

Review of Operations

Julie Phillips

Chief Executive Officer
BioDiem Ltd

A decorative graphic in the bottom left corner consists of a light blue triangle with a network of white lines and dots, similar to the header bar's design.

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FY2017 Highlights



- Overview
- LAIV Influenza vaccine program
- Antimicrobial (BDM-I) program: Opal Biosciences Ltd



FY2017 Corporate



- Successful capital raising of \$1.149m through a nonrenounceable entitlement offer of convertible preference shares.
- Income from royalties and milestone payments totalling \$132,165.
- \$207,493 from the R&D Tax Incentive
 - Continued **cost reduction**
 - **Explore divestiture** of LAIV program
 - **Opal Biosciences:** to complete BDM-I assignment completion & undertake capital raising

LAIV Influenza Vaccine Program



WHO meeting on live attenuated influenza vaccine effectiveness

20-21 September 2016, WHO Headquarters, Geneva, Switzerland

http://www.who.int/immunization/research/meetings_workshops/live_attenuated_influenza_vaccine_effectiveness_sept_2016/en/

Global Action Plan for Influenza Vaccines (GAP)



Global Action Plan for Influenza Vaccines (GAP) was a comprehensive strategy to reduce the present global shortage of influenza vaccines for seasonal epidemics and pandemic influenza in all countries of the world through three major approaches:

- Increase in seasonal vaccine use
- Increase in vaccine production capacity
- Research and development

GAP was launched in 2006 and closed in 2016.

More about GAP
GAP PROJECTS

http://www.who.int/influenza_vaccines_plan/en/

LAIV Influenza Vaccine Program

cont'd

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Pandemic & avian 'flu:

On-going vaccine development program at IEM, St Petersburg, Russia.

Thermostable powder delivery:

US Dept Health & Human Services SBIR Phase I and Phase II contracts awarded to Universal Stabilisation Technologies Inc

Additional publications supporting the safety and efficacy of BioDiem's LAIV technology.

Studies to explore LAIV vaccine effectiveness

Efficacy of a Russian-backbone live attenuated influenza vaccine among children in Senegal: a randomised, double-blind, placebo-controlled trial



John C Victor, Kristen D C Lewis, Abdoum Diallo, Mbayame N Niang, Ibra Diarra, Ndongo Dia, Justin R Ortiz, Marc-Alain Widdowson, Jodi Fese, Rebecca Hougland, Shannon L Emery, Kathryn E Lafont, Kathleen M Neuzil



Summary

Background Live attenuated influenza vaccines have been shown to significantly reduce influenza in diverse populations of children, but no efficacy studies have been done in resource-poor tropical settings. In Senegal, we assessed the efficacy and safety of a live attenuated influenza vaccine based on Russian-derived master donor viruses and licensed as a single dose.

Lancet Glob Health 2016;
4: e955-65
Published Online
October 11, 2016
[http://dx.doi.org/10.1016/S2214-1098\(16\)30301-7](http://dx.doi.org/10.1016/S2214-1098(16)30301-7)

Efficacy of a Russian-backbone live attenuated influenza vaccine among young children in Bangladesh: a randomised, double-blind, placebo-controlled trial



W Abdullah Brooks, K Zaman, Kristen D C Lewis, Justin R Ortiz, Dofi Goswami, Jodi Fese, Amina Tahla Sharmawi, Kamun Nuhar, Mustajibur Rahman, Mohammed Zaar Rahman, Buz Barin, Muhammad Yunus, Alicia M Fry, Joseph Bresee, Taimim Azim, Kathleen M Neuzil



Summary

Background The rates of influenza illness and associated complications are high among children in Bangladesh. We assessed the clinical efficacy and safety of a Russian-backbone live attenuated influenza vaccine (LAIV) at two field sites in Bangladesh.

Lancet Glob Health 2016;
4: e946-54
Published Online
October 11, 2016

LAIV Influenza Vaccine Program

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Changchun BCHT Biotechnology Co (China)

- Completed a Phase I study of seasonal LAIV vaccine.
- Completed Phase II study (n ~ 600) of seasonal LAIV vaccine.
- Completed Phase III study (n ~ 9000) of seasonal LAIV vaccine.

Results will be used to support marketing application for BCHT's seasonal LAIV vaccine in China.

BioDiem entitled to receive royalties on the sales in the private sector in China.



Outlook – LAIV Vaccine Program



-  Seek external interest in LAIV technology licence
-  Await and consider results of LAIV effectiveness studies (underway) and impact on future royalty payments to BioDiem
-  Board decision based on best return for BioDiem shareholders





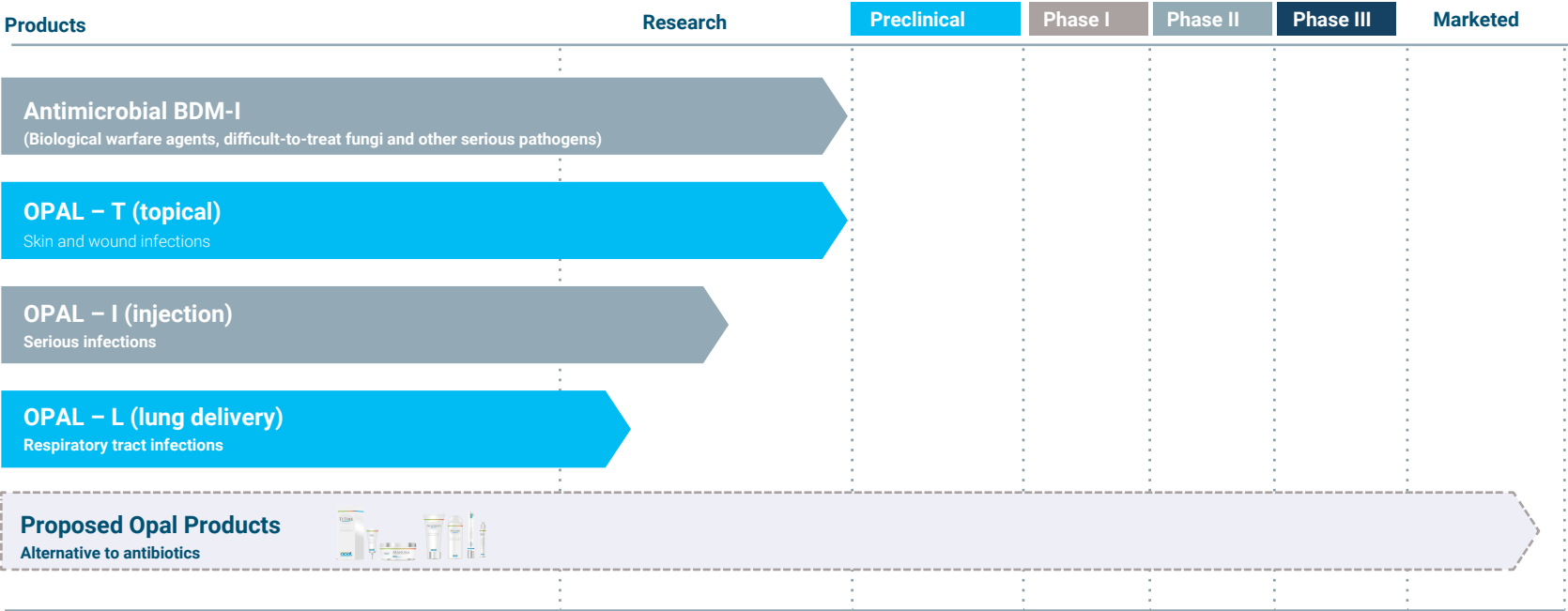
***Opal Biosciences Limited is an innovative player in infectious disease treatment.
An Australian company committed to tackling a serious global health threat:
antimicrobial resistance***



FY17 Highlights

- **Mechanism of action understanding:** how BDM-I kills bacteria & fungi
- **Intellectual Property strengthening:**
 - new patent;
 - allowance of additional patent in the US
- **Opal-T (topical formulation of BDM-I):** pilot testing of prototypes
- **New business opportunity** (early revenue-generation)

Opal Biosciences' Pipeline





Mechanism of action

ASM/ESCMID Conference on Drug Development
to Meet the Challenge of Antimicrobial Resistance
September 6-8, 2017 · Boston, Massachusetts

Complimentary Pre-Conference Workshop:
Antibiotic Development Bootcamp
September 5, 2017



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WESTERN SYDNEY UNIVERSITY
Ingham Institute
AR&MEG

Investigating the Mechanism of Action and Clinical Utility of the
Novel Antimicrobial BDM-1

M. Radzieta^{1,2}, B. Espedido^{1,2}, C. Malladi², J. Coorsen², M. Killingsworth³, S.J. van Hal⁴, J. Phillips⁵ & S.O. Jensen^{1,2}

¹AR&MEG, Ingham Institute for Applied Medical Research, Liverpool, AUS; ²MSRG, School of Medicine, Western Sydney University, Sydney, AUS; ³Sydney South Western Pathology Service, Sydney, AUS; ⁴Royal Prince Alfred Hospital, Sydney, AUS; ⁵BioDiem Ltd, Melbourne, AUS





Mechanism of action cont'd



ARC Linkage grant:

Prof Yaoqi Zhou, Dr Joe Tiralongo
and Dr Yuedong Yang

*Novel antimicrobial target
discovery by an integrated
approach.*

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IP Strengthening

Title	Granted	Pending
Antimicrobial and radioprotective compounds	<i>Australia, Canada, France, Germany, Great Britain, Japan, USA, Russia</i>	
Method of treating <i>Scedosporium</i> spp. infection	<i>Australia, USA</i>	<i>Canada, Europe, HK</i>
BDM-I Therapy		<i>(PCT lodged August 2017)</i>



Opal-T

Round 1: Three prototypes passed stability testing

Pilot testing:

- Against *N. gonorrhoea* (causes gonorrhoea); MRSA (causes serious infections)
 - *In vitro* results
 - All three prototypes active against MRSA and *N. gonorrhoea*.
 - *In vivo* result v MRSA with only one formulation – insufficient activity shown

Next steps: repeat with additional formulations





Two Medical Needs



- 1) Infections are becoming **more difficult** to treat due to
- overuse of antibiotics in livestock
 - antibiotic resistance, and
 - few new antibiotics.

Need new anti-infective agents



- 2) Doctors are being urged to curb use of antibiotics.
- adopting “wait and see” approach
 - concern about risk of withholding antibiotics

Need effective alternatives to antibiotics

Current alternatives to antibiotics are poor, of dubious quality and unsophisticated.



Medical Need: Alternatives To Antibiotics





New Products - Alternatives To Antibiotics






New Business Opportunity

- ➔ Range of commercial products
 - **quick to market** opportunities
 - **alternatives to antibiotic treatment**
- ➔ Income from product sales invested in the development of **novel technologies**
- ➔ **Products to be out-licensed** in other territories

New anti-infective agents

Medical Need #1

 The current market needs new anti-infectives.
There are few new treatments available.

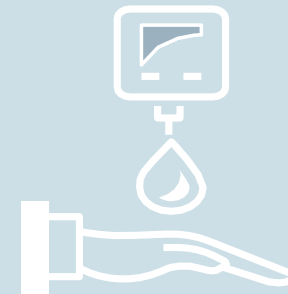
Opal's business addresses this need by: Development of novel products, Opal-I, Opal-T, and Opal-L based on BDM-I technology



Opal-I



Opal-T



Medical Need #2

Alternatives to current antibiotics



The current market needs effective alternatives to current antibiotics. Doctors are being asked to curb prescribing of antibiotics due to rising antibiotic resistance.

Opal's business addresses this needs by: Development of effective alternatives to antibiotics (products due to launch 2019-2020)

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Expert Advisors



Tania C Sorrell AM, FAHMS

Deputy Dean, Sydney Medical School & Head, Westmead Clinical School; Professor and Director Marie Bashir Institute for Infectious Diseases & Biosecurity, University of Sydney; Director, Centre for Infectious Diseases and Microbiology, Westmead Institute for Medical Research; Service Director, Infectious Diseases and Sexual Health, Western Sydney Local Health District.



HAK-KIM CHAN, PhD, DSc

Professor of Pharmaceutics (Advanced Drug Delivery) Faculty of Pharmacy University of Sydney



Sharon Chen PhD

Clinical Associate Professor Medicine (Immunology and Infectious Diseases) Westmead Clinical School Centre for Infectious Diseases & Microbiology



Slade Jensen PhD

Associate Professor Infectious Diseases and Microbiology, School of Medicine Antibiotic Resistance and Mobile Elements Group, Ingham Institute Western Sydney University



Richard Buchta PhD MBA

Managing Director, Formulytica Pty Ltd

Capital Raising

Opal Biosciences Limited is seeking an investment of **AUD\$1.5 million**.

Summary of the offer:

Share issue price: AUD\$0.25

Number of shares on issue: 10,515,012

Options @ 25c: 1 for 1

Oversubscriptions: of up to \$1,000,000 may be accepted

Fully diluted post-issue: 22,515,012

Opens: Nov 2017 **Closes:** Feb 2018 (est)

Outlook



Open capital raising and complete



Product-based business to commence
in first half 2018 with revenues generated in 2019.



Opal-T gel proof-of-concept results due in early FY18 for novel product.



Builds on existing profile/unmet need and creates revenue-generating business