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## ASX Announcement

### BIODIEM REPORTS CONTINUED PROGRESS IN DEVELOPMENT OF ANTIMICROBIAL BDM-I

#### Key Points

- **Preclinical data supports BDM-I as a broad-spectrum antimicrobial for a wide range of major market infectious diseases**
- **Activity in life-threatening indications resistant to existing therapies suggests potential for accelerated development and market access**
- **Activity demonstrated against a wide range of disease-causing bacteria, fungi, protozoa and parasites in a number of ongoing screening studies**
- **Formulation projects in discussion with specialised groups.**

**Melbourne, 18 October 2012:** Australian infectious disease therapy and vaccine development company BioDiem Ltd (ASX: BDM) announced today that it continues to make solid progress on its antimicrobial program with advancing preclinical data, new partnerships in negotiation, and a number of new key patents strengthening BioDiem's intellectual property.

BioDiem is developing an antimicrobial compound with broad-spectrum activity named BDM-I. The compound has demonstrated activity against a wide range of disease-causing microbes such as bacteria, fungi, and parasites and is currently being researched as a treatment against 'superbugs' or antibiotic-resistant bacteria and fungi. These organisms are of major concern to international healthcare agencies as the number of available treatments for these infections shrinks.

This is being recognized by major regulatory agencies who are catching up to clinical need: in 2012 the United States signed into law the Generating Antibiotic Incentives Now Act, which authorizes the US FDA to allow an additional five years of marketing exclusivity for antibiotics that treat infections with the potential to pose a serious threat to public health, including antibiotic-resistant infections such as MRSA. This incentive will increase the attractiveness of BDM-I to potential licencees for development in life-threatening infections.

The rise in resistant infections has energised investment in novel antimicrobials. The market for anti-infectives was valued at US\$53 billion in 2011 and is forecast to exceed \$100 billion by 2015. The antifungals market was valued at US\$9.4 billion in 2010 and estimated to reach US\$11.3 billion in 2014.

#### Target medical applications for BDM-I

In preliminary studies, BDM-I was found to be active against notable fungal species such as *Aspergillus fumigatus*, strains of fungus that are resistant to many existing antifungal medications. These fungal infections are particularly dangerous for patients whose immune systems are compromised, and serious infection can kill very rapidly.

Studies have also shown BDM-I's activity against the parasite which causes schistosomiasis. This is largely a disease of the developing world which causes impairment of growth and cognitive development in patients. There are currently 200 million people infected with schistosomiasis with 600 million people at risk. Higher concentrations of BDM-I were demonstrated to more rapidly kill this microorganism in preclinical screening studies, a positive sign for drug development in this indication.

The most recent patent for BDM-I was granted in Canada, covering the compound for indications that have been covered by US and European patents (particularly in the area of sexual health) while also extending additional coverage to conditions (explained below) such as dangerous bacterial infections like MRSA, a high-profile strain of antibiotic-resistant “Golden Staph”. This infection is of major concern to global healthcare systems, adding a significant burden to hospital infection control and patient costs each year.

To date, BioDiem has been granted patents supporting BDM-I’s antimicrobial activity in the United States, Europe, Canada, China, Russia, Singapore, South Africa and Australia. The collective patent claims for BDM-I further position the company to claim a share in the massive antimicrobial market.

The indications currently covered by BDM-I’s collective patents are:

- **A variety of bacterial infections:** BDM-I’s broad spectrum activity suggests the capacity for wide usage against infection of wounds, mucosal membranes, enteric (intestinal) infections and sepsis (blood infection).
- **Common sexually transmitted infections:** common infections such as gonorrhoea, trichomoniasis and candidiasis which may develop from bacterial or fungal infections leading to common female complaints such as vaginal inflammation or the increased likelihood of HIV infections and reproductive issues.
- **Malaria:** a parasitic disease carried by mosquitoes which affects hundreds of millions of people worldwide each year. Malaria caused approximately 655,000 deaths in 2010. Current treatments are meeting increasing resistance and often have undesirable side effects.
- **MRSA:** a high-profile strain of antibiotic-resistant “Golden Staph” of major concern to global healthcare systems, contributing a significant burden of illness made more costly by resistant infections and the disease’s increased spread.
- **Tuberculosis:** A bacterial infection that predominantly attacks the lungs. TB is second only to HIV/AIDS as the greatest cause of deaths worldwide attributable to a single infectious agent.

BDM-I has delivered a range of exciting results to date. The broad spectrum activity it has displayed suggests considerable value, as multiple potential therapeutic indications can be outlicensed, providing multiple revenue streams to BioDiem. BioDiem has strategically positioned itself as a developer of therapies for a range of diseases with large unmet medical need that are often not prioritised for early-stage development by larger drug development companies.

### Partnerships and Collaborations for BDM-I

BioDiem’s partnering strategy across its programs focuses on collaboration with reputable partners for early-stage work to validate technologies and speed development. For the antimicrobial program, the largest partners have been the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), the National Institutes of Health and the Queensland Institute of Medical Research (QIMR).

BioDiem retains full commercial and intellectual property rights in relation to the work being conducted on BDM-I by its R&D partners.

### Accelerating BDM-I’s Development

To support out-licensing opportunities of BDM-I, BioDiem is progressing:

- (i) Further validation of BDM-I’s antimicrobial activity**  
BioDiem is progressing plans for *in vivo* proof of concept testing in models of target diseases including in fungal, bacterial and parasitic models (schistosomiasis). Demonstration of activity in one or more of these models will provide a basis for outlicensing discussions.
- (ii) Further studies to explore the breadth of BDM-I’s activity**  
Expanded sets of screening studies are underway. BioDiem continues to utilise NIAID’s In Vitro Assessment and Antimicrobial Activity Service<sup>2</sup>. Depending on the results and NIAID approval, BioDiem in the future may use NIAID’s Animal Models of Infectious Disease Service<sup>3</sup> to further evaluate BDM-I’s activity.
- (iii) Enhancement of BDM-I’s commercial applications**  
Preclinical studies have used oral and intravenous delivery of BDM-I. The breadth of BDM-I’s activity lends itself to a wide variety in routes of administration including injection, creams, eyedrops, inhalation, etc. BioDiem is progressing work to explore new ways of enhancing BDM-I’s delivery. This will enhance the drug’s commercial attractiveness as it will have wider scope for product lines.

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<sup>1</sup> NIAID is the National Institute of Allergy and Infectious Diseases, an institute of the US National Institutes of Health (NIH)

<sup>2</sup> <http://www.niaid.nih.gov/LabsAndresources/resources/dmid/invitro/Pages/invitro.aspx>

<sup>3</sup> <http://www.niaid.nih.gov/LabsAndResources/resources/dmid/animalmodels/Pages/default.aspx>

## Summary

BioDiem continues to build the evidence supporting BDM-I's potential as a broad-spectrum antimicrobial drug. The intellectual property position has continued to be strengthened, and project work has been advanced with an eye to enhancing the commercial prospects of this asset. Further updates regarding BDM-I's development will be reported in upcoming months.

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## About BioDiem Ltd

BioDiem is an ASX-listed company based in Melbourne with an international focus on discovering, developing and commercialising world-class research and technology targeting cancers and infectious diseases. BioDiem's core technologies include the Live Attenuated Influenza Virus (LAIV), the SAVINE platform and the BDM-I antimicrobial compound. BioDiem has also in-licensed vaccine technologies from Australian National University and the University of Canberra with initial target indications of dengue fever and hepatitis respectively.

The LAIV influenza vaccine is an intranasal vaccine to prevent infection from seasonal and pandemic influenza. The LAIV influenza vaccine can be produced using both egg-based and cell-based manufacturing methods. The cell-based LAIV vaccine has completed a Phase II clinical trial in Europe. The egg-based LAIV vaccine technology is licensed to the World Health Organization as part of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply.

The LAIV influenza vaccine is marketed as Nasovac™ in India by the Serum Institute of India, and has been licensed to China-based Changchun BCHO Biotechnology Co. The LAIV vaccine was in-licensed from the Institute of Experimental Medicine in St Petersburg, Russia where it has been used for over a decade in many millions of people - children, adults and the elderly. The LAIV is administered by nasal spray and induces a rapid immune response in the mucosal lining of the nose and pharynx.

The LAIV is also being developed as a viral vector for making novel non-influenza vaccines for different diseases including cancers. Viruses have the ability to generate proteins prolifically and can be programmed to produce disease-specific proteins. As part of a vaccine, disease-specific proteins can help generate a beneficial immune response. BioDiem is advancing its two new vaccine and vaccine vector programs in partnership with France-based developer VIVALIS and the Royal Melbourne Institute of Technology (RMIT).

SAVINE (patented Scrambled Antigen Vaccine) is a platform technology for the design of antigens for incorporation into vaccines targeting an immune response to a range of different diseases. SAVINE antigens are encoded as synthetic genes which, together with a delivery technology such as BioDiem's LAIV-based vaccine vector technology, can be used to develop novel vaccines.

BDM-I is a synthetic compound targeted at the treatment of serious human infections. BDM-I is in the preclinical stage with outlicensing as the intended outcome. BDM-I is active against a range of pathogenic micro-organisms including gram-positive and gram-negative bacteria, fungi and protozoa. Key patents have been granted in both Europe and the US around BDM-I's antimicrobial activity, including activity against *Plasmodium falciparum*, responsible for causing the most commonly severe form of malaria, and *Trichomonas vaginalis*, the protozoan responsible for causing a common sexually transmitted disease named trichomoniasis.

BioDiem is also developing BDM-E, a tetra peptide synthetic compound, as a treatment for ophthalmic disorders. The US Food & Drug Administration (USFDA) has granted Orphan Drug designation to BDM-E for the treatment of retinitis pigmentosa, a serious degenerative disease of the retina.

BioDiem's research is ongoing in partnership with internationally recognised research groups.

For additional information, please visit [www.biodiem.com](http://www.biodiem.com)

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