**Press release** 



BIODIEM LTD ABN 20 096 845 993

Level 10, South Tower, 459 Collins Street, Melbourne, Victoria, 3000 Australia

 Phone
 +61 3 9613 4100

 Fax
 +61 3 9613 4111

 Email:
 info@biodiem.com

 Web:
 www.biodiem.com

# From cells to therapeutics Vivalis

# VIVALIS

Reuters: VLS.PA – Bloomberg: VLS FP 6, Rue Alain Bombard 44800 Saint-Herblain

France

 Phone
 +33 2 28 07 37 10

 Fax
 +33 2 28 07 37 11

 Email:
 info@vivalis.com

 Web:
 www.vivalis.com

# BIODIEM AND VIVALIS BEGIN COLLABORATION TO TEST PRODUCTION OF THE LAIV VECTOR ON THE EB66<sup>®</sup> CELL LINE

**Melbourne (Australia), Nantes, Lyon (France) 9 May 2012:** Australian vaccine development company BioDiem Ltd (ASX: BDM) today announced that it has begun a research collaboration with France-based VIVALIS (Euronext code: VLS), a biopharmaceutical company with expertise in vaccine production technologies. The collaboration involves investigation of the synergy of BioDiem's proprietary virus, LAIV, and VIVALIS' proprietary cell line, EB66<sup>®</sup>. Successful results from this investigation could be used as a basis for a new agreement between the companies in order to test the feasibility of development of BioDiem's LAIV as a vector in VIVALIS' proprietary cell line. Viral vector technology is used in vaccines to deliver immune-stimulating proteins into the body. VIVALIS is undertaking this initial research to further the high potential value of this technology in BioDiem's non-influenza vaccine applications.

BioDiem has considerable in-house expertise around the Live Attenuated Influenza Virus (LAIV), having an existing LAIV-based technology for the production of influenza vaccines, currently generating licensing revenues in India and China. BioDiem has proposed developing the LAIV as a versatile 'vector' (carrier) technology, which could be used to create a variety of new vaccines (both therapeutic and preventative). This proposed vector would be developed to have the additional advantages of a good safety profile and low toxicity (as the virus backbone is already weakened), excellent virus characterisation from extensive prior work, and the ability to be customised to target particular diseases.

This initial collaboration involves VIVALIS confirming that BioDiem's LAIV strains grow satisfactorily in VIVALIS' proprietary cell line EB66<sup>®</sup> and examining any effects on the virus' characteristics. During this stage BioDiem's long-term collaborator, and LAIV developer, the Institute of Experimental Medicine in St Petersburg, will send an LAIV expert to work on-site with VIVALIS in France.

This initial program is estimated to take up to ten weeks. Following successful demonstrations of growth and productivity, BioDiem will look to negotiate another agreement with VIVALIS regarding a longer-term research project aimed at developing a stable LAIV vector technology incorporating EB66<sup>®</sup> as a base platform for growth.

VIVALIS is an ideal vaccine development partner, with a strong commercial mindset, a history of successful partnerships and great technology in the internationally established EB66<sup>®</sup> cell line. We are excited to be beginning this collaboration and moving forward on the LAIV vector project" said BioDiem Chief Executive Officer, Julie Phillips.

Franck Grimaud, CEO, and Majid Mehtali, CSO, co-managers of VIVALIS jointly stated, "Advancing the EB66<sup>®</sup> platform into novel areas is an objective we have maintained from the initial launch of the platform. This agreement with BioDiem, the second EB66<sup>®</sup> agreement since January 1<sup>st</sup>, continues these objectives by moving our EB66<sup>®</sup> technology into applications like those being developed by BioDiem in the therapeutic and preventative vaccine fields. We look forward to working with BioDiem in this program and the possibility of expanding our relationship into a process development, a future commercial license and biomanufacturing agreement as we both advance the field of vaccine design and development."

Terms of the agreement were not disclosed.

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### Next Financial Press Release: July 19, 2012, after NYSE Euronext market closing: Second Quarter 2012 Revenues

# 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 for vaccines. BioDiem's lead technology is the Live Attenuated Influenza Virus (LAIV) technology, which has been developed as an intranasal vaccine to prevent infection from seasonal and pandemic influenza.

The LAIV influenza vaccine can be produced using egg-based and cell-based manufacturing methods.

The cell-based LAIV vaccine has completed a Proof of Concept (Phase II) clinical trial. 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. This allows governmental and non-governmental organizations or private companies in developing countries to produce seasonal and pandemic vaccines in eggs. The LAIV influenza vaccine is marketed as Nasovac<sup>™</sup> in India by the Serum Institute of India. The LAIV is also being explored as a viral vector for use in the development of novel non-influenza vaccines.

In December 2011 BioDiem acquired Savine Therapeutics Pty Ltd. Savine is a platform technology for the design of antigens for incorporation into vaccines targeting a range of different diseases.

# About LAIV Technology

The Live Attenuated Influenza Virus (LAIV) vaccine was in-licensed from the Institute of Experimental Medicine in St Petersburg, Russia, where it has been approved and used in its present form 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 vaccines are based on 'Master Donor Strains' that have been rendered 'cold adapted' and temperature sensitive, such that they will not replicate readily at temperatures above 33°C, as found in the lungs. The administration of the live vaccine stimulates mucosal, cellular and humoral immune responses (which are required to optimise the effective prevention of influenza), without causing the disease. For additional information, please visit www.biodiem.com

# Contact

#### Investors

Julie Phillips, Chief Executive Officer BioDiem Ltd Phone +61 3 9613 4100 Email jphillips@biodiem.com

# Media

Tom Donovan Buchan Consulting Phone +61 3 8866 1224 / +61 422 557 107 Email tdonovan@buchanwe.com.au

## About VIVALIS (www.vivalis.com)

VIVALIS (NYSE Euronext: VLS) is a biopharmaceutical company that provides innovative cell-based solutions to the pharmaceutical industry for the manufacture of vaccines and proteins, and develops drugs for the prevention and treatment of unmet medical needs. VIVALIS' expertise and intellectual property are leveraged in three main areas:

# EB66<sup>®</sup> Cell Line

VIVALIS offers research and commercial licenses for its EB66<sup>®</sup> cell line, derived from duck embryonic stem cells, to pharmaceutical and biotechnology companies for the production of therapeutic and prophylactic viral vaccines, virosomes, VLP's, and recombinant proteins (with a focus on monoclonal antibodies having enhanced cytotoxic activity). EB66<sup>®</sup> cell line based vaccines are currently in clinical trials in the USA and Japan. Through these programs VIVALIS receives upfront, clinical stage milestone payments along with royalties on licensees net sales.

## VIVA|Screen<sup>™</sup> Human Antibody Discovery Platform

Customized solutions for the discovery, development, and production of fully human monoclonal antibodies are now offered by VIVALIS. Through these programs VIVALIS receives upfront, clinical stage milestone payments along with royalties on licensees net sales.

# <u>3D-Screen<sup>™</sup> Drug Discovery Platform</u>

VIVALIS performs discovery and development, up to pre-clinical evaluation, of original small chemical molecules identified with its proprietary platform, 3D-Screen<sup>TM</sup>. This unique screening platform is designed to identify original molecules that alter the three-dimensional structure of a target protein, thus modulating its biological function through an innovative mode of action. VIVALIS is building a portfolio of proprietary new chemical entities for the treatment of hepatitis-C virus infection. VIVALIS also offers on a service basis to develop ready-to-use customized 3D-Screen<sup>TM</sup> HTS assays directed against target proteins of interest.

Based in Nantes & Lyon (France) and in Toyama (Japan) VIVALIS was founded in 1999 by the Grimaud Group (ca. 1,600 employees), a worldwide leader in animal genetic selection. VIVALIS has established more than 30 partnerships and licenses with world leaders in this sector, including Sanofi Pasteur, GlaxoSmithKline, Transgene, Pfizer Animal Health, Kaketsuken, Kitasato Daiichi Sankyo Vaccine, Merial, Merck Animal Health, and SAFC Biosciences. VIVALIS is a member of the French ATLANTIC BIOTHERAPIES and LYON BIOPOLE bioclusters and a member of the Japanese HOKURIKU INNOVATION CLUSTER FOR HEALTH SCIENCE in Toyama.

VIVALIS Listed on Euronext Paris – Compartment C of NYSE Euronext Reuters: VLS.PA – Bloomberg: VLS FP Included in NYSE Euronext's SBF 250, CAC Small 90 and Next Biotech indexes



This document contains forward-looking statements and comments on the company's objectives and strategies. No guarantee can be given as to any of the events anticipated by the forward-looking statements, which are subject to inherent risks, including the risk factors described in the company's document de référence, changes in economic conditions, the financial markets or the markets in which the company operates.

# **Contacts**

#### VIVALIS

Franck Grimaud, CEO Email: investors@vivalis.com

#### **NewCap**

Financial communications agency Axelle Vuillermet / Pierre Laurent Tel.: +33 (0) 1 44 71 94 91 Email: vivalis@newcap.fr