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Announcement

BioDiem/Opal Biosciences Investor presentation at Wholesale Investor

Melbourne, 26 February 2016:

BioDiem's CEO, Julie Phillips presented at the Wholesale Investor Life Science & Healthcare Showcase, held at ASX Offices, Exchange Centre in Sydney on 25th February 2016. The event targeted investors and included life science and healthcare companies. The BioDiem/Opal presentation focused on BioDiem's revenue-generating LAIV Vaccine program, and its antimicrobial BDM-I, which is being commercialised through BioDiem's subsidiary, Opal Biosciences.

- ENDS -

About BioDiem Ltd

BioDiem is an Australian biopharmaceutical company that is focused on developing and commercialising vaccines and infectious disease therapies. BioDiem's business model is to generate income from partnerships including with other vaccine and infectious disease treatment companies through existing and new licences to its LAIV vaccine and other technologies. Income comes from licence fees and royalties on sales.

BioDiem's lead technology is the LAIV (Live Attenuated Influenza Virus) vaccine technology used for production of seasonal and pandemic influenza vaccines and is given intranasally. This technology is licensed currently to two commercial partners, in India and China, and is licenced to the World Health Organisation as part of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply. Serum Institute of India's Nasovac-S™ is based on BioDiem's technology and is already marketed in India.

BioDiem's antimicrobial technology, BDM-I, is being developed through its subsidiary, Opal Biosciences Ltd. For additional information, please visit www.biodiem.com.

About Opal Biosciences Ltd

Opal Biosciences is an Australian biotechnology company and an innovative player in infectious disease treatment. The unmet need for new anti-infectives is due to increasing resistance to existing antibiotics, more widespread and common difficult-to-treat infections, and the paucity of upcoming new treatments. This need has spurred the EU and US to introduce significant financial incentives to encourage development of new anti-infectives. Opal is currently seeking funding to support the next stage of development of our products:

- Opal-I, an injectable product, and
- Opal-T, which can be applied to the skin.

For more information, please visit www.opalbiosciences.com.



Therapies and vaccines for infectious diseases

Wholesale Investor

Life Science & Healthcare Showcase

25 February 2016

Julie Phillips, CEO

@biodiem

@opalbiosciences

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Challenges



Increasing resistance

To antibiotics – major concern
healthcare systems worldwide



Hard to treat

Fungal infections, affecting
vulnerable patients



No Rx available

-**totally resistant** tuberculosis
-**totally resistant** gonorrhoea



Product pipelines diminish

Large Pharma moved away from
anti-infective research

Core development programs



Target



Core Technology

Influenza vaccines (seasonal and pandemic)



LAIV vaccine – licensed in multiple countries

*Pandemic = new emerging flu virus;
low population immunity*

Infectious disease therapies
(for hard-to-treat and serious
Infections)



Influenza Vaccines

LAIV - nasal spray to prevent 'flu



Needle-free nasal delivery

No trained personnel and blood/sharps precautions unnecessary



Extensive clinical and market experience > 100m doses

In Russia efficacy and safety in >500,000 adults/140,000 children



Broader immune response

Than seen with inactivated influenza vaccines



High yields



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



No adjuvant required

Influenza vaccines

Live Attenuated Influenza Virus: LAIV

Disease Targets		Current Partners	Development Status
Influenza – Seasonal & Pandemic		WHO SII (India) BCHT (China) IEM (Russia)	<ul style="list-style-type: none"> Marketed License revenues FY15 \$180,000 <p>Growth through sales & new licences</p>
Avian (Bird) Flu		IEM/WHO	<p>Clinical trials completed in</p> <ul style="list-style-type: none"> Thailand & Russia <p>Avian flu library tested in ferrets & FIH trials (stored at CDC, Atlanta)</p>

LAIV Influenza vaccine - India

Nasovac-S – seasonal influenza vaccine

- Produced by Serum Institute of India
- Marketed in India
- Distributed by Cipla (May 2015)



- WHO prequalification (October 2015)
- **Royalties to BioDiem**



LAIV Influenza vaccine - China

Changchun BCHT Biotechnology Co

* Clinical trials to commence 2016 *

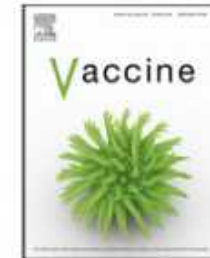




Contents lists available at ScienceDirect

Vaccine

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



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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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

Core development programs



Target

Influenza vaccines (seasonal and pandemic)

*Pandemic = new emerging flu virus;
low population immunity*



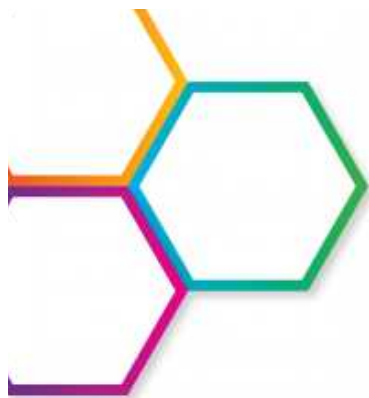
Core Technology

LAIV vaccine – licensed in multiple countries

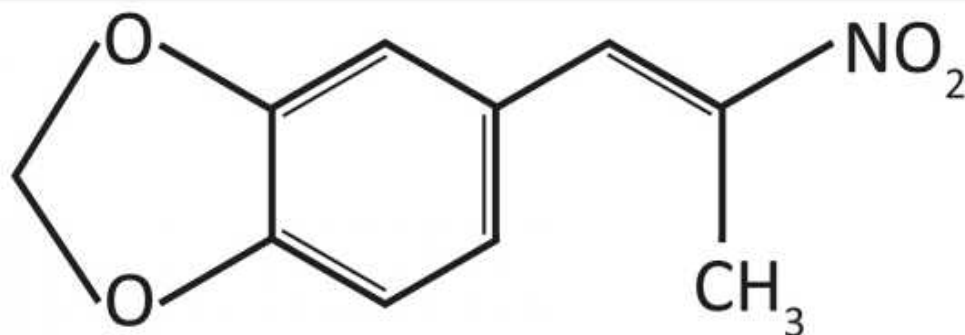


Infectious disease therapies
(for hard-to-treat and serious
Infections)





INTRODUCING OPAL TECHNOLOGY



- **Selective activity** shown against important human pathogens, incl. resistant bacterial and fungal
- Currently selected for **three US programs** (NIH & USAMRIID)- drug-resistant TB, *Pneumocystis* spp, *F. tularensis*.
- Potential for various routes of administration.
- Currently seed capital raising for proof-of-concept *in vivo*.



NIAID/USAMRIID PROGRAMS

Drug resistant Tuberculosis (TB)*



Pneumocystis



Biowarfare target



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

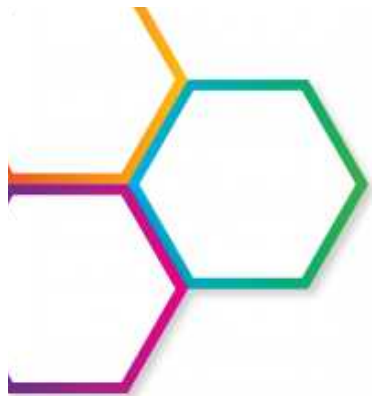
** Contract No. HHSN272201100012I

*** Contract No. HHSN272201100018I

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





POTENTIAL PRODUCT LINE



Intravenous Use (Injection)



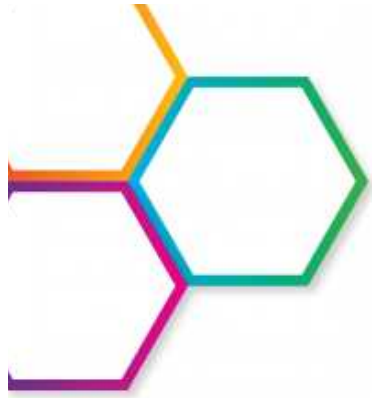
Topical Use (Gel, ointment, spray)



Oral Use (Tablets, capsules, syrup, mouthwash)



Lung (Inhalation)



GLOBAL COLLABORATIONS

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



THE UNIVERSITY OF
SYDNEY

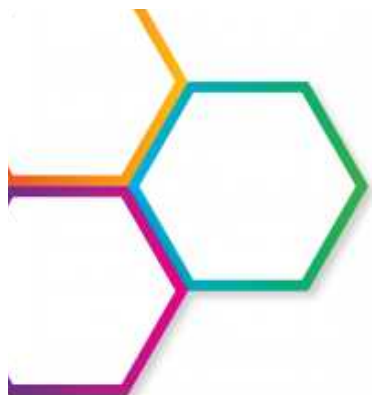


National Institute
of Allergy and
Infectious Diseases

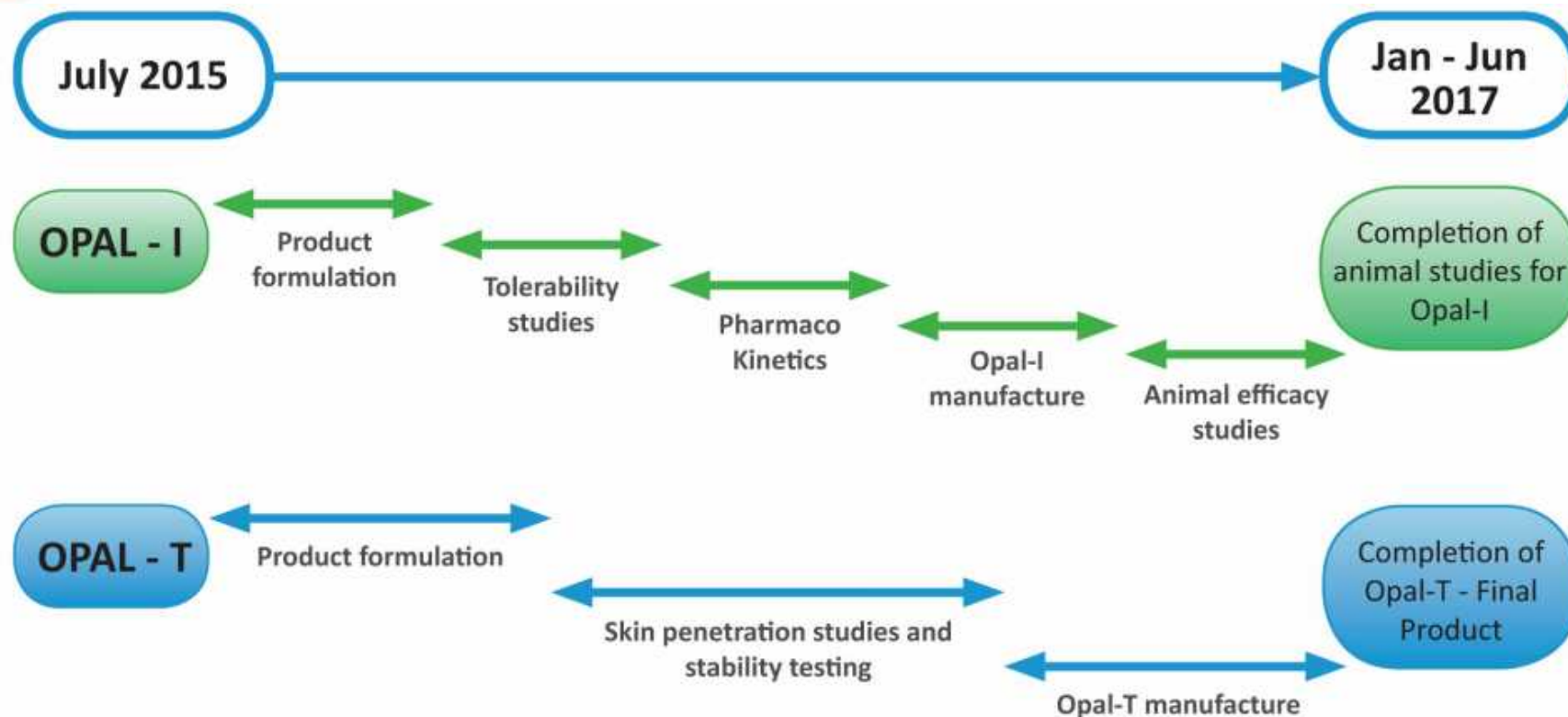


<http://www.niaid.nih.gov/LabsAndResources/resources/dmid/invitro/Pages/invitro.aspx>
<http://www.niaid.nih.gov/labsandresources/resources/dmid/animalmodels/Pages/default.aspx>





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**

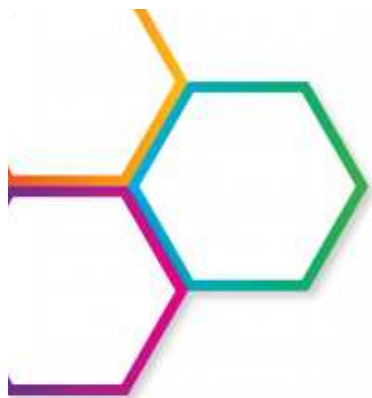
PharmaTimes
DIGITAL

**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,
Transparency 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.

Why invest in BioDiem?

- BioDiem has ***successfully licensed*** its flu vaccine into the largest markets in the world.
- ***A proven track record*** of license growth, e.g. BCHT (China) and the Serum Institute of India.
- Exposure to ***multiple exciting opportunities*** for disease treatments with high market need.
- ***Global partnering strategy*** with research leaders accelerates development and delivers more for each research and development dollar.
- ***Exposure to***
 - Revenue growth with a commercial technology; and
 - High potential earlier stage anti-infective, Opal Biosciences Ltd.



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