

CEO Presentation

Julie Phillips

CEO and Director, BioDiem Ltd

A decorative geometric pattern is located in the bottom left corner of the slide. It consists of several overlapping triangles and lines in shades of blue and white, creating a modern, abstract design.

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FY2018 Highlights



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

FY2018 Highlights



- Finalisation of Opal Biosciences Ltd (“Opal”) de-merger in Nov 2017 and assignment of all BDM-I IP rights into Opal in Mar 2018.
- Successful placement of \$0.6m into Opal in Feb 2018.
- Income from royalties and milestone payments totalling \$119,397 .
- \$205,621 from the R&D Tax Incentive
- BCHT completed Phase III clinical trials and submitted marketing application to CFDA
- Reinstatement of Medimmune’s LAIV in the US by the CDC’s ACIP for use in the 2018-19 influenza season.

LAIV Influenza Vaccine Program



Medscape

News > Medscape Medical News

Nasal Flu Vaccine Back on CDC List of Recommended Vaccines

Troy Brown, RN
February 22, 2018

3 Read Comments



Added to Email Alerts

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) voted 12 to 2 Wednesday to recommend returning the nasal live attenuated influenza quadrivalent vaccine (LAIV4; *FluMist*, MedImmune) to its list of recommended influenza vaccines for the 2018-2019 influenza season, after rejecting it the last 2 years.

LAIV Influenza Vaccine Program

cont'd

BioDiem

Changchun BCHT Biotechnology Co (China)

- Completed Phase III study (n ~ 9000) of seasonal LAIV vaccine
- Submitted application for marketing to Chinese National Medical Products Administration (previously Chinese FDA)

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





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

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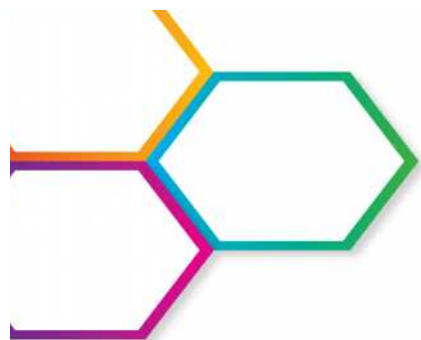
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FY18 Highlights - Corporate

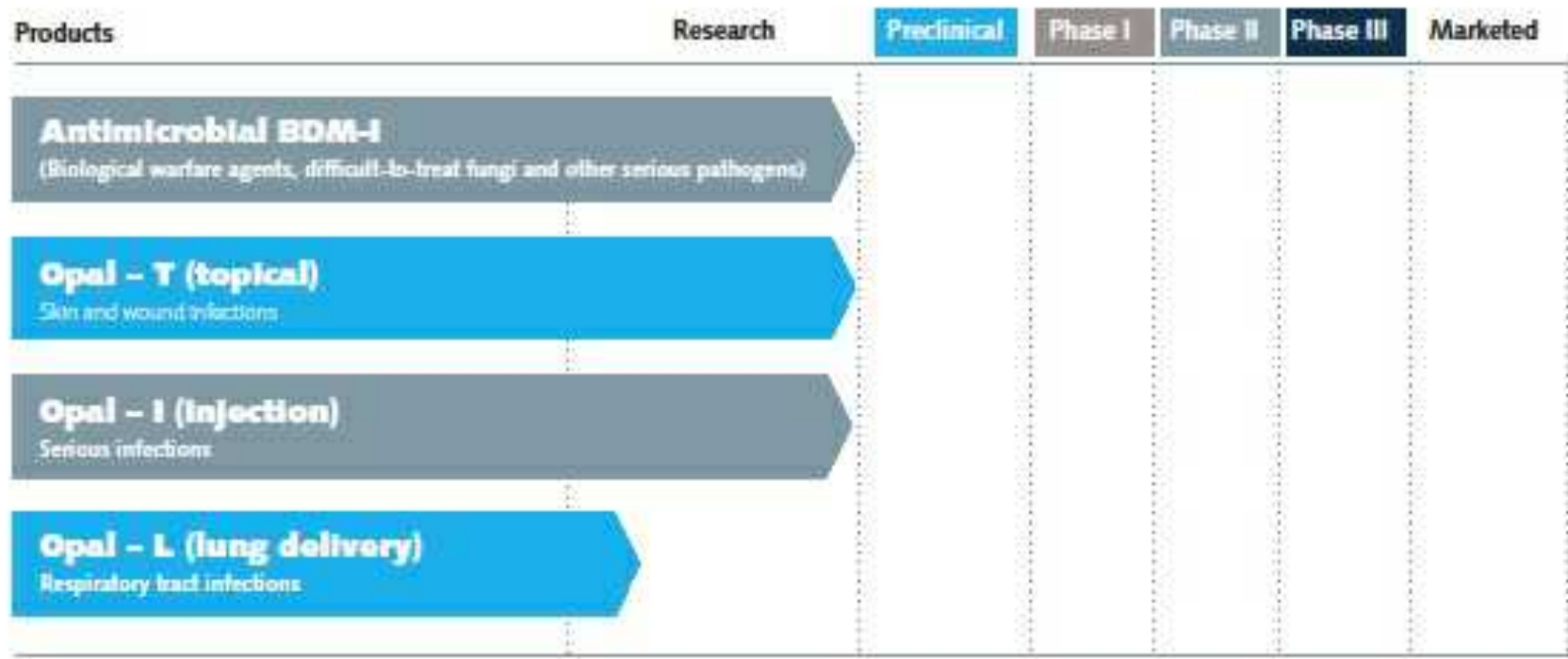
- De-merger of Opal Biosciences Ltd (“Opal”) from BioDiem Ltd
- Successful placement of \$0.6m in Feb 2018.
- Assignment of all BDM-I IP rights into Opal in Mar 2018.
- Appointment of Mr Ken Windle and Mr Peter Snowball to the Opal board of directors in Mar and Aug 2018, respectively.
- Award of an Innovation Connection grant of \$50,000 in Apr 2018.



FY18 Highlights - Operations

- Opal-T gel in a mouse wound model (*in vivo*) effect against highly resistant strain of *S. aureus*; bacteria responsible for causing serious infections.
- Lab demonstration (*in vitro*) inhibiting growth of resistant strains of *N. gonorrhoea*; responsible for the sexually transmitted infection, gonorrhoea.
- Completed formulation revision of Opal-I (injectable) in preparation for proof-of-concept and development studies.
- Proteomics studies describing where BDM-I targets bacteria
- New patent grant in Europe & US; and new PCT lodgement

Opal Biosciences' Pipeline





Mechanism of action

21



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

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}

¹ARMEG, 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; ⁵BioDerm Ltd, Melbourne, AUS

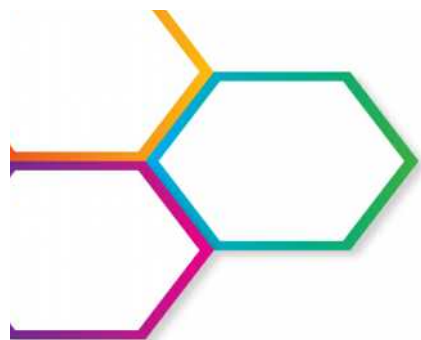


ASM/ESCMID Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance
September 6-8, 2017 - Boston, Massachusetts

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



BDM-I appears to affect ATP Synthase and *de novo* UMP synthesis, and both of these are important for cell wall synthesis.



Opal-I

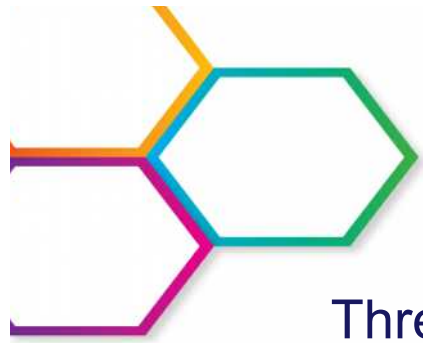
Entrepreneur's Program: Innovation Connection Grant

Formulytica Pty Ltd:

- Revised intravenous formulation
- Short term stability confirmed

Next steps: proof-of-concept and development studies





Opal-T

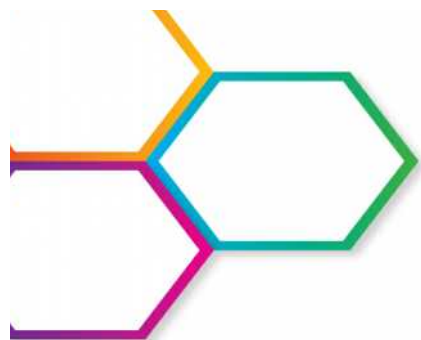
Three prototypes passed stability testing

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 – on hold





BDM-I vs resistant *N. gonorrhoea*

- effective against all strains
- better than ciprofloxacin against 9 strains

Resistant bacterial strain	Resistance (antibiotics)
Neisseria gonorrhoeae, MDR (WHO-K, CCUG 57597)	CIP-HR, CRO-NS, PEN-R (CH), TET-R
Neisseria gonorrhoeae, MDR (WHO-L, CCUG 57598)	CIP-HR, CRO-NS, PEN-R (CH), AZM-I
Neisseria gonorrhoeae, MDR (WHO-M, CCUG 57599)	CIP-R, PEN-R (P), TET-I
Neisseria gonorrhoeae, MDR (WHO-N, CCUG 57600)	CIP-R, PEN-R (P), TET-R
Neisseria gonorrhoeae MDR (WHO-V, NCTC 13818)	PEN-R, AZM-R, CIP-R, TET-R
Neisseria gonorrhoeae MDR (WHO-W, NCTC 13819)	PEN-R, AZM-I, CIP-R, TET-R
Neisseria gonorrhoeae MDR (WHO-X, NCTC 13820)	PEN-R, CRO-NS, AZM-I, CIP-R, TET-R
Neisseria gonorrhoeae MDR (WHO-Y, NCTC 13821)	PEN-I, CRO-NS, AZM-R, CIP-R, TET-R
Neisseria gonorrhoeae MDR (WHO-Z, NCTC 13822)	PEN-R, CRO-NS, AZM-R, CIP-R, TET-R

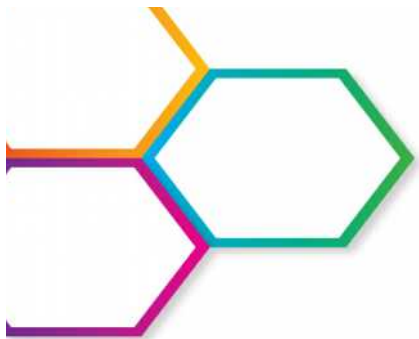
In vitro broth dilution assay (CLSI) conducted by Eurofins Taiwan Mar 2018
BDM-I tested against 14 reference strains per Unemo *et al.*
J Antimicrob Chemother 2016 71:3096



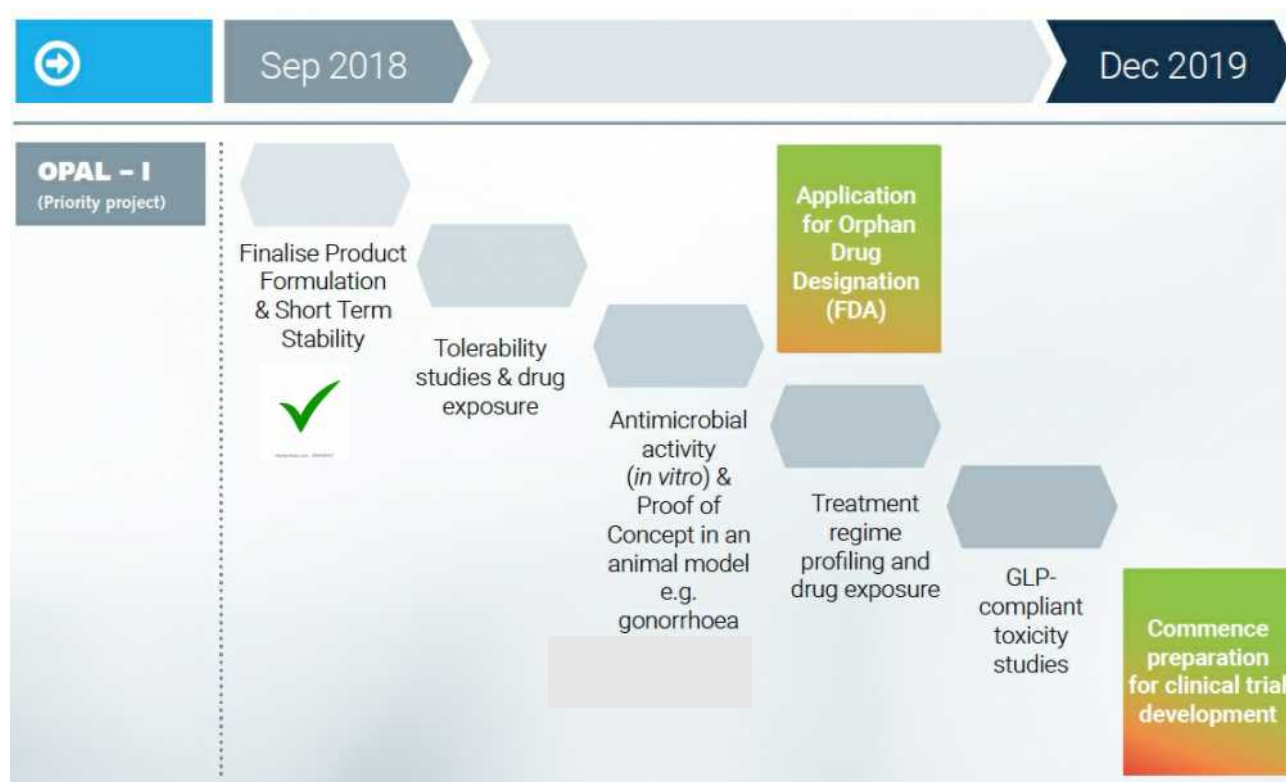


IP Strengthening

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, Europe, HK, USA</i>	<i>Canada</i>
Treatment of staphylococcal and enterococcal infections using substituted nitrostyrene compounds		<i>PCT lodged August 2017</i>



Opal Development Plan



Outlook



Await feedback from the regulatory review of BCHT's application for marketing in China



Continue to seek external interest in LAIV technology licence



Opal Biosciences:

- Continue capital raising; seeking grant funding
- Finalise mechanism of action profiling
- Continue liaison with external groups such as NIAID, USAMRIID and WHO's GARD-P
- Opal-I tolerability/MTD and proof-of-concept testing
- Orphan Drug Designation; QIDP status