AusBiotech Ltd

Response to the Productivity Commission Draft Report on Public Support for Science and Innovation

20 December 2006

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1 Introduction

The Productivity Commission (PC) Research Study into Science and Innovation (the Study) has generated vibrant debate about the national economic, social and environmental benefits derived from publicly-funded science and innovation in Australia.

Following its initial submission to the Study (the Submission) and with the release of the Draft Research Report (the Report) in November 2006, AusBiotech Ltd (AusBiotech) is pleased to provide further comment on the specific contribution of the Australian biotechnology sector in the context of the Report. AusBiotech is Australia's biotechnology industry organisation representing over 2,400 members covering the human health, agricultural, medical device, environmental and industrial sectors in biotechnology. Its members have taken a keen interest in the process of the Study.

In general terms, AusBiotech supports the draft findings of the PC, though it brings the PC's attention to the objections and clarifications outlined within this Response. AusBiotech agrees with the position taken by several respondents to the Report, including the Medical Devices Industry Action Agenda Implementation Group (MDIAAIG), which note the strong focus of the report on the R&D aspects of innovation, even though R&D makes up only 30% of business expenditure on innovation. AusBiotech believes that important innovation in the biotechnology sector takes place with regard to non-R&D activities, including translational research and process-related improvements, and that this should be recognised by the PC in their assessment of the benefits of public support for science and innovation.

In preparing this response, AusBiotech has drawn on its experience attending the PC Roundtable held in Canberra on 29 November 2006, where a range of issues were identified by the PC as requiring further input. AusBiotech will address these issues in a biotechnology context, as well as some others raised within the report itself.

Emerging from these Roundtable discussions were the following key points relevant to the biotechnology sector.

- Government needs to articulate a vision of Australia as an innovative country and should not settle for 'average' levels of R&D. In a competitive global environment, we need to be above average. Australia's biotechnology sector is increasingly achieving international recognition. Government needs to support the growth of the scale of the Australian biotech sector. Measures to achieve this include:
    - encouraging mergers at the right time for the right price by permitting transferability of tax losses to add value to companies being acquired
    - ensuring incentives for R&D (eg: R&D tax concession) are at globally competitive levels to attract investment and activity such as clinical trials to Australia.
- The PC wanted to better understand how technology developed in public research organisations (PROs) can be shared with industry. AusBiotech draws the PC's

attention to the mechanisms which the biotechnology sector has in place and could intensify, as referred to in the Submission including clustering, intermediaries and the AUTM model. These are discussed in 4.3 below.

2 Impacts, spillovers and social benefits

The PC expressed an interest in expanding its understanding of the social benefits and spillovers derived from publicly funded science and innovation. AusBiotech strongly supports the PC's consideration of externalities in relation to public sector innovation. While there are economic benefits accruing to science and innovation, and these should not be underestimated, the societal impact of advancements in biotechnology is significant and in many instances life changing. Public support of science and innovation is critical where research may generate significant externalities.

AusBiotech's 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. Therefore the impacts of activity in the biotechnology field are many and varied.

The impacts of biotechnology research resonate not just in purely economic terms, but have significant effects on advancements in fundamental areas such as:

- human health (eg: the development of new therapeutics and diagnostic tools)
- animal and plant health (eg: identifying quality traits in plants and animals for enhanced production outcomes or enhancing specific characteristics of crops)
- industrial biotechnology (the significant advancements in biofuel technology and production, the new advancements and manufacturing capability of bioplastics)
- the environment (eg: to create bacteria that break down waste).

In this context, AusBiotech endorses draft finding 4.1 from the Report:

Taking account of multiple sources of evidence, the Commission considers that there are significant positive economic, social and environmental impacts from publicly supported science and innovation.

Australian advancements in the medical research sphere alone have resulted in diverse developments with widespread human health impacts, such as:

- Australia being the first country to provide penicillin to the general public, leading to a Nobel Prize for Howard Florey
- the Bionic ear
- sleep apnoea devices
- cervical vaccine, developed by the Australian of the Year 2006, Ian Frazer
- spray-on skin, developed by the Australian of the Year 2005, Fiona Wood

- cause and treatment for stomach ulcers, resulting in a Nobel Prize for Barry Marshall and Robin Warren in 2005
- influenza drug, and the potential to develop a bird flu vaccine
- world's first nanotechnology drug in clinical trials.

In its submission to the PC, AusBiotech noted examples (page 6) with enormous social benefits such as:

- The community and individual impact of hearing-impaired children having access to life-changing hearing enhancement. A child implanted with a Cochlear ear implant can expect to have equal life chances as a child born without a hearing defect. The child can go to regular education facilities and participate unhindered in family, social and community activities. This enables a more integrated, inclusive community rather than one excluding or isolating members.
- The broader societal impact of efficient and effective medical care. As ageing populations grow as a proportion of the total, there will be a greater proportion of the population requiring medical intervention to support chronic and critical conditions. The medical application of biotechnology advances will allow the ageing population to take a more active part in broader society. This will bring with it a range of broader societal benefits, as well as decreasing the burden on the public purse. Thanks to medical devices such as cardiac implants, increased longevity, together with decreased morbidity, will reduce hospitalisation requirements and costs.
- The local impact of rehabilitative medical care. People suffering severe burns following trauma such as experienced in Bali or more commonly in motor accident and domestic fires are dislocated form their normal lives with consequences for their local communities. Solutions offered by companies such as Clinical Cell Culture provide opportunities for these people to return to work and reconnect with their communities. A small-medium enterprise (SME), Peplin is working on a melanoma vaccine, which would have significant impacts for young people, who are vulnerable even if the disease itself emerges later in life.

In relation to employment, social and economic benefits are symbiotic and the Australian biotechnology industry has the potential to further expand its contribution in the following ways:

- increase the number of people it employs
- increase the retention of knowledge workers
- 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.

Further, with adequate support, the Australian biotechnology sector has the potential to provide significant future spillovers, by transforming the way people produce and consume over the next decades, and by addressing issues of global concern. This is part of the drive towards a 'bioeconomy', addressed in the Submission (page 17), and examples 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. A 'bioeconomy' is an environment in which spillovers and other broad, beneficial impacts are far more likely to occur.

3 Impediments to the innovation system

At the Roundtable, the PC was keen to understand more about impediments to innovation, particularly in relation to workforce and infrastructure issues, and the impacts of the grant systems.

For the biotechnology sector, one of the most critical elements of success is ensuring the supply of suitably qualified scientists and researchers. This includes consideration of skills and training (scientific, business and entrepreneurial skills), the promotion of scientific career opportunities, and ensuring that government programs support these aims. This issue was addressed in Chapter Five of the Submission.

It is imperative to support the future growth of the biotechnology industry so that science and technology become a career of choice for future generations. Besides early promotion of the sector to current and future Australian students, it is recognised that it is also important to attract quality researchers from around the world. In order to do so, Australia needs to have incentives and more public investment in research careers, and a biotechnology sector that is acknowledged as world class.

Further, there is a disproportionate number of Australian scientists in overseas public and private medical research facilities. Reasons for this include the less favourable salary conditions in Australia and a reluctance to return to significant HELP debts (Higher Education Loan Programme, formerly HECS/PELS) awaiting their return. To combat this, Australia needs to offer world class jobs and a competitive, attractive taxation environment.

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 and to allow for frequent secondment between research institutions and industry. This strategy has proven successful in other countries, such as the USA. There are several effective programs already in place to address these workforce issues (detailed on page 36 of the Submission), including VESKI, the Innovation Skills Fund, and the Federation Fellowship. AusBiotech believes such programs should be continued and expanded.

Given the acquisitive nature of the biotechnology sector, it needs 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 business development skills within the biotechnology sector that should be further supported, such as the Young Achievement Australia program (page 37 of the Submission). There are also a

number of international business skills development programs outlined in 5.2 of the Submission which should be given strong consideration.

Access to publicly funded scientific infrastructure is another area with significant room for improvement, as addressed in Chapter Four of the Submission. There are schemes in place that offer an improved access model, including CSIRO's Australian Growth Partnerships and Technology Access Grants (piloted by the Small Technologies Cluster in Victoria). AusBiotech encourages closer consideration of these schemes in the context of the PC's interest in workforce and infrastructure related impediments to science and innovation.

Overall AusBiotech endorses draft finding 5.1 from the Report:

Several impediments to innovation should be addressed:

- *major publicly funded research infrastructure should be priced to maximise utilisation, while avoiding congestion;*
- *there should be national consistency in the application of privacy regulation and in ethical review of multi-centre research;*
- *published papers and data from ARC and NHMRC-funded projects should be freely and publicly available; and*
- *there should be greater flexibility in pay structures for teachers to help address science and maths teacher shortages.*

At the same time, AusBiotech wishes to draw the PC's attention to the specific recommendations on this subject included in the Submission, namely:

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 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 Seventeen

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

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.

4 Commercialisation and Utilisation

The PC was particularly interested to understand mechanisms to ensure the commercialisation of technology developed in publicly funded institutions. This is an area where the biotechnology sector has its own particular characteristics in the broader context of innovation and commercialisation.

4.1 Commercialisation and Industry Growth

AusBiotech strongly supports the critical role PROs play in ensuring that a high standard of basic research continues to underpin the Australian biotechnology sector. Therefore, **AusBiotech supports draft finding 6.1:**

Decision making within universities in relation to the transfer, diffusion and utilisation of research outputs should not focus unduly on an objective of commercialisation to the detriment of maximising the social return from the public's investment.

However AusBiotech disagrees with the point of view expressed by the Institute of Public Affairs (IPA) in 6.15 of the Report:

The Institute of Public Affairs drew attention to how the size of the Australian market and other factors influence opportunities for commercialisation in the biotechnology sector… the truth is that the scope for full-scale commercialisation of biomedical product in Australia is greatly limited by the size of its market, the absence of large, local firms and barriers to overseas markets… Australia's greatest potential lies in the application of biotechnology to agriculture and food.

While it is true that Australia's small market size has an impact on opportunities here, it is wrong to therefore limit the potential of the Australian biotech sector to agriculture and food. As proven by:

- Australia's indigenous world class medical device/biotechnology companies, such as Cochlear, ResMed and CSL, and
- the interest shown in Australian innovation by international participants at the AusBiotech conference in November 2006, with eight of the world's top ten pharmaceutical companies in attendance

Australian biotechnology discoveries also have world potential in a range of applications.

In its Submission, AusBiotech has suggested a number of ways government can contribute to the scale growth of the industry. AusBiotech refers the PC to the specific recommendations on this subject included in the Submission, namely:

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 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 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.

4.2 Government Funding at Value Inflections

AusBiotech does agree with other comments in this section, such as 6.35, 6.36 and 6.47, particularly the importance of government funding being available at the right time and in the right measure to propel biotech companies to the next value inflection at which they will attract further funding from the market.

AusBiotech contends that 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 (or proof-of-concept) stage, such as where a working prototype exists. However, basic research funding programs often fall short of this critical milestone.

The following paragraphs from the Report mirror points made in AusBiotech's own Submission, and AusBiotech endorses them from their various sources:

> **6.35:** *Limited access to venture capital was claimed to seriously constrain the ability of start-up and early stage firms to commercialise knowledge and technology:*
>
> > *Research Australia's Beyond Discovery report examined the competitiveness of 100 Australian biotechnology companies and reveals important barriers to success. A key finding was a serious lack of funding for emerging biotechs. (Research Australia sub. 33, p. 3)*
> >
> > *Too often the Board witnesses companies going offshore simply because they cannot secure the type of support (the risk money) needed in Australia. Whilst large companies use earnings (or in some*

> *instances capital raising) to finance innovation, start-ups do not have such reserves as a source of finance. (Industry Research and Development Board sub. 77, p. 5)*

It is often suggested that lack of funding leads to other undesirable outcomes as well, such as firms: issuing public offerings earlier than similar firms overseas; seeking to license their knowledge and technology relatively early (which can mean the value of the intellectual property is heavily discounted); and adopting a cautious approach to patenting because of the difficulty of covering the cost of protecting their intellectual property.

The AIC has proposed that superannuation funds be required to invest 0.1 per cent of their assets in early stage venture capital.

> *An early-stage capital base of $1 billion (equivalent to 0.1 per cent of total assets) could build a pipeline of hundreds of new opportunities every year, and would significantly increase the capital available to start-up and early stage businesses. (sub. 28, p. 2)*

6.36: *The Go8 has identified a lack of funds to support proof-of-concept activities as one of the key constraints on university research commercialisation (2006a):*

- *Public funding for university research typically stops at the point when the research question has been answered, or the funding runs out.*
- *Industry requires proof of the commercial potential of the IP before it will invest.*
- *This is why initiatives such as the Pre-Seed Fund, run under BAA [Backing Australia's Ability], have not led to much increase in investment at the proof-of-concept stage of the process. Those in charge of the funds see it as too commercially risky to invest at this early stage.*
- *Universities are obliged to target their teaching and research funding on these activities — many of which promise more immediate returns on investment and are financially less risky than investment in research commercialisation.*
- *In Australia there exist a number of funds specifically set up to invest in technologies emerging for publicly funded research organisations (eg, UniSeed, the ANU/MTAA fund, the WestScheme Fund). However, these too tend to invest following proof-of-concept because of the risk factor (2006b, p. 1).*

Reflecting these concerns, the Go8 has proposed a new proof-of-concept funding mechanism — the 'Innovation Stimulation Fund'. Under its proposal the Australian Government would provide $45 million over three years on a competitive basis to encourage universities to invest in research of commercial potential at the proof-of-concept stage.

While these are very pertinent suggestions and reflective of AusBiotech's own recommendations, it is also reasonable to agree with the caution expressed in the Report by AEEMA:

> **6.47:** *However, a proliferation of programs, and their constant change, can increase costs to business in attempting to navigate through the assistance on offer and satisfy various reporting requirements. For example, AEEMA argued that:*
>
> > *But perhaps the most crippling obstacle to effective support for innovative processes and products in Australia is the overwhelming belief in industry that the multiplicity of policy programs, their attendant application processes and the myriad details sought by government for successful innovation assistance are far too time-consuming, costly and onerous. (sub. 51, p. 8)*

AusBiotech restates the specific recommendations in the Submission with which these statements align, namely:

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 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. This includes addressing issues such as a financial track record (which is difficult for emerging companies), the uneven nature of R&D expenditure, administrative and compliance burdens, and limitations on selling the technology in less than five years.

4.3 Clustering and Intermediaries

Clustering and intermediaries are also important mechanisms to ensure commercialisation of R&D. 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 discussed in 4.6 of the Submission, 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.

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.

At the Roundtable, the PC sought further input on the subject of intermediaries. A successful international example of an intermediary is the Association of University Technology Managers (AUTM) in the US, described on page 33 of the Submission. It 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 is 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.

AusBiotech refers the Productivity Commission to the specific recommendations on this subject included in the Submission, namely:

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 Eighteen

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

5 Taxation

AusBiotech is significantly concerned with the commentary and recommendations in relation to the R&D Tax Concession. **While the PC and AusBiotech are in agreement that the R&D Tax Concession can be improved, there is disagreement on the nature of the changes required to achieve that improvement.**

In the PC's report (Chapter 9, Key Points), it stated that:

Of particular concern is the basic R&D tax concession because it is available to all eligible firms whether or not the R&D would have been performed without support. It also assists R&D with low levels of spillovers such as incremental innovation.

AusBiotech submits that this generalisation is not supported by evidence and the experience of individual firms does not support this contention. Furthermore, even if the decision to undertake R&D is already fixed, the R&D Tax Concession can affect where those activities will be undertaken. Biotechnology is particularly multi-national in nature and this influence is critical.

Fundamentally, AusBiotech believes that the base rate is the true stimulus for innovation. To be competitive, Australia needs to improve the level of incentives offered to Australian and multi-national organisations. Specifically, AusBiotech recommends increasing the rate to 200% from its present level of 125%.

The Report (Chapter 9, Key Points) continues:

The effectiveness of the program could be improved by rebalancing support toward the premium component. That component could itself be improved by moving to a scheme based on changes to a firm's R&D intensity from a fixed base period.

Encouraging incremental R&D at the expense of encouraging other R&D will not achieve the desired objective of encouraging overall R&D in Australia. There can be no support for the contention that incremental R&D is of greater value to the Australian economy. The value to Australia is determined on the quality of the R&D and not only on the levels of expenditure.

Specifically, the use of an incentive based on incremental spend is in contrast to the collaborative and progressive nature of biotechnology R&D. R&D in biotechnology is undertaken in distinct and identifiable phases, typically by different organisations at different parts of the technology lifecycle. This 'supply chain' view of R&D is inconsistent with the incremental incentive which encourages and rewards internally-developed R&D.

AusBiotech would like to express its support for other recommendations made in Draft Finding 9.1, namely:

- *allowing access to the incremental scheme to start-up firm.*
- *relaxing the beneficial ownership requirement and the expenditure and turnover thresholds for the tax offset for the incremental scheme alone*

While there are obvious complications with providing a benefit for incremental innovation for new organisations, as a point of equity, it is important to address substantive differences in treatment between emerging and mature organisations under the R&D Tax Concession.

Furthermore, AusBiotech welcomes the recommendation to relax beneficial ownership requirements, expenditure and turnover thresholds for the tax offset program, effectively allowing organisations to 'cash out' the R&D Tax Concession.

Finally, AusBiotech suggests a change to the beneficial ownership requirements under the R&D Tax Concession. This would enable greater flexibility and investment by multinational organisations in particular and, more generally, by organisations engaged in more collaborative R&D.

In conclusion, AusBiotech would like to restate the following point made in the Submission:

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.

6 Conclusion

The process of the Study has generated robust discussion about Australia's position as an innovative nation and the role government can play to support this. AusBiotech believes a holistic view of innovation, including but not limited to R&D activity, is important in considering government support mechanisms. The spillovers and social benefits of publicly funded science and innovation are more likely to occur in an environment where the full spectrum of impacts of innovation are considered. Biotechnology is intrinsically global and Australia needs to enhance its competitiveness at every opportunity.

AusBiotech welcomes the continued partnership between between governments and the biotechnology and medial devices sector. AusBiotech is pleased to have been part of the debate that will frame the future direction of science and innovation policy, as the biotechnology and medical devices sectors are positioned to significantly contribute to Australia's future economic, social, industrial and environmental prosperity.