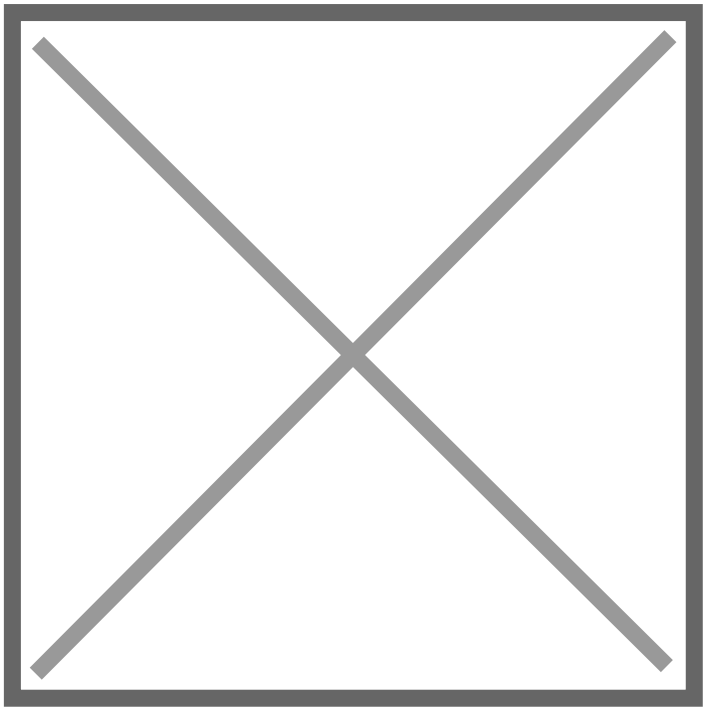


Australia's Biotech Burgeons

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The Australian biotech sector, now in a maturing phase, is bracing to leave its mark on the global stage.

A visit to the companies, institutes, and the government agencies in Australia clearly reflects an upbeat mood. The most talked about story in the industry circles is the Nobel Prize in Physiology or Medicine 2005 awarded jointly to Barry J Marshall and J Robin Warren "for their discovery of the bacterium Helicobacter pylori and its role in gastritis and peptic ulcer disease". Together, they found that the organism was present in almost all patients with gastric inflammation, duodenal ulcer or gastric ulcer. Based on these results, they proposed that Helicobacter pylori is involved in the etiology of these diseases. "The Nobel Prize-winning discovery by Marshall and Warren is firing up the Australian biological sciences to grow exponentially. The government is keen to encourage private investment and facilitate the commercial success of such discoveries," pointed out Dr Mark Bradley, chief executive officer, Australian Technology Park Innovations Pty Ltd (ATP Innovations).



The Australian scientists have a tradition of lateral thinking, technical excellence and global outlook. But what they traditionally lacked was commercialization of these technologies or research. The situation now is changing. "The industry has gone through the various phases of development and there has been a lot of learning in the curve. The sector now is in a phase that can be termed as maturing. Companies are maturing and are making good deals to consolidate," added Hamish Howthorn, director, life sciences and technology, ATP Innovations.

Industry grows

Australia is home to over 420 core biotech companies and 615 medical devices companies (as of December 2005). According to Sandra Fox, senior manager, International Operations, Invest Australia, this figure in 2001 was 190. Today, there are about 92 core biotech companies and over 80 medical device companies listed on the Australian Stock Exchange (ASX). About 40 percent of these 92 listed biotechs went public between 2003 and 2005. In FY 2003-04, there were 13 IPOs and in FY 2004-05, there were 12 companies, according to an Ernst & Young report. The total capital raised in 2004-05 was $134.4 million compared to $124.3 million in 2003-04, an increase of eight percent.

In fact, Australia accounts for half of the publicly listed biotechs in the Asia-Pacific as per the Ernst & Young's "Beyond Borders-Global Biotechnology" report. Ernst & Young had identified 671 public listed biotechs till the end of 2005 globally and

139 of them were in the Asia-Pacific. Australia accounts for nearly one-eighth of the total number of biotechs globally listed. And the market capitalization of Australia's 15 leading core biotechs was $9.78 billion in December 2005 compared to $8.26 billion at the end of 2004.

The VC funding is also on the rise. The biotech and healthcare sector attracted 19 percent of the total VC funding in 2004-05. In 2003-04, $450 million was invested as venture capital across the healthcare and bioscience sector. Australian Biotechnology News reported that Australian VCs invested more than $0.75 million per week in Australian biotech in 2003-04.

Market capitalization as on 6 December 2005 for biotechnology, medical devices and other healthcare companies whose stocks are listed on the ASX was $32 billion (157 companies) up from $20 billion in 2004. The market capitalization of Australia's 15 leading biotechnology, medical devices and other healthcare companies alone was $25 billion (as on December 6, 2005). And the total revenue of listed Australian biotech companies (December 2004) was over $1.5 billion.

From January to December 2005, Australian biotech companies announced 274 partnerships of which 72 percent were with organizations overseas.

Like elsewhere in the world, human health care accounts for the largest share of the biotech industry. Of the 92 biotechs, 48 percent of them are involved in human therapeutics, 16 percent are in agricultural biotech and 14 percent are in diagnostics. And there were 474 therapeutic products under development by the end of 2005. Australian inventors were granted 46 US biotechnology patents between January and November 2005 (compared to 47 for all of 2004).

There are approximately 20 companies offering contract scale up and manufacturing services in Australia, mostly for products to be used in clinical trials.

Government support

The Australian government and the state and territorial governments have been supporting the cause of the biotech sector through funding, world class R&D infrastructure development, promotion of trade, and skill development.

"The support for the biotechnology industry is motivated by two major policy statements-the National Biotechnology Strategy and the Australian government's 2001 innovation statement, Backing Australia's Ability," said Dr Roseline Yardin, manager, biotechnology, Department of State and Regional Development, New South Wales Government.

The total funding under "Backing Australia's Ability" is $6.3 billion over 10 years from 2001. In 2004, the Australian government announced the new Backing Australia's Ability-Building our Future through Science and Innovation package, which is investing an additional $4 billion into science and innovation. The Australian government provides substantial support for R&D. There is focus under it to make strong public investment in the development of the nation's biotechnology industry. In 2003, the government spent over $800 million in biotechnology R&D (Hopper and Thorburn 2005), which on a per capita basis is one of the highest internationally.

Further, Biotechnology Australia (BA) was created to assist in coordinating the government's approach to biotechnology. It comprises five Australian government partner departments (Agriculture, Fisheries and Forestry; Environment and Heritage; Health and Ageing; Industry, Tourism and Resources; and Science Education and Training). BA, with its partners, is responsible for developing and implementing the National Biotechnology Strategy which underpins the government's vision to ensure Australia captures the benefits of biotechnology, while protecting the safety of people and the environment. The National Biotechnology Strategy which has been in place since 2000 provides a framework through which the government and key stakeholders can work together to achieve the agreed vision for biotechnology.

Biotechnology Australia is an Australian government agency responsible for coordinating non-regulatory biotechnology issues, as well as providing balanced and factual information to the Australian community.

The government's Pharmaceuticals Industry Action Agenda was launched in association with industry in 2002 with the aim to double Australia's share of the global pharmaceutical industry by 2012. Also, in 2004, the government announced the Medical Devices Industry Action Agenda to accelerate industry development by harnessing its global potential.

The Australian government's flagship program to support the pharmaceuticals industry is the Pharmaceuticals Partnerships Program, or P3, which provides $110 million over five years in grants to the pharmaceuticals sector. The program promotes additional R&D throughout the entire pharmaceuticals value chain including biotechnology, originator and generic medicines companies. Participating companies in P3 receive 30 cents for each additional dollar they spend on eligible R&D in Australia. P3 is not restricted to companies that sell products on the Pharmaceutical Benefits Scheme, and ownership of intellectual property will not impact on the eligibility of R&D under the program. The next round for P3 will be in 2007.



The successful companies in Round 1 for P3 included Acrux DDS Pty Ltd, AGT Biosciences Ltd, Amrad Corporation Limited, CSL Ltd, Eli Lilly Australia Pty Ltd, Janssen-Cilag Pty Ltd, Mayne Pharma Pty Ltd, Merck Sharp & Dohme (Australia) Pty Ltd, Novogen Ltd, Pharmaxis Ltd, and Servier Laboratories (Australia) Pty Ltd.

The successful companies for Round 2 for P3 were Alchemia Ltd, Alphapharm Pty Ltd, CBio Ltd, Peplin Ltd, Pfizer Australia Pty Ltd, Prana Biotechnology Ltd, and Starpharma Pty Ltd.

The other major research funding bodies relevant to biotechnology and pharma are the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC). The government injected a further $462 million into health and medical research over six years from 1999-00, which doubled the NHMRC's annual budget in 2005. A total of almost $230 million in project and program grants for 2005 were announced by the NHMRC. (Hopper and Thorburn 2005, Bio-Industry Review, Australia & New Zealand).

Under Backing Australia's Ability, ARC funding increased by $554 million, doubling the funds for research by 2006.

In November 2004, the ARC linkage and discovery grants were announced allocating $287 million over five years with $52.7 million provided for biological sciences
and biotechnology.

State governments announced investments of almost $100 million in biotech related infrastructure in 2003/04 (Hopper and Thorburn 2005, Bio-Industry Review, Australia & New Zealand).

The $150-million per year Commercial Ready program offers competitive grants to encourage Australian companies to increase R&D, proof-of-concept and early-stage commercialization.

Further, the Australian State and Territory governments have joined with the New Zealand government to create a biotechnology partnership-the Australia-New Zealand Biotech Alliance (ANZBA). The Alliance's main objective is to provide all member jurisdictions with a significant international presence in biotechnology research and development and marketing.

Research and commercialization

The Cooperative Research Centre (CRC) program melds public and private-sector investment and R&D expertise. This program was set up in 1990 to establish formal, strategic seven-year agreements between research providers and users in the public and private sectors. CRCs are major drivers of biotechnology and biomedical innovation in Australia. A recent study by the Allens Consulting Group on behalf of the CRC Association revealed that for every A$1 of public funding invested in the CRC program, Australia's GDP rose by A$1.60.

More than 70 CRCs operate across a wide range of industry sectors. Nearly one-third are completely or partially involved in biotechnology, biomedical or environmental bioscience research. Over the last few years approximately 50 per cent of Australia's biotechnology companies have been spun out of publicly funded research institutes.

The sector is distinguished from other markets by its flexibility, open approach and focus on partnering for both primary research and commercialization. More than 70 percent of the 339 Australian biotechnology and other life sciences firm alliances announced during 2005 were with organizations outside the country.

Treatments for chronic obstructive pulmonary disease, the Kapanol-brand analgesic, continuous-wear contact lenses, synthetic Omega 3 fatty acids, and Granulocyte Colony Stimulating Factor and a vaccine for the Human Papilloma Virus all have their roots in intellectual property developed jointly between Australian biotechnologists and international companies. The depth and credibility of our biotechnology sector makes your biotechnology investment and partnering decision simple.

Clearly, Australia is on its way to become a biotechnology powerhouse. Excellent research facilities, innovative scientists, a can-do attitude and a strong but flexible regulatory regime are the factors that will be contributing in this development. Its biggest challenge is that of creating of a strong financing structure.

In a recent international benchmarking study undertaken by the Economist Intelligence Unit, Australia was ranked against the US, the UK, Germany, Japan, Singapore and India across a range of indicators including clinical trials, the intellectual

property system, the regulatory environment, investment and the business environment. Australia ranked second overall and first as a location to conduct clinical trials, a testament to the country's deep roots in scientific, agricultural and medical research.

Ch. Srinivas Rao in Sydney