BioDiem

Update

ASX:BDM | July 2012

BioDiem's new strategy delivers rapid progress

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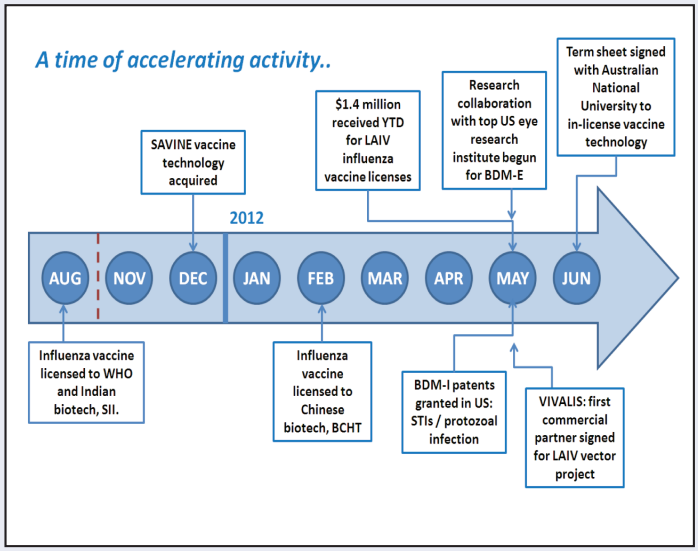
Dear Shareholders,

It has been a very successful twelve months. Our new focus on the huge potential in infectious disease therapies and vaccines has seen our portfolio expand and develop considerably, and I'm pleased to announce that we have made progress on all our programs and achieved a number of important milestones (right). The company's rapid progress is a testament to a focused and considered approach to advancing our robust product pipeline.

Recent achievements include:

1. $1.4 million received in the year to date from influenza vaccine licensing, including:
   (a) First revenues received from the launch of the Nasovac™ influenza vaccine by our partner, the Serum Institute of India; and
   (b) Revenues from a new licence for our vaccine technology for private sector sales in China through a new partner, BCHT Biotechnology Company;
2. Strengthening BDM-I's patent position and expanding the research and development of BDM-I targeting multiple serious bacterial, fungal and parasitic infections including golden staph, malaria, trichomoniasis, schistosomiasis and others;
3. A new research agreement with the Foundation Fighting Blindness and the University of Miami, helping evaluate the potential of BDM-E to treat Retinitis Pigmentosa and prepare the compound for outlicensing; and
4. Acquisition of new technologies to expand BioDiem's internal vaccine design capabilities for more disease targets.

BioDiem has established a solid and growing business in vaccine licensing, and we are committed to expanding the opportunities presented by our portfolio for multi-target infectious disease therapies. Our expertise and world-class



partnerships are generating considerable value from our unique assets, and our recent activity has launched us into an exciting phase of our development. In April 2012 the Chairman advised shareholders of our refocused strategy, including a determination to provide shareholders with a greater level of communication around our significant progress, a plan of which this newsletter is one part.

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

Yours sincerely,

Julie Phillips

Chief Executive Officer

BioDiem welcomes all inquiries.
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A new strategy: building on vaccine success to develop multiple solutions for infectious diseases

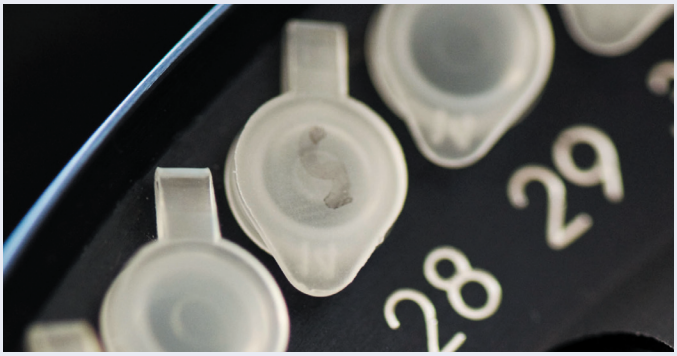
Since our strategy review in early 2012, BioDiem has a tighter focus on the development and commercialisation of vaccines and therapies for infectious diseases with large global markets.

The strong partnership with the World Health Organization (WHO) has provided access to the large developing markets of India and China, from which vaccine licensing revenue streams are now flowing. While continuing to grow this part of the business BioDiem will leverage its partnerships and expertise in the development of new vaccines and therapies.

The major programs target infectious diseases and related cancers. These are expanded on in this newsletter but, in brief, use our new vaccine design technologies (both in-house and in-licensed from leading research institutions) and BDM-I, which has displayed activity against a wide variety of infectious organisms. This includes those responsible for the fungal disease aspergilliosis, the antibiotic resistant "superbug" MRSA, and a chronic "neglected" parasitic disease of the developing world, schistosomiasis.

In line with the refocused strategy the BDM-E asset, while exciting, is being prepared for outlicensing to ensure BioDiem's focus remains on infectious diseases.

The result of these programs will be a differentiated offering in the huge and growing space of infectious diseases and related cancers. BioDiem has a strong proposition to investors in terms of the multiple diseases it is targeting as well as the types of therapies being developed – spreading our development risk and increasing prospects for further commercial success.



Addressing the major threat of antibiotic-resistant bacteria

A major issue in modern medicine is the rising incidence of antibiotic-resistant bacteria. Overuse and misuse of common antibiotics has encouraged the spread of dangerous strains often seen in hospitals. The leading example is MRSA (methicillin-resistant Staphylococcus aureus).

The same is also true for other microbes including *Aspergillus fumigatus*, the fungus which causes aspergillosis, a lethal invader of the airways which strikes at immune-compromised patients in particular.

Antimicrobials have recently returned to prominence as a key acquisition area for "Big Pharma", who are faced with thinning product pipelines in the area, off-patent offerings and increasing demand from healthcare systems for innovative products.

Work conducted at US Government-backed medical research institutions has demonstrated BDM-I's activity against MRSA and aspergillosis, among others. In fact, studies to date have shown BDM-I acting against a range of dangerous fungi, bacteria, and protozoa (a type of microbe).

The economic upside to this research is that a successfully commercialised BDM-I product may access a variety of very large markets with sustained growth. The antifungal market alone was valued at US$9.4 billion in 2010 while the antibacterial market is estimated to exceed an astounding US$46 billion by 2015.

In addition to these applications, BioDiem has recently strengthened BDM-I's position with granted patents in Europe and America covering the compound's activity against key agents responsible for malaria, the sexually transmitted disease trichomoniasis, and the common female health complaint vulvovaginitis (inflammation of the vagina). This has further bolstered the profile of BDM-I as a broad spectrum agent of huge potential.

The potential of BDM-I from anti-infective screening studies is exciting, and BioDiem is working hard to expand the data package around BDM-I in collaboration with highly-credentialed partners both in Australia and internationally. The next stage is to move into animal models, and BioDiem hopes to announce this next phase of development in the next 12 months.

MRSA

Methicillin (a type of antibiotic) – resistant *Staphylococcus aureus* is one of the most pressing concerns for staff in hospitals dealing with the repercussions of antibiotic overuse. A rapidly spreading infection, it can cause massive shock and death in victims. Treatment options are increasingly limited and the extra care required significantly boosts patient expenses. A new type of effective antibiotic, such as that under development by BioDiem, would be an incredibly valuable asset.

Dengue fever

Dengue fever is a disease caused by a mosquito-borne virus that affects between 50 and 100 million people a year, and according to the World Health Organization the incidence is increasing significantly. Although only a small percentage of cases are fatal, non-fatal cases can be extremely debilitating. There is currently no existing vaccine, although major player Sanofi is advancing a candidate into late stage trials, which has already attracted attention for its likely high price point and multi-dose regimen.

In June 2012 BioDiem announced the signing of a term sheet regarding the in-licensing of a technology from Australian National University which has shown promise in the development of a dengue fever vaccine.

Building a capacity for new vaccine generation: in-licensed technologies for development

In line with a strategy that will see BioDiem capitalise on its expertise with the LAIV technology, the Company has begun work developing a technology platform which could offer treatments for a variety of diseases including specific cancers like nasopharyngeal carcinoma and infectious diseases like dengue fever.

Vaccines are by definition prophylactic – they prevent a disease – but in recent years an interest has developed in therapeutic vaccines for infectious diseases such as AIDS and tuberculosis, as well as some cancers. This is an exciting area of the emerging vaccine market and BioDiem is strongly placed to capitalise on it.

The LAIV vector: new uses for a core technology

With the aim of extending its business focus, BioDiem plans to engineer a viral vector. A vector is essentially a smart way of changing a virus so it can 'jump start' the immune system, and can potentially be used for many diseases. The vector program will benefit from BioDiem's expertise with the Live Attenuated Influenza Virus technology and its inherent advantages such as a good safety profile.

BioDiem hopes to take this technology to the stage where it will aid the engineering of future vaccines for cancers such as nasopharyngeal carcinoma (NPC).

BioDiem recently announced that it has begun research collaboration with France-based VIVALIS, a biopharmaceutical company with expertise in vaccine production technologies. The collaboration involves investigation into whether VIVALIS' technology can support the development of the vector program. BioDiem expects to announce the outcome of the first stage of this project before September 2012.

The complementary SAVINE technology

In December 2011, BioDiem strategically acquired a technology called SAVINE. This allows BioDiem to create a wider range of possible vaccines, broadening the potential applications of the vector project and allowing for targeting of a wider disease range e.g. tuberculosis (TB). BioDiem is seeking a group with TB expertise to take the existing research work further.

Nasopharyngeal carcinoma (NPC)

NPC is highly prevalent in Asia and certain regions of East Asia and Africa. It is the most common cancer of the nasopharynx, the area at the top of the throat. Having NPC is strongly associated with a previous infection by the extremely common Epstein-Barr virus, so an effective vaccine against Epstein-Barr may significantly reduce the incidence of NPC.

Rounding out an offering in eye disease

Recently BioDiem announced a new research collaboration with the Foundation Fighting Blindness and the University of Miami to test BDM-E in protecting against Retinitis Pigmentosa. The research will be carried out at the Bascom Palmer Eye Institute, which is among the top-ranked eye research centres in the US.

The research study will help to evaluate the potential of BDM-E to treat Retinitis Pigmentosa and the spectrum of RP-like diseases in humans. This will enhance BDM-E's attractiveness for out-licensing or a sale in line with BioDiem's strategy for this asset.

Why BioDiem is a contender in flu vaccine technologies

In a market dominated by a handful of global vaccine players, why is BioDiem's technology succeeding in such huge markets? There are several aspects of the LAIV technology that lead to an advantage.

For example, vaccines derived from BioDiem's technology can be manufactured more quickly than for many competitors. This is a clear advantage in the face of a pandemic. The active components of vaccines are commonly grown in specially certified chicken eggs – and BioDiem's technology results in more doses per egg.

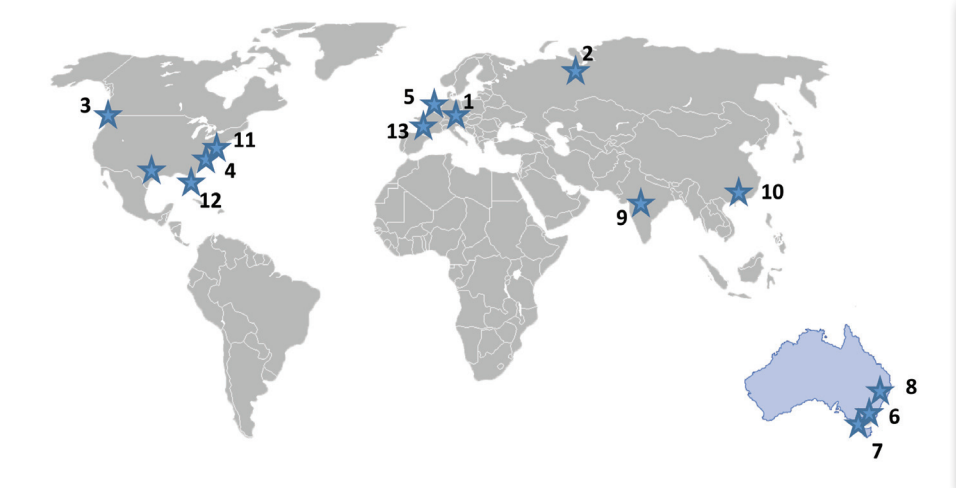
BioDiem's vaccine is delivered into the nose with a spray or a dropper. This is easier to use in children and reduces the need for trained staff and reduces the chance of unsafe injections.

Finally, BioDiem's technology allows for vaccines to be produced in cells in the lab (rather than eggs), an approach for which Phase I and Phase II European clinical trials have already been completed. This provides the ability to accelerate production even if egg supplies are limited – such as during an avian (bird) flu outbreak.

Work in progress

In 2009, BioDiem's long-standing flu vaccine technology partner, the Institute of Experimental Medicine (IEM) in St Petersburg, received US$2.5 million from an agreement with the global non-profit organization Program for Appropriate Technology in Health (PATH). This IEM-PATH agreement was for the development of new pandemic flu vaccines. This collaboration and funding has led to clinical trials which have commenced this year. The World Health Organisation have also contributed USD$3.6 million for the construction of a new laboratory at the IEM, which will provide LAIV vaccine strains for BioDiem's partners.

The major revenues to BioDiem from the influenza vaccine business division derive from new licensees for the private sector markets, as well as royalty and milestone payments from the existing licensees: the Serum Institute of India, and BCHT Biotechnology Co. in China. New licences can be issued for business in other new territories.



The World Health Organization (WHO)

For more than 60 years the WHO has been the world's largest public health organisation. An agency of the United Nations, it provides leadership on global health matters, shapes the health research agenda and policy, sets norms and standards, provides technical support to countries and monitors and assesses health trends. It is a particularly powerful advocate for the advancement of health standards in developing countries.

Our Partnering Network

BioDiem has one of the most wide-ranging partnership networks in the Australian life sciences sector. BioDiem's strategy is to engage highly credentialed partners to assist in developing key assets at low cost to BioDiem, enhancing asset value with little outlay. This gives BioDiem access to world-class research facilities while maintaining control of the core intellectual property.
It is a versatile model that BioDiem has been able to utilise to great effect.

These include agreements with:

1. The World Health Organization
2. The Russian Institute of Experimental Medicine
3. The Program for Appropriate Technology in Health
4. The United States Army Medical Research Institute for Infectious Diseases.
5. BioReliance UK: A preclinical research collaborator
6. The Australian National University
7. Monash University
8. Queensland Institute of Medical Research
9. The Serum Institute of India: one of the world's largest vaccine manufacturers
10. BCHT Biotechnology Company (China)
11. The Foundation Fighting Blindness: a leading US advocate for eye disease research
12. The University of Miami and the prestigious Bascom Palmer Eye Institute
13. VIVALIS: a France-based collaborator on the LAIV vector development project

Aspergillosis

Aspergillosis, like MRSA, is a dangerous fungal disease most commonly found in hospitals where it presents a particular risk to immune-compromised patients. It is often resistant to treatment and can rapidly cause severe infections that can lead to death.
A drug candidate like BDM-I that showed potential as an effective treatment for aspergillosis would represent a valuable asset for acquisition.

An expanding business in the world's largest markets

BioDiem's license arrangement with the World Health Organization (WHO) under the Global Pandemic Influenza Action Plan for the public sector in developing nations has given BioDiem access to the world's largest and fastest growing populations.

This access has enabled BioDiem to achieve agreements with major market players in both India and China: The Serum Institute of India and Changchun BCHT Biotechnology Company (BCHT). In the year to date these licenses have provided BioDiem with $1.4 million in revenue.

"We are very enthusiastic to build an LAIV influenza vaccine platform in China. The LAIV technology's versatility and ability to be administered without injection make it a very attractive asset we believe will be particularly competitive in China."

Dr Wei Kong, President of BCHT Biotechnology Co.

The Serum Institute of India (SII) now manufactures the swine flu pandemic vaccine Nasovac™ for the Indian market. This arrangement has started to produce a revenue stream for BioDiem with more than $790k received to date.

The SII also holds a non-exclusive license for the private markets in Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan and Sri Lanka. The SII's status as one of the world's top vaccine producers means its manufacturing standards and capacity are extremely high, and capable of meeting demand in these countries if supply agreements are reached.

In 2011 the WHO sublicensed BioDiem's LAIV technology to a well-positioned Chinese biotech, BCHT. The private sector licence between BioDiem and BCHT signed in February 2012 allows BioDiem to receive royalties from Chinese private sector market sales of seasonal and pandemic vaccines. Securing another licence for the LAIV technology was a significant milestone for BioDiem.

The outlicensing of the LAIV technology for vaccine manufacture has provided BioDiem with its first major revenues. The growth markets of India and China have the capacity to supply significant revenue streams, and BioDiem will work to support this growth while establishing further license agreements.

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.

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