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## ASX Announcement

19 August 2010

### COMMENTARY - FULL YEAR RESULTS

**Melbourne, Thursday 19 August 2010:** Australian biopharmaceutical development company BioDiem Ltd (ASX: BDM) today announced the release of its audited financial results for the year ended 30 June 2010.

The highlights of the year included:

- Close of the year with more than \$4m cash following a successful Rights Issue
- Reduced BioDiem R&D spend – significant clinical research work carried out by licencees
- Regain of the Japanese market rights to LAIV
- Portfolio review contributing two new projects with commercial focus
- Launch of LAIV intranasal vaccine product in India.

BioDiem ended the year with \$4.19m cash (2009: \$3.99m). The Company successfully raised \$3.51m through a Rights Issue during the year. No milestone payments were received during the year and the increased operating loss reflects this. An additional milestone payment from the company's licensee, Nobilon, would have been payable if they had chosen to retain the rights to the LAIV technology for the Japanese market, but BioDiem regained the rights for the Japanese market and this milestone payment was foregone. Obtaining the full Japanese rights to the LAIV technology, including manufacturing, enables BioDiem to out-license the complete Japanese rights package. Japan represents a lucrative potential market for BioDiem's technology, being the second largest pharmaceutical market in the world. The Company is actively pursuing potential partners for these rights.

BioDiem's expenditure on R&D for the 2009–10 period was significantly reduced with substantial costs being borne by commercial partners. Nobilon (now part of Merck) commenced Phase II clinical trials of the LAIV in Europe during the year and results are expected later in 2010. The cost of these trials in Europe was paid by Nobilon and most of the development costs for the LAIV H1N1 (swine flu) pandemic vaccine, launched in India, came under the World Health Organization (WHO) Global Pandemic Plan for increased vaccine supply in developing countries.

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. While the World Health Organization has reduced the threat level of the H1N1 pandemic, it has also urged countries to remain vigilant. The death rate due to H1N1 influenza is rising in India and H1N1 has become the predominant type of seasonal flu in many countries such as New Zealand. This underlines the continued importance of BioDiem's LAIV technology development in managing the influenza threat.

Twelve months ago, upon the arrival of a new CEO, Julie Phillips, BioDiem stated that it would conduct a complete review of its product portfolio. This was carried out and it identified two new commercial opportunities.

The first is the development of BDM-I as an antimicrobial for human use. BDM-I was previously investigated by the Company for use to enhance the growth of animals in the agricultural sector. However, research work completed at RMIT University in Melbourne, supplementing earlier Russian studies, demonstrated the potential value of BDM-I as an antimicrobial, effective against many serious human disease-causing microbes including, gram-positive and gram-negative bacteria and fungi. Resistance to treatment is a growing problem for many infectious diseases. Because of the potential for development of BDM-I for treatment of a variety of serious infections such as aspergillosis and MRSA (Methicillin Resistant *Staphylococcus aureus*) the Company intends to continue product development for human use. Analogue studies have been completed and support the value of the ongoing development plan for BDM-I as an antimicrobial.

The next steps will require a small number of confirmatory activity studies and testing in animal models of infectious diseases. On the results of these studies we intend to approach potential licencees to complete the development work and clinical trials. These licences can be issued for BDM-I development in different disease areas and provide BioDiem with an earlier revenue stream while we may also continue exploration in-house of the use of BDM-I in specific areas, for example invasive and superficial fungal diseases where high unmet medical need exists.

The portfolio review highlighted a further commercial opportunity for the LAIV technology. The Company is now exploring its use as a viral vector. This would involve use of the virus itself as a facilitator in vaccine design. 'Viral vectors' are viruses which are used as a delivery tool for proteins (antigens or epitopes) in vaccines. They deliver the specific proteins to elicit an immune response in the person vaccinated. The resulting vaccines can target a wide range of diseases depending on the choice of antigen or epitope which is presented. Initial target applications are nasopharyngeal carcinoma (NPC) and human respiratory syncytial virus (RSV) infection.

Nasopharyngeal carcinoma (NPC) is a cancer originating in the nasopharynx, the uppermost region of the throat, where the nasal passages and auditory tubes join the remainder of the upper respiratory tract. NPC differs significantly from other cancers of the head and neck in its occurrence, causes and treatment. It is vastly more common in certain regions of East Asia and Africa than elsewhere, and is Epstein Barr virus-related.

Human RSV infection is the single most important cause of severe respiratory illness in infants and young children and the major cause of infantile bronchiolitis (inflammation of the small airways in the lung). It is the most frequent cause of hospitalization of infants and young children in industrialized countries. In the USA alone, from 85,000 to 144,000 infants with RSV infections are hospitalized annually, resulting in 20%–25% of pneumonia cases and up to 70% of bronchiolitis cases in the hospital. The global burden of RSV is estimated at 64 million cases and 160,000 deaths every year. There is currently no vaccine available for RSV.

In addition, further research on the BDM-E project has been successful and will generate new intellectual property around this asset.

BioDiem's Chief Executive Officer, Julie Phillips, said 'During the past fiscal year BioDiem has consolidated its strategic plans to bring forward early commercialisation opportunities. A thorough product portfolio review revealed several additional projects that are suited for development with early stage commercialisation prospects. These are the development of BDM-I as an antimicrobial for human treatment and the development of the LAIV technology as a vaccine vector. We aim to licence these out at the earliest opportunity within the next 2-3 years. In addition, the company anticipates that it will start to receive royalty payments from the LAIV technology in developing countries within the next 12 months.'

## Audited results for announcement to the market

Name of Entity and ABN: BioDiem Limited ABN 20 096 845 993  
Reporting Period: 30 June 2010  
Previous Corresponding Period: 30 June 2009

	2010	2009	\$ Change	% Change
Revenue from ordinary activities	Nil	\$ 2,417,106	Down \$ 2,417,106	Down 100%
R&D Expenditure	\$ 1,850,161	\$ 2,388,462	Down \$ 538,301	Down 23%
Operating loss from ordinary activities	\$ (3,391,630)	\$ (1,513,742)	Up \$ 1,877,888	Up 124%
Operating loss attributable to members	\$ (3,391,630)	\$ (1,513,742)	Up \$ 1,877,888	Up 124%
Net tangible assets per security	5.39 cents	5.22 cents	Up 0.17 cents	Up 3%
Earnings per share	(4.40) cents	(1.98) cents	Down 2.42 cents	Down 122%

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

Further commentary on the results is provided in the Directors' report, which forms part of the report for the year ending 30 June 2010.

**-ENDS-**

### About BioDiem Ltd

BioDiem is an ASX-listed company, based in Melbourne, with an international focus on finding, adding value to and commercialising world-class research for vaccines, infectious diseases and other therapeutic areas. The company uses a cost-efficient approach to drug development through collaborations with academic centres of excellence, contract research organizations and partnerships with international pharmaceutical companies.

BioDiem's leading product is the Live Attenuated Influenza Vaccine (LAIV) technology, a novel intranasal vaccine being developed to prevent infection from endemic and pandemic influenza. The technology was licensed to BioDiem by the Institute of Experimental Medicine in St Petersburg. In 2004, BioDiem licensed the LAIV technology to Nobilon International B.V. (now part of Merck & Co, Inc.). It is currently in Proof of Concept (Phase II) stage clinical trials as part of its development for European registration. It has also been launched in India as NasoVac for protection against H1N1 influenza.

For additional information, please visit [www.biodiem.com](http://www.biodiem.com)

### Contact information

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**Biodiem Ltd**  
ABN: 20 096 845 993

**ASX Preliminary final report ~ June 30, 2010**

**Lodged with the ASX under ASX Listing Rule 4.3A**

This report is to be read in conjunction with any public announcements made by the company during the reporting period in accordance with the continuous disclosure requirements of the Corporations Act 2001.

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Status of Audit

Financial report

# BioDiem Limited

ABN: 20 096 845 993

Reporting period: 12 months ended June 30, 2010

Previous period 12 months ended June 30, 2009

## Results to be announced to the market

		<b>A\$'000</b>
Revenue from ordinary activities	Down 100 %	-
(Loss) from ordinary activities	Down 124%	(3,392)
Net (loss) for the year attributable to members	Down 124%	(3,392)

## Dividends

It is not proposed to pay a dividend

<b>Other information</b>	<b>June 30, 2010</b>	<b>June 30, 2009</b>
Net tangible assets per ordinary share	<b>5.39 cents</b>	<b>5.22 cents</b>

This preliminary final report is based on accounts which have been audited

The Financial Reports and commentary are attached.