

BioIndustry review of Australia

A review of the year just gone and predictions on the year ahead

by Lyndal Thorburn and Kelvin Hopper



This is an edited summary of some of the key highlights of the 2007 BioIndustry review for Australia and New Zealand, which was launched on 27 February 2007 by Innovation Dynamics¹.

Introduction

The Australian biotech and medical devices sector showed signs of consolidation and healthy growth in 2006, with increased mergers and acquisitions and fewer start ups. The number of core biotech companies held steady at 427 and the number of medical devices companies lifted only slightly to 625. New firm formation was slow during 2005/06 in both biotech and medical devices sectors. This was due, in part to the difficult market for financing, with only two biotech listings and two medical devices listing in calendar 2006, and few new venture investments into the sector.

The negative impact of the closure of the Biotechnology Innovation Fund in late 2005 continued to be felt. Despite

the incorporation of BIF into the new Commercial Ready program, relatively few small grants are being provided to new companies, so grants are now a smaller proportion of funding for new companies than was the case several years ago. This may also indicate a change in government priorities toward supporting more established companies and especially those that were formed earlier under BIF but struggled to get follow-on funding.

As a result of these trends, new companies that could be funded by parent organisations had the advantage in the last 18 months. In 2005/06 we are aware of only 19 start up core biotech companies and 9 medical devices startups (fewer than in 2005) but this year the closures balanced the commencements so there was little net change in the total number of companies in both sectors. As is usually the case, human therapeutics firms dominated the new biotech start-ups but there were no firms in food and beverages or diagnostics, a departure from recent trends. In the devices sector, there has been a shift away from drug delivery.

Reasons for optimism

Despite the difficult financing year, there are reasons to be optimistic. As at December 2006, the market capitalisation of the top ten biotech firms stood at \$13.205 billion and that of the top ten devices firms at \$8.47 billion. This is a very respectable jump of 44% and 23% in market cap respectively, over the same period in 2005. Staff numbers showed a corresponding increase.

In the longer term, Intersuisse's end of year analysis of all biotech stocks (excluding CSL) over the past 11 years¹ reported a compound annual growth rate of biotech stocks totalling 21.6% p.a., which is more than double the 9% p.a. of the All Ordinaries and the 9.3% p.a. of the NASDAQ Biotechnology Index. Over the immediate past 5.5 years however, their indices' CAGR have been around 7% pa compared with 10% for the All Ordinaries and 4% decrease in NASDAQ. Further, from their analyses of over 21 years, CommSec reported a healthy 25.5% growth for pharmaceuticals and biotech, compared with 14.1% for the All Ordinaries².

Other major trends in the year provide positive signs of the sector's continued growth. There has been an increase in interest in Australian biotech firms by companies overseas (as seen by alliances and acquisitions); there was a large jump in staff employed in biotech companies, the number of US biotech patents granted in 2006 has turned upwards, after several years of downtrend and the number of product in late stage clinical trials increased. These are indicative of the growing strength and maturity of the Australian industry even at a time of difficult funding.

Takeovers boosted by international interest

One of the major trends of the year was a large jump in the number of overseas takeovers of Australian firms. The year concluded with 45 takeovers, of which 8 were by companies overseas (Table 1). The previous two years had had only one such event (Advanced Ocular Systems' takeover of Regenera in 2005; and Axon Instruments' takeover by Molecular Devices Corporation in 2004). The total value of the transactions announced in 2006 was AU\$4.1 billion, assuming the Panbio deal is finalised as expected at the time of writing.

Table 1: Summary of major international takeovers of Australian firms, 2006

Purchaser	Australian company	Value	Comments
Hospira	Mayne Pharma	\$2,600 million	Hospira Inc. is a global specialty pharmaceutical and medication delivery company and is the leading U.S. injectable contract manufacturing business and they have a broad range of generic acute-care products medication.
Danaher Corporation	Vision Systems	\$791 million	Bidding war between Cytoc, Danaher and Ventana.
Ironbridge & Archer	3M Asia Pacific	\$455 million	Ironbridge & Archer acquired the 3M interests in the Asia-Pacific region including Australia and South Africa as part of a break-up of 3M's pharmaceuticals business worldwide.
Novozymes	Gropep	\$96 million	Novozymes is the biotech-based leader in enzymes and microorganisms.
Quest Diagnostics	Enterix	\$57 million	Quest has been distributing Enterix's faecal occult blood test in the US since 2003.
Bioton	Scigen	\$51 million	Bioton AG holds a substantial market share in several biopharmaceuticals (biosimilars) now off patent and acquired 90.5% of shares in ASX-listed Scigen then 100% to ensure markets for its own products and to acquire Scigen's novel compounds and supply licenses for the Asia-Pacific markets.
Inverness Medical Systems	Panbio	\$21 million	Proposal launched late in 2006 by Inverness, a major global developer, manufacturer and marketer of medical diagnostics.
Hospira	Bresagen	\$21 million	Bresagen was one of Australia's oldest companies formed in 1982, listed in 1999 and acquired in a fire sale by C-Bio Pty Ltd in 2005. The company earlier had a split personality, operating a contract biopharmaceuticals manufacturing business and doing research in transgenic animals and stem cells and drug development.
Chopin Opus One LP	Avantogen	\$5.5 million	Cayman Islands based private investment fund Chopin Opus One LP bid on Avantogen in September 2006.

Source: 2007 BioIndustry Review – Australia and New Zealand

▶ Leading technologies

Australian scientists and clinicians have been at the forefront of a number of research areas leading to innovation in biotech, and have been highly awarded for their discoveries. In 2006 we saw Ian Frazer receive the William Coley Award from the US Cancer Research Institute and appointed Australian of the Year for his pioneering work in HPV vaccines. The resulting product, Gardasil was developed by CSL and will be marketed by Merck. Elizabeth Blackburn, based in California, was co-recipient of the prestigious Lasker Award for 2006 and the Gruber Genetics Prize for her discovery of the function of telomerase and its role in cancer, ageing and repair.

In our 2007 report we highlight two areas of strength in Australia. Despite their long history, monoclonal antibodies have now come of age as therapeutics and are leading to a new range of blockbusters. Monoclonals have been the underlying technology in a number of major deals in Australia and overseas in 2006. CSL bought Zenyth for \$108 million, to acquire a portfolio of products, principally monoclonal therapies. Peptech was the recipient of \$178 million after the sale of UK based Domantis to GSK. Peptech had held a significant stake in Domantis. Evogenix is an exciting CSIRO spin out with novel monoclonal and protein optimisation technology. The federal and State governments have also lifted their commitment by allocating funds to a future mammalian cell culture facility.

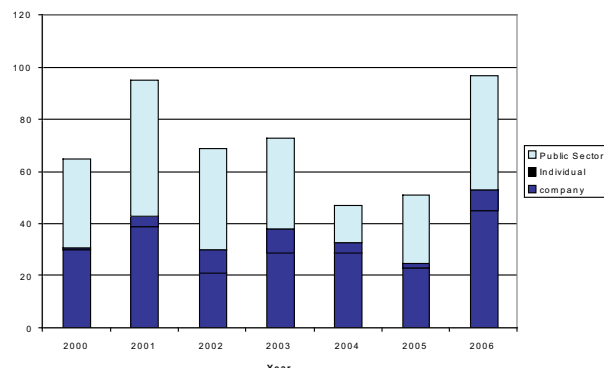
Neurobiology is another emerging area of strength in Australia but so far it is in infancy. Despite the unmet need for effective treatments in an ageing population, and the strength of Australia science in the area, there are few companies in the area. These include Prana Biotechnology, Neuren, Alzhyme and Bionomics.

Patents on the up and up

Patents are very important indicators of success in the biotech sector because of the importance of intellectual property as the foundation of inherent value in these companies. Australian organisations seek patents in the US because this country is likely to be the main market for their products or their partnerships. Hence, the number of US granted patents in biotechnology (a specific class in the US Patent Classification) is a good indicator of the strength of a biotech company's IP portfolio.

Over the last 5 years the trend in biotech patents granted to inventors in Australia has been shifting gradually downwards; however in 2006 there has been a sharp upward turn. It can be seen from Figure 1 that this is due to an increase in both the number of companies and number of research institutions which have been granted patents in the last twelve months. The reasons for this shift are not clear and would relate back to the time at which the patents were lodged (2003 or thereabouts).

Figure 1: US Biotech patents granted to Australian inventors, 2001 - 2006

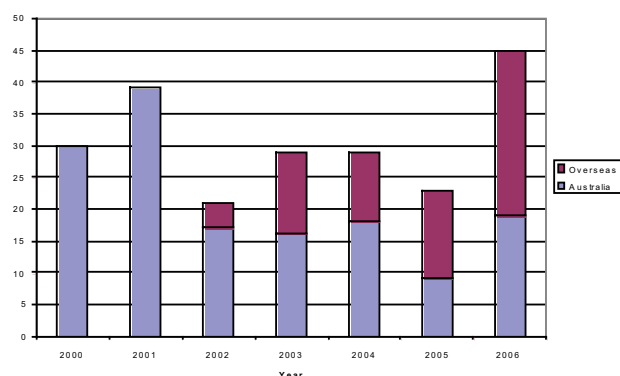


Source: Innovation Dynamics

In the calendar year 2006, 45 biotechnology patents were granted to inventors with Australian companies named as assignees. This much higher than calendar 2005 when 23 such patents were granted, and reverses a downward trend observed over the last 6 years. Of the 45 Australian inventors, 14 were based Victoria, 12 in Queensland, 5 in Western Australia, 5 in the ACT, 4 in New South Wales, and 5 in South Australia. More information about individual assignees is included in the 2007 BioIndustry Review. In general, however, patents are granted to a large number of assignees, with only one or two companies being granted more than one patent in any one year.

Given the rise in company patents, it is also interesting to note the increase in overseas assignees. In general, the trend has been for these patents to be invented by teams which contain one or a few Australian inventors in a larger international team (of up to 6 or 8 people). We presume that in many cases that this Australian inventor is working overseas with that team at the time, rather than doing the research alone in an Australian R&D institution or company as part of the international inventors group (Figure 2).

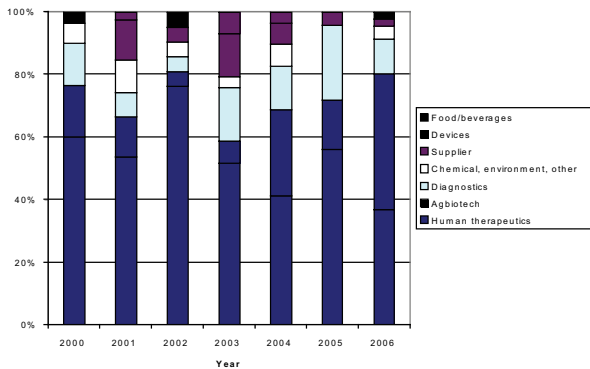
Figure 2: US patents granted to Australian inventors, company assignees



Source: USPTO, authors' analysis

► This year, 20 of the US biotech patents were granted to companies working in agricultural biotech, bucking the trends observed previously where a majority of US biotech patents were granted to companies working in human therapeutics (Figure 3). However it should be noted that over the years the proportion of patents granted to human therapeutics companies has been trending steadily downward. This is not necessarily a sign of disaster, as many of the patents used by biotech companies are granted to R&D institutions and then licensed out or assigned to companies.

Figure 3: Percentage of US biotech patents granted to companies in biotech sub-sectors, 2001 - 2006



Source: USPTO; authors' analysis

Trends for 2007

There has been considerable public philanthropic and government funding going into public health support and research, focusing especially on the causes of disease and their associations. The government announced major funding through the National Collaborative Research Infrastructure Scheme in late 2006. NCRIS aims to provide Australian researchers with major research facilities, supporting infrastructure and networks necessary for world-class research by granting \$542 million from 2005 to 2011. To date, cash and in-kind contributions of an additional \$642 million have been pledged.

In November 2006, the Minister announced the first nine investments, totalling \$381.7 million. Of this, 63% of the funds were dedicated to health and life sciences, with 39% allocated to fields of biotechnology and 23% allocated to related or supporting fields.

A new round of CRCs was also funded in December 2006, including four in biotechnology (Table 2). The combined funding of these CRCs will be \$113.83 million (37% of the total funding announced). Three of these CRCs will be headquartered in Victoria. These will focus on developing antibody-based therapeutics and diagnostic tests that target cell surface molecules expressed by white blood cells or cancers; strategic initiatives aimed at preventing hearing loss and improving communication through

research into biomolecular, genetic and physiological solutions to hearing retention, and integrated bioengineering; and commercialisation of new cancer therapeutics. The fourth CRC will be based in the ACT and will develop technologies to address biosecurity threats to grain.

Table 2: Successful CRCs, 2006 Selection Round

CRC	Status	Location	Funding (\$m)
CRC for Biomarker Translation	Developing from an existing CRC	VIC	30.59
The HEARing CRC	Developing from an existing CRC	VIC	32.55
CRC for Cancer Therapeutics	New	VIC	37.69
CRC for National Plant Biosecurity	Supplementary	ACT	13.00

Source: <https://www.crc.gov.au/Information/default.aspx>

Conclusions

Despite the earlier financial doom and gloom, and a total lack of media interest in life sciences, we see 2006 as a major turning point in the health innovation sector³. There are a number of pivotal trends in the industry in Australia and New Zealand that bode well for an excellent long term future. This appears contradictory at a time when funding for health and biotech has been so short during a record economic boom.

The lift in revenues in some of our larger companies and the next tier of biotech and devices firms, together with the start of strong international merger and acquisition activity, provides the evidence to Australian investors that the sector is moving away from its highly speculative beginnings. The international market appears to be revisiting Australia, slowly. Hopefully we will see more stability in company management & fewer CEOs changing over during 2007 and beyond. 

For further information about the BioIndustry Review and an order form, see page 24 of this issue of Australasian Biotechnology. Further information, including a contents page and list of tables and figure headings, is also available at www.innovationdynamics.com.au

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¹Darren Grubb, Intersuisse, 2006 Intersuisse winners and losers reported in BioTechnology News 7 January 2007, www.biotechnologynews.net/StoryView.asp?StoryID=71234.

²James, C (2006): The Top Sectors Over the past 21 Years, Economic Insights, CommSec.

³We think "tipping point" is overused and is designed to sell books, but we mean the same thing.