



Therapies for major infectious diseases and related cancers

Australian Life Science Investment Showcase:
San Francisco 20th June 2014

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Agenda



Company Overview



Challenges



BDM-I Antimicrobial



BDM-I Opportunity

Company Overview

Australian unlisted public company

As at April 30 2014

| | |
|--------------|-------------|
| Market Cap | ~ \$9 M |
| Shares | 163,082,800 |
| Shareholders | 919 |
| Options | 18,587,417 |

Hugh Morgan AC



Chairman

Julie Phillips



CEO

Dr Larisa Rudenko



Non-executive Director

Dr Arthur Li



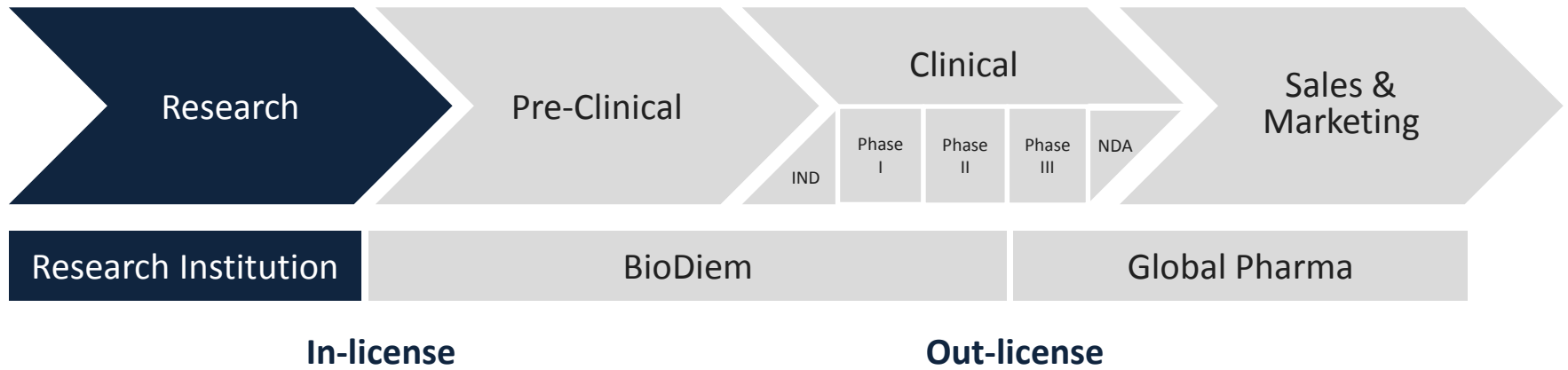
Non-executive Director

Don Brooks

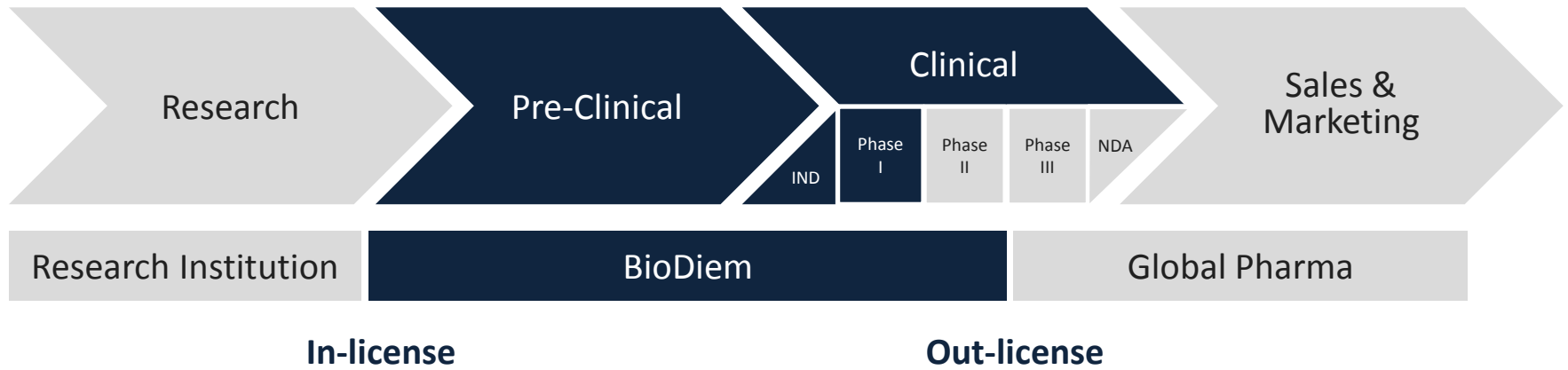


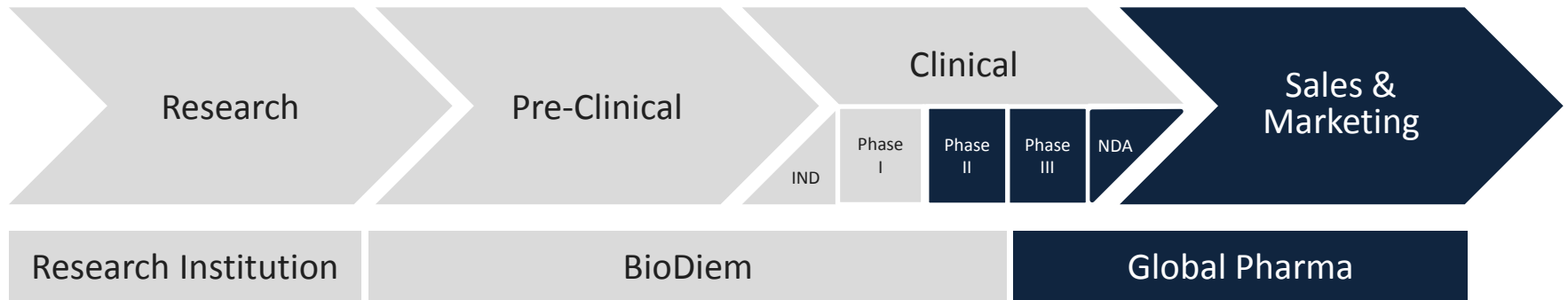
Non-executive Director

Business Model



Business Model





In-license

Out-license



Phase I trials

Testing the drug on healthy volunteers



Phase II trials

Testing the drug on a small number of patients with the disease



Phase III trials

Testing the drug on hundreds/thousands or patients with the disease



Global partnering & commercialisation network





Target



Core Technology

Influenza vaccines (seasonal and pandemic)



LAIV vaccine – licensed in multiple countries, further opportunities being pursued

Vaccine development platforms nasopharyngeal carcinoma, TB targets



SAVINE technology, LAIV viral vector technologies for novel therapeutic vaccines

Infectious disease therapies



BDM-I antimicrobial compound

Invasive Fungal Infection after Natural Disasters

Kaitlin Benedict and Benjamin J. Park

Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 20, No. 3, March 2014

OXFORD JOURNALS

Clinical Infectious Diseases

Bad Bugs, No Drugs: No ESKAPE! An Update from the Infectious Diseases Society of America

Dr. Arjun Srinivasan: We've Reached "The End of Antibiotics, Period"

FRONTLINE

October 22, 2013, 9:29 pm ET

THE VERGE

Gonorrhea is about to become impossible to treat

Antibiotic resistance means the STD might soon spread more aggressively



Australia Network News

Calls for action on 'dire' drug-resistant TB threat in Asia and the Pacific

By Jemima Garrett

Posted Mon 14 Apr 2014, 7:05pm AEST

Bulletin of the World Health Organization

Race against time to develop new antibiotics

CBCnews | Health

Superbug threat as grave as climate change, say scientists

'The international response has been feeble'

Thomson Reuters Posted: May 23, 2014 10:53 AM ET | Last Updated: May 23, 2014 10:53 AM ET



Increasing resistance

To antibiotics – major concern healthcare systems worldwide



Hard to treat

Fungal infections, affecting vulnerable patients



Increase in prevalence

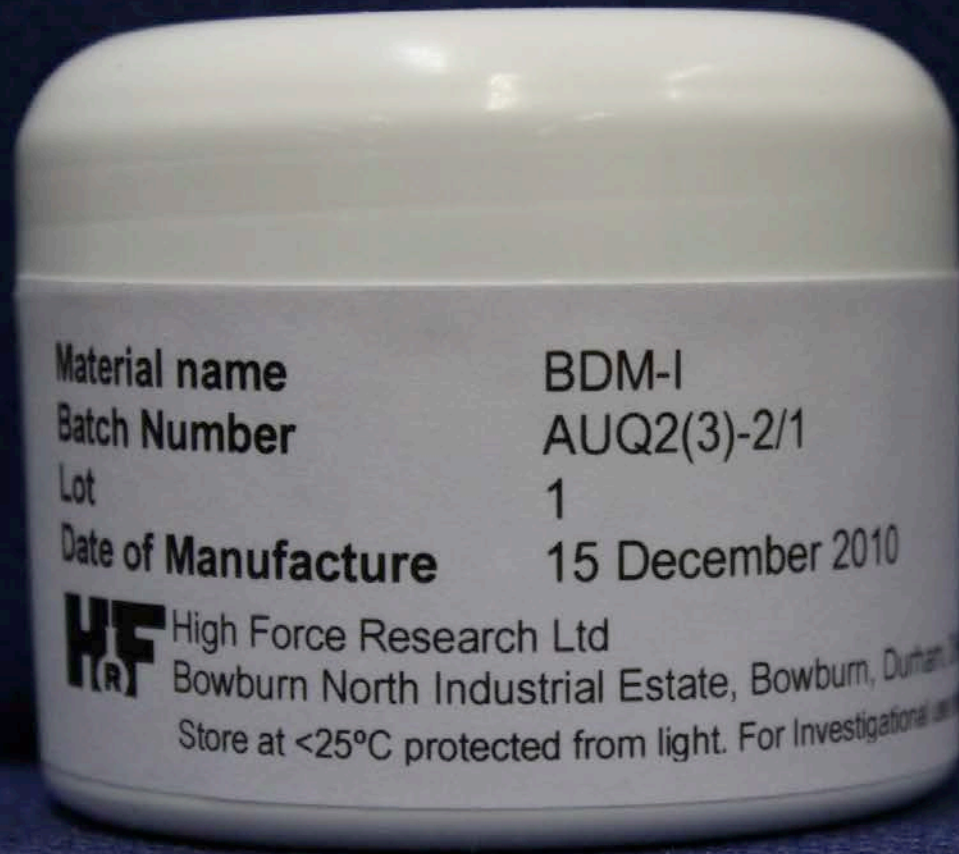
Due to climate change and vector movements.



Product pipelines diminish

Large Pharma focus on innovation, as product pipelines diminish

BDM-I: Antimicrobial



Invasive and superficial fungal infections

Some species of

- *Candida*
- *Cryptococcus*
- *Scedosporium*
- *Pneumocystis*

Drug-resistant tuberculosis & gonorrhoea

- *Mycobacterium tuberculosis*
- *Neisseria gonorrhoea*

Some protozoal infections

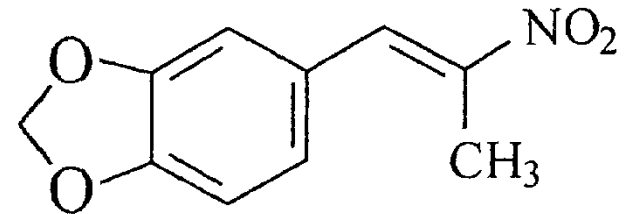
- *Trichomonas vaginalis*; *Plasmodium falciparum*

and others...

Inhibits new target

Protein Tyrosine Phosphatases (PTPs)

- Involved in cell signalling
- Mimics tyrosine



Heterogeneity of PTP function explains

- Selectivity within species
- Difference in function in mammalian cells

Antimicrobial spectrum

Unusually broad spectrum -

Some **but not all** bacteria, fungi, and protozoa. Not viruses.

Bacteria

Most active against G+ve cocci/rods; some non-enteric G-ve
Relatively low activity against Gram negative enteric rods

Fungi

Active against some *Candida*, *Scedosporium*, dermatophytic fungi and other pathogens

Protozoa

Activity against *Plasmodium* & *Trichomonas*

Viruses

No activity against viruses known to use PTP in the infection cycle (HIV, HSV). No enhancement of infection.

| Group | (µg/ml) | Group | (µg/ml) |
|--------------|--|----------------------|---|
| Fungi | MIC90 <i>C. glabrata</i> * 1 | G-ve bacteria | MIC <i>Neisseria gonorrhoeae</i> 2 |
| | MIC90 <i>C. glabrata</i> ** 2 | | MIC <i>Campylobacter jejuni</i> 0.5 -2 |
| | MIC90 <i>Coccidioides spp.</i> 0.25* | | Other bacteria - potential biological weapons |
| | MIC90 <i>Coccidioides spp.</i> 0.25** | | |
| | IC50 <i>P. carinii</i> <0.1*** | Parasite | <i>Schistosomiasis japonicum</i> |
| | IC50 <i>P. murina</i> 0.174*** | | LC50 Adults (5 days) LC50 Schistosomulae (24 hrs) |
| | MIC <i>Scedosporium prolificans</i> (three strains) 1-2 | | <i>Schistosomiasis masoni</i> LC50 Adults (5 days) LC50 Schistosomulae (8hrs) |

*50% Inhibition Endpoint

**100% Inhibition Endpoint

*** (based on %reduction ATP at Day3)

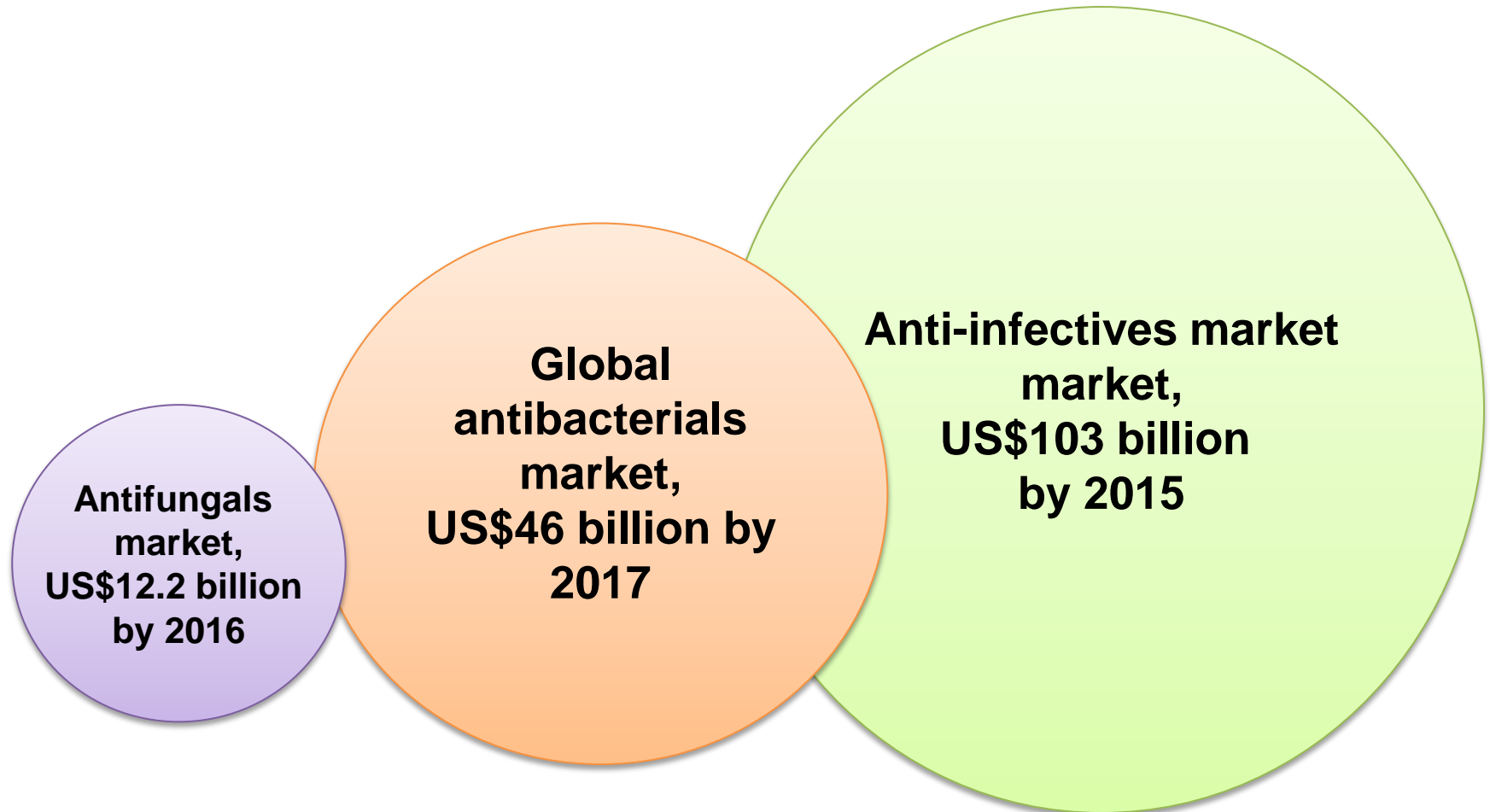
Inhibition of virulence factors:

- Motility (*Proteus*, *C. difficile* and *Campylobacter jejuni*)
- Pigment formation (*Serratia marcescens*)
- Endospore formation (*Bacillus* spp)

Current preliminary *in vitro* assays show

- inhibition of biofilm formation in *S. aureus* & *S. epidermidis*
- inhibition of adherence and invasion of gut epithelial cells by
Clostridium difficile & *Campylobacter jejuni*

Market Size Potential



| Product | Disease Targets | Current Partners | Development Status |
|--------------|-----------------------------|--------------------------------------|---|
| BDM-I | Tuberculosis & bioterrorism | US govt backed research institutions | Successful screening result: preparation for <i>in vivo</i> testing |
| | Pneumocystis | US govt backed research institutions | Successful screening result: preparation for <i>in vivo</i> testing |
| | Scedosporium | Australian site | Successful screening result: seeking disease models |

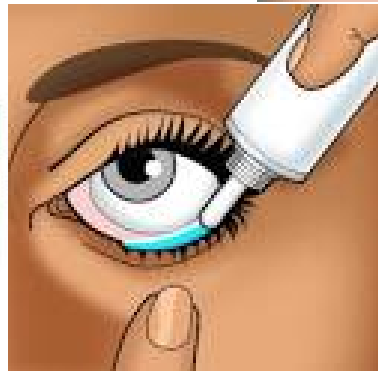
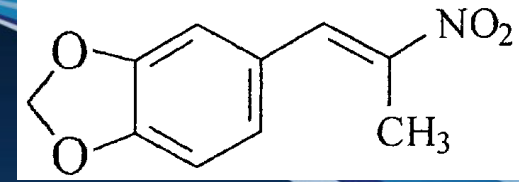
Further mechanism of action exploration

Analogue development

Formulation for proof-of-concept studies → multiple ROA options

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Potential Product Range





“Generating Antibiotic Incentives Now” legislation

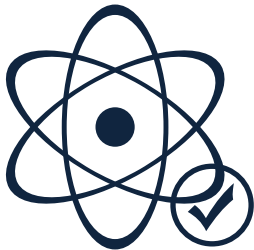
GAIN: How a New Law is Stimulating the Development of Antibiotics

May 28, 2014 | Project: [Antibiotics and Innovation Project](#)

On July 9, 2012, the Generating Antibiotic Incentives Now, or GAIN, provisions were signed into law by President Barack Obama as part of the [Food and Drug Administration Safety and Innovation Act](#). This bipartisan legislation extends by five years the exclusivity period during which certain antibiotics—those that treat serious or life-threatening infections—can be sold without generic competition. This additional period of exclusivity increases the potential for profits from new antibiotics by giving innovative companies more time to recoup their investment costs.

“GAIN seeks to increase antibiotics’
commercial value....”

BDM-I Opportunity



Complete
formulation
studies






BDM-I testing in
animal models



Clinical
trial in orphan
disease

Next steps:

- Proprietary formulation (incl for different ROA)
- *In vivo* testing and POC
- Orphan drug application

-  Global problem in infectious disease
-  BDM-I has
 - Activity against important pathogens
 - Novel mechanism of action; granted patents
 - Collaborations in place with world class facilities
-  Commercial opportunity for product and pipeline development
 - Life threatening and other infections
 - Attractive incentives e.g. GAIN legislation

**We seek investment & collaboration to develop BDM-I
towards use for niche high value
diseases and expanded product range**





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