Annual General Meeting

8 October 2013

Review of Operations

Julie Phillips

Chief Executive Officer

Global Challenges in Infectious Diseases

BioDiem

Increasing resistance

To antibiotics – major concern healthcare systems worldwide

Hard to treat

Fungal infections, affecting vulnerable patients

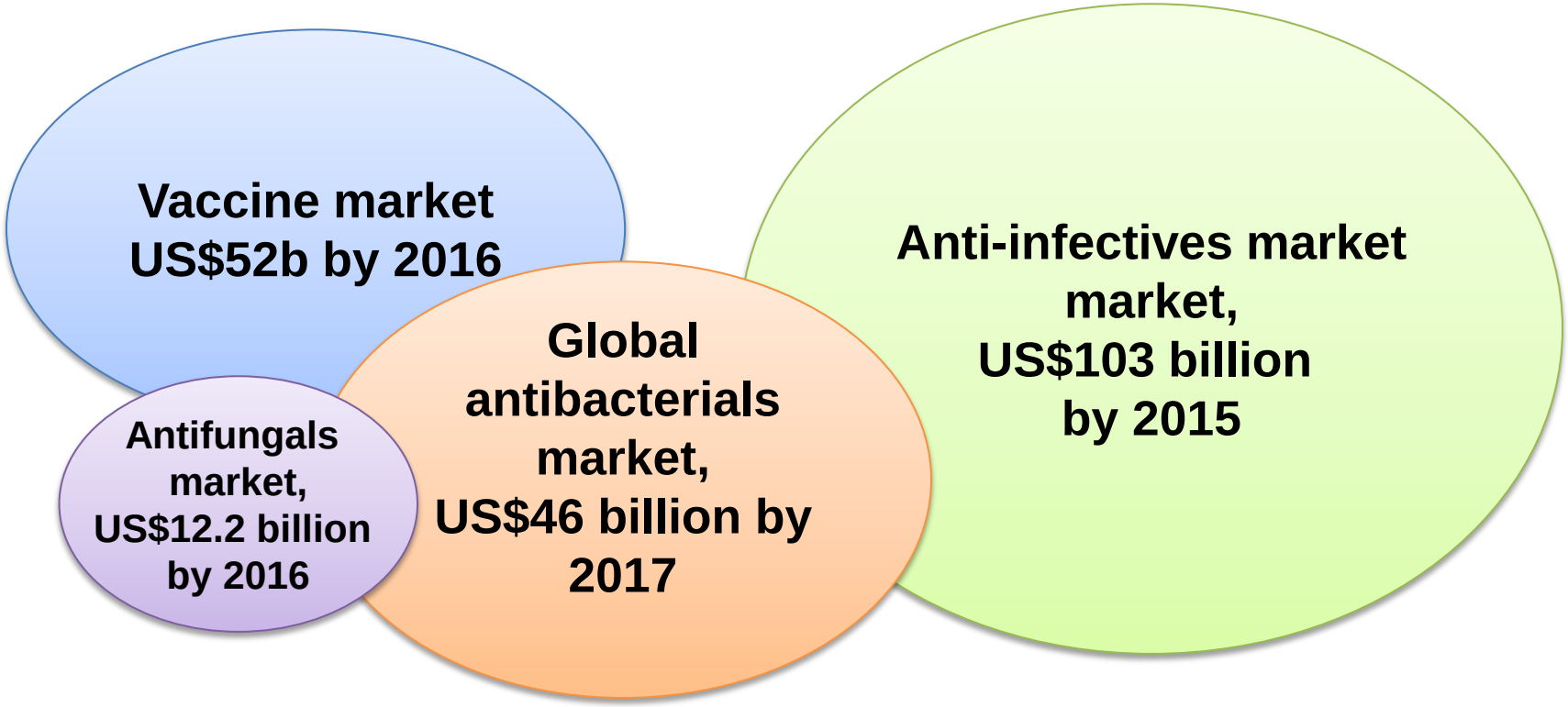
No vaccines available

For worldwide diseases eg. Therapeutic vaccines for hep B, C and D

Product pipelines diminish

Large Pharma focus on innovation, as product pipelines diminish > acquisition opportunities

Market Opportunity



Company Programs

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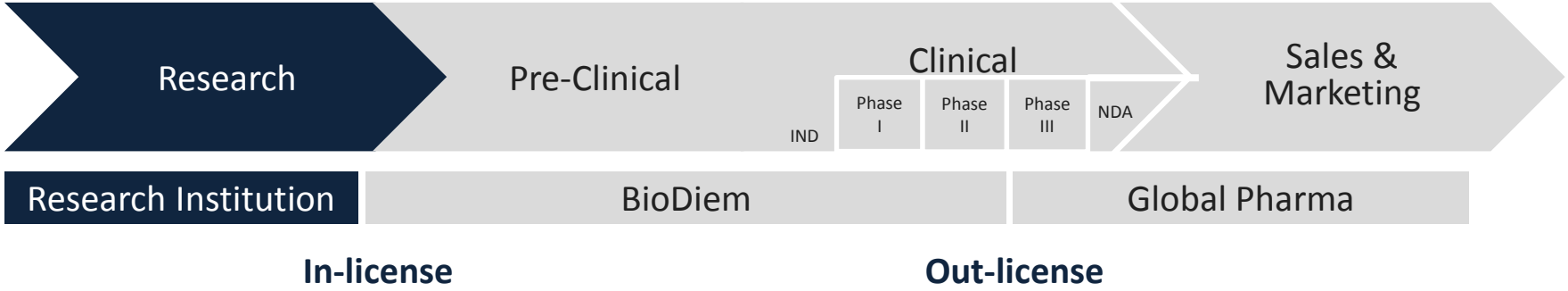
Target		Core Technology
Influenza vaccines (seasonal and pandemic)	→	LAIV vaccine – licensed in multiple countries
Vaccine development platforms Hepatitis B/D, nasopharyngeal carcinoma, TB	→	Hepatitis vaccine technology, LAIV viral vector, flavi and SAVINE technologies for novel therapeutic vaccines
Infectious disease therapies Fungal disease: difficult to treat Bacterial disease: MRSA Parasites: Schistosomiasis	→	BDM-I antimicrobial compound

Our business model



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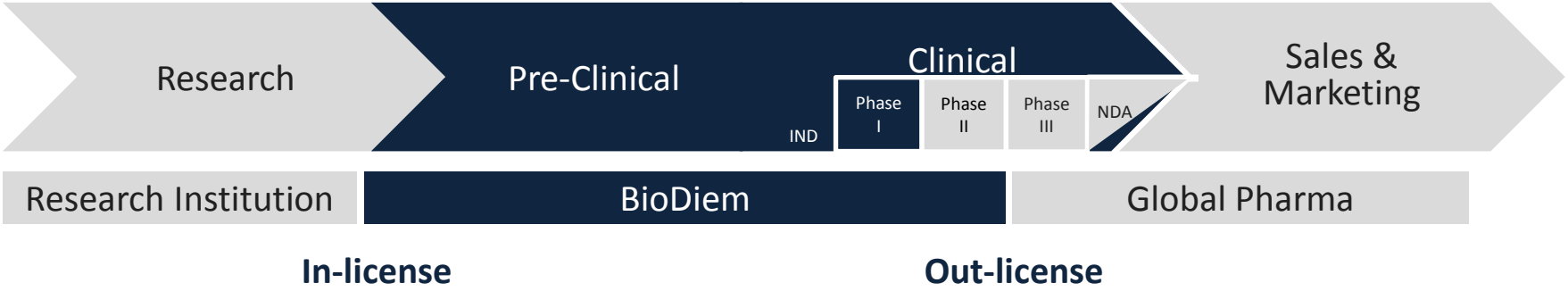
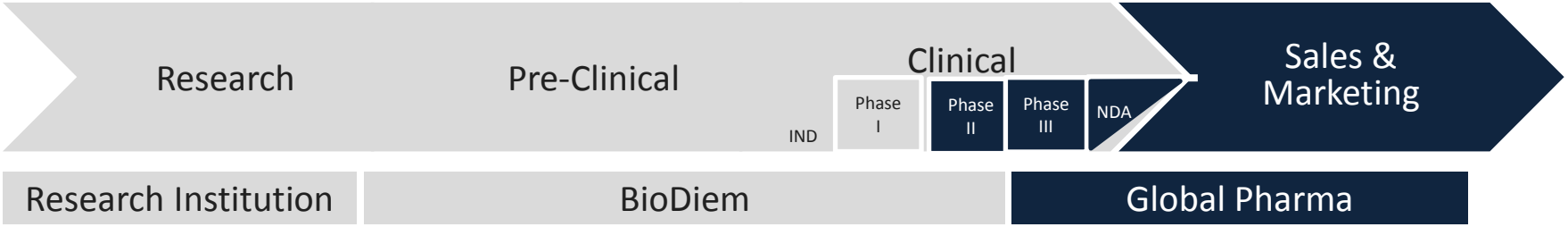


Our business model



In-license **Out-license**

Phase I trials
Testing the drug on healthy volunteers

Phase II trials
Testing the drug on a small number of patients with the disease

Phase III trials
Testing the drug on hundreds/thousands of patients with the disease

Global partnering/commercialisation network

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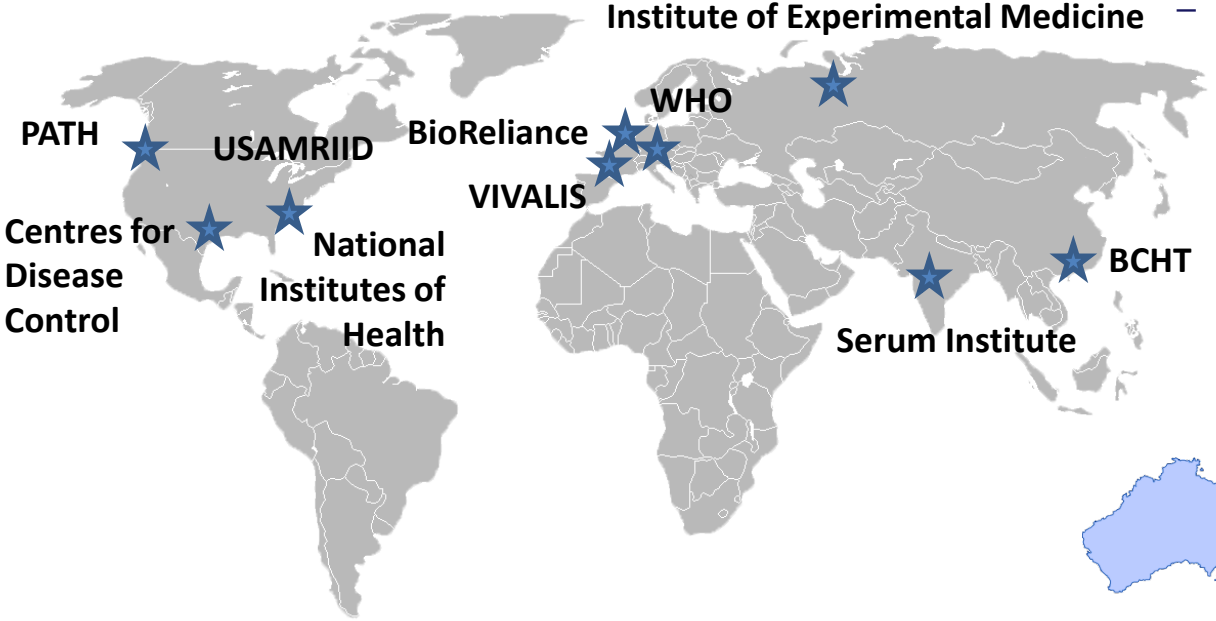
Successful partnering model supports :

- Ongoing product development
- Growth in royalty revenues
- Reduced development costs
- Retention of full control of IP



- QLD Institute of Medical Research
- Australian National University
- University of Canberra
- RMIT
- Griffith University

Key Developments in FY2013

- **Successful closure of $2m capital raising (end 2012)**
- **Enhanced company profiling**
  - **New York, Chicago, Singapore and Hong Kong**
- **Influenza vaccine program:** progress of licencees towards market approval
  - **Serum Institute of India: submission of marketing application for seasonal flu vaccine**
  - **Changchun BCHT Biotechnology Co: production facility progress and clinical trial application submission.**
  - **IEM developments: new WHO laboratory; extended avian (bird flu) & pandemic 'flu vaccine studies**
- **Antimicrobial (BDM-I)**: further development & commercial interest
  - **US Army Medical Research Institute of Infectious Diseases**
  - **US National Institutes of Health**
- **Vaccine development programs:** further development
  - **Hepatitis vaccine**: Proof-of-principle demonstrated
- **Decision to delist from the ASX (October 2013)**

Vaccine Development Pipeline

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	Research	Preclinical	Phase I	Phase II	Phase III	Marketed
Influenza vaccines (Seasonal & Pandemic)	Cell based production Egg based production Licensed to World Health Organisation for public market in Developing Countries Licensed to Serum Institute of India and Changchun BCHT Biotech Co. for certain Developing Country private markets					
LAIV Viral Vector platform	→					
Hepatitis D PLATFORM (Hepatitis D/Hepatitis B therapeutic vaccine)	→					
Flavivirus PLATFORM (Dengue fever, West Nile, Murray River encephalitis)	→					
SAVINE antigen technology (Tuberculosis, NPC)	→					

Flu vaccines

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Live Attenuated Influenza Virus: LAIV

Product	Disease Targets	Current Partners	Development Status
LAIV (Influenza)	Influenza – Seasonal & Pandemic	WHO SII (India) BCHT (China) IEM (Russia)	Marketed with license revenues $A0.75m FY2013 ($A1.3m FY2012) Phase II (cell-based technology) Seeking growth & out-licensing in more markets
	Avian (Bird) Flu	IEM/WHO	Clinical trials completed in Thailand and Russia

Influenza Program

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Live Attenuated Influenza Virus: LAIV
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 LAIVs 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.

Partnership

- IEM (St. Petersburg)
- CDC (USA)
- BioDiem (Australia)
- WHO
- PATH (USA)
- GPO (Thailand)
- Serum Institute of India (SII)
- BCHT (China)
- BARDA (USA)

Serum Institute of India

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- Technology transfer agreement signed in 2009;
- Development, preclinical studies and clinical trials with pandemic H1N1 LAIV. In epidemiological study the efficacy of LAIV was 78%. Registered in 2010 as “Nasovac”. During pandemic period SII produced more than 3 million doses of LAIV. In 2012 SII finalized WHO prequalification;
- Development, preclinical studies and clinical trials of seasonal LAIV. Registration in process;
- PATH carries out clinical trials with SII LAIV in Bangladesh and Senegal among children 2–5 years old;
- Ongoing studies for the development of LAIV in chicken eggs and possible use of cell line for production

Hepatitis Vaccine (therapeutic)

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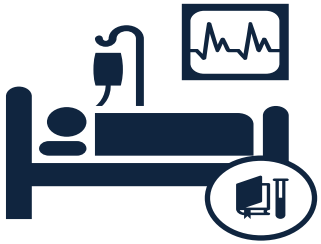
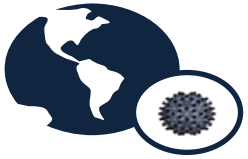


Hepatitis D



Hepatitis B

Hepatitis C

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R&D program underway

Proof of principle demonstrated (July 2013)

BDM-I Development Pipeline

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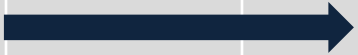
	Research	Preclinical	Phase I	Phase II	Phase III	On market
Bacterial targets (Biological warfare agents, MSRA, tuberculosis, other)						
Fungal targets (Difficult to treat fungi, incl. Scedosporium, Pneumocystis & Candida spp.)						
Parasitic targets (schistosomiasis, other)						

BDM-I antimicrobial disease targets

BDM-I currently in development as treatment against

- ‘superbugs’ such as antibiotic-resistant bacteria incl. TB, and others
- **hard-to-treat fungal** infections

Product	Disease Targets	Current Partners	Development Status
BDM-I (Antimicrobial)	Bacterial infections (tuberculosis, others)	US government backed research institutions	Entered *in vivo* testing in 2013; formulation development underway
	Fungal infections	US government backed research institutions	Entered *in vivo* testing in 2013; formulation development underway
	Parasitic diseases (schistosomiasis, others)	QIMR program	Entered *in vivo* testing in 2013; formulation development underway

BioDiem Summary

- **Significant progress in all key project areas** and in attractive market segments
- **Commercial licensees** of influenza vaccine technology on track in India and China
- **Commercial interest** in other vaccine and antimicrobial programs
- Successful leverage of commercial and non-commercial partnerships **to expand IP** and **accelerate development**
- Growing exposure to **multiple** high value commercialisation opportunities for **disease treatments with high market need.**
- **Focus on commercial path** and **further opportunities** for each technology

Outlook for next 12 months

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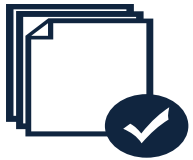


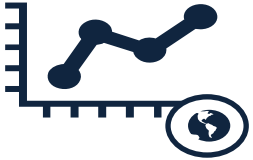
Additional license revenues

Further clinical trial results

Vector program progress

Continued growth in IP portfolio

Further hepatitis vaccine progress



Sales and use of LAIV in new territories

BDM-I testing results in animal models

Finalisation of BDM-E out-licensing or sale