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AGM 2019

Julie Phillips | Managing Director

29th November 2019

Opal Biosciences Limited is an innovative player in infectious disease treatment

An Australian biotechnology company committed to tackling a serious global health threat

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Opal Biosciences Ltd

An early stage biotechnology company focused on the development of new treatments for drug-resistant or hard-to-treat infections.

Opal's drug, BDM-I, has shown in the laboratory that it can kill many serious human disease-causing microbes including six "Urgent Threats" identified by the US Centers of Disease Control and Prevention (CDC) in its latest Report ☆.

☆ https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

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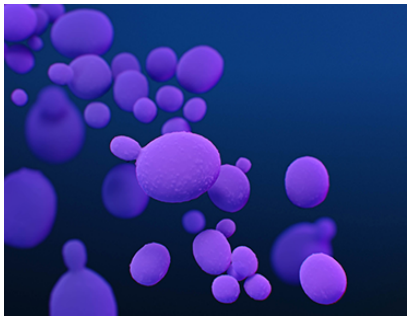
Board & Management

Board of Directors	
Hugh Morgan AO *Chairman*	*A well-known Australian businessman with international and local advisory roles.*
Julie Phillips *Managing director*	*Multinational pharma background in regulatory affairs, health economics and clinical trials*
Ken Windle *Non-executive director*	*Former senior international positions at GSK including Head of Global Commercialisation.*
Peter Snowball *Non-executive director*	*Background in financial markets including Barclays, Merrill Lynch and J B Were.*

Advisor	
Dr Jane Ryan	*PhD in Immunology and Biochemistry; Former Vice President (Global), Product Development and Strategic Marketing of Biota overseeing US$231m HHS-BARDA contract.* *Engagement consultant CSIRO manufacturing and and NED Anatara Lifesciences*

FY19 Highlights



New priority infection target found: *Candida auris*

New data from animal studies

Successful capital raising

Inclusion in CDC☆'s international call for action: Antimicrobial Resistance (AMR) Challenge

Financial markets executive, Peter Snowball, joined the board

New international patent filing

☆ US Centers of Disease Control and prevention

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FY19 Highlights cont'd

New priority infection target found: *Candida auris*

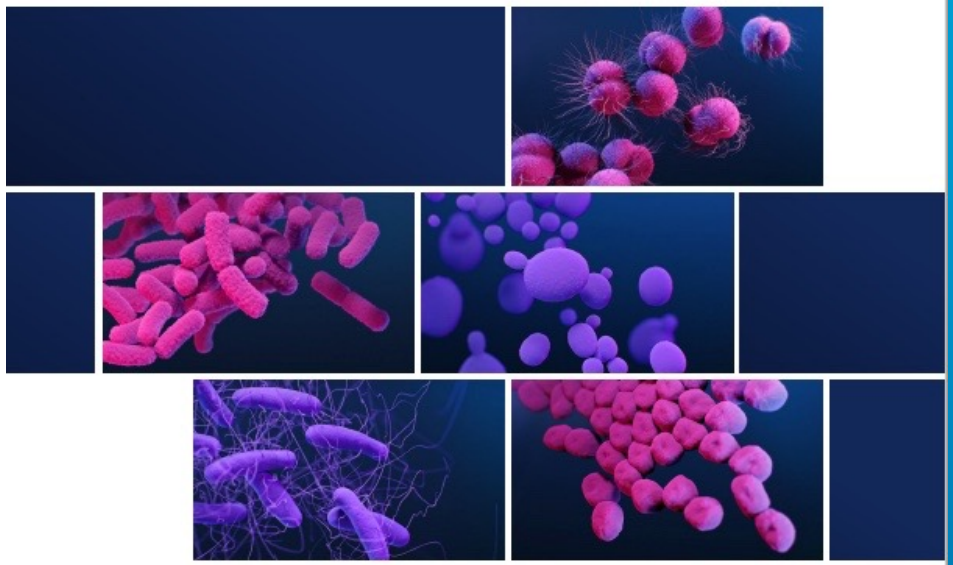
- New testing has found a disease threat which is new and serious and where, in the lab, BDM-I shows it works better than existing treatments.

New data from animal studies

- New studies have shown the amount of BDM-I that test animals can be given without side effects may be sufficient to kill disease-causing microbes

ANTIBIOTIC RESISTANCE THREATS
IN THE UNITED STATES

2019



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

"antibiotic-resistant bacteria and fungi cause more than 2.8 million infections and 35,000 deaths in the US each year. ***That means, on average, someone in the US gets an antibiotic-resistant infection every 11 seconds and every 15 minutes someone dies.*** *"*

Cash position

Opening cash position: FY2018

- **$422,395**

Average monthly cash burn (excluding receipts):

- $34,971

Receipts:

- $252,750 capital raising
- $53,469 received from R&D Tax Incentive
- $27,500 received from Grant

Closing cash position: FY2019

- **$336,466**

Post June 30

- $280,000 raised from early exercise of options

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Outlook FY2020

- **Further exploration of BDM-I's potential as a treatment for infections through our funds supplemented by**
  - Grant funding e.g. CARB-X☆
    - Application submitted November 2019
  - US agencies assistance
    - Ongoing
  - Feb 2020 option exercise to raise up to $326K
- Aiming for outlicence or preparation for clinical trial

☆ CARB-X is led by Boston University and is funded by various international public health, government and charitable agencies

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ADDITIONAL SLIDES

Antibiotics Currently in Global Clinical Development

DATA VISUALIZATION September 3, 2019 Topics: Antibiotics Projects: Antibiotic Resistance Tags: Superbugs Read time: 7 min

"As of June 2019, approximately 42 new antibiotics with the potential to treat serious bacterial infections are in clinical development. The success rate for clinical drug development is low; historical data show that, generally, only 1 in 5 infectious disease products that enter human testing (phase 1 clinical trials) will be approved for patients. "

nature reviews
microbiology

Review Article | Published: 19 November 2019

The global preclinical antibacterial pipeline

Ursula Theuretzbacher, Kevin Outterson, Aleks Engel & Anders Karlén

Nature Reviews Microbiology (2019) | Cite this article

*"The **innovative potential** of the **preclinical** pipeline compared with the **clinical pipeline** is encouraging but fragile."*

Theuretzbacher, U., Outterson, K., Engel, A. *et al.* The global preclinical antibacterial pipeline. *Nat Rev Microbiol* (2019) doi:10.1038/s41579-019-0288-0

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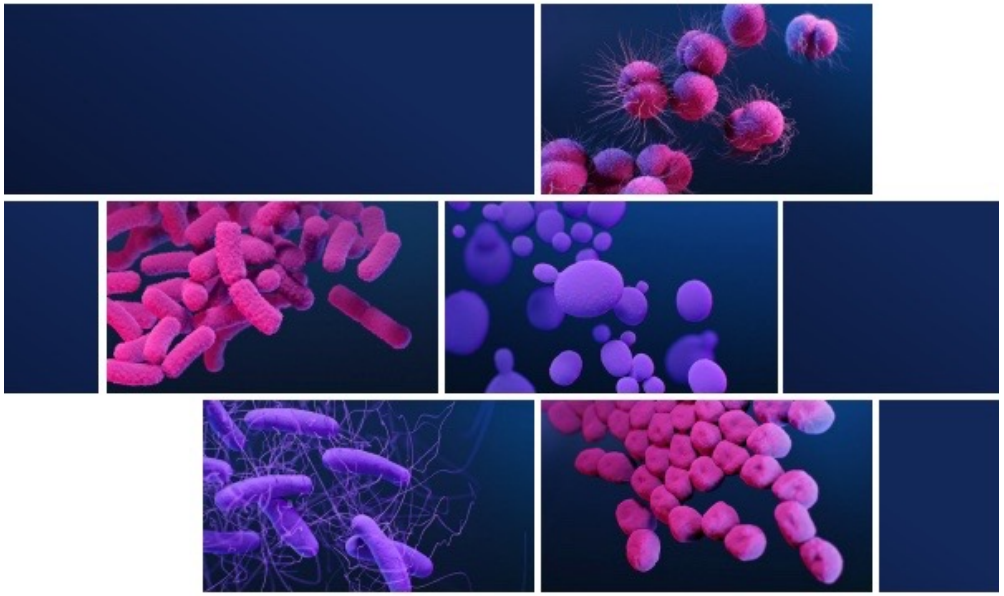

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https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

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Bacteria and Fungi listed in the 2019 AR Threats report

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Urgent Threats

- Carbapenem-resistant *Acinetobacter*
- *Candida auris*
- *Clostridioides difficile*
- Carbapenem-resistant Enterobacteriaceae
- Drug-resistant *Neisseria gonorrhoeae*

Serious Threats

- Drug-resistant *Campylobacter*
- Drug-resistant *Candida*
- ESBL-producing Enterobacteriaceae
- Vancomycin-resistant *Enterococci* (VRE)
- Multidrug-resistant *Pseudomonas aeruginosa*
- Drug-resistant nontyphoidal *Salmonella*
- Drug-resistant *Salmonella* serotype Typhi
- Drug-resistant *Shigella*
- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Drug-resistant *Streptococcus pneumoniae*
- Drug-resistant Tuberculosis

Concerning Threats

- Erythromycin-Resistant Group A *Streptococcus*
- Clindamycin-resistant Group B *Streptococcus*

Watch List

- Azole-resistant *Aspergillus fumigatus*
- Drug-resistant *Mycoplasma genitalium*
- Drug-resistant *Bordetella pertussis*

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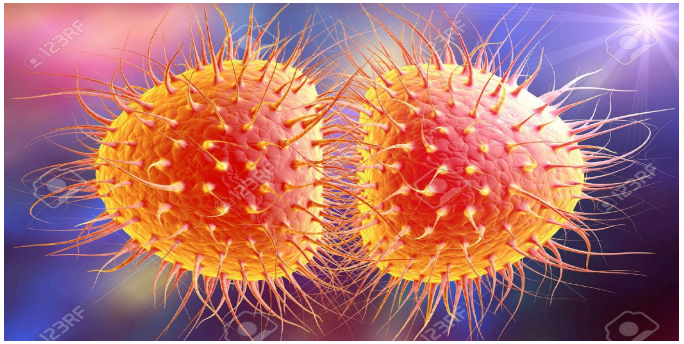
Where BDM-I has shown activity

The AMR Challenge

Number of Commitments by Country

"CDC is concerned about rising resistant infections in the community…."



URGENT THREAT

Drug-resistant ***Neisseria gonorrhoea***

- > 500,000 cases resistant infections each year (twice that in 2013).
- Developed resistance to all but one class of antibiotics
- 50% resistant to at least one antibiotic.
- contribute to significant adverse reproductive health outcomes, such as infertility in women and to new HIV infections especially in men.

BDM-I vs antibiotic-resistant *N.gonorrhea*

- effective against all strains
- better than ciprofloxacin against 9/14 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

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An emerging multidrug-resistant yeast

URGENT THREAT
Candida auris

- a cause of severe infections around the world.
- Often multidrug-resistant
- Can cause outbreaks in healthcare facilities
- Estimated mortality rate 30-60%

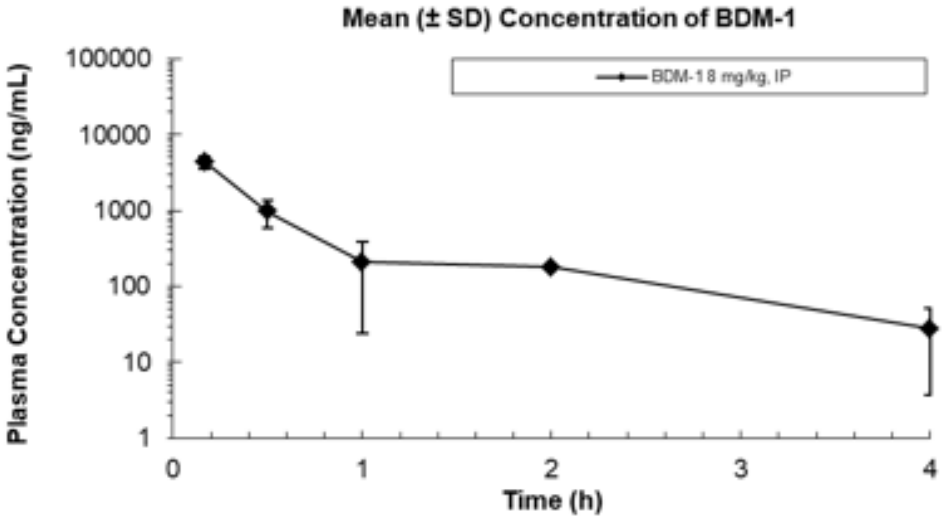
BDM-I MIC's (microgram/mL) versus marketed echinocandins

Species	Isolate	BDM-I		Fluconazole	Voriconazole	Posaconazole
		50%	100%	50%	100%	100%
C. parapsilosis	ATCC 22019	0.125	0.5	1	---	---
C. krusei	ATCC 6258	0.06	0.125	16	---	---
P. variotii	CLSI QC	0.125	0.25	8	0.125	≤ 0.03
C. auris	Cau1	0.125	0.25	>64	---	---
	Cau2	0.06	0.25	2	---	---
	Cau3	0.125	0.25	>64	---	---
S. apiospermum	SA1	0.03	0.06	---	1	---
L. prolificans	LP1	0.06	0.125	---	>16	---
	LP2	0.06	0.125	---	>16	---
Coccidioides	Cocci1	≤ 0.03	0.06	16	---	---
	Cocci2	≤ 0.03	0.06	8	---	---
	Cocci3	≤ 0.03	≤ 0.03	8	---	---
Apophysomyces	APO1	0.06	0.5	---	---	≤ 0.03
	APO2	0.5	4	---	---	0.25
	APO3	0.25	1	---	---	0.125

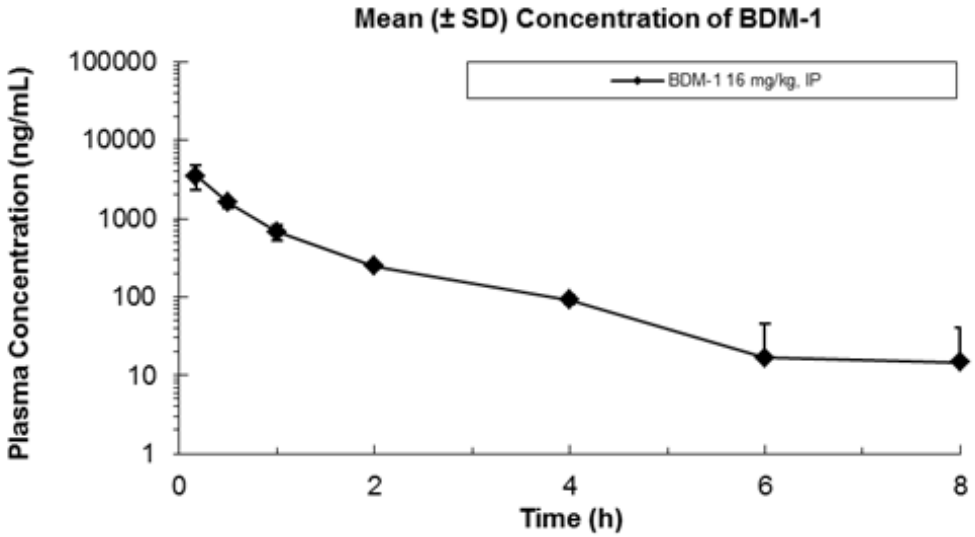
Blood levels after single dose (mouse) 8 & 16mg/kg (ip)

(maximum tolerated dose ~32mg/kg)

BDM-I (8 mg/kg, IP): Plasma



BDM-I (16 mg/kg, IP): Plasma



Next steps
2019 – 2020

- ✅ **CARB-X grant application**
- ✅ **Protein binding studies**

- ➡️ Additional PK studies
- ➡️ Hollow fibre testing
- ➡️ **Staph aureus model

- Orphan Drug Designation
- QIDP status – (Qualifying Infectious Disease Pathogen status)

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