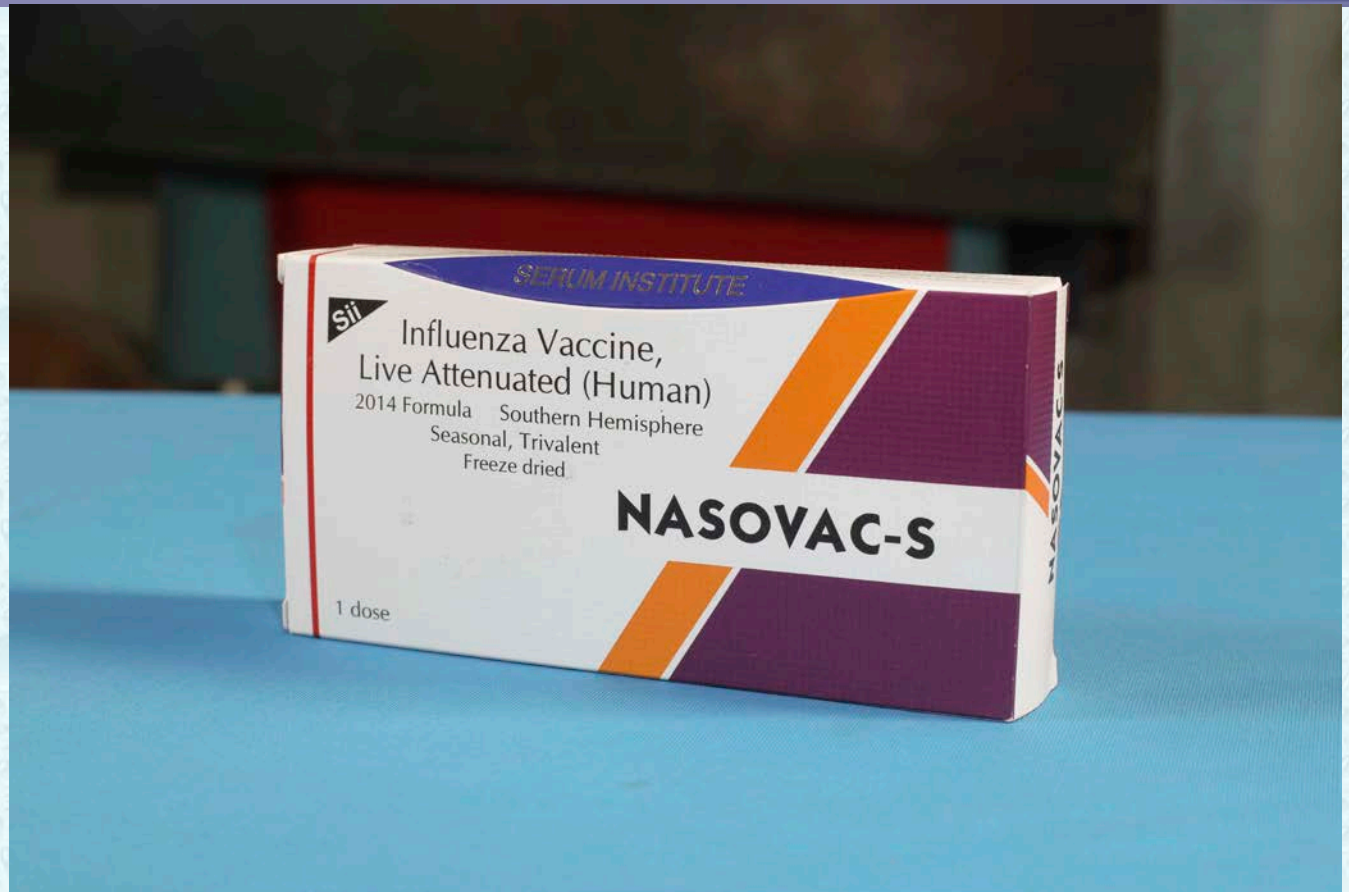

Manufacturing Facility: China

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Review of Operations

Julie Phillips

Chief Executive Officer

Highlights in FY2014

LAIV Influenza vaccine program: Commercial progress:

- Marketing approval of Nasovac-S (India)
- Product launch in India (July 2014)
- IND submission and production facility progress (China)
- Completion of extensive efficacy clinical trials in children in Bangladesh, Senegal

Antimicrobial (BDM-I) program: Commercial interest:

- Antifungal activity presented at ICAAC meeting in US
- Mechanism of action exploration (Pilot - Proof of concept trials: *reformulation required)*
- New US patent

Other programs: LAIV and BDM-I focus

Corporate activity:

- Successful delisting from the ASX (November 2013)
- Successful rights issue raising $0.8m (April 2014)
- Continued cost reduction

LAIV Influenza vaccine program

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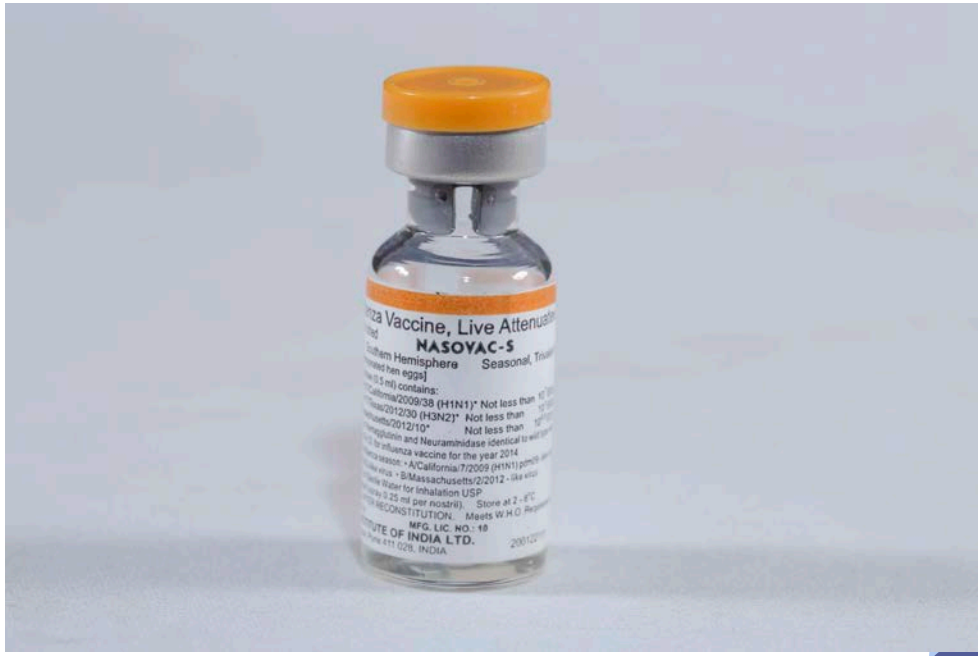
Commercial progress:

- INDIA:
  - Marketing approval of Nasovac-S
  - Product launch in India (July 2014)
- CHINA:
  - IND submission
  - production facility progress
- GENERAL:
  - Completion of extensive efficacy clinical trials in children in Bangladesh, Senegal (n=1761)
  - Pandemic influenza vaccine packages completed



Influenza Program

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Live Attenuated Influenza Virus: LAIV vaccine

Advantages

Needle-free nasal delivery
No trained personnel and blood/sharps precautions unnecessary

Broader immune response
Than seen with inactivated influenza vaccines

No adjuvant required

Extensive clinical and market experience in Russia
> 100m doses
efficacy and safety in >500,000 adults/140,000 children

High yields
In egg-based or cell-based production (with no reliance on eggs)

List of pandemic & potentially pandemic LAIV vaccines prepared at IEM RAMS

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Vaccine strain	Subtype	Wild-type parental virus	The stage of the study
A/17/duck/Potsdam/86/92	H5N2	A/duck/Potsdam/1402-6/86 (H5N2)*	Phase I-II clinical trials completed. The vaccine is registered in Russia
A/17/California/2009/38	H1N1	A/California/07/2009 (H1N1)**	Phase I-II clinical trials completed. The vaccine is registered in Russia, India and Thailand
A/17/mallard/Netherlands/00/95	H7N3	A/mallard/Netherlands/12/2000 (H7N3)**	Phase I clinical trials completed
A/17/turkey/Turkey/05/133	H5N2	A/turkey/Turkey/1/2005 (H5N1)*, clade 2.2	Phase I clinical trials completed in Russia, and phase II in Thailand
A/17/California/66/395	H2N2	A/California/1/66 (H2N2)**	Phase I clinical trials planned for 2013
A/17/Anhui/2013/61	H7N9	A/Anhui/1/2013**	Pre-clinical studies ongoing

* vaccine strain inherited only HA gene from wild-type parental virus and remaining 7 genes – from master donor virus, i.e. 7:1 genetic formula;
** vaccine strain inherited HA and NA genes from wild-type parental virus and remaining 6 genes – from master donor virus, i.e. 6:2 genetic formula.

Studies on seasonal trivalent LAIV

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Design (product)	Location	Number of subjects, age of subjects, randomization ratio	Outcomes measured	Sponsor/ Funder	Completion of study visits
Randomized, double-blind, active-controlled	India	n=110 each; children >2 years of age, adults >18 to <50, adults >50, 1:1 (lower dose: higher dose)	Safety, Immunogenicity	SIIL	Completed June 25, 2012
Randomized, double-blind, placebo-controlled	Bangladesh	N=300, children 2-5 years of age, 1:1 (standard dose: placebo)	Safety, Immunogenicity, Shedding	PATH/BMGF	Completed February 2, 2013
Randomized, double-blind, placebo-controlled	Bangladesh	N=1761, children 2-5 years of age, 2:1 (standard dose: placebo)	Safety, Efficacy against laboratory-confirmed influenza	PATH/BMGF	Completed December 2013 Safety follow-up extended 1 year
Randomized, double-blind, placebo-controlled	Senegal	N=1761, children 2-6 years of age, 2:1 (standard dose: placebo)	Safety, Efficacy against laboratory-confirmed influenza, Shedding	PATH /US Centers for Disease Control and Prevention/ BMGF	Completed December 2013

Source: Presentation by John Boslego, Director, Vaccine Development Global Program, PATH presentation at 7th Meeting with International Partners on

Prospects for Influenza Vaccine Technology Transfer to Developing Country Vaccine Manufacturers, 25-26 March 2014, Hyatt Regency Hotel, Dubai. (http://www.who.int/phi/Agenda_7thPartners_mtg.pdf). **SIIL:** Serum Institute of India Ltd; **BMGF**: Bill and Melinda Gates Foundation.

US Advisory Committee on Immunisation Practices recommendation (ACIP)

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Announcement by the US Centers for Disease Control (CDC) in June 2014 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.

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 63 / No. 32
August 15, 2014

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) — United States, 2014–15 Influenza Season

Lisa A. Grohskopf, MD[1], Sonja J. Olsen, PhD[1], Leslie Z. Sokolow, MSc, MPH[1], Joseph S. Bresee, MD[1], Nancy J. Cox, PhD[1], Karen R. Broder, MD[2], Ruth A. Karron, MD[3], Emmanuel B. Walter, MD[4] (Author affiliations at end of text)

Outlook for FY20155

LAIV influenza vaccine technology:

- Growth of early revenues from commercial activities
  - Product launch early FY2015
- Continuing support of commercial licencees: Serum Institute of India, Changchun BCHT Biotech
- Explore commercial opportunities in developed world markets
  - Egg and tissue culture production
  - Southern and northern hemisphere
- Collaborations with new technologies for future product enhancement

Antimicrobial (BDM-I) program

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Commercial interest:

- Antifungal activity presented at ICAAC meeting in US
- Mechanism of action exploration (pilot proof-of-concept trials: *reformulation required)*
- New US patent: skin & soft tissue infections (protozoal and vulvovaginitis previously granted)
- Commercial partner interest demonstrated
- Attractive US market initiatives

Antimicrobial (BDM-I): Spectrum of activity

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Invasive and superficial fungal infections

Some species of

- *Candida*
- *Cryptococcus*
- *Scedosporium*
- *Pneumocystis*

Drug-resistant tuberculosis & gonorrhea

- *Mycobacterium tuberculosis*
- *Neisseria gonorrhoeae*

Some protozoal infections

- *Trichomonas vaginalis; Plasmodium falciparum*

and others…

Antimicrobial (BDM-I): Novel mechanism of action

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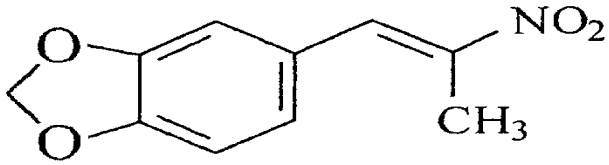
Inhibits **new** target

Protein Tyrosine Phosphatases (PTPs)

- Involved in cell signalling
- Mimics tyrosine



Heterogeneity of PTP function explains

- Selectivity within species
- Difference in function in mammalian cells

In vitro activity

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Group	(µg/ml)	Group	(µg/ml)
Fungi	MIC90 *C. glabrata* * 1 MIC90 *C. glabrata* ** 2	**G-ve bacteria**	MIC *Neisseria gonorrhoeae* 2 MIC *Campylobacter jejuni* 0.5 -2
	MIC90 *Coccidiodes spp.* 0.25* MIC90 *Coccidiodes spp.* 0.25**		Other bacteria - potential biological weapons
	IC50 *P. carinii* <0.1*** IC50 *P. murina* 0.174***	**Parasite**	*Schistosomiasis japonicum* LC50 Adults (5 days) LC50 Schistosomulae (24 hrs)
	MIC *Scedosporium prolificans* (three strains) 1-2		*Schistosomiasis masoni* LC50 Adults (5 days) LC50 Schistosomulae (8hrs)

*50% Inhibition Endpoint
**100% Inhibition Endpoint
*** (based on %reduction ATP at Day3)

Market Size Potential

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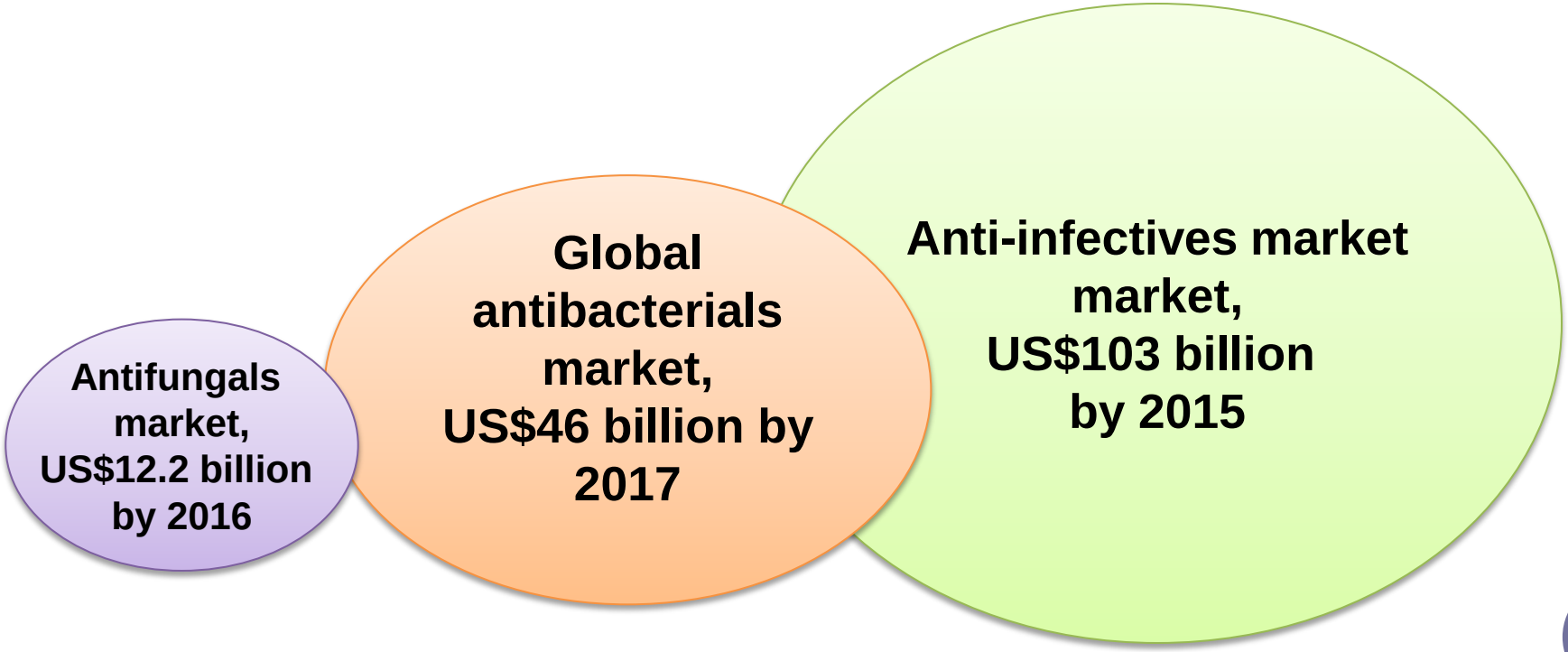


Poised for proof-of-concept

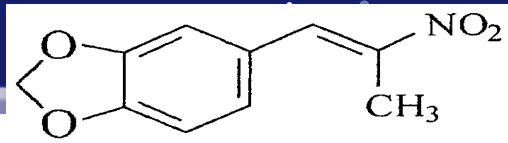
Product	Disease Targets	Current Partners	Development Status
BDM-I	Tuberculosis & bioterrorism	US govt backed research institutions	Successful screening result: preparation for *in vivo* testing
	Pneumocystis	US govt backed research institutions	Successful screening result: preparation for *in vivo* testing
	Scedosporium	Australian site	Successful screening result: seeking disease models

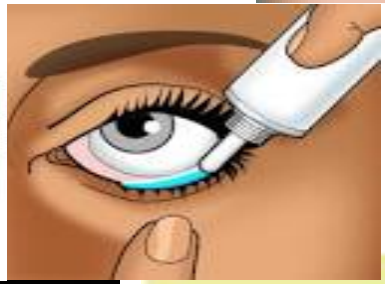
Further mechanism of action exploration

Analogue development

Formulation for proof-of-concept studies ➔ multiple ROA options

Potential Product Range





US "*Generating Antibiotic Incentives Now*" legislation

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GAIN: How a New Law is Stimulating the Development of Antibiotics

May 28, 2014 | Project: Antibiotics and Innovation Project

On July 9, 2012, the Generating Antibiotic Incentives Now, or GAIN, provisions were signed into law by President Barack Obama as part of the Food and Drug Administration Safety and Innovation Act. This bipartisan legislation extends by five years the exclusivity period during which certain antibiotics—those that treat serious or life-threatening infections—can be sold without generic competition. This additional period of exclusivity increases the potential for profits from new antibiotics by giving innovative companies more time to recoup their investment costs.

"GAIN seeks to increase antibiotics' commercial value…."

BDM-I Next steps

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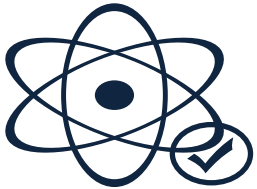

Complete formulation studies

BDM-I testing in animal models

Clinical trial in orphan disease

Proprietary formulation (including for different routes of administration)

In vivo testing and proof-of-concept

Orphan drug application

BDM-I Outlook

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Global problem in infectious disease

BDM-I has

- Activity against important pathogens
- Novel mechanism of action; granted patents
- Collaborations in place with world class facilities

Commercial opportunity for product and pipeline development

- Life threatening and other infections
- Attractive incentives e.g. GAIN legislation

Corporate activity

- **Successful rights issue raising $0.8m (April 2014)**
  - Of 24m options on issue, >6m have been exercised.
  - Remaining 18m expire in December 2014 (8c)
- **Successful delisting from the ASX (November 2013)**
  - Reduction of $279K in the FY14 year; DFS Equities matching service in place
- **Continued cost reduction**
  - Office move
  - Outsourced accounting/other
- **R&D Tax Incentive:** $0.583m refunded

Outlook for FY20155

1. **Commencement of royalties from Nasovac-S sales**
2. **LAIV Influenza vaccine program:**
   - **Developing countries:** further progress of licencees
   - **Developed countries:** new focus-
     - **Australia and US**

   New product development:
   - **New formulations/new commercial collaborations**
3. **Antimicrobial (BDM-I)**: accelerate to commercial endpoint, following reformulation and proof-of-concept studies
4. **Continued expenditure management**

BioDiem Summary

Globally there is a recognised need for

- **better influenza vaccines** and **uptake;** and
- **effective** anti-infective treatments

But

- There are few new influenza vaccine technologies with as **strong a safety history** or **with the benefits** of the LAIV technology, and
- For anti-infectives, **few new treatments** are in development at all.

Therefore, BioDiem is well-positioned to take advantage of the commercial opportunity

- to exploit and grow the commercial opportunities presented by our proprietary LAIV technology, and
- to promote and accelerate BDM-I's development towards the clinic for a sale or licence event.

Annual General Meeting

23 October 2014

Welcome to the 2014 Annual General Meeting of

BIODIEM LIMITED

3.00PM (AEDST) Thursday, 23 October 2014

at the offices of

Grant Thornton, Wills Room, Level 30,

525 Collins Street, Melbourne, Victoria, 3000

ITEMS OF BUSINESS

- Receipt and consideration of Accounts and Reports
- Resolution 1: Re-election of Director – Mr Hugh Matheson Morgan
- Resolution 2: Re-election of Director – Prof. Larisa Georgievna Rudenko

PROXY RESULTS

	Shares For	Shares Against	Discretionary	Abstain/ Exclude
Resolution 1	101,605,114	-	179,893	-
	99.82%	-	0.18%	-
Resolution 2	101,417,028	188,086	179,893	-
	99.64%	0.18%	0.18%	-

Entitled to vote - 163,087,800
Total voted - 101,785,007
Total valid proxies received - 38

Annual General Meeting

23 October 2014