



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

Julie Phillips, CEO

www.biodiem.com

(ASX:BDM)

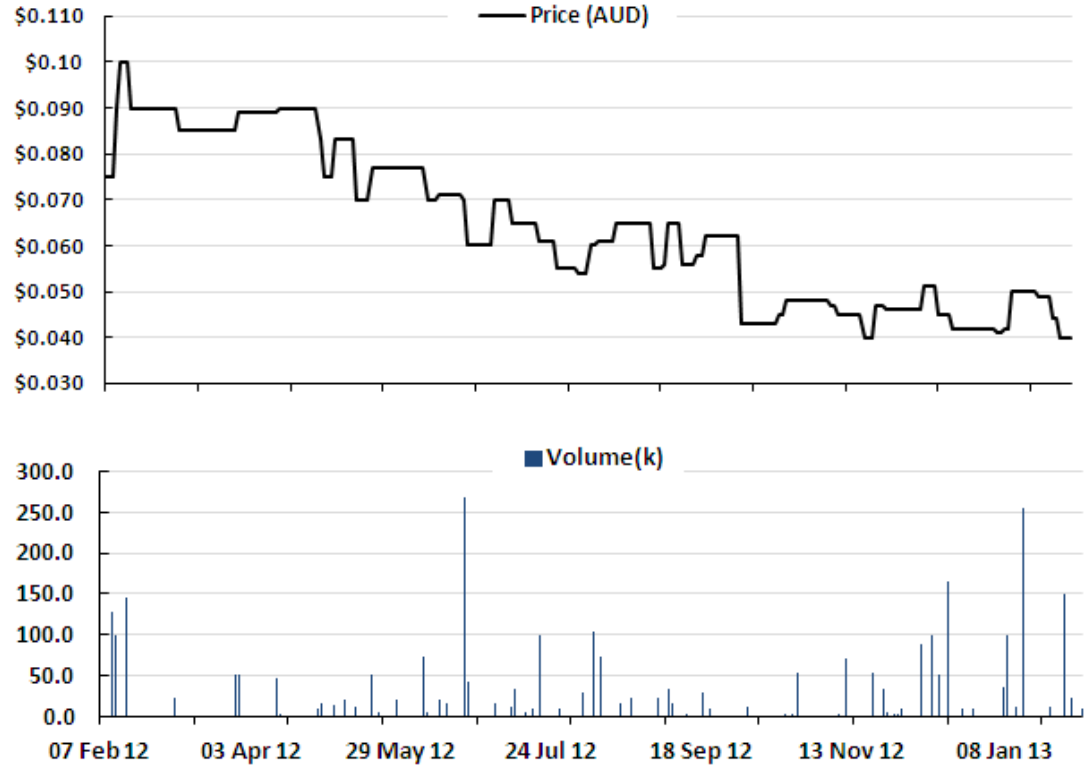
BioDiem Limited



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

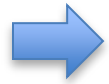
Don Brooks - Non-executive Director

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 BCHO 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








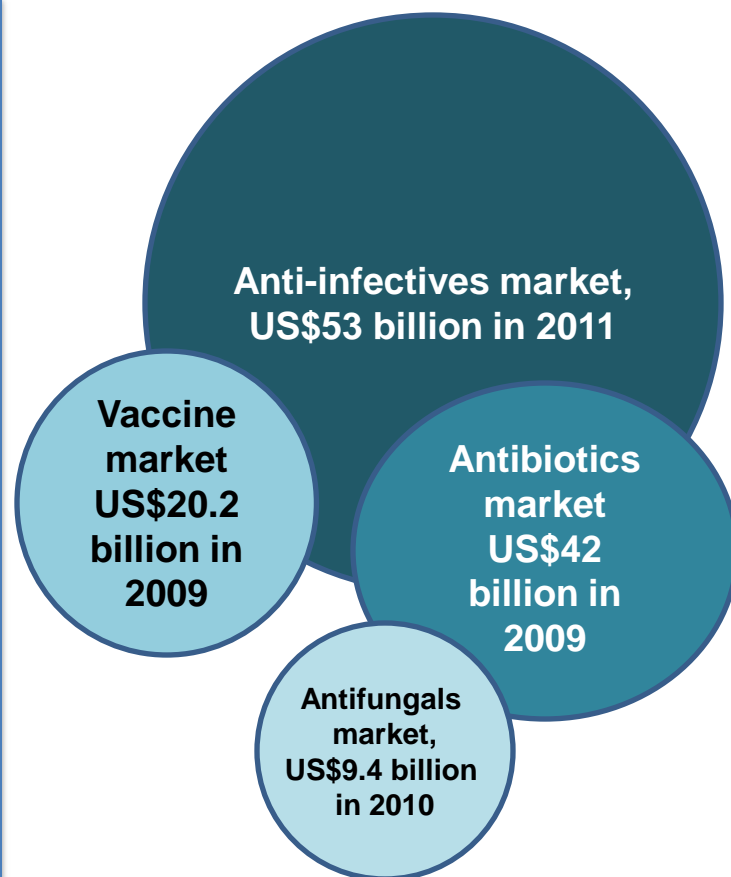
Extensive global partnership network with leading research institutions and companies

- 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

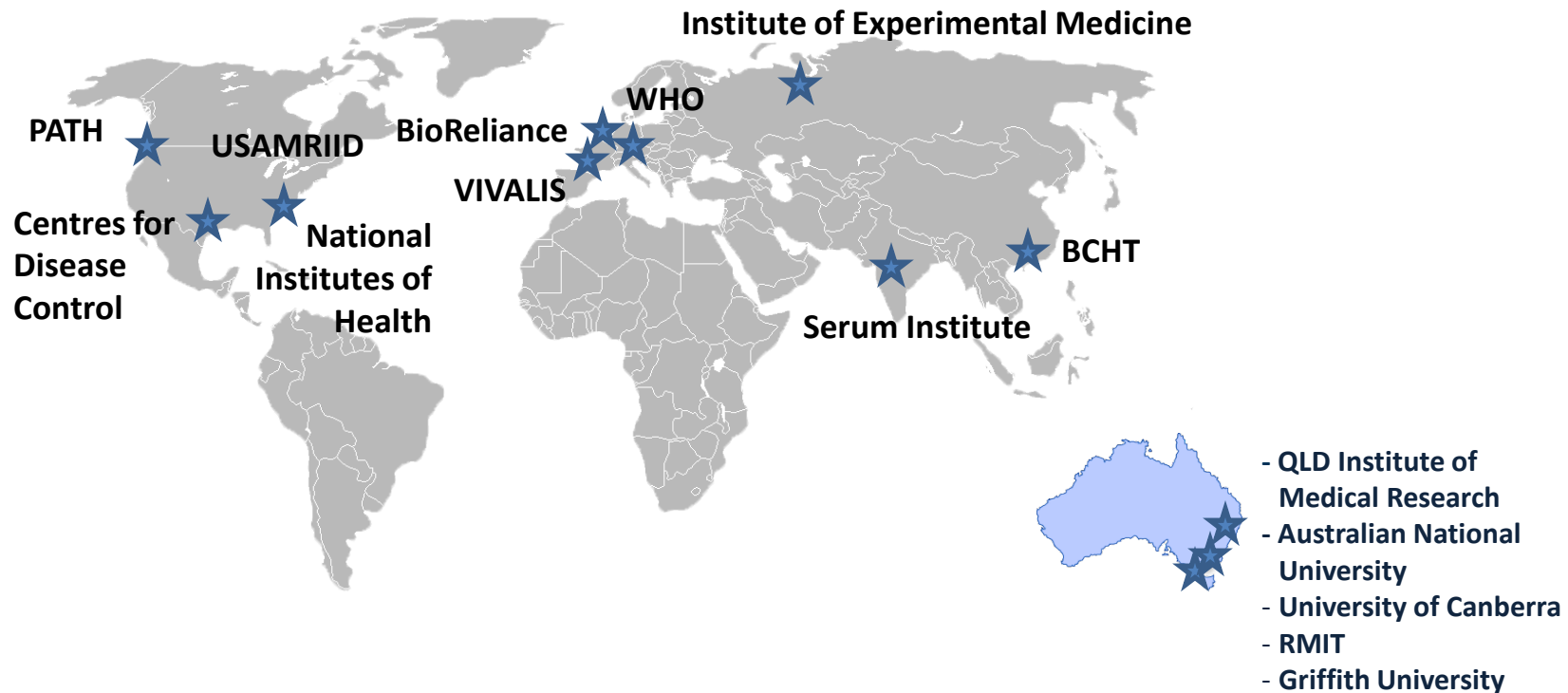


Company	Vaccine sales 2010	Compound annual growth rate % (2004-2009), Datamonitor 2010	Key products
 GlaxoSmithKline Biologicals	\$6.75 billion	21.5%	Infant combinations, hepatitis, influenza, HPV, rotavirus
 The vaccines business of sanofi-aventis Group	\$5.01 billion	18.5%	Infant combinations, meningococcal 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.

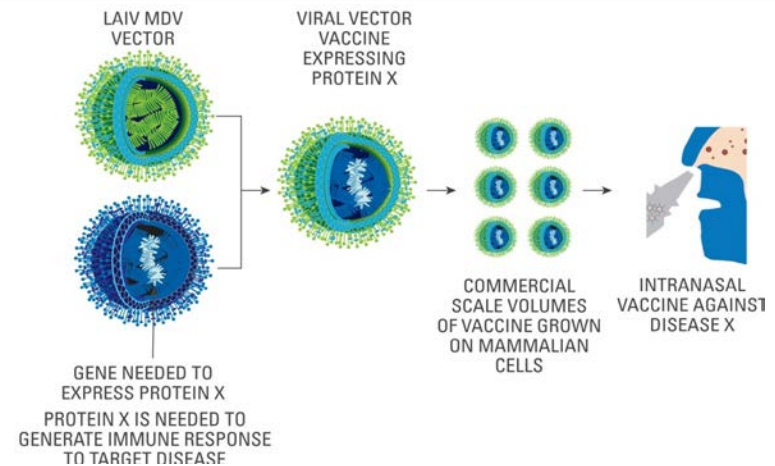
Product	Disease Targets	Current Partners	Development Status
LAIV Vaccine (Influenza)	Influenza – Seasonal & Pandemic	WHO SII (India) BCHT (China) IEM (Russia)	Marketed with license revenues of A\$1.3m FY2012 Phase II (cell-based production technology). BioDiem is seeking to grow and expand out-licensing 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
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



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
BDM-I (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.**