



biotech focus

Australia – the premier Asia-Pacific hub for biotech investment

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Australia is the number one biotechnology location in the Asia-Pacific and the sixth largest biotechnology centre in the world.¹ Australia's biotechnology sector has continued growing in recent years and the number of biotechnology companies in Australia has doubled in the past four years,² significantly strengthening the already very sound industry base. Of Australia's 448 biotechnology companies, more than 120 are listed on the Australian stock exchange with a total market capitalisation of over €18.27 billion (\$A30.6 billion) for the life sciences sector in 2006 (see footnote 1). The top ten Australian biotech firms of 2006 are listed in Table 1. The Australian biotechnology sector generates total revenue in excess of €1.06 billion (\$A1.78 billion).

Biomedicine is by far the largest sector of Australia's biotechnology industry, reflecting the nation's strengths in medical research. The biomedicine sector is supported by a number of world-leading institutes and clusters and Australian researchers excel in the molecular genetics of cancer, malaria, epilepsy, immunology, vaccine development, obesity, diabetes, neuroscience, assisted reproductive technology, stem cells and regenerative medicine.

A combination of excellent research facilities, innovative scientists and a strong but flexible regulatory regime have contributed to Australia's recent biotechnology success, with a strong focus on building Australia's science and innovation which supplement Australia's core strengths in biomedical research.

A comprehensive list of Australian biotechnology companies and their capabilities is available from AusBiotech, the peak body for the Australian biotechnology industry (<http://www.ausbiotech.org/directory/>).

Gateway to Asia

According to PricewaterhouseCoopers' (PWC) August 2007 *BioForum* report,³ more than half of the multinational companies and 62% of Asian companies surveyed agreed that the centre of gravity of the global pharmaceutical market is shifting from Europe and North America to Asia. To align themselves with this seismic shift, more multinational corporations (MNCs) are seeking to establish footholds in Asia, the report says. Australia is strategically located in the fast-growing Asia-Pacific region. Australia's top two trading partners are Japan and China and service exports to Asia are expanding rapidly. Australia's unique geography and time zone advantages, its cultural affinity with Asia, and its European/American business environment make it a perfect business bridge to Asia.

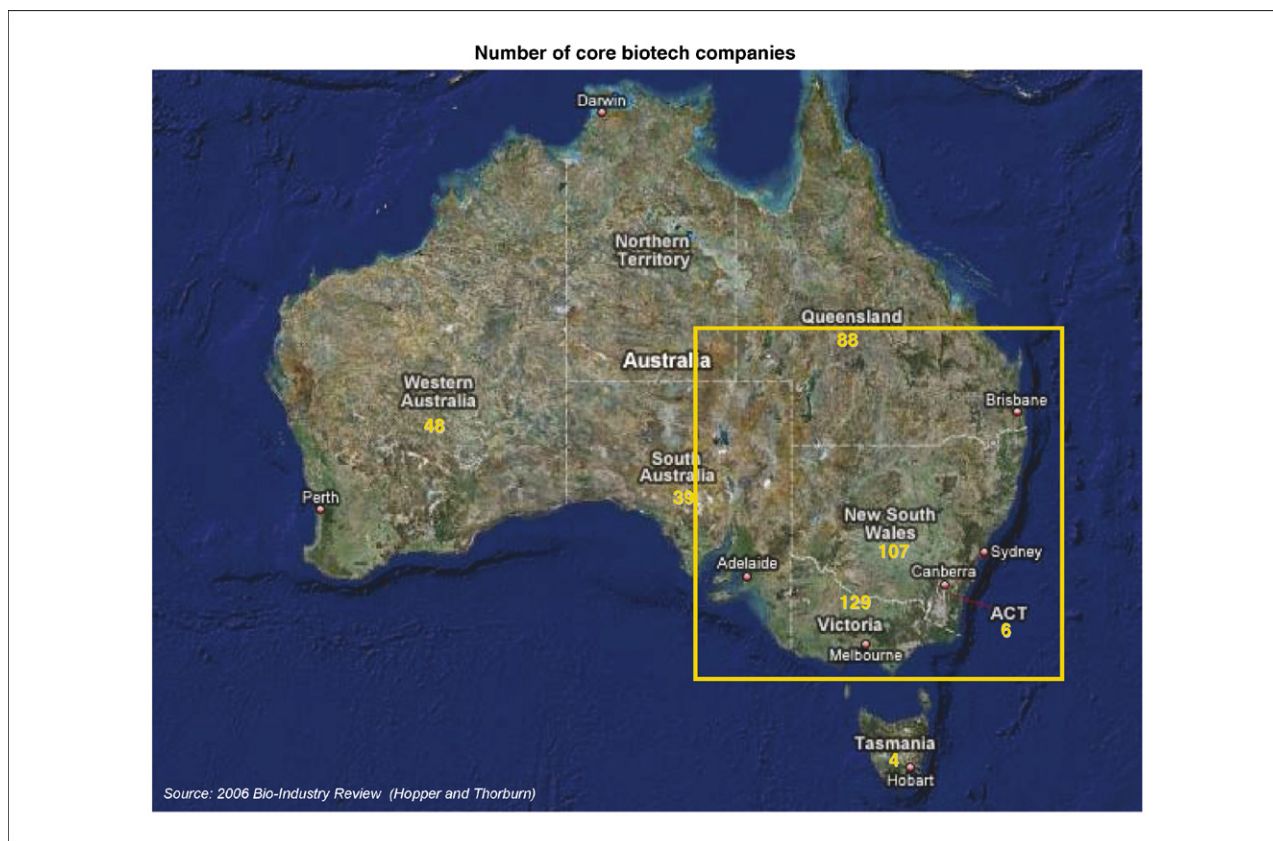
Australia offers MNCs and European biotechs a world-class R&D environment where IP is protected. Refer to Text Box 1 for information on Australia's R&D tax concessions for global companies. Australia's patent and copyright enforcement is ranked third in the Asia-Pacific region⁴ and its highly reputable legal and regulatory framework encourages enterprise

¹ Ernst & Young, *The Asia-Pacific Perspective, Global Biotechnology Report*, 2007.

² Biotech Business Indicators, November 2006, <http://www.industry.gov.au>.

³ PricewaterhouseCoopers *BioForum Edition 21, Quarter 4 FY 07*, released August 2007.

⁴ IMD World Competitiveness Yearbook 2007.



competition. Moreover, corruption levels in Australia are low, with Australia's corruption-free business environment rating ahead of the US, the UK, Canada, Switzerland, Germany and France, and most regional countries (see footnote 4).

Australian biotechs are also increasingly aware of this seachange in the global industry, and are looking to untapped markets in the Asia-Pacific, in the pharmaceuticals sector and other areas of biotechnology.

In May 2007, Polartech Limited commenced commercial scale manufacture of its real-time cervical cancer screening system, TruScreen, to launch in China, India and Malaysia as well as Europe, in line with the company's plan to target high-potential Asian markets, where PAP screening is not regularly performed.

Fermiscan is launching a world-first innovative test for the detection of breast cancer, based on analysing the molecular structure of a patient's

hair. The test is based on the Australian discovery that breast cancer changes the structure of hair in a way that can be detected by synchrotron X-ray diffraction. Earlier this year, Fermiscan signed a licensing agreement with Singapore's Avia Reed International for providing access to six markets throughout Asia. Fermiscan also has an agreement with Crosby Capital Partners for the Japanese market.

Novotech, Australia's largest independent contract research organization, has attracted the backing of leading regional biotech venture firms BioPacificVentures and Co-Investor Capital Partners for their further expansion in the US and to set up operations in India. Novotech's CEO, Alek Safarian, said the company's clients are increasingly interested in greater reach into Asia.

Conducting clinical trials in Australia

In an Economist Intelligence Unit pharmaceutical benchmarking analysis,⁵ Australia was ranked as the number one location for clinical trials amongst the countries surveyed, ahead of Germany, India, Japan, Singapore, the UK and the US. The report scored Australia strongly on costs, particularly against other OECD countries such as the UK, Germany, Japan and US. Australia's cost advantages lie in the hiring of skilled labour with its clinical trial costs comparable to Eastern Europe, while medical and research standards are on par with those of the US and Western Europe. Moreover, Australia's unique geographical and social characteristics – including its proximity to Asia-Pacific markets, its reverse seasonality to the Northern Hemisphere which allows firms to reduce the time required to trial new drugs or vaccines for seasonal diseases and an increasing

⁵ Economist Intelligence Unit, Benchmarking Study of the Characteristics of the Australian and International Pharmaceuticals Industries, November 2005.

BOX 1

R&D tax concessions for global companies

Australia has introduced a number of initiatives to support R&D, including a new tax concession provision. In recognition of the fact that MNCs typically hold intellectual property at their corporate headquarters, corporations who do their R&D in Australia but hold the relevant IP overseas are now eligible for a 175% R&D tax concession on incremental R&D. It has been developed to attract more companies to establish or expand their operations in Australia. More than 300 companies are expected to take advantage of this concession every year and estimates suggest that it will boost investment in Australian innovation by almost €600 million (A\$1 billion).



TABLE 1

Top ten biotech firms by market capitalisation, Australian stock exchange 2006 (source Hopper, K. and Thorburn, L.J. (2007) BioIndustry Review Australia and New Zealand)

Position in 2006	Company	URL	Specialisation	Market cap. 1 December 2006 AU\$5m (€m)	Market cap. 1 December 2005 AU\$5m (€m)
1	CSL Ltd	http://www.csl.com.au	Development and manufacturing of vaccines and plasma protein biotherapies	10,825 (6455)	7309 (4359)
2	Pharmaxis Ltd	http://www.pharmaxis.com.au	Chronic respiratory and autoimmune diseases and development of improved lung function tests	564 (336)	384 (229)
3	Cellestis Ltd	http://www.cellestis.com	Development and marketing of QuantiFERON [®] technology products for medical diagnosis and scientific research	345 (206)	207 (123)
4	Biota Holdings Ltd	http://www.biota.com.au	Anti-infective drug development. Biota's initial success was the discovery of zanamivir, licensed to GlaxoSmithKline and marketed as Relenza [™]	269 (160)	295 (176)
5	Novogen Ltd	http://www.novogen.com	Degenerative disease treatments such as cancer, heart disease, osteoporosis, chronic inflammatory diseases and inflammatory Bowel disease	251 (150)	529 (315)
6	Metabolic Pharmaceuticals Ltd	http://www.metabolic.com.au	Primarily developing a platform for the oral delivery of existing injected peptide drugs	215 (128)	120 (72)
7	PepTech Ltd*	http://www.peptech.com	Development of antibody and peptide-based human therapeutic products for the treatment of diseases in the areas of cancer and inflammation and products for fertility control in animals	215 (128)	205 (122)
8	Phosphagenics Ltd	http://www.phosphagenics.com	Discovery of new ways to enhance the bioavailability, activity, safety and delivery of proven pharmaceuticals and nutraceuticals products	211 (126)	131 (78)
9	Progen Industries Ltd	http://www.progen.com.au	Discovery and development of small-molecule-based cancer therapeutics	162 (97)	114 (68)
10	Clinuvel Pharmaceuticals Ltd	http://www.clinuvel.com	Developing its lead drug candidate CUV1647 in the area of UV and light exposure, as well as skin and skin disorders	148 (88)	61 (36)

NB: *In November 2007, Peptech merged with EvoGenix to create Arana Therapeutics.

TABLE 2

Australian biotech firms late stage products – December 2007

Company	URL	Lead product
Acrux	http://www.acrux.com.au	Marketing approval for Acrux's first product has been granted by the US FDA Estradiol MDTs® will be used to treat vasomotor symptoms associated with menopause
Arana Therapeutics (from the recent merger of Peptech and Evogenix)	http://www.arana.com	Phase II study of lead antibody ART621, for psoriasis is expected to commence in Q1/2008 and the Phase II rheumatoid arthritis program is planned to start in Q3/2008 The Phase II trials for PN 0621 are expected to commence in the first half of 2008 for the treatment of rheumatoid arthritis and other inflammatory diseases
Avexa	http://www.avexa.com.au	Positive results from Phase IIb clinical trial of Apricitabine for the treatment of HIV infection and Phase III is in planning
Chemgenex Pharmaceuticals	http://www.chemgenex.com	Positive preliminary data from the Phase II/III clinical trial of chronic myeloid leukaemia drug
Circadian Technologies (Vegenics)	http://www.circadian.com.au	Phase III in planning – prevents blockage of haemodialysis grafts
Clinuvel Pharmaceuticals	http://www.clinuvel.com.au	Phase III studies for CUV1647 – for light-associated skin disorders –started in June 2007
Halcygen Pharmaceuticals	http://www.halcygen.com	Registration of PK study to begin 2007 for antifungal – super-generic of itraconazole
Neuren Pharmaceuticals	http://www.neurenpharma.com	Phase III clinical trials for Glypromate® are currently underway in Australia, the United States and New Zealand to reduce cognitive impairment after cardiac surgery
Pharmaxis	http://www.pharmaxis.com.au	Phase III trials of respiratory drug Bronchitol, showing promising results. Trials have been conducted in Australia, New Zealand and the United Kingdom and application submitted to the US FDA to commence a US Phase III trial
Progen	http://www.progen.com.au	Phase III in planning for PI-88 for the treatment of liver cancer
Psivida	http://www.psivida.com	Pivotal Phase III clinical trial FAME™ (fluocinolone acetonide in diabetic macular oedema) currently underway The trial is studying the use of Medidur FA for the treatment of diabetic macular oedema (DME)
QRxPharma	http://www.qrxpharma.com	Phase III started in late 2007 as development program for lead product candidate Q8003IR, an immediate release dual-opioid pain therapy

incidence of western lifestyle diseases – make it an excellent hub for clinical trials.

Australia's regulatory process for clinical trials is efficient and timely – almost all clinical trials currently use the Clinical Trial Notification scheme. Once a trial has ethics committee approval, companies can notify the Australian Therapeutic Goods Administration (TGA) and start clinical trials within a week of receiving TGA acknowledgement. The TGA accepts data submitted from clinical trials overseas, if it follows Good Clinical Practice. Studies conducted in Australia meet international regulatory requirements, including those of the Food and Drug Administration (FDA) and the International Conference on Harmonisation (ICH).

These excellent conditions are reflected by the fact that some 700 clinical trials are carried out at more than 2000 sites in Australia each year.⁶ MNCs which regularly involve their Australian affiliates in international trials include AstraZeneca, Amgen, Bristol Myers Squibb, Biogen Idec, Eli

Lilly, GlaxoSmithKline, Merck Sharp & Dohme, Novartis, Pfizer and Roche. Leading Austrian biotech, Austrianova, has started conducting clinical trials in Australia, with a Phase I trial of its NovaCaps technology for inoperable pancreatic cancer currently underway.

R&D to commercial success

More companies in Australia are taking their drugs to Phase III clinical trials and beyond, signalling that the Australian biotech market is maturing and offering greater pipeline opportunities for large and global pharmaceutical companies.

Pharmaxis recently announced positive results for Phase III trials of respiratory drug Bronchitol, conducted at 22 hospitals across the UK, Australia and New Zealand. Pharmaxis has now applied to the US Food and Drug Administration to commence a US Phase III trial for the drug. Another ten Australian companies have products in the final stages of clinical development, including Acrux, Clinuvel Pharmaceuticals, Chemgenex Pharmaceuticals, Circadian Technologies, Neuren Pharmaceuticals, Halcygen, QRxPharma and Psivida. Table 2 lists Australian biotech firms with products in late stage clinical trials.

⁶ Medicines Australia from data supplied by Australia's Therapeutic Goods Administration (TGA).

Stem cell R&D opportunities

Australia is an international leader in stem cell research. In 2005, *Forbes* magazine stated that 'when it comes to listing stem cell start-ups and launching stem cell products, the surprising leader is Australia'. Since then, Australia has cemented its place at the forefront of stem cell research and this year hosted the 5th annual meeting of the International Society for Stem Cell Research, the first time the society's meeting had been held outside the US. The ISSCR noted that Australia's 'rich history of stem cell science' made a strong contribution to this year's conference.

In December 2006, the Australian Parliament enacted new legislation, giving approval to scientists to secure the right, under licence, to conduct therapeutic cloning research in Australia. This new legislation gives Australian scientists an opportunity to explore embryonic stem cell research under a strong regulatory framework and stay at the forefront of this technology. The Australian states of Queensland, Victoria and NSW have since followed suit, enacting complementary legislation, with Western Australia and Tasmania also considering complementary legislation. A key player in this arena is the Biotechnology Centre of Excellence at the Australian Stem Cell Centre (ASCC). The ASCC's research activities focus on adult stem cells, human embryonic stem cells, tissue repair mechanisms and immune system technology. The ASCC has established collaborative partnerships with ten stakeholder universities and research institutes across Australia.

International collaborations

The ability to add value to the research pipeline of major pharmaceutical and biotech companies has clearly made Australia increasingly attractive to international partners. Such partnerships include:

- **Walter and Eliza Hall Institute of Medical Research (WEHI) and Genentech Inc.** (announced 6 February 2007) – collaboration to undertake research into new cancer drugs and develop pre-clinical models.
- **Cytosia and Novartis** – €163 million (A\$274m) to develop orally active, small molecule therapeutics targeting JAK3 kinase for the prevention of transplant rejection and the treatment of autoimmune diseases such as rheumatoid arthritis.
- **G2 Therapies and Novo Nordisk** – €70 million (US\$102m) for developing and commercialising novel antibody-based therapies in inflammation and cancer.
- **Biota and MedImmune** – €77 million (US\$112.5m) for the development and commercialisation of its small-molecule compounds that aim to treat and prevent respiratory syncytial virus (RSV).
- **Biota and Boehringer Ingelheim** – a collaboration and licensing deal to develop and commercialise its nucleoside analogue drugs for the treatment of hepatitis C infections. The deal has a value of up to €70 million (US\$102 million).
- **pSivida and Pfizer** – signed a collaborative research and licensing agreement for controlled drug delivery technologies in ophthalmic applications worth €121 million (A\$203 million).
- **Australian Molecular Plant Breeding Co-operative Research Centre and BASF Plant Sciences** – a lucrative deal covering the next seven years to develop genetically modified wheat varieties in Australia.
- **Evogenix and the National Institutes of Health (US)** – Evogenix signed a cooperative R&D agreement with the NIH, under which

BOX 2

How to invest

The Australian Government provides a range of services to companies looking to invest in Australia. It helps biotechnology companies identify potential investment opportunities and partners for research collaborations, joint ventures and other alliances. Companies wishing to find out more about opportunities in Australian biotechnology and accessing markets in the Asia-Pacific should contact the Australian High Commission by email: london@invest.gov.au or telephone 020 7632 0011. Further information can be found website at <http://www.innovation.gov.au> and clicking on 'investing in Australia'.

researchers at the NIH will perform testing and initial clinical evaluation of Evogenix's new anti-cancer antibody therapeutics.

Financial performance

Over the 2006–2007 financial year, Australian biotechs performed solidly on the capital raising front, raising a record €298.58 million (A\$500 million) from rights issues, private placements and IPOs by drug development and device companies. Avexa, Acrux and Progen raised more than €95.54 million (A\$160 million) to support Phase III clinical trials and devices, companies Ventracor and Heartware raised an aggregate of €35.83 million (A\$60 million).

Australia's reputation as the premier biotech hub for the Asia-Pacific continues to attract interest from overseas partners – of the 388 partnerships formed with Australian biotechs in the past year, 67% was with overseas companies or agencies.⁷ Over the 2006–2007 financial year, collaborative R&D agreements were the most popular type of international alliances with publicly listed Australian firms. In the fourth quarter of 2007, most alliance partners were European (43%). That year, the UK was the most popular choice of European partners, with the €19.7 million (A\$33 million) merger of UK-based health management software producers iSoft Ltd with Australia's IBA Health Ltd being the largest fourth quarter alliance.

In 2007, a significant development in the growth of the critical mass of Australia biotech was the merger of therapeutic companies EvoGenix and Peptech Limited to form Arana Therapeutics, now one of Australia's biggest biotechnology companies.

The merger of EvoGenix and Peptech follows a string of recent success by Australian companies going to Phase III clinical trials, reinforcing their pipeline capabilities.

What is the future of Australian biotechnology?

Experts predict that Australia's biotechnology industry will continue to grow and mature.

Rhenu Buller, the Singapore-based global vice-president for pharma and biotech at Frost and Sullivan, recently told *Australian Life Scientist* that she expects the Australian biotech industry to grow by 10% per annum for the next three years.

With more drugs progressing through the pipeline to Phase II and III clinical trials, with more products such as the cervical cancer vaccine Gardasil on the market, and a continuing pattern of international investment and partnerships, there is no better time for European

⁷ Innovation Dynamics, January 2007.

investors to discover why Australia has one of the world's most attractive biotechnology industries, and is the ideal location for Asia-Pacific-based biotechnology investment. For more information on investment opportunities in Australia refer to [Text Box 2](#).

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