



**Therapies for major infectious  
diseases and related cancers**

**Julie Phillips, CEO**

[www.biodiem.com](http://www.biodiem.com)

(ASX:BDM)

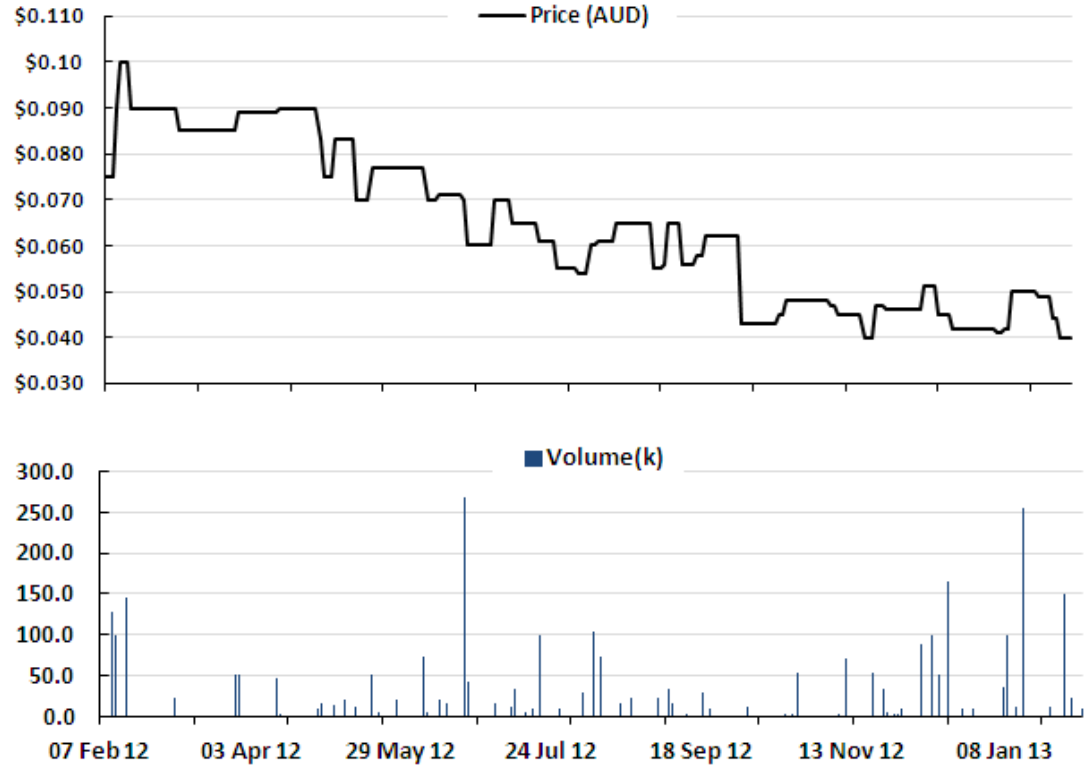
# BioDiem Limited



As at 08 February 2013	
Market Cap	\$6.13m
52 week range	\$0.02 - 0.10
Cash	\$2.33m
Shares	142,105,934
Shareholders	919
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



## Board of Directors

Hugh Morgan, AC - Chairman

Julie Phillips - CEO

Dr Larisa Rudenko - Non-executive Director

Dr Arthur Li - Non-executive Director

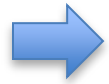
Don Brooks - Non-executive Director

# A compelling investment case



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

- Existing license income provides revenue base
- Existing licenses to WHO, Serum Institute of India & Changchun BCHT Biotech Co, China



**A strong pipeline of products with high value disease targets, including:**

- **Large markets:** influenza, schistosomiasis, hepatitis, TB
- **High-value niche markets:** fungal diseases, MRSA, sexually transmitted diseases, viral-related cancers
- **Influenza vaccine** already on the market








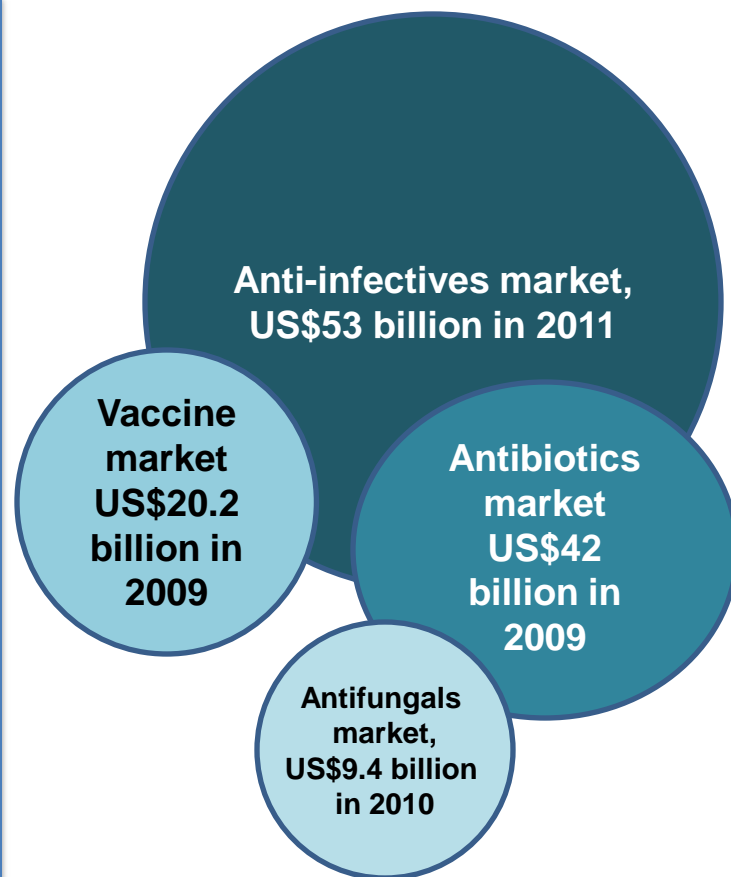
**Extensive global partnership network with leading research institutions and companies**

- Including WHO, National Institutes of Health (USA), 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

# Operating within the largest healthcare markets

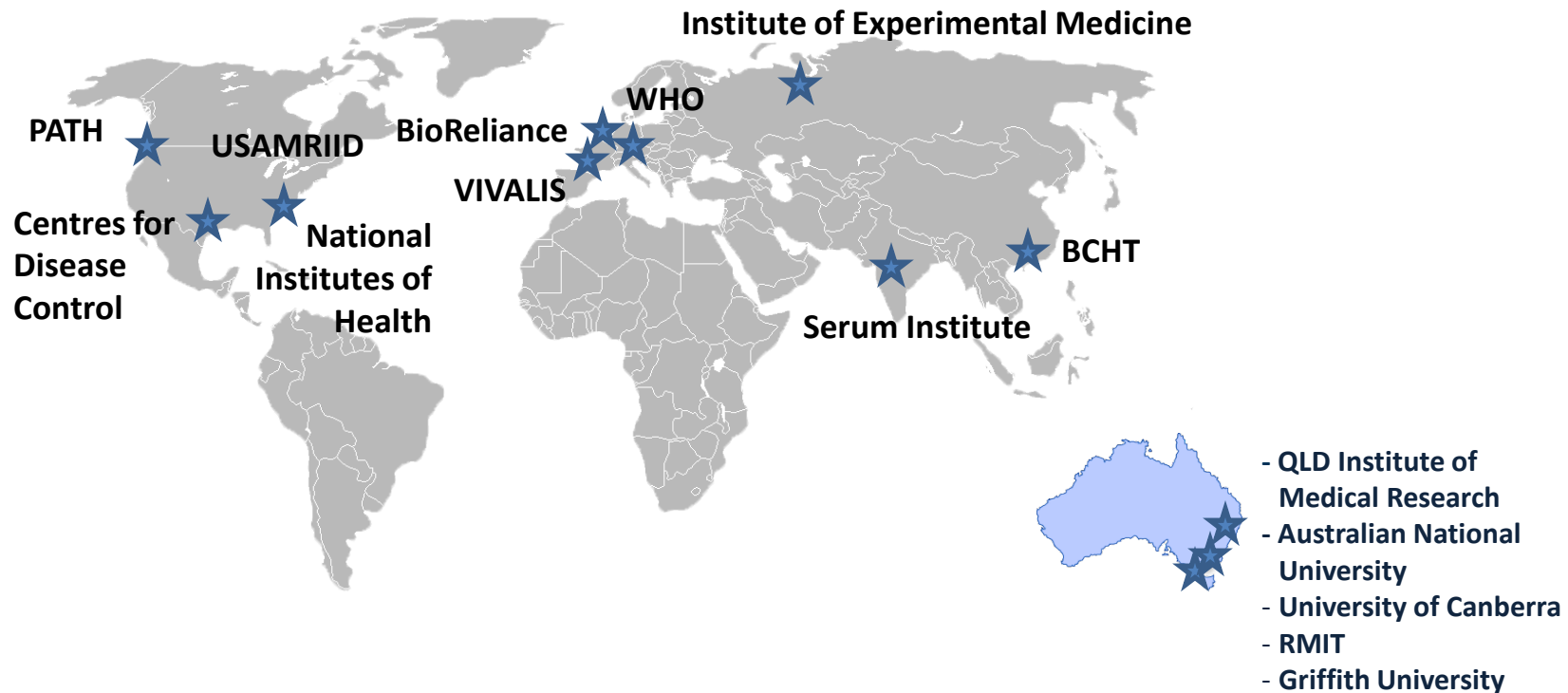


Company	Vaccine sales 2010	Compound annual growth rate % (2004-2009), Datamonitor 2010	Key products
 GlaxoSmithKline Biologicals	\$6.75 billion	21.5%	Infant combinations, hepatitis, influenza, HPV, rotavirus
 The vaccines business of sanofi-aventis Group	\$5.01 billion	18.5%	Infant combinations, meningococcal vaccines, influenza
	\$3.55 billion	25.3%	HPV, rotavirus, MMR-V vaccines
	\$3.67 billion	26.7% (2004-08)	Pneumococcal vaccines
	\$2.92 billion	36.4% (2006-09)	Influenza, meningococcal vaccines



# Global partnering & commercialisation network

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





# A growing business in flu vaccines

- **Current major revenue generator and growth business.**
- **Core vaccine product licensed to WHO as part of Global Pandemic Influenza Action Plan.**
- **Sublicenses in place with the Serum Institute of India Ltd (SII), and Changchun BCHAT Biotechnology Co. (BCHAT) of China.**
- **H1N1 (pandemic) influenza vaccine launched in India by SII in July 2010 (Nasovac™).**
  - Exclusive license 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.
- **International exports of seasonal flu vaccine by SII expected post-approval**
- **BCHAT deal for Chinese private sector market signed in February 2012.**
- **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. **New licenses** for LAIV are in negotiation.

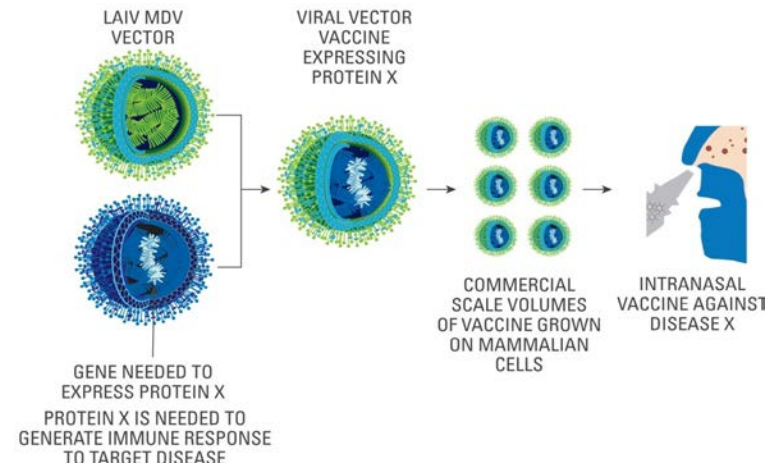
Product	Disease Targets	Current Partners	Development Status
LAIV Vaccine (Influenza)	Influenza – Seasonal & Pandemic	WHO SII (India) BCHT (China) IEM (Russia)	Marketed with license revenues of A\$1.3m FY2012 Phase II (cell-based production technology). BioDiem is seeking to grow and expand out-licensing 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
<b>LAIV Vector</b> (Vaccine delivery)	Vaccine development	VIVALIS	First stage of development project completed
<b>SAVINE</b> (Custom vaccines)	Nasopharyngeal carcinoma (NPC), tuberculosis (TB)	In-house	Seeking partner for more advanced data in animals





# Successful virus partnership with VIVALIS

- May 2012: BioDiem collaborated with **VIVALIS SA**, a leading French vaccine technology provider to demonstrate growth of the LAIV virus in VIVALIS' proprietary cell line.
- August 2012: BioDiem & VIVALIS announced **successful growth** of the LAIV virus in VIVALIS' EB66® cell line.
- The next stage will **use known techniques** to demonstrate creation of new, 'disarmed' viruses (vectors) carrying antigens **customised to fight specific diseases**.
- The results are significant for both companies:
  - Both the BioDiem LAIV virus and the VIVALIS EB66® cell line have produced vaccines that have been tested in **successful Phase II clinical trials**
  - The resulting human safety data will facilitate more rapid and lower cost commercialisation

## **Case study for Success:**

Partnering and acquisition strategy to build Vaccine development expertise paid off for Crucell, which was acquired by Johnson & Johnson in 2011 for \$US 2.3 billion.

# Path to commercialisation



**Goal:** Confirm feasibility of LAIV vector and license to vaccine developers.

**Progress:**

1. Vivalis S.A. (NYSE Euronext Paris: VLS, France) successful virus growth in EB66 proprietary cell line
2. Discussion with other cell line owners ongoing

One in six cancers is linked to a virus infection  
Platform technology → multiple new vaccine possibilities for cancers and infectious diseases

# Exciting 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
<b>BDM-I</b> (Antimicrobial)	Tuberculosis	US government backed research institutions	Will enter <i>in vivo</i> testing in 2013
	Fungal infections	US government backed research institutions	Success in expanded <i>in vitro</i> screening studies
	Parasitic diseases (schistosomiasis, others)	QIMR program	Will enter <i>in vivo</i> testing in 2013

# Antimicrobial disease targets



## Bacterial Infections

- Targeting bacterial infections such as MRSA (Golden Staph) and tuberculosis
- *In vivo* testing to commence in 2013 in selected models of disease

## Fungal Infections

- Targeting hard-to-treat infections in hospitalised patients including Aspergillus, Scedosporium, yeasts and others
- Positive screening results *in vitro*
- *In vivo* testing to commence in 2013 in selected models of disease

## Parasitic Infections

- Targeting Schistosomiasis, Malaria and others
- *In vivo* testing to commence at QIMR in 2013

***Patents granted in  
US, Europe 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.

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

1. Working with our partners to progress research into animal models of the disease
2. Maintaining our model of collaborative research with **reduced** outlay by BioDiem while retaining control of IP
3. Furthering discussions with potential (Big Pharma) licensing partners for the technology

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

# Hepatitis vaccine (therapeutic) development



- Rights licensed from the University of Canberra.
- R&D program underway

## *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.

## *Hepatitis C*

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



# Dengue fever vaccine (therapeutic) development



Rights licensed from the Australian National University

## *Dengue Fever*

- Technology licensed from Australian National University. No Dengue Fever vaccines on the market.
- Promising demonstration of vaccine effect in dengue fever model in the laboratory
- Publication pending
- Possible extension into other dangerous mosquito-borne disease targets



# Genetic eye disease treatment

- **US FDA granted Orphan Drug status** to BDM-E compound for treatment of genetic eye disease *retinitis pigmentosa (RP)*.
- Studies show BDM-E has biological effect in inflammation and eye disease models with **good safety profile demonstrated** at dosage used in clinical studies.
- Results presented at the International Society for Eye Research conference in July 2012 confirm the potential of BDM-E:
  1. **Reduced formation of abnormal blood vessel** growth;
  2. **Reduced the signs of damage** typical to retinitis pigmentosa; and
  3. **Improved the function of the retina** and inhibit the death of cells imperative for sight.
- Research is ongoing with USCF and Foundation Fighting Blindness to evaluate the potential of BDM-E to treat retinitis pigmentosa
- The encouraging results to date add momentum to BioDiem's plan to outlicense the BDM-E technology.

# Near term value drivers



## Next six months:

1. **Additional license revenues** from existing influenza vaccine technology;
2. **Phase I clinical trial results** for avian flu vaccine (results to support stockpiling) for future pandemic);
3. **Next stage of vector program** to demonstrate new viruses carrying antigens customised to fight specific diseases;
4. **Results** from expanded BDM-I bacterial/fungal/parasite studies;
5. **Hepatitis vaccine progress** including potential grants/partnering.

## Next twelve months:

1. **Expand sales** and use of LAIV in **new territories**
2. **New cell-based LAIV license** negotiations
3. Results from BDM-I testing in animal models for target diseases.
4. Completion of BDM-E out-licensing or sale

# Why BioDiem?



- 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. BCHT (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.**