



**Developing therapies for
infectious diseases and
related cancers**

Julie Phillips, CEO

www.biodiem.com (ASX:BDM)



Company Overview

Extensive technology portfolio targeting infectious diseases and cancers, supported by:

- Annual license income
- Licenses to World Health Organisation (WHO), Serum Institute of India (SII) & Changchun BCHT Biotech Co, China (BCHT)

A strong pipeline of products targeting high value disease targets with high unmet need including:

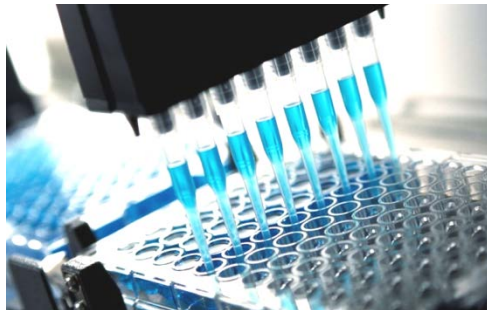
- **Large markets:** influenza (already commercial), schistosomiasis, hepatitis, tuberculosis (TB), malaria
- **Niche markets:** fungal diseases, MRSA, sexually transmitted diseases, viral-related cancers.

Extensive global partnership network with leading research institutions and companies:

- Including WHO, National Institutes of Health (USA), USAMRIID, PATH (Program for Appropriate Technology in Health), Centres for Disease Control and Prevention (US), VIVALIS, and the Institute of Experimental Medicine
- Partnering strategy accelerates development, lowers cost, while retaining IP control

Three core development programs

Target	Core technology
1. Influenza vaccines (seasonal and pandemic)	LAIV vaccine – licensed in multiple countries
2. Vaccine development platforms <ul style="list-style-type: none"> • Hepatitis B/D, nasopharyngeal carcinoma, TB targets 	SAVINE technology, LAIV viral vector, flavi- and hepatitis virus technologies for novel therapeutic vaccines
3. Infectious disease therapies <ul style="list-style-type: none"> • Fungal disease: difficult-to-treat • Bacterial disease: MRSA • Parasites: Schistosomiasis 	BDM-I antimicrobial compound





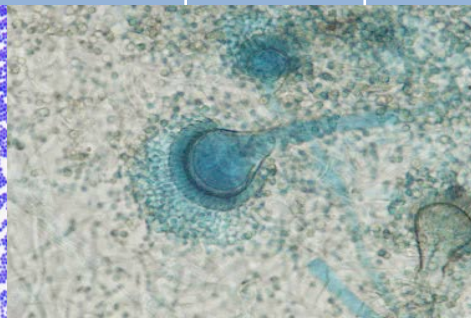
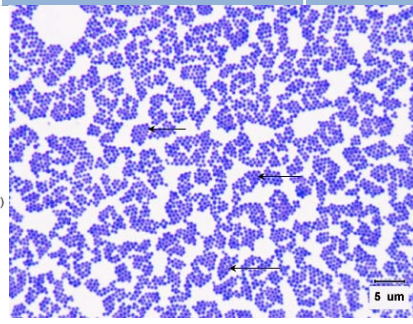
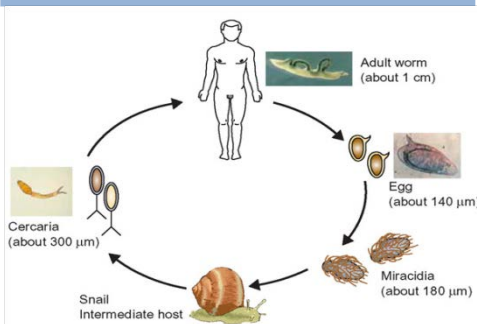
Vaccine Development Pipeline

	Research	Preclinical	Phase I	Phase II	Phase III	Marketed
Influenza vaccines (Seasonal and Pandemic)	Cell based production →					
	Egg based production →					
	Licensed to World Health Organisation for public markets 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)	→					



BDM-I Development Pipeline

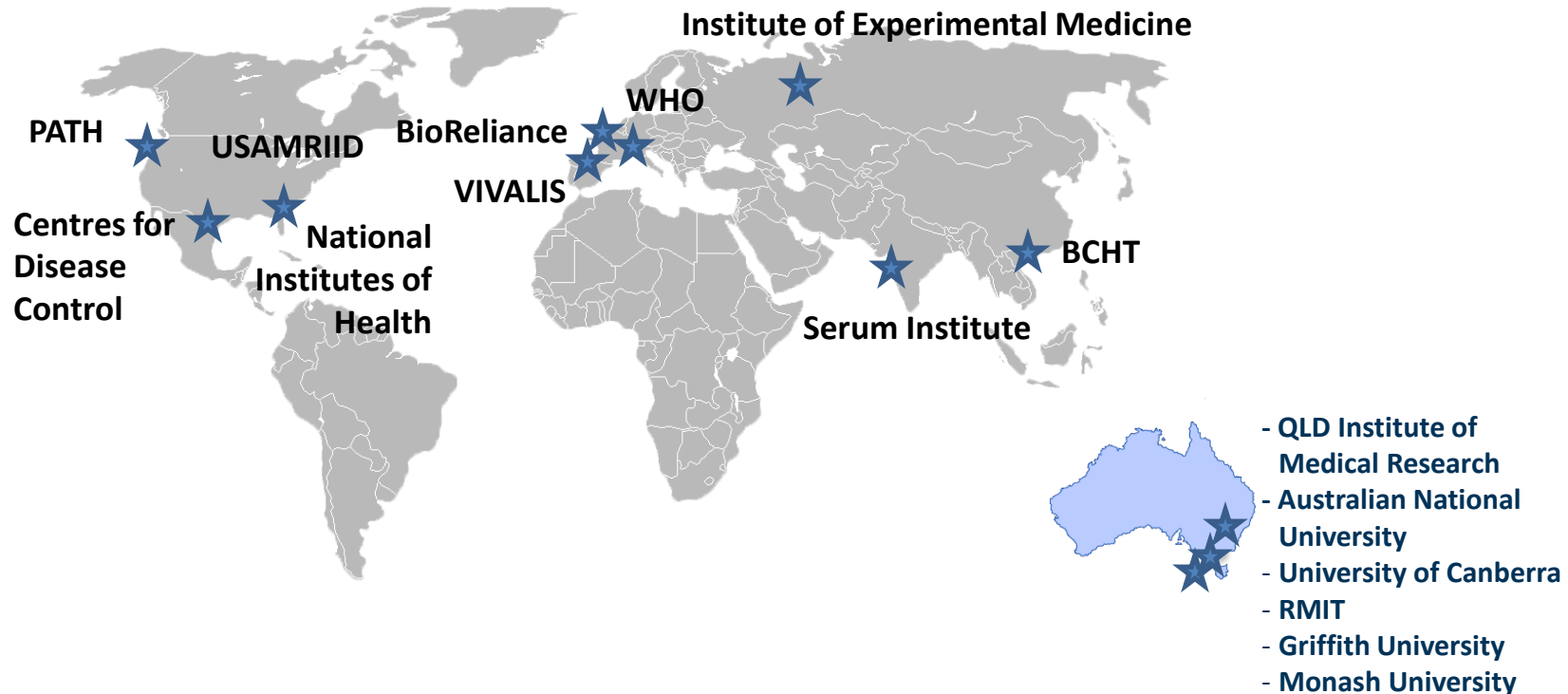
	Research	Preclinical	Phase I	Phase II	Phase III	On Market
Bacterial targets (Biological warfare agents, MRSA, tuberculosis, other)	➔					
Fungal targets (difficult-to-treat fungi, incl Cryptococcus & Candida)	➔					
Parasitic targets (schistosomiasis, other)	➔					



Global partnering/commercialisation network

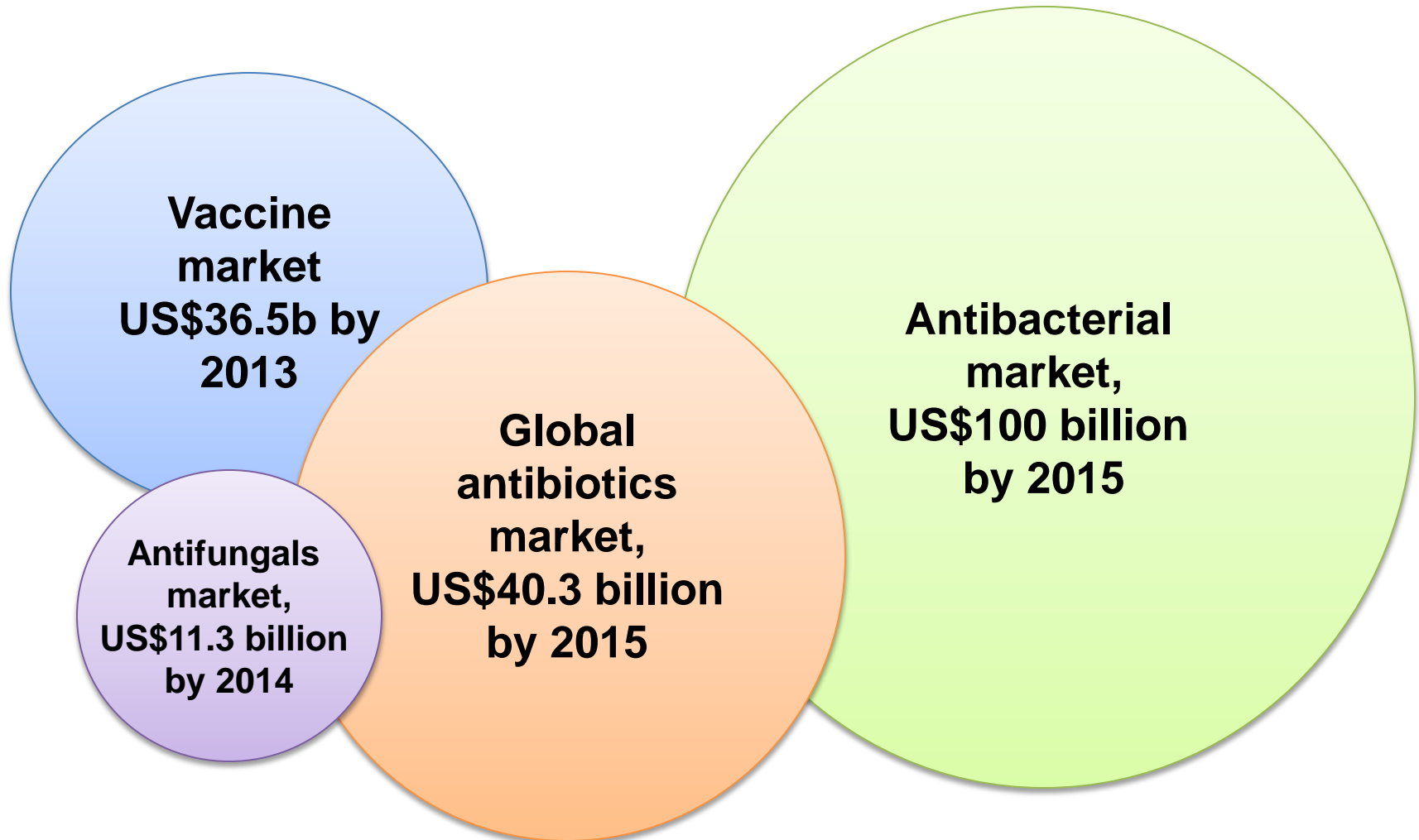
BioDiem

- Successful partnering model supports :
 - Ongoing product development
 - Growth in royalty revenues
 - Reduced development costs
 - Retention of full control of intellectual property



Operating in High Value Markets

BioDiem



A Growing Business in 'Flu Vaccines

BioDiem

- **Current revenue generator and growth business.**
- **Core vaccine technology licensed to WHO as part of Global Pandemic Influenza Action Plan.**
- **Licenses in place with the Serum Institute of India Ltd (SII), Changchun BCHT Biotechnology Co. (BCHT) of China, and GPO Thailand.**
- **H1N1 (pandemic) influenza vaccine launched in India by SII in July 2010 (Nasovac™).**
 - Exclusive licence signed with SII for private sector sales in India.
 - Non-exclusive license for Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan and Sri Lanka.
- **Expected international exports of seasonal flu vaccine by SII in 2013-14.**
- **Chinese private sector market licence signed in February 2012 with BCHT.**
- **Phase I clinical trials completed successfully in Russia and Thailand for Avian (Bird) flu vaccine.**

2011/12 flu vaccine licensing revenue of A\$1.3 million



BioDiem's 'Flu Vaccine Competitive Advantages

Live Attenuated Influenza Virus: LAIV

Advantages:

- 1. Needle-free nasal delivery:** no trained personnel, blood/sharps precautions necessary.
- 2. Extensive clinical and market experience (>100m doses)** in Russia with egg-based vaccine has established efficacy and safety in >500,000 adults and 140,000 children.
- 3. High yields** in egg-based production; can be manufactured in cell culture to meet pandemic need without reliance on eggs, such as during a bird flu pandemic.
- 4. Broader immune response** than seen with inactivated influenza vaccines.
- 5. No adjuvant required.**

Product	Disease Targets	Current Partners	Development Status
LAIV Vaccine (Influenza)	Influenza – Seasonal & Pandemic	WHO SII (India) BCHT (China) IEM (Russia)	Marketed with license revenues of A\$1.3m FY2012 Phase II (cell-based production technology). BioDiem is seeking to grow and expand out-licensing for both its cell-based and the egg-based influenza vaccine technology in multiple markets.
	Bird flu	IEM/WHO	Clinical trial completed in Thailand and Russia

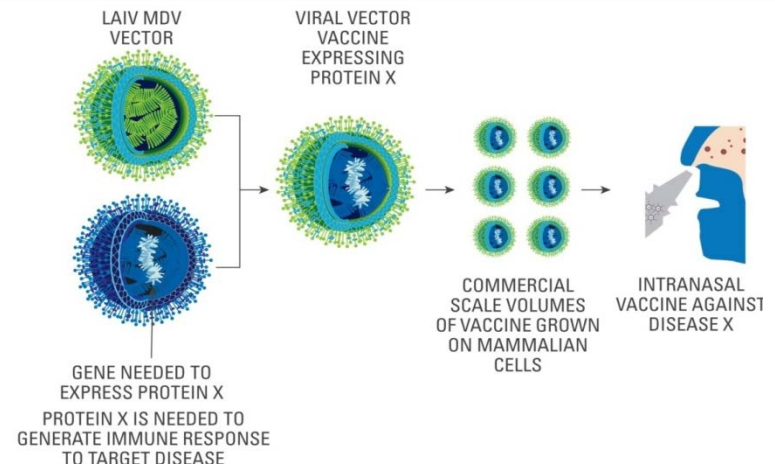


Versatile Proprietary Vaccine Platform Technologies

- Opportunity to target multiple infectious diseases and related cancers
- Licensing model to be pursued targeting other vaccine developers
- Complementary technologies acquired, broadening disease target range

LAIV Vector: A viral vector can deliver a customised protein into the body to produce a **Protective or Boosted** immune response to fight a disease e.g. nasopharyngeal cancer.

SAVINE: the “scrambled antigen vaccine” technology allows design of customised proteins e.g. NPC SAVINE for Epstein Barr virus-related diseases.



Product	Disease Targets	Current Partners	Development Status
LAIV Vector (Vaccine delivery)	Vaccine development	VIVALIS	First stage of development project completed
SAVINE (Custom vaccines)	Nasopharyngeal carcinoma (NPC), tuberculosis (TB)	In-house	Seeking partner for more advanced data in animals

BDM-I: broad-spectrum antimicrobial



- **Increasing resistance** to antibiotics is a major concern for healthcare systems worldwide.
- BioDiem's BDM-I antimicrobial has demonstrated activity against a **wide range** of disease-causing bacteria, fungi, protozoa and parasites in a significant number of screening studies.
- BDM-I's broad activity could claim a share of **several major** markets for **high value** diseases.
- Diseases being targeted include **tuberculosis and serious hospital infections**.
- BDM-I is currently being studied as treatment against 'superbugs' or antibiotic-resistant bacteria such as MRSA, and hard-to-treat fungal infections which affect vulnerable patients.
- Big Pharma are focusing on this space, and looking to acquire. Product pipelines are running dry so innovative products are in high demand.

Product	Disease Targets	Current Partners	Development Status
BDM-I (Antimicrobial)	Tuberculosis	US government backed research institutions	Will enter in vivo testing in 2013
	Fungal infections	US government backed research institutions	Will enter in vivo testing in 2013
	Parasitic diseases (schistosomiasis, others)	QIMR program	Will enter in vivo testing in 2013

BDM-I Antimicrobial Disease Targets

Bacterial Infections

- *In vitro* activity against MRSA, *Mycobacterium tuberculosis* and other G+ve and G-ve.
- *In vivo* activity/efficacy testing underway in selected models of disease.

Fungal Infections

- *In vitro* activity against hard-to-treat infections in hospitalised patients including Aspergillus, Scedosporium, yeasts and others.
- *In vivo* activity/efficacy testing underway in selected models of disease.

Parasitic Infections

- Targeting Schistosomiasis, Malaria and others.
- *In vivo* activity/efficacy testing in schistosomiasis animal model underway.

***Patents granted in
US, Europe, China
and Japan for major
disease indications***

Next steps for BDM-I antimicrobial

BDM-I has delivered a range of exciting results at world-class research facilities.

The variety of possible indications gives the asset considerable scope for producing significant value to shareholders and collaborators.

BioDiem will build on our **strong results to date** by:

1. Working with **current** and **new** partners to progress research into wider range of models of serious infectious diseases.
2. Seeking collaborators to expand opportunities for development of formulations for additional routes of administration
3. Furthering discussions with potential licensing partners to accelerate development of BDM-I in infectious disease indications.

Next steps: An accelerated development program with rapid market access for life-threatening diseases

Hepatitis D

- 20% mortality. Liver transplant for severe cases.
- Currently **no vaccines available**.

Hepatitis B

- Approx. 800,000-1.4m chronically infected in US.
- Currently no complete cure. Existing treatments cost US\$5k-\$35K p.a.

Further development envisaged for Hepatitis C

- The most common blood-borne infection in the US. Currently no vaccines available.
- New “triple cocktail” treatment achieves 80% cure and costs ~\$60K per patient treatment.

Technology rights licenced from the University of Canberra.

R&D program underway at the University of Canberra, Australia.

Preparation for entry into Phase I clinical trial in patients **in 2016**.

Development partners sought.

Dengue Fever Vaccine development

BioDiem

Dengue fever

- is an infectious disease caused by **mosquito-borne** dengue viruses (Den-1, DEN-2, DEN-3, DEN-4); prevalent in tropical and sub-tropical regions.
- treatment is non-specific and **preventative vaccines** are not yet marketed.

Work to date

- research conducted at the ANU has demonstrated vaccine effect in dengue fever model in the laboratory (publication pending).
- may extend to vaccines against other dangerous mosquito-borne disease targets including West Nile fever, Murray Valley encephalitis, Japanese encephalitis, etc

Technology rights licenced from the Australian National University.

Development partners sought.

Commercial Partners

BioDiem – Our Connection to the Region

The Serum Institute of India Ltd (SII)

SII is the world's 5th-largest vaccine manufacturer. Its products vaccinate half the world's children and it exports to more than 120 countries.

Exclusive licence signed by BioDiem with SII for private sector sales of **LAIV flu vaccine** (egg-based production) **in India**.

- Ongoing co-operation with BioDiem's partner, the IEM of St Petersburg, Russia (technology originator).
- Currently in production for seasonal influenza.
- Non-exclusive license signed with Serum Institute for Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan and Sri Lanka.

H1N1 (pandemic) vaccine launched in India by SII in July 2010 (Nasovac™).

Seasonal influenza vaccine in development for local and export markets.



**SERUM INSTITUTE
OF INDIA LTD.**

Commercial Partners



– Our Connection to the Region

Changchun BCHT Biotechnology Co. (BCHT) of China

Well-credentialed vaccine manufacturer in Jilin province.

Exclusive license of BioDiem's LAIV vaccine for the Chinese private sector market for influenza signed in February 2012.

Early revenues generated.

BCHT in the process of constructing new production facility at the Changchun National High Tech Industrial Development Zone in China.

Ongoing co-operation between BioDiem's partner the IEM of St Petersburg and BCHT scientists to facilitate development of LAIV influenza vaccine.



Photograph of the manufacturing facility building for the manufacture of seasonal influenza vaccine based on in-licensed LAIV technology from BioDiem.

LAIV influenza vaccine technology

- new and existing licences – LAIV vaccine technology;

Antimicrobial BDM-I

- antibiotic-resistant strains of pathogenic bacteria, fungi and parasites including tuberculosis, schistosomiasis and malaria.

SAVINE “scrambled antigen” vaccine technology:

- tuberculosis and Nasopharyngeal cancer (EBV-related)

Hepatitis therapeutic vaccine development

- hepatitis D and B

Flavivirus vaccine technology

- dengue and other mosquito-borne infections.



BioDiem Limited (ASX:BDM)

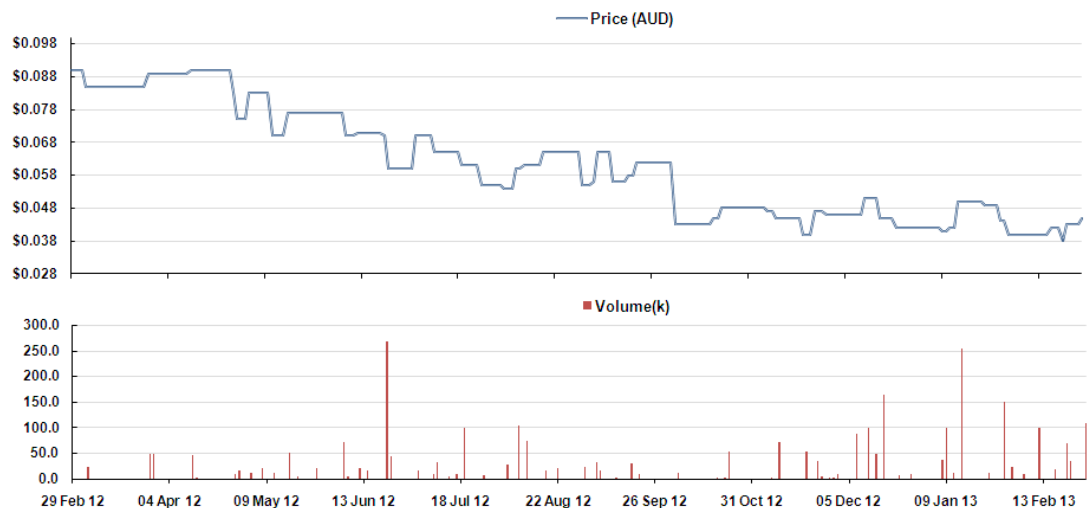
As at 28 February 2013

Market Cap	\$6m
52 week range	\$0.04 – 0.09
Cash at end of quarter as of 31 Dec 2012	\$2.33m
Shares	142,105,934
Listed Options	24,638,574

Company Focus

1. Flu vaccine technology licensed, generating revenues.
2. Vaccine and infectious disease therapies in development.
3. Multiple products focused on high value cancer and infectious disease targets.

BioDiem 12 Month Share Price and Volume



Strong leadership team



BioDiem's management team:



Chairman: Hugh Morgan AC

- President of Business Council of Australia from 2003-2005.
- Chairman of the Order of Australia Asscn Foundation
- Lafarge International Advisory Board member
- Former Director of the Board of the Reserve Bank of Australia



Non-executive Director: Prof Arthur Li

- Deputy Chairman of The Bank of East Asia
- Emeritus Professor of Surgery at The Chinese University of Hong Kong
- Numerous Chinese, Australian and HK appointments



CEO and Director: Julie Phillips

- Extensive experience in multinational pharma
- Pharmacist with technical background in regulatory affairs, pharmacoeconomics and clinical trials
- Previous Chief Executive Officer and Director of Australian biotech start-ups



Non-executive Director: Don Brooks

- Former Licensing Senior Counsel at Merck & Co.
- Former General Counsel for Entremed Inc.
- Numerous North American biotech consultancy roles



Non-executive Director: Prof Larisa Rudenko

- Head of Virology at Institute of Experimental Medicine
- Developed Russian clinical trials for LAIV
- World expert in LAIV
- Published more than 225 paper and 42 patents
- Honoured Scientist of the Russian Federation

Company Overview

- BioDiem has **successfully licensed its flu vaccine** to the largest markets in the world. Revenues of **A\$1.3m** in 2011/12 with revenue growth expected.
- A **proven track record** of new license growth, e.g. BCHAT (China) and the Serum Institute of India.
- **Global partnering strategy** with research leaders accelerates development and delivers more for each research and development dollar.
- Potential to engineer **multiple new vaccines** from BioDiem's technologies.
- **Exciting potential for BDM-I** across multiple acute and chronic infectious diseases with opportunities for accelerated regulatory approval.
- Exposure to **multiple** high value commercialisation opportunities for **disease treatments with high market need**.



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