

ASX Announcement

COMMENTARY – FULL YEAR RESULTS

Melbourne, 30 August 2012: Australian infectious disease therapy and vaccine development company BioDiem (ASX: BDM) today announced the release of its financial results for the year ended 30 June 2012.

BioDiem CEO Julie Phillips said: “The FY2012 financial results reflect strong revenue growth from vaccine licensing activities in India and China. We have a number of opportunities for expanding and extending current licenses into new markets. These two avenues summarise our operational focus for FY2013. The pipeline has been enhanced by the recent licensing of technologies from the Australian National University and University of Canberra.”

Key Highlights of the year included:

- Receiving license fees from the vaccine licensing business of \$1.33m.
- Achieving key milestones in the program for development of BioDiem’s ‘vector’ platform technology for the creation of customized vaccines.
- Grant of US and European patents for antimicrobial compound BDM-I, for treatment of vulvovaginitis; and grant of US patent around BDM-I for the major indications of malaria and trichomoniasis.
- Presenting preclinical results for orphan eye disease drug BDM-E at the International Society for Eye Research.
- Partnering with RMIT University to explore the customisation of BioDiem’s LAIV technology for new vaccines.
- Obtaining exclusive licenses for the commercialisation of technologies from the Australian National University and the University of Canberra for vaccine technologies for dengue fever and hepatitis respectively.
- Partnering with US-based Foundation Fighting Blindness (FFB) to expand study of BDM-E in a retinitis pigmentosa model. FFB is a leading national non-for-profit organisation driving research for treatments in eye disease.
- Signing a new LAIV vaccine licence with Changchun BCBT Biotechnology Co.
- Acquiring the SAVINE technology to broaden the range of novel vaccines that could be produced from BioDiem’s research programs.
- Commencing Phase I clinical trials in Russia and Thailand for the avian (bird) flu vaccine.

Results for announcement to the market

Name of Entity and ABN: BioDiem Limited ABN 20 096 845 993
 Reporting Period: 30 June 2012
 Previous Corresponding Period: 30 June 2011

FY12 Highlights

000's	2012	2011	\$ Change	% Change
Revenue generated	\$1,331	\$255	Up \$1,076	Up 421.7%
R&D Expenditure	\$(1,084)	\$(1,251)	Down \$167	Down 13.36%
Operating loss from ordinary activities	\$(1,059)	\$(2,618)	Down \$1,559	Down 59.54%
Operating loss attributable to members	\$(1,009)	\$(2,618)	Down \$1,609	Down 61.46%
	30 June 2012	30 June 2011		
Net tangible assets per ordinary share	\$0.0147	\$0.0245		

No dividends have been declared or are expected to be declared.

The Preliminary Final Report is based on accounts which are in the process of being audited.

Financial Position

BioDiem ended the financial year with \$1.37m cash (2011: \$2.58m). Revenues increased to \$1.33m (2011: \$0.26m) due to the out-licensing of BioDiem's LAIV influenza vaccine technologies to the Serum Institute of India and new Chinese commercial partner, Changchun BCHT Biotechnology Co. BioDiem's expenditure on R&D for 2011–2012 was \$1.08m (2011: \$1.25m). Overall the company reported a net loss of \$1.01m (2011:\$2.62m).

Project Update

BioDiem's operational structure is now divided into three major programs:

- **Influenza vaccine licensing business:** This division has generated an increase in revenue to approximately \$1.4 million in the year from influenza vaccine technology licenses to the Serum Institute of India as well as a Chinese commercial partner, BCHT Changchun Biotechnology Co. BioDiem is seeking to establish more out-licensing opportunities for both its cell-based influenza vaccine technology and the egg-based technology.
- **Development of the antimicrobial BDM-I:** A significant amount of preclinical work has shown BDM-I to have activity against a wide variety of bacteria, fungi, protozoa and parasites. Testing of BDM-I activity against the chronic infection, schistosomiasis, is encouraging. Patents have been granted in the US and Europe for the common female health complaint, vulvovaginitis, and now also in the US against malaria and a sexually transmitted disease, trichomoniasis. BDM-I is currently being researched as an innovative treatment against 'superbugs' or antibiotic-resistant bacteria such as MRSA, and the serious fungal infection, aspergillosis.
- **New vaccine technologies and the vaccine 'vector' platform:** BioDiem acquired Savine Therapeutics to expand and complement its existing vaccine technology suite. BioDiem has in-licensed technologies from the ANU and University of Canberra for complementary platform technologies targeting dengue fever and hepatitis, respectively.

BioDiem has initiated a plan to investigate the feasibility of using BioDiem's proprietary LAIV technology for the creation or customisation of new vaccines. BioDiem has signed a research collaboration agreement with RMIT University to explore the development of a vaccine 'vector' that can be customized to prevent and/or treat specific diseases. In collaboration with France-based VIVALIS, BioDiem has achieved the successful growth of its proprietary virus in VIVALIS' proprietary cell line which brings the collaboration a step forward in the development of a customizable vaccine vector.

Outlook

BioDiem has passed a series of significant milestones in a period of intense activity following a refocus of the company's strategy on infectious disease therapy and vaccine development. Across BioDiem's diverse portfolio are a number of opportunities for outlicensing, building on the existing revenue-generating vaccine licensing business in India and China. Development risk is spread across a number of projects at various stages of development, and the Company has clear priorities for those programs which have the best chance of delivering near-term revenue streams.

BioDiem also intends to further leverage its partnerships to venture into a number of markets with new commercial opportunities. This includes pursuing the licensing of alternative LAIV vaccine production technologies (e.g. cell-based production) which allow for higher yield production volume and does not rely on egg supply.

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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

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