Submission to the Productivity Commission Research Study into Public Support for Science and Innovation in Australia

AusBiotech

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1 Introduction

1.1 AusBiotech and the Australian Biotechnology Sector

AusBiotech Ltd (AusBiotech) is Australia's Biotechnology industry organisation, which represents over 2,400 members covering the human health, agricultural, medical device, environmental and industrial sectors in biotechnology.

AusBiotech is dedicated to the development, expansion and prosperity of the Australian biotechnology industry by providing initiatives to drive sustainability and growth, outreach and access to markets, and representation and support for members nationally and around the world.

AusBiotech has offices in each Australian state, and represents all the relevant players in the commercialisation of Australian bioscience in the national and international marketplaces. It is structured as a not-for-profit limited guarantee company which is managed by a Board elected by the members.

The membership base includes biotechnology companies ranging from start-ups to mature multinationals, research institutes and universities, specialist service professionals, corporate, institutional, individual and student members from Australia and overseas.

1.1.1 What is Biotechnology?

Biotechnology is a broad term generally used to describe the use of biology in industrial processes such as agriculture, brewing and drug and medical devices development. The term includes the production of genetically modified organisms (GMOs) and the manufacture of products from them. Recent activity in biotechnology involves directly modifying the genetic material of living things, or recombinant DNA technology (‘genetic engineering’).

Biotechnology is being applied in many areas including:

- human uses (eg: the development of new therapeutics and diagnostic tools)
- DNA profiling and cloning (eg: identifying quality traits in plants and animals for enhanced production outcomes)
- food (eg: enhancing specific characteristics of crops)
- the environment (eg: to create bacteria that break down waste).

1.1.2 Australia’s biotechnology sector

Australia has a globally competitive industry that outperforms what would be expected from the local market’s size, available labour force and resources. World class biotechnology innovations developed in Australia include:

- Australia being the first country to provide penicillin to the general public
- the Bionic ear
- sleep apnoea devices
- HPV vaccine
- spray-on skin
- cause and treatment for stomach ulcers
- influenza drug, and the potential to develop a bird flu vaccine
- world’s first nanotechnology drug in clinical trials.

However, the industry is still small when compared with the USA and European nations. Biotechnology Australia, the Federal Government’s biotechnology agency, highlights the competitive strengths of Australia’s biotechnology industry as including:

- a strong international reputation for quality of science and intellectual capital
- a quality and readily available supply of graduates with excellent training and skills
- increasing Federal and State government support through funding and infrastructure support, and the identification of biotechnology as a national priority for investment attraction.

Australia is also developing its reputation as an effective environment for clinical trials, with particular strength in the Phase II stage. Indeed, Australia is ranked highly on an international basis as a cost-effective, professional environment for such trials as determined by the Economic Unit of the Department of Industry Tourism and Resources. This has been evidenced by growing clinical trial infrastructure such as Cancer Trials Australia, the Nucleus Network, Institute of Drug Technology Australia Limited, CMAX Pty Ltd, NHMRC Clinical Trials Centre, Q-Pharm Pty Ltd, Neurosciences Victoria and Novotech, amongst others.

Trials have also been undertaken in Australia by international companies including Amgen, GlaxoSmithKline, Eli Lilly, Roche, Pfizer, Bristol Myers Squibb, Merck Sharp and Dohme, AstraZeneca, Quintiles, Novartis and Servier. In addition and importantly, Australian companies are also contracting local organisations to conduct clinical trials which often contribute to international marketing approvals.

Australia is world renowned for scientific excellence in a range of biotechnology disciplines and supporting fields including:

- genetics
- molecular biology
- medical research
- immunology
- oncology
- plant and agricultural biotechnology.

Australia has an innovative and cost-effective research base. Compared to ten countries in Europe, North America and Asia as of January 2006, Australia was ranked the second most cost-effective location to conduct biotechnology research over the past ten years, behind Singapore. Austrade sees Australia's high ranking due partly to a strong supply of highly-qualified scientists, with more graduates in the fields of science and technology relative to other fields than in other developed countries.

1.2 Productivity Commission Research Study into Science and Innovation

The Australian biotechnology sector contributes across the broad spectrum of science and innovation. As the peak industry body of this sector, AusBiotech welcomes the Productivity Commission Research Study into Science and Innovation (the Study) and believes it is a timely opportunity for public comment on the impact of publicly-funded science and innovation in Australia. AusBiotech is pleased to provide its insights, analysis and recommendations to this Study, in line with the following Terms of Reference.

The Commission is requested to:

1. *Report on:*
    - *the economic impact of public support for science and innovation in Australia and, in particular, its impact on Australia's recent productivity performance;*
    - *whether there are adequate arrangements to benchmark outcomes from publicly supported science and innovation and to report on those outcomes as measured by the benchmarks.*

    The analysis should cover all key elements of the innovation system, including research and development, taking into account interaction with private support for science and innovation, and paying regard to Australia's industrial structure.

2. *Identify impediments to the effective functioning of Australia's innovation system including knowledge transfer, technology acquisition and transfer, skills development, commercialisation, collaboration between research organisations and industry, and the creation and use of intellectual property, and identify any scope for improvements;*
3. *Evaluate the decision-making principles and programme design elements that:*
    - *influence the effectiveness and efficiency of Australia's innovation system; and*
    - *guide the allocation of funding between and within the different components of Australia's innovation system;*

    and identify any scope for improvements and, to the extent possible, comment on any implications from changing the level and balance of current support;
4. *Report on the broader social and environmental impacts of public support for science and innovation in Australia.*

AusBiotech would be pleased to engage further with the Productivity Commission (PC) in the course of this Study. We seek the opportunity to invite the Study's Commissioners and team members to visit relevant sites that will enhance their understanding of the key messages of this submission, and to participate in public forums or roundtables that are conducted in the later stages of the Study.

1.3 Partnership with Government

AusBiotech enthusiastically acknowledges Federal and State Government support for the sector, which has been essential to the successes achieved so far. The Federal Government is applauded for its very tangible support of biotechnology infrastructure and skills, and a number of State Governments have also significantly contributed to the robust biotechnology sector that is growing rapidly. Highlights of government support for the sector include:

- visible support for the industry, including Ministerial presence at international events
- strong basic research funding, especially recent increases in National Health and Medical Research Council (NHMRC) funding, NHMRC program grants and Centres of Excellence
- recognition of the need for translational research (eg: Cooperative Research Centres (CRCs), Australian Research Council (ARC) Linkage grants, NHMRC Development grants)
- support for research infrastructure (eg: National Collaborative Research Infrastructure Strategy (NCRIS))
- support for top researchers (eg: Federation Fellowships)
- support for innovation and commercialisation, particularly programs under *'Backing Australia's Ability'*
- strong support for venture capital, including the Innovation Investment Fund (IIF), Pre-Seed Fund, Venture Capital Limited Partnerships (VCLP)
- strong leadership in intellectual property (IP) regulation, both domestically and internationally
- Action Agendas for Medical Devices and Pharmaceuticals, and
- the National Biotechnology Strategy, launched in July 2000.

This culture of collaboration between government and the biotechnology sector provides a sound platform from which the sector will continue to grow. This document seeks to highlight both success stories and impediments to success, which if redressed, would allow the sector to magnify its current contribution to Australia's economic, social and environmental well-being.

1.4 Key issues for the biotechnology sector

AusBiotech has canvassed the views of its members in relation to this Study and has identified three key issues that are covered by this submission. They are:

1. Government support for biotechnology
2. The relationship between the biotechnology sector and other elements of the research and development (R&D) community
3. Skills, training and human resources

In order to address these issues in the context of the Study's scope, it is critical to first establish a framework for the discussion. This includes profiling the biotechnology sector, identifying the principal stages of the biotechnology 'life cycle', identifying the drivers and dynamics of the sector and defining the key terminology used. There are many cases where the definition of terms, such as 'proof of concept' or 'commercialisation', differs in the biotechnology context from mainstream usage.

The framework for this discussion is outlined in Section 2 of this document, however the diversity and complexity of the sector means that generalisations are at times necessary to ensure clarity of the messages. Individuals and some companies within the sector may report different experiences and viewpoints and AusBiotech has sought to accommodate these wherever possible.

2 The innovation life cycle for biotechnology

In addressing the needs of the biotechnology sector, it is important to begin with an understanding of the intricacies of its 'life cycle'. This includes the costs and risks associated with each stage, the interaction of different parties across the continuum, and the role government can and should play in supporting the complex evolution of new scientific discoveries.

The R&D process is not an evenly spaced progression, and different phases of development require various levels of intervention. In Australia this cycle operates efficiently in many cases, however at some points of the cycle there are noticeable deficiencies in the Australian infrastructure, capabilities and capacity.

2.1 Profile of the Australian biotechnology sector

There are numerous parties involved in the process of biotechnology innovation, including:

- scientists and researchers in public research organisations
- start up companies
- venture capitalists
- expansion and medium size companies
- large pharmaceutical and medical device companies.

For its size, the Australian Biotechnology Industry contributes strongly to the Australian economy and makes a significant contribution to the health and well-being of consumers

Australia is currently ranked number 6 in the global biotechnology market behind the US, Canada, Germany, the UK and France, with key features of the sector including:

- 420 dedicated biotech firms Australia wide in 2006, up from 190 in 2001, with 20 new firms formed in 2004/2005
- 6,100 employees
- market capitalisation of Australia's 15 leading biotech firms of $9.08 billion (at the end of Quarter 3, 2005), which is 11% higher then the same Quarter in 2004
- 135 biotech firms listed on the Australian stock exchange as at February 2006
- high levels of venture capital investment, from both local and international sources
- $377.8 million of biotechnology R&D in the 2004/2005 financial year, positioning biotechnology ahead of food manufacturers, metal products manufacturers and electronics manufacturers
- 12 Australian bioscientists who received major national or international awards in 2004/2005
- grants awarded to Australian researchers in 2004/2005 by US research institutes and foundations totalling almost US$70 million (A$93 million), and covering R&D projects in malaria, viral diseases, vaccines and other major threats
- 384 alliances of Australian companies and R&D institutions in 2004/2005, including 51 international collaborative R&D agreements, 52 international licensing agreements and 41 international distribution agreements
- exports of Australian pharmaceutical products and medical devices for the 12 months to June 2006 reaching $4.3 billion.

2.1.1 Social and economic contribution of biotechnology

As ageing populations grow as a proportion of the whole population, they will drive significant increases in public and private health care budgets. Health budgets will increase as there are more people in the age groups which incur the highest health care costs, as people live longer and as treatment costs rise. However, there will be fewer taxpayers in younger populations to fund it.

Technology-based biotechnology products and medical devices have demonstrated the capacity to reduce the burden on health care budgets and other forms of Government support. The Cochlear implant is a notable example. A child implanted with a Cochlear ear implant can expect to have equal life chances as child born without a hearing defect. The child can go to regular education facilities and participate unhindered in family, social and community activities.

People suffering severe burns following trauma such as experienced in Bali or more commonly in motor accident and domestic fires represent a major loss to the workforce and a cost society. Solutions offered by companies such as Clinical Cell Culture that more rapidly and effectively return these people to the workforce make a significant contribution to Australia's economy.

The Australian Biotechnology Industry has the potential to:

- increase the number of people it employs
- absorb and re-skill workers from traditional industries
- foster the development of new 'supply chain' businesses around innovative technologies
- generate domestic wealth, including increased export dollars and tax revenue
- improve health outcomes as well as delay, reduce and prevent the onset of higher health costs, and
- respond rapidly to emerging health issues world wide.

While the sector is growing rapidly, there are knowledge and infrastructure gaps across the spectrum and between the players, limiting its true potential. This document seeks to highlight those gaps and make recommendations to remedy them.

2.2 The Biotechnology Life Cycle

The diagram below shows the process of biotechnology discovery, from basic research to launching a product to market.

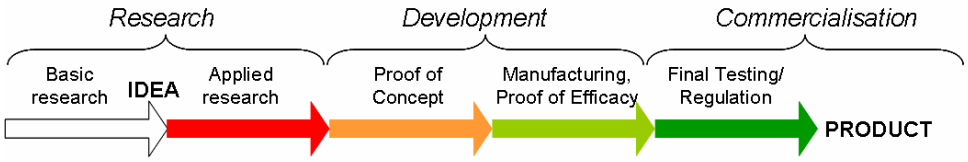

Figure 1: Basic Biotechnology Discovery Process

2.2.1 Definitions

Figure 1 has been designed based on the following definitions of key terms:

Basic research (also called fundamental or pure research) has as its primary objective the advancement of knowledge and the theoretical understanding of systems. It is exploratory and often conducted without any specific end in mind, although it may have unexpected results pointing to practical applications. Basic research generates theories that provide the foundation for further applied research.

Applied research is done to solve specific, practical questions derived from basic research. Applied research can be carried out by academic or industrial institutions, or by the private sector directly. Often, an academic institution such as a university will have a specific applied research program funded by an industrial partner interested in that program.

- In drug development, applied research typically includes activities such as: research on a specific gene or protein (a 'target') implicated in a disease that may be suitable for targeting with a new drug, followed by target validation in vitro and in vivo, through to identifying a potential drug candidate or family of drug candidates.

- In medical device development, applied research typically includes the development of the core of a new technology or new application of an existing technology, followed by the development of a prototype.
- In developing a new GM crop, applied research typically includes conducting high-throughput screening of genetic databases to identify valuable plant traits that can be used in conventional breeding and valuable genes that can be used to improve plants through biotechnology; applying screens to broad categories of interest and identifying multiple leads that are then investigated.

Proof of concept is a short and/or incomplete realisation of a certain method or idea to demonstrate its feasibility, or a demonstration in principle to verify that some concept or theory is probably capable of exploitation in a useful manner. The proof of concept is usually considered a milestone on the way to a fully functioning product. In the commercialisation of biotechnology ideas this use of proof of concept helps establish viability, technical issues, and overall direction, as well as providing feedback for budgeting and other forms of commercial discussion and control.

- In drug development, proof of concept typically includes activities such as: demonstrating that at least one of the family of potential drug candidates is effective in an animal model, followed by steps to optimize the activity of the new drug.
- In medical device development, proof of concept typically includes demonstration that the prototype works in a model system (e.g. an animal model) followed by refinement steps in manufacturing and assembly of the prototype.
- In developing a new GM crop, proof of concept typically includes testing gene configurations in plants to screen for desired performance and determining which leads show the most promise for application to core crop plants.

Proof of efficacy is an initial demonstration that a product under development works in the way intended, is safe to use, and provides benefit to its intended user. Manufacturing is required to scale up the production of prototypes to the volume required to perform proof of efficacy testing. This stage is subject to strict regulation in the biotechnology sector.

- In drug development, proof of efficacy typically includes activities such as pre-clinical testing, toxicology, Phase I (safety) trials in humans and culminates with Phase II (efficacy) trials in humans.
- In medical device development, proof of efficacy includes the equivalent steps leading up to initial safety and efficacy trials in humans.
- In developing a new GM crop, proof of efficacy typically includes conducting lab and field-testing of genes in plants to select the product candidates that can be commercialised and can meet regulatory requirements.

Final testing is a large scale demonstration that the product works at a standard acceptable under a defined set of government regulations. In a medical context it indicates that the product has a therapeutic effect and is at least as good as other available interventions to which it has been compared in a clinical trial.

- In drug development, final testing and regulation includes Phase III (large scale efficacy) trials in humans and the process of registering a new drug with the appropriate regulatory body (eg: the Therapeutic Goods Administration (TGA) in Australia and the Food and Drug Administration (FDA) in the US.
- In medical device development, final testing and regulation typically includes large scale clinical trials and registration through the appropriate regulatory body.
- In developing a new GM crop, final testing and regulation typically includes demonstrating the efficacy of a biotechnology trait in elite germplasm, developing regulatory data as appropriate, producing bulk seed for potential sale, developing plans for commercialisation and launch, and responding to regulatory processes as appropriate.

2.2.2 Life cycle participants and risk factors

AusBiotech strongly believes that basic research in biotechnology is the natural domain of medical research institutes, universities, CRCs, divisions of CSIRO and other publicly funded research

organisations (PROs). The standard of science in Australian PROs is world class and provides a sound foundation for the sector. A clear separation of basic research by PROs from the development process will ensure these high standards are maintained and not diminished by commercial imperatives.

The costs, risks and time frames associated with converting excellent science to marketable products are of a magnitude that make it difficult for the majority of Australian participants to remain involved for the entire life cycle of development. This makes partnering between small and large organisations an essential part of product development.

Figure 2 below presents typical life cycle scenarios for the development of a new drug, a medical device and a genetically modified (GM) crop.

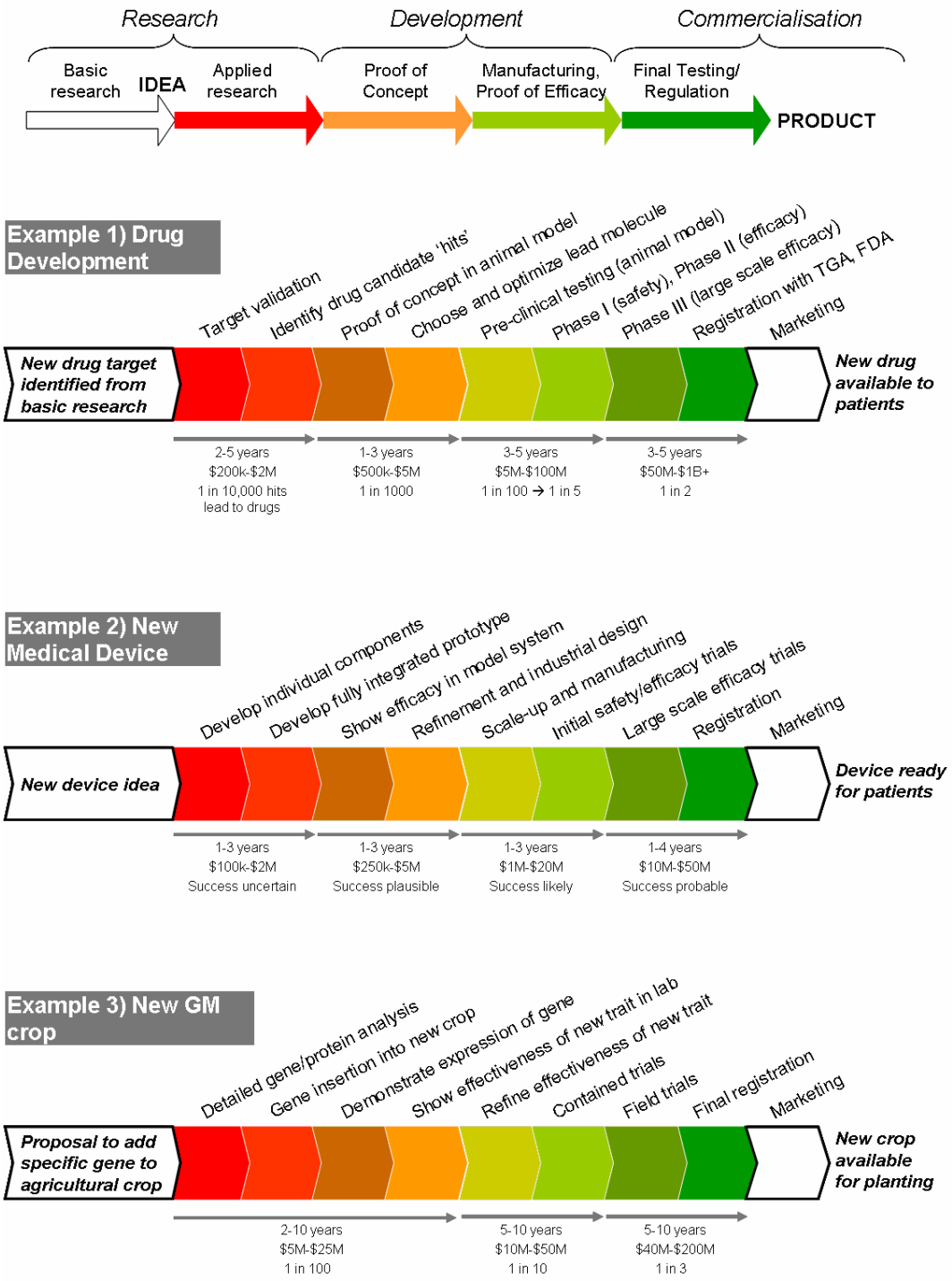

Figure 2: Typical Biotechnology Life Cycle for Drug, Medical Device and GM Crop

In summary, a conservative estimate of the average time, cost and risk involved for each of these scenarios is:

- Development of a new drug:
    - 12-15 years development time
    - Average cost in 2000 was $1 billion
    - 1 in 10,000 chance of success, 5-15% following proof of concept.
- Development of a new medical device:
    - 4-13 years development time
    - $10 million - $60+ million, depending on various factors which may arise during each stage of development
    - 10-25% success rate.
- Development of a new GM crop:
    - 15-20 years development time
    - $55 million - $100+ million, depending on the regulatory package required. The regulatory package may cover human and animal health and safety, food safety and labelling, impact assessments on the environment, agricultural farming systems and domestic and export market access
    - 1-5% success rate.

Figure 3 below indicates the key players at each stage of the biotechnology life cycle.

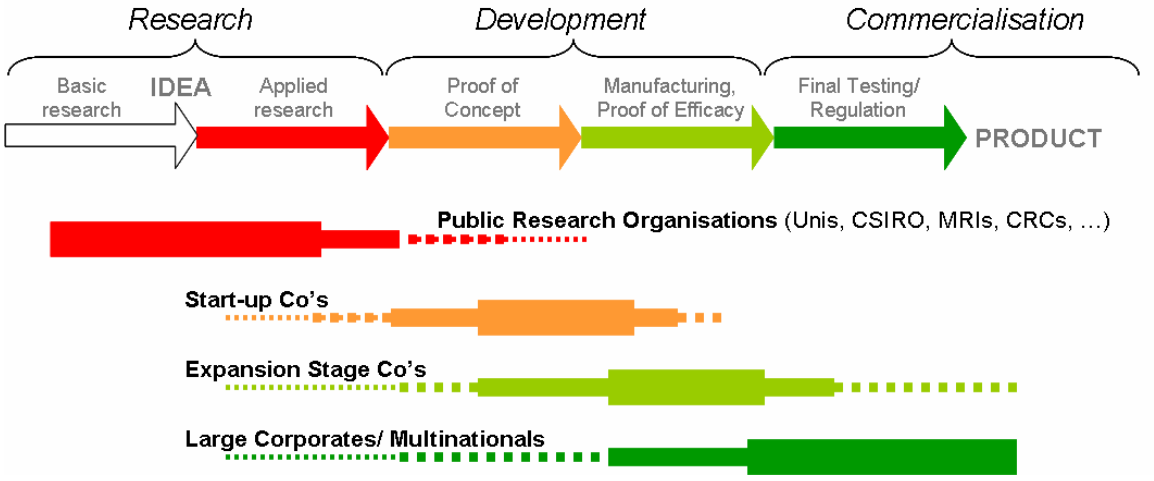

Figure 3: Key Players in Biotechnology Life Cycle

As a general statement, PROs are increasingly being driven by commercially focused KPIs, which lead them beyond the research phase and into the development phase of the life cycle. AusBiotech believes commercial drivers for PROs impede their ability to deliver the excellent basic research upon which the sector relies.

Given the obvious challenge presented by the time, cost and risk factors above, it is imperative that the Australian biotechnology sector is:

- underpinned by excellent science in public research organisations
- appropriately structured, including the right mix of players, whether small or large
- well resourced
- able to access institutional infrastructure, such as CSIRO facilities and the Synchrotron
- nurtured by appropriately funded and structured government programs, a supportive tax environment and flexibility for strategic interventions by government
- linked to the global value chain, from basic research to product sales.

Currently, there are segments of the life cycle which are functioning effectively, and others where certain financial and policy interventions could substantially enhance the performance of the biotechnology sector.

2.2.3 From Basic and Applied Research to Proof of concept

Basic blue sky research is an important element of Australia's innovation system and requires solid ongoing funding from Government. Expenditure over the past 15 years has shown excellent dividends in technologies developed for the market. There is a need in the biotechnology sector to more efficiently recognise and capture value as and when it is created. This element of the biotechnology life cycle requires a balance between curiosity or blue-sky research and that driven by commercially focussed applied research.

Where research is identified with commercial potential, it is important that such applied research be strongly market focussed rather than technologically focussed. In this respect it is important that there is a mechanism to make an early assessment of the market potential of early stage research. This helps to ensure that effort is not wasted on applied research for which there is no market need. While this is brutally expressed by some players in the sector as 'kill fast and kill cheap', it is a practical reality that cannot be ignored.

The proof of concept stage following basic research provides for the development of intellectual property in a way that extends the protection and applicability of that property, improves confidence in its anticipated commercialisation, underpins the validity of its claims and demonstrates its value. There is currently a gap in both funding and capability for this stage in Australia.

At each stage of development there is a key milestone that represents a value inflection point recognised by industry and capital markets. It is necessary for basic research funding programs to support the development of technology to an appropriate value inflection point, where investors can see clear opportunities and become involved. This is generally the lead optimisation stage, such as where a working prototype exists. However, basic research funding programs often fall short of this critical milestone.

2.2.4 Proof of efficacy

The next stage of the life cycle sees research move beyond the proof of concept stage to proof of efficacy. This stage is in most cases still too early to secure commercial funding from venture capitalists or industry partners, and it frequently becomes a critical funding gap in the life cycle.

AusBiotech believes strongly that funding should be structured to support organisations at this stage as they are frequently forced to form a company prematurely, simply to secure further funding from government schemes. Acting under financial pressure, there are many cases of small companies entering less than optimal deals that could have been avoided if they were financially supported through this stage, and able to structure a later deal around a more developed product with demonstrated commercial potential. Government support at this sensitive stage needs to be structured to advancing the technology to the next value inflection point, at which stage it is more likely to attract funding from venture capital or other sources.

A demonstration of the phenomenon of premature company formation is the high number of Australian stock exchange (ASX) listed biotechnology companies with small market capitalisation. There are 146 listed health sector companies in Australia, which is comparatively high. By contrast there are only 40 listed health sector companies in Germany. Of the ASX listed companies, 23% of these have less than $10 million market capitalisation and 57% have less than $50 million. Companies with market capitalisation as low as $4 million are listed on the ASX, whereas major European exchanges consider companies with a market capitalisation of less than €150 million (A$250 million) as 'small'.

In part this is due to the Australian biotechnology sector being smaller and less mature than overseas markets, but the funding gap is also a major contributing factor. This fragmentation undermines the strength of the sector and could be addressed through targeted government support.

Venture Capitalists

Venture capitalists operating in Australia have been reluctant to enter the process at this earlier stage of development. Not only is it highly risky, but without significant reserves to invest in

subsequent financing rounds, early stage investors risk having their involvement diluted as other investors come on board. (This is another factor that contributes to the high number of listed companies with small market capitalisation.) Venture capitalists need to be able to identify a clear future value inflection point that will attract a follow-on investor.

Some angel investors, high net worth individuals and philanthropists may support projects at this stage. However this segment is less structured in Australia than in other markets, where angel investors typically become involved later in the life cycle.

Pre-Seed Funds

The Pre-Seed Fund (PSF) program was introduced as part of *Backing Australia's Ability*, to help increase the commercialisation of Australian Government research. It seeks to encourage the private sector to take a more active role in funding and managing the commercialisation from universities, CRCs, CSIRO and other PROs.

The PSF program has established four venture capital funds to invest in PRO projects, managed by experienced venture capitalists. This program has had some success addressing the funding gap at this stage of the life cycle, however its value could be increased by adopting enhancements discussed in Section 3 of this document.

2.2.5 Phase I, II and III trials

This is a very costly stage of the biotechnology life cycle in terms of the time, risk and funding required, especially for Phase II and III trials. Clinical trials for drug development are generally divided into three separate phases. The scale of these phases is typically:

- Phase I involving 20-80 patients to demonstrate safety
- Phase II involving 100-300 patients to demonstrate efficacy in a small sample population and
- Phase III involving 1000-5000 patients.

The conduct of Phase I trials in Australia is being assisted by clinical trial infrastructure such as CMAX in Adelaide, Nucleus in Victoria and GlaxoSmithKline's Phase I Group in Sydney. While Phase III trials are generally global in nature, there is great potential to increase Australian involvement in Phase I and II trials, which is addressed in Section 3.

2.2.6 Measuring success in the biotechnology life cycle

While it is desirable to increase the likelihood of Phase I and II activity occurring in Australia, there also needs to be a pragmatic understanding that most Australian biotechnology companies ultimately reap their greatest returns from the global market. This means that selling a technology offshore (for the right price) or being acquired by a larger local or overseas partner can be a measure of success for a local biotechnology company.

For example, the sale of Memtech offshore led to benefits to the Australian biotechnology sector through re-investment of funds and skill by the entrepreneurial founder of Memtech, Denis Hanley, into a number of other companies, such as CathRx and Universal Biosensors. A similar example is found in the medical devices industry with the role played by Pacific Dunlop and Paul Traynor, giving rise to expertise that spawned numerous companies such as Nucleus, Telectronics, AMBRI, and Elastomedic,

In particular, when it comes to Phase III trials, the enormous costs and technical risk involved mean that the end product must be saleable in a very large market, typically the USA. Effectively this requires Phase III trials to be conducted in the US to achieve FDA approvals. As Australian firms currently receive no assistance for this, they are often forced to sell out to larger US companies at this stage.

The biotechnology sector has significantly contributed to both foreign and local investment in Australia. In Quarter 3 2005, 29 Australian biotech firms entered into partnerships, an increase in partnering activity of 70% from Quarter 2. The majority of partnerships were with US companies (44% of the Quarter 3 total), while 28% of the Quarter 3 total were local partnerships. Most of the remainder were EU partnerships.

Examples of successful Australian companies at different growth stages of the life cycle are addressed in the case studies below and include:

a. Biota (expansion stage drug company with more than 1 product)

b. Optiscan (expansion stage medical devices company with more than 1 product)

c. CSL (an acquirer of technology and smaller companies and an international player).

Case Study - Biota

Biota is a biotechnology company focussed on the discovery and development of human pharmaceuticals and in particular, anti-viral drugs. Biota was formed initially to develop zanamavir, which GSK now markets as Relenza™. Biota now has grown from a single product company to a company with a drug pipeline and key industry partnerships.

Biota's portfolio includes:

- the world's first neuraminidase inhibitor (NAI) for influenza A & B (marketed as Relenza™ by GSK)
- innovative point of care influenza diagnostic tests (marketed by Inverness Medical-BioStar Inc)
- second generation, long-acting NAI (in development in collaboration with Sankyo, Japan)
- oral antivirals for RSV (partnered with MedImmune in a US$112m deal)
- oral antivirals for human rhinovirus (Phase I)
- new antivirals for hepatitis C.

Recent highlights include stockpiling of Relenza™ for avian/pandemic influenza, an RSV licensing deal with MedImmune and commencement of Phase Ib for BTA798 (human rhinovirus).

Some of the benefits from this that flow to Australia are:

- the global recognition of Biota's expertise in antivirals, and therefore Australia's excellence in discovery and commercialising great science
- a spend of in excess of $26m in 2005/07 in research and development activities, predominantly in Australia which supports local research institutions, manufacturers, clinical centres and consultants. This level of expenditure is planned to increase in the ensuing years
- the employment of 55 full time staff, many of whom have been attracted to the global expertise in antivirals of Biota
- the prestige to Australia of successfully collaborating with major global pharmaceutical companies and bringing valuable expertise and foreign currency to Australia
- the prestige of exclusively winning over US$14m in US National Institutes of Health grants for Biota's Long Acting Neuraminidase Inhibitor (LANI) program.

Case Study - Optiscan

Through a four year collaboration with Pentax, and using its own technology, Optiscan developed a flexible endo-microscope which has recorded product sales revenues of $3.23 million on the back of its the March 2006 release.

Sales of the product have been recorded in Europe, the US, Asia and the Middle East, and the company forecast sales in the first half of the 2006-07 financial year will be higher than in the second half of 2005-06. The company has posted a 25% reduction in losses at $3.9 million, and at the end of the financial year had $6.7 million in cash and equivalents.

It has been suggested that a minimum of 200 units per year would need to be sold to break even, and for the first year of sales, Pentax is committed to selling at least 80 units. 47 systems with 71 miniaturised scanner sets were provided to Pentax in the four months from the launch until the end of the financial year.

Optiscan has completed design and development of its second commercial product, a preclinical research instrument likely to be used by drug companies and doctors involved in preclinical studies. Optiscan is also in the process of finalising a second partnership to develop a rigid endo-microscope, for which there is an international market of over $US1 billion, and has commenced pilot clinical trials in Australia and Germany.

Case Study - CSL's Gardasil

The HPV vaccine, Gardasil, being brought to market currently by CSL, has its foundation in basic research conducted in Australia by Professor Ian Frazer. The technology was developed by CSL through Phase I. To take it to Phase II and III trials, CSL partnered with Merck, who spent $700 million. The Phase III trials were conducted in the US, as FDA approval is essential to ensuring a global market for the product. Typical margins for products of this type are around 70% which will

accrue to Merck. CSL will receive a 7% royalty on sales. While this level of royalty is commensurate with the risk and investment borne by each party, it also highlights the opportunity cost to Australia of not being more closely involved in the Phase II and Phase III trials.

Issues in Summary

- The Australian Biotechnology sector has an extremely positive impact on the economic, social and environmental welfare of Australia.
- Biotechnology R&D is dependent on an intricate life cycle, which must be carefully considered when identifying appropriate support programs for the biotechnology sector.
- Lack of funding at the proof of concept stage prevents certain projects from reaching key development milestones required to attract investor and/or industry partners.
- Australian biotechnology companies are seeking private capital, such as through ASX listing, too early in their development due to an insufficiency in funding programs and venture funds at the proof of efficacy stage.
- There needs to be greater understanding that Australian biotechnology companies reap their greatest returns on the global market, but that this can also lead to direct benefits to the Australian economy.

Recommendations

Recommendation One

Ensure that government support and intervention in the biotechnology sector is underpinned by a clear understanding of the complexities, dynamics and specific drivers of the sector.

Recommendation Two

Adjust government programs to ensure they advance recipients to the next value inflection point in the lifecycle, where they are more likely to attract funding from the market. (Please refer to Section 3 for detailed recommendations in relation to specific programs.)

Recommendation Three

Extend the scope of biotechnology activity across the lifecycle by specifically supporting the conducting of Phase I and Phase II trials in Australia.

3 Government support for biotechnology

The biosciences have potential, through activities in health, agriculture, industry and energy, to build the next basis of economic foundation, just as today we see a society driven by digital technologies. Biotechnology could transform the way people produce and consume over the next decades, and address issues of global concern. Examples of this include:

- agricultural developments to help provide food, recover soil health and solve broader socio economic problems for the estimated 9 billion inhabitants of tomorrow's world and
- the refinement of bioenergy, produced from biomass or other sources, which could have a significant impact on reducing countries' reliance on foreign energy sources and dependence on fossil fuels.

This concept of a 'bioeconomy' of the future requires strong policy leadership by Government and must be appropriately planned for in Government's allocation of industry support.

To date, Government support for Australian biotechnology, at both a Federal and state level, has been an important factor in the growth and development of the sector. The National Biotechnology Strategy which was launched in July 2000 provided funding of $30.5 million over three years for targeted initiatives to support the Australian Government's vision for biotechnology. This strategy was further boosted by another $66.5 million funding under the *Backing Australia's Ability* package to fund the Biotechnology Centre of Excellence, the Australian Stem Cell Centre and the Biotechnology Innovation Fund. The recent $500 million increase over four years to the NHMRC grants program is also very welcome.

The Federal Government was also instrumental in creating a venture capital sector, with the introduction of the Early Stage Venture Capital Limited Partnership. This investment scheme provides flow through tax treatment and a complete tax exemption for income, both revenue and capital, received by its domestic and foreign partners.

State governments, including Victoria, Queensland, NSW, Western Australia and South Australia also offer targeted and effective programs aimed at boosting the biotechnology sector.

There is a need to emphasise the linkage between government support and outcomes, rather than measuring success by grants dispensed. AusBiotech believes that patents granted to companies (but not to PROs), commercialisation revenue generated and the number of sustainable, cash-positive companies are strong outcomes by which the effect of government support should be measured.

AusBiotech believes the most valuable contribution of PROs is through basic research, and that KPIs requiring them to commercialise technology diverts them from this. Broad increases in direct Government funding, as well as through Australian Research Council (ARC) and National Health and Medical Research Council (NHMRC) grants should continue to be made to support PROs in this pursuit.

Case Study – South Korea

South Korea provides an interesting example of how highly targeted government support and intervention has been instrumental in growing the biotechnology sector. The South Korean government has a clearly articulated goal of making the country the world's seventh most important biotechnology location by 2015. The government's biotechnology R&D fund has tripled since 2000 to $709 million and it has invested heavily in research parks, as well as addressing regulatory issues such as IP protection laws and international safety standards. The effectiveness of the government's deliberate strategy is demonstrated by the fact that South Korea's ranking for biotech global competitiveness rose from from 20th in 1999 to 14th in 2004.

While there is a significant range of government support programs in place in Australia, in certain cases there is friction between programs, which reduces their effectiveness, or there are structural issues that, if addressed, could help to further unlock the potential of the sector. For the purpose of

this discussion, programs have been broadly classified as ‘Research’, ‘Development’ and ‘Commercialisation’ stage programs, as depicted in Figure 1.

3.1 Support at Research stage

ARC Linkage and NHMRC Development grants

Australian Research Council (ARC) Linkage Grants support R&D undertaken to acquire new knowledge involving risk or innovation and are collaborative between higher education facilities and industry. Proposals may include:

- basic research undertaken to acquire new knowledge without looking for long-term benefits other than the advancement of knowledge
- basic research undertaken to acquire new knowledge directed into specified broad areas that are expected to lead to useful discoveries
- applied research to acquire new knowledge with a specific application in view. Such research is undertaken either to determine possible uses for the findings of basic research or to determine new ways of achieving some specific and predetermined objectives.

ARC Linkage Grants offer a maximum of $500,000 per annum up to a maximum of five years and can include any discipline of research. Applicants must have a partner organisation from outside the public research sector for the duration of the research.

National Health and Medical Research Council (NHMRC) Development Grants support the development of health or medical research with commercial potential and potential benefit to the Australian community, through funding for commercialisation at the early proof of concept stage. The scheme aims to bridge the gap between high-end basic research and development required to make a project commercially attractive to investors.

Although it is encouraged, NHMRC Development Grants do not require that there be a commercial partner in place when making an application. Funding is normally awarded for one year to a maximum of $200,000, although this may be extended to three years dependent on satisfactory achievement of agreed milestones. Applications must demonstrate commercial potential through a formula or prototype, and a plan for developing commercial potential.

The intentions behind these grant programs are sound however improvements in their implementation could deliver superior outcomes. In evaluating applications, Government assessors should consider high standard criteria that must be achievable. The top criterion is excellent science. More industry representation would enhance the selection panels that assess projects, both to assist in giving a realistic view on the viability of research development, and to help forge important links between researchers and industry.

The application process for these grants is also onerous in both time and resources required, particularly given the high failure rate. A preferred alternative would be a two-stage process, where projects are pre-screened on the basis of a more simple initial review, with a higher success rate for those projects that progress to a more rigorous review at stage two.

There have recently been increases in NHMRC grants, which is a great advance in providing additional support in this area. However while NHMRC creates a nexus between universities and medical research institutes (MRIs), MRIs are later prevented from accessing Pre-Seed funding (see below), which limits the commercialisation of developments.

The NHMRC Development Grant Program and the ARC Linkage Grants Program could also be extended to fund proof of efficacy research. Although important sources of funding, these schemes are very limited in scope and not commercially focussed. They should be available on a competitive basis to all Australian researchers, especially where the applicant has an industry sponsor.

3.2 Support at Development stage

As described in Section 2, funding programs for basic research often fall short of supporting technologies to the appropriate level of development that will naturally attract other sources of funding, such as venture capitalists or Pre-Seed Funds. There are several commercialisation funds

in Australia, including ANU Connect (ACT), UniSeed (Queensland), Bio Innovation SA's Terra Rossa Capital and Murdoch Westscheme Enterprise Partnership.

These funds provide very valuable commercialisation resources and expertise, as well as a clear and consistent process to access finance. The proof of concept is however a critical step that occurs earlier in the life cycle, requiring a careful balance in recognising the commercial and market potential of basic research as early as possible, without undermining the basic research with commercial concerns.

3.2.1 Proof of concept fund

There are several overseas models which have specifically targeted the transition from basic research to proof of concept – a phase of development that venture capital will not ordinarily address. The case studies below outline these alternative models. Of the three, the Scottish Proof of Concept Program is one which AusBiotech believes would translate well to the Australian environment.

Case study - Scotland

Scotland has developed the Proof of Concept Program (the Program) which is directly focused on the need for funding in this area. The purpose of the Program is to examine the market potential for a product and the steps involved in taking it to market. The fund offers a repayable grant of $100,000 to $500,000, where the IP can return to be further developed through basic research if the initial project proves unviable.

The Program was established in 1999 as a result of the Knowledge Economy Taskforce which concluded that there was a funding gap around the proof of concept stage. This gap restricted the flow of technology from the laboratories to the market place. Scotland was seen to need strengthened linkages between its higher education institutes, research institutes, the National Health Service (NHS) and the Scottish Enterprise Cluster Teams.

The Program was initially launched as a three year, £11 million program, but has since almost quadrupled in value to £43 million. To date there have been six rounds of funding within the categories of life sciences, microelectronics, food and drink, optoelectronics, digital media and creative industries, communications technologies, forest industries, tourism and energy. The program is currently supporting 172 projects worth over £28.1 million and has created over 400 new jobs.

The program is operated by the Scottish Enterprise in partnership with key stakeholders including the Scottish Executive, Universities Scotland, the Scottish Agricultural & Biological Research Institute and the Scottish Higher Education Funding Council. Proposals are required to show commercial potential and meet the Scottish Enterprise's cluster priorities. Funding is available for non-competitive, pre-commercialisation activities being undertaken in government-funded Universities, research institutes and NHS establishments. Funding is awarded against 100% direct attributable costs and there is no maximum duration for projects, although they are reviewed on an annual basis.

Case Study - UK

The UK Government has established a Higher Education Innovation Fund (HEIF), where a substantial 'third-stream' of public funding gives universities better access to capital for the early stages of the commercialisation process.

The Australian Government's Commercial Ready program provides this type of assistance to private firms, however tax exempt organisations (usually PROs and their spin-offs) are specifically excluded from accessing this program. The HEIF model bridges this gap and stimulates the commercialisation process.

Case study - India

India has established the Small Business Innovation Research Initiative (SBIRI) to address the funding gap towards the end of the research phase of the biotechnology life cycle. SBIRI supports high-risk pre-proof of concept research in small and medium companies. The scheme is publicly funded and supports private companies and collaborations between PROs and industry in the development of products and processes. It is applicable only to the field of biotechnology and aims to:

- strengthen those existing private industrial units whose product development is based on in-house innovative R&D
- encourage other smaller businesses to increase their R&D capabilities and capacity
- create opportunities for starting new technology-based or knowledge-based businesses by science entrepreneurs
- stimulate technological innovation
- use industry as a source of innovation and thereby fulfil government objectives in fostering R&D
- increase private sector commercialisation derived from Government funded R&D.

3.2.2 Pre-Seed Fund

The Pre-Seed Fund (PSF) is administered by AusIndustry as part of *Backing Australia's Ability*, and is designed to assist the commercialisation of research from PROs . Under this program there are four Pre-Seed Fund Managers, three of which invest in Life Sciences. The Fund Managers provide management and technical advice regarding commercialisation of projects. The program offers expansion stage funding aimed at the highest risk projects, and Government contributes $3 for every $1 of private investment. The program offers a Government allocation of $72.7 million for the 10 year duration of the program, with a total allocation of $104.1 million including private sector contributions. Investments can be made into individual projects or established companies. Companies must either be controlled by a PRO or use intellectual property that is at least 50% owned by a PRO.

Managers will acquire an equity interest in the companies or projects and will provide advice to develop the commercial potential of technology. The maximum amount invested is $1 million per project with a total of $72.7 million available in the program. Ultimately the managers will divest their interest to later stage investors.

The PSF program has now been operating for three years, and has been responsible for venture capitalists investing at an earlier stage of development. While the program seeks to address an essential need in the biotechnology life cycle, some of the program criteria limit its effectiveness. These could be addressed to greatly enhance its impact, as follows:

- PSFs should accommodate developments from medical research institutes, which is not currently permitted.
- The maximum investment in any project or company is $1 million. These funds should be expanded to invest up to 10% of the fund size per investment, as the current $1 million cap in certain circumstances severely limits the ability of participants to reach the value inflection points required to secure follow-on finance from the marketplace. Additionally, the PSF equity becomes diluted out early as they lack the ability to invest in subsequent finance rounds.
- PSFs should be permitted to co-invest such that the maximum investments of both PSFs are additive, to ensure adequate funding to drive the technology to the next value inflection point. Under the current rules, if PSFs co-invest they are capped at a total of $1 million.
- Allow PSFs to invest in companies that are based on IP derived from Medical Research Institutes. For example, NHMRC project grants have created important linkages between universities and MRIs, yet some of these opportunities can not be funded by the PSFs because the IP is more than 50% owned by an MRI.

3.2.3 Venture Capital

If projects at development stage received adequate Government funding to take them to the next value milestone, taking into account the recommendations above relating to Pre-Seed Funds, they will be much more attractive to venture capitalists at a later stage.

Government funding is much more amenable to this early stage development than private capital, especially as involvement by more than one venture capitalist with divergent views can cause substantial external pressures. A system where Government contributes funding in the nature of a loan, repayable on successful commercialisation of the technology, could fulfil this need in the

market while being a sustainable means for Government support. Projects should still be required to establish that there is a real market for the product in order to qualify for funding.

3.2.4 Commercial Ready

The Commercial Ready scheme has many benefits and offers funding of up to $5 million for successful projects. This includes matching funds where there is a technical risk that would otherwise prevent funding from other sources. There is potential to improve the utility of the scheme for the biotechnology sector by addressing the following issues:

- Applicants must be able to show three years of financial history and two years forward cash flow. Small biotechnology companies may not be able to demonstrate this sort of track record and are therefore under pressure to show a matching level of finance for the Commercial Ready grant available at the initiation of a project. This is inconsistent with the structure of venture capital backed companies where funding is provided based on the achievement of certain development milestones. Applicants cannot use other grants as matching funding, further limiting the utility of the scheme for smaller biotechnology companies.
- Only incorporated companies can apply for the scheme. This creates an incentive to establish businesses solely for the purpose of attaining grants before they are in the ideal commercial position to do so. While the formation of a company establishes good structure and discipline for commercialisation activities, it also brings reporting requirements and administrative burdens that are difficult for smaller companies to support, and can divert them from developing their research. Allowance should be made for unincorporated bodies to apply in certain circumstances.
- There remain excessive administrative reporting requirements to comply with the scheme and these add significant compliance cost to small business.
- The three year timeline is very strict and not consistent with the process of product development that will inevitably see timeline slippages.
- The inability for IP to be sold within five years of the Commercial Ready grant without prior Commonwealth approval limits opportunities for biotechnology companies.

3.3 Support at Commercialisation stage

This final stage of the biotechnology life cycle is no less complex than those that precede it. It incorporates clinical trials, registration of a product with the TGA and probably the FDA, marketing and sales processes. It is also potentially the most expensive stage, costing around $600 million or more over a 3-6 year period. There is increasing Phase I and II activity in Australia, however this is often the point at which local developments are lost offshore. This can be due to a lack of infrastructure and critical mass, but also due to more generous incentives for clinical trials in other countries.

While the practical reality of the global market drives many Phase III trials to be conducted in the US, there are opportunities for government intervention to stimulate Phase I and II activity in Australia, and to position it as one of the sites used for global clinical trials.

There needs to be a tax incentive for large companies to help smaller companies by facilitating Phase I, II and III testing in Australia. This could include passing on tax credits to these larger companies when they acquire a smaller company. The credits may be worthless to the smaller company, which may have been operating at a loss. These tax credits would make smaller companies a more attractive acquisition prospect, helping to progress the technology along the continuum. Further, increasing the R&D Tax Concession rate to 200% and allowing the reimbursement claims as a tax credit would put Australia on a more equivalent footing with other countries as a location for clinical trials.

Other suggested tax reforms are addressed in 3.5 below.

3.4 Government support in the biotechnology life cycle

Figure 4 synthesises the issues outlined above to show the current gaps in funding at different stages of the biotechnology life cycle, and summarises opportunities to adjust both government and private sector funding to address these gaps. Specifically, the diagram identifies:

- existing sources of public funding, and where these should be adjusted to better align with the biotechnology life cycle
- existing sources of private funding, where this should be increased, and where it would be preferable to have public funding to avoid small companies being pressured into incorporation
- stages of the life cycle at which companies are vulnerable to being forced into incorporation or premature grant applications just to access enough funding to continue to operate.

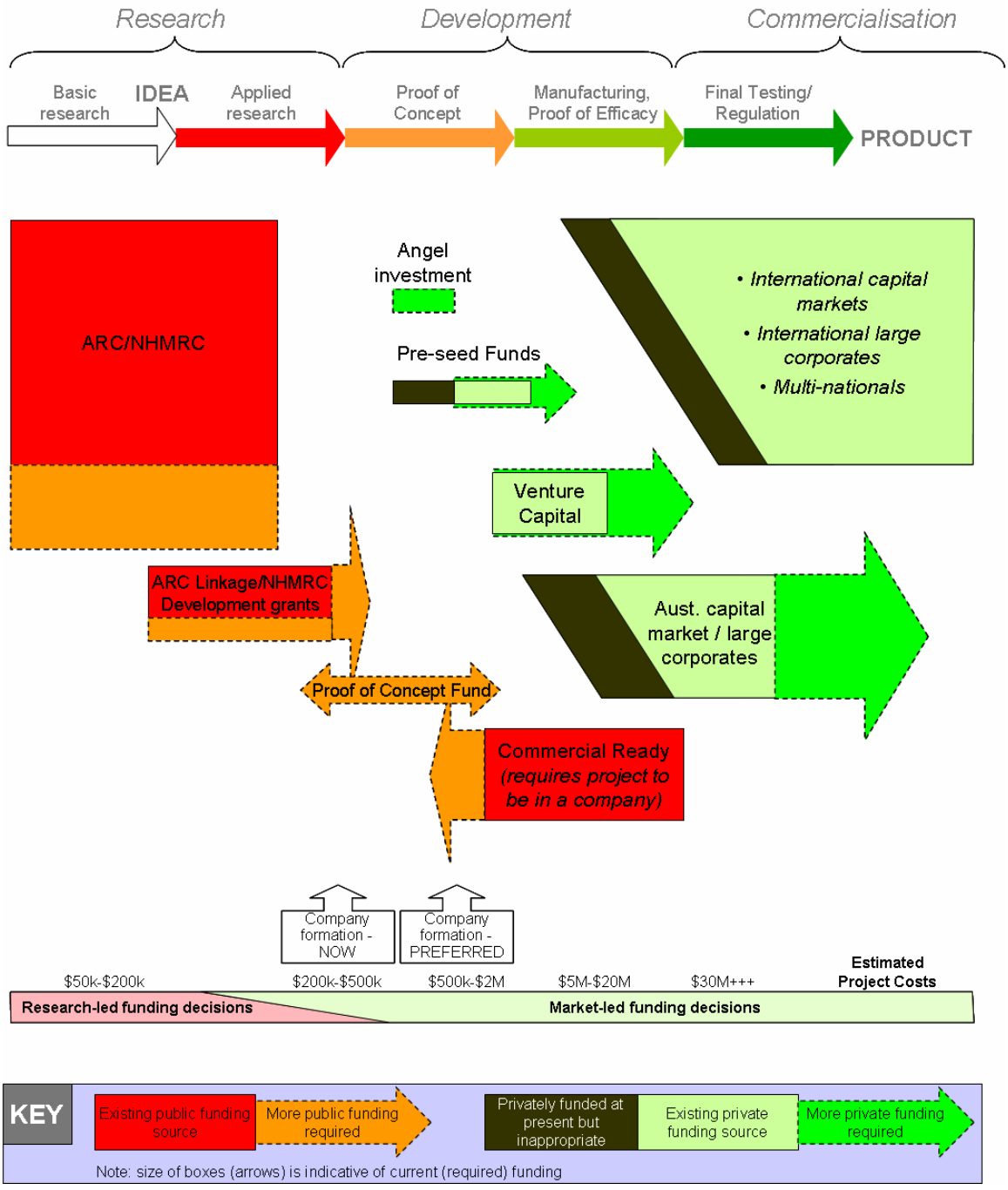

Figure 4: Funding in the Biotechnology Life Cycle

As depicted above, AusBiotech's key recommendations to address the funding gaps that currently exist in the biotechnology life cycle include:

- ARC Linkage and NHMRC Development funding should be increased in size and extended to include greater support to progress R&D to the proof of concept stage
- A proof of concept fund should be introduced, similar to the Scottish model
- Angel investment should be encouraged and resourced for well-informed investment, or non-managerial opportunities through schemes such as MIT's Alumni-funded research investment
- Pre-Seed Funds should be encouraged at the later end of the proof of concept stage, and extend into the proof of efficacy stage
- Large international investors and corporations play an important role at the final testing and commercialisation phase, as they have the ability to fund it. However their involvement earlier in the life cycle at the proof of efficacy stage may not always ensure the optimal outcome for a smaller company, which may commercialise its product prematurely in order to strike a deal
- Australian investors and large corporations should be encouraged to extend their involvement in the Final Testing stage.
- The Commercial Ready program should be expanded in size and scope.

3.5 Taxation reform

The R&D Tax Concession has the advantage of separating profitable from non-profitable firms and of providing support on a consistent basis, rather than in a competitive situation where the outcomes are more uncertain.

The level of support provided by the R&D Tax Concession needs to be increased to have a significant effect on the amount of R&D being undertaken in the biotechnology sector. Australia is one of only three OECD countries that have been decreasing tax support for R&D over the last decade. In real terms, the Australian R&D Tax Concession is worth only 7.5 cents in the dollar.

In comparison:

- Canada offers a flat 20% tax credit (from the first dollar spent)
- Ireland also offers this and full tax deductibility on R&D expenditure
- Japan offers a flat 10% plus 15% for SMEs
- Singapore's equivalent concession to Australia's 125% is 200%
- China offers a 150% deduction
- Korea offers tax holidays of up to 7 years for high-tech companies, including land packages, as part of its aim to become the world's seventh largest biotechnology contributor
- France allows a 50% R&D credit, including a 10% flat credit and a 40% credit for R&D expenditures in excess of average R&D spending over the two previous years.

The Australian R&D Tax Concession requirement for an incremental increase in spending only rewards internally developed R&D, rather than R&D gained through collaboration or acquisition. As collaboration and acquisition is a vital element of the biotechnology life cycle, this scheme should be broadened to allow for transferability of R&D tax credits in these circumstances. The lack of transferability of tax benefits that arise through the R&D Tax Concession means that these benefits are lost through many transactions, and this may be a contributing factor in the lack of industry consolidation. As an example, the CSL acquisition of Zenyth could see tax benefits associated with more than $100 million of R&D expenditure lost through the change of ownership,

With the increasingly close linkage of Australian biotechnology companies into the global value chain, there should also be recognition of the necessity of some off-shore R&D expenditure. This does not currently qualify for the R&D Tax Concession without pre-approval from AusIndustry, and even then only 10% of the total project cost is eligible. The 'beneficial owner' requirements for

accessing the Concession mean that subsidiaries of multi-national entities are prevented from accessing the benefit, as patents on their discoveries are likely to be held by the head office. Ironically, it is these large multinationals which have the greatest capacity to increase R&D spending.

The R&D Tax Concession is also of no benefit to companies returning tax losses, as is often the case within emerging companies in the biotechnology sector. Therefore, concessions may not be seen for many years, and are often too late to deliver real assistance. Companies which achieve funding windfalls in any one year may stand to lose 10% withholding and potentially 30% company tax. In future years, without ongoing milestone profits, these companies will again run at a loss, adversely impacted by the tax they had to pay on their one profit-making year.

Many of these issues have been identified by the Intellectual Property Research Institute of Australia in an article entitled *Taxation Problems in the Commercialisation of Intellectual Property*, Rider et al, January 2006[1].

The case studies below highlight some international examples of alternative approaches.

Case Study - UK

R&D Tax Credits in the UK act to either reduce a company's tax bill or to provide a cash sum for some small or medium sized companies. This cash sum may be a more useful system in the Australian context, where small unprofitable biotech companies in the process of developing technology can still have the capacity to receive support through taxation policy.

Case Study - Superannuation Fund Investment

Australia also requires tax reform to encourage increased investment and capital flows into the biotechnology sector, for example through the encouragement of super fund participation. Large life science investment funds should be established with experts from the pharma/biopharma industry that will ensure outstanding financial management and leadership to actively manage the portfolios of companies from idea to market. This will require the expansion of existing, and the creation of new schemes to encourage such investment, including tax, product reimbursement and patent protection incentives.

Dr Peter Farrell, chairman of medical device group ResMed and a world-renowned entrepreneur, has called for Australia's superannuation funds to commit 5 percent of their funds to support innovative companies. While it is accepted that such a move would bring with it some risk, potential returns are great. Dr Farrell has said that universities such as Harvard and Yale in the US invest up to 30% of their endowments in high-risk, high-reward investments.

This is a potentially controversial suggestion, not universally supported in the biotechnology sector. In general, participants in the biotechnology field want to see a robust sector, well supported by government programs, which attracts investors on its own merits. However, there is a need to encourage the recognition of biotechnology as a valid investment opportunity for superannuation funds, as it is currently under-represented in superannuation portfolios.

3.6 Public Health Policy

Health procurement policy could be more proactive in its support of local biotech companies, especially as Government is the primary purchaser of its outputs. The Government's strong focus on cost reduction in health procurement, while beneficial to the public purse, does not create an environment favourable to value-adding R&D activity. The Government's focus on pushing down the purchase price is predicated on the assumption that Australian biotechnology companies develop products primarily for offshore markets and that development costs will be recovered in those larger markets. However, in reality there are products developed by local companies with Australia as the lead market, and AusBiotech seeks a policy that recognises and supports this.

This could work in the form of a 'lead market offset plan'. For example, where the Australian Pharmaceutical Benefits Scheme (PBS) is the first public health listing of the new drug or device, a premium price could be paid in acknowledgement of the development costs invested here. This price could decline as international sales increase. Such a policy would stimulate the sector to conduct more Phase I (and possibly Phase II) trials in Australia.

[1] http://www.ipria.org/publications/Reports/Taxationproblems.pdf

The US government has recently invested US$2 billion in investigating cell culture flu vaccines to deal with pandemics. This acts as an incentive for CSL to focus much of its pandemic vaccine development work in the US rather than the Australian market.

The US also recently used its NIH grant scheme to support manufacturers of flu vaccines to increase their production capacity to 200 million doses, the level required in case of a pandemic. On a normal basis, production capacity of 80 million doses is sufficient, but would be inadequate in a pandemic. The US government recognises this as a public health imperative and effectively finances the idle capacity of the vaccine manufacturers to ensure sufficient domestic production capacity.

This is an excellent demonstration of alignment between health and industry policy, an approach that, if implemented here, would benefit both the public health system and the biotechnology sector in Australia.

3.7 Infrastructure and policy alignment

The lack of alignment of industry and health policies is evident in relation to infrastructure also. Hospitals have a largely untapped capacity to facilitate the development of early stage research, which would be of enormous benefit to the growth of innovation.

It is recommended that the Government support Australian hospitals to become FDA accredited, so that clinical trials could more frequently be conducted here rather than in the US. There is currently an opportunity to integrate Australian hospitals more closely with the R&D community. Awareness is an important factor in building these leverage opportunities. For example, fewer Australians are involved in clinical trials than US patients on a per capita basis[2].

Ad hoc arrangements should be formalised throughout the health system to consistently leverage R&D possibilities in hospitals. For example, following childbirth the donation of cord blood, a key element of stem cell research and blood products manufacture, is promoted dependant on an individual hospital's policy and resourcing. A standardised collection policy across the entire hospital system would raise awareness of this important and largely untapped resource and its potential R&D applications, providing enormous benefit to the biotechnology sector.

Government needs to recognise the cost of running infrastructure, not just creating it. Often no ongoing funding is provided once infrastructure is created. It is recommended that for all infrastructure projects commissioned, 70% of funding should be for capital, 20% for ongoing support, and 10% for subsidising access to small and worthy companies. All these factors should be considered in determining the real cost associated with infrastructure investments, and will help to address the high cost of access frequently experienced.

3.8 Clustering

Clustering is one important mechanism for biotechnology firms to share expertise, equipment and ideas. Clustering involves the close geographical co-location of research institutions, and includes designated R&D parks such as the Australian Technology Park in Sydney and Technology Park in Adelaide. These parks are particularly useful for small companies that require access to lab space that is not readily available and would otherwise require capital for construction, to which these companies may not have access. Clustering also increases knowledge sharing and allows for greater innovation than would occur if firms were acting alone.

Increased government investment in research parks and clustering (building on state efforts) should be supported at all levels including basic research, clinical translation and commercialisation. Such a strategy must also be well co-ordinated with a focus on forging strong links between centres of excellence in order to eliminate duplication and unproductive competition.

Australia already has several active and successful clusters in place:

- In Queensland a biotech cluster has been established in association with the Institute for Molecular Bioscience at the University of Queensland.

[2] Benchmarking study of the characteristics of the Australian and International Pharmaceuticals Industries, A study undertaken by the Economist Intelligence Unit for the Australian Government Department of Industry, Tourism and Resources, Invest Australia and the Victorian Department of Industry, Innovation and Regional Development, September 2005.

- In Victoria, the Geelong Region Biotechnology Cluster Project has been set up with the support of the Victorian Government's *Regional Innovation Clusters Program*.
- The Monash University Science, Technology, Research and Innovation Precinct (STRIP) is also located in Victoria, accommodating the Monash Institute for Medical Research, as well as corporate enterprises, and is renowned for its high-tech industries and research facilities.
- The South Australian Research and Development Institute (SARDI) is South Australia's peak research and development organisation and has 14 locations throughout the state which facilitate programs that focus on innovative and cost-effective technologies. These are aimed at meeting emerging market needs that underpin internationally competitive and ecologically sustainable industries.
- The Waite Agricultural Research Institute is situated at the University of Adelaide and has the largest concentration of expertise in the Southern hemisphere in the areas of plant biotechnology, cereal breeding, sustainable agriculture, wine and horticulture and land management. It houses 1000 staff and postgraduate students and its combined annual research expenditure is more than $110 million.
- AusBiotech's Medical Device Network (MDN) is a national organisation which facilitates the development of an Australian medical device industry through connecting product developers with services they need, linking clinicians and researchers with funding bodies and helping industry to commercialise their inventions. MDN caters for individuals and firms throughout the entire life cycle of medical devices.

State governments are committed to building infrastructure, although for effective clusters to develop this will require some coordination. AusBiotech supports specialised biotechnology clusters around Australia, to ensure critical mass and eliminate duplication. Other examples of successful state-supported clusters include the biofuels cluster in Western Australia and South Australia's strong focus on agriculture related biotechnology.

AusBiotech strongly encourages ongoing state and federal government support for clustering and is willing to participate in a national co-ordination strategy to minimise duplication between the states. The case studies below demonstrate the commitment to clustering in some competing biotechnology locations internationally.

Case Study - USA

Institutions in the state of Colorado have focussed on establishing centres of excellence and research parks in close proximity to the University of Colorado, in order to maximise collaboration efforts.

The state of Illinois put one quarter of the last $250 million of R&D spending into research parks, whereas Victoria put in only 0.5% of the last $250 million into infrastructure designed to benefit industry.

Case Study - India

The Indian Government is also encouraging a "clustering" of research institutions and the establishment of collaborative knowledge networks, as well as supporting the creation of at least ten biotechnology parks by 2010. It is further proposed that a central body will be set up for the promotion of the parks and tax and import concessions will be offered to biotechnology companies located within the parks (National Biotechnology Development Strategy).

A significant feature of the pharmaceutical industry in India is the fluidity and variety of its inter-company relationships. It has relied to a considerable degree on contracting and outsourcing, especially upstream in R&D through various licensing arrangements and downstream through co-marketing agreements. Its major advantage is in providing access to the broadest spectrum of physical and intellectual resources, combined with potentially greater operational flexibility than might be possible with all activities integrated into a single company. Together with this, there has also been a strong emphasis on the sharing of information through the creation of collaborative knowledge networks.

The foundation of the networks is IT-based, and the greatest positive impact is likely to be in R&D, where systems can contribute to faster approval and market introduction of products.

Issues in Summary

- The interaction of NHMRC and ARC grants needs to ensure a focus on commercial outcomes and make the application process for these grants more efficient and less onerous.
- Some criteria of the Pre-Seed Fund limit the effectiveness of an otherwise beneficial program, especially the limitation of investment to a maximum of $1 million.
- Medical Research Institutes are ineligible for access to the Pre-Seed Funds. This means that these valuable organisations are missing out on vital investment funds, despite presenting very attractive investment opportunities.
- The Commercial Ready Scheme needs to be revised so that it more appropriately fulfils the needs of the Australian biotechnology sector.
- There is a lack of infrastructure and critical mass to support Phase I, II and III clinical trials in Australia, resulting in many developments at this stage being lost off shore.
- Australia's R&D Tax Concession is not in line with similar schemes in other countries. Further, it only rewards internally developed R&D, not recognising R&D gained through collaboration and acquisition, which discourages merger and acquisition activity within the sector.
- Industry and health policies are not developed in conjunction with each other, resulting in a missed opportunity to leverage hospitals' capacity to facilitate the development of early stage research. The lack of alignment means there is no real incentive for local biotechnology discoveries to be fully developed to clinical trials in Australia.
- Clustering and research parks are a valuable way to develop the potential of the sector and should be fully supported by national and state governments.

Recommendations

Recommendation Four

Continue to expand ARC and NHMRC grant schemes to ensure ongoing support for basic and applied research in Australia. Encourage participation of industry partners in these schemes to strengthen commercial applicability, but without compromising core research focus.

Recommendation Five

Create a Scottish-style Proof of Concept fund (3.2.1) to strike the balance of quickly assessing the market potential of a new discovery, but without compromising basic research through the introduction of commercial pressures.

Recommendation Six

Adopt the recommended changes to the Pre-Seed Fund program (3.2.2) to enhance its effectiveness.

Recommendation Seven

Create a loan scheme (as described in 3.2.3) to help projects progress to the stage where they are more attractive to venture capitalists.

Recommendation Eight

Adjust Commercial Ready guidelines (as per recommendations in 3.2.4) to make the scheme more accommodating of small and medium size biotechnology enterprises.

Recommendation Nine

Stimulate growth in the sector, including Phase I and Phase II clinical trial activity, by

- permitting acquiring companies to benefit from the unutilised R&D Tax Concession credits of the company they acquire
- increasing the R&D Tax Concession to 200% to make Australian incentives for this activity competitive with other countries.

Recommendation Ten

Adjust R&D Tax Concession guidelines to act as a true stimulus for R&D by:

- increasing it to 200%

- allowing transferability of tax credits as part of the acquisition process
- accepting greater levels of off-shore R&D by Australian companies
- considering cash grants, rather than tax credits, for smaller companies.

Recommendation Eleven

Use tax concessions to require superannuation funds to increase current levels of investment in biotechnology companies.

Recommendation Twelve

Improve alignment of national health and industry policy, including:

- development of a 'lead market offset plan' to support local companies that develop new biotechnology products with Australia as the primary market
- assistance for Australian hospitals to achieve FDA accreditation for clinical trials
- encouragement of a partnership approach between hospitals and the biotechnology sector to raise awareness of the contribution of biotechnology to national health and to promote clinical trials.

Recommendation Thirteen

Ensure that government funded health infrastructure projects have a realistic funding split to ensure both ongoing support and maintenance, as well as subsidised access for biotechnology companies.

Recommendation Fourteen

Federal Government to support effective biotechnology clustering by adopting a national co-ordinating role to avoid duplication by the states. AusBiotech is willing to participate in this national approach.

4 Relationship of the biotechnology sector with other elements of the R&D community

As a knowledge-intensive industry, the biotechnology sector is characterised by the fact that in the course of the biotechnology life cycle companies interact across the full spectrum of the R&D community, including university research departments, medical research institutes, CSIRO and CRCs. It is imperative that these interactions occur efficiently and effectively to enhance the impact and societal uptake of the knowledge transferred and to return maximum value on the public funds invested.

Biotechnology companies report a range of experiences in dealing with these organisations, with the common view being that the science produced in the Australian R&D community is world class. However, whilst the links have steadily grown over many years there is still scope for improvement in these interrelationships also, not just in terms of overcoming the inherent cultural differences between academia and business, but in terms of access to key expertise and facilities at critical points in product development. If these areas are addressed, AusBiotech believes outcomes for the sector could improve significantly. Greater collaboration between publicly funded organisations would realise synergies and present more attractive investment opportunities.

4.1 CSIRO

CSIRO is Australia's largest publicly funded research organisation and as such is a critically important provider of R&D services and facilities to the biotechnology sector. CSIRO has a long history of involvement with the sector, either as providing the R&D that forms the basis for new companies and ventures or by bringing biotechnologies into existing sectors such as in many areas of traditional agriculture. Its annual budget for biotechnology projects is in the order of $200 million per year, making it Australia's biggest player in biotechnology R&D.

In addition to providing the operational R&D, CSIRO plays a significant support role for the industry through training and educational activities ranging from primary school programs to post doctorate opportunities for new scientists. In addition CSIRO operates a Biotechnology Strategy Group which is a cross-functional team that scans for future opportunities and provides advice to policy makers on biotechnology activities across particular sectors and disciplines. Partly due to its history, CSIRO is particularly strong in agricultural, environmental and industrial applications for biotechnology, and slightly less active in the medical and pharmaceutical applications.

4.1.1 Interaction with industry

One of the strengths of CSIRO's involvement in biotechnology is that its scale and breadth crosses sectoral boundaries, opening up new areas of application. A key example of this is CSIRO's efforts in functional foods where two of the National Research Flagships focus on both food production and processing research as well as understanding of nutrition-related diseases; by linking these efforts and building sufficient scale significant health benefits can be delivered. Another emerging opportunity lies in biofuel R&D through linking both the agricultural biotechnology and energy technology sectors.

CSIRO is also keen to develop new business models for meeting commercial goals and contributing to the public good. In the biotechnology sector, spin-off companies are traditionally the approach taken by the industry to commercialise IP, however this may not always be the most appropriate model. CSIRO seeks to encourage exploration of other technology transfer options, including licensing of new plant cultivars and development of new agricultural and environmental practices.

Amongst the key drivers of CSIRO's activity are the National Research Flagships, which are aligned with the National Research Priority framework and with the goal of meeting national challenges. In essence, the Flagships aim to deliver:

- strong, sustained economic growth, new industries, competitive enterprises and quality jobs
- healthier, more productive lives for Australians
- clean, cost-efficient energy
- more productive and sustainable use of water
- sustainable wealth from our oceans
- growth and prosperity for regional Australia.

CSIRO's focus on these priorities and orientation towards addressing strategic issues that will emerge 20 years hence mean that it is not always ideally placed to support the broad range of the biotechnology sector's immediate and ongoing requirements. This divergence in research agendas and CSIRO's focus on agriculture and other existing sectors is demonstrated by the fact that CSL, Australia's largest indigenous pharmaceutical company, has no current active engagement with CSIRO, as CSIRO has historically had little involvement in CSL's particular sphere of medical research.

4.1.2 Cost and KPIs

As a general statement, CSIRO is seen to be a relatively expensive provider of both R&D services and access to technical facilities. Many biotechnology companies do use CSIRO facilities due to the fact that they provide the best local service, however AusBiotech would welcome initiatives to make CSIRO facilities and services more accessible to SMEs. CSIRO is currently exploring some schemes, such as the Australian Growth Partnership model which could result in deferred payment for contract research in exchange for a share of IP generated. This would make CSIRO services more accessible particularly for SMEs.

Until this model gains approval, CSIRO has been trialling a similar scheme, using the resources of the Division of Molecular and Health Technologies. The approach is to offer scientific resources on the basis of flexible business models, using a risk-adjusted mixture of up-front payment, IP sharing, royalties, milestone payments and equity options, depending on what suits particular SMEs and their investors. There is however risk for CSIRO that in deferring some or all of its returns, these returns may not materialise.

AusBiotech supports such programs and recommends that CSIRO's KPIs be structured to create incentives to improve partnering and integration with industry. This would help to foster a culture of collaboration and support for Australian companies, as distinct from CSIRO itself trying to develop the capacity and culture to take products to market.

Case Study - US National Labs

In the US there is a national lab system run by the US Department of Energy, consisting of nine multi-program labs including those at Lawrence Berkeley and Pacific Northwestern. This system does not require these institutes to earn revenue, allowing them to focus on quality research. While there is a selection process for contracted research, some requirements on IP generated through research, and the need for acknowledgment in publications, there is no fee-per-service.

4.2 Universities

There should be a clear separation of university research funding from the requirements for commercialisation. Having a system of peer review, good science, and a lack of commercial targets is important to the growth of Australian innovation. Formal commercialisation requirements can create perverse incentives for generating revenue, however AusBiotech recognises the value of universities contributing to the biotechnology sector through being outwardly focused and product driven in their research and facilities.

University/Industry collaborations exist, enabling researchers to receive free advice on commercialisation from industry collaborators, which would otherwise be expensive to obtain. Examples of this type of collaboration include:

- The LaTrobe University Biotechnology Research Centre works closely with industry on wastewater issues, including liaising with industry on commercial gene probe development.
- The Mackinnon Project is a recognised leading program in sheep and beef consultancy. The Project is based at the University of Melbourne Veterinary School at Werribee and offers services including farm management, consultancy, farmer training programs, contract research and post graduate training programs.
- The Melbourne University Plant Molecular Biology and Biotechnology Unit also has a number of ongoing collaborative projects with the seed and horticulture industry.

Much of the interchange between universities and industry is based on informal methods of industry monitoring of the research that is occurring. However, this approach has proven quite effective.

It is important that universities are comfortable with industry engagement and have experienced business development personnel in key positions to foster this. It is also essential that personnel from all research institutions become more aware of the innovation development process. This should include the risks related to appropriately timed injections of funding and appropriate levels of institution and industry intervention, particularly in IP ownership. These are issues that can affect the successful development of a product.

A concentrated effort is required to raise the standards of business and commercialisation skills within universities, and projects are under development to address this. AusBiotech is currently in discussion with the Melbourne Business School about a biotech-specific short course in management.

Case Study - India

India has introduced the Scheme for Visiting Scientists from Abroad. Under this scheme, each year ten to fifteen eminent scientists from technologically advanced countries are invited to take up visiting professorships and industry sponsored chairs in university biotechnology departments. The objective of the scheme is for India to gain an insight into frontier areas of biotechnology and related business management undertaken in more technologically advanced nations, thereby increasing knowledge and improving India's own biotechnology sector.

Case Study – Canada

Canadian universities have recently created 1,000 additional scientific positions at the professorial level. This is a demonstration of university support for the sector on a large scale, which will help to attract scientists with a broader range of skills and experience, in turn building a more dynamic and innovative sector.

4.3 Cooperative Research Centres

AusBiotech looks favourably on the work undertaken by CRCs in the biotechnology sector and encourages the requirement for CRC engagement with local industry as a funding criterion.

The ability of companies to make broader contributions to the CRC than funds alone should be recognised in industry engagement. The large number of academic contributors and sometimes complex governance arrangements in CRCs means that the pace of activity is slower than industry would like.

CRCs often demonstrate a preference to share developments internationally, meaning that the IP value is diminished for potential local commercialisers. Similar to the universities, the CRCs would benefit from improved commercialisation skills to ensure that the later stage research they commercialise is well supported with IP provisions and business plans.

On occasion, the multinational collaborators in a CRC will 'cherry-pick' the IP, resulting in the IP ownership being transferred offshore. This could be addressed by improving the initial set-up of CRCs to make clear provision for legal and beneficial ownership of IP by the CRC itself. This will assist CRCs in using its IP to assist the local biotechnology sector.

Further, interaction of smaller companies in CRC research and technology uptake could be assisted by the extension of the R&D Tax Concession to CRC contributions from these smaller companies.

CRCs play a critical role in linking PROs and industry, and have an ability to cross geographic, sectoral and educational boundaries that make them an invaluable contributor to science and innovation. IP from CRCs can be used to feed local development pipelines. A prime example of this is the CRC for Hearing giving rise to Dynamic Hearing Pty Ltd, which licensed technology to Cochlear.

4.4 Access to facilities

Biotechnology companies need greater access to facilities, such as those provided by CRCs and CSIRO, in order to fulfil their R&D requirements. One option to enhance this access would be the provision of Technology Access Grants, as has been piloted at the Small Technologies Cluster (STC) in Scoresby, Victoria[3].

STC is providing small cash grants and discounted access for SMEs, developers and early stage investigations to use the advanced facilities available at the cluster. The STC is creating a centre of excellence through the clustering of accessible skills, technologies and capabilities in micro-nano-biotechnology research, manufacturing and commercialisation. It is offering access to state-of-the-art facilities and a highly trained workforce in a clustered and highly interactive environment. The STC is also working with national and international firms interested in innovation partnerships.

The type of assistance offered by the STC includes:

- assistance to start up companies for prototyping
- leveraged support to researchers leading to a larger project within the cluster
- leveraged funding in other support proposals (for example, ARC linkage program)
- leveraged support that created new capability, skills or equipment for the cluster.

This creative approach ensures more equitable access to highly specialised, world class facilities that may be unaffordable for smaller companies if they were only available at market rates.

Technology Access Grants should be developed by Government to encourage the formation of clusters and the sharing of equipment in such clusters and research parks.

4.5 Intermediaries and Networks

Intermediaries are involved in facilitating technology transfer between organisations, to foster further development and commercialisation. The process usually involves the encouragement of technology sharing or commercialisation strategies through a model that protects the IP of the individual companies involved. A forum is also created where these linkages can progress through the intermediary where they would otherwise be unlikely to in the normal course of business. Networks can have a similar impact, as they contribute to skills development, particularly in relation to technology transfer techniques.

An Australian example of an intermediary is the InnovationXchange Network, run by IXC Australia Limited. The organisation facilitates IP collaboration between organisations, universities and governments through its Intermediary Service. IXC Intermediaries, who are specialist innovation, commercialisation and business deployment staff, work inside member organisations under a strict Code of Ethics and confidential structure, to search for and create connections for business growth, without prematurely exposing sensitive information. IXC Intermediaries are able to access each other's intellectual property and R&D base so they know what members need and what they can offer. They can then seek out opportunities and assist members to engage directly with each other.

There are also many overseas examples which are of interest.

Case Study - UK

In the UK, the role of the Bioscience Unit in the Department of Trade and Industry is to develop and maintain relations with companies and intermediaries. Relationship Managers develop and maintain contacts with key companies and trade associations, whilst Knowledge Specialists

[3] http://www.stc-melbourne.com/images/assets/stc%20access%20program.pdf

research, analyse and compile data for international benchmarking and comparisons of overseas Government policies and incentives.

Case Study - India

India has also recognised the need to foster greater collaboration between research institutions with the Government proposing to create several national/regional technology transfer cells to service clusters of institutions. These cells would evaluate technology, identify potential commercial uses and develop and execute IP protection strategies.

Case Study - US

In the US the Association of University Technology Managers (AUTM) is a global network of members representing more than 350 universities, research institutions, teaching hospitals, government agencies and many companies involved with managing and licensing innovations. It was established in 1974 in recognition that inventions funded by the US government were not being commercialised to their full potential. It is now involved in the commercialisation of innovations, and in the provision of professional development and networking opportunities for technology transfer professionals.

The AUTM has contributed to a substantial increase in technology transfer activity. Prior to 1980, fewer than 250 patents were issued to US universities each year and innovations were rarely commercialised. However, between 1991 and 2004 annual invention disclosures increased by more than 290% to 18,178, new patents filed increased nearly 450% to 11,089 and new licenses and options executed increased about 510% to 5,329.

4.6 Clustering

While it has already been discussed in the context of government support, clustering is an important way to facilitate industry interaction with research institutions and improve linkages between different elements of the innovation system. This requires the close geographical co-location of universities with biotech companies. As already discussed, clusters are established in Brisbane, Sydney and Melbourne and developing in Western and South Australia. Clusters are successful because they provide an environment for organic exchange, creating an information hub through infrastructure as an alternative to directing funds into technology grants. Enabling organisations, such as Bio21, are also important in creating informal links between industry and universities.

It is important that clustered organisations be physically proximate, preferably within walking distance of each other. Social mechanisms are also important, such as ‘innovators in residence’ programs and discussion groups.

Case Study - US

The Colorado Bioscience Park Aurora at Fitzsimons is a 160-acre, $4.3 billion facility adjacent to the University of Colorado Health Sciences Centre and Hospital and the Children’s Hospital. It can accommodate early-stage, start-up and established bioscience companies and through an affiliation between the University of Colorado and Fitzsimons Redevelopment Authority and any company in the facility, is able to access the new core labs in the research complex. This is a development which has effectively leveraged public health infrastructure in support of biotechnology activity, as recommended in section 3.7.

Issues in Summary

- CSIRO makes an important contribution to the sector and must continue to improve partnering/integration with industry.
- University research funding should be of a sufficient magnitude to support R&D without the need for commercial targets.
- Creative programs are needed to encourage the sharing of essential facilities by CRCs and the CSIRO, in order to overcome access problems for SMEs that hinder the growth of the sector.
- Intermediaries play an important role in facilitating knowledge transfer, technology development and commercialisation.

- Clustering and networks are essential to facilitate closer industry interaction and require national co-ordination.

Recommendations

Recommendation Fifteen

CSIRO should be encouraged through its KPIs to develop schemes such as the proposed Australian Growth Partnerships, which will improve the affordability of its facilities for SMEs.

Recommendation Sixteen

Universities should be encouraged through their KPIs to continue to develop partnerships with industry. At the same time, their funding levels should be high enough to allow them to focus on basic and translational research, without needing to generate income through commercialisation.

Recommendation Seventeen

Federal Government should develop a scheme, such as Technology Access Grants, to improve the accessibility of publicly funded infrastructure.

Recommendation Eighteen

AusBiotech to work with the Federal Government to explore new and expanded intermediary concepts, such as the AUTM model.

5 Skills, training and HR

The scope of the Study calls for the consideration of skills as a potential impediment to the effective functioning of the innovation system. With the right support, a virtuous cycle will emerge: the expansion of the sector positions biotechnology as an appealing career choice, in turn attracting a high calibre of practitioners covering the full skill set the sector requires.

Australia has the advantage of having one of the top biotech education environments in the world. This needs to be better supported and leveraged to provide beneficial outcomes to industry, namely skilled researchers, commercially capable and astute business people, world class scientific discoveries and highly marketable products.

As Australia's biotechnology sector continues to mature, many of the issues around skills, training and HR will be solved by the emergence of biotechnology practitioners with a greater breadth of experience and expertise. However, this capacity building can be hastened by strategic government intervention.

5.1 Biotechnology careers strategy

5.1.1 A career of choice

It is widely acknowledged that active promotion of scientific careers is necessary to ensure the ongoing supply of skilled practitioners needed to support the biotechnology industry in the future. AusBiotech regularly conducts career awareness programs for biology and chemistry students around Australia. There are other school based programs, such as CSIRO's science education centres and student/teacher resources, and this sort of promotional activity is vital to the future growth of the industry. The case study below demonstrates another model for encouraging young people to pursue a scientific career.

Case Study - India

In conjunction with the National Bioresource Development Board, the Indian Department of Biotechnology has introduced the Vacation Training Programme on Bioresources for School Children, in order to attract more science students and to generate interest in the field of biotechnology. The main objective of the programme is to give students some training on sustainable utilisation and conservation of bioresources, as well as to raise awareness about the relevance of bioresources in day to day life. Universities, Research Institutes, Colleges and Registered Societies (NGOs) with well established biotechnology units have been invited to apply to host students of this programme.

5.1.2 Remuneration

In attracting quality researchers from around the world, Australia needs to have incentives and more public investment in research careers. Scientific salaries in Australia are just not competitive when compared with other countries. As noted by the Baker Heart Research Institute's submission to the Productivity Commission, this has resulted in university cut offs for science degrees remaining static for years, indicating that students are not attracted to scientific careers because of the low pay, prolonged training phase and poor career opportunities.

5.1.3 Australia's scientific Diaspora

Early research experience overseas should be encouraged with a push to then re-attract these early to mid career scientists back to Australia, as done in Scandinavia and Japan through investment in infrastructure and creation of a dynamic sector.

This can be difficult when researchers working overseas realise the amount of HELP debt (Higher Education Loan Programme, formerly HECS/PELS) awaiting on their return. Reducing this disincentive could assist in attracting these scientists, entrepreneurs and managers back from larger biotechnology markets in the US and Europe.

There is a disproportionate number of Australian scientists in overseas public and private medical research facilities due to the less favourable salary conditions in Australia.

5.1.4 Career path

There are problems for researchers who step out of academia to pursue careers in industry in that they may find they are unable to re-enter the ARC/NHMRC program due to the criteria to demonstrate recent research success.

A healthy interchange of personnel between industry and research institutions requires this issue to be addressed. Building a vibrant biotechnology sector will be enhanced by mechanisms for the frequent exchange of personnel through secondment between research institutions and industry. There are several effective programs already in place, which AusBiotech believes should be continued and expanded.

Case Study - VESKI

The Victorian Endowment for Science, Knowledge and Innovation (VESKI) Fellowships seek to attract expatriate Australian researchers to re-enter the ARC/NHMRC system. VESKI also offers a Foundation Fellowship for non-Australian citizens, in addition to Australian citizens, who wish to undertake research in Victoria. The principle objective of the fellowships is to enhance Victoria's intellectual capital in science, knowledge and innovation for the benefit of the public. This is effectively achieved by subsidising the salary of the individual scientists who return to academia from industry.

VESKI Fellowships allow research to be undertaken in Victoria for up to five years. Fellows receive up to $100,000 per year against matched funding and in-kind contributions from a Host Organisation such as an academic/research institution or company. Fellowships are awarded annually and are drawn from the fields of ICT, Biotechnology, Design, Advanced Manufacturing, Environment Technologies, the Enabling Sciences and Technologies.

The recipient of VESKI's inaugural Victorian Innovation Fellowship, Professor Andrew Holmes, has been awarded over $500,000 in funding over five years. Professor Holmes has returned to Australia from Cambridge University and will be located in the soon to be opened Bio21 Molecular Biology and Biotechnology Institute.

Another of VESKI's 2004-2005 fellows, Dr. Gareth Forde was awarded a Fellowship of $200,000 over three years. Dr. Forde returned to Australia also from Cambridge University to join Monash University's Department of Chemical Engineering to work on a research project on plasmid DNA (pDNA) purification for gene therapy and vaccine applications. The objective of this project is to develop a patentable industrial process for the production of pDNA, which will be scaleable and commercially viable.

Case Study - Innovation Skills Fund

The Innovation Skills Fund is an investment of $12 million by the Queensland Government to attract and retain top researchers and PhD students in strategic priority areas to Queensland. The Innovation Skills Fund consists of three funding schemes:

- Smart State Premier's Fellowships to entice experienced and distinguished research leaders to Queensland. These are valued at $250,000 per year over five years.
- Smart State Fellowships for outstanding early and mid career researchers, valued at $150,000 and $300,000 respectively over three years.
- Smart State PhD Scholarships, which provide funding for graduates of outstanding ability to undertake PhD research at Queensland universities. These scholarships are valued at $7,000 per annum for up to three years to 'top up' the Australian Postgraduate Award. An additional completion bonus of $1,500 is also payable.

Case Study - Federation Fellowship

The ARC also funds a Federation Fellowship valued at over $250,000 salary plus on-costs and research start-up costs for up to five years. This is designed to attract and retain outstanding Australian and non-Australian researchers currently working overseas. The fellowships are offered with a view to building and developing world-class research capacity in Australia that will result in economic, environmental, social or cultural benefits for Australia, to support Australia's knowledge base and to foster strong links between researchers and industry both in Australia and abroad.

5.2 Business development skills

It is vital to the success of the biotechnology sector to have the right mix of skills available. This includes access to scientists and non-scientists with both industry awareness and strong business development and management skills.

There are initiatives taking place within Australia that contribute to the development of skills within the biotechnology sector that should be further supported. One example is the Young Achievement Australia program (detailed below), with teams of skilled PhD level students developing model biotechnology companies, allowing them to hone the skills they will need later in their careers.

AusBiotech is currently in discussion with the Melbourne Business School to develop tailored management courses for the biotechnology sector. There are also many international examples.

Case Study - UK

The UK Department of Trade and Industry's 'Biotechnology Exploitation Platform Challenge' awards grants on a competitive basis over four years to employ and train specialist biotechnology Business Development Managers. The role of such Managers is to audit bioscience intellectual property at universities and other research institutions to identify and progress ideas for commercialisation, and to mentor the academics involved in such work (BEP challenge).

Case Study - UK/Singapore

The UK offers a global entrepreneurs program, sourcing and importing talented people who have already successfully established a business to do so again, teaming them up with a well-networked chair, who can help steer the company within the UK business environment. A similar Biopolis program exists in Singapore. This aims to create Singapore as a focal point for scientific talent; attracting top international talent through the creation and support of a clustering infrastructure which encourages cross-disciplinary research and bridges private and public sector research.

Case Study - India

India is in the process of creating a model for undergraduate and postgraduate curricula in life sciences with the future needs of the industry firmly in mind. This includes extended industry internships and short-term placements for students at research institutions and study of regulatory matters, IP and bio-enterprise management in biotechnology degrees. This will help to develop commercial, management and business skills within the biotechnology community.

Case Study - USA

In the US several higher education institutions are creating bioscience programs within their business schools and academic faculties to grow industry and general commercial awareness of researchers. For example, the Stanford Graduate School of Business offers a biosciences course in conjunction with the schools of engineering and medicine, so that students can develop the skills required to commercialise innovations. The curriculum includes inventing, patenting, early prototyping and developing new concepts, with students from engineering, medical and business backgrounds working in teams to solve a real problem[4].

5.3 Entrepreneurship in a biotechnology context

To be successful in developing an entrepreneurial biotechnology sector, the key tenet of 'create and be acquired' must be appreciated. There are many new entrants to the market every year and it is not sustainable for all of these companies to grow into large organisations. Rather than attracting foreign companies to Australia, government could strategically intervene to target key individuals from overseas, while also ensuring that local companies have access to the optimum skill set.

Case Study – Young Achievement Australia

An example of how a local entrepreneurial skill set can be developed is Young Achievement Australia's Biotechnology Entrepreneur Program (BEP). This 24-week program of business skills and commercialisation awareness program offered to students and junior scientists, predominantly

[4] http://www.gsb.stanford.edu/about/fromthedean.html

in biotechnology and small scale technology/nanotechnology. It has been well supported by the Victorian Government and the Australia New Zealand Biotechnology Alliance and is now being extended to other states. During the program, students simulate the establishment of a real company and develop real products, which they sell. The program requires students to:

- form a company, sell shares to raise capital
- appoint management positions
- write the company code of ethics
- prepare a business plan
- conduct market research and establish a product
- manufacture, advertise and sell the product
- prepare an annual report
- liquidate the company and return profits to the shareholders.

There have been several cases of projects being so successful that they have been reincorporated at the end of the program and have continued to flourish as stand-alone operations.

Given the varied needs of the sector, it is also unrealistic to expect Australian companies will remain purely Australian. International partnerships are often necessary for the successful development of IP. Of all biotechnology companies created, it should be anticipated that 95% of these will be acquired, 97% by global companies and 3% by Australian entities. Awareness of the transience and acquisitive nature of biotechnology companies is fundamental for a spirit of entrepreneurship to thrive within Australia.

Issues in Summary

- Lack of incentives and less than comparable salaries for Australian researchers compared with the rest of the world has resulted in scientific careers being less attractive in Australia.
- The structure of the ARC/NHMRC program makes it difficult for researchers who step out of academia to pursue careers in industry to then re-enter the program.
- Australia lacks the depth of business skills and entrepreneurial spirit necessary to ensure that innovations are being commercialised and value is being appropriately captured.

Recommendations

Recommendation Nineteen

Adjust criteria for ARC and NHMRC grants, which currently require recent success. This acts as disincentive for scientists to step out of research to expand their commercial experience, or return from overseas.

Recommendation Twenty

Support and expand programs (outlined in 5.1.4) that address impediments to scientific career paths, to ensure Australia is an attractive location to pursue a scientific career.

Recommendation Twenty-one

Explore options such as the UK BEP challenge and closer collaboration with local business and management skills to support business skills capability building in the sector.

Recommendation Twenty-two

Support and expand training programs for young scientists to gain commercial understanding (eg: Young Achievement Australia's BEP program). Promote business development courses in a biotechnology context, either by supporting existing initiatives (5.2) or actively encouraging new ones.

6 Summary and Recommendations

Australia's biotechnology sector makes a significant contribution to the national and international science and innovation landscape, with an impact that is vital to the economic, social and environmental well-being of Australia. It is a broad and underpinning technology, contributing to human health as well as agricultural, industrial and marine technologies.

Developments being made in biotechnology now could potentially hold the key for the tomorrow's prosperity, both domestically and in addressing issues of global concern such as ageing populations, energy and food shortages. Such developments also contribute to the emergence of the 'bioeconomy'. Biotechnology has been described by Victoria's Minister for Innovation, The Hon John Brumby, as 'the fourth great revolution, after agriculture, industry, and information'.

Australia is well positioned for success, based on its excellent basic research and emerging cohort of companies – but biotechnology is an incredibly fast-moving area and we need to be advancing quickly to compete. The clock is ticking fast for Australia, with regard to getting the right template to see our biotechnology sector appropriately supported and positioned to deliver future success.

Biotechnology is intrinsically global - over 200 cities worldwide have 'Biotechnology Strategic Plans'. Participants in the sector must constantly focus on the global market. Case studies cited in this submission outline international examples that Australia should consider in addressing the shortcomings of our current innovation system. Among these examples are a number of references to India, the country that has just rated Bill Gates ahead of Ghandi as their most revered figure, and a country worth watching closely in the field of biotechnology.

AusBiotech welcomes the continuing partnership between governments and the biotechnology sector, as strong policy leadership and appropriately structured support are essential to ensuring that the full potential of the sector is realised. With the adoption of the recommendations summarised below, the sector will continue to develop and contribute to the nation's health and prosperity.

6.1 List of Recommendations

Recommendation One

Ensure that government support and intervention in the biotechnology sector is underpinned by a clear understanding of the complexities, dynamics and specific drivers of the sector.

Recommendation Two

Adjust government programs to ensure they advance recipients to the next value inflection point in the lifecycle, where they are more likely to attract funding from the market. (Please refer to Section 3 for detailed recommendations in relation to specific programs.)

Recommendation Three

Extend the scope of biotechnology activity across the lifecycle by specifically supporting the conducting of Phase I and Phase II trials in Australia.

Recommendation Four

Continue to expand ARC and NHMRC grant schemes to ensure ongoing support for basic and applied research in Australia. Encourage participation of industry partners in these schemes to strengthen commercial applicability, but without compromising core research focus.

Recommendation Five

Create a Scottish-style Proof of Concept fund (3.2.1) to strike the balance of quickly assessing the market potential of a new discovery, but without compromising basic research through the introduction of commercial pressures.

Recommendation Six

Adopt the recommended changes to the Pre-Seed Fund program (3.2.2) to enhance its effectiveness.

Recommendation Seven

Create a loan scheme (as described in 3.2.3) to help projects progress to the stage where they are more attractive to venture capitalists.

Recommendation Eight

Adjust Commercial Ready guidelines (as per recommendations in 3.2.4) to make the scheme more accommodating of small and medium size biotechnology enterprises.

Recommendation Nine

Stimulate Phase I and Phase II clinical trial activity in Australia by:

- permitting acquiring companies to benefit from the unutilised R&D Tax Concession credits of the company they acquire and
- increasing the R&D Tax Concession to 200% to make Australian incentives for this activity competitive with other countries.

Recommendation Ten

Adjust R&D Tax Concession guidelines to act as a true stimulus for R&D by:

- increasing it to 200%
- allowing transferability of tax credits as part of the acquisition process
- accepting greater levels of off-shore R&D by Australian companies
- considering cash grants, rather than tax credits, for smaller companies.

Recommendation Eleven

Use tax concessions to require superannuation funds to increase current levels of investment in biotechnology companies.

Recommendation Twelve

Improve alignment of national health and industry policy, including:

- development of a ‘lead market offset plan’ to support local companies that develop new biotechnology products with Australia as the primary market
- encouragement of a partnership approach between hospitals and the biotechnology sector to raise awareness of the contribution of biotechnology to national health and to promote clinical trials.

Recommendation Thirteen

Ensure that government funded health infrastructure projects have a realistic funding split to ensure both ongoing support and maintenance, as well as subsidised access for biotechnology companies.

Recommendation Fourteen

Federal Government to support effective biotechnology clustering by adopting a national co-ordinating role to avoid duplication by the states. AusBiotech is willing to participate in this national approach.

Recommendation Fifteen

CSIRO should be encouraged through its KPIs to develop schemes such as the proposed Australian Growth Partnerships, which will improve the affordability of its facilities for SMEs.

Recommendation Sixteen

Universities should be encouraged through their KPIs to continue to develop partnerships with industry. At the same time, their funding levels should be high enough to allow them to focus on basic and translational research, without needing to generate income through commercialisation.

Recommendation Seventeen

Federal Government should develop a scheme, such as Technology Access Grants, to improve the accessibility of publicly funded infrastructure.

Recommendation Eighteen

AusBiotech to work with the Federal Government to explore new and expanded intermediary concepts, such as the AUTM model.

Recommendation Nineteen

Adjust criteria for ARC and NHMRC grants, which currently require recent success. This acts as disincentive for scientists to step out of research to expand their commercial experience, or return from overseas.

Recommendation Twenty

Support and expand programs (outlined in 5.1.4) that address impediments to scientific career paths, to ensure Australia is an attractive location to pursue a scientific career.

Recommendation Twenty-one

Explore options such as the UK BEP challenge and closer collaboration with local business and management skills to support business skills capability building in the sector.

Recommendation Twenty-two

Support and expand training programs for young scientists to gain commercial understanding (eg: Young Achievement Australia's BEP program). Promote business development courses in a biotechnology context, either by supporting existing initiatives (5.2) or actively encouraging new ones.