



Biotechnology Melbourne, Australia Industry Profile

Victoria, led by its capital Melbourne, is an innovative hub for world-class science. Victoria's life sciences industry is moving closer towards becoming one of the world's top five biotechnology locations. In the last 10 years, the Victorian Government has invested A\$3.4 billion into science, technology and innovation.

Victoria is home to 139 biotech companies, 13 major medical research institutes, seven teaching hospitals and nine universities. In 2007-08, listed life science firms in Victoria generated export sales of around A\$320 million, produced sales in excess of A\$7.2 billion, and recorded an aggregate net profit of A\$593 million.

Growing sustainable companies

Melbourne is home to:

- CSL, one of the world's top ten biotech companies
- 50 per cent of the top 20 biotech companies listed on the Australian Stock Exchange
- almost 75 per cent of Australia's top biotech companies by market capitalisation
- 47 listed life science companies, which have a combined market capitalisation of A\$22 billion as at December 2008.

Melbourne's listed life science companies currently have 85 life science products on the market, with twelve Phase III and 39 Phase II clinical trial programs underway.

Focusing on creating a competitive business environment

Access to finance is the key driver for innovative industries – investors are attracted to a competitive business environment that delivers certainty through appropriate, flexible regulatory frameworks.

In the past year, the Victorian Government has:

- lifted the moratorium on GM crops
- established a framework for environmentally sustainable bio-discovery
- advanced a system to streamline ethical review of multi-site clinical trials
- become the first Australian state to launch an 'SBIR' program (*Smart SMEs Market Validation Program*).



www.biotechnology.vic.gov.au

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Victoria
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Expanding international networks

Our life science sector continues to form global partnerships and alliances to boost investment in our biotechnology industry. Recent examples include:

- a global collaboration agreement between the Melbourne-based Walter and Eliza Hall Institute of Medical Research (WEHI) and the California-based biotech company Genentech Inc. to discover, develop, manufacture and commercialise a new class of broad-spectrum cancer therapeutics; and
- the longstanding relationship between US pharmaceutical company Pfizer and Victorian pharmaceutical manufacturing company IDT Australia that has led to Pfizer's A\$20 million investment in a pharmaceutical containment facility at IDT's Boronia site.

In the past year, Victoria has:

- forged and strengthened significant international collaborations with the US, Israel, Canada, New Zealand, India and China
- entered into a world-first collaboration with the Californian Institute for Regenerative Medicine

- become the home to Bio-Net Asia Pacific (BNAP), a pan-Pacific network of biotechnology industry associations
- announced that Melbourne is to host the first BNAP meeting at AusBiotech 2009 (27–30 October, 2009).

Committing to investment

In the past year, the Victorian Government has:

- announced a further A\$300 million commitment to science, technology and innovation, bringing our total investment over 10 years to A\$3.4 billion.
- launched *Innovation: Victoria's Future* which includes, A\$165 million for *Victoria's Science Agenda and Biotechnology Bridges* and A\$50 million towards a new A\$100 million *Victorian Life Sciences Computation Initiative*
- committed a further A\$78.8 million to the Victorian Cancer Agency – a dedicated agency to accelerate translational cancer research to deliver improved patient outcomes.

Melbourne's International Biotechnology Conference Program

Date	Conference	Location
27–30 October 2009	Ausbiotech 2009, including the first Bio-Net Asia Pacific (BNAP) meeting	Melbourne Convention and Exhibition Centre (MCEC)
10–12 November 2009	Fourth International Conference on Coexistence between Genetically-Modified (GM) and non-GM based Agricultural Supply Chains (GMCC '09)	MCEC
20–21 November 2009	Asia Pacific Conference on Metabolic Syndrome	Sofitel, Melbourne
20–25 March 2010	World Congress on Internal Medicine 2010	MCEC
3–6 May 2010	International Federation on Ageing, 10th Global Conference	MCEC
28 June–1 July 2010	11th International Symposium on the Genetics of Industrial Microorganisms	MCEC
15–20 August 2010	12th International Congress of Parasitology (ICOPA 2010)	MCEC
6–8 September 2010	7th Australasian Viral Hepatitis Conference	The Sebel, Albert Park, Melbourne

Photography acknowledgements:

Walter and Eliza Hall Institute

Monash Centre for Electronmicroscopy

Australian Regenerative Medicine Institute



Industry Highlights

Prana's PBT2 prevents synaptic loss in Alzheimer's (Mar 2009)

Melbourne-based Prana Biotechnology Ltd (ASX: PBT; NASDAQ: PRAN) showed that its lead compound for the treatment of Alzheimer's disease, PBT2, in addition to its previously reported benefits, also prevents the loss of synapses (the space) between neurons that underlies the process of neurodegeneration in Alzheimer's disease. The effects of PBT2 in a Phase IIa clinical trial in early Alzheimer's disease were published in the journal *Lancet Neurology*.

Large Relenza order boosts Biota earnings (Jan 2009)

Biota Holdings Limited (ASX: BTA) announced that GlaxoSmithKline (GSK) has been awarded a significant contract by the UK Department of Health for A\$10.6 million treatment courses of Relenza™ (zanamivir). The UK Government's decision to purchase zanamivir is consistent with recommendations published by the European Medicines Agency (EMA) and the UK's Royal Society and Academy of Medical Sciences recommends the diversification of antiviral stockpiles to include zanamivir in addition to Tamiflu® (oseltamivir). Whilst financial terms have not been disclosed, Biota estimates that the contract may represent a royalty income of up to A\$18 million.

Stem cells approved for world-first osteoarthritis clinical trial (Jan 2009)

Melbourne-based biotech Mesoblast (ASX: MSB; USOTC: MBLTY) is trialling adult stem cell treatment in humans for the prevention of knee osteoarthritis. The Phase II clinical trial will evaluate Mesoblast's 'off-the-shelf' adult stem cell product, RepliCart, for which the company was awarded the 2008 Frost & Sullivan United States Stem Cell Market Technology Innovation of the Year.

Positive Phase III trial results for Clinuvel (Jan 2009)

Clinuvel (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) has reported very positive results from Phase III testing of its drug afamelanotide, which works to boost the body's natural melanin production. The drug has been tested in patients suffering from rare skin diseases such as EPP, an extreme allergy to sunlight. Fourteen Swiss subjects who took part in the trial applied for and were granted a year's extra access to afamelanotide. As of 29 January 2009, the US Food and Drug Administration (FDA) has allowed afamelanotide to proceed for clinical trials in the US under Investigational New Drug (IND).

Ovarian cancer diagnostic test has 98 per cent accuracy in clinical trials (Dec 2008)

Melbourne-based diagnostics developer HealthLinx Ltd (ASX: HTX) reported a 98 per cent accuracy rate in early-stage

diagnosis of ovarian cancer using its OvPlex diagnostic. Two new biomarkers have been substituted in the second-generation OvPlex test (which has five biomarkers in total), resulting in a highly increased accuracy. HealthLinx aims to introduce the product for sale in late 2009 or early 2010.

Leukaemia treatment from Melbourne biotech ChemGenex performs well in clinical trials (Dec 2008)

Victorian-based biotech ChemGenex (ASX: CXS; NASDAQ: CXSP), based in Geelong, reported positive interim clinical data from patients enrolled in its ongoing Phase II/III trial of omacetaxine mepesuccinate in chronic myeloid leukaemia (CML) patients with the T315I mutation who are resistant to Gleevec therapy. There are currently no effective drug treatments for the increasing number of CML patients with the T315I mutation. In the recent trial, 80 per cent of chronic phase patients showed less cancer cells in their blood, and another 20 percent recorded less disease in their bone marrow.

Starpharma's VivaGel inhibits human papillomavirus (HPV) (Dec 2008)

Starpharma (ASX: SPL; USOTC: SPHRY) has shown that SPL7013, the active ingredient in its topical microbicide VivaGel, inhibits all the strains of HPV known to cause cervical cancer. The new data support earlier findings that VivaGel may have potential for reducing the risk of genital HPV infection – a factor in the development of virtually all cases of cervical cancer.

Vaccine wins International Prix Galien (Nov 2008)

Australia's biggest biotech, CSL (ASX: CSL), has been awarded the International Prix Galien for its cervical cancer vaccine, Gardasil. Gardasil was developed by acclaimed Australian immunologist Ian Frazer. Gardasil has been licensed to over 100 countries worldwide. The vaccine against human papilloma virus prevents 70 per cent of cervical cancer cases.

Nucleus Network: Emerging Exporter 2008 (Oct 2008)

Nucleus Network, a Melbourne-based clinical research organisation, won the Governor of Victoria's Export Award in the Victorian Emerging Exporters category. The company is fast developing an international reputation as a world-class destination for early-stage clinical trials and complex medical research studies. Nucleus Network currently generates an estimated \$11 million in export revenues annually.

CSL acquisition of Talecris Biotherapeutics (Aug 2008)

CSL announced the acquisition of US plasma business Talecris Biotherapeutics for US\$3.1 billion (the biggest takeover by an Australian company in 2008), strengthening Victoria's global credentials as a strong competitor in the plasma therapeutics market.

Key Victorian Research Infrastructure

Discovery

Australian Genome Research Facility (AGRF)

www.agrf.org.au

Australian Proteomics Computational Facility (APCF)

www.apcf.edu.au

Australian Synchrotron

www.synchrotron.org.au

Bio21 Collaborative Crystallisation Centre (C3)

csiro.au/science/Bio21

FlowCore – Core Flow Cytometry Facility

www.flowcore.com.au

Monash Centre for Electron Microscopy (MCEM)

mcem.monash.edu.au

Proteomics and Metabolomics Victoria (PMV)

www.pmv.org.au

Victorian Centre for Functional Genomics

Zebrafish Core Research Facility

Diagnostics and Therapeutics Development and Manufacture

Centre for Drug Candidate Optimisation

www.pharm.monash.edu.au/cdco

Cooperative Research Centre (CRC) for Advanced Composite Structure

www.crc-accs.com.au

CSIRO Protein Engineering

csiro.au/science/Engineering-Proteins

CTx – Cancer Therapeutics CRC

www.cancerCRC.com

IDT Australia

www.idtaus.com.au

Melbourne Centre for Nanofabrication

www.nano.monash.edu

Monash Antibody Technologies Facility

www.matf.monash.org

Monash Micro Nanophysics Research Laboratory

www.eng.monash.edu.au/non-cms/mnrl

Preclinical Validation and Clinical trials

BioGrid Australia

www.biogrid.org.au

Cancer Trials Australia

www.cancertrialsaustralia.com

Clinical Pharmacology and Therapeutics Laboratory

www.austin.org.au/Page.aspx?ID=566

Cogstate

www.cogstate.com

Integrative Neuroscience Facility (INF)

www.hfi.unimelb.edu.au/inf

Neurosciences Trials Australia

www.neurotrialsaustralia.com

Nucleus Network

www.nucleusnetwork.com.au

Victorian Brain Bank Network

www.mhri.edu.au/NNTC.htm

Victorian Cancer Biobank

www.viccancerbiobank.org.au

Case study

Breakthrough in new high-energy pasture grasses

Thanks to groundbreaking work by Victorian scientists at the Department of Primary Industries (DPI), beef, sheep and dairy farmers may be able to reduce the amount of feed required for livestock, by using new high-energy pasture grasses. The breakthrough research reduces the non-digestible content and increases the nutrition value of two common pasture varieties: ryegrass and tall fescue. Stock can obtain more energy from these genetically modified (GM) grasses, reducing the amount of pasture that farmers require for each animal.

For the Victorian dairy industry, the development of these high-energy pasture grasses will enable improved milk production from the same farm footprint. In 2008, the Australian Federal Gene Technology Regulator granted DPI a licence to plant a limited amount of these pasture varieties, with the first Australian field trials of these grasses scheduled to take place over the next two years.

Whilst the trials are for proof-of-concept research and not for commercial release, the ultimate aim of the research is to give farmers access to pastures with improved quality and energy content for stock feed. With climate change and the prolonged drought reducing the amount and quality of pasture that many farmers have available for stock, the research being conducted by DPI scientists has the potential to provide significant on-farm benefits, while helping to ensure that Victorian farmers remain competitive in Australian and international markets.

Case study

Victorian GMP facility attracts international deal

IDT Australia is a leading Victorian biotechnology company that develops and manufactures key ingredients for anti-cancer drugs, hormone therapy and antibiotics. IDT specialises in the development, scale-up and production of active pharmaceutical ingredients (APIs) to international standards of Good Manufacturing Practice.

In August 2008, Victorian Premier John Brumby opened IDT Australia's A\$20 million active pharmaceutical ingredient manufacturing facility – one of the largest contract-development facilities of this kind in the world. This new state-of-the-art facility has enabled IDT Australia to secure a containment development contract to manufacture a potent antibiotic for US pharmaceutical company Pfizer Inc.

IDT has 25 years' experience in the development and production of pharmaceutical products for local and international clients. Evolving out of the Victorian College of Pharmacy, IDT's highly specialised work is delivering important health benefits while also generating high-skilled jobs and export income for Victoria.

For further information

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