BioDiem

Annual General Meeting

23 September 2010

Agenda

- Chairman’s Overview
- Review of Operations
- Questions
- AGM Resolutions

Review of Operations

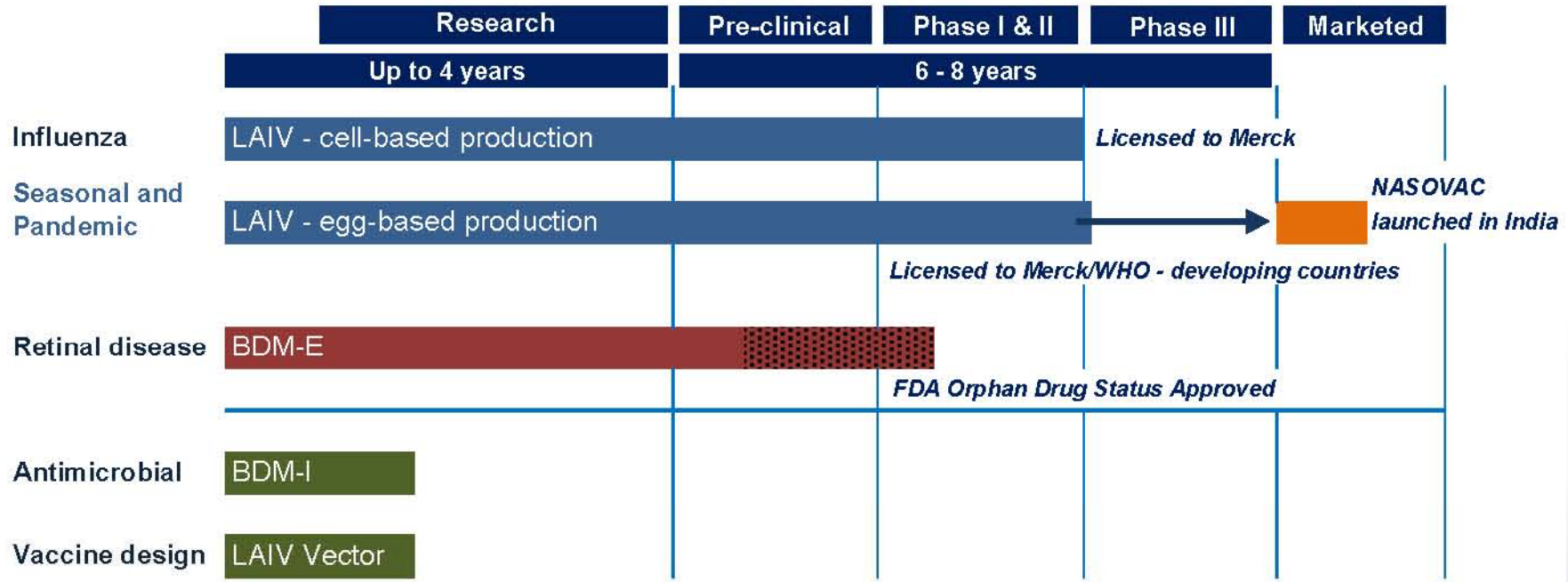
Julie Phillips

Chief Executive Officer

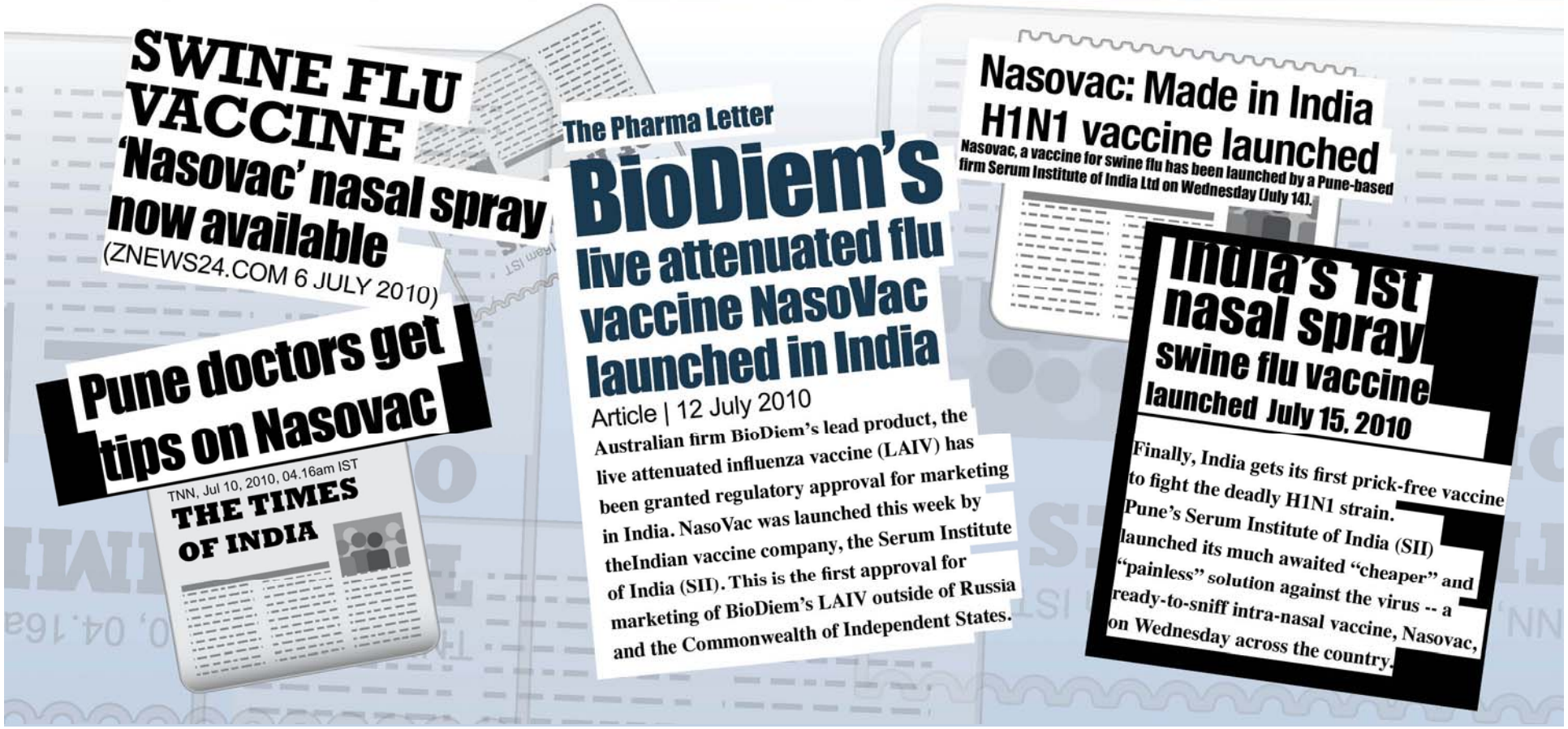
Achievements FY 2009-2010

Phase II clinical trial with Nobilon/Merck – seasonal influenza		*Report due end 2010*
WHO sublicences issued		September 2009
Strategic review of project portfolio		November 2009
	LAIV vector project	
	BDM-I reorientation to serious human infectious disease	
Japanese rights for LAIV gained		December 2009
First LAIV product launch via WHO program (“Nasovac” in India)		July 2010
H5N1 animal trials with CDC		Presented in Hong Kong September 2010
FDA Orphan Drug status granted BDM-E (Retinitis Pigmentosa)		September 2010
Successful completion of Rights Issue - $4.5m raised		September 2010

Development Pipeline



BioDiem


SWINE FLU VACCINE
'Nasovac' nasal spray now available
(ZNEWS24.COM 6 JULY 2010)
Pune doctors get tips on Nasovac
TNN, Jul 10, 2010, 04.16am IST
THE TIMES OF INDIA
The Pharma Letter
BioDiem's live attenuated flu vaccine NasoVac launched in India
Article | 12 July 2010
Australian firm BioDiem's lead product, the live attenuated influenza vaccine (LAIV) has been granted regulatory approval for marketing in India. NasoVac was launched this week by theIndian vaccine company, the Serum Institute of India (SII). This is the first approval for marketing of BioDiem's LAIV outside of Russia and the Commonwealth of Independent States.
Nasovac: Made in India H1N1 vaccine launched
Nasovac, a vaccine for swine flu has been launched by a Pune-based firm Serum Institute of India Ltd on Wednesday (July 14).
India's 1st nasal spray swine flu vaccine launched July 15, 2010
Finally, India gets its first prick-free vaccine to fight the deadly H1N1 strain.
Pune's Serum Institute of India (SII) launched its much awaited "cheaper" and "painless" solution against the virus -- a ready-to-sniff intra-nasal vaccine, Nasovac, on Wednesday across the country.

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

BioDiem's LAIV

- Cold-adapted, intranasal, live attenuated influenza vaccine (LAIV)
- Proprietary master donor virus strains (no patent required)
- Safe, highly immunogenic and effective (>100 million doses distributed)
- Needle-free delivery (intranasal) (No trained personnel, blood/sharps precautions)
- Induces broad immune response
  (mucosal, systemic and cell-mediated responses similar to natural infection)
- High yield in egg & cell-based production (to meet pandemic need)

Seasonal Influenza

- *Nobilon/Merck licence - Europe & Asia (manufacturing only for NAFTA)*
- *BioDiem licence - Japan & sales/marketing rights for NAFTA*

Key Developments:

- Phase II trial completion of cell-based LAIV product; report due end 2010
- Merck/Schering-Plough acquisition completed in November 2009
- Merck announced Boxmeer operations phase-out in July 2010
- Early stage discussion of LAIV cell-based development plan with Merck

Pandemic H5N1(avian flu) **development at the CDC**

Goal of the program

- Is LAIV is a more efficacious pandemic vaccine than inactive vaccines in development?

Results

- LAIV used in ferret study was from cell-based, not egg-based production
- LAIV provided greater protection compared to the inactivated vaccine against heterologous variants of influenza viruses (cross-protection)
- IgA antibodies correlated well with protection
- This criteria will be used for registration of LAIV

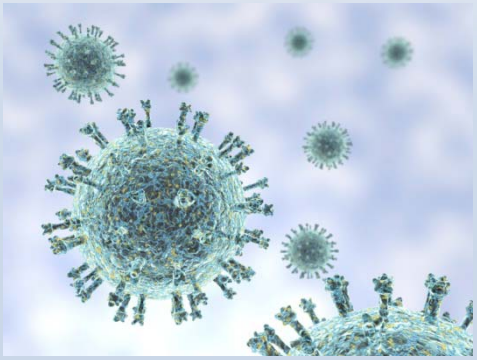
WHO Pandemic Influenza Program

- LAIV made available to WHO as part of Global Pandemic Influenza Action Plan *(free licence for public markets)*
- WHO has signed sub-licences with the Government Pharmaceutical Office of Thailand and the Serum Institute of India Ltd (SII)
- H1N1 (pandemic) launched in India by SII in July 2010 (“Nasovac”)
- Product launch expected in Thailand early 2011
- BioDiem eligible to receive royalties from sales into *private markets*

PATH Vaccine Solutions Collaboration

Program 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 developing countries
- PATH is providing funding of up to US$3.6m to the IEM/other contractors
- H5N1 and H7N3 reassortant production underway
- Preclinical studies (chicken & ferret) underway in US & Netherlands
- Clinical trials planned for April 2011



Benefits of not-for-profit support

- Access WHO and other international infrastructure for vaccine development using external funding
- Enhances portfolio of products available for commercialisation e.g. new pandemic vaccines for outbreaks such as avian influenza (H5N1) and other potential pandemics
- Enhanced access to private markets in developing countries
- Faster registration of egg-based vaccine
- Potential for enhanced and earlier flow of income from royalties

Next steps for LAIV Program

- Continue preparation of seasonal & pandemic strains for WHO licencees
- Negotiate licence for Japanese territory and NAFTA rights ➔ revenue
- Negotiate licence for sales into private markets per WHO agreement ➔ revenue
- Discuss LAIV cell-based development plan with Merck
- Pursue H5N2 & other pandemic vaccine early registration in developing countries
- Publication of studies conducted with CDC
- Conduct pre-clinical/clinical studies of H5N1 & H7N3 under PATH collaboration

Other Projects

Julie Phillips, CEO

BDM-E

- Novel peptide - licensed to BioDiem for territories outside Russia
- BioDiem's studies show BDM-E has biological effect in:
  - cell growth and death
  - inflammation
  - several animal models of retinal disease
- Found to be safe in the doses tested in clinical trials
- FDA granted Orphan Drug status for *retinitis pigmentosa*

Next steps for BDM-E Program

- Complete studies to protect analogue Intellectual Property
- Completion/publication of studies
  - pre-clinical & mechanism of action/disease models
- Complete outlicencing package
- Pursue partner for retinitis pigmentosa development (orphan disease)
- Pursue partner for exploration of wider indications (e.g. Alzheimer's disease)

BDM-I

- Novel synthetic product for use as an antimicrobial
- BDM acquired all commercial rights worldwide (for royalties on sales)
- BDM-I has demonstrated broad-spectrum activity *in vitro* against important human disease-causing agents (pathogens)
- US Patent – Notice of Allowance
- Proposed development plan for serious clinical infections
  e.g. bacterial and fungal

Next Steps for BDM-I Program

- Preparatory studies
  - routes of administration and formulation
  - pharmacology & toxicology profiling
- Disease model set-up
- Proof of concept studies
- Co-development/partnering exploration
- Outlicence for one or more indications

New Project: LAIV Vector

- Based on LAIV influenza virus
- Platform technology for vaccine design & production

Viruses

- are a tool commonly used by molecular biologists to deliver genetic material into cells
- have evolved efficient & specialised machinery to transport their genetic material into the cells they infect

The LAIV virus has potential important advantages compared to other viruses used as vector systems

Next Steps for LAIV Vector Program

- Produce starting materials (cell bank and master virus stock)
- Confirm feasibility
- Demonstrate usability in disease-specific vaccine examples:
  - cancer target (Epstein Barr virus-related)
  - infectious disease target (respiratory syncitial virus)
- Co-development/partnering exploration
- Proof of concept testing

➔ **revenue from research outlicences**

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