

The BioDiem logo is centered on the slide. It features the word "BioDiem" in a blue serif font, with a series of small blue dots arranged in an arc above the letters "i" and "e".

Annual General Meeting

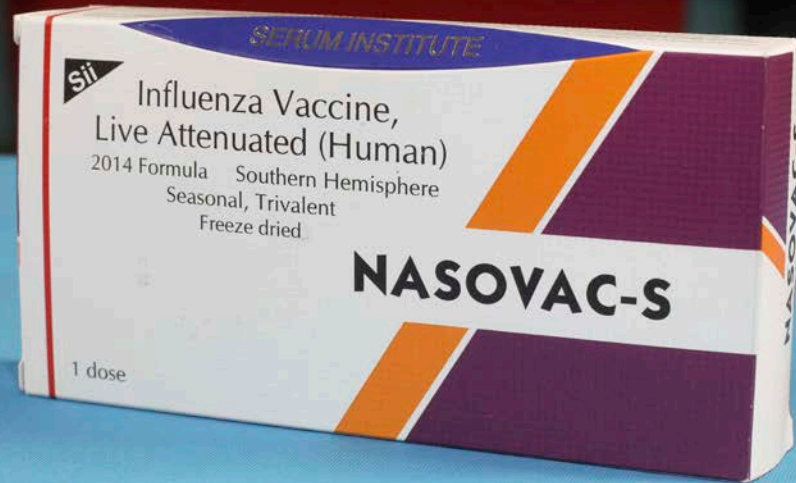
23 October 2014

Agenda

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

Product launch: India – Nasovac-S™

BioDiem



Manufacturing Facility: China



Review of Operations

Julie Phillips

Chief Executive Officer

The slide features a dark blue header with the BioDiem logo in the top right. The main content is centered on a white background. There are decorative blue circles in the top left and bottom right corners.

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

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



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

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

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/p/hi/Agenda_7thPartners_mtg.pdf). **SIIL:** Serum Institute of India Ltd; **BMGF:** Bill and Melinda Gates Foundation.

US Advisory Committee on Immunisation Practices recommendation (ACIP)



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, MD¹, Sonja J. Olsen, PhD¹, Leslie Z. Sokolow, MSc, MPH¹, Joseph S. Bresee, MD¹, Nancy J. Cox, PhD¹, Karen R. Broder, MD², Ruth A. Karron, MD³, Emmanuel B. Walter, MD⁴ (Author affiliations at end of text)

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 BCHO 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

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



Invasive and superficial fungal infections

Some species of

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

Drug-resistant tuberculosis & gonorrhoea

- *Mycobacterium tuberculosis*
- *Neisseria gonorrhoeae*

Some protozoal infections

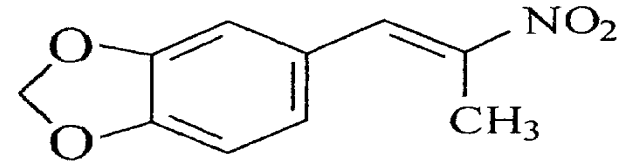
- *Trichomonas vaginalis*; *Plasmodium falciparum*

and others...

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

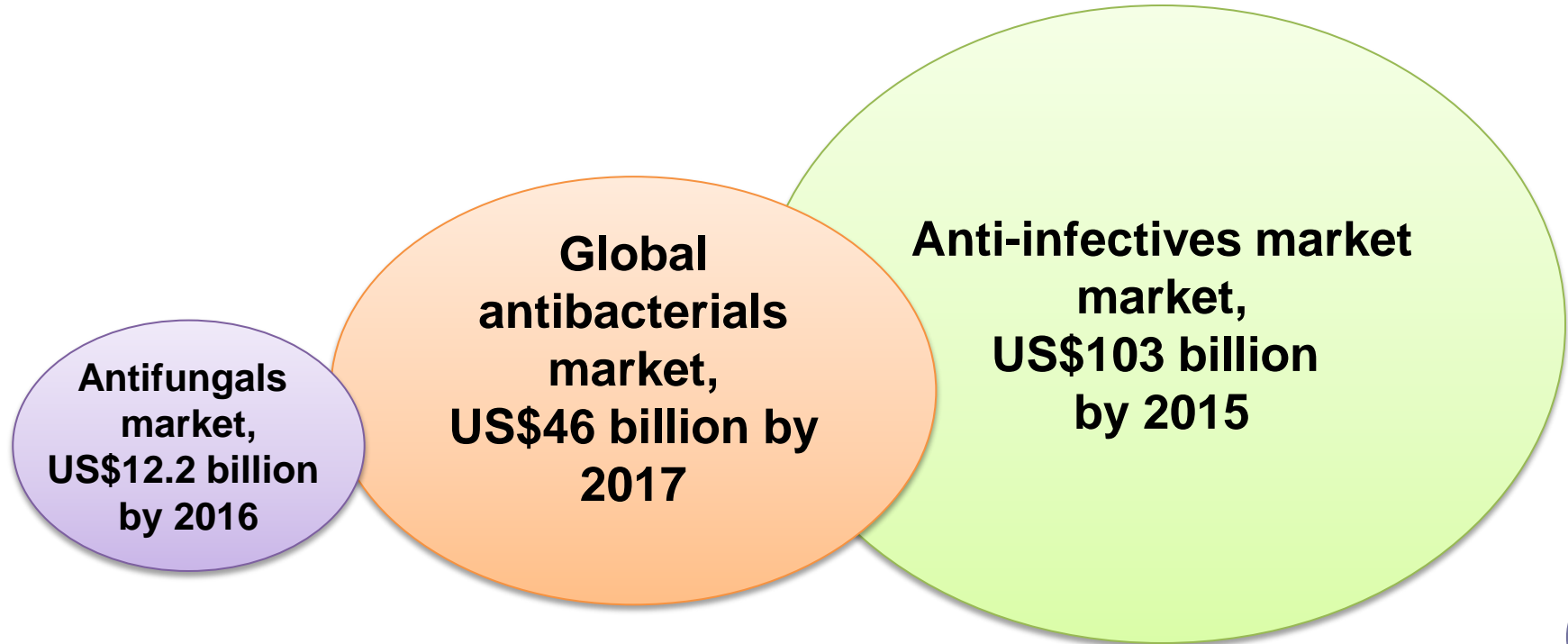
Group	(µg/ml)	Group	(µg/ml)
Fungi	MIC90 <i>C. glabrata</i> * 1	G-ve bacteria	MIC <i>Neisseria gonorrhoeae</i> 2
	MIC90 <i>C. glabrata</i> ** 2		MIC <i>Campylobacter jejuni</i> 0.5 -2
	MIC90 <i>Coccidioides spp.</i> 0.25*		Other bacteria - potential biological weapons
	MIC90 <i>Coccidioides spp.</i> 0.25**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

*50% Inhibition Endpoint

**100% Inhibition Endpoint

*** (based on %reduction ATP at Day3)

Market Size Potential



Poised for proof-of-concept

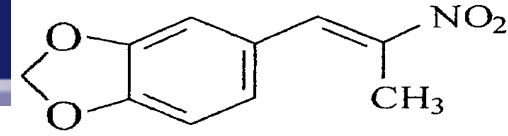
Product	Disease Targets	Current Partners	Development Status
BDM-I	Tuberculosis & bioterrorism	US govt backed research institutions	Successful screening result: preparation for <i>in vivo</i> testing
	Pneumocystis	US govt backed research institutions	Successful screening result: preparation for <i>in vivo</i> 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

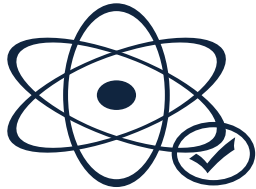
GAIN: How a New Law is Stimulating the Development of Antibiotics

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



Complete
formulation
studies

Proprietary
formulation
(including for
different routes of
administration)



BDM-I testing in
animal models

In vivo testing
and proof-of-
concept



Clinical
trial in orphan
disease

Orphan drug
application

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



- **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

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

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.

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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

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