



Melbourne
Doing Business Globally **Australia**

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Biotechnology

STRATEGIC DEVELOPMENT PLAN FOR VICTORIA 2004



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foreword

The biotechnology revolution is creating exciting new opportunities and challenges for Victoria, Australia and the world.

Launched in 2001, the Victorian Biotechnology Strategic Development Plan is positioning Victoria to capitalise on our biotechnology strengths to achieve the Victorian Government's aim of making the State one of the top five biotechnology locations in the world by 2010.

This is an ambitious goal, but one Victoria is well on track to achieving.

Many of the Plan's targets have been met – Victoria's international profile in biotechnology has risen strongly and the number of companies, levels of investment and employment have grown.

By 2005, the Victorian Government will have invested more than \$500 million in projects to strengthen the biotechnology sector, including building leading-edge science infrastructure, developing dedicated biotechnology precincts and backing the commercialisation of Victorian biotechnology research.

With nearly 4 out of 10 of Australia's core and diversified biotechnology firms and more biotechnology employees than all other Australian States combined, Victoria is clearly Australia's biotechnology leader.

The Victorian Biotechnology Strategic Development Plan 2004 recognises Victoria's achievements in biotechnology, responds to the changing local and global biotechnology environment and sets new targets for Victoria's biotechnology sector.

The 2004 Strategy identifies new actions the Victorian Government will take to boost the State's capacity to take full advantage of the many opportunities being generated by Victoria's world-class biotechnology research.

While maintaining a strong emphasis on the State's research and development base, the 2004 Strategy shifts the focus of Government efforts towards ensuring that the products of Victoria's biotechnology research make it to the vital pre-market stage – and beyond.

The strategy recognises that while action from government is essential to meeting the challenges ahead, strong partnerships between industry and the research community are also vital to the future strength and growth of the State's biotechnology sector.

The coming decades will be exciting and demanding times in biotechnology. The Victorian Biotechnology Strategic Development Plan 2004 continues the Victorian Government's record of leadership and achievement in building Victoria's capacity to reap the benefits of the biotechnology revolution and go forward as a national, regional and global leader in biotechnology.



A handwritten signature in white ink that reads "Steve Bracks".

Steve Bracks MP
Premier



A handwritten signature in white ink that reads "John Brumby".

John Brumby MP
Minister for Innovation

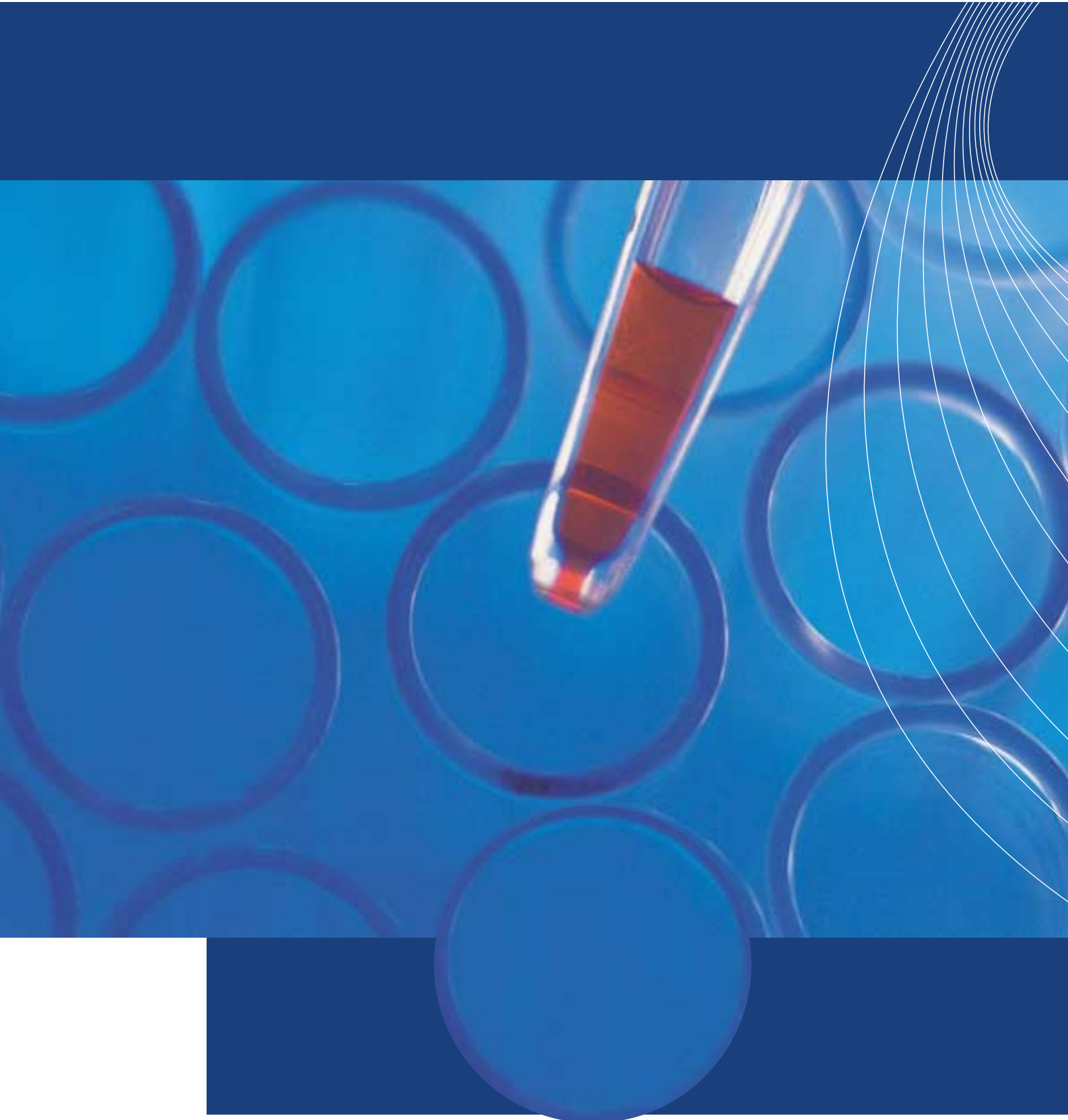


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executive summary



executive summary

Recent scientific discoveries are facilitating a revolution in biotechnology that will have a profound impact on our health and quality of life over the century ahead. This biotechnology revolution is creating opportunities and challenges for Victoria, Australia and the world. The Victorian Biotechnology Strategic Development Plan (the Plan) is positioning Victoria to capitalise on what many predict will be the biotechnology age.

The Plan was launched in 2001 and concentrated primarily on strengthening Victoria's research and development base with significant investments in infrastructure and capability building.

Considerable progress has been made. Many of the targets set in the 2001 Plan have already been achieved. Victoria's international profile has risen strongly and the number of companies, levels of investment and employment have grown.

The Victorian Government, through the Department of Innovation, Industry and Regional Development, has provided substantial investment in new infrastructure to support biotechnology developments. It has strengthened the science and technology base and invested considerable resources and effort in creating new alliances and strengthening existing ones between governments, industries and research organisations, here and overseas. It has showcased Victoria's industry to the world and promoted informed community discussion about the issues surrounding biotechnology.

There also have been dramatic changes and breakthroughs in the global biotechnology industry. New issues, challenges and opportunities have emerged. For example:

- there have been major technical developments, including the mapping of the human genome;
- governments worldwide have increased their commitment to biotechnology industry development;
- business models of major companies are changing; and
- capital markets are continuing to play a critical role in the development of biotechnology companies and the geographic location of biotechnology firms.

Ernst & Young was appointed in November 2003 to assist the Department of Innovation, Industry and Regional Development to undertake stakeholder consultation, review progress and identify what needs to be done to encourage further growth for biotechnology in Victoria. The review contributed to the refinement of a Strategy to reflect achievements under the Plan and a changed and changing global biotechnology environment.

Progress to date against targets set in 2001

2001 Plan Targets

Progress to Date

Target 1 - Start up companies

The establishment of 50 new start-up companies based in Victoria by 2005.

68 new core and related biotechnology start-up companies were established between 2000 and 2002.

Target 2 - Research and investment partnerships

At least five new research or investment partnerships with local or international biotechnology related companies will be established by 2005 with a combined project value of \$25 million.

At least ten new research or investment partnerships have been formed, with a combined project value in excess of US\$120 million. They include:

- AMRAD with Merck Inc;
- Neurosciences Victoria with Schering AG; and Prana;
- AGT Biosciences with the Institutes of Pharmaceutical Discovery; Merck Santé; and ChemGenex Therapeutics;
- Biota with Sankyo;
- Meditech with Novozymes; and
- Acrux with Eli Lilly; and VIVUS Inc.

Target 3 - Clinical trials

An increase in clinical trial research investment by 50% by 2005.

- Bristol-Myers Squibb (BMS) established an R&D hub in Victoria, the first outside the US. BMS is spending \$17 million p.a. on Australian R&D.
- The Royal Children's Hospital and Murdoch Children's Research Institute will be preferred providers for paediatric clinical trials for Quintiles Transnational.
- Clinical Trials Victoria and the Centre for Clinical Studies (Phase I clinical trial facility) have been established with Victorian Government support.
- Clinical trial applications to the National Health and Medical Research Council (NHMRC) increased by 30% from 1999-2000 to 2001-2002.

Target 4 - Manufacturing

The creation of three significant manufacturing facilities by 2010.

Manufacturing facilities worth more than \$184.5 million have been secured. Those announced publicly include:

- GlaxoSmithKline – \$13m fine chemicals facility in Port Fairy;
- CSL – \$10m Nucleic Acid Testing facility;
- Mayne – \$45m expansion of facilities in Mulgrave;
- Cardinal Health – \$6m expansion of facilities at Braeside;
- Institute of Drug Technologies (IDT) – \$2.5m investment in manufacturing; and
- Vital Biotech, the first Australian biotechnology company to list on the Hong Kong Stock Exchange – \$3m new manufacturing facility.

Target 5 - Community information

Community groups believe that they have been informed and involved in the policy development process.

- Community groups contributed to the development of the 2001 Plan.
- 17 Community Information Forums on biotechnology have been held.
- Victorian Biotechnology Ethics Advisory Committee established.
- Gene Technology Access Centre established.
- Biotechnology web site developed: www.biotechnology.vic.gov.au.

Note: Throughout this document, unless otherwise specified, all \$ refer to Australian dollars.

Strategy for the Biotechnology Strategic Development Plan 2004

The Vision driving the Strategy remains the same: by 2010 Victoria will be recognised internationally as one of the world's top five biotechnology locations for the vibrancy of its industry and quality of its research.

To achieve the Vision, the 2004 Strategy will build on the progress already made under the Biotechnology Strategic Development Plan 2001 to generate a sustainable industry able to develop products to the pre-market stage and beyond.

In doing so, the 2004 Strategy will maintain the strength of Victoria's research and development base and continue to address issues such as access to capital markets, people and skills development.

Increasing competition worldwide means there is a continuing need to drive innovation by bringing together new people, new ideas and different approaches to solve problems.

An overarching theme of the 2004 Strategy is 'connectivity' – within and between disciplines and between segments of the industry, here and overseas, and with emerging and traditional industries – to maximise the mutual benefits converging technologies can deliver.

The initiatives in the 2004 Strategy build on the five priority areas of action identified in 2001.

They are designed to:

- Improve connectivity.
- Facilitate increased investment in Victorian biotechnology.
- Attract and develop skills in strategic areas.
- Improve access to platform technologies and build infrastructure in specific areas of the product value chain, meet gaps and provide focus for international investment.
- Promote Victorian biotechnology.
- Support a sound regulatory environment and the provision of balanced and accurate information to the community.

As many of the targets set in 2001 have been achieved, new targets to 2007 have been established. The 2007 targets are ambitious and require a commitment by industry, the research community and government to work together.

The Victorian Biotechnology Strategic Development Plan 2004 will ensure Victoria maintains and enhances its biotechnology leadership in a dynamic, changing and challenging global environment.

2004 Plan Targets

Target 1 – Patents

- By 2007, granted US biotechnology patents per annum from Victoria's R&D base to exceed 120.

Target 2 – Infrastructure

- Establishment of additional bioprocessing facilities for Victorian firms and research sector by 2007.

Target 3 – Research and Development

- Corporate biotechnology R&D expenditure to exceed \$500 million per annum by 2007.

Target 4 – Venture Capital

- Venture capital investment in Victorian biotechnology to exceed 40% of the national annual venture biotechnology investment by 2007.

Target 5 – Partnerships

- Deals with a combined project value to exceed \$1 billion in aggregate by 2007.

Target 6 – International Leadership

- Victoria is recognised internationally as the leading location for marsupial genomics by 2007.



introduction



introduction

Biotechnology: a new word for an old practice

Biotechnology is a modern word for a practice that is thousands of years old. It is the application of what we know about living organisms and their components to make new products and to develop new industrial processes.

Biotechnology as it was practised thousands of years ago provided the world's first beer. Today, thanks to the discovery of DNA, the chemical basis for the genetic code common to all living organisms, biotechnology is providing new treatments for previously untreatable diseases, more productive agriculture and a healthier environment. Industries that use biotechnology include:

- Health – pharmaceuticals and diagnostics.
- Agriculture – plant breeding, animal breeding, veterinary products and diagnostics.
- Environment and resources – pollution control, land bioremediation, water treatment, minerals extraction and processing and pest management.
- Food and beverage processing – starters, enzymes, fermentation.
- Industrial applications – further processing of agricultural products (e.g. oils, fibres), bioprocessing and generation of industrial enzymes.
- Energy production – biomass.

Governments, industry and the community understand that this new technology has the potential to bring benefits but that it could also lead to adverse impacts. Sound regulatory systems are important to manage potential risks or adverse impacts.

Capturing value from biotechnology

Capturing the benefits of biotechnology involves a number of steps, often described as a 'value chain' as illustrated in Figure 1. The value chain has the following elements:

- Research or discovery (the generation of new knowledge).
- Product identification and optimisation (the new knowledge is applied to provide a solution to an unmet need).
- Product testing (the concept is tested in clinical or field trials).
- Market (product manufactured and sold in the marketplace).

The further along the value chain Victorian firms can develop biotechnology products, the greater the economic and social value generated for the State.

Figure 1: The biotechnology value chain



The role of government

Progress from discovery to market can take a long time and requires a high level of investment. For example, the average cost of developing a new biotechnology medicine is estimated to be US\$800 million. Success is underpinned by innovation and strong enabling conditions for growth.

Governments, state and federal, have a vital role to play in facilitating growth and development in the biotechnology sector. They do this by creating the right conditions for the industry to succeed, by setting the policy and regulatory framework and through constructive intervention to address market failures.

The specific aim of the Victorian Government is to facilitate the development of biotechnology to deliver economic, social and environmental benefits to all Victorians. It does this by:

- Establishing a robust regulatory framework to ensure that ethical and safety standards are met and the community is well informed and confident about the directions of the industry.
- Developing networks and connections to bring people, research and ideas together.
- Investing directly in new infrastructure, research and skills development in partnership with industry and the research community.
- Encouraging and facilitating new local and international investment.
- Promoting Victoria and the industry internationally.

However, governments can only do so much. Ultimately, growth and development can only come from a strong commitment by industry and the research community to work together.



Victorian biotechnology

Victoria has a strong science and technology base, particularly in the areas of health and medical research and agri-food. This technology base includes:

- Six dedicated biotechnology precincts.
- More than 20 medical research institutes such as the Walter and Eliza Hall Institute of Medical Research, the Ludwig Institute for Cancer Research, the Monash Institute for Reproduction and Development, the Howard Florey Institute of Experimental Physiology and Medicine and the Macfarlane Burnet Centre for Medical Research and Public Health.
- Universities with internationally recognised capabilities in life sciences and related disciplines, such as: Deakin, LaTrobe, Melbourne, Monash, RMIT, Swinburne and Victoria.
- An excellent public health system, including seven major teaching hospitals.
- Agricultural research and development centres of expertise such as Primary Industries Research Victoria's centres (including the Plant Biotechnology Centre and the Horsham Grains Innovation Park), the Joint Centre for Crop Improvement, the Victorian Centre for Plant Functional Genomics and Food Science Australia.
- The Commonwealth Scientific and Industrial Research Organisation (CSIRO) including the Divisions of Health Sciences and Nutrition, Livestock Industries (Australian Animal Health Laboratory), Molecular Science, and Plant Industry.
- Cooperative Research Centres including the CRC for Bioproducts, CRC for Microtechnology, CRC for Innovative Dairy Products, CRC for Cochlear Implant and Hearing Aid Innovation, CRC for Molecular Plant Breeding, CRC for Chronic Inflammatory Diseases and the Vision CRC.

Victoria's biotechnology medical research base has considerable strengths in a wide range of areas including oncology, anti-infectives and immunology (incorporating vaccines and diagnostics), cardiovascular disease, neuroscience, stem cells, diabetes and reproductive technologies.

Victoria also has a strong agri-food sector, with 24% of the national agricultural food production workforce and 32% of the national food-processing workforce in Victoria.¹ Victoria's agriculture research strengths in biotechnology can claim world leadership in the following areas:²

- pasture plant genomics and molecular genetics and their applications in molecular plant breeding;
- genome mapping for both vegetable and oilseed Brassicas; and
- identifying bioactive molecules which have nutraceutical activity in both dairy cattle and in humans.

Victoria offers an attractive business environment based on its socio-political stability, AAA credit rating from Standard and Poors and Moody's, open and transparent financial systems, transparent legal and regulatory environments, strong intellectual property safeguards, high quality public health systems and superior quality of life.³ Victoria's advanced manufacturing base

and cost-competitive infrastructure have attracted international companies such as GlaxoSmithKline, Bristol-Myers Squibb, Amgen, Gilead, Bayer, Applied Biosystems and Varian.

The strength of Victoria's innovation base together with a strong and stable economic operating environment mean that the cost and quality of location rating for conducting biomedical R&D in Melbourne is highly favourable, ahead of Boston, San Diego, Munich, South-east England and Dublin (Figure 2).⁴

Victoria is recognised as having a sound regulatory environment. For many years the Victorian biotechnology industry has developed and adhered to a range of practice codes and protocols that ensure research and applications of biotechnology are undertaken within a sound scientific risk assessment and ethical framework.

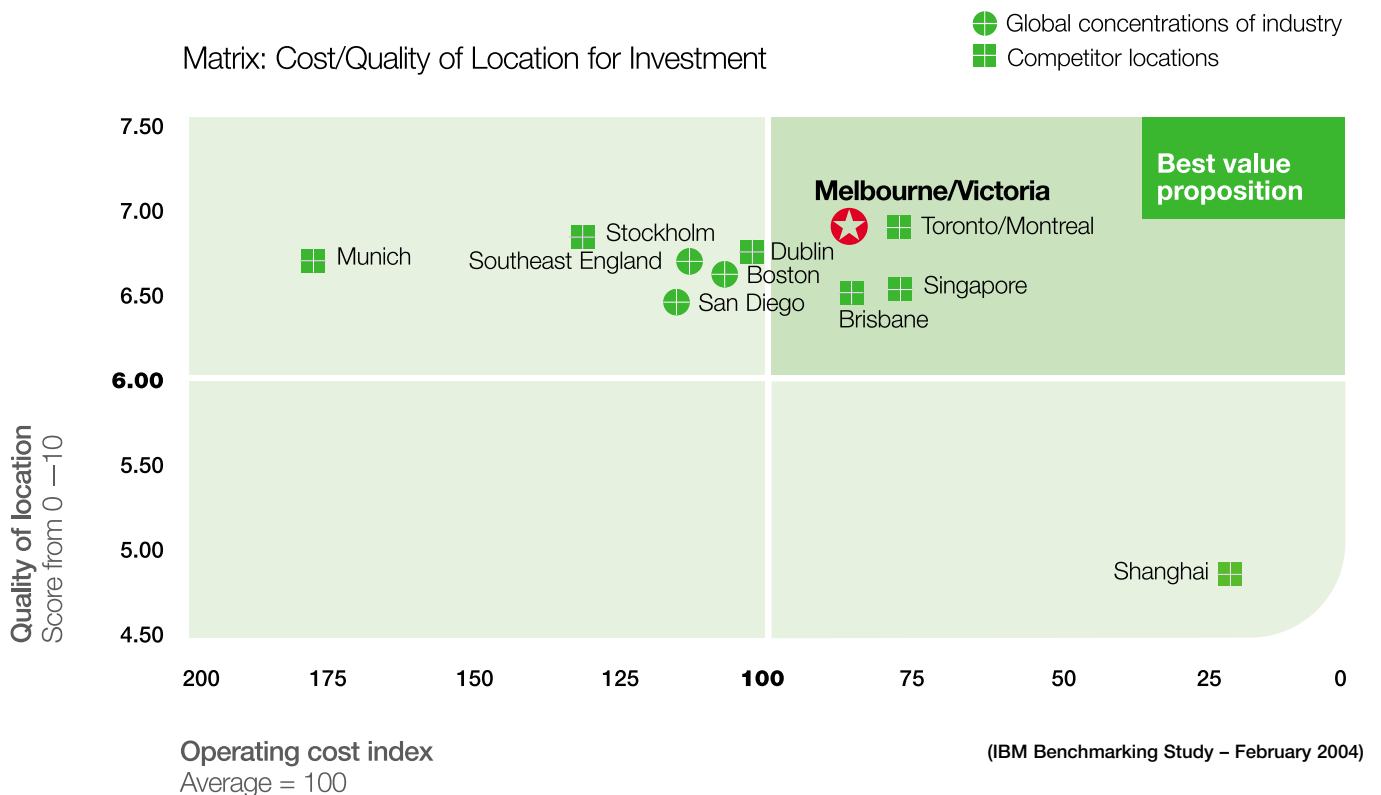
As a result of these factors and Victoria's strong science and technology base:

- More than 39% of Australia's biotechnology companies are based in Victoria.⁵
- Victoria's AMRAD has secured Australia's largest ever biotechnology deal with Merck Inc.
- CSL Ltd, Australia's largest biotechnology company and arguably the corporation with greatest capacity to take early

stage research through to full commercialisation, is headquartered in Victoria.

- Six Victorian medical and pharmaceutical companies have been offered more than \$45 million under the first round of the Australian Government's new Pharmaceuticals Partnership Program, which is more than half of the funds available.⁶
- Victoria employs more people in biotechnology firms than all the other States put together.⁷
- In 2003, the largest share (37%) of venture capital investment in Australia was in Victorian companies.⁸
- Victoria is Australia's leading generator of US granted biotechnology patents.⁹
- The proportion of public sector research and development spending dedicated to biotechnology-related areas is highest in Victoria of all Australian states and territories.¹⁰

Figure 2. Benchmarking Biomedical Research and Development

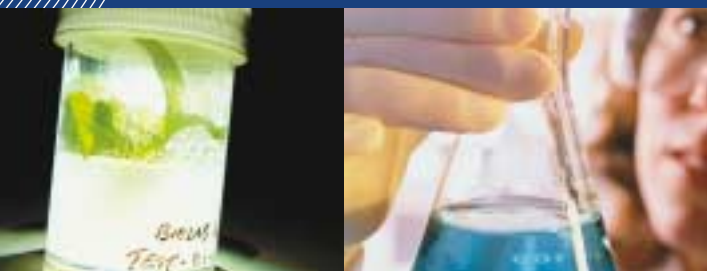


4 IBM Business Consulting – Plant Location International, 2004
5 Hopper and Thorburn, 2003 Bio-Industry Review – Australia and New Zealand

6 Minister for Industry, Tourism and Resources. 'Vic Companies Awarded \$45M to boost pharmaceutical R&D' (Press Release, 22 April 2004)
7 Hopper and Thorburn. 2003 Bio-Industry Review – Australia and New Zealand.
8 Australian Bureau of Statistics
9 Hopper and Thorburn. 2003 Bio-Industry Review – Australia and New Zealand.
10 Ibid.



review



review

of the biotechnology strategic development plan

The Victorian Government launched its Biotechnology Strategic Development Plan in 2001 to position the State to capitalise on what many predict will be the biotechnology age. The Plan concentrated primarily on strengthening Victoria's research and development base with significant investments in infrastructure and capability building.

A dynamic and effective strategic plan must respond to developments and changes in the industry and environment in which it operates. Strong progress already made, changes in the international environment and the emergence of new issues and trends in Australia led to the need to review and refresh the Victorian Biotechnology Strategic Development Plan.

Environmental scan

Biotechnology is a dynamic global business driven by research and development. Significant events over the past three years have transformed the biotechnology environment, including:

- The human genome has been mapped and fields such as bioinformatics, proteomics, stem cells and bionanotechnology have rapidly developed.
- Governments worldwide have increased their commitments to biotechnology development.¹¹
- The business models of major companies have changed.¹²
- Investment in biotechnology continues to be volatile.

For example:

- The US capital market's investment in biotechnology reached US\$32 billion in 2000 but since then has dropped to US\$12 billion in 2001 and US\$10 billion in 2002.¹³
- International capital markets have picked up since June 2003 when US-based Genentech released positive data from a late-stage clinical cancer program.¹⁴ This announcement was followed by other companies successfully reaching a number of clinical milestones and cementing several alliances and acquisitions.
- A change in leadership at the US Food and Drug Authority has improved the regulatory approvals process. Product approvals are being processed more quickly (there were 10 approvals in 2003) and industry observers believe investor appetite for biotechnology is improving.¹⁵

During 2001-04 Victoria's science and technology infrastructure base has strengthened, stimulated by major investments by

both the Victorian and Australian Governments. For example:

- The Office of the Gene Technology Regulator (OGTR) was established.
- Victoria's biotechnology company base continued to grow, despite a tough environment.¹⁶
- The Federal Biotechnology Centre of Excellence was won by the National Stem Cell Centre consortium bid and is headquartered in Victoria.
- Victoria passed stem cell legislation to regulate research involving surplus IVF embryos and the National Health and Medical Research Council (NHMRC) has recently granted licenses for the creation of new human embryonic stem cell lines from such embryos.
- Many Australian states, including Victoria, have adopted a cautious approach to the commercialisation of genetically modified food crops.
- Victoria has commenced building the Australian Synchrotron, a crucial piece of R&D infrastructure for biotechnology, due for completion in 2007.

International strategic alliances are essential to the future growth of the Victorian biotechnology sector. The Victorian Government has entered into a number of strategic alliances including the Australia-New Zealand Biotech Alliance, a bilateral biotechnology agreement with New Zealand and a Memorandum of Understanding with China's Jiangsu Province. The Government has also established the BioMelbourne Network to deliver a range of activities including international trade missions, seminars, forums and workshops for Victorian biotechnology.

The Premier and Minister for Innovation continue to lead Victoria's delegation to the annual BIO meeting in North America. Over the past four years the Victorian delegation has been the largest in the overall Australian mission. Australia had the fourth largest foreign delegation at BIO2003. Connecting with international industry on a regular basis, including advice from a panel of international expert advisers, is an important part of Victoria's biotechnology strategy.

11 A Brookings Institution Survey of 77 city and 36 state economic development agencies in the USA indicated that 83% have listed biotechnology as one of their top two targets for industrial development. Ernst & Young identified over 20 major biotechnology development plans for cities, states or locations around the world. An interesting indicator of this trend is the recent redevelopment of strategic plans by well-established biotechnology locations focussing on maintaining their leadership in the face of emergent competitor locations.

12 Hopper and Thorburn, 2003 Bio-Industry Review – Australia and New Zealand

13 G. Steven Burrill, 'Biotech 2003: ... a look at 2003, and an early look at 2004', Presentation in November 2003

14 Blake and Pachecz, Biotechs Bounce Back. Shares. April 2004.

15 G. Steven Burrill, 'Biotech 2003: ... a look at 2003, and an early look at 2004', Presentation in November 2003

16 Hopper and Thorburn, 2003 Bio-Industry Review – Australia and New Zealand.

Review process

Ernst & Young was appointed in November 2003 to assist the Department of Innovation, Industry and Regional Development to undertake stakeholder consultation, review progress and identify what needs to be done to encourage further growth for biotechnology in Victoria.

An International Advisory Committee (IAC) was appointed to challenge the outcomes of the stakeholder review process and to provide an international perspective. The IAC comprised:

- Mr Jeremy Curnock-Cook, Chairman, BioScience Managers Ltd, UK (venture capital);
- Dr Geoff Duyk, Partner, Texas Pacific Group, US (serial biotechnology entrepreneur/venture capital);
- Prof Ismail Kola, Senior Vice President, Basic Research, Merck Research Laboratories, US (pharmaceutical research and development);
- Dr Murray McLaughlin, President & Chief Executive Officer, Foragen Technologies Management Inc, Canada (venture capital/agricultural biotechnology);
- Dr Marty Rosenberg, Senior Vice President & Chief Scientific Officer, Research & Development, Promega, US (drug discovery and development);
- Dr Sue Foden, Adviser to Merlin Biosciences, UK (venture capital);
- Prof Julian Savulescu, Uehiro Professor of Applied Ethics, Oxford University, UK (bioethics); and
- Assoc Prof Jonathan West, Founder and Faculty Director, Harvard Life Sciences Project, Harvard Business School, US (biotechnology strategy).

Consultations with industry stakeholders and other industry participants indicated that to date, the Plan has had a positive impact on the emerging biotechnology sector. The Plan was considered to have played a key role in stimulating growth and providing direction, from both the commercial and academic perspectives. Areas that were considered particularly effective and appropriate were development of infrastructure and international marketing.

Progress against 2001 targets

In 2001 five targets were set to measure the progress of the Plan. Significant progress has been made against each target.

Target 1 – Start up companies

The establishment of 50 new start-up companies based in Victoria by 2005.

Result to date

The number of listed and privately held biotechnology companies continues to increase. Victoria is Australia's leading

Figure 3: Growth in total R&D expenditure of Victorian listed biotechnology companies

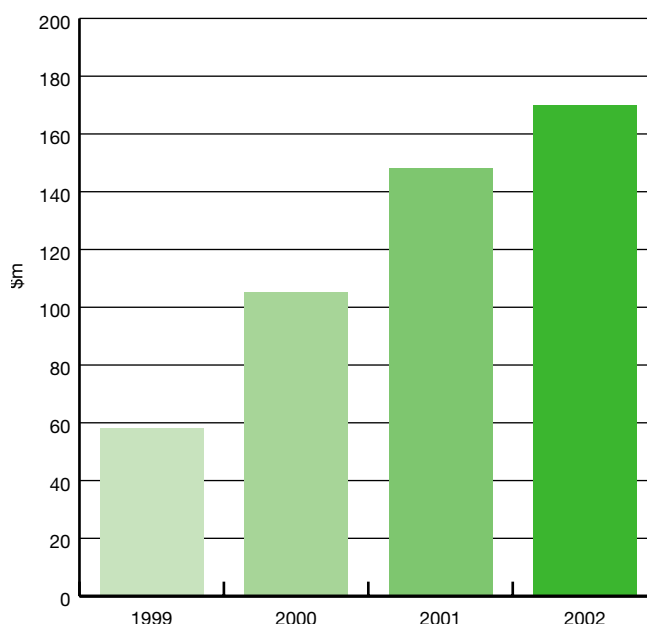


Table1: New biotechnology companies established in Australia - 2000-2002¹⁷

State	Companies			Percent National Total	New Firms Established 2000 – 2002
	Core	Diversified	Total		
Victoria	124	81	205	39%	68
New South Wales	86	53	139	26%	41
Queensland	64	15	79	15%	34
West Australia	41	11	52	10%	17
South Australia	28	11	39	7%	11
Australian Capital Territory	10	2	12	2%	7
Tasmania	5	1	6	1%	0
Northern Territory	0	1	1	0%	0
National	358	175	533	100%	178

biotechnology state on this measure. In May 2003 Victoria was home to 124 core biotechnology companies and 81 biotechnology-related companies. This represents 39% of the national total.¹⁸ From 2000 to 2002, 68 new core and related biotechnology start-up companies were established in Victoria (Table 1).¹⁹

Listed biotechnology companies have also continued increasing their research and development expenditure (Figure 3).²⁰ Victorian companies account for 51% of the total national research and development expenditure by all listed biotechnology companies.

In 2003, Victoria had the highest level of biotechnology related employment and employed more people in core biotechnology firms than all the other States combined (approx 51% of 5,644 employees Australia-wide).²¹ Average firm size in Victoria was also higher, at 25.4 staff per firm, compared to South Australia (19.0) and NSW (14.9).²²

Research employment has also strengthened with a 44% increase in research staff in Victoria's public research organisations since 1999.²³

Target 2 – Research and investment partnerships

At least five new research or investment partnerships with local or international biotechnology related companies will be established by 2005 with a combined project value of \$25 million.

Result to date

The target has already been exceeded, with combined investments in excess of US\$120 million.²⁴

Examples of partnerships include:

- AMRAD with Merck Inc;
- Neurosciences Victoria with Schering AG; and Prana;
- AGT Biosciences with the Institutes of Pharmaceutical Discovery; Merck Santé; and ChemGenex Therapeutics (refer case Study A);
- Biota with Sankyo;
- Meditech with Novozymes; and
- Acrux with Eli Lilly; and VIVUS Inc.

Australian and Victorian research have been recognised through international patent activity, with Australian inventors named on 230 biotechnology patents granted by the US Patent Office between 2000 and 2002. Australia ranks in the top ten OECD countries in terms of biotechnology patents issued by US authorities.²⁵

Victoria figures prominently with a total of 84 patents and in the period of 2000-2002, Victoria's share of US patents rose from 32% of Australia's total to almost 38%.²⁶

Target 3 – Clinical trials

An increase in clinical trial research investment by 50% by 2005.

Result to date

There are indications that significant progress has been made in clinical trials activity in Victoria, although investment amounts are not available publicly.

Bristol-Myers Squibb (BMS) announced a research and development hub in Melbourne, the first of its kind outside of the US. BMS is investing \$17 million per annum in Australian research and development. The hub coordinates clinical trial activity across Australia and New Zealand for BMS.²⁷

Case Study A

ChemGenex Pharmaceuticals

Local biotech company a global player

One of Victoria's leading biotechnology companies, AGT Biosciences, announced a merger with US-based ChemGenex Therapeutics in April 2004, creating a new genomics-driven company, ChemGenex Pharmaceuticals.

The merger creates a major new international biopharmaceutical company with a fully integrated research platform from early discovery through to compounds in Phase 2 clinical trials for cancer. The new company will have leading-edge capabilities for drug discovery and development.

ChemGenex Pharmaceuticals will have key centres in:

- Melbourne - A human genomics centre at the International Diabetes Institute with over 44,000 human DNA samples;
- Geelong - Existing AGT Biosciences facilities at Deakin University, animal models and functional genomics;
- San Antonio, Texas, USA - the AGT Biosciences Centre for Human Statistical genomics; and
- Menlo, Park California, USA - ChemGenex Therapeutics' existing facilities for preclinical drug development and clinical trials.

The creation of ChemGenex Pharmaceuticals reflects the depth of Victoria's biotechnology research and company base and is an example of how collaboration between industry and researchers can occur at a global level.

case study

20 Compiled by Ernst & Young from Ernst & Young Australian Biotechnology Reports (1999, 2001) and the Victorian Biotechnology Industry Report 2003 (Thorburn and Hopper)

21 Hopper and Thorburn, 2003 Bio-Industry Review – Australia and New Zealand

22 Ibid

23 Dept of Innovation, Industry and Regional Development, Victoria

24 Ibid

25 Andrew Devlin, 'An Overview Of Biotechnology Statistics In Selected Countries' (STI Working Paper 2003/13, OECD)

26 Thorburn and Hopper, Victorian Biotechnology Industry Report 2003

27 Bristol-Myers Squibb Australia, 'Bristol-Myers Squibb Elevates Australia To A Global R&D Hub As Annual Spend Tops \$17 Million' (Press Release, 20 March 2003)

In 2004, Victoria's Royal Children's Hospital and Murdoch Children's Research Institute announced that they are preferred suppliers for paediatric clinical trial contract research for Quintiles Transnational. Quintiles Transnational is one of the world's leading providers of information, technology and services for the trial, development and regulatory approval required to bring new medicines to market.

The Therapeutic Goods Administration (TGA) and the NHMRC have initiated a review of clinical trial activity across Australia. The outcomes of this review are expected mid 2004. However, figures to date show that the number of clinical trial applications submitted to the TGA increased by 30% from 1999-2000 to 2001-02. In 2001, more than 1100 trials had been approved or were underway in Victoria.²⁸

The Victorian Government has supported the establishment of Clinical Trials Victoria (CTV) as a world-class centre facilitating clinical trials. CTV provides researchers with access to the resources and facilities enabling them to secure innovative, high quality clinical research trials.

The Centre for Clinical Studies (CCS), a founding partner of CTV, has been constructed at the Alfred Medical Research and Education Precinct. It is a world class, secure, Good Clinical Practice Phase 1 clinical trial facility.

It is expected that the establishment of CTV and CCS will lead to increased clinical trial activity in Victoria.

Target 4 – Manufacturing

The creation of three significant manufacturing facilities by 2010.

Result to date

Victoria has secured a number of manufacturing facilities since the release of the 2001 Plan.²⁹ For example:

- GlaxoSmithKline has opened a new \$13m fine chemicals facility at its existing Port Fairy site.
- Vital Biotech, the first Australian biotechnology company to list on the Hong Kong Stock Exchange, is investing \$3m in a new manufacturing facility.
- The Institute of Drug Technologies (IDT) is investing \$2.5m in new manufacturing facilities.
- Two key players in Victoria's biotechnology and pharmaceutical industry are spending more than \$100m on major expansions of their manufacturing facilities.
- Mayne has announced a \$45m expansion of its facilities in Mulgrave.
- Cardinal Health will spend \$6m expanding its facility at Braeside.

A number of other projects are under investigation.

Target 5 – Community information

Community groups believe that they have been informed and involved in the policy development process.

Result to date

Community groups have been informed and involved in the policy development process, including during the development of the 2001 Plan.

Seventeen Community Information Forums on biotechnology have been held, mostly in rural and regional Victoria. The forums were co-sponsored with local councils and attracted more than 440 people. The forums stimulated community discussion and feedback was positive.³⁰

The establishment of the Victorian Biotechnology Ethics Advisory Committee provides a forum for obtaining input from a range of stakeholders in relation to ethical matters concerning biotechnology in Victoria.

The Victorian Government has also helped to establish the Gene Technology Access Centre (GTAC) in Parkville, an education facility to introduce gene technologies to secondary school science educators and students.

A comprehensive website with a searchable directory of Victoria's research and corporate biotechnology base is available at www.biotechnology.vic.gov.au.

Other significant achievements

In addition to the targets set in the 2001 Plan Victoria has made significant progress in securing funding and investment for biotechnology.

Capital investment

Between 1998 and 2002 Victoria continued to attract venture capital investment (+26% growth) against a national downturn (-39%).³¹ Biotechnology businesses require substantial operating capital to sustain their development and Victorian biotechnology companies have enjoyed a relatively high share of total capital raising in Australia.

Victoria is currently enjoying a surge in venture capital activity that is creating a healthy environment for fast growing technology companies. In 2002-03, the largest share (37%) of venture capital investment in Australia was into Victorian companies.³² This represents a 20% increase above the previous year and an upward trend over the last three years in venture capital investment in Victoria.

Improved conditions for venture capital investment in Victoria are set to continue following the introduction by the Victorian Government of limited partnership legislation in 2003. The introduction of the legislation was an Australian first and will ease constraints for international investment into Victoria. These reforms create an investment framework similar to most US States and send a clear message to potential overseas investors that Victoria is a competitive, attractive and welcoming place to do business.

Case Study B

Science, Technology and Innovation (STI) Infrastructure Grants Program Victorian Government commitment to biotechnology

The STI Infrastructure Grants Program is one of the biggest grants investment programs in science and technology infrastructure in Australia. The grants support leading-edge biomedical, environmental, agricultural, manufacturing and ICT projects which are generating economic, environmental and social benefits across metropolitan and regional Victoria.

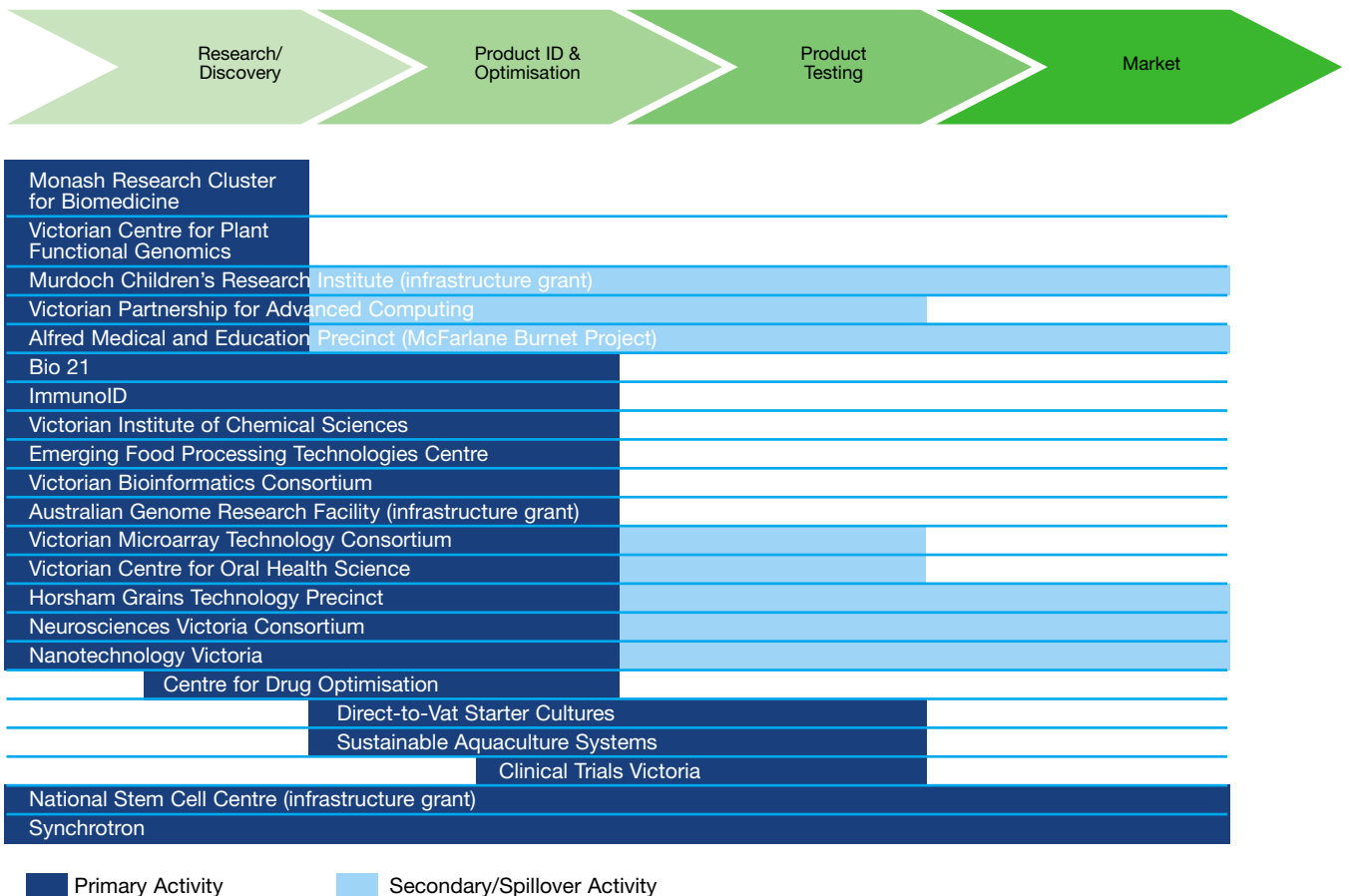
The total value of biotechnology related projects funded through the program now amounts to \$760m, a leverage factor of 4.4:1 on the initial Government STI support of around \$140.2m. This means the Victorian Government has facilitated over half-a-billion dollars of new investment in 26 strategic biotechnology projects with the investments continuing to grow.

Most of the biotechnology projects funded under the program focus on the research and early development end of the value chain (Figure 4)³³.

One of the stand out biotechnology success stories is Neurosciences Victoria, which in addition to receiving a \$13.34m STI Infrastructure Grant, has attracted over \$100m in public and private support, including \$25m from Schering AG.

Without strategic investment from the Victorian Government, the Victorian biotechnology sector would not be as well positioned to take advantage of growing international biotechnology markets.

Figure 4: STI Initiative – First Generation: Biotechnology Programs Against the Value Chain



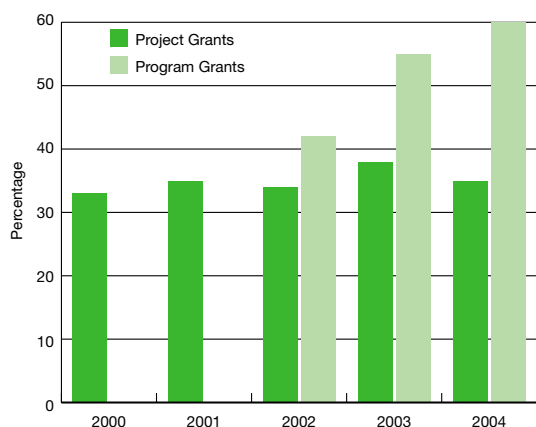
33 Department of Innovation, Industry and Regional Development, Victoria, STI Outcome Monitoring Tool December 2003

Research and Development funding

Victoria's share of NHMRC grants has risen in recent years. Victoria has been particularly successful in securing a large proportion of program funding since the introduction of these grants in 2002 (Figure 5).³⁴

To date, Victoria has been highly successful in competing for Commonwealth research funding. Major biotechnology infrastructure projects now based or headquartered in the State which have received some Federal support include: the National Stem Cell Centre (\$101.4m); the National Neuroscience Facility (\$18m MNRF); the Victorian Bioinformatics Consortium (\$450,000 ARC); the Victorian Centre for Oral Health (\$21.2m CRC); Federation Fellowships (\$12.4m); the Australian Genome Research Facility (\$14m); and the Australian Mathematics Science Institute (\$18.9m ARC & DEST).

Figure 5. Victorian share of NHMRC Grants 2000 – 2004



Victorian companies have gained funding from many Federal programs under the umbrella of the National Biotechnology Strategy. These include: the Biotechnology Innovation Fund (\$8m); R&D Start (\$44.3m); the Innovation Access Program (\$5m); ARC Discovery Grants (\$55m); ARC Linkage Project Grants (\$23.8m); and CRC program (\$98m).³⁵

Six Victorian biotechnology and pharmaceutical companies have been offered more than \$45 million under the first round of the Australian Government's new Pharmaceuticals Partnership Program, which is more than half of the funds available.³⁶

Review of platform technology capabilities in Victoria

One of the priority areas for action of the 2001 Plan was to develop Victoria's research base, particularly by providing opportunities for growth in biological science and research infrastructure. Platform technologies are technologies that can be used by a wide variety of users and facilitate a broad range of application based activities. Access to appropriate platform technologies can reduce costs and avoid unnecessary

duplication of facilities, enhance the international competitiveness of R&D and provide an environment that promotes effective networking and collaboration.

In 2002, the Government established a Platform Technology Steering Group (PTSG) with members nominated from leading Victorian research organisations. Working parties were also established to provide advice to PTSG about specific technologies. The PTSG concentrated on seven platforms that were demonstrated to be of critical value to Victoria.

A draft Biotechnology Platform Technology Report has been completed by the PTSG. This report makes recommendations relating to:

- bioinformatics skills and training;
- improved bioprocessing skills, coordination and infrastructure;
- proteomics coordination;
- microarray technology training and development for commercial application;
- animal housing and breeding to service the needs of the growing biotechnology sector;
- synchrotron science education and strategic relationship building; and
- clinical trials insurance, ethics and training.

The PTSG identified a further suite of platform technologies that require investigation in the future, including preclinical development, genomics, functional metabolomics, bioimaging, structural biology and containment areas for housing plants.

International Congress of Genetics

Victoria was host to the XIXth International Congress of Genetics in July 2003. The Congress attracted more than 2,700 delegates from 72 nations and provided an opportunity for scientists, business people, government and the community to discuss progress in the world of genetic research and celebrate the 50th anniversary of Watson and Crick's discovery of the structure of DNA.

Six Nobel Laureates headed the scientific program, along with many of the world's leading geneticists. An extensive public participation program engaged a wide cross-section of the community in a series of forums, lectures and workshops. The Congress attracted significant world-wide media attention, with more than 120 journalists in attendance.

For one marvellous week science elbowed its way into Australian newspaper headlines and evening TV news bulletins, jostling for space with politics, economics, sport and the intimate details of the love lives of celebrities. The source of the brief revolution was the 19th International Congress of Genetics at Melbourne's World Trade Centre. Not only was it the biggest scientific conference staged in Australia, it was the best publicised.

Graeme O'Neill, The Sunday Herald Sun, July 13, 2003.

³⁴ National Health and Medical Research Council statistics

³⁵ Australian Government, Summary of Contestable Funding Programs within Backing Australia's Ability, October 2003

³⁶ Minister for Industry, Tourism and Resources, 'Vic Companies Awarded \$45m to boost pharmaceutical R&D' (Press Release, 22 April 2004)

Dedicated biotechnology precincts

Victoria's biotechnology base has been strengthened through the development of six dedicated biotechnology precincts that bring together universities, research organisations, hospitals and industry. Four precincts specialise in the biomedical sector and two in agriculture.

- The Parkville precinct is a major centre for medical and bioscientific research, education and clinical trials and is the focal point for the Bio21 development. Founding members of Bio21 are Melbourne Health, the University of Melbourne and the Walter and Eliza Hall Institute of Medical Research, with a further twelve joining and associate members including the Howard Florey Institute, Murdoch Childrens Research Institute, Austin Biomedical Alliance, Ludwig Institute for Cancer Research and major hospitals.
- The Alfred Medical Research and Education Precinct in Prahran is an integrated biomedical research and development centre that brings together two major medical research institutes – the Baker Heart Research Institute and the Macfarlane Burnet Centre – with the Alfred Hospital and the Monash University School of Medicine to share infrastructure and undertake collaborative research.
- The Monash Cluster in Clayton provides a focus for biomedical and other biotechnology research. Organisations involved in the cluster include Monash University and Monash Science Technology Research and Innovation Precinct (STRIP), the Monash Institutes for Health, Monash Institute for Reproduction and Development, National Stem Cell Centre, the Victorian Bioinformatics Consortium, the Southern Health Care Network, CSIRO and NanoVic. The region has a number of leading science and technology oriented manufacturing companies and will be the home of the Australian Synchrotron.
- The Austin Biomedical Alliance Precinct brings together world class research groups including Austin Health, University of Melbourne, Austin Research Institute, National Stroke Research Institute, Ludwig Institute for Cancer Research, Brain Research Institute, Australian Centre for

Posttraumatic Mental Health, Institute for Breathing and Sleep, and Epilepsy Research Institute. A \$320 million redevelopment of the Austin and Repatriation Centre was announced by the Government in August 2000 with \$15 million in matching funds for redevelopment of the research precinct.

- The Bundoora Plant Bioscience Precinct hosts La Trobe University, the La Trobe Research and Development Park and RMIT Bundoora campus and includes a range of organisations spanning industry sectors such as Rio Tinto's Research and Technology Centre, the Plant Biotechnology Centre and the Walter and Eliza Hall Institute Biotechnology Centre.
- The Werribee Technology Precinct incorporates mixed research and industry hubs of excellence in biotechnology including veterinary applications, agribusiness and environmental sustainability, with links to the Victoria University of Technology, the Victorian Institute of Animal Science, the Austin Research Institute and industry.

Securing the synchrotron

A synchrotron is a device that accelerates particles to produce intense light. The unique features of the light are used in scientific, industrial and medical applications to analyse the molecular structure of matter.

The Victorian Government has invested \$157 million in the Australian Synchrotron which will be opened in 2007.

Synchrotron science has a wide range of applications in biotechnology including pharmaceutical, medical, food and diagnostic product development. It can also be used for forensics. Examples of some uses of synchrotron light include imaging of proteins (protein crystallography) to assist understanding of protein structure for drug development, human medical imaging to assist in the targeted treatment of diseases like cancer, and imaging the interaction of molecules during food processing to improve product development.³⁷

The synchrotron is essential infrastructure for growing the biotechnology sector.

Artist's impression of the Australian Synchrotron, opening in 2007.
Credit: Architectus/Thiess.



Stem cell legislation

Stem cell research holds great promise for the development of cures for some of the most serious diseases, including cardiac disease, lung disease, diabetes, stroke and neurological disease.

Victoria is a major player in the international stem cell sector. Initiatives being undertaken at the National Stem Cell Centre headquartered in Melbourne will consolidate Victoria's leadership position and build on the strengths of research groups at Monash University, the Peter MacCallum Cancer Centre, the Royal Children's Hospital and the Walter and Eliza Hall Institute, as well as leading stem cell company Stem Cell Sciences, which has one of its three international nodes in Victoria.

The Victorian government is actively supporting stem cell research and has passed legislation to regulate research involving surplus IVF embryos which will allow this work to progress whilst addressing ethical issues.

Case Study C

The National Stem Cell Centre *Scientific excellence linked with Industry*

The National Stem Cell Centre (NSCC), headquartered in Victoria, is a major Australian collaborative initiative uniting leading academic researchers with the international biotechnology industry to develop innovative therapeutic products to treat a range of serious injuries and debilitating diseases.

The NSCC was established as a Biotechnology Centre of Excellence in 2002-03 with grants of \$43.5m from the Australian Government and \$11.375m from the Victorian Government. The Australian Government announced a further \$57.9m in new funding in 2004 to support the Centre's activities over the five years from 2006 to 2011.

Academic partners of the NSCC include Victoria's Monash University, Howard Florey Institute, Peter MacCallum Cancer Centre, University of Adelaide, University of New South Wales, University of Queensland and Victor Chang Cardiac Research Institute.

The NSCC's first industry partnership was reached in 2003 with US biotechnology company LifeCell Inc in a world-first licence and collaboration agreement.

The NSCC builds on Australia's existing expertise in stem cell and related platform technologies to lay the foundations for delivering stem cell therapies.

Revolutionary new approaches resulting from stem cell research could radically improve ways to treat diseases to the benefit of millions of people now and into the future. Specifically, stem cell research holds great promise for cures for diseases such as Parkinson's, cancer, diabetes, congestive heart failure, respiratory diseases, spinal cord injuries and stroke.

Regenerating heart muscle following a heart attack, renewing a functional insulin-producing pancreas in patients with diabetes and reversing the neuronal damage in patients suffering from Parkinson's disease are just some of the potential outcomes of this fundamental research.

Technology Commercialisation Program

The Victorian Government's STI Initiative – First Generation recognised commercialisation of technology as a priority action area to enhance Victoria's international competitiveness. The Technology Commercialisation Program (TCP) was introduced in 1999-2000, providing \$20 million over four years to increase the rate of commercialisation. It did this by making available skilled expertise to assist entrepreneurs to manage the transition from concept to sustainable business.

Under the program, the Victorian Government contracted a number of service providers to deliver a range of services to entrepreneurs with technologies that have sound commercial application. BIOCOMM, a technology management and commercial development company dedicated to the life sciences, including biotechnology, was established with funding from the TCP.

Case Study D

BIOCOMM

Supporting commercialisation

Established under the Victorian Government's Technology Commercialisation Program, BIOCOMM is an international life sciences technology management and commercial development company, specialising in:

- scientific and commercial assessment;
- licensing;
- competitive intelligence and market analysis;
- business planning;
- new company development; and
- seed finance.

BIOCOMM has a membership structure for research organisations and has raised a \$11.5 million seed capital pool from investors experienced in life sciences. The company aims to bring together some of the world's leading education, research and commercial organisations and maximise commercialisation benefits in the biotechnology and life science markets. International linkages have been established with global biotechnology, biomedical & pharmaceutical companies, institutions and academic organisations.

BIOCOMM has received Government support to assist with establishment and early operating expenses to support its commercialisation activities. The company has already contributed significantly to the development of biotechnology in Victoria through achievements such as:

- investing in Cryptopharma, a respiratory drug company from the University of Melbourne;
- building a strong international presence in licensing, with six international licensing transactions completed and a further twenty-one projects under contract to partner;
- building a wide base of academic and commercial clients across Australia and overseas;
- assessing and advising on more than 400 opportunities; and
- training six academics in commercialisation of biotechnology.



the 2004 strategy



the 2004 Strategy

To achieve its Vision of Victoria being recognised internationally as one of the world's top five biotechnology locations, the Victorian Government will continue its efforts to build capacity to add value to the State's world-class research and development base.

The Government will also act to ensure that Victoria enjoys the social and economic benefits from biotechnology, including improved therapeutics, diagnostics and devices, increased productivity, sustainability and safety and, ultimately, improved quality of life for Victorians.

The 2001 Plan identified five priority areas for action:

1. Developing a biotechnology skills base.
2. Developing Victoria's research base.
3. Commercialising Victoria's biotechnology.
4. Building the State's corporate base and marketing the State's capabilities.
5. Providing Government leadership and support.

These areas remain vital for positioning Victoria as a leading biotechnology location.

The 2004 Strategy will build on the progress already made under the Biotechnology Strategic Development Plan to generate a sustainable industry able to develop products to the pre-market stage and beyond.

In doing so, the 2004 Strategy will maintain the strength of Victoria's research and development base and continue to address issues such as access to capital markets, people and skills development.

The 2004 Strategy shifts the focus of the State's efforts further along the value chain.

The overarching theme of the 2004 Strategy is connectivity: building greater alliances, partnerships and connections within science and technology sectors (agricultural, medical, environmental, chemical, nanotechnology, informatics and devices). These linkages are important to build critical mass locally, to facilitate international partnerships, to leverage other governments' investments in science and technology and to 'leap-frog' competitors.

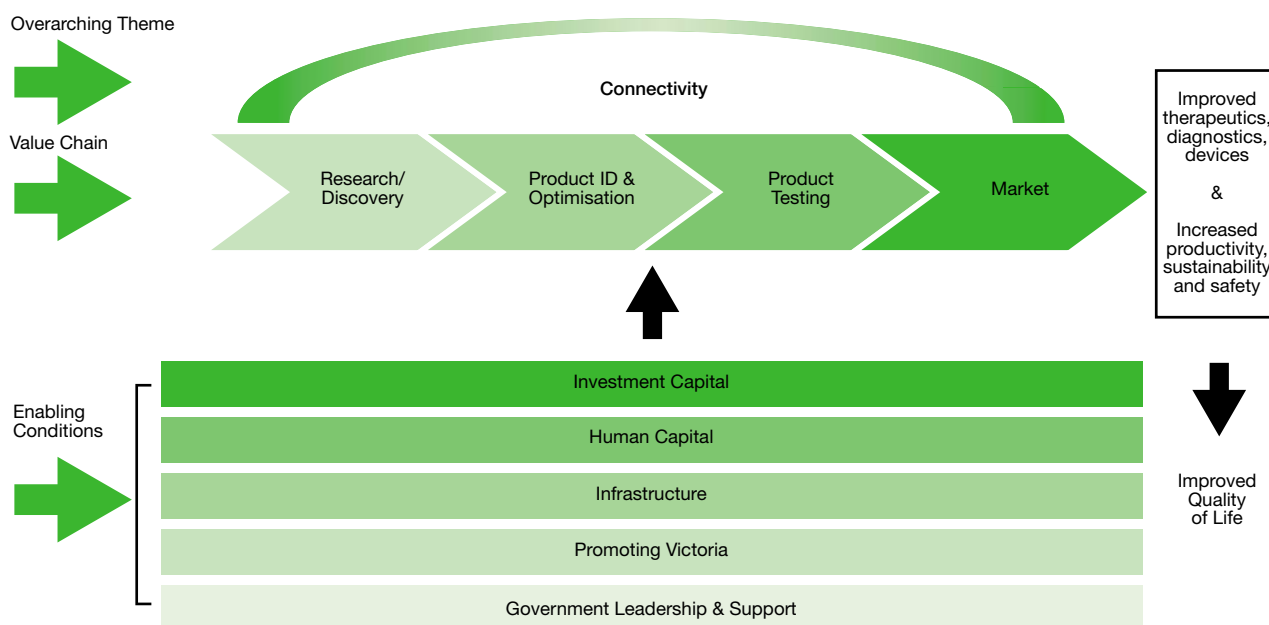
The initiatives in the 2004 Strategy build on the five priority areas of action identified in 2001.

They are designed to:

- Improve connectivity.
- Facilitate increased investment in Victorian biotechnology.
- Attract and develop skills.
- Improve access to platform technologies and build infrastructure in specific areas of the product value chain, meet gaps and provide focus for international investment.
- Promote Victoria.
- Support a sound regulatory environment and the provision of balanced and accurate information to the community.

The 2004 Strategy framework is outlined in Figure 6.

Figure 6: Summary of the 2004 Strategy framework



Case Study E

The Kangaroo Genome Project

A chance to bound ahead

Victoria has a lot to learn from the biology of the kangaroo and the wallaby and a lot to gain from what we learn. The Victorian Government has made a commitment to provide \$4.5 million to the Kangaroo Genome Project, a partnership between the Australian Genome Research Facility and the US-based National Institutes of Health (NIH), one of the world's premier international scientific research institutions.

The organisations will cooperate to sequence the genome of a marsupial (the Tammar wallaby was selected as representative of the kangaroo family). The project is one of a number that may give Victoria the chance to 'bound ahead' of its competitors.

Marsupials have unique attributes that make them of special value in mammalian studies centred on reproduction, fertility, seasonal breeding, pregnancy, lactation and sex determination and differentiation. For example, kangaroos are born with immature but functional lungs that allow respiration for a highly underdeveloped newborn. The outcomes of such research could improve survival prospects for human newborns following premature birth.

The project is a unique opportunity for Victoria to claim a top 5 position in the area of marsupial genetics; it connects Victoria's areas of strength in agricultural and medical biotechnology; it will strengthen our international links; and it has the potential in the longer term to deliver new products that will expand investment and agricultural export opportunities.

In short, the project is about local, international and cross-disciplinary connections and capturing the value of Victorian research.



Dr Sue Forrest, Director of the Australian Genome Research Facility, with Wrigs, a Tammar wallaby

Building linkages – Connectivity

In *Beyond Borders*, Global Biotechnology Report 2003,³⁸ Ernst & Young rates Australia as sixth in an assessment of the Top 12 biotechnology countries. With more than 40% of Australian biotechnology, the challenge for Victoria is to connect with other biotechnology markets to build scale, attract international investment and get access to global markets. For this reason, the Premier and Minister for Innovation continue to lead Victoria's delegation to the annual BIO meeting in North America.

In 2003, Melbourne hosted the XIXth International Congress of Genetics. The strong message from the six Nobel Laureates and other distinguished international leaders who attended the Congress was that Victoria and Australia must be part of 'big science' to be a player on the international stage. As a result of the connections made at the Genetics Congress, the US National Institutes of Health (NIH) has made an unprecedented offer to Australia to provide 50% of the funding required to sequence the genome of a kangaroo (the Tammar wallaby). Victoria demonstrated leadership by accepting the offer and providing \$4.5m in funding to the Project.

The Project promotes both connectivity across local sectors of strength (agriculture, health biotech and bioinformatics) and between Victoria and the international community. Co-funding the Project with the NIH means Victoria is partnering one of the world's premier international scientific research institutions.

The importance of connectivity is recognised internationally through major funding programs such as the European Union's Sixth Framework Program.³⁹ Under this program large multi-partner, multi-national and multi-disciplinary consortia are being established to undertake objective-driven research that will deliver knowledge for new products, processes and services. Such integrated projects and networks of excellence bring together a critical mass of resources and expertise to reach ambitious goals aimed at either increasing Europe's competitiveness or addressing major societal needs.

International co-operation with countries beyond the European member (and associated) states is seen as an integral part of the Sixth Framework Program and opens the door to significant opportunities for Australia and Victoria.

Victoria is exploring collaboration in major integrated projects and association with leading networks of excellence. This is strongly supported and encouraged by European partners who already see the significant added value of Victorian involvement.

Connectivity drives innovation by bringing together new people, new ideas and different approaches to solve problems.

Both the Victorian and Australian Governments have recognised the importance of supporting networks through initiatives such as the BioMelbourne Network and the Australian Research Council's Research Networks program.

Victoria is also a founding member of the Australia-New Zealand Biotech Alliance and a participant in the Australian Government's Biotechnology Liaison Committee, which includes representatives of all States and Territories and the Federal Government. These links deliver better coordination and access to various biotechnology support programs and government activities.

Greater connectivity provides the opportunity to consolidate and strengthen Victoria's science and technology base.

Actions

To improve connectivity, the Victorian Government will:

- Continue to work with international industry groups such as the US Biotechnology Industry Organisation (BIO).
- Facilitate the development of international alliances and joint projects to achieve critical mass and leverage other regions' investments in research and development infrastructure.
- Support participation in major international biotechnology projects that link disciplines and sectors, such as the Kangaroo Genome Project.
- Support initiatives for exploiting advanced technologies for healthcare.
- Continue support for network organisations, such as the Australia-New Zealand Biotech Alliance, BioMelbourne Network, AusBiotech and ARC Research Networks, to generate connectivity across disciplines and sectors.
- Continue to support selected international meetings in Victoria.
- Provide support for Victorian-headquartered Cooperative Research Centres relevant to the Biotechnology Strategic Development Plan.

Attracting investment capital

The investment required to take a biotechnology product from discovery through to proof-of-concept in the pre-market phase is generally in the order of US\$30 million to US\$40 million. A further US\$400 million to US\$800 million is required to bring concepts to market. In view of the changing international industry environment, companies must sustain themselves with little or no revenues until they can reach that point.

Some commentators have argued that Australian biotechnology has too many small companies and that the industry does not have ready access to the development capital required to take products to the proof-of-concept stage or to build companies with a portfolio of projects. One view is that Australia does not have the depth of capital markets or the 'patient capital' (investors prepared to accept longer-term returns) to support such activity. Another view is that while Australia has the fourth-largest pool of privately managed investment capital in the world, much of it managed in Victoria, existing risk-management (selection and diversification) vehicles are inadequate.

The lack of access to development capital often means that Australian companies are forced to list on the Australian Stock Exchange earlier than they should. This often leaves them short of the funding targets they require, exposes them to shorter investment horizons and puts them in a difficult position for raising follow-on funding.

A recent review of the Victorian venture capital sector identified that commercialisation skills and mentoring, in addition to access to appropriate finance, are appropriate areas for government action.⁴⁰

Actions

To facilitate increased investment in the biotechnology industry and encourage commercialisation skills development, the Victorian Government will:

- Support industry-led initiatives that promote the development of biotechnology commercialisation skills, technology transfer and access to finance through VicStart, the Victorian Government's new commercialisation-focused program under the Science, Technology and Innovation (STI) Initiative – Second Generation.
- Convene an expert working group to address issues underlying access to development capital.
- Establish an Entrepreneur in Residence program in local organisations, including venture capital firms, institute/university technology transfer offices and biotechnology companies.
- Support the InnovationXchange Trusted Intermediary Program to connect sources of innovation to sources of external support and resources.
- Continue support for the Young Achievement Australia Biotechnology Entrepreneurs program for postgraduate biotechnology students.



Infrastructure – People and skills

A growing industry needs to ensure an adequate supply of people with skills in strategically important areas. While Victoria is recognised for its strong research skills – particularly in immunology, cancer, stem cells, neuroscience, diabetes, reproduction, cardiovascular and agriscience – there is a need for a larger pool of people with experience in taking a product to market within an international context. That includes all aspects from product development through to trials and regulatory affairs, deal making and marketing.

Gaps currently exist in a number of specific areas, such as commercialisation and technology transfer, as well as access to appropriate training programs, including Good Manufacturing Practice (GMP) bioprocessing skills.

Given the rapid growth in the biotech sector worldwide over the past three years, Victoria is not alone in facing these developmental problems.

Government can play a role in addressing some market needs, by acting as a catalyst in the development of training and industry skills solutions, while continuing to attract and retain the best scientists.

Victoria's education system, including schools, TAFEs and universities, is internationally recognised for producing outstanding biotechnology researchers and workers. There is a need to ensure that the supply of skilled and appropriately qualified graduates and post-graduates meets future needs – particularly in the disciplines of chemistry, mathematics, genetics, molecular biology and ICT.

In 2003, the Victorian Government launched the Victorian Expatriate Network (VEN), an international network of science, technology and ICT professionals. VEN aims to facilitate

international collaborations, business opportunities and knowledge exchange between Victoria and expatriates. Keeping VEN members informed of scientific and ICT developments in Victoria enables them to act as ambassadors and promote Victorian science, biotechnology and ICT in their adopted homes.

Also in 2003, the Victorian Government established VESKI (the Victorian Endowment for Science, Knowledge and Innovation) with a \$10 million endowment to support the return of expatriates. VESKI's Victorian Innovation Fellowships offer expatriates with an outstanding record of achievement in biotechnology and other areas of strategic priority for Victoria, matching funds of up to \$100,000 a year for up to five years to undertake research in Victoria.

Actions

To facilitate development of skills, the Victorian Government will:

- Establish a fellowship program to attract to Victoria leaders and potential leaders in strategic areas.
- Improve the provision of training and education that meets industry needs, including GMP bioprocessing skills.
- Build on the Vocational Education and Training sector's capacity to supply the skills required for growth in the biotechnology industry in Victoria.
- Work with schools, TAFEs and universities to develop and deliver programs to build the educated and creative workforce required by the biotechnology sector in Victoria.
- Support programs that develop critical skills in tertiary students and beginning workers, for example, the Undergraduate Research Opportunities Program for science students.
- Increase support to the Victorian Expatriate Network to enhance its ability to track expatriates, link into their networks and engage them in activities such as mentoring.
- Continue to work with recognised international experts.

Infrastructure – Platform technologies

Platform technologies are technologies that can be used by a wide variety of users to facilitate a broad range of application based activities. Access to appropriate platform technologies can reduce costs and avoid unnecessary duplication of facilities, enhance international competitiveness of R&D and provide an environment that promotes effective networking and collaboration.

The Platform Technologies Steering Group's (PTSG) draft report identifies gaps and makes recommendations for actions in a number of areas of importance for the development of Victorian biotechnology. Two areas, pilot-scale manufacturing (bioprocessing) and early product trials (field and clinical) have been identified as priorities in the 2004 Strategy, based on the PTSG findings, stakeholder consultation and advice from the International Advisory Committee.

The report also identifies a suite of platform technologies that require investigation in the future. The Government will continue to work with industry and the research community to address the gaps identified and assess additional requirements in emerging technologies.

Actions

To improve access to appropriate platform technologies, the Victorian Government will:

- Develop an action plan to address recommendations made in the Platform Technology Report for Victoria.
- Continue support for the PTSG to assess platform technology requirements in areas such as preclinical development, genomics, functional metabolomics, bioimaging, structural biology and containment plant housing.

Pilot-scale manufacturing

The translation of biotechnology research into products in the medical and agricultural fields occurs through the manufacture of small molecules, such as aspirin, or large molecules derived from bioprocessing, such as insulin.

Bioprocessing is the production of material including protein-based medicines, agricultural products and enzymes for industrial purposes using biological systems such as yeast, bacteria, mammalian cells and insect cells.

While Victoria has some capacity in bioprocessing and pilot-scale manufacture, it is fragmented. The greatest need is for pilot-scale Good Manufacturing Practice capability to complete pre-development activities and to commence formal product trials. A study commissioned as part of the 2001 Plan found there is a local and international shortage of bioprocessing capacity. If this shortage continues, access by companies wanting to commence formal trials will become difficult and more expensive.

There are a number of benefits to be gained from building capability in bioprocessing. It would help Victoria capture the benefits of its research infrastructure and develop more cost-effective methods for the manufacture of biological products. Increased bioprocessing capacity would provide an opportunity to increase clinical trials activity by increasing the product available to conduct early stage trials. Work currently being done overseas could be attracted back to Victoria. Increased capacity could allow Victoria to exploit the predicted global shortfall in biological production over the next 5-10 years.

The size of the global marketplace is significant. For example, biotherapeutics (biologically derived products that exert a therapeutic effect in humans or animals) are manufactured using bioprocessing. The global market for biotherapeutics is currently valued at US\$24 billion and is growing at 21% pa.⁴¹



Actions

To increase Victoria's bioprocessing capability, the Victorian Government will:

- Establish a Protein Production Roundtable to determine how to best meet future requirements for expression of proteins.
- Facilitate the establishment of infrastructure to develop novel methods of bioprocessing to improve productivity and reduce the costs of biological manufacturing.
- Encourage the establishment of pilot scale bioprocessing facilities in Victoria.
- Attract a leading international pharmaceutical or biotechnology anchor company undertaking bioprocessing.

Early product testing

Translation of research to the market involves considerable product testing. In the agricultural sector this occurs through field trials and in the health sector through clinical trials.

Field trials are regularly performed in Victoria. Most of the trials have strong links with the National Plant Breeding programs for which Victoria assumes responsibility. Two examples are the National Brassica Improvement Program based at the Horsham Grain Technology Precinct and the Pasture Plant Improvement Program based in Hamilton. Other research includes the use of molecular markers to speed up plant breeding, molecular detection methods for plant health diagnostics and biosensors for measuring stress levels in plants induced by biotic and abiotic factors.

Early stage clinical trial capabilities are essential for Victoria to develop new pharmaceutical products and medical devices to a stage attractive to partners and investors.

Victoria's excellent public health system, concentrated biotechnology precincts and ethnically heterogeneous population provide an attractive environment for conducting clinical trials.

While Victoria has clinical trials capability, particularly at Phase 3, and already undertakes clinical trials for major international companies, there is a need to build stronger links and develop the infrastructure for Phase 1 trials to translate research into clinical testing. The formation of Clinical Trials Victoria as a coordination point and the Centre for Clinical Studies, a world class Phase 1 facility, are important steps as the previous lack of sufficient Phase 1 clinical trial facilities in Victoria and Australia-wide has meant that local biotechnology companies have had to perform this work in the USA or UK/Europe. Sourcing these services overseas is expensive and



time-consuming for local companies. Once a clinical trial program is taken off-shore, it is often easier to perform follow up Phase 2 work in the same location, so much of the value of the research is lost to Victoria.

The worldwide clinical trials market is substantial. Clinical trials form the largest single expense for new drug development and expenditure on research and development by the pharmaceutical industry is currently estimated to be over US\$45 billion a year.⁴²

Victoria enjoys some of the investment in clinical trial research undertaken by major pharmaceutical companies but this investment is highly mobile. The most important determinant of investment decision-making in this area is the speed with which ethics committee approval can be obtained. Lack of coordination and mutual acceptance of ethics review processes are significant barriers and disincentives to undertaking clinical trials in Victoria. Minimising such barriers will provide an opportunity to attract a greater share of the international market.

A mutual recognition protocol has been piloted by a number of groups of Victorian cancer researchers. Adoption of similar streamlined processes for ethical review would be an important step forward.

Actions

To increase Victoria's early product testing capability, the Victorian Government will:

- Facilitate the establishment of sufficient early stage clinical trial facilities to meet local and international demand.
- Ensure seamless coordination of Victoria's capabilities in clinical trials and encourage the streamlining of ethics review processes.
- Minimise barriers to conducting clinical trials to improve the regulatory environment for product testing.

Promoting Victoria

Victoria's international biotechnology profile has increased significantly since the release of the 2001 Plan. However, more and more, governments around the world are recognising the importance of biotechnology.

To be recognised as a world leader and to attract international partnerships, investment and skilled people, Victoria must continue to expose its products and research to the world and showcase its high-level capabilities and skills.

Actions

To raise the international profile of Victorian biotechnology, the Victorian Government will:

- Continue to support inbound and outbound investment and partnering delegations, including annual BIO conventions, Aichi World Expo 2005 and visits by key international influencers, in a coordinated approach with the Committee for Marketing Australian Biotechnology.
- Convene an industry driven Asia-Pacific market focus group through BioMelbourne Network and the City of Melbourne to identify and progress opportunities for greater interaction and exchange within our region.

42 Ernst & Young



Government leadership

Biotechnology has the potential to touch all areas of our lives and it is crucial that governments ensure development in this area is underpinned by sound public policy. The Victorian Government has developed five policy principles for its actions associated with biotechnology. They are:

- to optimise the economic, environmental and social benefits of biotechnology;
- to protect and promote the health of the Victorian community;
- to assure environmental safety and sustainability;
- to require that all actions are undertaken within an ethical framework; and
- to ensure there is full consultation, communication, transparency, monitoring and accountability.

Actions

To build upon these principles, the Victorian Government will:

- Ensure a whole of government approach to biotechnology within Victoria and strengthening of coordination with other Australian governments through involvement in the Australia-New Zealand Biotech Alliance and the Biotechnology Liaison Committee.
- Enhance the ability of the wider Victorian community to engage in informed debate particularly in the areas of ethics and issues arising in relation to the application of biotechnology.
- Continue the Victorian Biotechnology Ethics Advisory Committee to advise on issues of ethical concern to the Victorian community and complement the work of the National Gene Technology Ethics Committee.
- Undertake ongoing monitoring of the implementation of the Victorian Biotechnology Strategic Development Plan.
- Produce reports to review progress and update the Plan every 3 years.



measuring progress



measuring progress

In the absence of internationally consistent measures, Victoria has established a number of targets to measure progress under the Plan.

As many of the targets set in 2001 have been achieved, new targets to 2007 have been established. The 2007 targets are ambitious and require a commitment by industry, the research community and government to work together.

2004 Plan Targets

Target 1 – Patents

- By 2007, granted US biotechnology patents per annum from Victoria's R&D base to exceed 120.

Target 2 – Infrastructure

- Establishment of additional bioprocessing facilities for Victorian firms and research sector by 2007.

Target 3 – Research and Development

- Corporate biotechnology R&D expenditure to exceed \$500 million per annum by 2007.

Target 4 – Venture Capital

- Venture capital investment in Victorian biotechnology to exceed 40% of the national annual venture biotechnology investment by 2007.

Target 5 – Partnerships

- Deals with a combined project value to exceed \$1 billion in aggregate by 2007.

Target 6 – International Leadership

- Victoria is recognised internationally as the leading location for marsupial genomics by 2007.

The Department of Innovation, Industry and Regional Development's Office of Science and Technology has developed an Outcome Monitoring Tool to evaluate the Science, Technology and Innovation (STI) Initiative – First Generation Program that paralleled the 2001 Plan. Data collected by the Outcome Monitoring Tool includes: income/funding from other sources (federal government and private sector investment), patent filings, numbers of post-graduate students, publications, collaborations and commercial alliances.

The Outcome Monitoring Tool will be applied to relevant new initiatives to establish a more detailed analysis of progress against the 2004 Plan targets.

The OECD has recently identified for the first time an agreed statistical definition of biotechnology. In addition, the OECD has recognised that as biotechnology becomes increasingly viewed as a strategic sector, the need for reliable biotechnology statistics from which informed policy decisions can be made will continue to grow. The OECD is working with member and observer countries to develop methodological tools for measuring biotechnology and is developing a framework paper that will identify a set of standard statistical definitions.

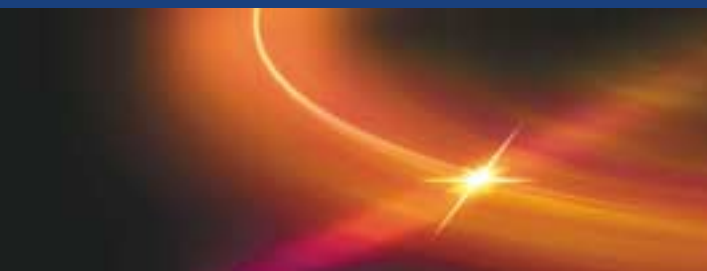
The Australian Bureau of Statistics is also examining biotechnology statistics and definitions and conformity with international data collection.

The Victorian Government will continue to monitor the progress of these activities and adopt relevant statistical definitions and measurement tools as they emerge.

Better measures and the ability to contrast and compare will deliver better decision-making by governments, research organisations and companies and a more informed community.



the future



the future of biotechnology

The biotechnology industry is dynamic and fast growing. In the past, biotechnology referred to the use of recombinant genetic engineering or the manipulation of genes for the development of new products. Today, biology, chemistry and small technologies are converging to create a broader 'life sciences' focus, leading to the discovery and development of products for:

- human healthcare (therapeutics, diagnostics, drug delivery, cell and gene therapy and drug/device combinations);
- wellness (not just sickness);
- agriculture (food, feed, fibres);
- environmental sustainability (bioremediation);
- bio-based industrial processes; and
- bio-based energy.

According to industry observers and analysts, the rapid development of new enabling technology tools such as proteomics, single nucleotide polymorphisms (SNPs), bionanotechnology and metabolomics is driving the revolution in biotechnology and will have a major impact on the future of medicine and agriculture.

In addition to these new technologies, other drivers for change in the future include:

- an ageing population;
- changes in the delivery of healthcare away from hospital 'in-patient' care with the introduction of new therapeutic methods and devices;

- greater consumer interest and access to functional foods to promote health, with sales expected to double by 2010; and
- bioterrorism (in 2003, the USA allocated US\$2.4 billion to boost bioterrorism research and development).

Concerns over energy, security, global warming and depleting oil reserves are driving increased interest by traditional industries, such as the chemical industry, in the opportunities that biotechnology can offer through new technologies such as biomaterials and bioprocessing. Major corporate investments in biotechnology have been made recently by the chemicals industry, in particular polymer producers such as DuPont and Cargill/Dow Polymers.⁴³

The Victorian Biotechnology Strategic Development Plan is a living document that will ensure Victoria continues its biotechnology leadership in a dynamic and changing environment. The 2004 Strategy will maintain the strength of the State's research and development base. It will continue to address issues such as access to infrastructure, capital markets, people and skills development. It will move Victoria's industry further along the value chain and translate the new knowledge created by Victoria's strong research and development base into products that deliver social, economic and environmental benefits to all Victorians.

43 G. Steven Burrill, 'Biotech 2003: ... a look at 2003, and an early look at 2004', Presentation in November 2003.

list of acronyms

ARC	Australian Research Council
BIO	Biotechnology Industry Organisation (USA)
BMS	Bristol-Myers Squibb
CEO	Chief Executive Officer
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CRC	Cooperative Research Centre
CTV	Clinical Trials Victoria
DEST	Department of Education, Science and Training
DNA	Deoxyribonucleic Acid
DSTO	Defence Science and Technology Organisation
GMP	Good Manufacturing Practice
GTAC	Gene Technology Access Centre
IAC	International Advisory Committee
ICT	Information and Communication Technologies
IDT	Institute of Drug Technologies
IVF	Invitro Fertilisation
MNRF	Major National Research Facilities
NIH	National Institutes of Health (USA)
NHMRC	National Health and Medical Research Council
NSCC	National Stem Cell Centre
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
PTSG	Platform Technology Steering Group
R&D	Research and Development
RMIT	RMIT University (former Royal Melbourne Institute of Technology)
SNP	Single Nucleotide Polymorphisms
STI	Science, Technology and Innovation
TAFE	Technical and Further Education
TCP	Technology Commercialisation Program
UK	United Kingdom
USA	United States of America
VEN	Victorian Expatriate Network
VESKI	Victorian Endowment for Science, Knowledge and Innovation
VET	Vocational Education and Training

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contact information



The Department of Innovation, Industry and Regional Development is the lead agency with responsibility for delivery of the Biotechnology Strategic Development Plan, coordinating effort with industry, research organisations, universities and government agencies on a whole of Government basis.

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