



BioDiem

Annual General Meeting

19 October 2015



Chairman's Overview

Hugh Morgan AC

Chairman, BioDiem Ltd

Review of Operations

Julie Phillips

Chief Executive Officer,
BioDiem Ltd

Highlights in FY2015 and update

LAIV Influenza vaccine program: Commercial progress:

- Commencement of royalty income from sales of Nasovac-S (India)
- WHO Prequalification approval of Nasovac-S – Oct 2015.
- Approval to conduct clinical trials in China (Changchun BCHT Biotechnology Co) – Sep 2015
- Publication of clinical trials supporting value of LAIV seasonal and avian flu vaccines.

Antimicrobial (BDM-I) program: Opal Biosciences Ltd

- Formation of wholly-owned subsidiary Opal Biosciences Ltd and shareholder approval for IP transfer.
- Successful ARC Linkage grant for \$250,000 to Griffith University for BDM-I research
- Additional US and European patents
- Continued mechanism of action work at Western Sydney University

Corporate activity:

- Successful raising of \$0.834m from exercise of Dec 2014 options.
- \$0.128m from the R&D Tax Incentive
- Continued cost reduction

LAIV Influenza vaccine program

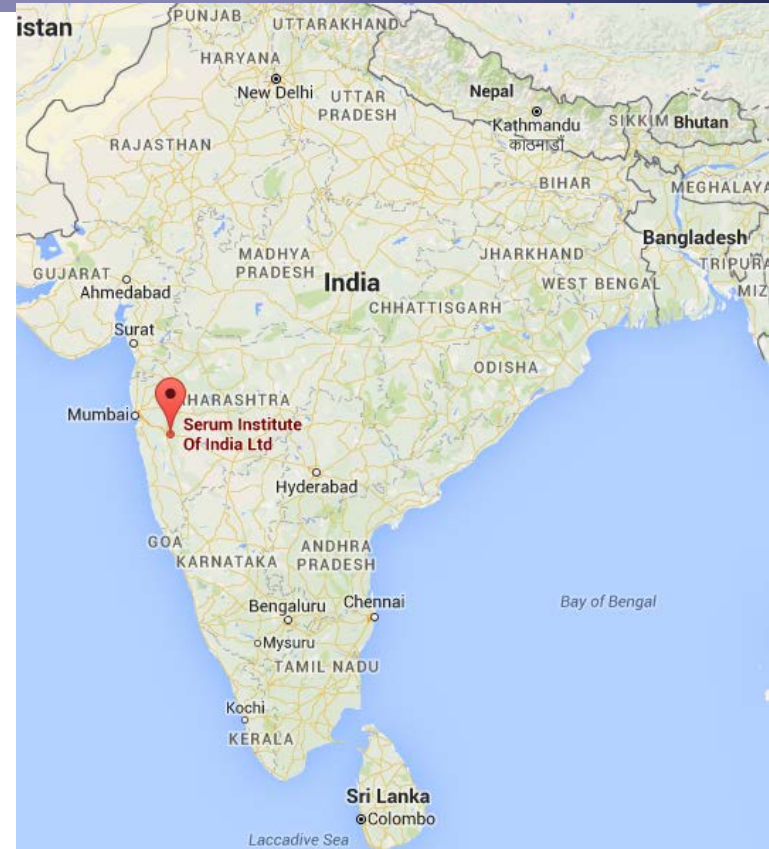
Commercial progress: INDIA:

Nasovac – pandemic influenza vaccine

- Product launch in India (2010)
- Royalties to BioDiem from sales in India
- WHO prequalification (2012)

Nasovac-S – seasonal influenza vaccine

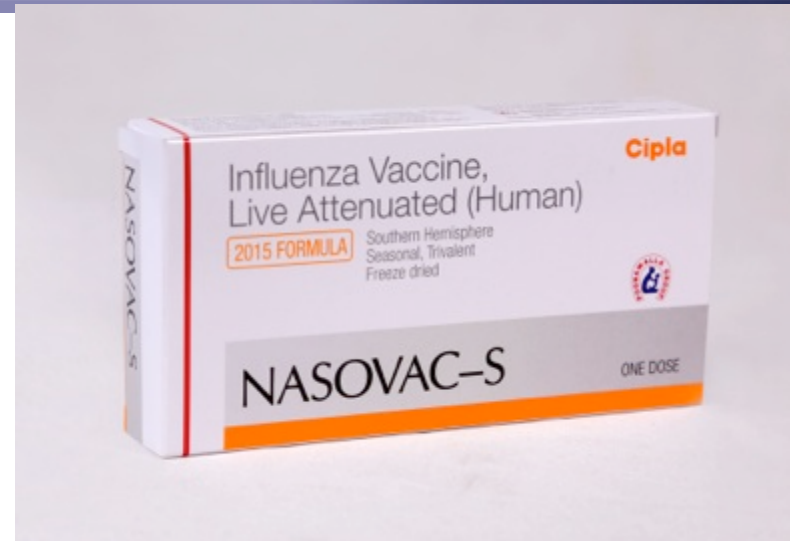
- Product launch in India (July 2014)
- Royalties to BioDiem from sales in India



LAIV Influenza vaccine program

Commercial progress: INDIA:

- Cipla – SII distribution agreement for India (May 2015)
- WHO prequalification (October 2015)



Serum Institute territories

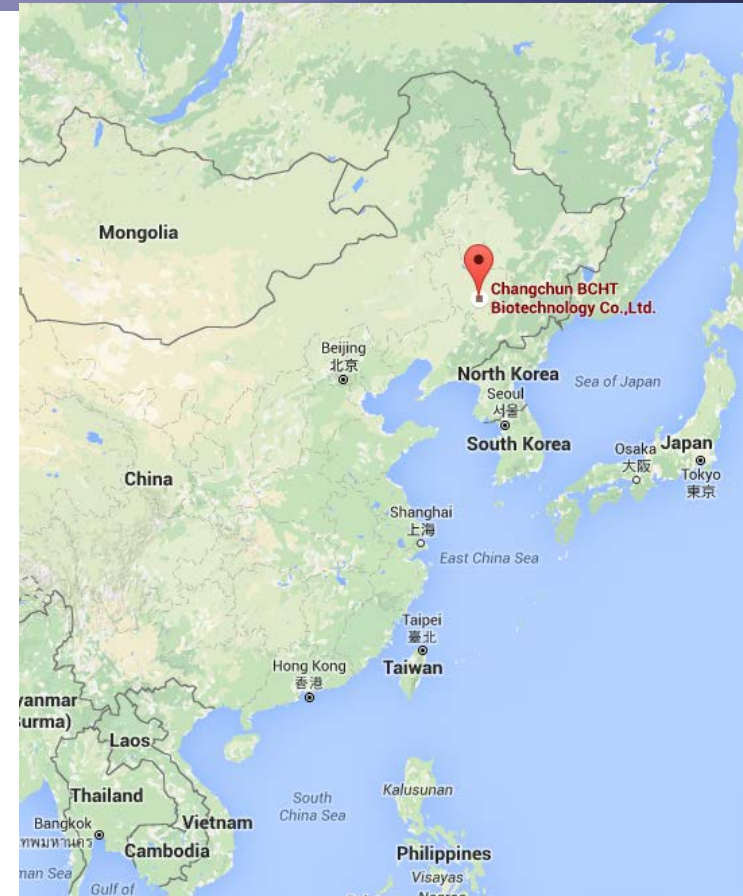
- India (exclusive)
- Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan, Sri Lanka and New Zealand, Myanmar.

LAIV Influenza vaccine program

Commercial progress: CHINA:

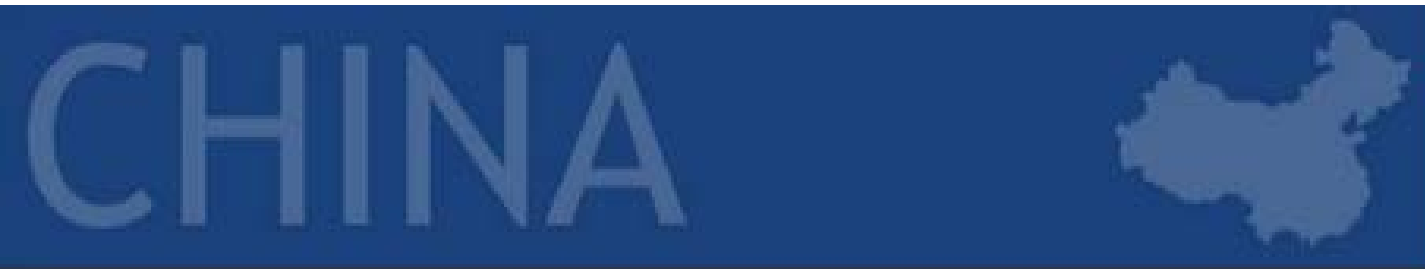
Changchun BCHT Biotechnology Co has completed:

- the technology transfer from St Petersburg
- process and assay development
- building construction completed
- equipment purchase completed
- clean facility constructed
- pilot plant and quality systems audit and upgrade completed (to meet WHO prequalification requirements)



Commercial progress: CHINA:

- CFDA IND approval (Sep 2015)
- Clinical trial commencement expected in December 2015



Live Attenuated Influenza Virus: LAIV vaccine

Advantages



Needle-free nasal delivery
No trained personnel and blood/sharps precautions unnecessary



Broader immune response
Than seen with inactivated influenza vaccines



No adjuvant required



Extensive clinical and market experience in Russia
> 100m doses
efficacy and safety in >500,000 adults/140,000 children



High yields
In egg-based or cell-based production (with no reliance on eggs)



ELSEVIER

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine



BioDiem

Safety of Russian-backbone seasonal trivalent, live-attenuated influenza vaccine in a phase II randomized placebo-controlled clinical trial among children in urban Bangladesh



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ARTICLE INFO

Article history:

Received 4 December 2014

Received in revised form 9 April 2015

Accepted 13 April 2015

Available online 24 April 2015

Keywords:

Live attenuated influenza vaccine

Clinical trial

ABSTRACT

Introduction: Live-attenuated influenza vaccines (LAIVs) have the potential to be affordable, effective, and logistically feasible for immunization of children in low-resource settings.

Material and methods: We conducted a phase II, randomized, double-blind, parallel group, placebo-controlled trial on the safety of the Russian-backbone, seasonal trivalent LAIV among children aged 24 through 59 months in Dhaka, Bangladesh in 2012. After vaccination, we monitored participants for six months with weekly home visits and study clinic surveillance for solicited and unsolicited adverse events, protocol-defined wheezing illness (PDWI), and serious adverse events (SAEs), including all cause hospitalizations.

Results: Three hundred children were randomized and administered LAIV ($n = 150$) or placebo ($n = 150$). No immediate post-vaccination reactions occurred in either group. Solicited reactions were similar between

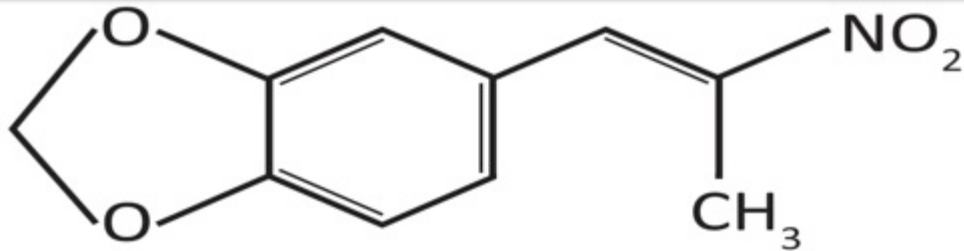
List of pandemic & potentially pandemic LAIV vaccines tested in clinical trials

| LAIV subtype | Wild-type parental virus | Designation | Reference |
|--------------|-------------------------------|--------------|---------------------------------|
| H1N1pdm | A/California/07/2009 | H1N1pdm Len | Rudenko et al., 2011 [56] |
| H5N2 | A/duck/Potsdam/1402-6/86 | H5N2 Pot Len | Rudenko et al., 2008 [38] |
| H5N2 | A/turkey/Turkey/1/2005 | H5N2 Tur Len | Rudenko et al., 2015 [39] |
| H7N3 | A/mallard/Netherlands/12/2000 | H7N3 Len | Rudenko et al., 2014 [40] |
| H2N2 | A/California/1/66 | H2N2 Cal Len | Isakova-Sivak et al., 2015 [41] |
| H7N9 | A/Anhui/1/2013 | H7N9 Len | N/A ¹ |

Antimicrobial (BDM-I) program



INTRODUCING OPAL TECHNOLOGY



- **Opal Technology** – selective activity against important pathogens
- Potential for resistant bacterial and fungal pathogens
- Currently selected for three US programs (NIH & USAMRIID)
- Potential for various routes of administration.

NIAID/USAMRIID PROGRAMS

*Drug resistant Tuberculosis**



Pneumocystis



Biowarfare target



These projects have been funded with Federal funds from the NIH/NIAID/DAID

** Contract No. HHSN272201100012I

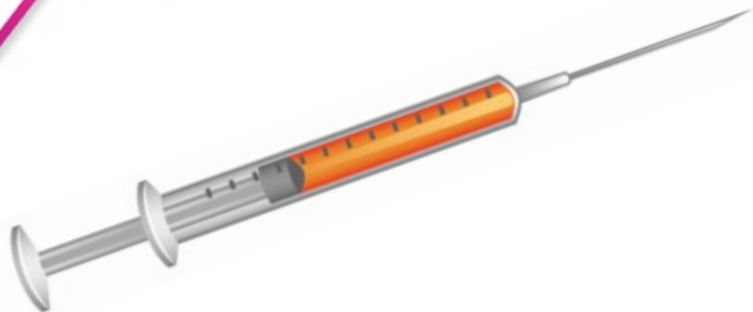
*** Contract No. HHSN272201100018I

**** Contract No. HHSN272201000029I / HHSN27200002 /A51

#This project has been supported by the U.S. Army Medical Research Institute of infectious Diseases (USAMRIID) under its



POTENTIAL PRODUCT LINE



Intravenous Use (Injection)



Oral Use (Tablets, capsules, syrup, mouthwash)



Topical Use (Gel, ointment, spray)



Lung (Inhalation)



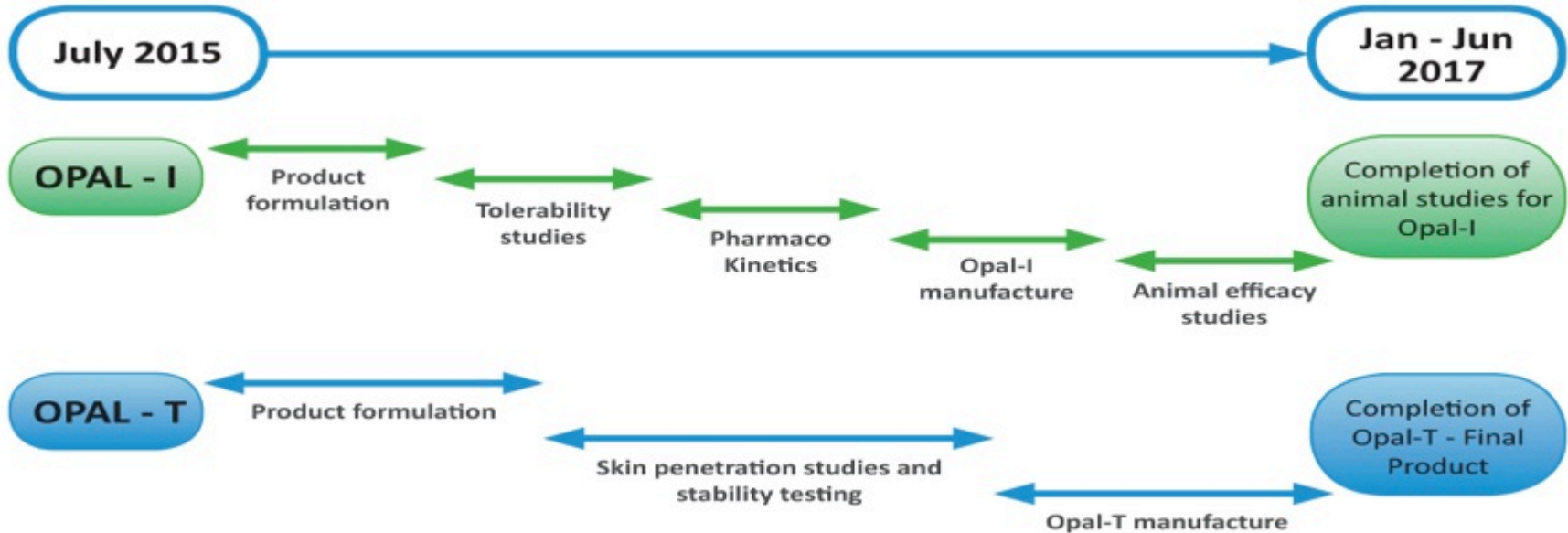
OPAL'S DEVELOPMENT PLAN

With an international team and development plan in place, Opal Biosciences Limited is raising up to **AUD\$4m** to develop its Technology.

- Opal-I, an injectable product
- Opal-T, topical product

Our commercial objective is to out-license or sell the technologies to a larger pharmaceutical company for clinical trials and marketing.

OPAL'S DEVELOPMENT TIMELINE (Indicative)



THE MARKET

Antifungals
market,
US\$13.9b

Antibacterials
market, **US\$46b**
by 2019

Anti-infectives
market, **US\$103b**
by 2015

**Bloomberg
Business**

PharmaTimes
DIGITAL

Merck to Buy Cubist for
\$8.4 Billion to Add Antibiotics

**Roche inks \$750M antibiotic
pact with Meiji and Fedora**

Ref: Global Antifungal Therapeutics Market: Trends and Opportunities (2014-2019) Daedal Research, August 2014

Anti-infectives – A Global Strategic Business Report, Global Industry Analysts, Inc. MCP-6156, February, 2010.

Antibacterial Drugs Market- A Global Industry Analysis, Size, Share, Growth, trends and Forecast, 2013-2019,

Top Market Research, March 2014

opal
Biosciences



US GOVERNMENT INCENTIVES

1. **The GAIN (Generating Antibiotic Incentives Now) Legislation**
2. **FDA's Priority Review:** FDA's goal is to take action on an application within 6mths (compared to 10mths).
3. **Orphan Drug Designation:** Sponsor of the drug entitled to development incentives (tax credits, extended market exclusivity).
4. **FDA's Fast Track Process:** Designed to facilitate the development, and expedite the review of much needed new treatments.



GLOBAL COLLABORATIONS

The Opal Technology project brings together a wealth of international expertise.



THE UNIVERSITY OF
SYDNEY



RMIT
UNIVERSITY



Queensland Institute of
Medical Research



National Institute
of Allergy and
Infectious Diseases



USAMRIID
United States Army
Medical Research Institute
of Infectious Diseases

<http://www.niaid.nih.gov/LabsAndResources/resources/dmid/invitro/Pages/invitro.aspx>
<http://www.niaid.nih.gov/labsandresources/resources/dmid/animalmodels/Pages/default.aspx>

The logo for Opal Biosciences, featuring the word "opal" in a blue, lowercase, sans-serif font with a horizontal rainbow bar above it, and the word "Biosciences" in a smaller, black, sans-serif font below it.

opal
Biosciences

- **Successful raising of \$0.834m for exercise of Dec 2014 options.**
- **\$0.128m from the R&D Tax Incentive**
- **Continued cost reduction**
 - Office move
 - Outsourced accounting/other
- **De-merger of BDM-I: formation of Opal Biosciences**

LAIV influenza vaccine technology:

- Growth of revenues from commercial activities
 - Product launch early FY2015
 - Export and possible sales to current licensed territories
 - New territories (developed and less developed countries)
- Continuing support of commercial licencees:
 - Serum Institute of India, Changchun BCHO Biotech
- Collaborations with new technologies for future product enhancement
 - Thermostable powder delivery
 - Universal vaccine

Opal Biosciences

- Continue development of Opal-I and Opal-T
- Continue capital-raising (local and international)
- Continue commercial discussions
- Aim to licence out/sell or IPO by end 2017

Complete placement and small capital raising

Key criteria for success

Income: LAIV royalties, milestone and other payments and future contribution from Opal Biosciences (Opal).

Opal was formed in May 2015 to commercialise the antimicrobial technology, BDM-I through external investment.

Ongoing cost-effective program expenditure:

Significant non-dilutionary funding of BioDiem and Opal's program; and leverage of existing funds by leverage through grants.

Income and expenditure management continues to maximise program and company value



Welcome to the 2015 Annual General Meeting of
BIODIEM LIMITED

2.00PM (AEDST) Monday, 19 October 2015

at the offices of

Grant Thornton, Wills Room, Level 30,
525 Collins Street, Melbourne, Victoria, 3000



ITEMS OF BUSINESS

- Receipt and consideration of Accounts and Reports
- Resolution 1: Re-election of Director –
Prof. Larisa Georgievna Rudenko
- Resolution 2: Amendment to Constitution



PROXY RESULTS

| | Shares For | Shares Against | Discretionary | Abstain/ Exclude |
|---------------------|-------------------|-----------------------|----------------------|-----------------------------|
| Resolution 1 | 53,195,940 | - | 26,690 | - |
| | | | | |
| Resolution 2 | 53,177,301 | 18,639 | 26,690 | - |
| | | | | |

| | |
|---------------------------------------|-------------------|
| Entitled to vote - | 875 |
| Total voted - | 16 |
| Total valid proxies received – | 53,222,630 |

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