

PRIME MINISTER'S SCIENCE, ENGINEERING AND INNOVATION COUNCIL

THIRD MEETING - 25 JUNE 1999

AGENDA ITEM 3

INNOVATION IN MEDICAL BIOTECHNOLOGY

Introduction

At the first meeting of PMSEIC, on 29 May 1998, an independent Working Group presented an agenda paper entitled 'Profiting from the Biotechnology Revolution'. The paper discussed issues affecting biotechnology innovation in Australia and focused primarily on the agricultural sector. In conclusion, the paper recommended that: 'the issues identified by the working group, on opportunities and options for profiting from the biotechnology revolution, should receive further consideration by Government'.

At the second PMSEIC meeting, on 4 December 1998, Mr Peter Wills noted in a paper summarising the findings of the Health and Medical Research Strategic Review that Australia faced 'an exciting opportunity to build on its strength in health and medical research to create a healthier and more prosperous nation as we enter the age of biotechnology'.

In order to advance the Government's consideration of these issues, a PMSEIC Working Group was subsequently established to specifically examine innovation in the medical biotechnology sector. The Working Group comprised:

- Professor Richard Larkins (Chair), Chairman, NH&MRC and an *ex officio* PMSEIC Council member;
- Dr Geoff Brooke, Director, Bioscience Unit, N M Rothschild & Sons (Australia);
- Dr Hugh Niall, CEO, Biota Holdings Ltd;
- Professor Vicki Sara, Chair, Australian Research Council and an *ex officio* PMSEIC Council member;
- Mr Peter Wills, AM, Chairman, Garvan Institute and Chairman, Health and Medical Research Strategic Review, 1999.

Medical Biotechnology

The biotechnology industry has enormous potential to create wealth and jobs for Australia well into the next century. It covers many fields including medicine, agriculture, forestry, marine, aquaculture, manufacturing, mining, military and the environment. It also has significant potential to assist traditional industries in the agricultural and mineral resources sectors to remain competitive. There are more than 180 businesses engaged in biotechnology in Australia. Of these, 85 are listed on the Australian Stock Exchange and have a capitalisation close to \$5 billion (1% of the Australian market).

This paper was prepared by an independent working group for PMSEIC. Its views are those of the Working Group, not necessarily those of the Commonwealth

About one third of Australia's biotechnology businesses are dedicated to medical biotechnology. Of these, 32 are public companies. Australia's biotechnology enterprises are predominantly small in size; the only large businesses being subsidiaries of multinationals. With a small domestic market and highly specialised products, most have a global orientation and more than three quarters are exporters. Medical biotechnology offers the prospect of new and improved pharmaceuticals to address major diseases, improved methods of diagnosis and improved preventive medicines. It also offers opportunities for containing health costs and improving the quality of life of the aged and infirm. There is growth potential in terms of both therapeutic gains and market size. There are currently many unmet clinical needs which could be addressed through biotechnology. In addition, change in the structure of the pharmaceutical industry over the last few years has created opportunities for small companies to play a role in global health care.

Australia has a number of strengths in medical biotechnology including:

- world class expertise in some fields of medical research, including genetics, molecular biology, cancer research and immunology;
- well placed geographically to access expanding regional markets;
- structures which promote close cooperation between universities, public research institutes and industry (such as the ARC SPIRT program¹); and
- a clinical trial system (Phase II and Phase III) which is recognised internationally and which is relatively inexpensive.

However, the industry in Australia also suffers from a number of problems which combine to stifle investment and reduce the potential for innovation and commercialisation. These factors include:

- declining government support for basic research and skills training;
- a business culture which does not favour expenditure on R&D;
- low expenditure on R&D in Australia by multinational pharmaceutical companies;
- a lack of financial resources for high-risk early-stage product development;
- inadequate management of intellectual property, particularly by public institutions;
- inadequate understanding among scientists of commercial matters and among business professionals of scientific matters;
- inadequate access of scientists to skilled technology transfer services;
- a shortage of industry expertise, particularly in management of product development; and
- lack of industry development compared with strong biomedical research effort.

Despite a relatively strong public research base, the ability of Australian companies to develop and commercialise scientific discovery is generally weak. The start-up of fledgling businesses is expensive and commercial opportunities are often sold prematurely to produce a necessary injection of funds. There is little support for creation of small business infrastructure. In sales or licensing agreements, Australian medical biotechnology enterprises are often in a weak negotiating position as they do not have the level of corporate experience available to the larger partner. There is a lack of good business management expertise and a lack of good accounting and legal advice relevant to the medical biotechnology sector. Although some of the larger firms are starting to develop this expertise, Australia is still a long way behind Europe and the US. Thus, for a variety of reasons, many of Australia's smaller and medium sized biotechnology companies are constrained in their ability to grow and thereby prevent Australia from capturing

¹ Strategic Partnerships with Industry - Research and Training Scheme supports collaboration between universities and industry.

full economic returns from the resources, both capital and intellectual, vested in its fundamental research institutions.

Support for Health and Medical Research

In response to the findings of the Health and Medical Research Strategic Review, chaired by Mr Peter Wills (*The Virtuous cycle - Working together for health and medical research*), the government announced in the May 1999 Budget extra funding to the NHMRC of \$614 m over 6 years. This will take annual expenditure for the NHMRC from \$165 m to \$350m in the year 2004-5. In addition, the government allocated:

- \$20m to consolidate Australia's disparate medical research community into a smaller cluster of 'centres of excellence';
- funding of \$20m over 4 years for the establishment of a National Institute of Clinical Studies; and;
- \$20 m over two years for independent health and medical research institutes for capital works to establish or augment physical facilities.

These moves will strongly assist the medical health sector consolidate and expand its research base, one which will provide a strong foundation for innovation in medical biotechnology.

Support for Biotechnology

Both government and industry interest in biotechnology is rapidly gaining momentum. In addition to increased funding for the NHMRC, the 1999-2000 Federal budget contained two major expenditures aimed at increasing Australia's competitiveness in biotechnology:

- (1) an allocation of \$10m over two years for establishment of a Commonwealth agency, Biotechnology Australia in the Department of Industry, Science and Resources, which will function through a senior Ministerial Biotechnology Council; and
- (2) an allocation of \$7.5m to establish an Office of the Gene Technology Regulator within the Health and Aged Care portfolio and which is expected to be self funding by 2002. The Working Group believes that there is now an opportunity to build on these important initiatives to assist Australian industry further capitalise on innovation in medical biotechnology.

Both the Queensland and Victorian governments have made recent commitments to support the biotechnology industry. In Queensland, biotechnology is to be boosted with a new Centre for Biomolecular Science and Drug Discovery and incubation centre at the Gold Coast Campus of Griffith University which will join the Institute for Molecular Bioscience at the University of Queensland. In Victoria, the City of Melbourne engaged the Boston Consulting Group to carry out a study of the impact of biotechnology which concluded that biotechnology could become a \$24 billion industry for Melbourne within 10 years, spawning 25 to 50 companies within the next five years. However, the report also concluded that this growth would only eventuate if urgent action was taken on four issues: the need to find seed venture capital, the development of a value-creating research and development environment; brokering more contracts between business and the scientific community; and the nurturing of start-up biotechnology companies.²

The number of conferences held in 1999 also indicates increasing interest in biotechnology innovation and commercialisation. In March 1999, the Australia Biotechnology Association held a symposium entitled 'A Roadmap for Commercialisation of Biotechnology' and in June 1999, as part of Medical Research Week, the Australian Society for Medical Research sponsored a forum

² The Age, 14 May 1999.

on 'Research, Investment and Commercialisation for Health. In October, there will be a second 'Commercialising Health Innovations Forum' (in Melbourne). The print media too has shown increasing interest in medical biotechnology and now regularly reports the vicissitudes of some of Australia's high profile biotechnology companies such as Biota, Amrad and CSL.

Support for Basic Research and Research Training

To develop and maintain an internationally competitive edge in medical biotechnology requires a very strong foundation of basic research. The economic importance of basic research as the source of future innovations has been recognised in recent years by countries such the US, UK and Japan through increases in funding for basic research. Notwithstanding additional funding of some 9 per cent for medical research, Australia's 1999-2000 Budget indicates a decline of 5.5 per cent in the funding of basic research in universities through the targeted research program. This is in addition to a 2.3 per cent decline for all other sources of funding for higher education research and research training.³

Advances in medical biotechnology are derived from basic research in science. The development of the anti-flu drug Relenza, for example, was made possible by understanding the protein structure of the virus and how it interacts in the receptors to produce influenza. A drug could then be designed to block the locking of the virus in the receptor. The majority of innovative drugs such as this are designed and developed from the physical sciences, which provide an understanding of protein structure and interactions. Similarly, the biological sciences underpin much of cancer research. For example, extensive studies of the genetics of fruit flies and identification of the fruit fly gene structure has led to the isolation of cancer genes related to the most common form of cancer, basal cell carcinoma, as well as the common brain tumour, medulloblastoma and other solid tumours including colon, gastric, pancreatic, testicular and ovarian cancer.

As pointed out in the Wills review of medical research, advances in medical research are dependent upon access to leading edge technologies and infrastructure. For example, X-ray crystallography was essential in determining the structure of the influenza virus and the design of Relenza. Moreover, the highest quality training of researchers, which includes skills training for these technologies, is essential for building the next generation of internationally competitive researchers and innovators.

In the Australian innovation system universities account for 78 per cent of all expenditure on basic research. Moreover, as the providers of research training, the universities underpin the activity of the entire Australian R&D system. Ensuring a successful medical biotechnology future for Australia by providing new discoveries and innovations for the world market, will require the maintenance of a sound base of internationally competitive basic research and research training.

Basic research is a legitimate role for government and innovation and commercialisation in medical biotechnology is dependent on good fundamental research. For Australia to take full advantage of the Government's recent Budget initiatives to make medical biotechnology a strategic priority area, the level of funding for basic research and research training in universities needs to be increased. A thriving research sector would support industry to move firmly into the knowledge based economy and create wealth for Australia.

³ Science and Technology Budget Statement 1999-2000, Department of Industry Science Resources.

Recommendation

- 1. Building upon Government recognition of the importance of medical research, that the underpinning research base and research training in universities be enhanced to ensure international competitiveness.**

Barriers to Investment

The viability of companies engaged in biotechnology depends primarily on sources of finance, sources of innovation and strategic alliances. Of these, the most important is finance (see below - Survey of Biotechnology Enterprises). While the realisation of profits in medical biotechnology is potentially large, there is a high degree of risk associated with financial investment in biotechnology because it is difficult to determine whether a research project has any chance of commercial success. In addition, commercialisation of biotechnology is an extremely expensive business and lead-times for return on investment are necessarily long. Because of these factors, larger, traditional finance institutions remain reluctant to invest in biotechnology in Australia. With limited access to venture and development capital, small biotechnology enterprises in Australia are often forced into listing as a public company too soon.

Compared to many other countries with high technology industries, Australia's tax arrangements are uncompetitive. Factors which contribute to this situation include high corporate and income tax rates, the overall complexity of tax arrangements (which include indirect taxes such as payroll tax, fringe benefits tax, stamp duty, land taxes, etc) and the cost of compliance for business enterprises. This situation deters multinational companies from investing in Australia and hampers the emergence of Australian enterprises.

Capital Gains Tax

Most importantly, the potential for return on investment in small biotechnology enterprises is significantly decreased in Australia by provisions relating to capital gains tax (CGT). As described in detail in the Review of Business Taxation (the 'Ralph Review'), this tax deters both internal investors, because there are other more favourable forms of investment in Australia, and overseas investors because it is internationally uncompetitive. The Health and Medical Research Strategic Review also highlighted the detrimental impact that the CGT regime has had on investment in medical R&D in Australia and previous representations have been made to PMSEIC on this subject. The Working Group strongly supports the conclusions made in those reviews that investment in innovation in Australia will continue to be stifled until a more favourable CGT regime is implemented.

Recommendation

- 2. That the government reduce capital gains tax liability for long-term active investment in new biotechnology ventures in a similar model to the recently introduced UK arrangements and apply this to all investors including superannuation funds, to encourage medium to long-term investment in biotechnology enterprises.**

Share Options

The impact of the current tax regime is also felt in the area of discounted employee share options. Share options are routinely given to employees of overseas biotechnology companies as part of compensation packages. The main purpose is to provide an incentive for the employee to stay with the company and contribute to its growth. For key employees (senior management and talented scientists), the number of options granted is sufficiently large to offer the chance of

wealth should the company be successful. This balances the very real risk that the company may fail, and allows the recruitment of staff from more secure jobs. A subsidiary reason is that the use of options conserves cash for the early stage company by allowing the payment of lower salaries.

Under Division 13A of the Income Tax Act, qualified option schemes allow employees to defer for up to ten years the discount benefit of the option, provided a number of conditions are met. One of these is that no employee may be awarded options over more than 5% of the company's shares. In practice this is not usually a problem since even key employees are not usually awarded so much. A greater problem is that the options are ultimately taxed at the employee's top marginal rate, usually as ordinary income but under some circumstances as capital gain.

The employee is foregoing salary, in effect making an investment in the company, for a possible future benefit based upon a rise in the share price which may never occur. This is not equivalent to salary sacrifice since the usual salary 'sacrifice' is made for an immediate and tangible benefit which is not at risk. This is substantially equivalent to an outside investor making an investment in the company's shares. It is not equitable for the outside investor to be taxed at a more favourable rate than the employee. This is not the case at present, but if, as recommended in the Wills Report and foreshadowed in the Ralph Review, a more favourable CGT regime is implemented, employee options should be treated similarly.

Recommendation

- 3. That the government change provisions relating to discounted share options for employees so that unrealised gains are not taxed and realised gains are taxed at the (reduced) rate applying to outside investors holding shares for the same time period.**

Limited Liability Partnerships

In terms of raising venture capital, limited liability partnerships have advantages over conventional partnership arrangements in that liability is restricted to 'general' partners. However, they are disadvantaged by the fact that they are taxed as if they are public companies which, in effect, negates the advantage. Thus there is no reason for small enterprises to form a limited liability partnership when, from a financial point of view, this may be the most favourable structure to use. The Working Group supports the recommendation made by the Review of Business Taxation for change in this area.

Company Mergers

Impediments to the profitable expansion of the biotechnology industry also occur through taxation provisions relating to the merger of companies. When two companies merge, any unrealised gain in the value of shares is taxable. This acts to deter small biotechnology companies from merging when it may be in their best interests to do so. The Working Group believes that, as a general rule, tax should only apply to realised profits and, more specifically, believes that financial penalties incurred through company mergers be removed.

Recommendation

- 4. That the government change provisions relating to business mergers so that unrealised gains are not taxed.**

Overseas Pension Funds

Industry in Australia now operates in a global investment environment with funds potentially available from a wide range overseas investment institutions. One large source of venture capital and development finance is overseas pension funds. In the US and UK pension funds are exempt from capital gains tax in their home countries. However, if those pension funds are invested in Australian companies, the profits are subject to CGT by the Australian government. This acts as a disincentive to investment in Australian companies by those funds and they will not become available until Australia become more internationally competitive.

Australian Superannuation Funds

Superannuation funds in Australia now control net assets exceeding \$100 billion. While in the past these institutions have been reluctant to allocate funds to high risk areas such as biotechnology, there are signs that this attitude is changing particularly in relation to IT investment. This may be in part due to the fast growth of the superannuation industry as a whole in recent years. Changes to the CGT regime to make investment in high-risk enterprises potentially more profitable, would ensure that funds from this source were more forthcoming.

Specific Government Industry Assistance Programs

There are a number of specific government programs which aim to assist industry. These include the R&D Start Program, the Innovation Investment Fund, the Pharmaceutical Industry Investment Program, the Venture Awareness Program and the Investment Ready Program. The Working Group notes that these schemes are essential in a system that provides no other way of encouraging private investment in R&D. In other words, the existence of such government support programs is symptomatic of a fundamental flaw in the financial system in Australia such that private sector investment in R&D is inhibited rather than facilitated. If the investment environment was improved through changes to the tax regime, such programs would eventually become redundant. Failure to revise the CGT regime would inevitably result in continuation of these schemes. The Working Group also notes that industry assistance programs and government policies relating to industry are subject to frequent change. This contributes to the difficulty and uncertainty of financial planning for many enterprises in the medical biotechnology sector involved in long-term R&D.

Following the introduction of the 150% Tax Concession for R&D in 1986, business expenditure on R&D increased considerably. However, the reduction of the concession from 150% to 125% in 1996 has resulted in a downturn in private sector R&D. The decrease in the value of the concession has been criticised by many groups and there has been a concomitant demand for it to be reinstated. The Working Group believes that the Tax Concession has been instrumental in changing the way R&D is viewed by the private sector and has contributed directly, and indirectly, to economic growth and employment in Australia.

Lack of Management Skills in Biotechnology Enterprises

While biotechnology enterprises frequently decry the availability of venture and development capital in Australia, investment fund managers and industry consultants point to the lack of business planning and business structuring by small and medium biotechnology enterprises as a major impediment to their ability to access finance. Because many newly established small biotechnology businesses have poor management and do not present capable business plans, their funding proposals are frequently rejected. Thus it may appear that there is less venture capital available than is actually the case.

The more important point, however, is that there is a critical shortage of enterprise management expertise in Australia and there are few people who have a sophisticated understanding of product development and commercialisation processes. In America and Europe there are many skilled product development managers who move between businesses and between industry sectors. However, in Australia, there is a general lack of good managers with experience in product development and available to move into the medical biotechnology sector. In addition, there is very little understanding of investment options among Australian biotechnology companies.

Many research scientists have a poor understanding of even basic commerce, especially the importance of intellectual property. Undergraduates have almost no awareness of the commercial potential of science. There is a need to train scientists to be aware of commercial interests that may arise from their research.⁴ There is also a need to train some MBA graduates in basic science concepts so that future managers and investors have an understanding of the unique issues of biotechnology innovation. It should be noted, however, that there is not necessarily a need to train all scientists to be managers, rather a need to give them an overview of what the product development process is and where potential for commercialisation might lie.

If Australia is to fully respond to the challenge of strong market participation in medical biotechnology, effort must be put into addressing future education needs now. Universities must be in a position to be able to respond to industry's education needs. In addition, Australia needs to be more creative in the type of courses it offers, both at graduate and postgraduate levels. A linked academic/commercial career pathway needs to be more strongly developed in universities. The government's budget initiative of providing \$25m over three years to fund innovative new programs for science teaching in the fields of information technology and biotechnology, based on collaboration between industry and universities, is a start in the right direction.

Promoting Exchange and Mobility

A recent study by the Academy of Science has found strong evidence that Australian scientists have difficulty in establishing and maintaining contact with overseas research institutes.⁵ The study also found that there are too few opportunities for overseas exchange which was primarily a consequence of the fact that there were too few schemes in Australia which provided adequate support for overseas experience. Junior scientists frequently miss out because the awards system is intensely competitive and Australia's weak currency deters overseas travel by researchers. The Academy noted that scientific research was becoming increasingly globalised and competitive, and thus recommended that a national scheme be established to support outstanding young scientists gain experience in overseas research positions.

Because opportunities for science research managers to work in large multinational companies are limited in Australia, it is necessary for research scientists, and particularly those with an aptitude for management, to gain the necessary experience in large companies or research institutions overseas. Through employment in overseas countries, potential biotechnology enterprise managers can gain the knowledge and skills needed to manage successful product development; expertise which cannot be gained in Australia simply through training courses or through small business activities.

⁴ Though some universities have already responded to the need for teaching across disciplines. For example, in a joint venture, the University of Adelaide and the University of Texas are offering a 12 month pilot course which will lead to a professional certificate in science and technology commercialisation (*The Australian*, 5 May 1999, p. 44).

⁵ Australian Academy of Science *International Networks and the Competitiveness of Australia's Science and Technology*, February 1999.

The Working Group believes that the Government should actively promote the transfer of Australian scientists, particularly from the public sector, to overseas research institutions and companies. To this end it should provide post-doctoral fellowships for Australians to work in overseas companies, particularly in positions where product development experience will be gained. However, any scheme to assist scientists to move into jobs overseas should have attached to it a requirement, upon financial penalty, to return after a specified period of time. The Working Group also believes that the Government should actively seek to attract back to Australia expatriates with expertise in product development management.

In addition to assisting Australian scientists gain experience in overseas companies, the Working Group believes that there is a need for greater mobility of scientists between the public and private research sectors. Public scientists should be given credit for periods of time spent overseas, or in private enterprise within Australia, which would enhance their employment and promotional prospects in their home institution.

Recommendations

- 5. That the government introduce a scholarship scheme for post-doctoral students to work overseas in a medical biotechnology product development role. Such a scheme should include payment of airfares and a contribution equal to half the salary otherwise paid by the cooperating institution or business. Recipients must return within 5 years or they have to repay the scholarship. Austrade should have a role in finding placements for the scheme.**
- 6. That the government introduce a scheme to locate Australian scientists working in large overseas institution or companies and provide inducements for them to return to Australia.**
- 7. That the Government encourage the ARC, through the SPIRT Program, to enhance the mobility of scientists between the private and public sectors.**

Commercialisation of Public Sector R&D

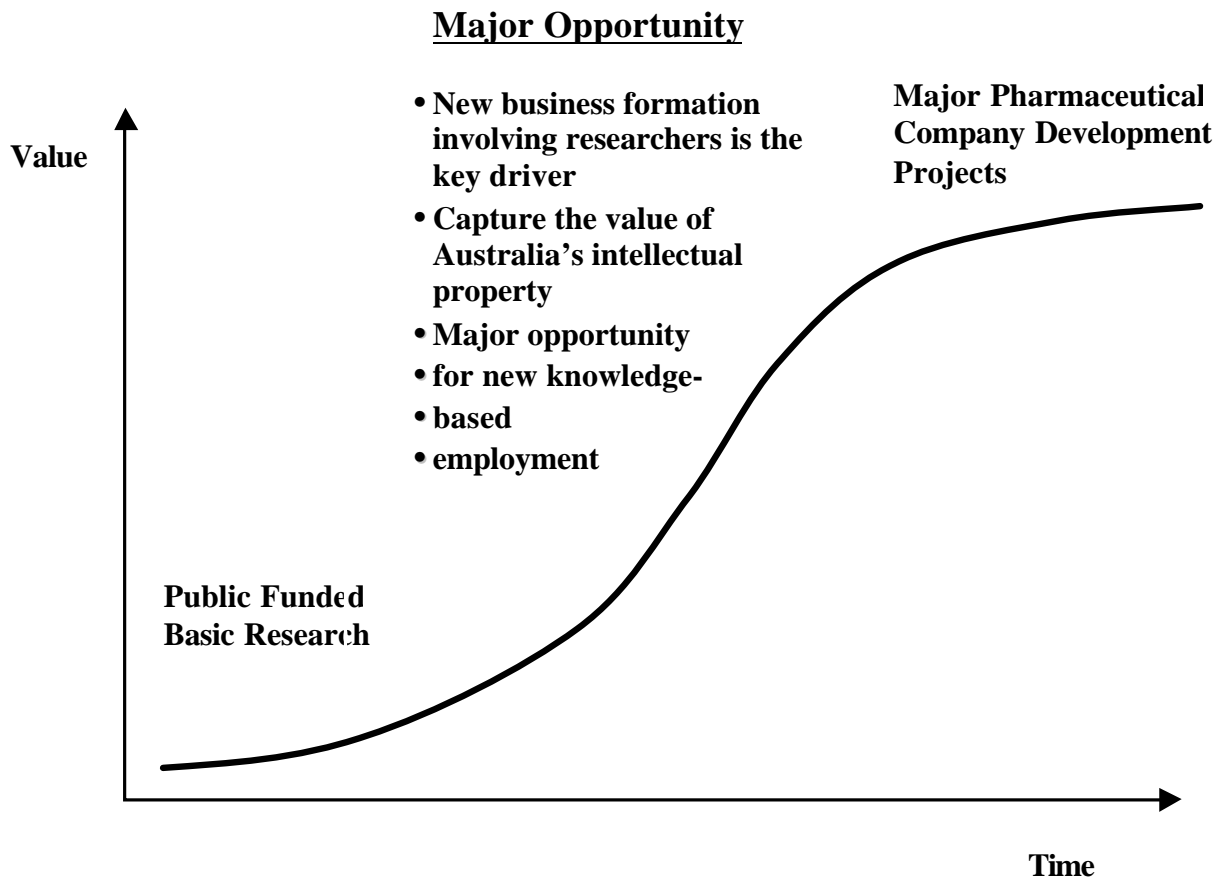
As with many other areas of applied research, there is generally a low level of commercial uptake of results from public-sector research institutes involved in medical biotechnology in Australia. For the most part, public institutions sell their intellectual property too soon to capture any real benefit or value added. Too often intellectual property is sold at a point just prior to spin-off and the enormous benefits that may be obtained through the development process are not pursued. The loss to Australia in terms of value-added not gained is illustrated in Figure 1, below.

While most universities have formed technology transfer offices, researchers have not been able to take full advantage of spin-off opportunities emanating from their work. For the most part this has been due to the lack of:

- financial resources within technology transfer offices, particularly to manage intellectual property;
- quality management expertise vested in those offices;
- incubator support programs; and

- financial incentives for academics to pursue commercial opportunities.

Figure 1 - Typical S-Curve for value creation in the pharmaceutical industry (Source: *The Virtuous Cycle - working together for health and medical research*, Health and Medical Strategic Review, 1999, p. 7).



The patenting of intellectual property and the ongoing management of an intellectual property portfolio can be very expensive. Establishment of patent rights costs between \$50,000 and \$100,000 over the first three years. Management over the life of the patent (generally 10-15 years) may cost another \$100,000 - \$200,000. Each university technology transfer office manages hundreds of patents and, while expenses may be shared with commercial partners, the protection of intellectual property is still a costly activity.

Lack of sufficient funding for university technology transfer offices has also resulted in a lack of good management expertise and advice. Because it has been compulsory in most universities for staff to use their own university technology transfer offices, they have not had the opportunity to obtain advice from the private sector (which is an anti-competitive situation). In other countries, notably America, public institutions are encouraged to take ideas through to development stage with subsidised incubator facilities and scientists are able to hold personal equity in any business they create.

The Working Group strongly believes that public research institutions must be encouraged and assisted to capture value added. Public sector scientists must be able to hold personal equity in

any businesses they create while still holding staff positions, providing conflict of interest issues are resolved. As with the private sector, better linkages between public research institutions and industry are required to ensure that more biotechnology products will be developed for manufacture and export by Australian companies. The Working Group believes that there is still a need for public sector technology transfer offices but that they must be adequately resourced and that staff must be given freedom to seek professional advice from alternative, commercial business.

A major source of difficulty for entrepreneurial scientists is the lack of recognition given to academics for commercial endeavour. Recognition and promotion in universities is still very much based on the system of peer review and accreditation through journal publications (the 'publish or perish' phenomenon). However, for academics involved in business activities, there is a commercial imperative in not publishing results ('publish and perish') and thus no academic recognition comes from the work. Similarly, due recognition is not accorded academics for time spent working in industry and thus mobility between academia and industry is stifled. There needs to be a new system which rewards entrepreneurship as well as scholarship (patents as well as publications) and which recognises the value of mobility between academia and industry.

Recommendations

- 8. That institutions involved in publicly funded research remove restrictions requiring staff to use technology transfer offices and allow staff to use the services of commercial businesses for advice on matters relating to finance, law and intellectual property management.**
- 9. That universities find ways to promote employment flexibility and actively encourage mobility between universities and industry.**
- 10. That universities recognise industry secondment and commercial activities as well as publications in assessing academic promotion.**
- 11. That constraints on staff employed by public research institutions holding equity in companies or performing research in companies while holding staff positions be removed, providing conflict of interest issues are resolved, and incentives put in place for them to do so.**

Intellectual Property

Overall, it appears that the Australian biotechnology industry is ill-equipped to handle the products patenting system and management of intellectual property is generally poor. Often Australian enterprises do not have readily available information about requirements for an international patent application and because many small biotechnology enterprises in Australia are undercapitalised, the costs involved in intellectual property patenting are prohibitively high. This problem is compounded when small biotechnology enterprises attempt to form strategic alliances with major companies in order to access assets such as finance, manufacturing or marketing resources in return for the licensing or sale of their trade intellectual property (their major tradeable asset). However, because they lack corporate experience in intellectual property management, they may be placed in a weak negotiating position. Thus in some cases assistance may be needed in negotiations so that their intellectual property is protected.

There is generally poor management of intellectual property within publicly funded institutions. Within universities there are two major problems. First, there is a general lack of understanding by scientists of intellectual property management (for example, when to not publish research

results, what due diligence processes are and where intellectual property may fit in with other patents). Second, there is a gap in funding between the registration of intellectual property for patenting and the development of that intellectual property to a stage where a business enterprise may express an interest in it (pre-seed or 'twinkle' funding). As discussed earlier, lack of funding arises primarily as a result of the uncompetitive nature of venture capital investment in Australia. University technology transfer offices vary greatly in their expertise and experience in intellectual property management and the resources available to assist scientists capitalise on their research.

Although there is starting to be a change in this culture in Australia, and eventually an increase in experience among enterprise managers will ease the problem, there is currently a need for industry and government to be more pro-active in promoting intellectual property management skills both among the private and public sectors. There is a need to network and share skills in the area of intellectual property protection. Elsewhere in the world, both government agencies and the private sector are aggressively pursuing intellectual property protection. To compete with these countries in medical biotechnology, Australia's attitude to patenting intellectual property must change to be aggressive also.

'No Australian Disadvantage' Clause

The May 1998 PMSEIC agenda paper 'Profiting from the Biotechnology Revolution' stated that: 'Government funding of biotechnology should be given on the understanding that recipients agree to a 'no Australian disadvantage' clause in any sale, licence or partnership arrangement, or for technology only to be licensed, not sold'.⁶ However, this approach is inconsistent with government policy to move away from protectionist activities and, in reality, may constrain negotiations with prospective joint venture partners or licensees, thus creating new restrictions. Because joint venture opportunities are so important to financing of potential biotechnology enterprises in Australia, it is important that they not be inhibited or marred by protectionist regulations. The Working Group believes that, overall, the advantages of Australia not being disadvantaged in joint venture licensing agreements are outweighed by the disadvantages and thus that they should not be compulsory.

Recommendation

- 12. That, in the case of medical biotechnology research, clauses relating to 'no Australian disadvantage' not be made compulsory for public institutions in their sale or licensing of intellectual property.**

⁶ PMSEIC May 1998 *Profiting from the Biotechnology Revolution*, p.6.

Survey of Biotechnology Enterprises

During the course of the study the Working Group sent out a questionnaire to 25 enterprises which had started up in the biotechnology sector since 1990. The questionnaire noted that the way in which business enterprises become established and function in Australia is strongly influenced by the regulatory and financial environment set by government and that some of these actions act as a constraint to industry development. The questionnaire then asked: 'If you could change three things, controlled by government, which affected the establishment and growth of your business, what would they be?'. Replies were received from 16 biotechnology enterprises. Detailed replies are provided in Appendix A. Results were considered both quantitatively (by giving each answer a weighted score according to priority⁷ - see Figure 2 below) and qualitatively as discussed below.

Clearly the most important matters of concern to new biotechnology businesses were the ability of businesses to access early stage funding (raised by 10 respondents, 5 of whom rated it first in order of priority, and four rated it second) and the related concern that the current capital gains tax regime inhibited the flow of investment capital to early stage medical biotechnology enterprises (raised by 9 respondents, 5 of whom rated it first in order of priority). Also related to this was the issue of special tax treatment for start-up companies to assist them survive the early years of income-stream establishment (raised by 5 respondents of whom three ranked it second).

Eight respondents raised matters relating to special government industry assistance programs (four of whom ranked them first in order of priority):

- changes to grants system (ranked 1 in order of priority);
- create of a funding program to allow people to investigate business (not research) opportunities in the biotechnology area (1);
- develop an accreditation process which will recognise businesses performing genuine R&D work (1);
- government programs should be run by industry (1);
- restructure aspects of the START grant scheme matching funds, based on equity raised or existing R&D contracts, should be applicable to the entire R&D spend (2);
- faster processing of applications for assistance, eg. START (2);
- remove the current ceiling of \$20,000 on contract R&D (3); and
- AusIndustry requirements that prohibit research institutions from acting as the source for matching funds for start up's (3).

Only one respondent raised the issue of the R&D Tax Concession, recommending that it be reinstated at 150%.

Three respondents raised matters relating to government regulation as follows:

- 'Construct a genuine 'level playing field' in Australia re regulatory requirements. Most times Australian companies are required to 'toe the line' whilst imported products often don't meet full regulatory requirements' (1).
- Create a sound regulatory environment: 'We have been impacted by a lack of regulation relating to the ownership of biological resources in Australia. Also we have been affected by the wildlife and protection act as it relates to the export of genetic material from Australian organisms' (3).

⁷ The first issue listed was given a score of 3, the second given a score of 2 and the third given a score of 1. Scores were then added for each issue.

- 'The regulatory and Medicare process in Australia often places higher demands on domestic manufacturers and exporters than it does on foreign importers' (3).

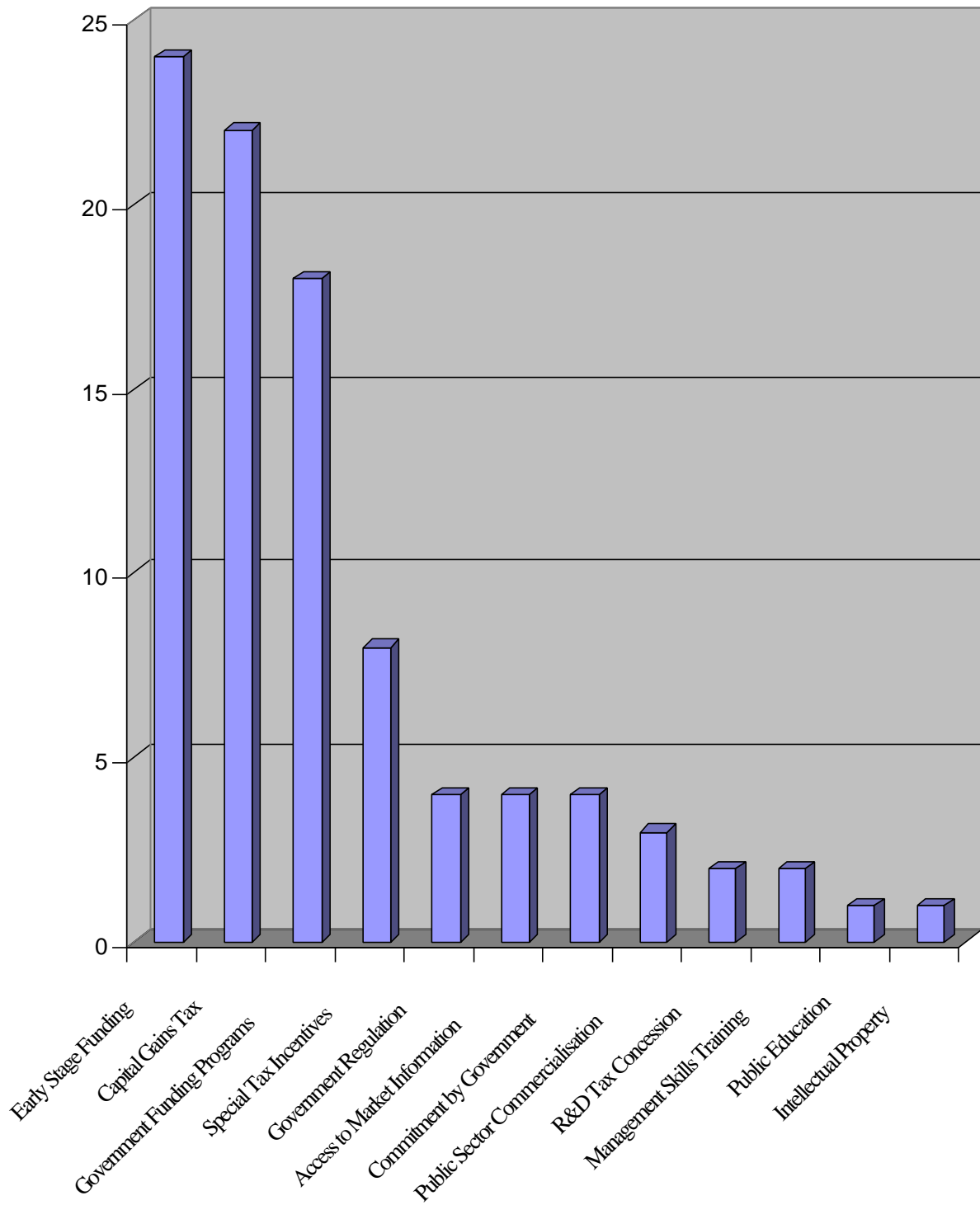
Finally, a range of other comments related to:

- Increased Public Sector Commercialisation - force academic research to commercialise (1).
- Intellectual Property - faster and more sympathetic licensing of IP to start-up companies (3)
- Public Education - Improve public education (3)
- Management skills training - provide Incentives to the education sector to train appropriate managers (3); and provide a means by which more people are educated and trained with the skills necessary to successfully start, develop and grow new entrepreneurial growth ventures (3).
- Access to Market Information - More assistance in information sharing about early stages of commercialisation (1, 2, 3).
- Increased Commitment by Government - visible and credible internationally profile of government is crucial (1); and national coordination of science parks/incubators (3).

Conclusion

The first half of 1999 has seen a rapid rise in interest in medical biotechnology displayed by all players: the research sector, government and industry. This has been promoted most recently by the Government's rapid response to the findings of the Health and Medical Research Strategic Review and commitment to substantially increase funding for the NHMRC. There are strong indicators that innovation in medical biotechnology will make valuable contributions to both the health of Australians and the knowledge-based economy of Australia over the next decade. Should this happen, medical biotechnology will become a working example of the innovation process for other industry sectors. There are four main requirements for the medical biotechnology sector to grow in Australia: world class research and development; adequate flow of capital; strong linkages between the research sector and industry; and the development of enterprise management expertise.

Figure 2 - Issues For New Biotechnology Enterprises (Weighted Scores)



Appendix A - Detailed Responses from Biotechnology Enterprises.

Question

The way in which business enterprises become established and function in Australia is strongly influenced by the regulatory and financial environment set by government. Some of these act as a constraint to industry development. If you could change three things, controlled by government, which affected the establishment and growth of your business, what would they be?

Enterprise A

1. If I had to name 3 things we need from government they would be commitment, commitment and commitment. But I will cheat and count them as one. If you need a model, we have one - a new one but an excellent one - in Peter Beattie. In the short time since he was elected the progress biotechnology has made in Queensland has been spectacular. Indeed, if the other States don't get their act together soon there is no question about where the Australian biotechnology industry will be based. Nor has he restricted his activities to Queensland. He has recognised that Australia is too small a base to support a significant biotechnology industry by itself. The market is international and the business is rapidly moving towards one founded strongly in partnerships. We therefore need to be both visible and credible internationally. Premier Beattie personally led the Australian delegation to the BIO Conference (the main annual international conference for the industry) and this created considerable impact. While there he announced Queensland's 10-year plan for biotechnology. I cannot overemphasise the value of this kind of activity. With political will most things are possible; without it they are very difficult.

2. Some incentive (probably tax-based) which encourages a company to locate here rather than elsewhere. Germany, responding to its recent release from the bonds of the very green lobby, has gone overboard in terms of incentives and there is a view that in the longer term this may be detrimental in that too many of the companies attracted might not be viable without external support. Clearly there is a balance to be struck here, but there is no doubt that some concrete assistance at the challenging start-up phase could be extremely beneficial.

3. Incentives to the education sector to train appropriate managers. I believe the industry does not benefit from a surfeit of 'bean-counters', and it certainly is not best served by the scientists who have the ideas leaving the bench to attempt to commercialise them. Rather, dual training is necessary, so that personnel with a clear grasp of the essentials behind the industry also have the management skills to deliver to the markets.

Other comments:

It would be really nice to see support for the Australian Biotechnology Association. If the ABA could access a small amount of funding to allow it to get on its feet and appoint a manager with the necessary skills, the local industry would benefit enormously.

Enterprise B (est. 1998)

1. Ready availability of seed capital (ie. to develop ideas into Business Plans including the use of consultants).
2. Faster processing of applications for assistance (eg. START and other business assistance).
3. Faster and more sympathetic licensing of IP to start-up companies.

Enterprise C (est. 1994)

Please excuse the extra points but felt it worthwhile. These have been sketched out very quickly in an ad hoc fashion.

1. Little heed seems to be paid to studying the Israeli model of biotechnology industry development. The successes and failures of that country's efforts are worth investigating when framing Australian government industry policy. It is encouraging to see that two new offices have been set up by the Federal Government designed to support biotechnology industry development. It is also encouraging to note that the government is generally supportive of industry development - although this is something of a motherhood statement. Our concern is that the new offices be less bureaucratic, more effective and more approachable than has previously been the case. For example, the Biotechnology Task Force and the Office of Biotechnology represent a general goodwill by government for industry development. Nevertheless, they are, like a number of other offices, remote, difficult to approach and - whilst a great repository of enthusiasm and eagerness to help once entered - are essentially ineffective. Invariably these initiatives are benign in intent, less so in practice. We think it is far more reasonable to drive these sorts of coordination efforts or communication bodies out of industry with departmental or ministerial advisers sitting in to listen rather than have them driven out of the government bureaucracy.

2. The ASX has established the Enterprise Market which enables unlisted groups to raise capital investment funds (akin to venture capital). This in a manner which is not fragmented and which overcomes Australia's small wealth base and lack of true VC providers. A tremendous initiative. Australia's small population, its concomitant limited wealth base, overwhelming bureaucracy and conservative investment stance has always been an enormous impediment to start-up companies. The ASX-EM helps overcome this. Further support would be given if the Superannuation Fund pool were encouraged to invest a small percentage of its holdings into higher risk vehicles in Australia. Tax rebates for investors investing in Australian start-ups/initial growth companies would also support access to desperately needed VC.

To a large degree the above represents growth capital. Access to immediate start-up capital is also critical. This needs to be made available at levels as low as a few thousand dollars up to the \$100,000 mark. Beyond this the growth capital providers can take over. In a country with limited population and therefore limited wealth base such as Australia government support for high risk technology start ups is critical. That catalyst needs to be made available as described above.

The industry R&D tax rebate needs to be made available at > 100% levels. We agree that it has been abused previously but independent assessment of such investment by a regulatory authority may address that issue. Perhaps, in addition or as an alternative to this, a method that may support a more honest R&D investment would be to enable a greater rebate to apply to R&D undertaken through independent groups outside of the company (eg: external R&D attracts say 200% rebate, internal say 150%). In other words it becomes a business expense without excluding the ability to undertake highly commercially sensitive R&D in-house and lose expenditure incentive.

3. Provision of a structured, open architecture, industry incubator/s is critical (not just in biotechnology but in any advanced technology industry). Attempts have been made to provide various facilities in various states (eg: manufacturing) but there seems to be no national coordination of science parks/incubators/manufacturing resources and services. The open architecture enables a range of start ups and growth companies to engage in higher risk R&D without losing ownership of their IP - and to do so in a cooperative fashion with other groups. This distributes expertise and shares technical resources, enables exchange of ideas and encourages work with finance and business development providers. The Taiwanese model is highly applicable in this regard.

4. Previously many Universities have maintained a commercial development office which seeks to provide the framework and assistance needed to develop IP from within the University. Yet these have not been roaring successes. Their ability to attract finance "angels" has been poor - although to a degree the same problem limiting VC resources in Australia apply to this issue (ie: we do not have access to the VC markets of the UK, US or Europe). One problem has been that the University commercial office has been campus based and reaching out to industry. But the Japanese model of industry offices reaching in to support R&D and IP development would likely be far more effective in the Australian context. This would give companies access to skilled personnel and, in return, would fund students and research labs or support development of commercial relationships and industry skills.

5. Reduce the cost of establishing a company. This is a direct impediment to young people wanting to establish a formal vehicle. The cost of establishing an ACN is ludicrous. Initiatives under the current government tax reform program to reduce tax levels is a positive one. Current corporate tax levels are a direct and enormous drain on a groups' ability to support its own development (as well as employment and export activity) by reducing access to its own growth capital derived from profits. A reduction of personal income tax levels is also critical if we are to encourage greater self reliance and personal responsibility. In doing so we free up disposable income for investment into established and growth markets.

6. Reduce or eliminate payroll tax. Reduce Workcover subscriptions or reward those companies with safe operating environments with lower premiums. Alternatively, enable self insurance (within legislative requirements) in a competitive insurance market for public liability and worker safety. Clearly reduction or elimination of payroll tax (a key source of State income) will require a major change in Commonwealth funding distribution mechanisms. A major problem emerging is that it is likely that NSW and Victoria may be able to reduce or eliminate payroll tax making it difficult for states like SA, Tas. etc to keep or attract industries - especially startups.

7. Funding models for University research needs to be changed. Funding should not be "soft". Currently, a 12 month grant for a project that may run 2 or 3 years is crazy. What ends up happening is that the lab takes a month or so to set up and get into a routine, it makes a series of starts and stops, then gets into productive work. But no sooner is this established than people start to worry about whether they will have an income next year, will they be able to pay the mortgage?, feed the kids? etc. At that point concentration on the research work drops off because of the inherent worry. Staff and students begin looking around for new jobs or writing new grant applications. Out of a 12 month grant you get maybe 6 productive months. A waste of money. It would be far more sensible to provide set period grants for 1, 2 or 3 years for short term projects - in full - so that people know where they stand.

For long term projects - and main labs or departments - block 5 year grants should be provided. During that period there is enough time to set up, do good work (with the mind free of the constant money worry on the grant front), report on it, train undergrads and post graduates and support Hons., MSc and PhD programs. At the end of the 5 year period the research group can be subject to a reporting process which examines published results, or an independent review of work done to assess unpublished results. This means that publishing pressure is not present although it does not preclude publishing. Work that is good can be assessed and if it comes up to scratch a further 5 year block grant can be awarded.

This process is competitive. It encourages and rewards with income and stability productive and innovative groups. It rewards and enables those engaged in research that may not see a published or commercial result in the first round of funding without threat. It provides stability in the research and training environment and supports establishment of industry and commercial links (industry or investors respond more favourably to stability over time). It also avoids the resource duplication and bureaucracy inherent in the CRC model.

The process is fully auditable and accountable. It addresses the main issue of human factors such as the need for a measure of employment and income stability - a critical component for good research to be done (review historical funding of science in UK and Europe in 17th, 18th and 19th centuries as an example).

8. The "structured" PhD programs now so favoured by a number of institutions is a bureaucratic obstacle to students. Whilst the motivation for such is understandable the implementation has really been around supporting the weaker students needing their hands held. That is not what a PhD is about. Unfortunately it has turned into a bureaucratic monster and is distracting and annoying for the PhD's we look to as research staff. It impedes and frustrates the truly enthusiastic and interested post-grad student - and can turn them away from that formal work. We don't believe the country can afford to lose those minds.

9. To encourage good people into biotech development and industry a clearer defined career path must be set out in the sciences. The ad hoc, informal and "quaint" buddy network is inappropriate in this day and age. Far more formal, professionally recognised and industry linked career paths exist in engineering, geosciences and medicine. Why should this not equally apply to the general, biological and medical sciences? This is critical, especially the defined career path and the establishment of a professional institute.

Enterprise D (est. 1998)

1. Taxation: the high current capital gains tax makes Australia relatively unattractive for overseas investors, compared to say USA. The change from 150% to 125% for investment in R&D also reduces investment.

2. Early stage funding schemes, with government involvement in early planning stages, based on competitive applications, for new product development. These would combine new technology development and commercialisation and would combine aspects of an NHMRC grant and a business plan. It could be a category of NHMRC applications.

3. More assistance in information sharing about early stages of commercialisation - for an innovative scientist it is a long and involved process gaining an understanding of the world of business practice. For example a schemes to support travel to conferences such as Bio in the USA would be useful.

Enterprise E (est. 1994)

A. General Comments

Medical biotechnology has a long start-up period between concept verification/prototype and a positive cash flow situation. During this bridging "pre-Start-Up" period, there is an extensive (and expensive) requirement for a) process validation activities b) field testing (eg clinical trialing) c) regulatory approvals (domestic & overseas) d) market analysis & e) business plan development. The extent of this effort is usually greatly underestimated and initial seed money (whatever its source) becomes increasingly exhausted. Paradoxically, significant venture capital in Australia is easier to obtain at the concept/seed stage than at the start-up stage. At "seed", the more "daring" venture capitalists can be wooed with being in on the ground floor of "conceptual" scenarios with dreams of large returns. Australian venture capitalists generally take a short term focus of a significant percentage return on their money in 1-2 years; the 1-3 year validation / regulatory approval (domestic & overseas)/ start-up process does not fit this scenario.

Similarly, government Start-Up grants tend to be generally modest and are targeted primarily at expansion regimes - if you have a dollar you can get a dollar. However, once the seed money is diminished, Start Grants are no longer accessible at the time when the business most needs the support. Export Development Grants are only available retrospectively at a time when one has

their product(s) on the market. It is easy for a business to lose momentum due to restricted cash flow, to miss windows of opportunity and to stumble on the threshold of success.

B. Response To Question:

1. Easier access to funding (government & private) and assistance at the pre-Start-up phase (after prototype / concept verification) with:

- a) Business plan development (including detailed market intelligence & analysis)
- b) Manufacturing process validation
- c) Regulatory approvals (Australia & overseas)

(This could take the form of targeted grants, tax concessions to investors and government subsidised access to business & marketing information and expertise.)

2. Start-Up companies often have limited resources restricting their access to the appropriate information and expertise required for immediate success. Subsidised access to marketing information and business planning expertise would assist in the development of appropriate business plans that would not only assist in private fund raising but provide the appropriate base to get through Start-Up into the expansion phase.

3. The regulatory and Medicare process in Australia often places higher demands on domestic manufacturers and exporters than it does on foreign importers. A scheme should be implemented to facilitate rapid access to Australian (and overseas) markets of Australian innovations. This , perhaps, could take the form of a two stage approval process wherein a temporary "qualified approval" is granted allowing domestic access under specified conditions while more extensive data/information is gathered.

Enterprise F (est. 1998)

1. Ready availability of patient Venture/Seed Capital is essential to providing the funds necessary start, grow and develop new business ventures, especially in the Biotechnology area. It is a well documented fact that early stage funding is very difficult to find for entrepreneurial growth ventures in Australia. This is referred to as the Equity Gap. The Govt has assisted already through establishment of the Innovation Funds but could provide more funding in this way. A preferred means of assistance would be legislation or at least strong moral suasion placed upon the country's Superannuation funds, which have billions of dollars in investment funds requiring them to place say 1% into biotechnology venture capital investments. This would immediately solve the problem of lack of capital.

2. Introduce a Capital Gains Tax regime that is competitive with the USA capital gains tax laws. Investors are loath to wear the higher risks associated with Biotechnology investments unless there is a commensurate probability of a higher return in the future. Current capital gains tax laws ensure approximately 50% of any gains made by individuals go to the Tax Office. This is unrealistic and punitive given the risks that must be borne by Biotechnology investors. Accordingly such taxes limit the availability of capital for Biotechnology investments.

3. Provide a means by which more people are educated and trained with the skills necessary to successfully start, develop and grow new entrepreneurial growth ventures. An excellent tertiary course in this regard is the program run by the Australian Centre for Innovation and Entrepreneurship at Swinburne University. Australia is very good at world class science and research but falls down badly at the commercialisation aspects. Education can assist in providing a remedy to this problem.

Other comments:

The USA is a classic live case study that Australia would be wise to emulate. Due to the American's cultural affinity for Biotechnology and High Technology investments, support for entrepreneurs, ready availability of venture capital and economic policies and framework (including tax regime) that provides incentive to entrepreneurs and investors to start new technology ventures, Research, Development & Commercialisation activities are flourishing. The benefits from such incentives include, amongst other things, the creation of new jobs and generation of export earnings.

It is not rocket science to suggest that Australia should follow the US model as is typified by the economic growth of areas such as Silicon valley and Boston. If we did this I am confident Australia would reap the benefits currently being derived in the US.

Enterprise G (est. 1992)

Our experience has been that Australia's tax and financial climate does not provide sufficient incentive for venture capital and other financial institutions to take medium to longer term risks. That is, investing in the commercial development of promising R&D which is still at a comparatively immature stage. If anything, this problem is exacerbated by the stock market boom - if an institution has funds to invest, would these go to a fledgling biotechnology company with a lot of good ideas and the prospect of innovative future products, or into blue chip stocks with a solid track record of increasing shareholder value? Of course, the problem is well recognised, but little seems to have been done to materially improve matters. While the recent introduction of the Government's innovation incentive scheme is commendable, it's but a drop in the bucket of what's needed. In the case of our biotechnology company, even though Australia is the major market for our initial future products, we had to go offshore for our venture capital after all our efforts to find an Australian source were unsuccessful.

Enterprise H (est. 1994)

1. Develop an accreditation process which will recognise the businesses performing genuine R&D work. This process when developed will be able to distinguish between tax driven incentives and real research. It will allow the R& D companies to report specifically on individual R&D projects over a number of years and allow the horizon to move from annual to R&D project length.
2. Develop incentive schemes for those companies identified in 1. such as:-
 - Sales tax exemption
 - Higher R&D rebates for expenditure
 - Increased depreciation allowances
 - No pay roll tax on R&D personnel
 - No GST on R&D purchases
3. Remove the current ceiling of \$20,000 on contract R&D provided that the contract company in turn is an accredited R&D business or the project they are contracted to perform is part of the original R&D project.

Enterprise I (est. 1997)

1. Creation of a funding program to allow people to investigate business (not research) opportunities in the biotechnology area. This should provide salary for the principal and then support to prepare a business plan or evaluate the opportunity. This is a program that would support entrepreneurs in a pre-start-up phase. The outcome should be either a business plan or a

document detailing the screening of the opportunity and the reasons that it was not suitable to move to BP stage.

2. Probably a restructure of the CGT in relation to investing money in very high risk ventures.
3. A sound regulatory environment. We have been impacted by a lack of regulation relating to the ownership of biological resources in Australia. Also we have been affected by the wildlife and protection act as it relates to the export of genetic material from Australian organisms.

Other comments:

There is far too much focus on research/development and its 'commercial' applications and not enough on actually getting businesses up and running. Look at your last question "Major field of research/development:", how about "Business focus" or "Major markets"

Enterprise J (1999)

1. Replace or abolish capital gains tax - a number of markets offshore have capital that could be available for investment into Australian start-ups and technology companies. This is particularly true of countries, such as the US, where the capital markets are more mature and knowledgeable. While there is evidence of an excess of venture capital in Australia, there are impediments to access to such money, including competition from other businesses, the administrative process that must be travelled to get access to this money, the high thresholds placed on "minimum investment" by VC companies who have limited people to cover those investments they do make. A capital gains tax discourages offshore investment in Australia and hinders risk taking by those who seek to commercialise on new technologies and startups.
2. More active encouragement of Business Angel type funding. There remains a very large gap in funding for startup companies that fall below the thresholds set by Venture Capitalists. The Enterprise Market does not appear to be working as planned and access to funding for startups and development companies needing less than \$2m is very difficult. Canada appears to have placed considerable emphasis on this area and appears to be having a number of successes.
3. Better public education - there is a lot of concern at present in the general public about Genetically Modified Organisms (GMOs) and genetic engineering. I believe that this could reach a serious crisis point where the public start questioning science in general and a growing mistrust develops. The public need better education of the issues and the role of science, genetics etc in society, and a forum for informed debate.

Enterprise K (est. 1990)

1. Put Australia on an equal footing with the successful U.S. model. The U.S. System forces academic research to commercialise. Thus, in obtaining grants, they must seek out commercial partners, as a general rule. The Australian academic model parallels the British model where commercialisation is not stressed when obtaining grant money. The two should be unconditionally linked together. This would force a cultural change within academia.
2. Change the investment rules for Pension (Not Venture) Funds to equate to the U.S. model. This model, after forcing academia to commercialise, then supplies capital to the commercial partner, by allowing Pension Funds to allocate up to 5% of their assets to high technology industries. This figure is low enough not to risk superannuation returns over the long run. Venture Funds are already allowed to put 100% of assets into risk ventures.
3. The way of course, the Government changes the pension fund rules is via a tax on funds that do not invest in biotechnology. A carrot and stick approach that does not conflict with the Federal Treasury's view of forgoing tax revenue.

Other comments:

Differentiate the tax rates for capital gains. High technology capital gains should attract a lower rate of tax to more traditional forms of investment. The basic concept of risk/return that could be structured to be revenue neutral to the Federal Government. The May 1999 Budget was positive for academic biotechnology institutions. The May 2000 Budget should now focus on incentives to biotechnology corporations, marry the two in consecutive Federal Budgets.

Enterprise L (est. 1998)

1. Revision to current capital gains tax provisions. The proposals outlined in the Health and Medical Research Strategic Review are fully supported as, based on our discussions with overseas investors, we believe they would significantly increase our ability to raise equity.
2. Restructure aspects of the START grant scheme Matching funds, based on equity raised or existing R&D contracts, should be applicable to the entire R&D spend. In our case, the R&D contract is fully funded and fully licensed and our pharmaceutical partner would have it no other way. This results in being ineligible, whereas having the same funds covering two partial projects would leave us eligible. IP and patent costs should also be eligible expenditure from START grants. This is what the biotechnology industry needs, yet is not currently allowed.
3. Additional changes to the environment, investment culture and regulatory environment which permits early stage assistance to new biotechnology start up companies. Increases in each of these areas will enable greater sourcing of funds and development of start ups.

Enterprise M (est. 1998)

1. Easier access to funding - particularly during the 'take it to market' stage. This is when most SMOs have great financial difficulty. Current venture capital sources tends to want to 'mortgage the farm' in a way that almost ensures loss of most equity.
2. Availability of market research data. Most small companies cannot afford the multi thousand dollar cost of the most useful reports.
3. Construct a genuine 'level playing field' in Australia re regulatory [requirements]. Most times Australian companies are required to 'toe the line' whilst imported products often don't meet full regulatory requirements.

Enterprise N (est. 1997)

1. **Enterprise N** is a spin off from [a]CRC and as such is not eligible for the R&D Start Scheme where the technology being developed is a program within the CRC. The government does not want to see double dipping occurring which I agree with, however, there is usually a lot of work that needs to be done in developing IP and CRC's do not usually have a bottomless pit. This policy necessitates that partners (usually overseas) need to be found earlier in the development pathway.
2. The government should re-introduce the 150% R&D Deduction.
3. Government at Federal, State and local levels should look at emulating the Boston/Cambridge and Quebec models for developing the critical mass in biotechnology ie., all levels look at taxation in its various forms and make it attractive for companies to start. In Queensland very few biotechnology companies are located close to universities or research institutes (Vaccine Solutions is an exception).

Enterprise O

1. Introduce a Capital Gains Tax regime that is competitive with the USA capital gains tax laws. Investors are loath to wear the higher risks associated with biotechnology investments unless there is a commensurate probability of a higher return in the future. Current capital gains tax laws ensure approximately 50% of any gains made by individuals go to the Tax Office. This is unrealistic and punitive given the risks that must be borne by biotechnology investors. Accordingly such taxes limit the availability of capital for biotechnology investments.
2. Due to the very long lead times through to commercialisation and the inevitable high investment costs, particularly for pharmaceutical approvals, a concessional corporate tax rate should be offered to, say, the first 5 years of profitable trading. Such a corporate rate of tax should be in the range 10-15%.
3. In order to make investing in biotechnology companies more attractive and again due to the long lead times required before returns are received, Initial or New Capital subscribed to listed and accredited Biotechnology companies should be tax deductible. This would be subject to the subscribers holding the shares for a minimum length of time - say 3 years. If the shares are not held for 3 years then the tax deduction should be clawed back - as in the old MIC scheme.

Other comments:

It is absolutely vital that Australia takes initiative in these areas. Otherwise we will lose the opportunity to become competitive with other countries that adequately promote and support their Biotechnology industries.

Enterprise P (est. 1994)

1. Lack of financial incentives (tax or otherwise) for Australian Super Funds to allocate a greater proportion of funds into medical biotechnology
2. Capital gains taxation regimes for start ups for the 1st 3-5 years
3. AusIndustry requirements that prohibit research institutions from acting as the source for matching funds for start up's