

# Update

ASX:BDM

January <u>2013</u>



## New results and IP assets emerge from development programs

#### Dear Shareholders,

Since our last newsletter, BioDiem has made significant progress on our key development programs.

To begin with excellent news: in August, we achieved major milestones with our French partner, VIVALIS, demonstrating the successful and abundant growth of BioDiem's virus in a VIVALIS cell line for the development of a virus-based vector for infectious diseases. A stable vector platform technology would offer the ability to create many new vaccines for different indications, and be a significant asset in its own right. In December BioDiem completed a renounceable rights issue raising \$2.0 million. The funds will be used primarily to continue the development of the Company's portfolio of vaccine and antimicrobial therapies targeting infectious

In late November our partner, the Serum Institute of India, advised us that it will file documents with India's drug regulator and the World Health Organisation which, once approved, will allow international export of vaccines based on BioDiem's LAIV technology. We will have more news on this in 2013. We receive royalties from product sales from our flu technology in the private sector of developing countries. International expansion opens the opportunity for licensing of the cell-based LAIV production method, as well as new sales licenses for developed countries.

Apart from this, our Chinese partner, BCHT Changchun Biotechnology is currently advancing a major investment in the development of LAIV-based seasonal influenza vaccines based on BioDiem's LAIV technology. BioDiem expects to receive significant further royalties from this vaccine, as detailed in this newsletter.

The BDM-I antimicrobial compound has been granted additional patents in Europe and Japan to strengthen BDM-I's patent portfolio as a broad spectrum antimicrobial. BDM-I is now patented in the world's three largest pharmaceutical markets - the US, Europe and Japan - significantly adding value to future partnering and out-licensing opportunities.

In November, BioDiem entered a research agreement with Queensland-based Griffith University to examine ways to expand its BDM-I antimicrobial program, through creating new variants of BDM-I that may be more soluble and suitable for a variety of additional commercial preparations.

In line with the company's refocussed vaccine strategy, BioDiem partnered with RMIT University in July for the development of new non-influenza vaccines through the customisation of BioDiem's proprietary viral technology (LAIV). BioDiem has provided seed funding for this project, and in partnership with RMIT, we will seek further Government grant funding to progress development of these vaccines.

#### Contents

New results and IP assets emerge from development programs

International partners deliver significant progress towards royalty growth

Tapping into Australian science

Exciting data matched with new patents and reformulation research: BDM-I

**Expansion of our partnering network** 

Research presented from eye disease program

We are proud of the rapid and valuable progress made in 2012, and are working hard to build shareholder value by boosting the commercial opportunities for our vaccine technologies and antimicrobial compounds through our partnerships with leading research and commercial organisations, enhancing our patent coverage and expanding our out-licensing opportunities.

Our focus is on delivering value-adding milestones from this activity in 2013.

Key milestones for 2013 under our development strategy include:

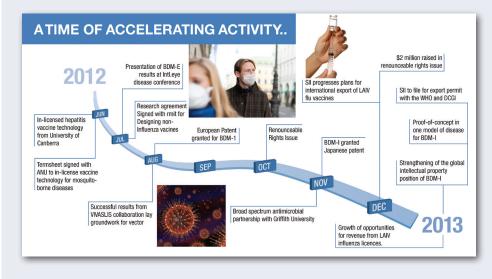
- proof-of-concept in one model of disease for BDM-I
- strengthening of the global intellectual property position of BDM-I
- growth of opportunities for revenue from LAIV influenza licences.

I look forward to sharing our progress in the months ahead.

Yours sincerely,

Julie Phillips

Chief Executive Officer





### **Update**

# International partners deliver significant progress towards royalty growth

BioDiem's international partnering network gives the company access to most of the world's developing nations through its partnership with the World Health Organisation (WHO). Through this partnership, BioDiem is generating revenues in the world's largest growing economies — India and China - through the Serum Institute of India (SII) and BCHT Changchun Biotechnology (BCHT) in China.

In late November our partner, the SII, advised BioDiem that in 2013 it will file documentation with domestic agencies and WHO to allow international export of flu vaccine products based on BioDiem's LAIV technology. The SII is the world's fifth largest vaccine manufacturer by volume, and vaccinates half the world's children.

Royalties from private sector sales in developing countries will flow to BioDiem and an expansion of potential markets for this vaccine should be matched by growth of BioDiem's royalty streams.

This development is a powerful validation of the value added to BioDiem's global capacity by the partnership with the Serum Institute. The SII has also acquired a Netherlands-based vaccine company and signalled interest in expanding into developed countries, which may assist progress towards a further licensing of the LAIV technology for private market sales in developed nations.





Photograph of the manufacturing facility building for the manufacture of seasonal influenza vaccine based on in-licensed LAIV technology from BioDiem.

Meanwhile, our Chinese commercial partner BCHT is in the process of constructing a substantial new production facility at the Changchun National High-Tech Industrial Development Zone in China. The facility is made up of two buildings, one intended for the manufacture of the BCHT's proprietary rabies vaccine and another intended mainly for the manufacture of influenza vaccines based on BioDiem's LAIV technology.

The facility is almost completed with a 4,800 meters<sup>2</sup> floor area and BCHT has so far invested a substantial amount in this manufacturing plant, an indication of BCHT's assurance and confidence in the commercial opportunity presented by their vaccines based on BioDiem's LAIV technology.

In the first quarter of 2013, BCHT is also planning to lodge an application with the Chinese FDA for the approval to conduct human clinical trials of LAIV flu vaccines, an encouraging step towards supplying the large Chinese private market. BioDiem is pleased with the progress of both our commercial partners in India and China which is consistent with the company's work to increase royalty revenues.



#### Vaccine development

In the last quarter BioDiem achieved two major milestones in its partnership with France-based VIVALIS for the creation of new non-influenza vaccines. Firstly, the successful growth of BioDiem's proprietary virus in VIVALIS' EB66 cell line. Secondly, this growth was at encouragingly high levels, to create a platform for the next investigative stage of vector development and manufacture. The project leverages advantages from both BioDiem's virus (which offers a high safety profile and low toxicity and ease of delivery) and VIVALIS' cell line (which has been used in commercial vaccine production for clinical trial in the US) both would facilitate a shorter and more cost-effective path for the development of vaccines). The next stages of this arrangement are in planning.

### **Tapping into Australian** science

BioDiem has an exceptional local partnership network with several of Australia's leading academic institutions. In 2013 BioDiem will continue to integrate complementary technology with its existing portfolio for the creation of vaccines targeted against a range of infectious diseases. Since our last update, BioDiem has established three new local partnerships — RMIT University, The University of Canberra and Griffith University to add to its extensive partnering network.

#### These partnerships cover:

- Investigating the use of BioDiem's well-understood LAIV technology for the creation
  of non-influenza vaccines, targeting the Epstein Barr virus (and the throat cancer
  it causes) with RMIT University. Prospectively, this program has the potential to
  target a number of infectious diseases and related cancers.
- The research and development of hepatitis vaccines with The University of Canberra (UC). BioDiem and UC are developing therapeutic vaccines against hepatitis B and D.
- Signing a term sheet for the research and development of vaccines against dengue fever with **Australian National University**.

Please refer to the July Newsletter 2012 for more information on BioDiem's full international and domestic partnerships.

Please email BioDiem info@biodiem.com if you would like a copy of the July 2012 Newsletter or visit the Investor Relations section of our website)







# Update

### Accelerating the development and commercialisation of BDM-I

BDM-I is a compelling investment proposition for accelerated development as global healthcare systems are increasingly aware of antibiotic resistant infections, a result of the misuse and overuse of common antibiotics in patients. The market for anti-infectives was valued at US\$53 billion in 2011 and was forecast to exceed \$100 billion in 2012.

In line with BioDiem's new corporate strategy, the company has established strategic research partnerships to develop BDM-I as a treatment for a range of infectious diseases.

BDM-I has promising preclinical evidence to encourage its development as a broad-spectrum antimicrobial against a wide range of infectious diseases with large markets.

Recently, BDM-I gained a Japanese patent covering its use in the areas of sexual health. BDM-I's patent portfolio now successfully covers the world's largest pharmaceutical markets — US, Europe and Japan.

BDM-I has demonstrated activity against a wide range of disease-causing agents responsible for serious human infections ranging from sexual health problems to diseases prevalent in developing nations, for example, tuberculosis. These results have been generated from research in collaboration with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), the National Institutes of Health and the Queensland Institute of Medical Research (QIMR), while BioDiem has retained full commercial and intellectual property rights for the work conducted.

BioDiem is progressing further validation of BDM-I's antimicrobial activity using NIAID1's In Vitro Assessment and Antimicrobial Activity Service<sup>2</sup>. Depending on the results and subject to approval, BioDiem intends to use NIAID's Animal Models of Infectious Disease Service<sup>3</sup> to further evaluate BDM-I's activity.

BioDiem is also exploring an expanded testing program of BDM-I against microorganisms against serious human diseases such as "superbugs" (disease-causing agents that are resistant to common antibiotics and therapies) and against microorganisms commonly used in bioterrorism.

The accelerated development of BDM-I is further supported by the United States signing into law the Generating Antibiotic Incentives Now Act 2012, which authorises 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. This incentive further boosts the attractiveness of exciting early-stage candidates like BDM-I to potential licensees. BDM-I may also be a candidate for Orphan Drug status from the FDA which would accelerate its regulatory path in niche diseases that currently have poor treatment options.

- NAID 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/ invittro.aspx
- $^3\ http://www.niaid.nih.gov/LabsAndResources/resources/dmid/animalmodels/Pages/default.aspx$



### Biodiem's progress in eye disease

In July, BioDiem presented positive results from formal studies of the BDM-E eye disease drug at the International Society for Eye Research (ISER) Conference in Berlin. BDM-E has shown potential to treat retinitis pigmentosa, a type of inherited degenerative eye disorder.

BDM-E has been granted Orphan Drug designation by the FDA, which accelerates its development to lead to use in patients as retinitis pigmentosa currently has no effective treatment options. BioDiem is currently in partnership with the Foundation Fighting Blindness in the USA for the investigation of BDM-E's preclinical applicability. BioDiem's intends to outlicense BDM-E as part of its strategy to focus on infectious disease.

"We see huge opportunity in building a LAIV influenza vaccine platform in China."

Dr Wei Kong, President of BCHT Biotechnology Co.

#### **About BioDiem**

BioDiem is an ASX-listed biotechnology company (BDM), based in Melbourne, with a focus on being a global vaccine and therapy company targeting infectious diseases. With existing revenues from vaccine licenses in India and China, the company uses a cost-efficient approach to portfolio development through collaborations with a global partnering network.

#### Contact Us

BioDiem Ltd
Level 11, 470 Collins S
Melbourne Vic 3000
T: + 61 (3) 9613 4100
E: info@biodiem.com