Update Report

BIODIEM

Moving forward in vaccines

BioDiem

Date: 28 March 2012

Name:	**Biodiem Limited**
Country:	**Australia**
Price:	**AUD 0.04**
ISIN Code:	**AU000000BDM0**
Reuters Code:	**BDM.AX**
Market Cap (AUD m):	**6.0**
EV (AUD m):	**3.7**
Cash & cash eq. (AUD m):	**2.3**
Shares outstanding (m):	**142.1**
Volume:	**17,500**
Free float:	**100%**
52-week Range:	**0.04-0.09**

AUD mln (1 USD = AUD 0.94)	**2009A**	**2010A**	**2011A**	**2012A**
Revenues	2.99	-	0.205	1.33
Net Loss/Profit	-1.51	-3.39	-2.62	-2.62
Net loss per share (cents)	-1.98	-4.4	-2.57	-0.99
R&D costs	2.39	1.85	1.25	1.08
Cash increase/(decrease)	-1.52	0.231	-1.59	-1.23
Cash and marketable sec.	3.99	4.19	2.58	1.36

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Executive Summary

BIODIEM LIMITED

- Biodiem Limited (ASX: BDM) is an Australia-based listed biotechnology company with a focus on being a global vaccine and therapy company targeting infectious diseases. The strength of BioDiem's global partnering network is a key advantage of the Company. Its partners (the WHO and the NIH among others) are world-leading institutions that have in some cases given BioDiem ease-of-access to major markets (e.g. China and India), and in others access to world-class research institutions where preclinical data is being generated to support the company's assets at little cost to BioDiem.

- Its leading project is the commercialized Live Attenuated Influenza Virus (LAIV) program. LAIV is a novel intranasal vaccine that is being developed 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 egg-based LAIV vaccine has been launched in India as Nasovac™ for protection against H1N1 influenza by Serum Institute of India (SII). Last year, BioDiem also licensed the LAIV technology to Changchun BCHT Biotechnology for the Chinese private sector market, for a vaccine against pandemic and seasonal influenza using the egg-based manufacturing method.

- Biodiem's strategy is to grow a diverse vaccine business. This is being achieved through leverage of its existing LAIV technology to develop as a viral vector, and also through acquisition of new technologies to boost the breadth of potential disease targets. The SAVINE (scrambled antigen vaccine) technology was acquired in December 2011 and in June 2012, BDM acquired both a therapeutic hepatitis vaccine technology and also dengue fever-based technology. Recently, Biodiem announced the results of a successful collaboration with French based biotech company VIVALIS to test the production of its LAIV in VIVALIS' cell line.

- Parallel to the LAIV technology, Biodiem is developing two compounds: BDM-I and BDM-E. BDM-E was discovered in Russia, and has been successfully used in some Russian clinics for the compassionate treatment of ophthalmic disorders. In September 2010 BioDiem received Orphan Drug designation from the United States Food and Drug Administration (FDA) for BDM-E for the treatment of Retinitis Pigmentosa. BDM-I is a novel compound with impressively broad preclinical activity against a range of pathogenic micro-organisms including bacteria, fungi and protozoa. The continued rise in antibiotic-resistant strains of bacteria such as MRSA has led to significant interest in such compounds. In the last year, BDM-I strengthened its patent position with additional patents in the US, Japan and China. Recently, BioDiem also renewed its contract with the NIH to test BDM-I's activity against a range of infectious fungi. The US Military is continuing its interest in BDM-I against biological warfare agents.

- BioDiem has successfully funded its research and development activities through equity funding and cash inflows via partnerships as well as royalties it received on the LAIV technology. Currently, BioDiem has AUD 2.3 million cash with revenues in 2011/12 of AUD 1.3 million, predominantly from vaccine licensing revenues. The first product launch outside Russia and the CIS for the LAIV technology took place in India in July 2010 with an H1N1 (swine flu) vaccine, Nasovac™, being marketed by the Serum

Institute of India (SII). SII expects to file for a permit this year at the WHO to export the vaccines using BioDiem's LAIV technology. This provides great possibilities for BioDiem as SII is the fifth largest vaccine producer in the world and already vaccinates half of the world's children.

- Certain important news expected in the next 12 months could drive the stock up: royalty-generating licences with companies in developing countries for private market sales of LAIV influenza vaccine for the egg-based (via WHO) seasonal and pandemic influenza LAIV vaccine; royalty generating licences with companies using cell-based manufacturing technologies of seasonal and pandemic LAIV flu vaccines; licences and or partnerships on components or entire package for the vector program; licences and/or partnerships for the therapeutic hepatitis vaccine platform; sale of BDM-E; proof of concept in at least one model of disease for BDM-I and a possible partnership of BDM-I, other technology acquisitions focused on development and commercialization of vaccines.

- BioDiem has multiple products targeting multiple diseases at different stages of maturity, including some generating royalty revenues. This deep and robust portfolio targeting very large markets provides BioDiem with an improved probability of success and de-risks an investment. We therefore believe that BioDiem is heavily undervalued compared to its current share price.

1. Company Overview

BioDiem (ASX:BDM) is an emerging Australian biotechnology company focused on the development and commercialization of vaccines and vaccine technologies. Its leading technology platform is the Live Attenuated Influenza Virus (LAIV) technology. LAIV is used to develop a novel intranasal vaccine for influenza. The LAIV technology is licensed to the WHO and the Serum Institute in India (SII). The cell based version of LAIV has already completed Phase II clinical trials in Europe as part of development for European approval.

In 2009 BioDiem authorised the Institute of Experimental Medicine (IEM) to share the LAIV technology with the WHO to support its "Global Pandemic Influenza Action Plan to Increase Vaccine Supply" for developing countries. The vaccines developed through the WHO program are manufactured using eggs. Sublicences have been issued to the Serum Institute of India, the Government Pharmaceutical Office, Thailand and Changchun BCHT Biotech in China.

In August 2011 BioDiem entered into a direct private sector licence agreement with the Serum Institute of India (SII) for the LAIV supply in certain territories. Under the new licence with BioDiem the Serum Institute holds an exclusive licence to the egg-based LAIV technology for the private market in India and a non-exclusive licence for the private markets in Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan and Sri Lanka.

At the end of 2011, BioDiem acquired Australian vaccine company Savine Therapeutics. Savine's key asset is the patented Scrambled Antigen Vaccine (SAVINE) technology. This platform technology can be used to design antigens that are able to be incorporated into vaccines for different diseases. Starting with one or more key proteins from microbes or cancers targeted to generate an immune response, a 'scrambled' antigen, or a SAVINE, is fully re-engineered and synthesised in such a way that it can retain key immunologically-relevant characteristics. 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 design novel vaccines. Work has been conducted in both tuberculosis and the Epstein Barr virus-related cancer, nasopharyngeal carcinoma with the SAVINE technology.

In June 2012, BDM acquired an exclusive licence for a flavivirus-based technology (with a dengue fever target) from the John Curtin School of Medical Research at the Australian National University. Dengue fever is the lead indication, but the technology may also facilitate the development of vaccines against a number of other infectious diseases including Murray River encephalitis and Japanese encephalitis. In the same month the company signed an exclusive license with the University of Canberra for a novel vaccine technology targeting hepatitis B and D, which currently have no curative treatment.

BioDiem's antimicrobial candidate BDM-I is in programs with the US Military and also the NIH for infectious

disease targets including biological warfare agents and antibiotic-resistant bacteria and fungi. In vivo testing will commence in 2013 including in a disease model of tuberculosis. BioDiem has also contracted the QIMR to continue to explore the effect of BDM-I in a schistosomiasis animal model building on earlier succesful results.

Business Strategy

With its current partnerships in place and also making future partnerships, BioDiem has the ability to fund its operations primarily through the revenue that the company generates. That is an important component of the strategy and it sets BioDiem apart from the majority of other biotechnology companies.

One of the overriding benefits of BioDiem's partnering network is the ability to accelerate the development of its programs. Partnering is a corner stone of its business strategy.

BioDiem's partners take the form of:

- licensees whereby it receives royalties and upfront fees,
- research collaborations whereby the partner covers the vast majority of development costs, and
- commercial collaborations whereby BioDiem sells its vaccine products but does not receive a royalty – these cases are on compassionate grounds.

This is proving a strong strategy with revenues starting to flow in and with its product development programs developing without the necessity for BioDiem to investment significant R&D costs. Of most importance is that in all cases, BioDiem retains the ownership of all the products. There is also clearly a subtle endorsement BioDiem receives due to the well known and highly selective organisations with which they are partnering.

Partnerships

By partnering its products, BioDiem can tap into the resources and expertise of these groups, and there is also a very strong financial contribution that goes directly to the company's bottom line. With most of its partnerships, the vast cost to resource and accelerate the development of these treatments is carried by the partner which can be worth many millions of dollars to BioDiem. That also gives BioDiem the advantages of retaining the intellectual property which is essential if it wants to derive maximum value once the products are commercialised.

Institute of Experimental Medicine (IEM), Russia

The Institute of Experimental Medicine achieved international prominence early in the 20th century, when Nobel Prize winner Pavlov worked with dogs to establish the central nervous system basis of conditioned reflexes. The IEM has developed a broad-based research capacity in many areas of biology and medicine. In 1956 the IEM's Department of Virology, under Academician Anatoly Smorodintsev, developed live vaccines against polio and in 1959 against measles. These vaccines and derivatives of them were used throughout Russia. After years of research in these and other areas of viral infection the Department turned its attention to influenza. They were able to develop an attenuated form of the influenza virus which would serve as the basis for a safe, live influenza vaccine. In 2001 the IEM entered into a Commercialisation Agreement with BioDiem,

whereby worldwide rights (outside of Russia and the CIS) to the LAIV technology were granted to BioDiem in exchange for a royalty payment. The IEM continues to develop pandemic influenza vaccines including avian influenza and is conducting trials in Russia in this indication for which a broad immune response, such as seen with the LAIV, would prove highly beneficial.

World Health Organization (WHO)

BioDiem contributes to the WHO's Global Pandemic Influenza Action Plan by licensing the WHO to transfer an egg-based live attenuated influenza virus (LAIV) vaccine production technology to developing country manufacturers. The agreement is a non-exclusive licence designed to support wider distribution of the LAIV influenza vaccine in developing countries. Whereas public sector usage is royalty-free, royalties will flow to BioDiem directly from private sector sales. BioDiem has authorised the Institute of Experimental Medicine (IEM) to supply LAIV reassortants to the WHO for use by its sublicencees. The vaccines developed through the WHO program are manufactured using eggs. In September 2009, the WHO issued sublicences to the LAIV technology to two companies: the Serum Institute of India, Pune, India and the Government Pharmaceutical Office, Bangkok, Thailand; and in 2011 to BCHT in China. In July 2010 the Serum Institute of India launched its H1N1 (swine flu) pandemic vaccine, called Nasovac™, in India. This vaccine is a result of the WHO collaboration using BioDiem's technology. BioDiem receives royalty payments on sales of this product in the private market as it will on product from BCHT in China and Thailand GPO once launched in the private market.

Serum Institute of India

Serum Institute of India (SII) is a manufacturer of many vaccines in India. The company is managed by the Poonawalla group - fully owned by Cyrus Poonawalla. The company is the fifth biggest vaccinemaker by volume, the top four being GlaxoSmithKline, Sanofi-Aventis, Merck and Novartis. Half the children in the world are immunized by vaccines made by the company, which is the world's biggest maker of measles and DTP vaccines. Serum produces a billion doses a year selling in 140 countries. It is one of the world's lowest cost producers of vaccines and had sales of USD 250 million and net profits of USD 107 million. The company expects to increase its yearly sales to USD 500 million by 2015. The company said last year that it want to file for a permit at the WHO to export vaccines using BioDiem's LAIV technology. This could mean an important boost for BioDiem's revenues from license income.

Changchun BCHT Biotechnology Co

Changchun BCHT, based in the Jilin Province, was qualified as a high-tech company by the Science and Technology Bureau of the Jilin Province in 2004. The company is focused on R&D, production and sales of innovative medicines, including preventative HIV vaccines. The company has independently researched, developed and manufactured the Varicella vaccine with more than ten other innovative products in pre-clinical and clinical testing. The company's subsidiary Jilin Maifeng Biopharmaceutical Co Ltd, produces and sells

internationally recognized rabies vaccine which has been independently researched and developed by the company. BCHT is currently in the process of constructing a large new production facility at the Changchun National High Tech Industrial Development Zone in China. One of the two new buildings is intended for the manufacture of influenza vaccines based on BioDiem's LAIV technology. In the next few months, BCHT is also planning to file for an application at the Chinese FDA for the approval to start human clinical trials of LAIV flu vaccines to supply the large Chinese private market.

VIVALIS (now Valneva)

VIVALIS is a French based biopharmaceutical company providing 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. The company was founded in 1999 with the aim of better understanding the biological properties of embryonic stem (ES) cells and to use this knowledge for practical applications in human and animal health. Currently, VIVALIS is world leader in ES cells. This has led to the development of its proprietary EB66 platform, a series of documented cell lines derived from chicken and duck ES cells. Its EB66 cell lines grow in suspension in serum-free medium, reach high cell densities and are highly susceptible to most viruses currently produced on chicken eggs or fibroblasts. In August last year, Vivalis announced the successful growth of BioDiem's virus on its EB66 cell line. This growth was at high levels, enough to create a platform for the next stage of development. This would facilitate a shorter and most efficient development of vaccines. Vivalis merged with Intercell in March 2013 to form Valneva.

Program for Appropriate Technology in Health (PATH) Program

PATH is an international nonprofit organization that transforms global health through innovation. In August 2009 the Institute of Experimental Medicine (IEM), the originator of BioDiem's Live Attenuated Influenza Virus (LAIV) technology, entered into a development and collaboration agreement with the PATH, an international non-profit organization to develop prototype pandemic LAIVs for use in developing countries. The aim of this collaboration is to speed the development of live attenuated influenza vaccines that can be a safe, low-cost, and highly effective method for enabling real-time response against an influenza pandemic which is likely to hit developing countries hardest. The first stage of this agreement has seen use of BioDiem's cold-adapted master donor LAIV virus bearing avian or human influenza virus genes from viruses with pandemic potential. Preclinical studies of the vaccine candidates have been completed and clinical trials are planned shortly. PATH will provide financial and technical support to the Institute of Experimental Medicine and third party contractors to a maximum of USD 3.6 million.

Centers for Disease Control and Prevention (CDC)

The aim of the Cooperative Research and Development Agreement (CRADA) between BioDiem and the US Center for Disease Control and Prevention (CDC) was to develop a vaccine candidate against the H5N1 avian influenza based on BioDiem's technology. Preclinical studies to assess the infectivity, immunogenicity and protective efficacy of the H5N1 LAIV versus the standard inactivated influenza vaccine have been successfully completed. The results support the value of the LAIV vaccine technology in protection against the H5N1 virus. In particular it was demonstrated that the cell-based manufacturing method, which allows rapid scale up in the case of a pandemic, produced successful results and that the LAIV vaccine provided greater cross-protection against variants of the H5N1 virus than the inactivated vaccine. This feature could be extremely advantageous in the event of an avian flu outbreak. Also in such a situation, access to chicken eggs could be compromised and so the ability to manufacture flu vaccine rapidly in mammalian cells would give an advantage. Previous published work has demonstrated the efficacy of cell-produced LAIV vaccine vs. egg-produced vaccine in ferret studies.

2. Influenza vaccines: An Introduction

Most people who get influenza will recover in one to two weeks, but some people will develop life-threatening complications (such as pneumonia) as a result of the flu. Millions of people in the United States — about 5% to 20% of U.S. residents — will get influenza each year. An average of about 36,000 people per year in the United States die from influenza, and more than 200,000 have to be admitted to the hospital as a result of influenza. Anyone can get the flu (even healthy people), and serious problems from influenza can happen at any age. People age 65 years and older, people of any age with chronic medical conditions, and very young children are more likely to get complications from influenza. Pneumonia, bronchitis, and sinus and ear infections are three examples of complications from flu. The flu can make chronic health problems worse. For example, people with asthma may experience asthma attacks while they have the flu, and people with chronic congestive heart failure may have worsening of this condition that is triggered by the flu. Influenza A viruses are divided into subtypes based on two proteins on the surface of the virus: the hemagglutinin (H) and the neuraminidase (N). There are 15 different hemagglutinin subtypes and 9 different neuraminidase subtypes, all of which have been found among influenza A viruses in wild birds. Wild birds are the primary natural reservoir for all subtypes of influenza A viruses and are thought to be the source of influenza A viruses in all other animals. Most influenza viruses cause asymptomatic or mild infection in birds; however, the range of symptoms in birds varies greatly depending on the strain of virus. Infection with certain avian influenza A viruses (for example, some strains of H5 and H7 viruses) can cause widespread disease and death among some species of wild and especially domestic birds such as chickens and turkeys.

Influenza viruses can change in two different ways

One is called "antigenic drift." These are small changes in the virus that happen continually over time. Antigenic drift produces new virus strains that may not be recognized by the body's immune system. This process works as follows: a person infected with a particular flu virus strain develops antibody against that virus. As newer virus strains appear, the antibodies against the older strains no longer recognize the "newer" virus, and reinfection can occur. This is one of the main reasons why people can get the flu more than one time. In most years, one or two of the three virus strains in the influenza vaccine are updated to keep up with the changes in the circulating flu viruses. So, people who want to be protected from flu need to get a flu shot every year.

The other type of change is called "antigenic shift." Antigenic shift is an abrupt, major change in the influenza A viruses, resulting in new hemagglutinin and/or new hemagglutinin and neuraminidase proteins in influenza viruses that infect humans. Shift results in a new influenza A subtype.

When shift happens, most people have little or no protection against the new virus. While influenza viruses are changing by antigenic drift all the time, antigenic shift happens only occasionally. Type A viruses undergo both kinds of changes; influenza type B viruses change only by the more gradual process of antigenic drift. Increasing risk for pandemics calls for better vaccines. Every year the World Health Organisation (WHO) determines which virus constraint is expected to be the cause of the next season's flu infection. The WHO gets its information from its labs based all over the world that continuously monitor the flu virus. About 10 months prior to the flu season the vaccine manufacturers are informed about the virus constraint after which the vaccine can be produced. Here it is a first movers market. The producer that is the first to put its vaccine on the US market will gain a considerable part of the market. Speed and adequate capacity are therefore drivers for gaining market share.

The vaccine market: From dull place to hot spot

The vaccines market is undergoing major changes since the recent years, with globalization being at the forefront of all the changes. Dynamic changes brought about by the globalization include regulatory coordination, increased financial support for low-income countries, provision of intellectual property rights through WTO agreements, and the emergence of vaccine manufacturers of developing countries as major market players. However, one major negative aspect of globalization is the evolution of new contagious diseases, including potential threat from bioterrorism. This has, nevertheless, opened a new avenue for vaccine manufacturers, who are coming out with new vaccines to combat bioterrorism.

Unlike several life science sectors that felt the impact of the global crisis, the human vaccines market remained resilient to the global economic recession. Irked by weakened pipelines and growing pressure from patent expiries, the big pharma majors such as AstraZeneca and Pfizer found vaccines industry a safe avenue to invest and register guaranteed revenues. Regional players from the fast developing vaccine markets, such as India and China, are primarily engaged in meeting demands of public supply for routine and immunization vaccines. Increased demand for more number of pediatric vaccines especially in the developing countries, and surging demand for more number of travel vaccines represents the other growth drivers.

GBI Research predicts that the market will grow at a Compound Annual Growth Rate (CAGR) of 3.9% during the 2011–2018 period from USD 2.9 billion to USD 3.8 billion. The major drivers in the market are growing disease awareness, wider vaccination coverage and rising government support for immunization. Limited production capacity, high investment and strict regulations act as barriers for new entrants. The seasonal influenza vaccine market is expected to reach USD 3.8 billion by 2018, at a CAGR of 3.8%. The US seasonal influenza vaccine market is the most attractive of those covered in the report in terms of value. It is forecast to increase from USD 1.6 billion in 2011 to USD 2.2 billion in 2018, at a CAGR of 4.8% due to the large elderly population, higher disease awareness and the fact that it is now more convenient to be

vaccinated. Governments in the top seven nations have responded positively to the threat posed by pandemic

and seasonal influenza outbreaks. A particular challenge is immunizing a country's population in a short time, as vaccines are produced in limited doses by a limited number of manufacturers. This has led to the development of various national immunization programs in the top seven countries to counter this high demand in a pandemic situation. Through these programs, governments can not only immunize those at risk of infection but can also raising awareness of influenza among the general public. These programs have successfully increased vaccination coverage in the top seven countries and coverage is forecast to grow further in the forecast period and beyond.

Next to the so called top seven nations, the Asia-Pacific (APAC) region is an attractive market for seasonal influenza vaccine manufacturers. Major drivers in the market is increasing awareness, increasing vaccination coverage in the APAC countries and rising government support for immunization against seasonal influenza. Major restraints of the market are variable demand and limited production capacity. Traditional egg based manufacturing of seasonal influenza vaccines is being replaced with cell culture vaccines. Cell culture based production of vaccines is expected to reduce the problems associated with the production and use of seasonal influenza vaccines which will further increase the vaccination coverage in the APAC region.

GBI Research forecasts the market to grow at a Compounded Annual Growth Rate (CAGR) of 8.9% during the period 2010-2017 from USD 1,154.9 million in 2010 to USD 2,095.9 million by 2017. Major drivers in the market is increasing awareness, increasing vaccination coverage in the APAC countries and rising government support for immunization against seasonal influenza. Limited production capacity, high investment, and strict regulations act as entry barriers for new entrants in seasonal influenza vaccine market. Australia's seasonal influenza vaccine market is a large sized attractive market forecast to grow at a CAGR of 3.3% during 2010-2017 from USD 87.7 million in 2010 to USD 110.4 million by 2017.

Seasonal influenza vaccine market for China and India are forecast to grow at CAGR of 15.6% and 16.5% respectively during the period 2010-2017. Both of these markets are key markets for BioDiem, taking into account its current partnerships.

The outlook for the total vaccines market remains positive as well, backed by the growing public awareness. Growth would also be dependent on the level of investments in research to determine new technologies. Stronger support from both governmental and non-governmental agencies, such as the WHO and UNICEF, introduction of new vaccines with increased safety and effectiveness, and easy accessibility of vaccines to general public are expected to drive the sales of vaccines in the following years. Key growth propellers for the vaccines market revolves around the development of new therapeutic and prophylactic vaccines for combating HIV/AIDS, Congenital Abnormalities, Malaria, SARS and Cancer, apart from other fatal diseases. Further, technological advancements in the molecular genetics domain would be the major factor driving growth of the human vaccines market.

Prophylactic vaccines constitute the largest earners in the Human Vaccines market. Presently, vaccines are

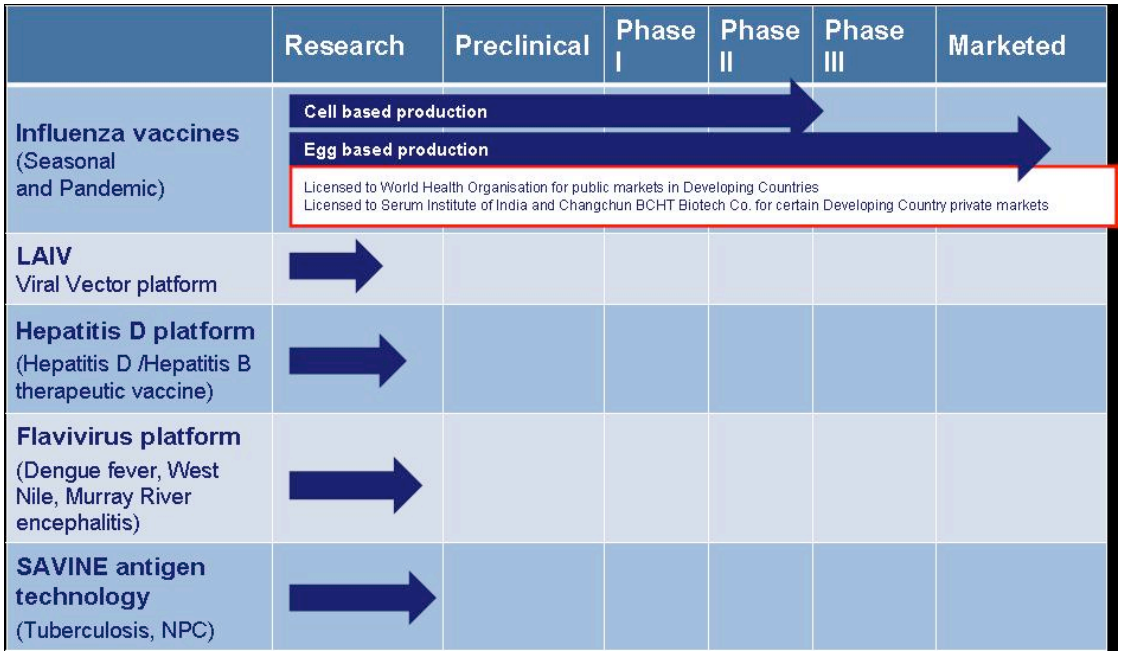
available for select diseases, such as Diarrhoea (Rotavirus), Tetanus, ARI (Pneumococcus), Measles, Pertussis, and ARI (Haemophilus influenzae type B), presenting significant unmet medical needs for several other diseases. Prevnar, Gardasil, Infantrix/Pediatrix, Fluzone, and IPOL were few of the best-selling vaccine brands in the recent years. Other vaccine brands witnessing encouraging gains include Rotarix, Cervarix, and RotaTeq. Therapeutic vaccines are expected to spring major surprises in the years ahead. Therapeutic vaccines are projected to grow rapidly over the coming years. Companies are investing a major chunk of research resources in developing therapeutic vaccines, capable of fighting diseases such as cancer, AIDS, and other fatal diseases.

The US represents the largest market for prophylactic human vaccines, accounting for more than half of the global market. However, growth is forecast to emanate mostly from the developing regions of Asia-Pacific, Latin America, and Rest of World. Asia-Pacific is projected to register the fastest growth of about 15% over the analysis period.

Vaccine	**Company**	**Indication**	**Sales 2012 (USD m)**
Prevnar	Pfizer	Bacterial infection	3718
Gardasil	Merck	HPV	1631
Varivax	Merck	chickenpox	1273
Pentavalent HIB	Sanofi	pediatric	1184
Pediatrix	GSK	pediatric	1162
Fluzone	Sanofi	influenza	1149
Hep vaccines	GSK	Hepatitis	969
Zostavax	Merck	Shingles	651
RotaTeq	Merck	Pediatric/rotavirus	601
Pneumovax	Merck	Bacterial infections	580
Synflorix	GSK	Bacterial infection	578

3. Product Pipeline

BioDiem has one of the strongest and deepest product pipelines in the sector with its vaccine products generating recurring revenues and development programs that have the potential to treat well know diseases such as TB, hepatitis and antibiotic resistant infections that currently have no or ineffective treatments. With many of these products BioDiem has an opportunity for rapid commercialisation due to the very high unmet need to find better treatment options.



Source: BioDiem

Product	Disease Targets	Current Partners	Development Status
LAIV Vaccine (Influenza)	Influenza – Seasonal & Pandemic	WHO SII (India) BCHT (China) IEM (Russia)	Marketed with license revenues of A$1.3m FY2012 Phase II (cell-based production technology). BioDiem is seeking to grow and expand out-licensing for both its cell-based and the egg-based influenza vaccine technology in multiple markets.
	Bird flu	IEM/WHO	Clinical trial completed in Thailand and Russia
Product	**Disease Targets**	**Current Partners**	**Development Status**
LAIV Vector (Vaccine delivery)	Vaccine development	VIVALIS	First stage of development project completed
SAVINE (Custom vaccines)	Nasopharyngeal carcinoma (NPC), tuberculosis (TB)	In-house	Seeking partner for more advanced data in animals
Product	**Disease Targets**	**Current Partners**	**Development Status**
BDM-I (Antimicrobial)	Tuberculosis	US government backed research institutions	Will enter *in vivo* testing in 2013
	Fungal infections	US government backed research institutions	Success in expanded *in vitro* screening studies
	Parasitic diseases (schistosomiasis, others)	QIMR program	Will enter *in vivo* testing in 2013

BioDiem's lead product is the Lead Attenuated Influenza Virus (LAIV) technology. The LAIV technology serves two purposes: firstly, as a basis for production of novel intranasal vaccines to prevent infection from seasonal and pandemic influenza. The LAIV vaccines can be manufactured by traditional egg-based production methods or by advanced cell-based production methods. Secondly, BioDiem believes that the LAIV may also serve as the basis for a "viral vector" technology. Viral vectors are viruses which are used as a delivery tool for proteins (antigens or epitopes) in vaccines to generate a helpful immune response in the host.

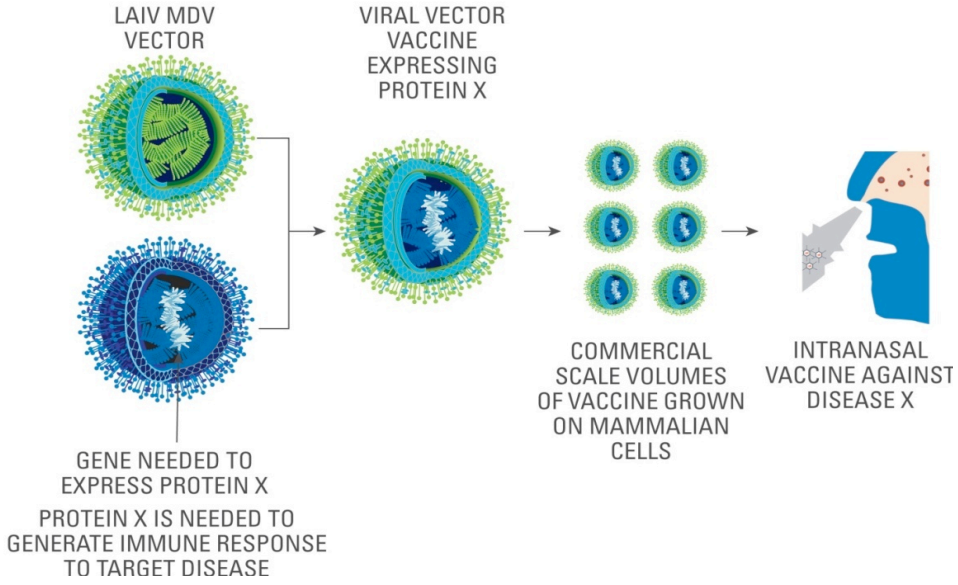
BioDiem has two other assets: BDM-I: a novel compound active against a range of pathogenic micro-organisms including bacteria, fungi and protozoa. It is being developed as an antimicrobial agent for human use. BDM-E – a tetrapeptide being developed as a treatment for ophthalmic disorders. The company intends to sell or licensing out this compound.

Adding to the pipeline, in December 2011 BioDiem acquired Savine Therapeutics. Savine's key asset is the patented Scrambled Antigen Vaccine (SAVINE) technology. This platform technology can be used to design antigens that are able to be incorporated into vaccines for different diseases.

With its core development programs addressing very large markets that currently have suboptimal treatment or opportunities for vast product improvements, BioDiem seems to be operating in the right space. The vaccine market, of which the company is already accessing albeit on a small scale right now is open for BioDiem to pursue via its partners markets and also attract the attention of very large pharmaceutical players jostling for market share and new product differentiators.

BioDiem's Live Attenuated Influenza Virus vaccine (LAIV)

BioDiem is using the Live Attenuated Influenza Virus vaccine technology, which was in licensed from the IEM in St- Petersburg, Russia. The LAIV vaccine 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. BioDiem Master Strains grow at 25°C. The administration of the live vaccine stimulates a broad mucosal, cellular and humoral immune response (all of which are required to optimise the effective prevention of influenza), without causing the disease. The LAIV influenza vaccine is marketed as Nasovac in India by the Serum Institute of India (SII).



In 2011, BioDiem regained the rights to its Live Attenuated Influenza Vaccine (LAIV) candidate from Nobilon International B.V., a member of the MSD group (known as Merck in the United States and Canada). MSD's decision to return the rights to the LAIV technology came as a result of the company's on-going pipeline prioritization efforts. BioDiem has exclusive rights to commercialize the LAIV technology outside Russia and the Commonwealth of Independent States. Unlike the more traditional influenza vaccinations, which are injected, the LAIV vaccine is a nasal spray and contains live viruses. However, the viruses are attenuated (weakened) and do not cause serious illness.

The LAIV vaccine has a number of advantages. Extensive clinical trials and over fifty years use in Russia have established the safety and efficacy profile of the LAIV vaccine. The LAIV vaccine is suitable for rapid production via cell-based manufacture giving a high yield and can also be manufactured using eggs with an increased yield compared to other vaccine technologies.

One major advantage of the LAIV vaccine over the standard flu shot is that it is a nasal spray so does not require injections or trained personnel. This makes it easier to use and administer. It also appears that vaccination using the LAIV offers immunological advantages in that it produces immunity similar to natural infection thus creating a broader immune response involving mucosal, humoral and cellular immunity. Inactivated vaccines do not induce mucosal immunity. It has been shown in several studies that the LAIV vaccine provides better herd immunity than inactivated vaccines. In particular, in the Novgorod school study, it was observed that influenza morbidity was significantly lower among nonvaccinated pupils and staff, where more than 50% pupils were vaccinated, compared with those schools, where pupils received inactivated influenza vaccine..[1] It has been demonstrated in Russian clinical trials that the LAIV vaccine provided 59%

[1] (*Ref. Rudenko L.G., Slepushkin A.N., Monto A.S., et al., Efficacy of live attenuated and inactivated influenza vaccines in schoolchildren, J. Infect*

protection in situations in which the epidemic influenza strain was different from the vaccine strain virus ("cross protection") [2]

BioDiem's LAIV provides broad protection against "drifted" variants of influenza. In years where the vaccine strain has not exactly matched the circulating strain of influenza, the standard inactivated flu shot has provided protection at little more than placebo rates. This is important because the WHO strain selection for seasonal vaccines is based on expectation of what strains will circulate which is extremely difficult to predict into the future.

Flu vaccines are available either as:

- TIV (flu shot (injection) of trivalent (three strains; usually A/H1N1, A/H3N2, and B) inactivated (killed) vaccine) or

- LAIV (nasal spray (mist) of live attenuated influenza vaccine.)

TIV works by putting into the bloodstream those parts of three strains of flu virus that the body uses to create antibodies; while LAIV works by inoculating against those same three strains that have been genetically modified to minimize symptoms of illness. LAIV is not recommended for individuals under age 2 or over age 50, but might be comparatively more effective among children over age 2.

LAIV Vector Technology

Viral vectors are a tool commonly used by molecular biologists to deliver genetic material into cells. This process can be performed inside a living organism (in vivo) or in cell culture (in vitro). Viruses have evolved specialized molecular mechanisms to efficiently transport their genomes inside the cells they infect. Delivery of genes by a virus is termed transduction and the infected cells are described as transduced. Molecular biologists first harnessed this machinery in the 1970s. Paul Berg used a modified SV40 virus containing DNA from the bacteriophage lambda to infect monkey kidney cells maintained in culture.

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dis. 168 (1993) 881-887).

[2] *(Rudenko L.G., Live attenuated vaccine in Russia: Advantages, further research and development.. In Proceedings of "Options for the control of influenza VI, Toronto, Ontario, Canada, June 17–23, 2007. //International Medical Press Ltd., 2008 . – P. 122–124. Grigorieva E.P., Drinevsky V.P., Doroshenko E.M., Erofeeva M.K., Desheva J.A., Maksakova V.L., RudenkoL.G., Efficacy of live attenuated cold-adapted reassortant influenza vaccine during the circulation of driftinfluenza viruses. Epidemiology and vaccinal prevention, 2009, 1 (44), pp. 45-53.)*

Viral vectors are tailored to their specific applications but generally share a few key properties.

- **Safety:** Although viral vectors are occasionally created from pathogenic viruses, they are modified in such a way as to minimize the risk of handling them. This usually involves the deletion of a part of the viral genome critical for viral replication. Such a virus can efficiently infect cells but, once the infection has taken place, requires a helper virus to provide the missing proteins for production of new virions.

- **Low toxicity:** The viral vector should have a minimal effect on the physiology of the cell it infects.

- **Stability:** Some viruses are genetically unstable and can rapidly rearrange their genomes. This is detrimental to predictability and reproducibility of the work conducted using a viral vector and is avoided in their design.

- **Cell type specificity:** Most viral vectors are engineered to infect as wide a range of cell types as possible. However, sometimes the opposite is preferred. The viral receptor can be modified to target the virus to a specific kind of cell. Viruses modified in this manner are said to be pseudo typed.

- **Identification:** Viral vectors are often given certain genes that help identify which cells took up the viral genes. These genes are called Markers, a common marker is antibiotic resistance to a certain antibiotic. The cells can then be isolated easily as those that have not taken up the viral vector genes do not have antibiotic resistance and so cannot grow in a culture with antibiotics present.

BioDiem's LAIV vector research aims to produce a platform technology to assist in the design of vaccines for different diseases including cancers. The initial phase of the laboratory work will be to ascertain the feasibility of the approach. The advantage of the LAIV virus technology is that it has a documented safety profile from its use in Russia over many years and through its use in the European clinical trial program as an influenza vaccine. BioDiem has access to GMP virus materials (LAIV) will enhance the value of the vector project. There are a number of critical steps in the project including importation and regulatory approvals for the biological starting materials, and the confirmation of the feasibility of using the LAIV, the 'flu virus itself, as a vector in an artificial model. Following this successful demonstration, specific cancer and infectious diseases will be targeted in animal models i.e. nasopharyngeal carcinoma and respiratory syncytial virus, respectively.

The table shows various vector systems in development for vaccine design. Viral vectors compare very favourably to other technologies.

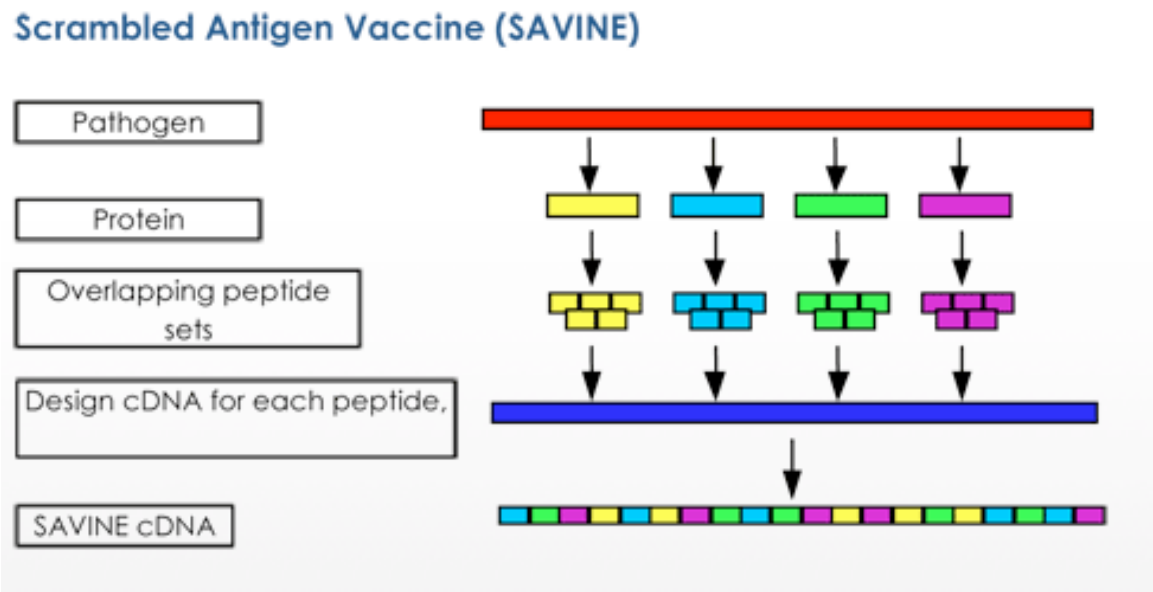
	Efficacy	Safety/ reactogenicity*	Protection of antigens from degradation	Targeted delivery	Adjuvant effect
Live-attenuated pathogens	+++	+	Various	Good	None per se
Killed pathogens	++	++	Various	Good	None per se
Subunit vaccines	+	+++	Weak	Weak	None per se
Viral/bacterial vectors	++	++	Various	Good	High
Liposomes	+	++	Moderate	Good	Various
Virosomes	++	++	Good (coated)	Good	Various
Virus-like particles (VLPs)	++	+++	Various	Good	Various
ISCOMs	++	+	Moderate	Good	High
Micro-/nanoparticles	+	++	Various	Various	None per se

*+ = safety/reactogenicity concerns; +++ = good safety/reactogenicity profile
ISCOMs=immunostimulating complexes

Source: Datamonitor

Acquisition of Savine Therapeutics highly complement to LAIV technology

In December 2011, BioDiem acquired Savine Therapeutics. Savine's key asset is the patented Scrambled Antigen Vaccine (SAVINE) technology. This platform technology can be used to design antigens that can be incorporated into vaccines for different diseases. Starting with one or more key proteins from microbes or cancers targeted to generate an immune response, a 'scrambled' antigen, or a SAVINE, is fully re-engineered and synthesised in such a way that it can retain key immunologically-relevant characteristics. 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 design novel vaccines. The SAVINE technology is a method for designing synthetic vaccines that stimulates and enhances the body's immune system. Synthetic genes are designed and constructed such that they encode 'scrambled' protein sequences from infectious agents or cancers, packaged appropriately for delivery to the body using standard genetic-based delivery vectors.



The SAVINE technology has significant advantages over traditional whole gene or attenuation vaccine approaches as well as more recent epitope-based approaches. These advantages include:

- Enhanced Safety: Safety is improved because the biological functions of the selected proteins/genes are destroyed by the fragmentation and 'scrambling' of the protein sequences. In this way the entire sequences of key immunogenic, but potentially dangerous, proteins can now be included in a vaccine (e.g. cancer & HIV).

- Extended Population Coverage: SAVINE offers more complete population coverage than epitope-based approaches because all the potential T cell epitopes are incorporated under the SAVINE technology. In this way SAVINEs are more similar to whole pathogen-based approaches. Moreover, processing and presentation of pathogen epitopes to the immune system is often improved because a) the original structure of selected proteins is destroyed and b) the synthetic DNA utilizes optimised amino acid codons that often improve expression of the designed synthetic protein. Incorporation of maximal sequence information means that SAVINE therapies will have application in populations with diverse ethnic spreads. Additionally, the efficacy of cancer SAVINEs is less likely to be affected by the ability of cancers to escape immune control by down-regulating targeted antigens.

- Cost Effective Development: SAVINE therapies remove the need to isolate specific DNA, fully characterise pathogens or cancer antigens or identify epitope sequences. The relatively small number of components in SAVINEs while still encoding large amounts of immunological information means that SAVINEs will be cost effective to manufacture.

SAVINE had validated four constructs for nasopharyngeal carcinoma (NPC) and other Epstein Barr virus (EBV) related lymphomas, tuberculosis (TB), HIV, and HCV.

The SAVINE technology is one example of BioDiem's strategic acquisition to bolster its existing technology portfolio via complementary additions. The driving rationale is to expand the number of disease targets possible at low cost, enhancing the chances of successful development and/or outlicensing.

BDM-E: Ophthalmic Eye Disease

In September 2010 BioDiem received Orphan Drug designation from the United States Food and Drug Administration (FDA) for BDM-E for the treatment of Retinitis Pigmentosa. BioDiem's preclinical work in Retinitis Pigmentosa has demonstrated promise. In vivo studies have shown that BDM-E is able to reduce the degree of damage to the retinal cell layers. It has also been shown to exert a degree of protection over the retina in models of this disease. In another research model of light damage it prevented photoreceptor apoptosis (programmed cell death). Through the use of BDM-E in Russia and results of an earlier clinical trial, BDM-E has already shown a good safety profile in the dose administered.

Preclinical studies at Monash University and the University of Melbourne have demonstrated that BDM-E produces positive effects in retinopathy of prematurity, a model of eye disease. These studies have been extended to other laboratory eye disease models such as diabetic retinopathy and age-related macular degeneration. Supported by this work, the company has submitted a new provisional patent covering BDM-E analogues. This will further strengthen the patent position of BDM-E and enhance its attractiveness for out licensing or a sale in line with BioDiem's strategy for this asset. The research results were presented in July 2012 at the International Society of Eye Research (ISER) meeting in Berlin, Germany.

In May 2012, BioDiem announced a research agreement with the Foundation Fighting Blindness (FFB) in the United States. This further preclinical work is being conducted at the Kearn Family Center for the study of Retinal Degeneration, headed by Dr. Matthew LaVail at the University of California, San Francisco, and is testing BDM-E in a model of the inherited degenerative eye disorder RP. The study will help to evaluate the potential of BDM-E to treat retinitis pigmentosa and the spectrum of RP-like diseases in humans.

BioDiem's strategy for BDM-E is to finalise its data package in preparation for sale or outlicensing. The strategic focus on vaccines and therapies for infectious diseases and specific cancers has meant the most appropriate way for BioDiem to extract value from BDM-E is via a high-value divestment. The current preclinical program with the FFB is in aid of this objective.

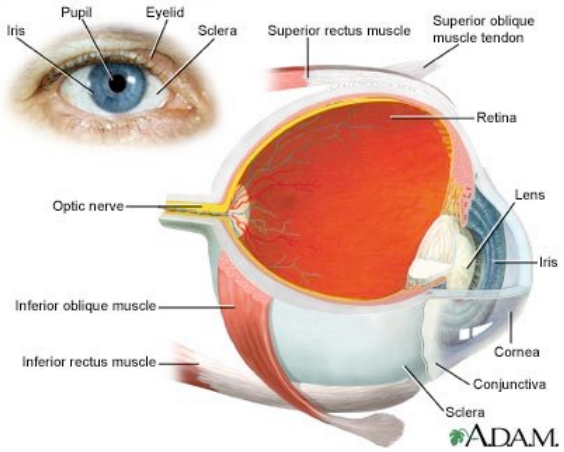
BioDiem acquired the rights for BDM-E, outside of Russia, from the Institute of Bioregulation and Gerontology (IBG) in St Petersburg. The Institute had undertaken both preclinical and clinical data to support the development of this product. To date, one clinical trial with BDM-E has been completed by BioDiem in

diabetic macular oedema. This was a Phase I/II randomised, double-blind, placebo-controlled study undertaken to Good Clinical Practice (GCP) standards in Russia and completed in August 2007. The study compared the safety and efficacy of once daily subcutaneous administration of 10 μg BDM-E for ten consecutive days with that of placebo. Efficacy was determined by optical coherence tomography (OCT) and visual acuity.

BDM-E was well tolerated by the patients in this study and there were no Serious Adverse Events (SAEs) or ocular events considered to be related to BDM-E administration. However, there was no statistically significant difference from placebo in OCT or visual acuity measurements following BDM-E treatment. It has been suggested that this may be due to the dose being too low, or to the indication being relatively insensitive to BDM-E. These concerns have led to a proposal to investigate BDM-E in a different and potentially more sensitive indication of retinitis pigmentosa (RP), with a study design which will include higher doses. Furthermore, to increase the appeal of BDM-E to major pharmaceutical companies, the study will be conducted under a US IND. This updated development plan provides timelines and costings for a Phase I clinical trial in healthy volunteers to be followed by a Phase IIa study in RP. The IND will be filed for the Phase I study, and Phase II clinical study initiated under a protocol amendment to the IND. In September 2010 the United States Food and Drug Administration (FDA) granted Orphan Drug designation to BDM-E for the treatment of Retinitis Pigmentosa.

Retinitis Pigmentosa

Retinitis pigmentosa (RP) is a group of genetic eye conditions that leads to incurable blindness. In the progression of symptoms for RP, night blindness generally precedes tunnel vision by years or even decades. Many people with RP do not become legally blind until their 40s or 50s and retain some sight all their lives. Others go completely blind from RP, in some cases as early as childhood. Progression of RP is different in each case. RP is a type of progressive retinal dystrophy, a group of inherited disorders in which abnormalities of the photoreceptors (rods and cones) or the retinal pigment epithelium (RPE) of the retina lead to progressive visual loss. Affected individuals first experience defective dark adaptation or nyctalopia (night blindness), followed by reduction of the peripheral visual field (known as tunnel vision) and, sometimes, loss of central vision late in the course of the disease



Normal vision

As seen by a person with retinitis pigmentosa

An estimated 100,000 people in the U.S. have RP, mainly caused by mutated genes inherited from one or both parents. Mutated genes give the wrong instructions to photoreceptor cells, telling them to make an incorrect protein, or too little or too much protein. (Cells need the proper amount of particular proteins in order to function properly.) Many different gene mutations exist in RP. In Usher syndrome, for example, at least 14 disease-causing genes have been identified.

BioDiem's preclinical work in Retinitis Pigmentosa has demonstrated promise. In vivo studies have shown that BDM-E is able to reduce the degree of retinal damage of the retinal cell layers. It has also been shown to exert a degree of protection of the retina in models of this disease. In another research model of light damage it prevented photoreceptor apoptosis (programmed cell death). Through the use of BDM-E in Russia and results of an earlier clinical trial, BDM-E has already shown a good safety profile in the dose administered. Nonclinical studies at Monash University and the University of Melbourne have demonstrated that BDM-E produces positive effects in retinopathy of prematurity, a model of eye disease. These studies have been extended to other laboratory eye disease models such as diabetic retinopathy and age-related macular degeneration. A review of the most recent nonclinical data is being undertaken to ascertain whether additional intellectual property can be established around analogues of BDM-E. The results completed thus far are commercial-in-

confidence pending appropriate intellectual property protection. Subject to the results of the data review an out licensing package will be finalised and study results presented and published in international forums. A partner is sought to continue the development of BDM-E for the indication of retinitis pigmentosa and other eye diseases.

BDM-I Antimicrobial

Impressively broad preclinical activity has brought this asset to the fore of BioDiem's early-stage portfolio, especially in the light of its activity against both "neglected' diseases of the developing world (e.g. schistosomiasis) and treatment-resistant strains of microbes like Staphylococcus aureus (MRSA) and Aspergillus fumigatus.

The fight against bacterial infection represents one of the high points of modern medicine. The development of antibiotics in the 1940s offered physicians a powerful tool against bacterial infections that has saved the lives of millions of people. However, because of the widespread and sometimes inappropriate use of antibiotics, strains of bacteria have begun to emerge that are antibiotic-resistant. These new, stronger bacteria pose a significant threat to general welfare and health—and a challenge to researchers.

Bacterial infections can be caused by a wide range of bacteria, resulting in mild to life-threatening illnesses (such as bacterial meningitis) that require immediate intervention. In the United States, bacterial infections are a leading cause of death in children and the elderly. Hospitalized patients and those with chronic diseases are at especially high risk of bacterial infection. Common bacterial infections include pneumonia, ear infections, diarrhea, urinary tract infections, and skin disorders.

Under normal circumstances, people are protected from bacterial infection by a healthy immune system. In a world of increasing numbers of survivors of cancer treatment and people living with HIV, there in a increasing spread of infections taking advantage of the weaker immune system. This includes fungi e.g. aspergillus and candida.

BioDiem's BDM-I is a novel compound active against a range of pathogenic micro-organisms including bacteria, fungi and protozoa. The continued rise in antibiotic-resistant strains of bacteria such as MRSA has led to significant interest in such compounds. Research work completed in the United States and Australia, supplementing earlier Russian studies, has demonstrated the potential value of BDM-I as an antimicrobial, effective against many serious human disease-causing microbes. As the inventors of the technology, the IEM conducted very broad spectrum antimicrobial studies of BDM-I.

The method selected was agar diffusion method, analogous with that used for antibiotic assays, also in consideration of the lack of solubility. A very large group of antibiotics (15) was used as comparators, and as the screening data was generated, clinically relevant strains were included for genera or species in which

antimicrobial activity had been observed.

The data demonstrated BDM-I to be broad spectrum and active against strains not sensitive to any of the selected antibiotics or sensitive to a minimal number.

Testing results from the National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIH NIAID's) In Vitro Assessment for Antimicrobial Activity Service turned out to be encouraging. BioDiem has now entered the NIH's NIAID's Animal Models of Infectious Disease Service to further evaluate BDM-I's activity in in vivo models.

The company will be seeking interested partners to develop BDM-I further for the indications of serious fungal and bacterial diseases. The company will also seek collaboration with drug delivery technology companies to expand the routes of administration for which the product can be developed. BioDiem will approach potential licencees to complete the development work and clinical trials. Because of the increasing levels of antibiotic resistance in the community as well as in hospitals, interest in BDM-I is rising.

In February this year, BioDiem announced that BDM-I started a new phase of research with the US Army Medical Research Institute of Infectious Diseases (USAMRIID). This phase will include studies in an animal model to confirm the available drug concentration provided by different routes of administration and an efficacy evaluation in an animal model for a number of highly infectious pathogens.

Antibacterial market worth billions and growing faster

The pharmaceutical industry owes a great deal of its early prosperity to the development of antibacterial drugs, and as a consequence the market encompasses several of the oldest drug classes. The market is highly saturated and has significant generic penetration, yet still experiences continuous growth due to increasing sales volume, as well as the rise of premium-priced novel treatments for resistant bacteria (for example, Pfizer's Zyvox (linezolid)). Key drivers for this market include the growing number of people with weakened immune systems, such as the elderly and immunosuppressed patients (HIV patients and organ recipients, for example). However, the development of antibacterials has become increasingly unattractive to big pharma for a number of reasons:

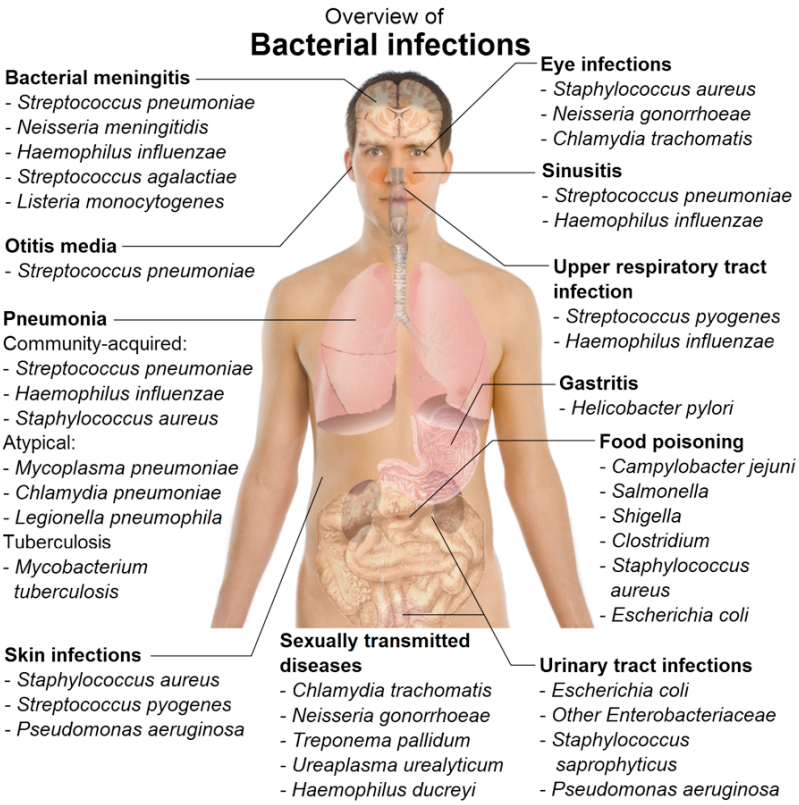
short antibacterial drug lifecycles; the fact that antibacterial therapy is acute, not chronic; the mature nature of the market, which is characterized by low growth and high generic penetration; and the raising of the bar for the statistical standards needed to show the efficacy of experimental drugs in clinical trials. A key factor contributing to shorter drug lifecycles is bacterial resistance.

Shorter lifecycles increases the risk to drug developers (as they have less time to recoup their R&D investments); restricts sales growth (as many governments have introduced schemes to limit antibiotic use to combat resistance issues such as methicillin-resistant Staphylococcus aureus (MRSA) – which BDM-I has

displayed activity against - and prioritizes the need for intensive lifecycle-management strategies (for example, developing an extended-release formulation).

The antibacterials market is highly fragmented and can be split into two major groups: the larger community market (estimated at 62% of total antibacterial sales), with a lower average drug price and growth prospects; and the smaller but more attractive hospital market, with a higher average drug price and growth prospects. There is no single market-leading drug or class of antibacterials. Penicillins (for Gram-positive pathogens) and cephalosporins (for Gram-positive and Gram-negative pathogens) are the most widely used antibacterials, followed by fluoroquinolones for Gram-negative pathogens. Macrolides are popular for respiratory- and urinary-tract infections — the two commonest indications for antibacterials.

Antibiotic resistant infectious diseases impose a significant burden on society, and surpass USD 30 billion in annual direct treatment costs in the U.S. alone. The high cost stems from several key factors: (1) Individuals infected with drug resistant organisms usually have a poor prognosis and are more likely to require hospitalization and (2) drug-resistant infections acquired in hospitals nearly triple the cost of hospital stays. The cost of antibiotic resistance is expected to grow larger as medical experts anticipate record increases of antibacterial resistance in the next decade. Survey shows mounting costs from antibiotics resistant bacteria. In 2000 and 2001 the Agency for Healthcare Research and Quality did a Nationwide Inpatient sample of hospitals in the US. All inpatient discharge data from 994 hosptials, representing around 14 million inpatient stays, were analyzed to determine the association of S Aureus infections with length of stay, total charges and in-hospital mortality. S Aureus infection was reported for 0.8% of all hospital inpatients, or 292,045 stays per year. Inpatients with the infection had to stay on average 3 times longer and therefore 3 times to total charges of USD 48,824 instead of USD 14,141. Next to the cost, the risk of in hospital death was 5 times higher than inpatients without the infection. The S Aureus infections represent a growing burden to hospitals all over the world with the bacteria becoming more resistant to current antibiotics treatments. The potential benefit to hospitals in terms of reduced use of resources and costs as well as preventing S Aureus infections are significant.



As one example of BioDiem's work developing the multi-target potential of the BDM-I asset, the Company has also commenced work with Prof Don McManus of the Queensland Institute of Medical Research (QIMR) to investigate BDM-I in a proof of concept (POC) model against schistosomiasis, also known as bilharzia. The Company said last month that Prof McManus and QIMR would proceed with a broader proof-of-concept investigation looking at multiple parasite strains and at different lifecycle stages. If successful, BioDiem will then continue into an efficacy study in schistosoma-infected mice.

Schistosomes are flatworm (Platyhelminth) parasites responsible for the severe human disease schistosomiasis (Bilharzia) in tropical developing nations. Currently 200 million people are infected, with 600 million people at risk. There is great need for novel therapeutic drugs and prophylactic treatments for the disease.

Schistosomiasis is obviously one of the recognised neglected diseases of the developing world causing significant morbidity. This may open the way for non-dilutionary funding for the further development of BDM-I.

4. Management Capabilities

BioDiem for long have been investing in developing a team of experts that have a focus on patient outcomes and can deliver results. Its senior management team is highly experienced in the preclinical and clinical development of new drugs as well as early stage commercialisation.

Management Team

Julie Phillips, Managing Director and Chief Executive Officer

Ms Phillips was appointed to the position of Chief Executive Office on July 1, 2009 and was appointed a director on May 7, 2010. She has a strong background in the biotech and pharmaceutical industry, having worked as the CEO and director of start-up Australian biotechnology companies operating in the life sciences sector. Her technical background in clinical trials, regulatory affairs and pharmacoeconomic assessment/pricing of therapeutics was gained in multinational pharmaceutical companies with responsibility for market entry of new products in Australia and New Zealand.

John Rawling, Chief Financial Officer

Mr Rawling was appointed to the position of Chief Financial Officer in November 2012. He is a Chartered Accountant and Chartered Secretary with more than 30 years of experience working with both International and ASX listed companies. John currently works with Leydin Freyer Corporate providing company secretarial and financial services. He has previously held the position of Company Secretary/CFO for a number of small listed companies in the biotech, resources and financial services industries.

Hugh M Morgan AC, Chairman

Hugh Morgan is Principal of First Charnock. He is a member of the Lafarge International Advisory Board; an Emeritus Trustee of The Asia Society New York; Chairman Emeritus of the Asia Society AustralAsia Centre; President of the National Gallery of Victoria Foundation and Chairman of the Order of Australia Association Foundation. He is a Non-Executive Director of Hexima Limited. He was a Director of the Board of the Reserve Bank of Australia for 14 years. From 2003–2005 he was President of the Business Council of Australia. He is also immediate Past President of the Australia Japan Business Co-operation Committee and a Past Co-Chair of the Commonwealth Business Council and continuing Emeritus Director. He is a graduate in Law and Commerce from the University of Melbourne and was Chief Executive Officer of WMC Limited from 1986 to 2003. He was a Director of Alcoa of Australia from 1977 to 1998 and a Director of Alcoa Inc from 1998 to 2001.

Catherine Cropp, Projects Manager

Ms Cropp was appointed Projects Manager in 2010 and is responsible primarily for managing the LAIV vaccine vector and BDM-I anti-microbial projects. Cathy is a microbiologist with over 20 years experience in international quality/compliance, manufacturing and drug, biologicals and vaccine development management in both the international and domestic pharmaceutical and biotech sectors. Her core skills revolve around Good Laboratory, Manufacturing and Clinical Practice compliance on an international level. She has considerable knowledge in regulatory affairs and clinical development strategies and the development and implementation of manufacturing processes for investigational new therapeutic agents appropriate for clinical use.

Larisa Rudenko, Non executive Director

Professor Rudenko is Head of the Virology Department in the Institute of Experimental Medicine, St. Petersburg, Russia. Professor Rudenko worked with Academician Smorodintsev and has been responsible for the development and clinical trials of the live attenuated influenza vaccines in Russia. She is recognised as one of the world's leading experts in live attenuated influenza vaccines and as such has worked closely over the past 20 years with scientists at the Centers for Disease Control and Prevention, Atlanta, USA in developing effective influenza prophylaxis programs for use in children and in the elderly. She has published in excess of 225 scientific papers and 42 patents. Under her supervision, 11 PhD and 2 DSc theses have been prepared. In 1999 her contribution to medical science was recognised with the award of the title of Honoured Scientist of the Russian Federation. Professor Rudenko is currently leading the WHO and PATH programs, developing a new pandemic LAIV for developing countries.

Don Brooks, Non Executive Director

Don Brooks, a graduate of Columbia University School of Law, is a US-based lawyer, who for many years was Senior Counsel-Licensing at Merck & Co., Inc. and was formerly its Counsel for U.S. pharmaceutical operations and Counsel for its research operations. Don retired from Merck in 1993 and since that time has served as Counsel to a U.S. law firm representing clients in the biotechnology industry, as well as serving as an advisor to firms in the biotechnology and the pharmaceutical industry in general. He is also former general counsel of Maryland-based biotech company, EntreMed Inc.

Professor Arthur Li

Professor Li was appointed a Director on May 7, 2010. Professor Arthur Li was awarded the degree of Doctor of Medicine by University of Cambridge, UK. He is a well-credentialed and respected educator and surgeon who is currently Deputy Chairman of The Bank of East Asia and is Emeritus Professor of Surgery of The Chinese University of Hong Kong. He is a member of the Executive Council of the Hong Kong Special Administrative Region. He is also a director of AFFIN Holdings Berhad. Among his many previous appointments and associations, he has been a Council Fellow of the University of Melbourne, Dean of the Faculty of Medicine and Vice-Chancellor of The Chinese University of Hong Kong. Professor Li was the Secretary for Education and Manpower of the Government of HKSAR. He was also a member of the board of

Glaxo Wellcome plc. He is a member of the National Committee of the Chinese People's Political Consultative Conference.

Melanie Leydin, Company Secretary

Ms Leydin was appointed to the position of Company Secretary on 14 November 2012. She is a Chartered Accountant and is a Registered Company Auditor with more than 20 years experience in the accounting profession. In 2000 she established her own chartered accounting practice Leydin Freyer, specialising in audit and public company consulting. Melanie is a director and company secretary for a number of biotech, oil and gas, junior mining and exploration entities listed on the Australian Securities Exchange.

5. Competitive Landscape

Peer Group Company Profiles

We think the best comparables to BioDiem are companies which are working on:

• influenza vaccines;

• Intranasal and live attenuated vaccines

We have identified several companies that best fit this description.

MedImmune/AstraZeneca

MedImmune, headquartered in Gaithersburg, Maryland, became a wholly owned subsidiary of AstraZeneca in 2007. Since being acquired, MedImmune has remained a Maryland-based biotechnology development enterprise. It produces FluMist, a nasal spray influenza vaccine introduced in 2004. MedImmune acquired FluMist when it purchased Aviron in 2002 for US$ 1.5 billion. n June 2007, the National Institutes of Health (NIH) began enrolling participants in a Phase 1 H5N1 study of an intranasal influenza vaccine candidate based on MedImmune's live, attenuated vaccine technology. MedImmune said it was making a significant, rapid response with a vaccine to the novel H1N1 variant of influenza, known as swine flu. In June 2009 it won a Department of Health and Human Services (HHS) contract, worth $90m. Under the contract with HHS, MedImmune will continue to make its seasonal FluMist vaccine and also develop a vaccine targeted specifically at the novel H1N1 virus. MedImmune then won a second contract to test its nasal spray flu technology as a viable treatment for the H1N1. MedImmune received approval from the U.S. FDA for its intranasal novel H1N1 influenza virus in September 2009. The vaccine was approved for use in the European Union by the European Medicines Agency in 2011. Marketing approval in Europe, where it will be called Fluenz, is for the prevention of seasonal influenza in children aged from two to less than 18 years, though distribution will not likely begin until 2012. FluMist sales totalled USD 161 million in 2011, USD 174 million in 2010 and USD 145 million in 2009.

Johnson&Johnson/Crucell

Crucell is a global biopharmaceutical company focused on research development, production and marketing of vaccines, proteins and antibodies that prevent and/or treat infectious diseases. Crucell is one of the major suppliers of vaccines to UNICEF and the developing world. Crucell was the first manufacturer to launch a fully-liquid pentavalent vaccine. Called Quinvaxem(R), this innovative combination vaccine protects against five important childhood diseases. Over 200 million doses have been sold since its launch in 2006 in more than 50 GAVI countries. With this innovation, Crucell has become a major partner in protecting children in developing countries. Other products in Crucell's core portfolio include a vaccine against hepatitis B and a

virosome-adjuvanted vaccine against influenza. Crucell also markets travel vaccines, such as an oral anti-typhoid vaccine, an oral cholera vaccine and the only aluminum-free hepatitis A vaccine on the market. The Company has a broad development pipeline, with several product candidates based on its unique PER.C6) production technology. The Company licenses its PER.C6 technology and other technologies to the biopharmaceutical industry. Important partners and licensees include Johnson & Johnson, DSM Biologics, sanofi-aventis, Novartis, Wyeth, GSK, CSL and Merck & Co. Crucell is headquartered in Leiden, the Netherlands, with offices in China, Indonesia, Italy, Korea, Malaysia, Spain, Sweden, Switzerland, UK, the USA and Vietnam. Since 2011, Crucell is part of Johnson&Johnson.

Vaxin Inc (US)

Vaxin Inc. is an emerging biotechnology company developing vaccines and other biological products to address market and public health needs. The company uses proprietary technology for non-invasive delivery to the nasal passages or to the skin, and has shown proof of principle in animals and in initial human clinical studies. Vaxin uses the PER.C6 cell line, licensed from the Dutch biotechnology company Crucell, as the manufacturing substrate for production of RCA-free adenovirus-vectored vaccines. In 2009 the company announced that it has completed dosing of subjects in a Phase I clinical trial of its lead influenza vaccine being developed to protect humans against highly-virulent strains of influenza, including those that could result in a global pandemic. A randomized, placebo-controlled, dose-escalation Phase I trial in 48 healthy volunteers with safety and immunogenicity as primary endpoints, the trial is being conducted at the University of Alabama at Birmingham and is sponsored in part by Kolmar Korea, Co., Ltd., Vaxin's strategic partner for the Korean marketplace. Vaxin retains worldwide rights to this product, in all other territories.

AlphaVax (US)

AlphaVax is a privately held company, incorporated in the state of Delaware. The company is developing a vaccine technology with broad applications against infectious disease, cancer and biodefense threats. AlphaVax uses a specialized viral vector system to make alphavirus replicon vaccines called alphavaccines, which have shown protection in multiple models for infectious disease and cancer. Since 1998, the company has raised more than USD 154 million, with ~75% coming from corporate partner and grant funding. In October of 2007, AlphaVax concluded a phase 1 placebo-controlled, randomized, double-blind trial in 216 healthy adults, which evaluated the safety and humoral and cellular immune responses after one or two inoculations. The replicon vector expressed the hemagglutinin (HA) gene derived from the A/Wyoming (H3N2) strain of influenza virus. The vaccine was administered either subcutaneously or intramuscularly at two dosage levels, and was found to be safe and well tolerated irrespective of the route or the dose given. Based on the results in the initial influenza trial, in 2009 AlphaVax has initiated a Phase I/II study in a group of healthy, ambulatory elderly subjects (≥ 65 years old). No results were published as far as we know.

NasVax Ltd (Israel)

Israeli based company NasVax develops improved vaccines and immunotherapeutics. NasVax has three products in clinical development and five in preclinical development. The company is developing a intranasal influenza vaccine, which is currently in phase I/IIa. It uses its VaxiSome technology platform. According to the company, its influenza vaccine formulated with VaxiSome® demonstrates increased immunogenicity (HI antibodies) and / or efficacy relative to commercial vaccine in several animal models (ferrets, mice and rats) when administered via either intramuscular or intranasal routes. In an initial Phase I clinical study, the adjuvanted vaccine was well tolerated following a single intranasal dose with only minor local symptoms. In a second intranasal clinical study, the adjuvant effect of increased antibodies was not apparent.

6. Recent headlines

February 21, 2013:	Additional Antimicrobial Patent granted in China
February 14, 2013:	BioDiem extends cooperation with USA AMRIID
February 8, 2013:	Progress to POC testing of BDM-I effect against parasites
January 2, 2013:	BioDiem's BDM-I program continues in NIH program
December 12, 2012:	SII progresses international plans for BioDiem vaccines
November 21, 2012:	Japanese Patent Office grants BioDiem new patent for BDM-I
November 8, 2012:	BioDiem partners with Griffith University to enhance BDM-I
August 8, 2012:	Vivalis announces successful growth of BioDiem's LAIV virus on its EB66 cell line
July 19, 2012:	BioDiem signs research agreement with RMIT
June 26, 2012:	BioDiem secures rights to novel Hepatitis technology
June 25, 2012:	BioDiem signes Dengue Fever agreement with ANU
June 6, 2012 :	ANU to grant BioDiem exclusive license to novel technology to target infectious diseases
May 30, 2012 :	BioDiem partners with leading US Foundation Fighting Blindness on BDM-E compound
May 9, 2012 :	BioDiem starts collaboration with Vivalis to test production of LAIV vaccine
May 8, 2012 :	BioDiem Receives USD 844k in license fees for LAIV vaccine
May 3, 2012 :	BDM-I patent position strengthened with new US patent
February 9, 2012 :	BioDiem licenses LAIV technology to Changchun BCHT Biotechnology Co
December 14, 2011:	BioDiem acquires Savine Therapeutics
August 1, 2011 :	BioDiem Licenses LAIV Technology to Serum Institute of India
August 1, 2011 :	BioDiem Replaces Nobilon as Licensor of LAIV Technology to the WHO
August 1, 2011 :	Biodiem Regains Rights to LAIV Technology .

7. Patents Coverage

BioDiem's core patents and patent rights are based on early research and are supported by subsequent filings that extend the scope and jurisdiction of its intellectual property. BioDiem's intellectual property is its greatest asset. Over the past twelve months the company has continued to maintain our extensive intellectual property portfolio. BioDiem owns three patent families that protect its product portfolio. A brief summary of these is given below. In addition to the patents, the Company has specific "know-how" related to each product that would be considered "trade secrets" which also support the intellectual property protection conferred by the patents.

Product	Patent Summary	Granted	Pending
BDM-E	Tetrapeptide revealing Geroprotective Effect, Pharmacological Substance on its Basis and the Method of its Application. This patent protects the application of BDM-E for use as an agent that slows down the cell ageing process and prolongs cell life.	Australia Canada Europe Israel Japan USA	
BDM-I	Antimicrobial and Radioprotective Compounds. This patent protects the use of BDM-I as a treatment and/or prophylaxis of a microbial infection and in some territories as a protection from radioactive damage due to cancer therapy as well.	Europe Hong Kong Japan USA Russia Australia Singapore S. Africa China	Brazil Canada Malaysia
SAVINE	Synthetic Peptides and Uses therefore Synthetic polypeptide is disclosed, which comprises a plurality of different segments of at least one parent polypeptide, wherein the segments are linked together in a different relationship relative to their linkage in the at least one parent polypeptide to impede, abrogate or otherwise alter at least one function associated with the parent polypeptide. Synthetic polynucleotides are also disclosed that code for the synthetic polypeptides of the invention as well as expression constructs comprising the synthetic polynucleotides. Also disclosed are methods for constructing the aforementioned molecules and immunopotentiating compositions and methods for treating and/or preventing a disease or condition.	Australia New Zealand USA France Germany UK	

8. SWOT Analysis

Strengths

Well established vaccine technology

Partnerships with WHO and SII

Strong management and vaccine development expertise

Weakness

Operating losses cumulating year-on-year

BDM-E and BDM-I still in early stages of development

Opportunities

Partnerships and license agreement with large pharmaceuticals and organizations.

Transition from conservative business model to drug developer allows for potential significant valuation re-rating

Vaccine markets are growing rapidly and are enormous

Growing demand for influenza vaccines with proven track record

Growing demand for treatments of infectious diseases, particularly resistant infections.

Threats

Uncertainty with regard to patent protection and proprietary rights

Uncertainty of the outcome of BioDiem's research results

Uncertainty about the outcome of clinical trials of the products

9. Financials

For the half year ended 31 December 2012, BioDiem reported a net loss of AUD 1.2 million compared to a net loss of AUD 0.69 million in the same period last year. Revenue was practically nil this half-year period since no revenue came in from license payments from partners as was the case last year. However, its commercial partner Serum Institute of India progressed with its plan to allow international export of BioDiem's LAIV technology. SII is preparing to file documentation with the WHO and the Drugs Controller General of India to permit the export of seasonal flu vaccines using BioDiem's technology. This would be a substantial boost for BioDiem's potential future license income from SII.

Its cash position was strengthened with AUD 1.87 million raised through a Renounceable Rights Issue. Total cash at the end of the period amounted to AUD 2.33 million.

Financial Summary

AUD	**Dec 2012**	**Dec 2011**
Income Statement		
Revenues from licenses	2,500	549,901
Fees and royalty expenses	(21,657)	(109,993)
Gross Profit	(19,157)	439,908
Research & Development	(419,178)	(479,426)
Administration expenses	(751,495)	(712,531)
Operating Loss	(1,189,830)	(752,049)
Net Financial Income	(1,200,771)	(689,295)
Earnings per share	(1.11)	(0.68)

Balance Sheet		
Cash	2,324,909	1.821.230
Current Assets	2,464,038	1,914,078
Current Liabilities	267,812	250,997
Long term debt	-	-
Shareholders Equity	28,810,563	26,929,511
Accumulated Losses	(26,893,112)	(25,372,252)
Cash Flow Statement		
Opering Activities	(949,091)	(788,354)
Investing Activities	-	(10,000)
Financing Activities	1,925,392	-

Source: Company filings

Glossary

Adenovirus	Virus responsible for a wide variety of respiratory illnesses, like the common cold, pneumonia and bronchitis
Adjuvant:	A substance sometimes included in a vaccine formulation to enhance or modify the immune-stimulating properties of a vaccine.
Antigens:	Foreign substances in the body that are capable of causing disease.
Attenuated:	Weakened or treated in such a way that the ability of a micro organism (such as parasite or virus) to cause infection or disease is decreased.
Attenuated vaccine:	A vaccine in which live bacteria or viruses are weakened through chemical or physical processes in order to produce an immune response without causing the severe effects of the disease
Bacteria:	Single-celled microorganisms which can exist either as independent (free-living) organisms or as parasites (dependent upon another organism for life).
Booster:	A second or later vaccine dose given after the primary dose(s) to increase the immune response to the original vaccine antigen(s). The vaccine given as the booster dose may or may not be the same as the primary vaccine.
Endemic:	The continual, sometimes low-level presence of disease in a community.
Epidemic:	The occurrence of disease within a specific geographical area or population that is in excess of the normal level.
Immune response:	The reaction of the immune system to foreign substances.
Immune system:	The complex system (network of specialized cells and organs) in the body responsible for fighting disease. Its primary function is to identify foreign substances in the body (bacteria, viruses, fungi or parasites) and develop a defense against them. This defense is known as the immune response. It involves production of protein molecules called antibodies to eliminate foreign organisms invading the body.
Immunity:	Natural or acquired resistance provided by the immune system to a specific disease. Immunity may be partial or complete, specific or nonspecific, long lasting or temporary. Immunity is indicated by the presence of antibodies in the blood and can usually be determined with a laboratory test.

Immunogen:	A substance capable of provoking an immune response. Also called an antigen.
Immunogenicity:	The ability of an antigen or vaccine to stimulate immune responses.
Influenza:	Commonly called the flu, influenza is a highly infectious disease caused by viruses that infect the respiratory tract.
IND (investigational new drug)	The pre-approval status of an experimental drug or biologic (e.g. vaccine) after the U.S. Food and Drug Administration (FDA) agrees that it can be tested in people (generally done in order to collect sufficient data for licensure). "IND" often refers to the application to obtain this pre-approval status.
Infectious:	Capable of spreading disease. Also known as communicable.
Live-vector vaccine:	A vaccine that uses a non-disease-causing organism (virus or bacteria) to transport foreign genes into the body, thereby stimulating an effective immune response to the foreign products. This type of vaccine is important because it is particularly capable of inducing CTL activity.
Pandemic:	An epidemic occurring over a very large area.
Pathogen:	An organism (e.g. bacteria, viruses, parasites and fungi) that cause disease in human beings.
Phase 1 vaccine trial:	A closely monitored clinical trial of a vaccine conducted in a small number of healthy volunteers. A Phase 1 is designed to determine the vaccine's safety and immunogenicity in humans, its metabolism and pharmacologic actions and side effects associated with increasing doses.
Phase 2 vaccine trial:	Controlled clinical study of a vaccine to identify common short-term side effects and risks associated with the vaccine, to collect information additional on its immunogenicity, and to collect initial information on efficacy via live agent challenge of vaccinated volunteers. Phase 2 trials enroll some volunteers who have the same characteristics as persons who would be enrolled in an efficacy (Phase 3) trial of a vaccine. Phase 2 trials enroll up to several hundred participants and have more than one arm.
Phase 3 vaccine trial:	Large controlled study to determine the ability of a vaccine to produce a desired clinical effect on the risk of a given infection, disease or other clinical condition at an optimally selected dose and schedule. These trials also gather additional information about safety needed to evaluate the overall benefit-risk relationship of the vaccine and to provide adequate basis for labelling. Phase 3 trials usually include several hundred to several

thousand volunteers.

Placebo: An inactive substance administered to some study participants while others receive the agent under evaluation, to provide a basis for comparison of effects.

Prime-boost: Administration of one type of vaccine, such as a live-vector vaccine, followed by or together with a second type of vaccine, such as a recombinant subunit vaccine. The intent of this combination regimen is to induce different types of immune responses and enhance the overall immune response, a result that may not occur if only one type of vaccine were to be given for all doses.

Vaccine: A preparation that stimulates an immune response that can prevent an infection or create resistance to an infection.

Vector: In vaccine research, a bacteria or virus that does not cause disease in humans and is used in genetically engineered vaccines to transport genes coding for antigens into the body to induce an immune response.

Virus: A tiny organism that multiples within cells and causes disease such as chickenpox, measles, mumps, rubella, pertussis and hepatitis. Viruses are not affected by antibiotics, the drugs used to kill bacteria

Analyst: Marcel Wijma MSc
Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.

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