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Therapies for major infectious diseases and related cancers

Australia Biotech Invest
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Crown Conference Centre, Melbourne

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Challenges

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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

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Challenges

Increasing resistance

To antibiotics – major concern healthcare systems worldwide

Hard to treat

Fungal infections, affecting vulnerable patients

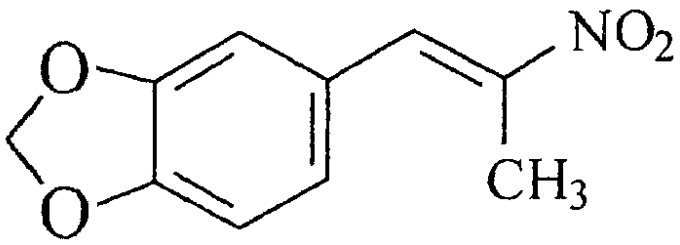
Increase in prevalence

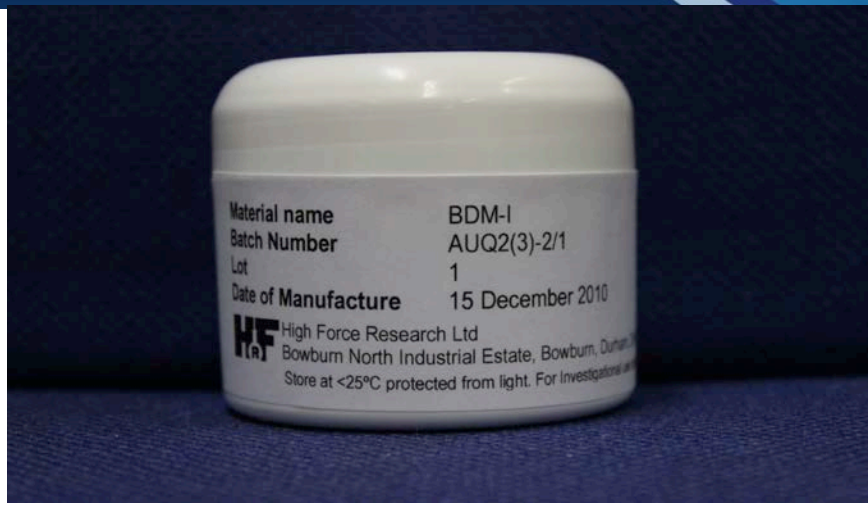
Due to climate change and vector movements.

Product pipelines diminish

Large Pharma focus on innovation, as product pipelines diminish

BDM-I: Antimicrobial





Novel mechanism of action: 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

Spectrum of activity

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…

In vitro activity

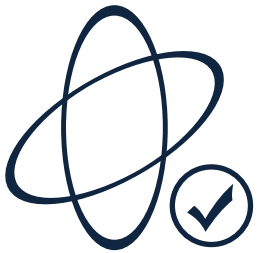
Group		(µg/ml)	Group		(µg/ml)
Fungi	MIC90 *C. glabrata*	* 1	**G-ve bacteria**	MIC *Neisseria gonorrhoeae*	2
	MIC90 *C. glabrata*	** 2		MIC *Campylobacter jejuni*	0.5 -2
	MIC90 *Coccidiodes spp.*	0.25*		Other bacteria - potential biological weapons	
	MIC90 *Coccidiodes spp.*	0.25**			
	IC50 *P.carinii*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

*50% Inhibition Endpoint
**100% Inhibition Endpoint
*** (based on %reduction ATP at Day3)

Poised for proof-of-concept

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

Next Steps:

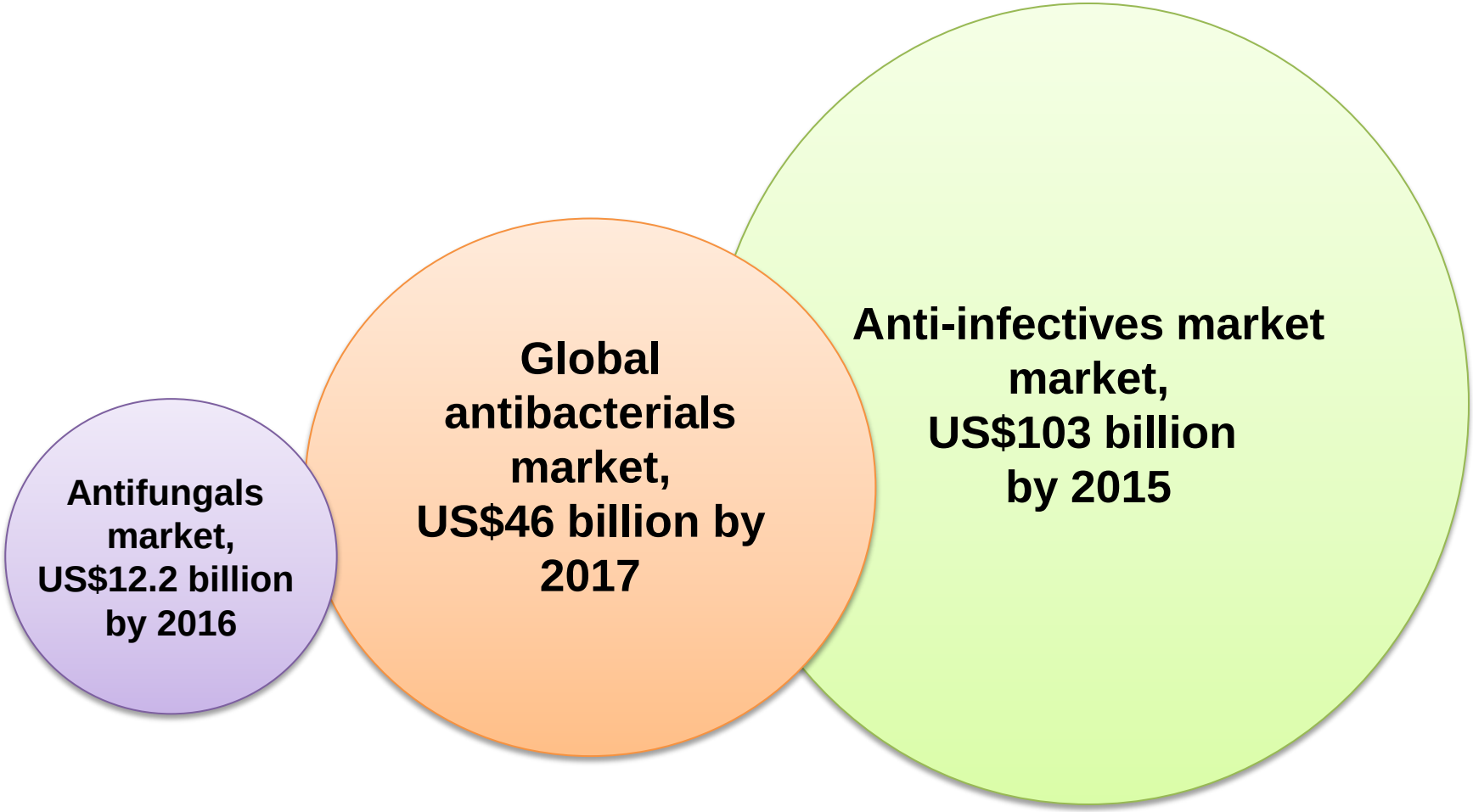


Complete formulation studies

BDM-I testing in animal models

Clinical trial in orphan disease

Market Size Potential



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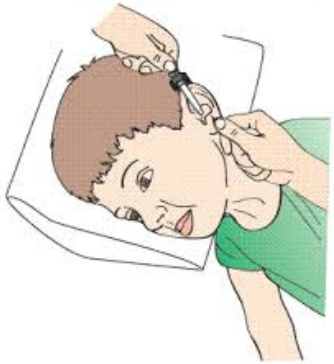
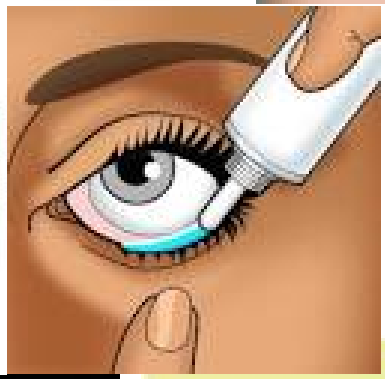
Potential Product Range





"*Generating Antibiotic Incentives Now*" legislation

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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…."

Opportunity

- Global problem in infectious disease

- BDM-I has
  - Activity vs important pathogens
  - Novel mechanism of action; granted patents
  - Collaborations in place with world class facilities

- Commercial opportunity for product/pipeline development
  - Life threatening and other infections
  - Attractive incentives e.g. GAIN legislation

- **Opportunity for investment & collaboration for development**
  - for niche high value diseases and
  - expanded product range

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