



BIODIEM LTD

ABN 20 096 845 993

Level 4,
100 Albert Rd,
South Melbourne, Victoria, 3205
Australia

Phone: +613 9692 7240

Web: www.biodiem.com

Announcement

BioDiem is presented at Wholesale Investor, Melbourne

Melbourne, 25 November 2015:

BioDiem's CEO, Julie Phillips presented at the Wholesale Investor Melbourne Showcase, held at Rydges Hotel in Melbourne on 25th November 2015. The event was designed to showcase innovative Australasian companies for an audience of investors. The BioDiem 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 Melbourne Showcase

Rydges Hotel, Melbourne

25 November, 2015

Julie Phillips, CEO
jphillips@biodiem.com

Safe Harbour Statement



This presentation is provided to you for information purposes only and should not be construed as an offer, and shall not form part of an offer, or solicitation to buy or sell any securities or derivatives. It should not be considered as an invitation to subscribe for or purchase any securities in BioDiem Limited. or as an inducement to make an offer or invitation with respect to those securities. No agreement to subscribe for securities in BioDiem Limited will be entered into on the basis of this presentation.

To the maximum extent permitted by applicable laws, BioDiem Limited and its affiliates make no representation and can give no assurance, guarantee or warranty, express or implied, as to, and take no responsibility for the authenticity, validity, accuracy, suitability or completeness of, or any errors in or omission, from any information, statement or opinion contained in this presentation.

The contents of this presentation are confidential. The presentation is being provided to you on the condition that you do not reproduce or communicate it to, or disclose it to, or discuss it with, any other person without the prior written permission of BioDiem Limited.

Challenges



Increasing resistance

To antibiotics – major concern healthcare systems worldwide



Hard to treat

Fungal infections, affecting vulnerable patients



No Rx available

TDR-TB (totally resistant tuberculosis)



Product pipelines diminish

Large Pharma focus on innovation,
as product pipelines diminish
> acquisition opportunities

Core development programs



Target



Core Technology

Influenza vaccines (seasonal and pandemic)



LAIV vaccine – licensed in multiple countries

Infectious disease therapies
Hard-to-treat and *serious*
human infections



BDM-I antimicrobial compound

Influenza Vaccines

Live Attenuated Influenza Virus: LAIV

Advantages



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

Flu vaccines

Live Attenuated Influenza Virus: LAIV

| Product | Disease Targets | Current Partners | Development Status |
|---------------------|---------------------------------|--|--|
| LAIV (Influenza) | Influenza – Seasonal & Pandemic | WHO SII (India) BCHT (China) IEM (Russia) | Marketed with license revenues FY15 A\$179,962 Egg & cell-based production Seeking growth & out-licensing in more markets |
| | Avian (Bird) Flu | IEM/WHO | Clinical trials completed in Thailand and Russia |

LAIV Influenza vaccine program

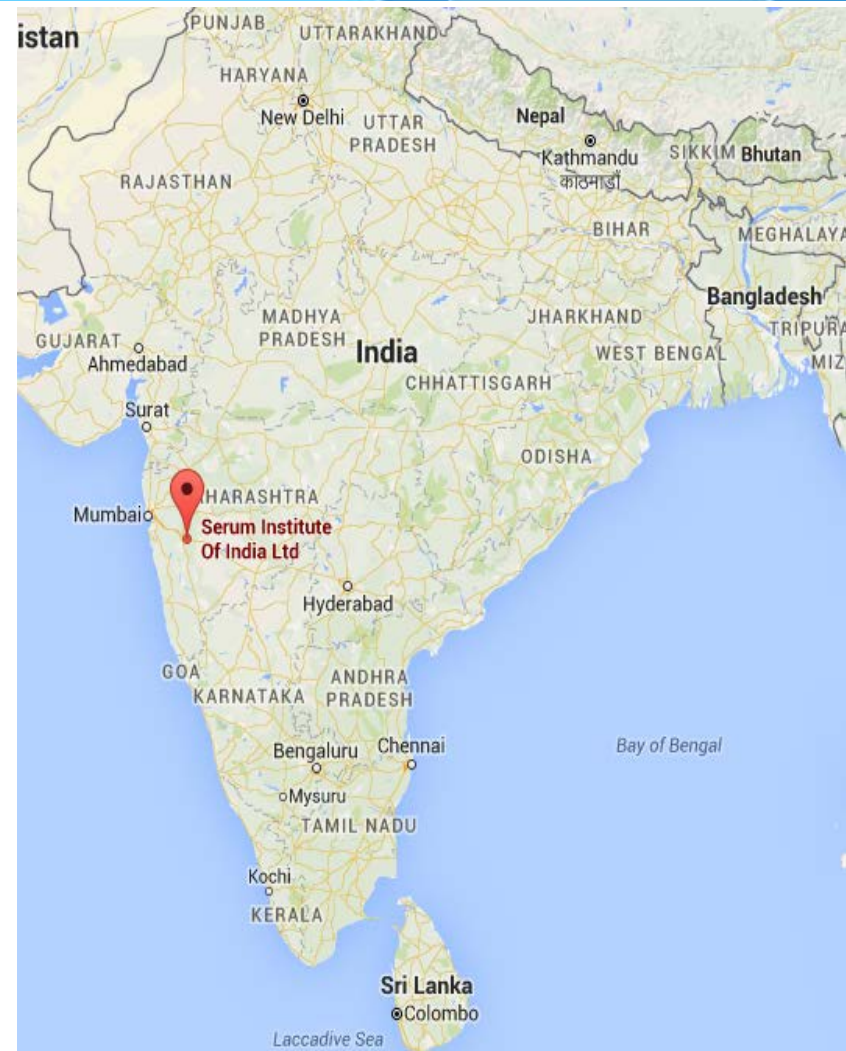
Commercial progress: INDIA:

Nasovac – pandemic influenza vaccine

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

Nasovac-S – seasonal influenza vaccine

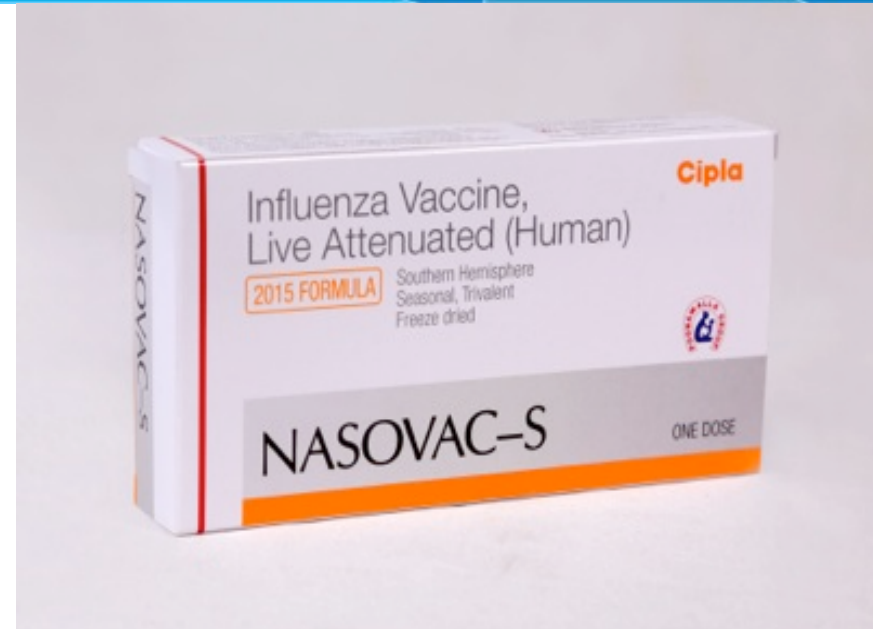
- Product launch in India (July 2014)
- Royalties to BioDiem from sales in India



LAIV Influenza vaccine program

Commercial progress: INDIA:

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



Serum Institute territories

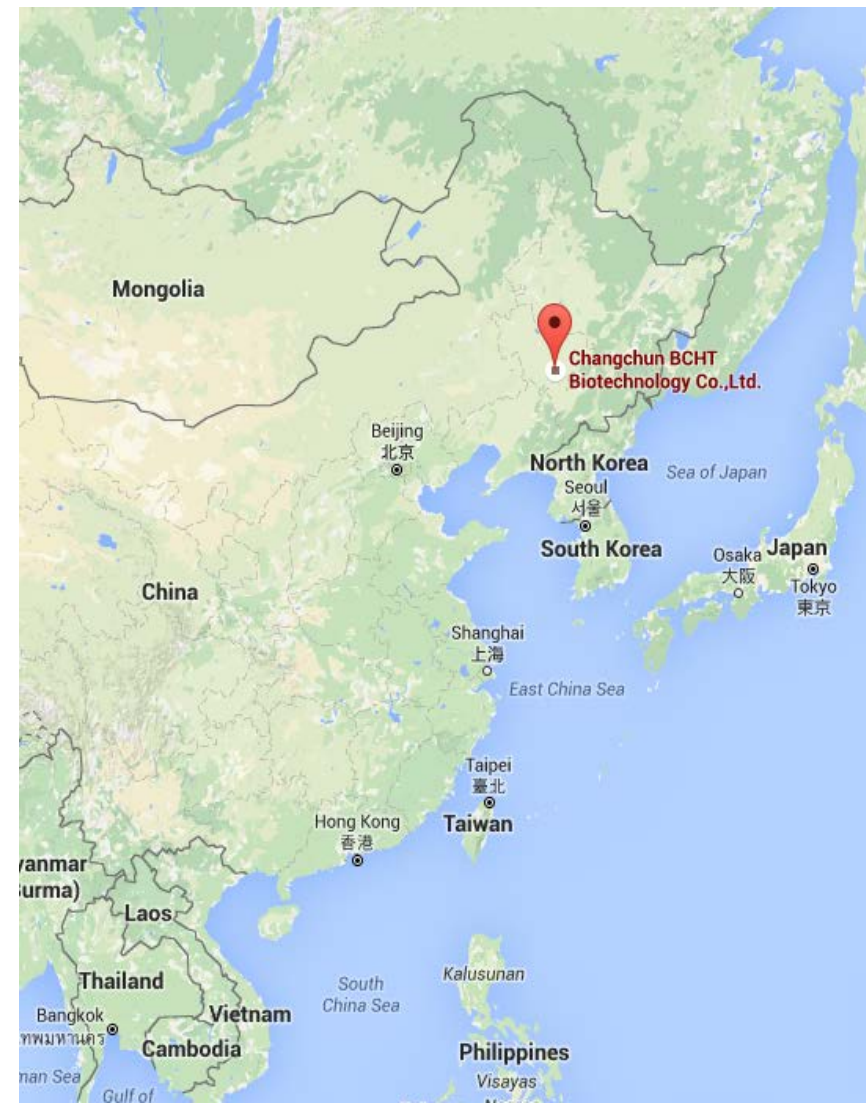
- India (exclusive)
- Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan, Sri Lanka and New Zealand, Myanmar.

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)



LAIV Influenza vaccine program

Commercial progress: CHINA:

CFDA IND approval (Sep 2015)

Clinical trial commencement expected in

December 2015





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

Justin R. Ortiz^{a,b,*}, Doli Goswami^c, Kristen D.C. Lewis^a, Amina Tahia Sharmeen^c,
Moshtaq Ahmed^c, Mustafizur Rahman^c, Mohammed Z. Rahman^c, Jodi Feser^a,
Kathleen M. Neuzil^{a,b}, W. Abdullah Brooks^{c,d}

^a PATH, Seattle, WA, USA

^b University of Washington, Departments of Global Health and Medicine, Seattle, WA, USA

^c International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B), Dhaka, Bangladesh

^d Johns Hopkins University, Baltimore, MD, USA

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 |

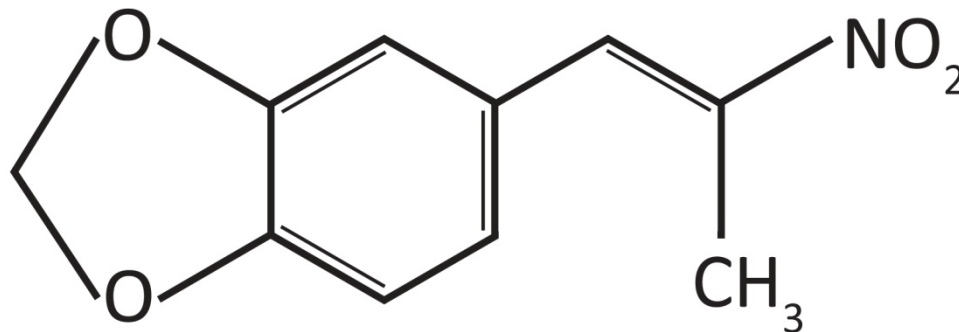


November 2015


*Opal Biosciences Limited is an innovative player in infectious disease treatment.
An Australian biotechnology company committed to tackling a serious
global health threat.*

Julie Phillips, Managing Director

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/DMID

** Contract No. HHSN272201100012I

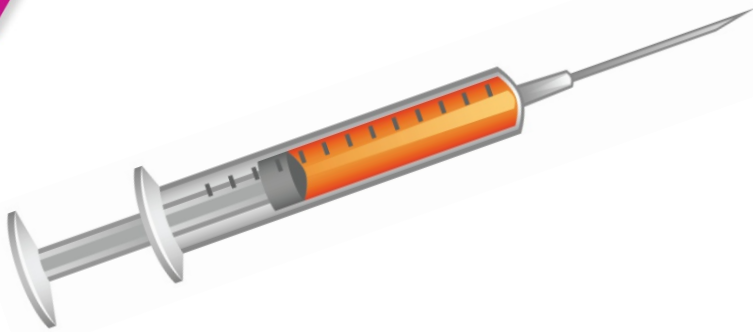
*** Contract No. HHSN272201100018I

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

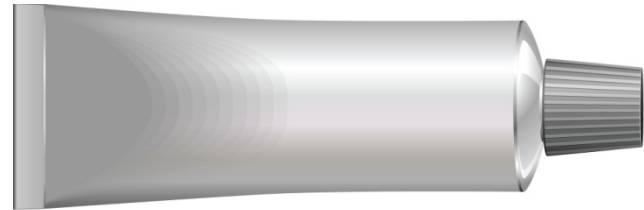
#This project has been supported by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) under its Material Transfer Agreement (MTA) with BioDigm Ltd.



POTENTIAL PRODUCT LINE



Intravenous Use (Injection)



Topical Use (Gel, ointment, spray)



Oral Use (Tablets, capsules, syrup, mouthwash)



Lung (Inhalation)

THE MARKET

Antifungals
market,
US\$13.9b

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

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

**Bloomberg
Business**

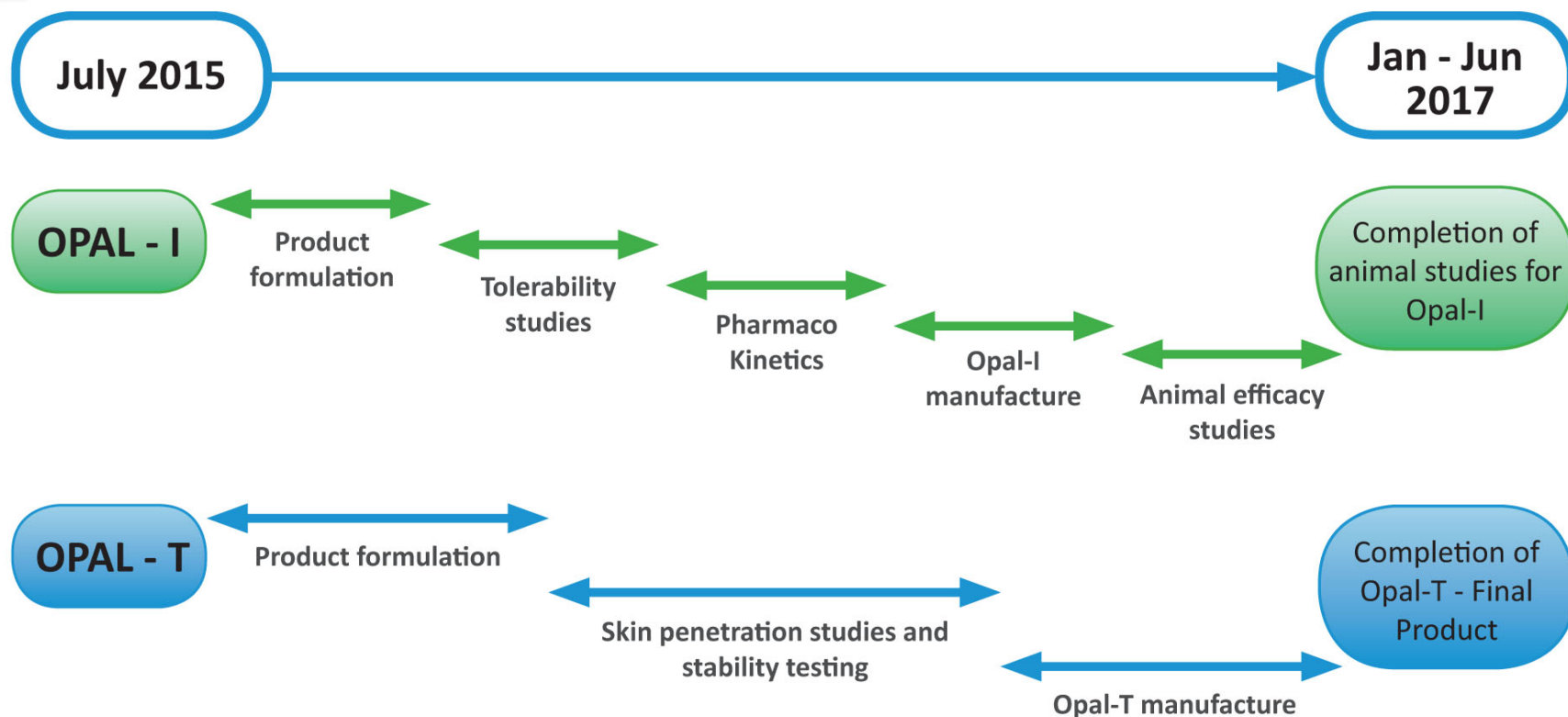
PharmaTimes
DIGITAL

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

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



OPAL'S DEVELOPMENT TIMELINE (*Indicative*)



Outlook for FY2016

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 product enhancement
 - Thermostable powder delivery
 - Universal vaccine

Complete placement and small capital raising

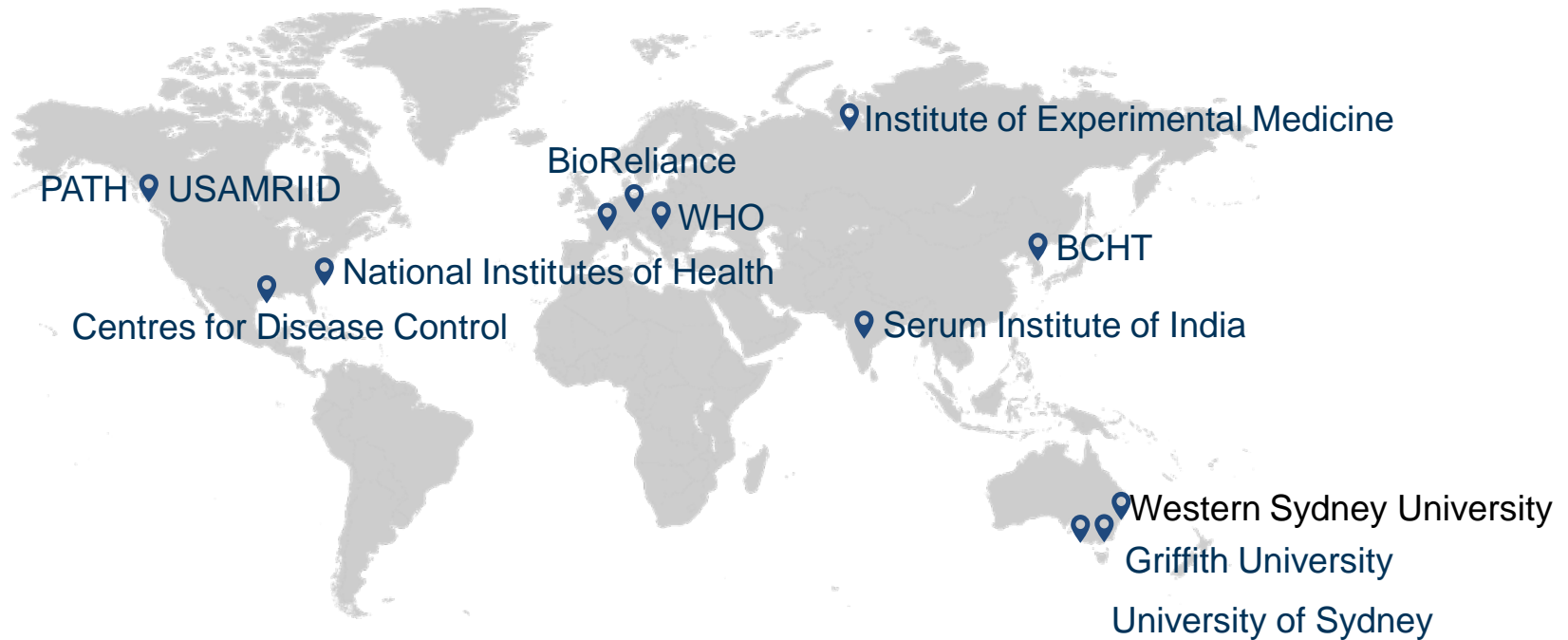
Outlook for FY2016 cont'd

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

Expanding Global Partnerships and Alliances

Global partnering & commercialisation network



Why invest in BioDiem?

- BioDiem has ***successfully licensed*** its flu vaccine into the largest markets in the world.
- ***A proven track record*** of new 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 in commercial technology; and
 - High potential earlier stage anti-infective, Opal Biosciences Ltd.



Therapies and vaccines for infectious diseases

Wholesale Investor Melbourne Showcase

Rydges Hotel, Melbourne

25 November, 2015

Julie Phillips, CEO
jphillips@biodiem.com