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other partner on that target. It's really very clean in terms of how you can divide up the field.

## **How do you see outsourcing from big pharma progressing in the mid to long term?**

I think there will always be outsourcing, but you have to ask yourself why do pharmaceutical companies typically outsource? Looking at competitor companies, it's not all about price. We have sometimes been the most expensive solution, but we have a reputation for delivering. It's all about quality and meeting expectations. The main reason pharma companies come to us is that they are looking for a solution to a problem or, especially with biotech companies, they want to run a whole integrated research programme. They want innovation. They are often looking for us to think outside the box in terms of creating a different solution, or

going about things in a different way than they would internally. Typically, in a lot of the programmes we are working on, there is a parallel effort progressing with the partner and they view us as an extension to their own research team, bringing a different approach to solving a problem. It isn't always about extra capacity either (although that can be important to a big company research group with too many projects to run); it is often about employing an external group with a different expertise. That is what people see when they come to us and work with us.

## **What metrics will you use in the next year and the next five years to assess the success of the company with respect to its scientific mission?**

What we are trying to do here is to build a company that isn't constantly trying to dip into the investor pockets. Clearly, that's where the contract research component is very

important – first we have to be focused in terms of running a robust, successful contract research business. The second thing is to build the upside value for the management, the staff and the investors by achieving success in our respiratory programmes. We need to achieve the goals we have set for ourselves. In this case, making the clinical milestones will be the absolute true measure of whether we are successful or not.

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\*For more information on this subject, see the Keynote review, Perspectives for cytokine antagonist therapy in COPD, by Willem I. de Boer pp. 95-108 in this issue.

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## Focus on biotechnology in Australia

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Continued attention to scientific and clinical excellence, and an industry with clear commercial opportunities, has allowed Australia to adopt first position in the Asia-Pacific (AP) region and sixth position among the top biotech countries in the world [1]. Biotechnology is one of Australia's fastest growing industries with ~370 core biotechnology companies listed in 2004 (there

were 190 companies in 2001), and 43% of these companies are in human therapeutics, 16% in agricultural biotech and 15% in diagnostics. The revenue generated from Australian biotech and devices companies rose from almost A\$1 billion (US\$778 million) in 2001 to ~A\$2 billion (US\$1.5 billion) in 2002–2003 [2]. This article provides a brief overview of the different biotech companies in Australia, the funding support available and the future for this industry within the AP region.

## **Innovation networks and infrastructure**

Australia has a strong culture of scientific endeavors arising from biotechnology departments in research institutes. The proportion of research spin-offs among new biotech start-ups is steadily increasing and, in the financial year (FY) 2003–2004, up to 66% of all new biotech firms were derived from such spin-offs. Universities were responsible for 23 out of the 28 research spin-offs, with the universities of Queensland and Melbourne, in particular, responsible for almost 50% of all spin-offs [2]. For example, IMBcom Pty Ltd commercializes biotechnology research

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drawn from the Institute of Molecular Bioscience (IMB) based at the University of Queensland. One of IMBcom's key activities includes the development of emerging technologies through the establishment of spin-off companies such as Xenome Ltd (a drug discovery company harnessing a unique variety of Australian venoms). Prana Biotechnology Ltd was established through the work of researchers at the University of Melbourne, the Mental Health Research Institute of Victoria, Massachusetts General Hospital, MA, USA and Harvard Medical School, MA, USA (e.g. metal protein-attenuating compounds for Alzheimer's disease). In 2004, Prana Biotechnology Ltd was able to fund its R&D activities further after winning an Australian Government grant worth A\$1.35 million (US\$1 million) and securing an investment of US\$20 million (A\$25.8 million) from US institutional and professional investors [3].

There are several Australian research institutes that are affiliated with major public hospitals, universities and health-related Cooperative Research Centres (CRCs), highlighting an interlinked innovation system feeding the commercialization pipeline for biotechnology. CRCs have an important role in the Australian innovation system by bringing together researchers and research users from universities, the public sector and industry. Recently, the CRC program received an additional A\$65 million (US\$50.3 million) in Australian Government support. There are now a total of 71 CRCs across Australia operating in six sectors: (i) environment; (ii) agriculture; (iii) information technology; (iv) communications technology; (v) mining; and (vi) manufacturing technology. In addition,

there are nine sectors in the medical science and technology area, such as the CRC for Asthma, the CRC for Cellular Growth Factors and the CRC for Diagnostics.

A major pillar of the Australian biotech innovation system is the Commonwealth Scientific and Industrial Research Organisation (CSIRO) – one of the largest and most diverse research organizations in the world, encompassing programs in the areas of health, agriculture and the environment. CSIRO has developed close ties with leading firms, such as Monsanto and Bayer, in USA, Europe and Japan, and is Australia's leading patenting enterprise with 3900 patents granted or pending to date [4]. CSIRO has various types of commercial agreements with both public and private organizations, for example, its work with Monsanto's *Bt* (*Bacillus thuringiensis*) genes (Bollgard® II) under licence to incorporate insect resistance into various types of cotton plants.

## Technology parks

Australia has some emerging biotech clusters developing in and on the outskirts of its major cities. The Australian Technology Park in Sydney, which focuses on biomedical, proteomics and bioinformatics research and medical devices, was founded in 1995 as a place where financiers, researchers and educators could work side-by-side. There are now 80 technology companies and four universities resident at this park.

Opened in May 2003, the state-of-the-art Bioscience Precinct located at the University of Queensland in St Lucia houses 700 scientists from the Institute for Molecular Bioscience, CSIRO and the Queensland Department of Primary Industries. The main areas of biomedical research at the Precinct include gene discovery, livestock and plant industries, and the development of sustainable ecosystems.

In Victoria, the Parkville–City Precinct accommodates 2000 researchers and received >A\$200 million (US\$155 million) in research funding. The Precinct includes some of Australia's world-class cancer research institutes such as the Walter and Eliza Hall Institute of Medical Research, Howard Florey Institute, the Ludwig Institute for Cancer Research and Peter MacCallum Cancer Centre, as well as companies such as CSL, Starpharma and Prana Biotechnology Ltd.

Adelaide, South Australia, has the Thebarton Bioscience Precinct and the Waite Precinct focusing on biomedical and agribiotech, respectively. The Thebarton Bioscience Precinct is home to the largest cluster of commercial medical bioscience companies in Australia, employing nearly 350 science and technology graduates. There are several biomedical companies located in the precinct, including GroPep Ltd, Bionomics Ltd, TGR Biosciences Pty Ltd, BresaGen Ltd, Idexx and Oxoid Pty Ltd. The Waite Precinct is a world-leading research and education centre for plant biosciences, viticulture, and land and water management. Beginning life as the University of Adelaide's plant research precinct, the Waite Precinct is now the largest single concentration of agriculture science R&D in Australia. Some of the Waite's partners comprise CSIRO Plant Industry Division, Australian Wine Research Institute, South Australian Research and Development Institute, Australian Centre for Plant Functional Genomics Pty Ltd (ACPFPG), Australian Genome Research Facility and Molecular Plant Breeding CRC. The ACPFG conducts commercially focused research using functional genomics to improve the resistance of wheat and barley to hostile environmental conditions such as salinity and drought.

Canberra, in the Australian Capital Territory, has a small population, but hosts the third largest biotechnology R&D cluster in Australia. The capital is home to many of Australia's leading biotechnology R&D institutions, including the John Curtin School of Medical Research and the Research School of Biological Sciences at the Australian National University (ANU), the Gadi Research Centre for Medical and Health Sciences at the University of Canberra, several CSIRO biotech labs specializing in plant biotechnology and environmental management, and the Australian Institute of Sport whose researchers are developing medical devices. The ANU's Innovation Centre hosts the Phenomix Corporation, medical device company ITL and a number of medical research R&D spin-off companies.

## International collaborations

The Ernst and Young 2003 Beyond Borders report states that Australia had 21 cross-

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border alliances in 2002, more than France and Switzerland, and 18 more than the nearest AP competitors, India, Japan and New Zealand [5]. These corporate partnerships provide international companies with access to new technology developed in Australia. For example, Schering AG, committed A\$25 million (US\$19.4 million) over five years to initiate a corporate partnership with Neurosciences Victoria and to develop commercial products for the prevention, diagnosis, treatment and cure of brain disorders such as Alzheimer's and multiple sclerosis. GlaxoSmithKline invests >A\$34 million (US\$25.6 million) per year to support >20 R&D projects and several clinical trials across Australia in areas such as cancer, cardiovascular disease, diabetes, HIV/AIDS and influenza.

In 2004, there have been a number of small- to medium-sized companies emerging with internationally focused business models, many already with revenue streams to complement their discovery programs. These companies are developing portfolios of technologies and progressing them further down the development pipeline. A few examples of these include Cerylid Biosciences, Biota Holdings and Virax Holdings.

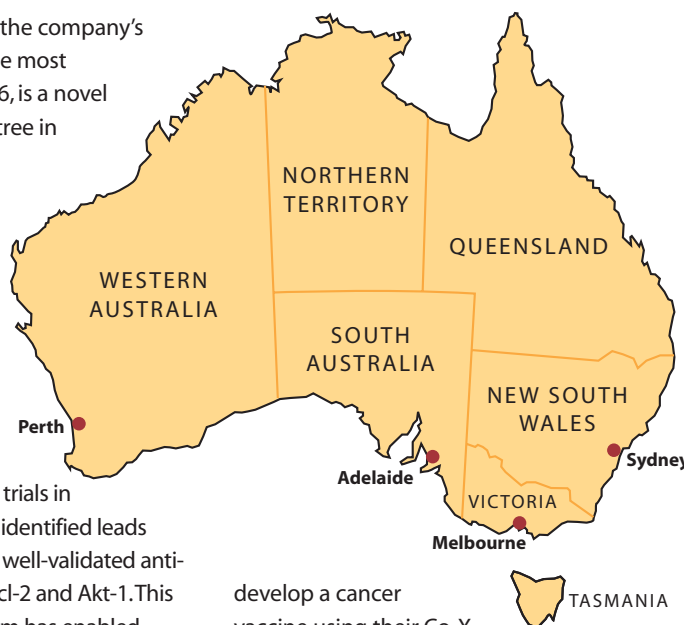
## Commercial success

One of the major advantages of chemical research in Australia lies in its biological diversity and that this diversity is largely an untapped resource. Cerylid Biosciences is one of several companies capitalizing on this potential. Cerylid owns an extensive library containing >600 000 natural product extracts incorporating samples from Australia, Antarctica and Asia, and ~150 novel, bioactive compounds have already been isolated from this collection. Cerylid has an internal discovery program used to develop a number

of anti-cancer leads from the company's natural product library. The most advanced of these, CBL316, is a novel molecule isolated from a tree in Sarawak, Malaysia. This compound has been tested at the National Cancer Institute (Bethesda, MD, USA) and appears to have a unique mechanism of action. Currently, CBL316 is in preclinical development and is scheduled to enter clinical trials in mid-2005. Cerylid has also identified leads against a number of other well-validated anti-cancer targets including bcl-2 and Akt-1. This powerful discovery platform has enabled Cerylid to establish drug discovery partnerships with international players, such as Aventis, Chiron, Chugai and Anadys Pharmaceuticals. In 2004, Cerylid merged with Kinacia, an Australian biotech company that develops novel anti-thrombotic technologies applicable to disease targets such as cardiovascular, inflammation and cancer – this combined entity will have a significant drug pipeline.

Biota Holdings, engaged in R&D of new pharmaceuticals, specializes in respiratory infectious diseases and has two products which are marketed worldwide: Relenza™, an antiviral treatment for influenza; and FLU OIA®, a rapid POC influenza A/B diagnostic kit. FLU OIA can also be used to test for avian influenza and, subsequently, has the potential to assist in the fight against recent outbreaks of the disease in Asia. Biota Holdings recently raised A\$20 million (US\$15.4 million) from its share purchase plan following the announcement to develop its second-generation influenza antivirals for biodefense stockpiling for the US National Institutes of Health.

Virax Holdings is an early-stage development biopharmaceutical company devoted to the development of immunotherapeutics for the treatment of autoimmune disorders, HIV/AIDS, cancers and infectious diseases. Virax's patented Co-X-Gene technology uses cytokines co-expressed with antigens to modify the human immune response. Virax has recently entered into a collaboration with the French biotech company, Transgene SA, to



develop a cancer vaccine using their Co-X-Gene technology for herpes papillomavirus with promising results.

## Growing financial strength

Australia attracts more private equity funds than any other country in the AP region (excluding Japan), accounting for 27% of all private equity invested in the region. In this respect, Australia is a major capital market in the AP region with a recorded average annual growth rate of 12.7% for the past seven years [6]. Venture capital invested in Australian healthcare and bioscience companies in 2003 was almost A\$205 million (US\$159 million) [2], and over A\$500 million (US\$389 million) was invested through initial public offerings (IPOs) and follow-on capital raisings in 2003 (for example, share placements following IPO) [7]\*. In the FY 2002–2003, almost 50% of the venture capital invested in biotech firms was aimed at seed stage, with a further 24% in start-ups and 19% in early expansion firms [2].

Investor interest in the Australian biotechnology sector continues to be strong in 2004 as biotech and pharmaceutical stocks lead the way on the Australian Stock Exchange (ASX). In the third quarter of 2004, eight biotech and pharmaceutical IPOs were conducted, raising a total of A\$98 million

\*Initial Public Offering refers to when a company issues shares for the first time to the public (in this case via listing on the Australian Stock Exchange) and raises capital by issuing these shares. Follow-on capital raisings refers to a company raising additional capital (source: [www.asx.com.au](http://www.asx.com.au)).





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## BOX 1

### Websites of interest

#### Ausbiotech

[www.ausbiotech.org](http://www.ausbiotech.org)

AusBiotech is the peak industry body representing the biotechnology sector in Australia.

#### Bioshares

[www.bioshares.com.au](http://www.bioshares.com.au)

Bioshares is published by Blake Industry and Market Analysis Pty Ltd, which provides market and company analysis of the Australian pharmaceutical and biotech industries for Australian and international funds management institutions, venture capital funds and other related industry groups.

#### Ausindustry

<http://ausindustry.gov.au>

An Australian Government Agency website providing information on research, industry and innovation in Australia.

#### Invest Australia

<http://www.investaustralia.gov.au/biotech>

Invest Australia's website provides information on the untapped biotech opportunities in Australia and how to establish a business in Australia.

(US\$76 million) between them. This activity builds on the results from the previous quarter, in which six more IPOs occurred raising A\$43 million (US\$33 million) [7] (Box 1).

The last two weeks of September 2004 saw four more IPOs from Australian biotechnology companies [7], all of which provided significant capital injections for companies at the leading edge of Australian innovation, including Avexa (specializes in anti-infectives), Acrux (drug delivery), Sunshine Heart (cardiac assistance) and Proteome Systems (proteomics and bio-IT systems) (Box 1).

The stock values of Australian life science grew to 30% over the first three quarters of the FY 2003–2004, outperforming the ASX All Ords (+14%)<sup>†</sup>, the NASDAQ Composite (+18%) and NASDAQ Biotech index (+10%) [8]. The ASX Healthcare and Biotech Index was valued

A\$27.1 billion (US\$21 billion) at the end of the third quarter in 2004, compared with A\$22.7 billion (US\$17.6 billion) at the end of the same period in 2003 [7]. A recent survey of 82 listed small Australian biotechs showed that they had cash reserves of A\$734 million (US\$570 million) at the end of FY 2003–2004, compared with A\$386 million (US\$300 million) in 2002–2003 (from a survey of 69 companies) [9].

### Government support

The Australian Government provides substantial support for R&D. Indeed, Australia outranks several countries in the Organisation for Economic Co-operation and Development (OECD), including USA, Japan, Canada and UK, on public expenditure on R&D as a percentage of their GDP [10].

On 6 May 2004, the Australian Government announced a new initiative, which will invest an additional A\$5.3 billion into science and innovation, bringing new funding under the Government's innovation program 'Backing Australia's Ability' to a total of A\$8.3 billion (US\$6.4 billion) over a period of ten years from 2001. There are a number of specific initiatives as part of this new program, including: (i) the Commercial Ready program, which provides >A\$1 billion (US\$778 million) over a period of five years starting from the FY 2006–2007; (ii) Commercialising Emerging Technologies (COMET) program, which provides A\$100 million (US\$77.8 million) over the next seven years; and (iii) the R&D Tax Concession with an estimated A\$390 million (US\$303 million) provided over five years from FY 2006–2007.

In May 2003, the Australian Government introduced a new flagship program to support the pharmaceuticals industry. The Pharmaceuticals Partnerships Program, or P3, commenced on 1 June 2004 and will run to 30 June 2009. P3 will offer A\$150 million (US\$116 million) in grants over five years to the pharmaceuticals sector by promoting additional R&D throughout the entire pharmaceuticals value chain, including biotechnology, originator and generic medicines companies (Box 1).

### Future perspectives

The Australian biotechnology industry is starting to evolve as one of the key global

hubs, in particular, as a strong base in the AP region. The industry has improved greatly over the past three years and is starting to see good early-stage opportunities, especially in biomedical areas, that can add to the global pipeline. A strengthened attention to sustainable business development models that generate revenue has assisted in creating opportunities for venture capitalists and investors. The industry is also starting to see merger and acquisition activity, which is helping to achieve a critical mass of research and commercial opportunity (i.e. one that can sustain itself and create long-term value over time).

Australia's peak biotechnology organization, AusBiotech, provides a vibrant and energetic framework that brings together all the relevant participants in the Australian biotechnology community through its national biotechnology conference – AusBiotech 2005, which will be held 20–23 November 2005 in Perth, Western Australia.

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<sup>†</sup>The Australian Stock Exchange (ASX) All Ords refers to the index that is made up of the weighted share prices of ~500 of the largest Australian companies. Established by ASX at 500 points in January 1980, it is the predominant measure of the overall performance of the Australian share market. The companies are weighted according to their size in terms of market capitalization (total market value of a company's shares) (source: [www.asx.com.au](http://www.asx.com.au)).