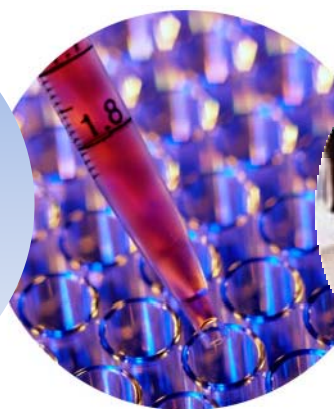




DEVELOPING  
PRODUCTS  
THROUGH  
GLOBAL  
PARTNERSHIPS



BioDiem

**Annual General Meeting  
24 September 2009**

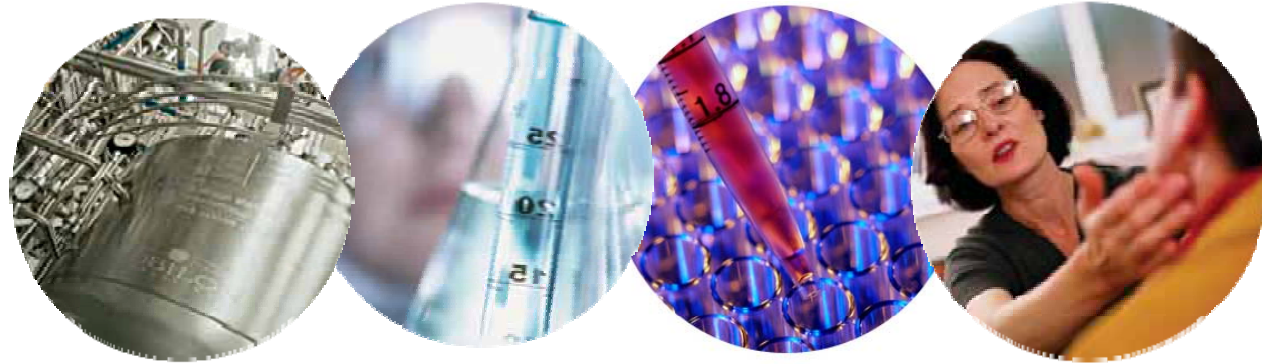
## AGENDA

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



DEVELOPING  
PRODUCTS  
THROUGH  
GLOBAL  
PARTNERSHIPS





## **REVIEW OF OPERATIONS**

**Julie Phillips, CEO**

**DEVELOPING PRODUCTS THROUGH GLOBAL  
RELATIONSHIPS**



## ACHIEVEMENTS FY 2008-2009

<b>LAIV Programs</b>	
<b>Seasonal Influenza</b>	
Phase I clinical trial with Nobilon/Schering-Plough	Treatment phase completed Results being analysed
<b>Pandemic Influenza</b>	
H5N2 Phase II clinical trial with IEM	Completed
H5N1 animal trials with CDC	Commencement delayed (now started)
<b>BDM-E Programs</b>	
Further pre-clinical studies in animal models	Completed/In progress
<b>BDM-I Programs</b>	
Additional academic work	Under review for new targets
<b>Corporate</b>	
Manage costs effectively and assess potential new projects	New project under review

# PRODUCT PIPELINE

Product	Indication	Research	Pre-clinical	Phase I	Phase II		Phase III
LAIV	Seasonal Influenza	→					
LAIV	Pandemic Influenza (H5N1 or H7N3)	→				★	
LAIV	Pandemic Influenza (H5N2)	→				★	
LAIV	Pandemic Influenza (H1N1) swine	→				★	
BDM-E	Retinal Eye Disease	→					
BDM-I	Antimicrobial	→					

★ Pandemic Vaccines can be registered after Phase II clinical trials

For personal use only

## **LAIV**

**A Live Attenuated Influenza Vaccine for  
the prevention of seasonal epidemic  
and pandemic influenza**

**Professor Larisa Rudenko, M.D., PhD, DSc.  
Non-executive director**

## KEY ADVANTAGES OF LAIV

### ***MANUFACTURING/PRODUCTION***

- Cell culture or traditional egg-based culture
- Cell culture production is more reliable – important in event of epidemic/pandemic

### ***DELIVERY***

- Intranasal delivery – easier than conventional injections
- Delivered to an optimal site for immune system
  - antibody and cell-mediated immunity
- Mimics natural route of infection

DEVELOPING  
PRODUCTS  
THROUGH  
GLOBAL  
PARTNERSHIPS

# SEASONAL INFLUENZA – NOBILON/SCHERING-PLOUGH

Nobilon is developing LAIV for seasonal influenza using state of the art cell culture for registration in Europe and Asia.

## Key Developments:

- BioDiem received US\$2 million milestone payment from Nobilon
- Nobilon received EU GMP (Good Manufacturing Practice) accreditation for its manufacturing facilities in the Netherlands
- Data from Nobilon's Phase I clinical trial of LAIV in seasonal influenza currently being analysed
- Phase II trial scheduled to commence shortly in Northern hemisphere winter

DEVELOPING  
PRODUCTS  
THROUGH  
GLOBAL  
PARTNERSHIPS





# PANDEMIC INFLUENZA H5N1 DEVELOPMENT AT THE CDC

*BioDiem/Nobilon/Schering-Plough/CDC = CRADA*

## **Goal of the program**

- To determine whether LAIV is a more efficacious pandemic vaccine relative to inactive vaccines in development
- Potential additional revenue stream to company – Product can be registered after Phase II results

## **Progress in L12M**

- Successfully generated a H5N1 reassortant using the LAIV Master Donor Strain
- Extensive safety testing completed
- Animal trials in progress currently
- Extended program for completion in February/March 2010

## WHO PANDEMIC INFLUENZA PROGRAM

- LAIV made available to WHO as part of Global Pandemic Influenza Action Plan
- WHO has signed sub-licences with the Government Pharmaceutical Office of Thailand and the Serum Institute of India Ltd. Additional sub-licenses to follow (NB: China and India represent major private markets)
- IEM received US\$2 million grant to facilitate reassortant production
- H5N2 and H1N1 LAIVs prepared
- H1N1 trials commenced in Russia and to commence in Thailand at end of September

## PATH VACCINE SOLUTIONS COLLABORATION

*Programme for Appropriate Technology in Health, an international non-profit organization whose aim is to improve the health of people around the world and break long standing cycles of poor health*

- Aim - to develop an affordable and accessible pandemic LAIV for distribution in the public sector of developing countries
- PATH will provide grants of up to US\$3.6m. to the IEM and the other contractors.
- H5N1 and H7N3 reassortant production underway
- Clinical trials planned for November 2010

## BENEFITS OF NOT-FOR-PROFIT SUPPORT

Joint strategy of BioDiem and Nobilon/Schering-Plough

- Access WHO and other international infrastructure for development of vaccines using external funding
- Enhances portfolio of products available for commercialisation by Nobilon/Schering-Plough e.g. new pandemic vaccine products in anticipation of outbreaks such as avian influenza (H5N1) and swine flu (H1N1)
- Enhanced access in developing countries (private market)
- Faster registration of egg-based vaccine
- Potential for enhanced and earlier flow of income from Nobilon/Schering Plough royalties



# NEXT STEPS FOR LAIV PROGRAMS

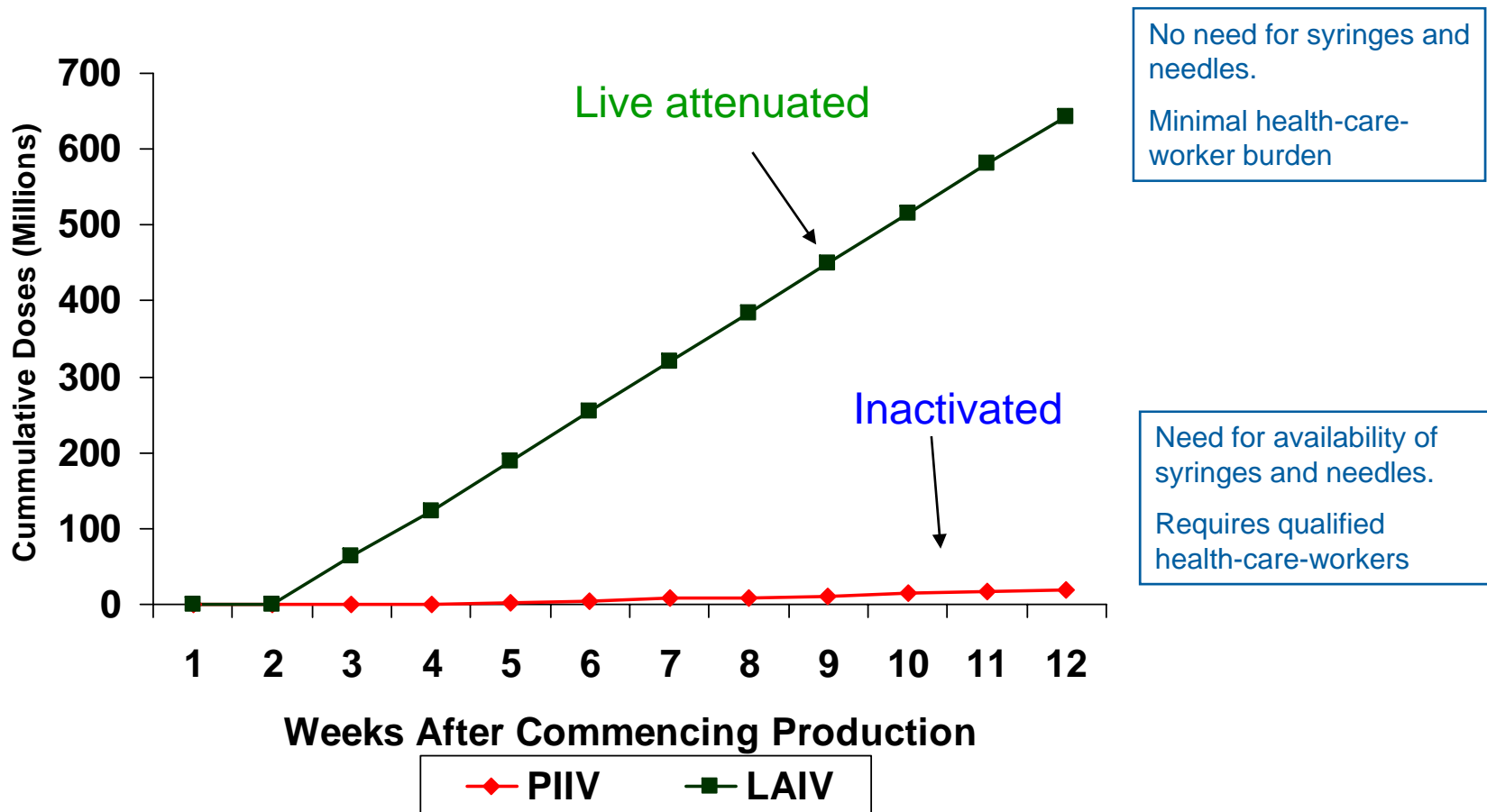
## SEASONAL INFLUENZA

- Results from Nobilon-Schering-Plough Phase I study in seasonal Influenza to be released
- Commencement of Phase II study in seasonal influenza with Nobilon/Schering-Plough

## PANDEMIC INFLUENZA

- H5N2 – Registered in Russia and included in WHO package to support early registration of pandemic vaccines in developing countries
- Animal studies with CDC to be completed in Feb 2010
- WHO – H1N1 clinical trials leading to registration
- PATH collaboration – Pre-clinical & clinical studies of H5N1 and H7N3

## MODELLING THE POTENTIAL PRODUCTION YIELD OF TWO INFLUENZA VACCINES IN A FIXED SIZE PRODUCTION FACILITY



Source: WHO

## **BDM-E**

**A tetrapeptide for ophthalmic  
for “back-of-the-eye” indications**

**Dr John Brown, Non-executive director**

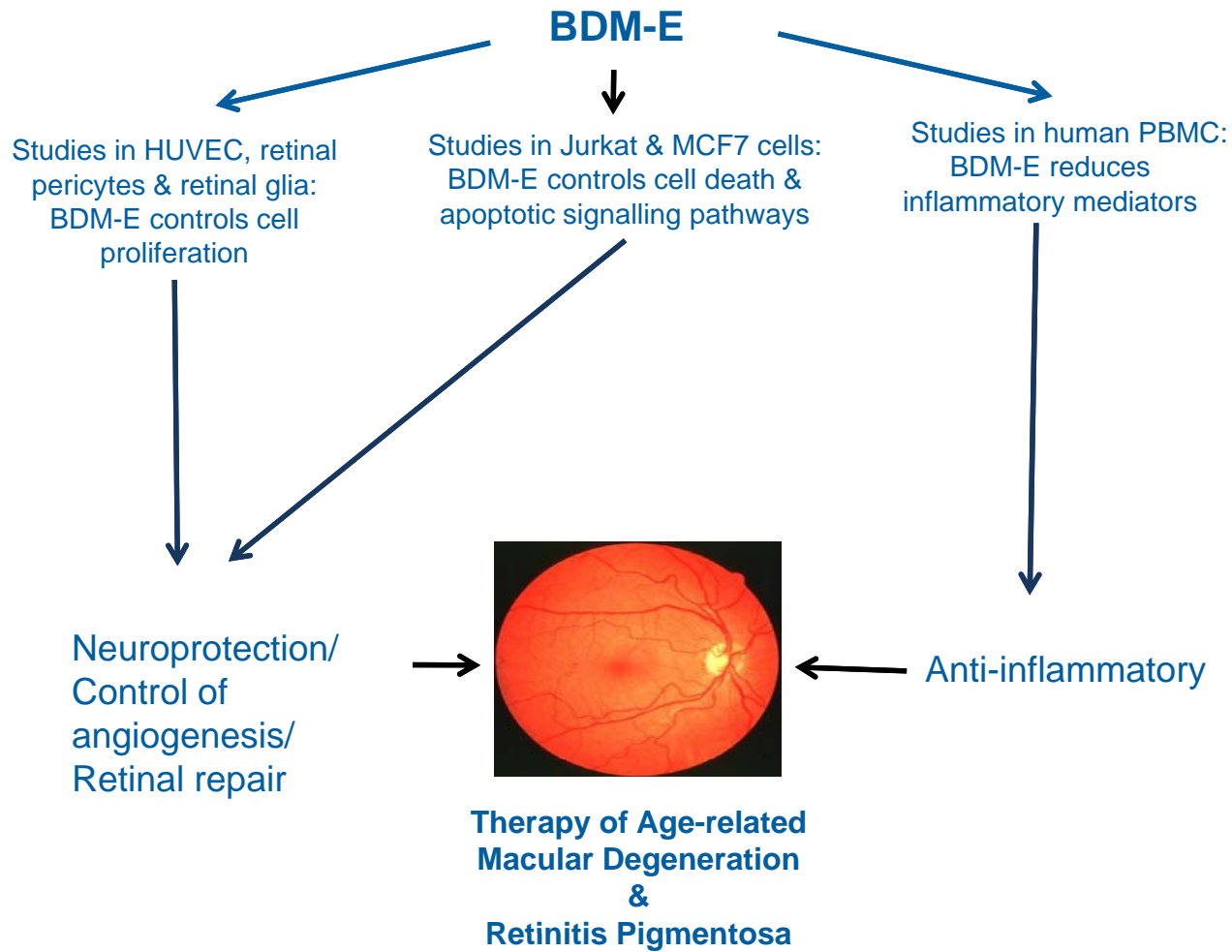


## MECHANISTIC STUDIES OF BDM-E

- BDM-E is a novel peptide already used to treat retinitis pigmentosa and dry age-related macular degeneration in Russia
- BioDiem has licensed BDM-E outside Russia
- BioDiem has now confirmed biology studies supporting the clinical use of BDM-E
- BioDiem's results show BDM-E has beneficial effects in:
  - Cell proliferation & apoptosis studies
  - Studies of inflammation
  - Studies of several animal models of human retinal diseases, including genetic models of retinitis pigmentosa.



# MECHANISM OF ACTION STUDIES TO DATE



*Studies performed at Universities of Cambridge UK & Wisconsin US*



# BDM-E EFFECTIVE IN EYE DISEASE MODELS

- A suite of animal studies completed at the University of Melbourne and Monash University, Australia, and in St Petersburg

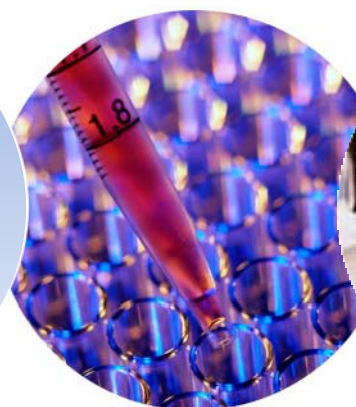
Animal Model	Clinical Disease Modeled	Status
Campbell Rats	Genetic model of Retinitis Pigmentosa	Completed +ve therapeutic
Rd/rd mice	Genetic model of Retinitis Pigmentosa	Completed Additional results awaited
Photic damage to mouse retina	Model of Retinitis Pigmentosa & Dry Age-related Retinal Degeneration	Completed +ve therapeutic
Retinopathy of Prematurity (ROP) in mice	Model of human ROP and proliferative retinopathies	Completed +ve therapeutic
Retinopathy of diabetic rats	Model of human Diabetic Retinopathy	Completed +ve therapeutic
Monocyte Chemo-attractant Protein-1 (MCP-1) knock-out mice	Model of Dry Age-related Macular Degeneration	In Progress

## NEXT STEPS FOR BDM-E PROGRAMS

- Completion of pre-clinical studies in animal models
- Publication of results once Intellectual Property protected
- Continuation of analogue screening (IP strengthening)
- Project strategy review
- Develop licencing package
- Seek partners



DEVELOPING  
PRODUCTS  
THROUGH  
GLOBAL  
PARTNERSHIPS



Julie Phillips, Chief Executive Officer

P: + 61 3 9613 4100

E: [jphillips@biodiem.com](mailto:jphillips@biodiem.com)

Level 10, South Tower  
459 Collins Street, Melbourne,  
Victoria, 3000, Australia

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