

DEVELOPING  
PRODUCTS  
THROUGH  
GLOBAL  
PARTNERSHIPS



  
BioDiem

**Annual General Meeting  
26 November 2008**

# Agenda

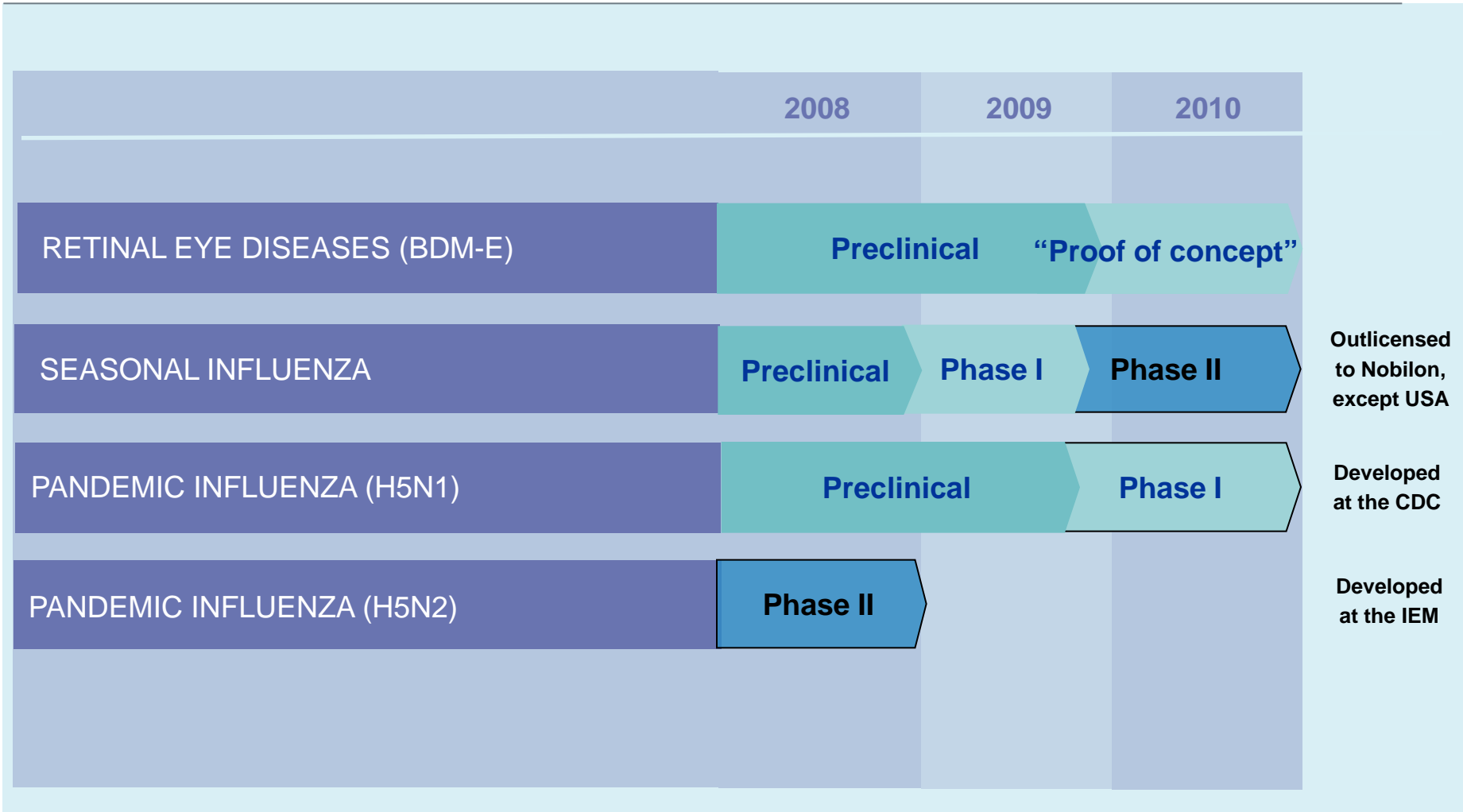
- **Chairman's Overview**
- **CEO's Report**
- **Questions**
- **AGM Resolutions**

# CEO Report

# What were BioDiem's goals for 2008?

- **BDM-E**
  - Complete further pharmacology studies in animal ophthalmic models
  - Complete API manufacture and formulation
  - Continue pre-clinical development for “proof of concept trial”
  - Further development towards opening IND with US FDA in 2009
  
- **LAIV**
  - Seasonal Influenza
    - Phase I begins with Nobilon/Schering Plough
  - Pandemic Influenza
    - Phase II trial begins with the IEM for H5N2
    - Complete development of H5N1 re-assortments with CDC
    - Begin animal trials on H5N1 with CDC
  
- **Corporate**
  - Continue to communicate with media, brokers and shareholders
  - Manage costs effectively and assess potential new projects as appropriate

# Product development pipeline



# BDM-E

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

# Indicative Target Product Profile

Criteria	Target
Formulation	Solution for Injection
Indication	Ophthalmic, back of the eye disease Neuroprotective and anti-Angiogenic
Target population	Age related retinal disease, likely 55+ Age independent patients indicated for Retinitis Pigmentosa
Safety	No significant adverse events Acceptable side effect profile
Efficacy	Anti-angiogenesis – equivalent to Lucentis <sup>®</sup> , or incumbent at time of registration Neuroprotective – better than placebo
Residues	No harmful salts or degradation products
Active	Tetra-peptide (AEDG)
Composition	Tetra-peptide (AEDG) in acetate or other counter ion

## Indicative Target Product Profile (cont'd)

Criteria	Target
Physics	Ready for use solution, in pre-filled delivery syringe for subcutaneous
Administration	Subcutaneous injection
Regimen	Chronic (daily) vs cyclical (periodic) use
Dose	Dose ranging study to be completed 10ug per day (current practice)
Presentation	Dependent on delivery: - Periodic: One dose and/or one course of treatment per device - Chronic: Multiple dose per device
Storage	Refrigerated (2 to 8°C)
Technology/Manufacture	Recrystallisation without preparatory HPLC
Regulatory	FDA and EMEA approvals



# Manufacture and Control Systems for BDM-E

- A manufacturing protocol has been developed with Genzyme Pharmaceuticals Inc
- The protocol used solution phase recrystallisation, rather than HPLC preparative procedures
- Key attributes of the protocol include:
  - Cost effective
  - Manufactured to GMP standard
  - High purity (> 98%)
  - Scalable, suitable for manufacture of kg quantities
  - Flexible, allows salt selection for further development studies
- Different counter-ion salts have been successfully manufactured for formulation optimisation

# BDM-E is effective in animal models for eye disease

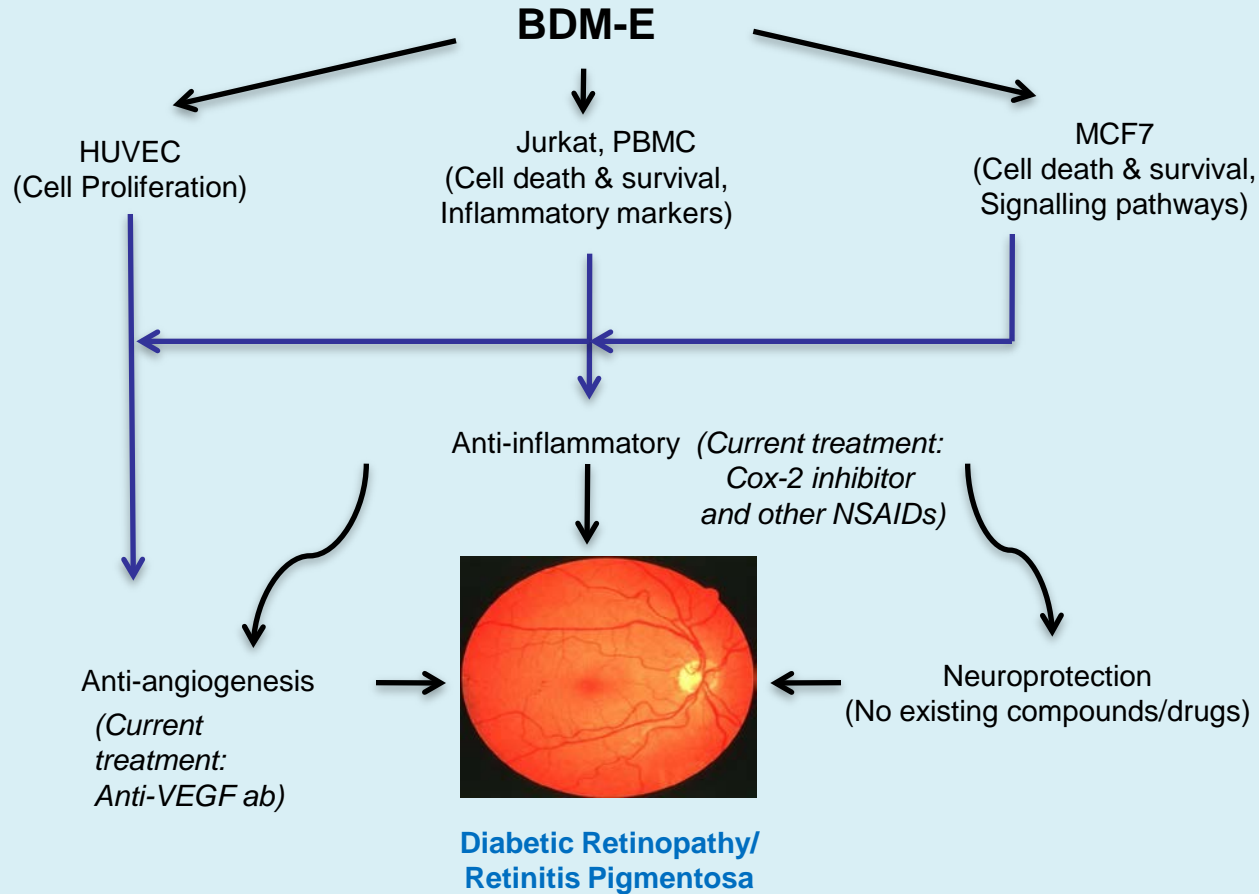
- A suite of animal studies are being completed at the University of Melbourne and Monash University, Australia

Model	Indication	Status
1. Campbell Rats	Inherited variety of Retinitis Pigmentosa	Completed in St. Petersburg
2. Late Retinopathy of Pre-maturity (ROP)	Diabetic retinopathy	Completed in August 2007
3. Early treatment of ROP	Diabetic retinopathy	Complete/Data being reviewed
4. Diabetic Sprague Dawley rats	Diabetic retinopathy	Complete/Data being reviewed
5. Mouse model of light damage	Retinitis Pigmentosa/ Dry AMD	Complete/Data being reviewed

## Animal work currently being performed

Model	Indication	Status
rd/rd mice	Inherited variety of Retinitis Pigmentosa	In progress
Monocyte chemoattractant protein-1 (MCP-1) knockout mouse	Age related macular degeneration (Dry & Wet AMD)	In progress
Series of studies in ROP mice assessing dosing regimen	Diabetic retinopathy	In progress
Series of studies in ROP assessing lower dosages	Diabetic retinopathy	In progress

# Mechanism of Action studies are ongoing



Note: Studies are being completed at Cambridge University, Addenbrooke Hospital, U.K.

## Next steps for the BDM-E program

- Undertake gap projects allowing for clinical assessment of product, including:
  - Completion of animal studies
  - Pharmacosafety and toxicology to GLP
  - Further formulation studies
  - Fill and finish of clinical grade API
  - Further Mechanism of Action studies
  
- “Proof of Concept” Trial
  
- Partner the program

# LAIV

A Live Attenuated Influenza Vaccine (LAIV) for the prevention of seasonal epidemic influenza and pandemic influenza

# The seasonal influenza market continues to expand

In February 2008, the US Centres for Disease Control and Prevention (CDC) Advisory Committee recommended to expand the recommended age for influenza vaccination :

- FROM: 6 months to 59 months
- TO: 6 months to 18 years of age



## Result:


1. Increases market by ~30 million doses per year in the U.S
2. Increases the attractiveness of BDM owned US marketing rights

## Seasonal development continues with Nobilon/ Schering Plough

Nobilon is developing LAIV for production using the next generation of cell culture, at its cost, for registration in Europe and Asia

Over the past 12 months, Nobilon/Schering Plough has:

- Developed vaccine seeds
- Defined the appropriate vehicle and delivery systems for cell culture manufacture
- Identified the device for nasal spray delivery



**LAIV should enter clinical trials in the coming  
Northern Hemisphere influenza season**



# LAIV significantly stimulated the main factors of immunity

## Goal of the program

- To validate the factors and parameters of immune response which will allow us to register new vaccines without epidemiological trials

## Progress in L12M

- Virus specific sIgA (a measure of local immunity) geometric mean titers (GMT) were 32.8% and 79.4% before and after vaccination in nasal secretions of treated volunteers, whereas the placebo group had no increase in sIgA GMT
- A significant increase in sIgA avidity (measure of antibodies functional activity) increased 2.5 - 8 times after immunization with LAIV, whereas the placebo group displayed no higher avidity
- Vaccination with LAIV delivered sufficient immunogenicity as observed by a significant increase in serum GMT's
- Virus specific memory/effector T-cells increased and remained in vaccinated persons on day 21 (after viral clearance) in contrast to the placebo group

# H5N1 development at the CDC

## Goal of the program

- To determine whether LAIV is more efficacious pandemic vaccine relative to inactive vaccines in development

## Progress in L12M

- Successfully generated a H5N1 reassortant using the LAIV Master Donor Strain
- Undergone extensive safety testing
- Extended program for completion in August 2009

# H5N2 completes Phase II trial with the IEM

## Goal of the program

- To evaluate the safety and immunogenicity of a H5 live influenza vaccine candidate

## Phase II study protocol

- Double blind, control study
- 100 participants, aged 18 – 49 were assigned in 2:1 ratio for vaccine or placebo
- Volunteers were given two does of vaccine (or placebo) 21 days apart
- Clinical examination of vaccines was conducted 7 days post vaccination for serum antibody response (as a measure of efficacy)

## Results

- To be published in December 2008

## Next steps for the LAIV program

- Seasonal influenza vaccine enters Phase I clinical trials with Nobilon/Schering Plough in Europe
- Pandemic vaccine
  - H5N1 completes animal study under the CRADA with CDC & Nobilon
  - H5N2 Phase II completed with the IEM, data reported to the market
  - IEM develops array of re-assortants for possible pandemic including H2, H7 & H9
- Seek a value accretive transaction for the US marketing rights

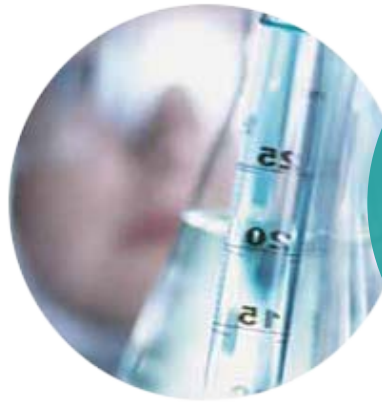
# Financials

## Statement of financial performance

FOR THE YEAR ENDED 30 JUNE 2008	2008	2007
	\$	\$
Revenue from licensing activities	1,119,407	1,300,678
Grants	-	(75,923)
Interest	333,417	215,049
<b>Revenues from ordinary and finance activities</b>	<b>1,452,824</b>	<b>1,439,804</b>
<b>Expenses from ordinary activities</b>		
Licence fees and royalties	(223,881)	(260,136)
Research and development	(3,529,332)	(3,231,504)
Administration and corporate	(2,170,117)	(1,800,031)
<b>Loss attributable to members of the company before tax</b>	<b>(4,470,506)</b>	<b>(3,851,867)</b>

# How did we perform in 2008?

- **BDM-E**
  - Complete further pharmacology studies in animal ophthalmic models ✓
  - Complete API manufacture and formulation ✓
  - Continue pre-clinical development for “proof of concept trial” ✓
  - Initiate clinical trials under international regulatory guidelines On track
  
- **LAIV**
  - Seasonal Influenza
    - Phase I begins with Nobilon/Schering Plough On track
  - Pandemic Influenza
    - Phase II trial begins with the IEM for H5N2 ✓
    - Complete development of H5N1 re-assortments with CDC ✓
    - Begin animal trials on H5N1 with CDC Delayed
  
- **Corporate**
  - Continue to communicate with media, brokers and shareholders ✓
  - Manage costs effectively and assess potential new projects as appropriate ✓



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