



Commercialising Australian Biotechnology

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Preface

This project was undertaken by Professor Michael Vitale of the Australian Graduate School of Management (AGSM), and was funded by the Australian Business Foundation (ABF) and the AGSM. The Australian Business Foundation sponsors research aimed at advancing new knowledge and detailing new thinking on what will make Australia more competitive and prosperous. This project is part of ABF's cornerstone study on new models for creating growth industries in Australia and for building global capabilities in Australian firms.

Acknowledgements

Thanks go first to the Australian Business Foundation and in particular to its Chief Executive, Ms Narelle Kennedy. Without their support, this project would not have been possible. The AGSM and its Research Director, Professor Eddie Anderson, are also thanked for their support.

Dr Philip Smith was a most capable research assistant and collaborator for the six months following the completion of his MBA at the AGSM. Philip contributed in particular to the data gathering and analysis aspects of the project. He is an excellent example of the potential, still largely untapped, for Australian MBA graduates to add value to the biotechnology sector. Associate Professor David Sparling of the University of Guelph, Ontario, Canada, was an equal contributor to an earlier research project, funded by the Australian Stock Exchange, which examined biotechnology firms that were already publicly listed. Although David had returned to Canada by the time this new project began, he was a willing and helpful sounding board throughout the research.

Finally, but most importantly, sincere thanks go to all of the managing directors, commercialisation officers, venture capitalists, and other senior managers who took time from their very busy schedules to meet with us during the course of this project. Their enthusiasm and dedication remains a constant inspiration.

About the Australian Business Foundation

The Australian Business Foundation is an independent, private sector think tank founded in 1997 and sponsored by the leading industry organisation, Australian Business Limited. It was established in response to concerns about Australia's declining position on world competitiveness benchmarks and fuelled by the urgency for fresh insights and practical intelligence to boost Australia's capabilities and global competitiveness. The Australian Business Foundation has a single mission – to conduct and disseminate ground-breaking research that advances knowledge and fosters new thinking and best practice on Australia's competitiveness, prosperity, and jobs. Details of the Foundation's research can be found at www.abfoundation.com.au

Michael Vitale
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Executive Summary

Background

The primary goal of this project was to create recommendations regarding both institutional policy and organisational strategy that would further the commercialisation of Australian biotechnology research. The recommendations for policy were to be aimed at building a visible, viable, and globally competitive biotechnology sector in Australia. The recommendations for strategy were to be aimed at improving the efficiency and effectiveness of Australian biotechnology organisations. Further, these recommendations were to be based on an understanding of the commercialisation process, including critical success factors and barriers to successful commercialisation. This understanding, in turn, was to be developed through interviews with early stage biotechnology firms and with the commercialisation offices of universities and medical research institutions.

Findings

The Australian biotechnology sector is not yet successful.

Despite decades of effort and hundreds of millions of dollars of spending, the Australian biotechnology sector continues to struggle to achieve a consistently positive image among investors, overseas partners, and consumers. Historically, only one drug – Biota's modestly successful Relenza – has been commercialised from Australian biotechnology research, and as of March 2004 the 40 listed Australian biotech companies had just 8 Phase I and 16 Phase II trials underway. Agricultural and industrial biotechnology, which might be thought to be natural extensions of the country's experience in agriculture and mining, remain essentially undeveloped. A number of Australian states have recently imposed bans on genetically modified crops, just at the time that other parts of the world are running out of scientifically plausible reasons for continuing such bans.

The sector is hampered by inconsistent and incomplete government policies, persistent difficulties in raising sufficient capital, and a shortage of experienced managerial staff. Unless attitudes and policies change, the sector is unlikely to achieve anything close to its potential.

Policies are inconsistent.

Commonwealth and State Governments speak the language of commercialisation, but have failed to put in place policies that encourage universities and research institutes to pay serious attention to the topic. The result is a significant underinvestment in commercialisation, to the point that some publicly-funded Australian intellectual property is not even protected, much less developed into commercially available products.

Government policies are unambiguous with respect to encouraging company formation, but often this formation occurs at such an early stage of development that the corporate structure becomes a substantial drain on resources that could otherwise be devoted to further research. Without adequate training or reliable sources of objective advice, Australian researchers are less likely to make appropriate choices with regard to commercialisation for themselves or for the country.

Funding and staff are difficult to find.

The amount of venture capital being invested in Australian biotechnology is insufficient to allow most of the companies already formed to reach maturity, and there is little reason to suppose that the companies that do survive will be anything other than the randomly-chosen winners of a game of biotech bingo. At the same time, Government policies continue to encourage the formation of still more biotechs, many of which have been accurately described as being less like companies and more like research projects with ABNs.

Venture capitalists claim that there is plenty of money to invest, but a shortage of investment-worthy propositions. If so, serious questions must be asked about the focus of Australian research and the capability of Australian research establishments to create realistic business plans. If not – if Australian venture capitalists have unrealistic expectations about the quality and price of the investments they are offered – then Australian biotechs must find either another source of funding or a way to get along without it.

Experienced staff are also in very short supply, and under current tax policies they will remain difficult and expensive to recruit from overseas until the sector becomes much more established.

There is a need for improvement.

On current indications the Australian biotechnology sector is likely to grow to resemble the Australian IT sector, which includes many integrators and users of IT but very few manufacturers, rather than resembling mining or wines, which began on the basis of a natural advantage and have grown through careful attention to customer needs and the occasional application of focussed government policies. Data from the IT sector clearly indicate that countries that manufacture the technology make quicker and better use of it; the same is likely to be true of biotechnology. The biotechnology window is still open, but it will not remain open forever. Some significant changes are needed if Australia is going to develop an economically significant biotechnology industry.

Recommendations

It's all about the money.

The most pressing need is to attract more capital to support focussed biotechnology research that will bring concepts closer to being products before a company is formed or the intellectual property is sold or licensed. Too often, promising research programs disappear into the “funding gap” that lies between applied research and market development. Additional research at that point is generally aimed at proving a concept and then developing it to the stage at which reasonable estimates can be made about the market potential of products based on the concept. In the US, the UK, and a few other countries, such applied research is heavily supported by philanthropic organisations and institution-specific research investment funds, which are virtually absent from the Australian landscape. Several promising ideas for attracting funding for focussed research have been put forward recently, and should be explored further.

Bringing concepts closer to the market before outside funding is sought should address the concerns of venture capitalists with respect to a lack of investable propositions. It is possible that fewer companies would be formed, but those that were created would be more likely to succeed.

Policy changes are needed.

Universities and research institutes should re-examine the intent and content of their policies on intellectual property, including the share of benefits paid to inventors. In return for receiving government funding for research, these institutions should be expected to devote enough resources to commercialisation to assure that the intellectual property developed by their staff is appropriately protected and then thoughtfully assessed for its potential commercial value. The existence and use of adequate commercialisation processes should become a factor in determining the amount of government research funding provided to a research institution. In addition, government policies that encourage early company formation, and that discourage experienced overseas managers from coming to Australia, should be reconsidered. Some of these policies appear to be driven much more by ideology than by economic reality, and the consequences have not been totally positive for the biotechnology sector.

Australian biotechs must acknowledge market realities.

Australian biotechnology companies themselves are already painfully aware that investor sentiment has swung away, perhaps permanently, from the blue-sky research models that prevailed in the past. The business model most in vogue at present is a hybrid that includes cash-generating activities as well as cash-burning ones. Ideally, these activities will be sufficiently well balanced to avoid the inconvenient need to seek additional funds before the company is well enough developed to support a good valuation. Although celebrating domestic success and feting local heroes is an Australian tradition, biotech companies must remember that their markets are overseas, specifically in America and perhaps in Europe and Asia as well. If they are to succeed, and indeed even to survive, Australian biotechnology companies must be “born global” in the sense that their products, processes, and strategies must be oriented to overseas marketplaces from the day they are formed.

It is important to acknowledge that the appropriate marketplaces may be those that deal in ideas, rather than in finished products. As a medium-sized country distant from the major pharmaceutical markets – the US alone consumes fully 50% of all drugs sold – Australia currently lacks some of the business systems required to bring pharmaceutical products to their final stage. Rather than trying to create these systems, it may make more sense to enhance the ability of Australian biotechs to recognise and increase the value of their research and early clinical concepts, and their skill at selling or licensing these to the appropriate customer. There need be no embarrassment about recognising geographical and economic realities and acting in a way that maximises benefits under the prevailing circumstances.

Chapter 1: Research Methodology and Report Structure

Research Objectives and Methodology

Objectives. This research project focused on early-stage Australian biotechnology companies, which generally have been created within a research institution but have not yet reached the stage of being publicly listed or being purchased by larger companies. The research proposal (16 June 2003) stated the project's objectives as:

1. To examine a sample of Australian biotechnology start-ups and describe the results they have achieved since formation, in particular the degree to which they appear to be achieving success. In addition, to describe the challenges these companies face, the impact of government programs, and the role of external institutions.
2. To create greater understanding of the process of commercialising Australian biotechnology innovations, including critical success factors and barriers to successful commercialisation.
3. To examine the start-up decisions made by research institutions and how those decisions are affected by internal policies and structures as well as by external influences.

Research Methodology. Given these objectives, it was decided to base the research on both qualitative and quantitative data. The qualitative data was to be collected through semi-structured interviews with the managing directors of a sample of start-ups, with technology transfer officers at research institutions, and with others in the sector. Given that the firms of interest are all privately held, it was anticipated that there would be little published information available about them, and indeed this proved to be the case. It was, however, possible to obtain useful information from the records of the Australian Securities and Investment Commission (ASIC) and from a database maintained by the *Australian Venture Capital Journal*.

Because the research is intended to be more than simply a description of the current state of biotechnology commercialisation in Australia, it was decided not to carry out a broad-based survey of the sector. As Hopper and Thorburn note in their recent review of biotechnology in Australia and New Zealand, "The Australian biotech industry has now reached the stage of being severely over-surveyed."¹ Moreover, this research was aimed at small firms – few of the companies eventually included have more than 5 employees – which would be expected to have difficulty finding time to complete a survey. It was also decided not to attempt to interview a randomly-selected sample of companies, again because our interest is in uncovering critical success factors and best practices, rather than in describing the situation of a "representative" group, whatever that term might mean. The sample selection process is described in detail in the next section.

Sample Selection. The first step was to create a list of early-stage biotechnology firms. A large set of candidate firms was created from a number of sources, including industry directories, lists of winners of Government grants, and a database maintained

by the *Australian Venture Capital Journal (AVCJ)*. The set was then narrowed to “core biotechnology” firms, which are defined as firms that:

- Add value on the basis of a patentable biological innovative step
- Face long development times and significant technological and market risk
- Need considerable up-front investment
- Have the potential to reach large markets
- Are neither listed companies nor subsidiaries of other companies

We found 84 such firms, spanning the fields of drug discovery, devices, and diagnostics. Most of the firms focus on human health, but there were a few agricultural biotechnology companies as well. These are exactly the kinds of firms whose success, and indeed whose very survival, has been much debated. Studying them could be expected to provide considerable insight into the future of Australian biotechnology.

Letters requesting an interview were sent to the oldest 50% of the 84 companies and were followed up by telephone. Nineteen firms (see Appendix 1) were interviewed during the course of the study. The primary reasons for not participating were lack of interest, lack of time, and schedule conflicts.

An interview guide was drawn up and pilot tested (see Appendix 3). The interview topics include the reason for company formation, the company’s results to date, a description of any barriers faced, and recommendations for policy changes and capability developments that would reduce these barriers. These topics were developed with reference to the overall goals of the project and the time constraints of the interview subjects.

Qualitative Data Gathering. Qualitative information about the sample companies was obtained through interviews, as described above. The interview subject in each case was the company’s Managing Director or Chief Executive Officer. In most cases two interviewers attended each interview and compared notes afterwards. Interviews were also held with venture capital firms, including the four pre-seed funds formed under the *Backing Australia’s Ability* program. These interviews included a discussion of each firm’s approach to investing in biotechnology, its view of the future of the sector, and recommendations for public policy, education, and other approaches to improve the success of commercialisation of biotechnology in Australia.

Because the great majority of biotechnology firms have their origins in a university or medical research institute, the approaches that these organisations take to commercialisation have considerable influence on the size and strength of the biotech sector. Therefore, interviews were held with commercialisation officers at sixteen Australian universities and research institutes, including CSIRO (see Appendix 2). These interviews covered each organisation’s strategy for commercialisation, its commercialisation policies and processes, the results obtained, any barriers encountered, and recommendations for improvements.

Quantitative Data Gathering. In parallel with preparation for qualitative data gathering, demographic information (location, age, products, management, funding, etc) was gathered from industry directories, ASIC records, and the Internet. Eight of the 84 companies are classified as “large proprietary companies”, and are therefore required to file detailed annual reports with ASIC. These reports were purchased and analysed.

Extensive use was made of the *Australian Venture Capital Journal* database of venture capital investments from 1996 to 2003. This database is widely regarded as the most accurate source of information regarding such investments; informal estimates of its inclusiveness range from 95% upwards. Each record in the database represents an investment by a given investor in a given investee – multiple investors in a given round, and multiple investment rounds, are represented by multiple records. In addition to the investor and investee, the record includes the date and amount of the investment, as well as the stage of the investee company – start-up, seed, early expansion, expansion, or turnaround. The database is divided by sector, including a broadly defined category called “Healthcare and Biotechnology”. The complete set of records for this category was purchased and analysed.

The next step in the analysis was to separate the records related to investments in core biotechnology companies, as defined above. The excluded records represented venture capital investments in gyms, aged care facilities, herbal medicine companies, a factory making false teeth, and a grower of pharmaceutical grade garlic. As interesting, and occasionally profitable, as these investments may have been, they were outside the scope of this research. The remaining records were then analysed to reveal patterns in venture capital investment in Australian biotechnology over the 1996 – 2003 period. The *AVCJ* database indicated that 34 of the 84 core biotechnology companies had received some Australian venture capital funding. This information was particularly useful in preparing for interviews with the sample companies.

Discussion of Preliminary Results. During the course of the study, a number of opportunities became available for presentation and discussion of preliminary results as they were developed. Presentations were given at a forum sponsored by Australian Technology Park Innovations; at ClubBio, the annual meeting of the Queensland chapter of AusBiotech; at the Department of Industry, Tourism, and Resources in Canberra; and at a meeting of the Deputy Vice-Chancellors (Research) of the Group of 8 universities. These presentations were useful both in improving the structure of the presentation of results and in sharpening the statement of the findings and recommendations of the project.

Report Structure

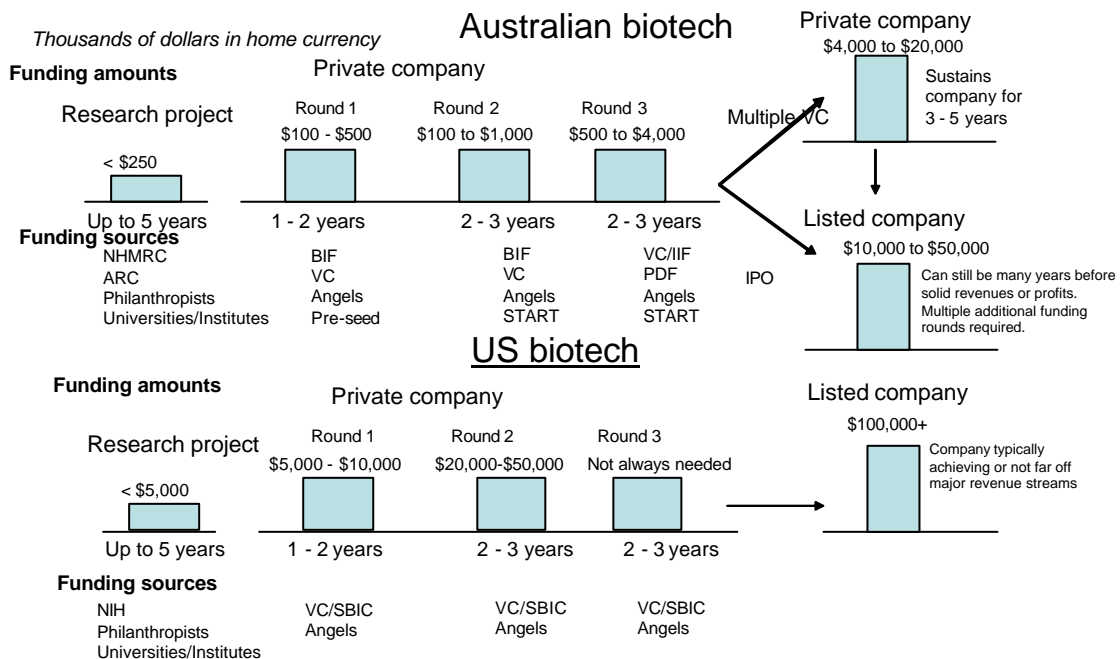
The report is structured into five chapters, beginning with this introduction. The following two chapters describe two defining parameters of the Australian biotechnology sector – the availability of funds and the commercialisation approaches of Australian universities. The fourth chapter describes findings from the sample companies, using the context developed in the previous two chapters, and the final chapter draws together conclusions based on these findings and an analysis of all of the data gathered during the study, and provides recommendations for advancing the biotechnology sector to help create a healthy and prosperous future for all Australians.

Chapter 2: Funding Early-Stage Australian Biotechnology

The Issue

Funding is an issue for any small firm, but the issue is particularly salient for new biotechnology firms due to the nature of the business. The time from company formation to first revenue, much less profit, can be very long. An earlier study of Australian biotechnology companies that listed between 1998 and 2002 found that the companies were, on average, about six years old when they listed. In the financial year ending 30 June 2003, fewer than half of these firms, which were by then almost a decade old on average, had any revenue from product sales; only two had positive cash flow, and only one was profitable. Most of the companies were sustaining themselves with government grants, interest, and the cash raised through public offerings. The latter two sources are not available to unlisted companies, which typically must seek multiple investment rounds. In Australia, the funds available for such investments are generally scant and hard to come by. Indeed, when asked about barriers to success, every company interviewed named raising funds first. The dynamics of the situation are illustrated in the figure below.

Figure 1. Commercialisation lifecycle of Australian and US biotech



Source: "Sustaining the Virtuous Cycle", *Investment Review of Health and Medical Research*, p. 123

Australian biotechnology companies typically raise far less money per investment round than their competitors in America and Europe and complete fewer rounds before listing. Although Australian biotechs pride themselves on their efficiency, and

tend to have lower labour costs than American or European firms, the enormous difference in funding means that Australian firms can run neither as far nor as fast as their overseas competitors. Biotechnology is clearly a globally competitive industry with few protected markets or barriers to trade. Moreover, biotechnology is unlike most other industries in that a discovery by one firm can effectively destroy the value of other firms' investments over a very short period. The company that gets to the solution first can take not only gold but silver and bronze as well. Australian firms enter this competition with a significant disadvantage.

How much money is available?

As indicated in Figure 1 above, funding for a newly-formed biotech company can come from a number of sources, including the university or institute in which the research was done, the traditional "three F's" (friends, family, and fools – the latter including private "angel" investors), and the researchers and others associated with the company. At a somewhat later stage, professional private equity investors may become involved. The four recently formed, government-subsidised "pre-seed" funds are also a potential source of funding. Over the longer term, however, most biotechs will seek venture capital (VC) funding. For this reason, our research included a careful look at the record of VC investment in Australian biotechnology.

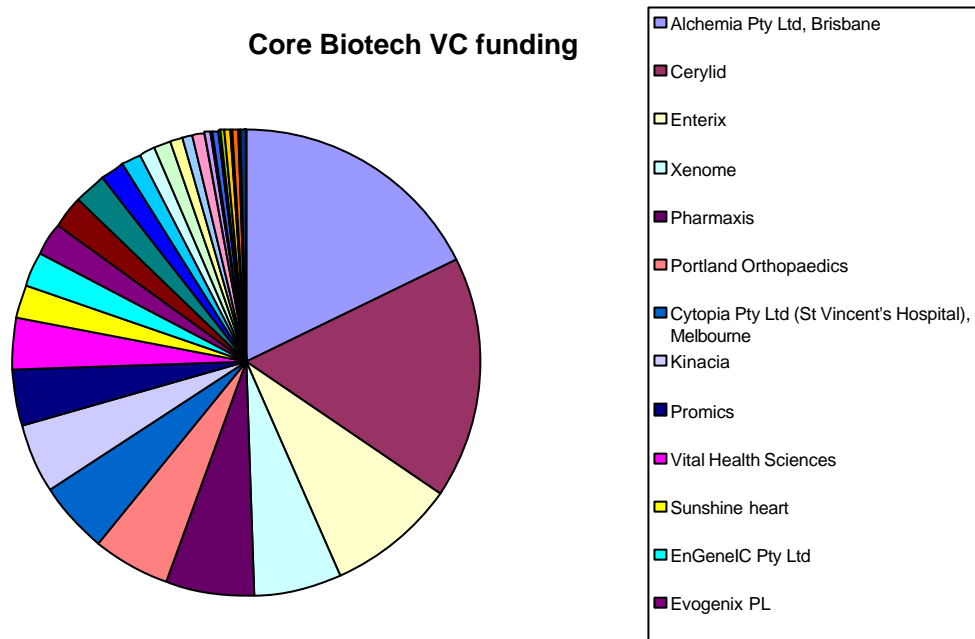
As described earlier, this portion of the research was based on a database maintained by the *Australian Venture Capital Journal*. Although by its very nature venture capital funding is somewhat difficult to track, this database is generally regarded as the most complete source of information about Australian VC investments. The investment records in the database are classified by the sector in which the investee does business. The complete set of records for the broadly defined "health and biotechnology" sector were purchased from 1996, when the database was created, through the end of the 2002 – 2003 financial year. Each investment record was then analysed independently by two researchers, who classified the investee as clearly in the core biotech sector, clearly outside that sector, or on the border. The independent classifications were then compared and the (very few) disagreements resolved.

This analysis indicated that over a seven-year period beginning in 1996, Australian venture capitalists have invested approximately \$130 million in core biotechnology companies. To put this number in perspective, in November of 2003 Australians bet approximately \$120 million on the Melbourne Cup at the state TABs alone. Another point of comparison is that on a single day, 6 February 2004, six American biotechs announced a total of US\$114 million in venture capital funding.² In other words, the total amount invested by Australian venture capitalists in Australian biotechnology companies *over the past seven years* is about the same amount as was bet on a single horse race, and less than the amount invested by American venture capitalists on a single day. No amount of quibbling over the accuracy of the *AVCJ* database or the definition of core biotechnology can alter the fundamental message: Australian biotechs are trying to compete in a global industry from a country in which the amount of venture capital funding is orders of magnitude less than that available to their overseas rivals. There is clearly no point in trying to compete in the same way as those vastly better-endowed firms. Over the long term Australia must invest more in biotechnology, but for the short term Australian biotechs must compete differently.

Where Does the Money Go?

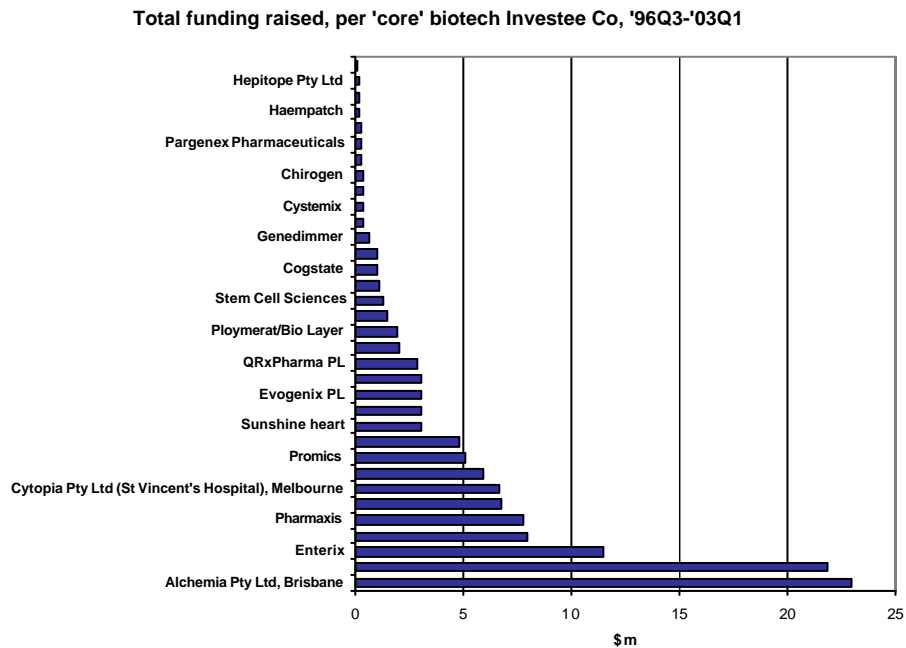
The \$130 million invested by Australian venture capitalists between 1996 and mid-2003 was received by 34 of the 84 privately-held core biotechnology firms. The funding was not, of course, distributed equally. Indeed, four of the thirty-four companies received fully half of the money.

Figure 2. Venture Capital Investment in Core Biotechnology 1996 – 2003



The average size of each investment was very close to \$1 million. As is often the case, however, this average is misleading. The amounts received by the 34 companies spanned a broad range.

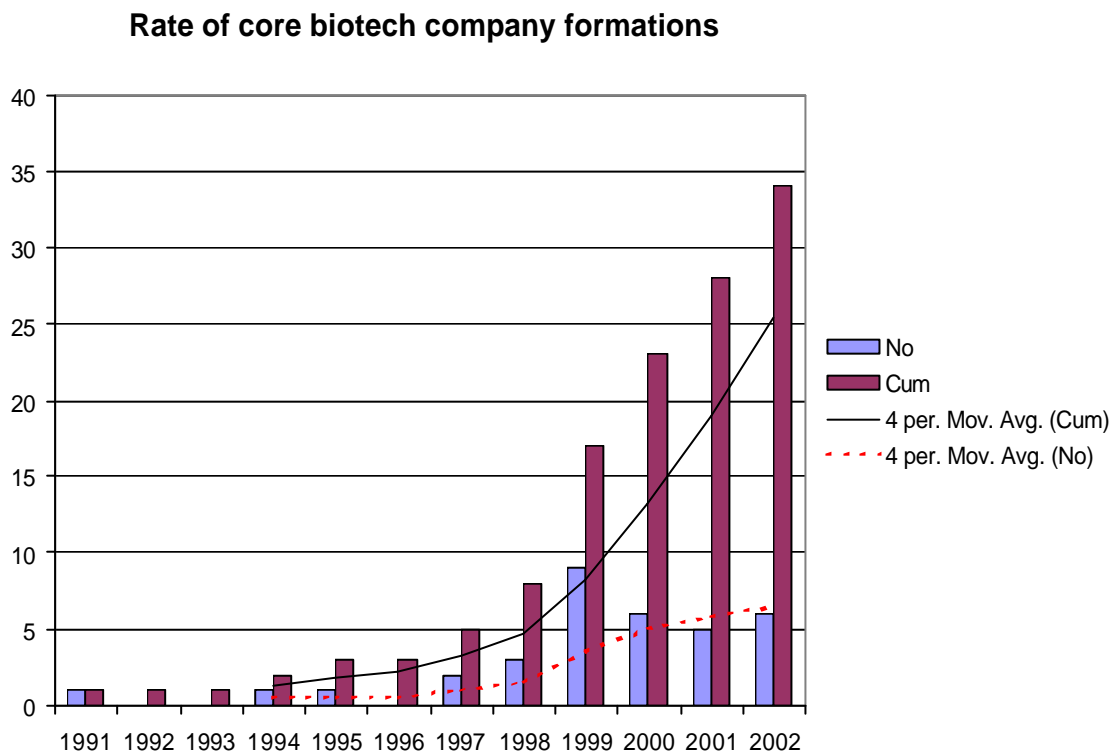
Figure 3. Venture Capital Investment by Company 1996 - 2003



The \$130 million was invested in 328 separate transactions, of which 11 were of an undisclosed amount. The remaining 317 investments have an average of \$1.2 million and a median of \$500,000 – clearly, most investments were small. Presumably, the “best” companies got the most money; an important point is that most companies got very little or nothing at all.

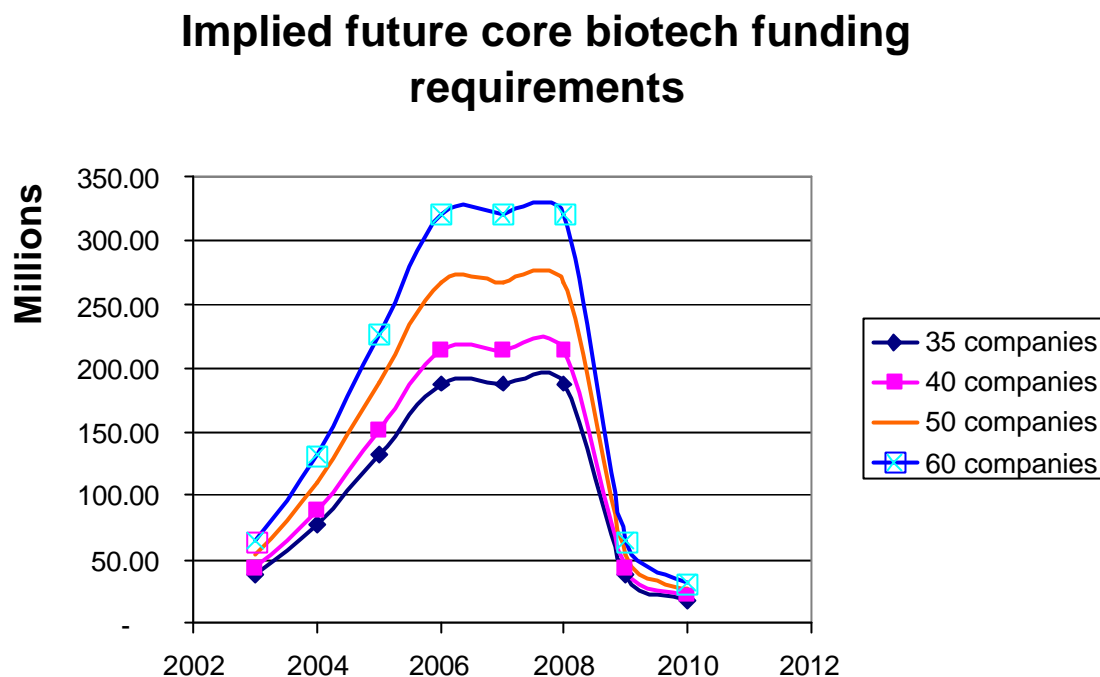
At the same time that existing small biotechs are struggling to gain funding, more companies are being formed. Company formation is an explicit goal of state and commonwealth government programs, including the Biotechnology Innovation Fund (BIF) grant program, and is a frequently cited benefit of university commercialisation efforts. The chart below suggests that these efforts are yielding the desired outcome.

Figure 4. Formation Rate of Core Biotechnology Companies



The chart covers the 34 core biotechnology companies that have received some venture capital funding since formation. The amount invested in each company to date was analysed and used to calculate how much venture capital would be required for each company to develop just one new drug. The same approach was used to determine how much would be needed if some of the currently unfunded companies were to be funded to carry out the same activity. The chart on the following page suggests that by 2005 more capital would be needed annually than has been invested cumulatively since 1996. This amount far exceeds the amount being invested now in the broad “healthcare and biotechnology” sector, and approaches the total amount of venture capital invested in Australia in some recent years. Clearly the level of VC investment in biotechnology is very unlikely to rise to this level. The other possible outcomes for a company that does not receive sufficient venture funding are to fail; to be acquired or merge with another company; to find another source of private capital; to go public; or to struggle on with whatever funds can be raised.

Figure 5. Venture Capital Funding Requirement Implied by Formation of New Biotechnology Companies



The details of the calculation behind the chart can of course be questioned. The general point is that the focus of governments and universities on company creation as an unquestioned good appears to overlook the difficulty of finding the funds to allow the companies to compete successfully over the longer term.

Where Does the Money Come From?

The analysis above indicates a degree of concentration among investee companies. A similar situation exists with respect to the investors: half of the total venture capital invested in core biotechnology between 1996 and 2003 was put in by 14% of the investors – just four companies. The VC picture is illustrated in the charts on the next page. The charts indicate that the Australian venture capital sector currently lacks investors who are willing to make multiple investments of a large average size or to invest a large sum in a number of companies. To some degree these outcomes are driven by the desire to spread risk and the need to comply with limits on the proportion of funds that can be invested in any one company. The latter limits can be particularly difficult given the relatively shallow pools of funds available to Australian VCs.

Of the 19 companies interviewed for our research, all but two had received some VC investment, and eight were among the top 13 companies listed in Figure 2 above. The general view of Australian venture capitalists was that they tend to be conservative and risk-averse compared to their counterparts overseas. Some interviewees felt that the small number of venture capital companies in Australia has led to a less than fully competitive and transparent marketplace for funding.

Figure 6. Average Deal Size vs Number of Deals, 1996 - 2003

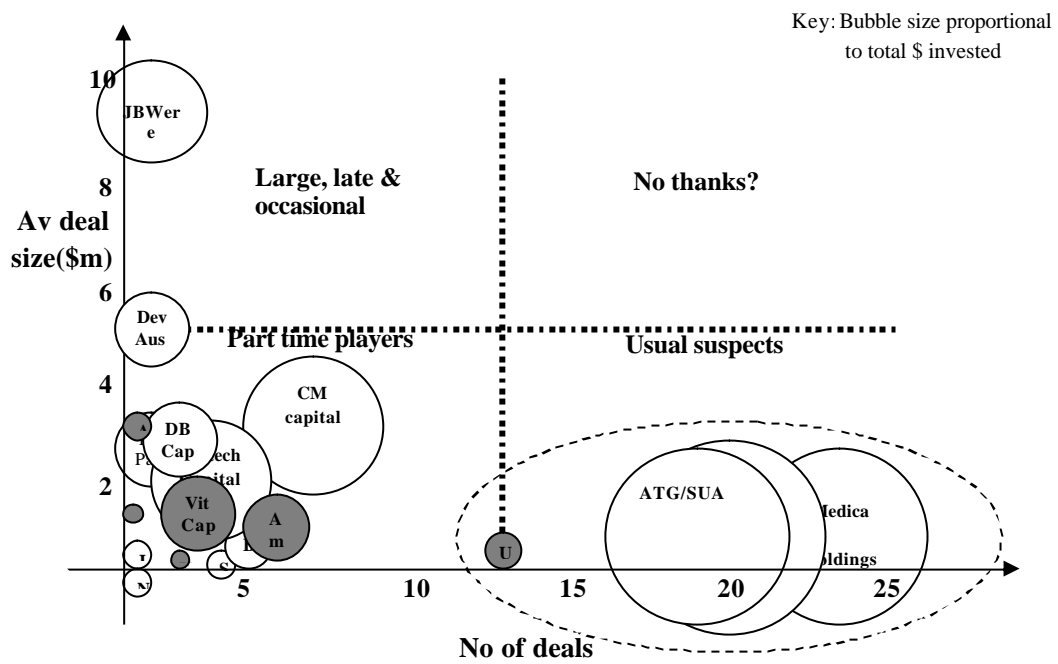
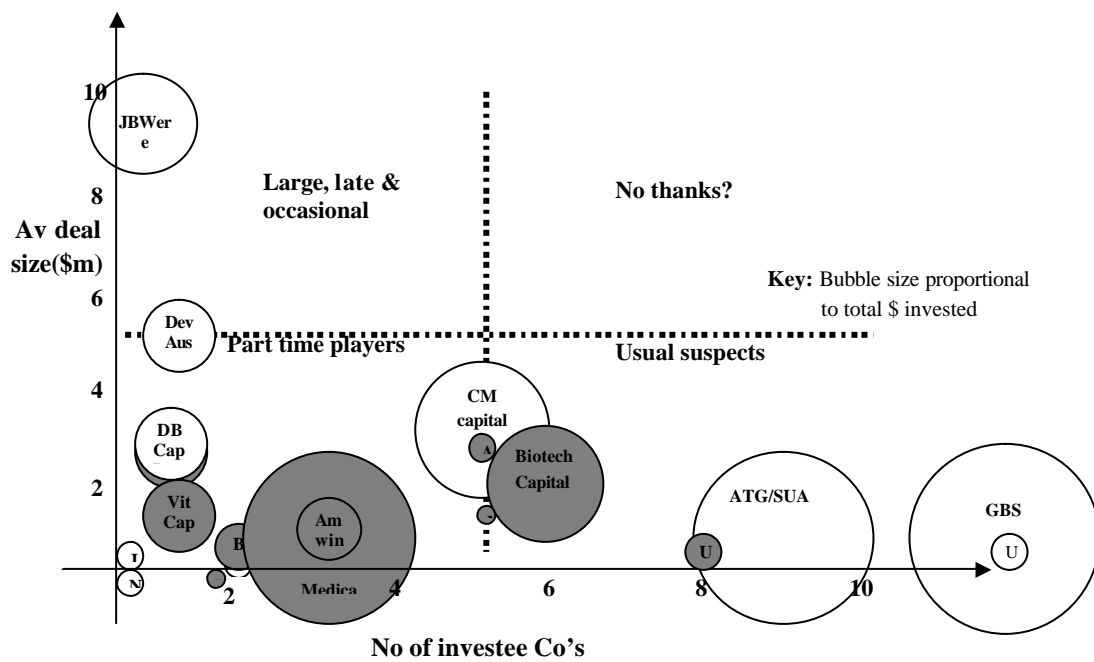


Figure 7. Average Deal Size vs Number of Investee Companies, 1996 - 2003



It might be argued that if opportunities for investment in Australian biotechnology were truly attractive, they would attract funds from overseas. To date, very little such investment has been made. Overseas venture capitalists, particularly Americans, have ample investment opportunities within their geographical and legal comfort zones; there is little incentive for them to take the additional risk created by increased distance and unfamiliar laws. Moreover, until very recently, Australian tax regulations and company law created a substantial disincentive for VC investment in Australia. Efforts to change this situation are underway, and the first Venture Capital Limited Partnership (VCLP) was announced in Victoria on 12 February 2004. The key element of the change is to tax VCLPs and Australian venture capital funds of funds (AFOFs) as flow through vehicles in accordance with internationally recognised best practice for venture capital. As welcome as such changes are, it is not yet clear how much actual capital they will attract.

What Do the Venture Capitalists Say?

Perhaps not unexpectedly, the venture capitalists interviewed for this research see the picture a bit differently. Many claim to have substantial sums to invest in biotech, if only the quality of deals on offer were better. Typically these venture capitalists agree to fund fewer than 5% of the companies that approach them; stories abound of poorly conceived business plans, inadequate protection of intellectual property, incomplete searches for prior art, and delusions of grandeur (and wealth) among boffins who perceive additional funding as their due and expect the same deference from venture capitalists that they receive as professors. In this view, the parlous state of young Australian biotechs is not due to a lack of available funding, but rather to a lack of investable businesses.

Separating cause and effect in this situation is a difficult and perhaps impossible task. Clearly there is room for improvement both in the underlying quality of the businesses seeking funding and in the way they present themselves for consideration. However, it is not clear if such improvement would actually lead to additional investment – perhaps it would just raise the threshold for venture capital funding. On the other hand, some investors believe that the conservative outlook of existing Australian venture capitalists creates opportunities. At least two groups, one led by legendary American biotech venture capitalist Steve Burrill, are currently raising funds to be invested in Australian biotechnology companies. The investment outcomes achieved by these funds may shed some light on the relative accuracy of the opposing views currently being expressed with so much heat.

Summary

The amount of venture capital being invested in Australian biotechnology is very much smaller than the amounts being invested in America and elsewhere. Whether the difference is due to a lack of business acumen and scientific skill on the part of prospective investees, or to a lack of insight and knowledge on the part of investors, may best be seen as a question of definition rather than a question of fact. The one undeniable fact is that Australian biotechs must find a way to succeed with much less funding than is available to their overseas peers and competitors. In this environment, the wisdom of encouraging early company formation may be questioned. While efforts to make additional funds available are underway and should be welcomed, the outcome of these efforts is unlikely to be felt for several years.

Chapter 3: Commercialisation in Universities and Research Institutes

The Issue

Scientific discovery drives biotechnology. The continued expansion of scientific knowledge, technique, and instrumentation means that patentable work must be done close to a library and a laboratory. The days of lone researchers making breakthroughs in their gardens or garages are almost entirely past. Indeed, every one of the 84 private core biotechnology companies identified in this research project had its origins in research done in a university, CSIRO, a hospital, or a research institute. Some of the companies are still housed in, and at least partially owned by, the institution where the research was carried out. Clearly, then, the commercialisation policies and processes of these institutions have a major influence on the development of the Australian biotechnology sector. It was therefore appropriate to include as part of this research project an exploration of these policies and processes.

The Research Process

Although published research into commercialisation approaches and outcomes among Australian institutions is scarce, there is reason to believe that the current situation could be improved. Only about 300 people are employed in commercialisation and commercialisation support activities across all of Australia's major research institutions and CSIRO.³ At many universities, a small handful of staff – and in some cases no-one at all – is responsible for the commercialisation of research flowing from thousands of academic staff across multiple faculties. The magnitude of the task is indicated in the following table. Eighteen universities reported employing one full-time equivalent staff or less for commercialisation.

Table 1. Fiscal Year 2000 Research Expenditures and Commercialisation FTEs

University	Research Expenditure in Millions of Dollars	Full-time Equivalent Staff Employed in Commercialisation Office or Company
Melbourne	290.7	5
ANU	284.4	7.3
Queensland	268.0	7
Sydney	255.2	6.5
UNSW	203.0	9
UWA	168.3	1
Monash	124.3	6

Source: National Survey of Research Commercialisation 2000, Tables A1 and A2

The results of this level of staffing are as might be expected. For example, a recent survey by Research Australia of 500 health and medical researchers found that only half of these researchers would know how to seek help if they identified commercial potential in their research.⁴ However, investment in commercialisation appears to pay off – although the “Group of 8” universities collectively spent only about 50% more on research in 2000 than the other 26 Australian universities as a group, they obtained almost four times as much royalty and licencing income, received more than three times as many US patents, and created more than three times as many start-ups.⁵ An

immediate question raised by these findings is why more is not being invested in commercialisation.

To get at the story behind the figures, interviews were held with commercialisation officers at 12 universities, including all of the “Group of 8”, at three medical research institutes, and at CSIRO (see Appendix 2). Multiple visits were made to CSIRO and to the University of Queensland, which is often cited as being “best practice” among Australian universities with regard to commercialisation. Generally several members of staff were interviewed at each institution, almost always including the head of the commercialisation office.

The interviews were semi-structured, based on a series of questions including the goals and strategy for commercialisation, policies with regard to invention disclosure, ownership of intellectual property (IP), and sharing of revenues, and processes for making decisions, particularly about whether to develop a particular opportunity and if so whether to attempt to sell the IP, licence it, or create a new company around it.

Findings

Goals and Strategy. Research institutions might pursue commercialisation for a variety of reasons, ranging from increasing the public good through to generating income. Most of the individuals interviewed reported that their institutions were not entirely clear about their goals for commercialisation. Indeed, the head of commercialisation at one university resigned his position a few weeks after an interview in which he expressed considerable frustration at the lack of direction from his vice-chancellor with regard to expected outcomes.

In an ideal world, goals drive strategy, and indeed those institutions with explicit goals for commercialisation tended to have well-developed strategies as well. One university, for example, pursues commercialisation largely for the sake of revenue. This university has a separate commercialisation company with well-paid staff whose backgrounds are in business rather than in academia. Decisions about which commercialisation approach to pursue tend to be biased towards licensing, which brings in revenue more quickly than a start-up. Another university sees the goals of commercialisation as primarily political – that is, the primary objective is to demonstrate to the government and the public that the money spent on research is producing useful results. This university expects to “lose money” on commercialisation – that is, there is no expectation that commercialisation will even be self-funding, much less a net revenue generator. For this university, income is a performance indicator, but not an end in itself. Its commercialisation office provides base infrastructure and business services for start-up companies and its staff come from academic backgrounds. A third university came to the view that the primary goal of commercialisation should be generating additional income for inventors. It dramatically reduced the size of its commercialisation office, stopped paying for patenting, and vested ownership of all IP in the academic staff who produced it. The results have been highly unsatisfactory – there has been little disclosure and even less commercialisation – and the strategy is being changed. The point remains that this university, like the other two described, had explicit goals for commercialisation and developed a strategy aimed at achieving those goals. To repeat, most of the universities interviewed did not have a set of clear and shared goals, and tended

therefore to struggle with commercialisation strategy. One reported result of this struggle was low staff morale and high staff turnover.

The record of Australian universities in generating income from licensing, options, and assignments mirrors that of American universities. In general, not much is earned – only ten Australian universities reported gross income of more than \$1 million in fiscal year 2000 – and the expense of generating that income can be relatively high.

Table 2. Gross Income Received and Legal Fees Expended, Fiscal Year 2000

University	Gross Income Received	Legal Fees Expended
Melbourne	\$ 52,000,000	\$ 600,000
Queensland	\$ 6,675,190	\$ 1,434,328
New England	\$ 6,075,407	\$ 11,928
New South Wales	\$ 4,446,000	\$ 559,000
Flinders	\$ 4,223,328	\$ 180,479
Sydney	\$ 1,823,253	\$ 615,622
Wollongong	\$ 1,810,000	\$ 53,000
QUT	\$ 1,283,597	\$ 54,580
UTS	\$ 1,256,961	\$ 125,000
Macquarie	\$ 1,065,300	\$ 248,210

Source: National Survey of Research Commercialisation 2000, Tables A9 and A10. Result for the University of Melbourne includes \$50,000,000 of cashed-in equity in Melbourne IT. Result for the University of New South Wales includes \$ 2,322,000 of cashed-in equity.

Universities that do very well tend to do so on the basis of one “jackpot”. Research in American universities found that the average annual income from a license was around \$64,000, while the average value of equity sold when a start-up company went public was almost \$ 1.4 million. If a few very large sales of equity were excluded, the average value of equity sold fell to about \$ 140,000.⁶ Some start-up companies will, of course, fail before going public. Universities thus face an important policy choice between licensing and start-ups, and it is to that and other policy choices that we turn next.

Policies. Interviews explored policies with regard to disclosure, IP ownership, sharing of benefits, and the licensing vs start-up decision. Again, in an ideal world these policy choices would be consistent with each other and with the university’s goals and strategy for commercialisation. Institutions that lacked explicit goals tended to be less clear and less consistent with their policy choices, presumably due to difficulty in anchoring and justifying those choices.

With two exceptions, the institutions require employees to disclose commercial inventions. A few require a signed acknowledgement of this requirement as a condition of employment; most rely on statements of policy in employee handbooks or other documents. Either the degree of inventiveness or the degree of compliance appears to vary widely. In fiscal year 2000, the University of Queensland accounted for nearly 30% of all invention disclosures among all universities, while 11 universities reported between 1 and 8 disclosures each, and 12 universities reported no disclosures at all. Similarly, the Peter MacCallum Cancer Institute accounted for

nearly half the invention disclosures among fifteen medical research institutes, while 9 of the institutes reported no disclosures at all.⁷ Commercialisation staff at some universities felt they had little support for pursuing non-disclosure, while others were so busy coping with what had been voluntarily disclosed that they had little enthusiasm for taking on more.

With the exception of one university, as noted above, the institutions interviewed asserted ownership of all intellectual property developed by their employees. Again, some institutions required written acknowledgement of this ownership as a condition of employment, while most relied on the common law description of the employer as “master” and the employee as “servant”. Students were always given initial ownership of their own IP, but some institutions required students to waive this right before being allowed to work on certain projects. Some universities vest IP ownership in a separate commercialisation company, while others retain ownership by the university as a whole. This decision appeared to rely as much on historical practice as on an analysis of the advantages and disadvantages of the options. Those interviewed generally felt that their institution’s IP policy was not as clear as it should be; in some cases the policy had not been reviewed for many years, despite many changes in the commercial and technological environments.

Nearly all universities divide revenues from IP licensing and sale on a 1/3 – 1/3 – 1/3 basis, with equal shares going to the university, to the inventor, and to the inventor’s school or department. This split appears to be based on historical practice rather than on any explicit analysis of the costs and benefits of a different arrangement. The medical research institutes and CSIRO adopt the practice common in the commercial world of taking all benefits for the institution. Again, the results of such policies on employee recruitment, motivation, and retention appear to be largely unexamined.

Different approaches to the licensing vs. start-up decision are suggested by the results for fiscal year 2000 indicated in the table on the following page. The difference in outcomes cannot be completely explained by a difference in underlying research activity or direction – institutional policy clearly plays a role. The question then becomes how these policies are formulated, executed, and tracked.

Four of the universities interviewed have a documented process for reaching a decision about whether to pursue an invention disclosure at all, and if so whether to focus on the sale or licensing of the technology, or on the formation of a start-up company. (Most of the universities allow their commercialisation offices a fixed period of time after a disclosure is made in which to reach an initial decision about whether to pursue the disclosure. If the university decides not to pursue a disclosure, then ownership of the IP generally reverts to the inventor, often with a provision for giving the university a small portion of whatever revenue is generated by the IP.) These processes include an assessment of the IP, a patent search, market research, and other investigations, the results of which are measured against the costs of licensing and of a start-up – estimated by one commercialisation officer at a minimum of \$200,000, not including staff time – and the availability of staff to support either licensing or a start-up. Several offices noted that their decisions are biased by the current government emphasis on start-ups and by performance measures that include the number of start-ups formed. Although the institutions seemed generally satisfied

with the results of their decisions, no examples were found of formal evaluation of the decision-making process or its outcomes.

Table 3. Licenses Executed, Start-up Companies Formed, and Patent Applications Filed for Fiscal Year 2000

Institution	Start-Ups Formed	Licenses Executed	Patent Applications Filed
Sydney	6	31	102
ANU	3	8	115
UWA	3	9	10
Monash	3	16	32
Griffith	2	19	1
La Trobe	2	5	7
Murdoch	2	0	0
Queensland	2	63	72
Southern Cross	2	4	15
Deakin	1	1	1
Flinders	1	3	16
Child Health Research Institute	1	4	2
Royal North Shore Hospital	1	2	1
CSIRO	13	168	178

Source: National Survey of Research Commercialisation 2000, Tables A3, A12, and A14

Staffing. All institutions interviewed noted some difficulty in finding and retaining qualified staff. The generally lower salaries paid by the institutions can create an obstacle to recruiting experienced people from industry, while initially inexperienced people have a tendency to leave once they have become attractive to the commercial sector. The recruiting problem is more difficult outside the capital cities. Several universities had experimented with staff bonus schemes, but all save one had abandoned those schemes after encountering difficulties in determining an appropriate basis for bonus compensation. The research did not include any interviewing outside of the commercialisation offices, so there is no objective basis for reporting the effectiveness of commercialisation staff nor their relationship with academic staff and administrators. Anecdotally, these relationships appear to span a range from close and cooperative to distant and distrustful.

Nearly half of the universities interviewed have adopted a “hub and spoke” model for staffing, in which some commercialisation staff are located in, and at least partially paid by, various faculties, while other staff remain in the commercialisation office to provide support and supervision. The initial goals of this model are to provide education and to promote disclosure by integrating commercialisation staff into the working environment of the researchers. This approach appears to have been quite effective wherever it has been tried, provided that the distributed staff have at least some background in the work of the faculty to which they are assigned and are able to interact successfully with the researchers in it.

Observations

In fiscal year 2000, the latest year for which figures have been released, Australian universities, medical research institutes, and the CSIRO spent more than \$ 2.8 billion on research, with the overwhelming majority of the money provided by Commonwealth and state governments. In that same year, these institutions received about \$ 103 million in income from commercialisation, nearly half of which came from a one-time event, the float of Melbourne IT.⁸ This income is, of course, not the only benefit that was generated by the research, nor is commercialisation the only reason for undertaking research – indeed, much of university research is done in areas in which there can be no realistic expectations for any commercial return at all. However, our interviews confirmed the story suggested by the hard data – Australian universities are devoting comparatively little effort, and in some cases no effort at all, to commercialisation. One consequence of this lack of investment in commercialisation may be that Australian academics are relatively poorly informed about the steps required to commercialise their research, and about the realities of the global biotechnology marketplace. In turn, they may have relatively little idea of how the companies they form are actually going to make money. This lack of awareness could well be the beginning of the cascade of activity that leads to premature listing and subsequent difficulty progressing beyond the embryonic stage.

A few vice-chancellors were described by commercialisation officers as strong supporters of their efforts, but more were termed indifferent or even hostile. Indeed, without clear performance expectations in the area of commercialisation, vice-chancellors could be expected to devote little attention to it. As noted above, the financial returns are generally small, in some cases insufficient to recover the cost of running the commercialisation office. The other potential benefits of commercialisation – increasing the public good, promoting economic growth, building closer ties with industry, and recruiting and retaining staff and students – are long term and difficult to measure. Attempts to require disclosure and assert ownership of IP are likely to irritate some members of academic staff. Commercialisation staff are difficult to find, expensive to employ, and hard to retain. If a vice-chancellor is neither philosophically attuned to commercialisation nor measured on it, it is less likely to occur – little wonder that one-third of Australian universities reported no income whatsoever from commercialisation in fiscal year 2000.⁹ The current situation is inconsistent – governments pour in money for research at one end of the system, but do not require any effort to convert the results of that investment into commercially available products or services. Suggestions for addressing this inconsistency are given later in the report.

Chapter 4: Findings from the Sample Companies

Introduction

This chapter describes the major findings from interviews with the 19 private “core biotechnology” companies that were included in this research project. These companies are listed and briefly described in Appendix 1. Each company is interesting, and each would be worthy of an individual case study. However, since the main aim is to identify lessons learnt, best practices, and recommendations for the future, and remembering that each company was promised confidentiality as a condition of participation in the research, the findings are presented in summary form, supplemented with anonymous examples and anecdotes as appropriate.

Issues

Funding. As indicated in chapter two, every company interviewed nominated, without prompting, funding as their biggest issue. Chapter 2 gives the quantitative dimensions of the situation – Australia is many millions of dollars short of venture capital funding for the biotechnology companies that already exist, leave alone the companies that continue to be formed. The interviews added a qualitative dimension to the picture, suggesting that cash is not the only piece missing from the funding puzzle. Although a few companies had positive comments about Australian venture capitalists, the majority of those interviewed saw the Australian VC industry as underdeveloped, inexperienced, and in pursuit of goals that are not compatible with the typical timeframes of biotechnology – one of the companies interviewed is pursuing a concept discovered thirty years ago, and another expects a further decade to elapse before bringing a product to market.

Five companies in the sample are developing medical devices or delivery mechanisms for established drugs. These companies reported less difficulty in raising money than the others, which are attempting to discover and develop new drugs. In general, devices come to market more quickly, have fewer regulatory issues, and are lower risk than drugs, and therefore are thought to be more attractive investments even though the potential returns are somewhat lower. In addition, devices are subject to the sort of continuous improvement through tinkering that Australians are said to be very good at.

Although a few Australian venture capital firms specialise in biotechnology, most feel that they lack sufficient scale in the sector to justify having a staff member who focuses on the area. At least two of the sample companies had deliberately shaped their product concepts so that VCs with no expertise in biotechnology could easily understand them. Another firm related the experience of meeting with a VC firm and being told, “We don’t have a biologist on staff, so we brought along our geologist instead.” There is obviously a chicken and egg problem here – VC funds without expertise in biotechnology tend to make few investments in the sector, and funds without investments in biotechnology tend not to acquire expertise. Few companies saw much prospect of a substantial increase in Australian venture capital funding for biotechnology in the near future.

On the other hand, at least two groups with strong overseas connections – one to Burrill & Co, perhaps the world’s best known private investor in biotechnology, and the other to MIT – are currently attempting to raise substantial amounts of capital for investment in Australian biotechnology. If both funds achieve their minimums, the amount raised will exceed the \$130 million invested in core biotechnology between 1996 and 2003. At least as important as the money from overseas may be the arrival of a new, and perhaps less risk averse, approach to investing in early- stage biotechnology.

Most of the companies also saw other sources of funds as problematic. Taxation and distance are, in the experience of the companies interviewed, difficult issues for overseas investors, who generally have many investment opportunities closer to home and in more favourable and better known tax environments. Some of the companies had received private equity investments, but private investors too tended to be inexperienced with biotechnology and somewhat suspicious of it. Several of the companies had formed relationships with overseas pharmaceutical, biotechnology, or consumer goods companies, as a result of which they had received milestone payments or other revenue. Executives of all of the companies recognised the importance of connections with overseas companies, but those without previous overseas experience found it difficult to form and maintain such relationships. Moreover, individual relationships once formed were constantly subject to the vagaries of corporate reorganisations, changes in focus, or the continuing series of mergers. One company’s long-planned and carefully rehearsed presentation to a corporate partner was effectively nullified when an unrelated fall in the partner’s share price sent managers scurrying to look after their superannuation investments rather than listening to a pitch from a tiny company based in Sydney. Other companies told similar stories, emphasising the difficulty of dealing with much larger companies on the other side of the globe. Unfortunately, given the complete lack of such partners in Australia and the importance of such relationships, many companies will have little choice but to continue to invest the time and resources required to seek and maintain partnerships.

More than one-third of the companies in the sample had received grants under the Biotechnology Innovation Fund (BIF) program. These grants offer up to \$250,000 in matching funds for firms to develop as businesses. Many recipients of BIF grants are able to find state government funds for their share of the matching, and thus can get something close to half a million dollars without investing much of their own cash. A few companies had also received START grants, which offer substantially more money but are much more competitive than BIF grants. Although BIF, START, and other grants were clearly welcome, it is obvious that companies – as opposed to research projects – must quickly move to find revenue by contract, rather than by grant, if they are to succeed.

In this difficult funding environment, many of the companies interviewed saw “listing early” as their only alternative. Although they were wary of the administrative overhead involved in a listing and running a public company, most managing directors expected to pursue this option at some point.

Staffing. The second issue for nearly every company interviewed was finding staff with relevant commercial experience. Few difficulties were reported in recruiting scientists, but finding people with expertise in commercialisation, deal structuring, or business development had been difficult for every company that had tried. The required expertise is generally acquired through working in the pharmaceutical industry, which is virtually non-existent in Australia. Thus the required staff must be recruited from overseas – a difficult, risky, and expensive proposition.

Some of those interviewed presented a slightly more nuanced view of the recruiting situation. They had no general difficulty in finding scientific staff, but they were not satisfied with the level of business acumen or the sense of urgency. Again, the lack of large pharmaceutical research laboratories leads to a shortage of researchers with commercial experience or orientation. “There is a very steep learning curve for researchers from academia,” one managing director commented, while another pointed out, “Salaries in the Australian academic sector are so poor that people who end up there are not cash driven – the good ones are highly competitive, but they don’t really want to get rich.” This manager found it difficult to find the appropriate mix of scientific and research experience and commercial motivation.

Australian tax regulations, particularly with regard to options, compound the difficulty of bringing staff from overseas to Australia. The tax treatment of options is complex – one company reported spending large amounts of money for advice without getting a clear answer – but in general options are taxable as income as soon as they are received, rather than when they are exercised. Staff receiving options thus may be liable for a large tax bill well before they have received the cash to pay for it. “Americans think our treatment of options is a joke,” one managing director said. Another commented that the view of the ATO appeared to be that everyone receiving options was a crook; several others noted that in the current tax environment options were of no motivational value whatsoever.

Conversations with recruitment firms suggested that the frustration with the staffing issue is nearly universal – even the head hunters are restless. In the view of some recruiters, Australian biotechnology executives are often unnecessarily detailed in their requirements for new staff and are willing (or perhaps able) to invest very little in staff development. The outcome is that Australian jobs go unfilled while candidates who get a tick in most, but not all, of the boxes find jobs overseas. This may be an indication of the relative immaturity of the Australian biotech sector or the inexperience of its managers; in either case the question is whether the sector can survive long enough for the problem to be solved by the passage of time.

Positives

Although generally optimistic about the prospects for their own companies, the executives interviewed were not able to identify many positive aspects of the Australian environment. BIF and START grants were certainly well regarded; for some of the companies interviewed, these grants had made the difference between survival and extinction. The Commonwealth government and the Victorian and Queensland state governments were seen as strong proponents of biotechnology, and Austrade was mentioned several times as an organisation capable of opening overseas doors for Australian biotechs. Finally, R&D tax credits were viewed positively, although the amount of paperwork required to get them was generally seen as

excessive. The cash rebate for R&D tax credits was also viewed positively, although the relatively low cut-offs for company size and R&D spending were seen as arbitrary and perhaps an indication that the government is not serious about promoting biotechnology.

Critical Success Factors

The companies interviewed are survivors. They were chosen from among the longest-established of the 84 private core biotech companies in Australia. Advice from the senior executives of these companies should therefore be regarded as well worth consideration. Most of this advice focussed on the creation and evolution of a company's business model.

Most of the companies interviewed have the long-term goal of drug discovery. Most have adopted a "hybrid" business model, which includes some sort of short-term cash-generating activities to fund the long-term discovery process. These short-term activities include cognitive testing, licensing out non-core aspects of technology, selling the rights to some lead compounds, and developing medical devices. On the cost side, the companies interviewed recommended avoiding large fixed costs by contracting for research, development, and manufacturing until the company could afford to bring these activities in-house.

Another acknowledgement of the funding situation for Australian biotechs was advice from quite a few of the companies with regard to products and markets. "We're not going to be able to fix the money problem," one managing director commented, "so we need to aim for niche markets." "Availability of funding is the rate-limiting step," another managing director said. "The number of leads we can pursue is directly related to the amount of money we can raise." The important point here is that planning for products and markets must incorporate a realistic view of the likelihood of gaining additional funding.

America represents fully 50% of the world market for pharmaceuticals, so companies pursuing drug development must assure that the US Food and Drug Administration (FDA) will approve their products. This necessity has implications for the entire development process, including pre-clinical trials. The companies interviewed recommended using a consultant or advisor with FDA experience from an early point in product lifecycle. Similarly, the companies recommended, and reported good results from, using specialist American patent lawyers to provide advice on patenting and IP protection in general.

A few of the companies interviewed had already tried selling their products in America, with mixed results. One company hired and trained a sales force of Australians, who were then sent to America to establish an American office and to sell a product that had already been highly successful in Australia. After six months, the team had not made a single sale. "If it doesn't say 'made in America,' the managing director of this company said, "It might as well say 'made in Afghanistan' – they're not going to buy it." The company replaced its sales force with Americans and took "made in Australia" off its packaging. They then presented themselves to the American market as a company with an interesting product that for some odd reason had been extensively tested and then sold in Australia. The revised sales approach has been highly successful. The challenge presented to Australia is to find ways by which

its biotechnology companies can retain their essential and valuable “Australianness” while fitting in with the customs and habits of overseas markets.

Only a few of the companies interviewed had any links to Asia or Europe, or any plans to establish such links. One company has an important and successful partnership with a Japanese company, and another has developed its links to the UK to the extent that it is about to move its headquarters there from Melbourne. For the most part, however, to the degree that the companies look overseas at all they are focussed on America and its established IP protection regime, well-studied regulatory processes, and potentially lucrative reimbursement schemes. It is prohibitively expensive for any one of these companies to explore individual overseas markets on its own; a government-sponsored market research project or study tour would be good ways of establishing the potential of overseas markets outside the US for Australia’s new biotechs.

Summary

Although there may be few real surprises in these findings, they are not unimportant. The ongoing difficulty of raising funds and finding staff must be taken into account in the business models and strategies of Australian biotechnology companies. Some argue that one impact of these factors is that Australia is unlikely ever to produce a runaway success – “the next Genentech” – but rather must content itself with a flock of niche players that will never accomplish much on the world stage. In this view, Australia’s role in the biotechnology industry will be about the same as its role in the information technology industry – at best an intelligent consumer of products owned and developed elsewhere. The final chapter includes some recommendations for avoiding this outcome.

Chapter 5: Conclusions and Recommendations

Overview

Australia is an acknowledged global player in two industries – mines and wines. The success of these industries is based on a significant amount of investment over a long period of time in areas where Australia has a substantial natural advantage – ore in the ground in the one case, soil and climate in the other. The effort and courage of those who built these industries is by no means diminished by pointing out the wisdom of their choice to compete in sectors where the playing field could be made more or less level. Moreover, once a claim is staked or the vines are in the ground, no-one else can dig up the ore or harvest the grapes – market conditions may change, but the total value of the investment is unlikely to be lost on the basis of someone else’s actions.

Biotechnology is a different story entirely. Australia is English speaking and has a stable political environment, a good education system, and a creative population. None of these advantages, however, is unique to Australia. If Australia chose for some reason not to allow mining, the ore under Australian soil would remain forever unexploited. If Australia chooses not to participate effectively in biotechnology, the discoveries that might have been made in Australia will simply be made elsewhere, even if somewhat later. The country has a choice, and success is not mandatory.

Given the manifold difficulties facing the Australian biotechnology sector, it would be relatively easy to develop a long list of reasonable recommendations for governments, universities, and the companies themselves. The true usefulness of a list of ideas, however, may be inversely proportional to its length. In that spirit, the report offers just three recommendations for each group of stakeholders – recommendations that are believed to be not just beneficial, but essential to the success of Australian biotechnology.

The Role of Government

Governments around the world play a large role in funding the research that drives advances in biotechnology. Because the Australian tertiary education sector is largely publicly funded, Australian governments play even more important roles. The findings of this report suggest that these roles are sometimes inconsistent and even conflicted. For example, the Commonwealth Department of Industry, Tourism, and Resources uses the BIF grant program to encourage company formation, while the Australian Taxation Office treats share options in a way that makes it difficult for new companies to recruit the staff that they need in order to grow. The Department of Education, Science, and Training gives universities money for research, but does not require them to devote any effort to the commercialisation, or even to the protection, of the intellectual property that the research generates. Our recommendations for government are primarily aimed at increasing the consistency of policy and activity.

G1. Reconsider the current policy emphasis on company formation, in light of the ongoing shortage of the money and people that are required for companies to grow beyond the embryo stage.

The focus on company formation appears to be grounded in ideology, rather than on economic fact or theory. Premature corporatisation can distract scientist-managers from their research and lock up intellectual property in isolated pieces. At the very least, ways should be sought to avoid forming companies as the only way of getting additional research funding (see R1 below). There is no suggestion here that enthusiastic entrepreneurs should be discouraged from pursuing their dreams. However, given that most biotechnology ventures originate in universities and research institutes, and that these institutions do not in general invest much in education about commercialisation, it may well be that a focus on company formation is leading to distorted decision-making about the most appropriate commercialisation pathway.

G2. Reconsider the tax treatment of share options, particularly in unlisted companies, and consider offering tax incentives for overseas Australians to return to work in Australia.

The current tax treatment of share options is difficult to understand and seemingly punitive in intent. Particularly for staff being recruited from America, where share options are a very common form of management incentive, the Australian approach offers very little motivation. A few fellowships are already available to bring high-profile scientists back to Australia; this program could be extended to the commercial sector by offering individual or company incentives to bring experienced biotechnology managers home.

G3. Develop a “carrot and stick” approach to encouraging universities and research institutes to pay more attention to commercialisation. Offer contestable funding for the improvement of commercialisation activities. Reduce research funding to institutions that do not develop effective approaches to commercialisation.

The third recommendation may seem particularly aggressive. The question to be answered is whether the Commonwealth and state governments are serious about commercialisation of the intellectual property that the public has paid to develop, or whether they will continue to act as if exhortation alone will somehow have a positive effect.

The Role of Research Institutions

Universities, research institutes, and the CSIRO are the birthplaces of virtually all Australian biotechnology companies. The behaviour of these research institutions therefore has a profound influence on the development of Australian biotechnology. It was surprising to see, even in some large institutions, a relative lack of resources

and lack of attention devoted to commercialisation, beginning with the identification and protection of intellectual property. There should be no expectation that every project undertaken by a research institution must lead to commercial returns, even over the long term, but it would appear reasonable to expect that the commercial potential of each project be considered, and that such potential be developed when possible.

R1. Seek ways to keep research projects in the institution longer, rather than forming companies at a very early stage.

The key is to find ways to allow the private capital markets to invest in a portfolio of carefully-managed research projects. One university has already secured funding from a state superannuation fund for this purpose. This and other avenues should be explored by other research institutions, with the goals of increasing funding for research and improving the chances of successful commercialisation.

R2. Adopt equitable, transparent, and ideally uniform policies regarding the ownership of intellectual property and the sharing of any benefits arising from IP commercialisation.

Many of the university commercialisation officers interviewed said that their institution's IP policies were out of date, not widely understood, and not always followed. This situation becomes particularly problematic for potential investors when researchers from several institutions, working under different IP regimes, collaborate on a project. Policies for sharing benefits should be re-examined to see what impact alternatives to the commonly-used "1/3 – 1/3 – 1/3" rule for sharing the proceeds of successful commercialisation would have.

R3. Develop clear goals for commercialisation, and strategies, policies, and processes that support those goals.

A clear understanding of the purpose of their activity would help commercialisation offices be more effective, as well as removing a potential source of misunderstanding in their interactions with research staff. Different institutions will, legitimately, have different goals for commercialisation, in line with their overall institutional goals, and will therefore have different commercialisation strategies, policies, and processes. The important point is that these, and their linkage to institutional goals, be made explicit.

The Role of Companies

Our recommendations for biotechnology companies are based on the experiences of a score of survivors, and on our findings with regard to the context in which these firms compete. There seems little reason to believe that funding will get much easier to obtain in the near future. Although incremental gains should be pursued, Australian biotechs are very likely to continue to receive significantly less funding than their overseas competitors. This reality must be reflected in the approach that the companies take to products and markets. A related reality, which also will not change soon, is that the major market for the majority of biotechnology is in the United States. This remains true whether a company aims to sell or license a product to "big

pharma” at an intermediate stage of development, or to somehow take a finished product to market on its own.

C1. Adopt strategies and tactics that reflect the realities of funding in Australia.

Although many Australian venture capitalists say there is already plenty of money around, and other groups are attempting to raise large pools of capital for investment in Australian biotechnology, the fact remains that venture capital is difficult to get, comes in small chunks, and is available from only a small number of firms. This environment, so different to that in America, may change over time, but for now young Australian biotechs must develop products, business models, and spending plans that reflect the current reality. Ideally the founders of these companies would be able to get advice on these matters from their institution’s commercialisation office. In reality, these offices do not even exist at some research institutions and are significantly under resourced at others. Other sources of advice include Commonwealth and state programs such as COMET and the NSW Enterprise Workshop, seminars sponsored by organisations such as ATP Innovations and the Australian Institute for Commercialisation, and consultants.

C2. Focus on the markets in America, Europe, and Asia, not the market in Australia.

Australia represents less than 1% of the world market for pharmaceuticals. Most biotechnology companies need to be “born global” in the sense that FDA approval should be a goal from the start. FDA approval will remain the “gold standard” for biopharmaceuticals and devices for the foreseeable future. Depending on their product, some companies may find it worthwhile to explore potential markets in Europe and Asia as well as in the US. Certainly Australian biotechs intending to sell or license their products to larger organisations, which will carry out the final stages of development and then marketing, should seek partners in Europe and Asia as well as in America.

C3. Be prepared to spend time and money recruiting staff, particularly in areas where commercial experience is essential.

At some future time the Australian biotechnology sector may have grown to the point that it is creating the experienced staff it needs. For now, however, the lack of large pharmaceutical companies and low business spending on research in general mean that many growing biotechnology companies will have to look offshore for the senior people they need. Changes to tax policy (see G2 above) would help attract such people, but recruiting from overseas will always be time consuming and expensive. This drain on resources needs to be factored in to a company’s business plan.

Appendix 1: Firms Interviewed

Firm Name	Location	Formed	Focus	Notes
Acrux	Melbourne	1998	Transdermal drug delivery	
CBio	Brisbane	2000	Autoimmune and inflammatory diseases	May merge and relist with Bresagen, which is currently in administration
Centec	Sydney	2001	Autoimmune and allergic diseases	Two BIF grants
Cerylid	Melbourne	1993	Discovery of new medicines from natural sources	Formerly Exgenix May merge with Kinacia, then list
Chirogen	Melbourne	2000	Synthesis of enantiomerically pure compounds	BIF grant
Cogstate	Melbourne	1999	Neurodegenerative disorders and conditions	ASX listing 13 February 2004
Cortical	Melbourne	2003	Inflammatory and proliferative diseases	BIF grant
Cytopia	Brisbane	1998	Cancer, immune disease	BIF grant
EnGeneIC	Sydney	2000	Anti-cancer pharmaceutical	BIF grant
Evogenix	Sydney	2001	Novel protein drugs	Formerly Diapep
Inhalix	Sydney	1998	Measuring and preventing personal exposure to health damaging airborne particles	In liquidation
Kinacia	Melbourne	1991	Blood clotting diseases	Formerly Thrombogenix
Portland Orthopaedics	Sydney	1999	Prosthetic devices	IPO 2004
Promics	Brisbane	1999	Autoimmune and inflammatory diseases	BIF grant
Proteome Systems Ltd	Sydney	1997	Proteomics technology, proteomic bioinformatics, and discovery of biomarkers and drug targets	IPO 2004
Stem Cell Sciences	Melbourne	1994	Cell-based gene and drug screening	Has moved to Edinburgh
Sunshine Heart	Sydney	2002	Artificial heart	
Vacquel	Brisbane	2001	Vaccine delivery systems and vaccines	BIF grant
Xenome	Brisbane	1998	New pharmaceuticals from the venom of Australian animals	Formerly Venoms BIF grant

Appendix 2: Commercialisation Offices Interviewed

Australian National University
Charles Sturt University
CSIRO
Garvan Institute (Sydney)
Griffith University
Institute of Molecular Biology (Brisbane)
Macquarie University
Monash University
Southern Cross University
University of Adelaide
University of Melbourne
University of New South Wales
University of Queensland
University of Sydney
University of Western Australia
Walter and Eliza Hall Institute (Melbourne)

Appendix 3: Interview Guide

AGSM Biotechnology Research Questionnaire

Date _____
Company _____
Person interviewed _____
Interviewee's position _____
Interviewer(s) _____
Company Case No _____

Section One: General Strategy and Product

1.1 Can you describe for us the primary type of work your company does?

1.2 What would you describe as the Key Success Factors to compete successfully in this area? What resources are you currently constrained by?

	Key Success Factors required	Current resource constraints
1		
2		
3		
4		

1.3 What is (are) your companies main area(s) of technology expertise

	Genomics
	Diagnostics
	Lead compound identification/screening. Targets
	Bioinformatics
	Services
	Biomaterials/bioactives
	Delivery mechanisms
	Libraries/databases
	Platform technologies
	Proteomics
	Tissue engineering
	Medical Devices

1.4 What were the reasons for company formation?

	Obvious commercial potential
	Desire to build a large life science company
	Just in case research became valuable/commercialisable in the future
	Tax/regulatory/legal liability reasons
	Remuneration / incentivisation of scientific staff

1.5 How many product lines do you have under development?

1.6 How would you classify your end product?

1.7 At what stage of the development pipeline (pre clinical – Ph 4) is your most advanced product?

1.8 How many years would you estimate you are from generating your first product revenues? _____

Section Two: Marketing

2.1 What percentage of revenue (capital for pre-revenue firms) is invested in market research? _____%

2.2 What is the primary market for your product (s) _____

2.3 What is the \$ size of the addressable primary market?

\$ _____ p.a

2.4 How many competitors are targeting this market and how substantial are they?

2.5 Given the above, what percentage of the addressable market would you estimate you could realistically capture in a years 1, 2 and 3 of production? Do you have a base, best and worst case scenario?

Year 1: Best _____ %, Base _____ %, Worst _____ %

Year 2: Best _____ %, Base _____ %, Worst _____ %

Year 3: Best _____ %, Base _____ %, Worst _____ %

2.6 What is the growth rate in this market? _____ % pa

2.7 What are the primary customer profiles and/or segments?

Section Three: Finance

3.1 What have been your historic sources of funding?

3.2 Do you have any joint ventures, alliances or licensing deals in place currently?

Yes/No

Details:

3.3 What do you anticipate as future amounts and sources of funding required getting to market?

3.4 Which government programs has the company been involved in and how helpful were these?

IP advice

General commercial advice

3.5 Does the company generate sales revenue? How much? What are the sales revenue as a proportion of capital raised so far?

Revenue last fin yr \$ _____
Revenue expected this yr \$ _____

3.6 Does your company generate operating profits, if so how much in the last year?

Profits last fin yr \$ _____
Profit expectation this yr \$ _____

Section Four: HR Issues

4.1 What is the level of commercial experience of the current MD/CEO?

Commercial Experience _____ yrs

Life science management experience _____ yrs

Life science commercialization experience _____ yrs

4.2 Does your company have a separate board of directors?

Yes/No

4.3 What are the combined years of commercial experience of the executive team?

Commercial Experience _____ yrs

Life science management experience _____ yrs

Life science commercialization experience _____ yrs

4.4 Does your company have a separate scientific advisory board?

Yes/No

4.5 Can you tell us the number of dedicated employees in each area?

R&D _____
Marketing, sales _____
Finance _____
Manufacturing _____
Gen Management _____

4.6 Have you experienced significantly disruptive internal management disputes since the company was founded?

Yes/No

If yes to 4.6, have these been resolved to the satisfaction of everyone involved?

Yes/No/NA

Section Five: IP Strategy

5.1 How would you describe the IP strategy you have adopted? (patents only, patents + trademarks, patents + trade secrets, trade secret only)

Patents only _____
Patents + Trade marks _____
Patents + Trade secrets _____
Trade secrets only _____

5.2 What were your major sources of IP strategy advice?

Specialist IP Lawyers _____
General lawyers, _____
Industry experts, _____
Consultants _____

5.3 How many patents has the company been issued? How many patents have been applied for?

Issued _____
For which countries _____
Applied for _____
For which countries _____

5.4 In your opinion, how robust or competitive would you describe your IP position as being

Extremely robust _____
Strong _____
Fairly strong _____
Arguable _____
Weak _____

Section Six: Challenges

6.1 In what general areas were the most significant challenges your company has encountered so far (top 3, in order)

Raising finance _____
Marketing, _____
Operations/Manufacturing < _____
R&D, _____
IP management strategy, _____
HR, _____
General strategy & deal structuring, _____
Other _____

6.2 **Financing**: What were the specific issues?

Raising capital, _____
General commercial issues, _____
Cash flow management, _____
Grant application process _____
Other _____

6.3 **Human Resources**: What were the specific issues?

Recruitment _____
Internal Management Issue _____
Hiring Error _____
Remuneration problems _____
Other _____

6.4 **Intellectual Property**: What were the specific issues?

Patent application problem _____
Claim drafting, scope _____
Patent portfolio decision _____
Patent strategy choices _____
Patent cost control _____
Other _____

6.5 **Operations**: What were the specific issues?

Production delays _____
R&D problems, _____
Missed developmental milestones, _____
Forecasting errors _____
Inventory management issue _____
Other _____

6.6 **Marketing**: What were the specific issues?

Market sizing errors, _____
Technology changes, _____
Insufficient market research, _____
Execution error _____
Other _____

6.7 **General strategy**: What were the specific issues?

Licensing errors, _____
Deal structuring errors, _____
Negotiation error _____
Other _____

Section Seven: Recommendations

7. Having been through the experience you have, what would be your advice to the following stakeholders to maximize the biotech industry's chances of gaining sufficient momentum to be self-sustaining.

7.1 **Investors**

- Angels

- VC's

7.2 **Government and quasi government organizations** eg IP Australia

- Govt seed financing bodies (START, BIF, COMET)

—
- IP Australia

- Industry bodies (AusBiotech)

7.3 Australian Tax Office

- Personal tax policy

- Corporate tax policy

- Capital gains tax regime

- R&D tax incentives

- GST

7.4 ASX and ASIC

- Listing requirements

- Second board for small tech companies

- ASIC regulations and reporting

7.5 Other would-be biotech entrepreneurs

Endnotes

¹ Hopper, Kelvin and Lyndal Thorburn, 2003 Bio-Industry Review Australia and New Zealand, Aoris Nova Pty Ltd and Advance Consulting & Evaluation Pty Ltd, 2003, p. 2

² The six were Xenoport, \$37million; Palatin Technologies, \$22.7 million; Icagen, \$19.5 million; Trillium Therapeutics, \$13.5 million; Advanced Viral Research, \$12 million; and Hyalozyme Therapeutics, \$9.2 million. Source: Fierce Biotech, www.fiercebiotech.com Investment announcements of this size are not unusual.

³ National Survey of Research Commercialisation, 2000, p. 21 (www.arc.gov.au)

⁴ Research Australia (2004), Health & Medical Researcher Opinion Poll 2003.

⁵ National Survey of Research Commercialisation, 2000 (www.arc.gov.au)

⁶ Bray, M. J., and Lee, J. N., "University revenues from technology transfer – licensing fees vs. equity positions," *Journal of Business Venturing*, September 2000, volume 15, number 5, pages 385 – 392.

⁷ National Survey of Research Commercialisation, 2000, Table A11

⁸ National Survey of Research Commercialisation, 2000, Tables A2 and A8

⁹ National Survey of Research Commercialisation, 2000, Table A8

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