6 Discussion

The aim of this study was to demonstrate the challenges inherent in the commercialisation of Australian biotechnology research. Garnsey's (1998) small growth model was used to assist with identifying obstacles to biotechnology innovation in Australia. Although other small firm growth models are available, the Garnsey (1998) model provides a guide to challenges of growth before the firm has been established. Such a perspective is essential for an industry where the process of moving the invention to innovation very clearly begins in a research institution before the founding of a firm.

The Garnsey (1998) model originated with reference to engineering firms with in-house production (as assumed by Penrose in 1959). Its author invited unusual types of resource building to be contrasted with the model to bring out distinctive features of ventures in particular sectors or with unusual business models. In accepting the author's invitation, the research question for this thesis asks, to what extent do the growth paths of Australian biotechnology firms compare with Garnsey's (1998) high tech engineering firm growth model?

The findings of the case studies are presented here within the framework of the Garnsey (1998) model. Beginning with the Access Phase, the discussion compares and contrasts the cases with the model to highlight the challenges of growth along the value chain from research institution to marketing and sales growth. The variables used to study the challenges are those identified by the model.

The growth paths of five Australian biotechnology firms described in Chapter 5 provide interesting comparisons with the model. Evidence from the five firms suggests they have not followed a sequential progression of resource access, mobilisation and generation. The research has identified iterations between the phases and, in some cases, another crossover phase between the Resource Access and Resource Mobilisation Phase.

6.1 Phase I: Resource Access

Material from the case studies is presented in tables 5.1–5.4 (Cochlear), 5.8–5.11 (Novogen), 5.14–5.17 (BTF), 5.20–5.23 (PSL) and 5.25–5.28 (CSD). The data in these tables are amalgamated and summarised in Appendix 6. The case study evidence has demonstrated that early challenges for the firm centre on the perception of opportunities and resourcing possibilities of the new, often revolutionary, scientific idea. Biotechnological firms are unique in many of the problems that confront them during their early formation or Resource Access Phase. Although a concept can prove feasible in the test tube and work well on test animals, its commercial feasibility in humans is very uncertain. Furthermore, requirements of various regulatory bodies necessitate very long and very expensive gestation periods that demand a continuous supply of scarce financial resources. These resources need to be obtained from stakeholders who are often emotionally inspired by the invention's possibilities but who do not understand the difficulty of reaching successful outcomes or the long time periods involved.

In this section the sources of problems in this phase are grouped under four main headings: the entrepreneur, the technology and the environment, and a fourth section focusing on financial resources that brings the first three sections together. The ability to access financial resources can be determined by broad structural influences in the environment as well as by firm-specific contingent factors. Building competencies to overcome these four sources of problems is essential in taking the technology out of the laboratory and establishing a company, before measures can be taken to mobilise the firm's technological competence and create marketing capability that will eventually provide it with resource generation and a return on investment.

6.1.1 Entrepreneur

In describing the entrepreneur, Garnsey (1998) refers the reader to Schumpeter's (1934) visionary who has to struggle heroically against obstacles, including a lack of interest and scepticism among potential capitalists, prohibitions on new technology, a dearth of customers, and inadequately trained labour. They are not capitalists (holders of large amounts of investable funds) and, therefore, must convince capitalists to provide sufficient capital to purchase the resources necessary to establish the company. The entrepreneurs in

this study have all demonstrated Schumpeter's entrepreneurial characteristics that were outlined in Chapter 3.

Given their academic background it is not surprising that the scientific entrepreneurs demonstrated a lack of commercial awareness on such topics as demand and supply, commercial manufacturing and funding strategies. However, to say they were commercially unaware oversimplifies the picture. Five of the seven entrepreneurs had some contact and experience in commercial markets. Clark never doubted that his device would improve the quality of life for the profoundly deaf even though physiologists of the day, both locally and internationally, thought it was outrageous to suggest that electrical stimulation of the inner ear could adequately reproduce frequency information to help profoundly deaf people understand speech. Ideas and a different way of doing things also fascinated Kelly of Novogen.

Keith Williams from PSL had always combined entrepreneurial flair with the highest standards of scholarship and was always pushing the boundaries between what was expected of a professor and what was entrepreneurial pursuit of commercial strategy. Similar to Clark and Kelly, Williams went against the trend. At the time, many researchers were being drawn to the more fashionable field of genomics, but he and his group took the long term view, that proteins would eventually be seen as the fundamental functional agents in the cell.

Vesey and Gauci of BTF were not as clearly entrepreneurial in their outlook as the above three examples. Being much younger, they had neither the level of scholarly prestige nor the entrepreneurial flair demonstrated by the other three scientists. However, their association with Williams, together with their successful association with Sydney Water, provided the impetus that was necessary to focus their drive for commercial ambition.

Agricultural industries have been considered to be among the first to work with genetically modified products. Cross-breeding processes took many years to develop seed with the required genetic make up. Hadley and Kahl would not consider themselves scientists, although TJ Higgins, 2ic to Dr Jim Peacock, head of the Plant Industry Division of CSIRO, has described farmers as among the best scientific researchers he has worked with. CSD was established with resource inheritance

(routines etc) in the experience of the two farmers, thus reducing the challenges for the fledgling company.

The science of biotechnology dictates that no one scientist can develop the technology on their own. As an example, devices can originate within a clinic but their development incorporates many different physical technologies, as demonstrated with the Cochlear case study. Thus key relationships in this industry are critical at the outset and require entrepreneurs to project their vision long before they think about launching a firm to operate in the commercial world. Clark needed to inspire scientific associates from a multitude of disciplines including audiologists, bio-engineers, speech and hearing therapists, psychologists, social workers and otologists. Without such a multi-disciplinary team Clark would never have been able to produce a prototype implant to inspire the Nucleus group of companies to undertake the manufacture and commercialisation processes of the device.

As outlined in Chapter 2, some aspects of knowledge are 'tacit'. They cannot be codified and transferred with blueprints and instructions. Such knowledge needs to be acquired by concrete practice and direct social contacts. Therefore experimentation in the form of learning by doing and learning by using gains particular importance in the development of the biotechnology product. Social networks are critical in facilitating learning opportunities in the industry. Moreover, biotechnology is unique in that a discovery by one firm can effectively destroy the value of others firms' investments over a very short period. The competitive tension within such environments has produced the legendary teams, outlined in Chapter 2, where adverse conditions are viewed as challenges to create new solutions in the drive to succeed ahead of the competition; coming second may mean that you no longer have a market.

In summary, all the entrepreneurs in this study worked at or were connected in some way to public research institutions, and were highly respected experts in their field with many years experience. They were all working in hostile environments in that they challenged the status quo in their industry and were driven to succeed. In all these firms the challenge was made with excellent timing and ahead of those following close behind. Had Clark started his research 20 years earlier, the micro-chip technology, so essential to his implant, would not have been sufficiently sophisticated. Fifteen years later and the competition would have been much greater. Similarly, Keith Williams

focused on proteins as the human genome project was nearing completion and its limits were about to be recognised. Hadley and Kahl recognised the Australian Government's objective of reducing the country's dependence on cotton imports and the benefits that government subsidies were about to bring to the industry. And several scientists were embarking on the study of signal transduction in genes that would eventually demonstrate the benefits of isoflavones for Kelly and his associates in Novogen.

For the scientists the issue of market demand was not really relevant. Being the first to make the deaf hear, or eradicating certain types of cancer or being able to diagnose disease with greater speed, was of greater importance to the vision of these entrepreneurs than driving expensive cars, owning yachts etc. The difference between the perspectives is demonstrated between Clark and Money, Cochlear's first CEO. Enabling one person to hear was enough inspiration for Clark. The commercially orientated Money, however, was not willing to commit Nucleus to manufacturing the device until a world-wide study to determine global demand had been completed. This demonstrated passionate drive for cutting edge science appears to be common in the biotechnology industry, and is outlined in Chapter 2. However, this very same passion becomes a critical problem in later stages of the firm's growth as commercial competence requirements dominate technological competence and the founder lacks the professional management skills or the taste for overseeing the details of production.

6.1.2 Technology

Chapter 5 highlighted the unique nature of each company's technology. The challenges impacting on the development of inventions in this industry are multi-layered. The PSL story provides an example of problems for the scientific entrepreneur. It was believed by 1999, for instance, that analysing proteins, what they produce, what they do and how they interact with each other would help scientists understand what role they play in preventing and treating diseases. However, studying proteins would require more processing capacity than mapping the human genome. There are about 35,000 genes but there are about 500,000–1,000,000 proteins. Those proteins that could be drug targets are available only in tiny quantities and thus are difficult to analyse. Proteins also change in response to variations in the cellular environment. Conventional techniques

for protein analysis were laborious, non-standardised and prone to contamination, and provided data that were unreliable or not easily reproduced. To achieve a sound understanding of protein functions, the whole process needed automating. But commercial information management systems were not available to enable a proteomics automation effort. Software needed to be developed to handle the huge amount of data from mass spectrometers that were used for protein identification. Software also had to be developed to allow automated image analysis of the protein spots on gels so as to archive, compare and determine differences between samples. Therefore PSL identified its market as developing laboratory instruments and supplies, laboratory services, as well as informatics including databases and software. This was before the company could even begin to think about its third tier of using the information gained from its instrument development to look for drug targets and develop diagnostic programs and subsequent drugs to treat disease. The broad range of possibilities is exciting but company strategy can create critical problems by spreading limited resources too thinly, as indeed PSL eventually discovered.

As a second example, for Clark the daunting challenge was to restore impaired brain function. In developing the bionic ear, one of his first challenges was to understand auditory brain science. In an effort to analyse the effects of electrical stimulation of the inner ear and hearing nerve on the brain centre, he conducted tests on animals. Yet the first six animals died. After extensive experiments he was able to determine that the brain cell responses were different for electrical stimulation from those for sound. Much higher rates of stimulation were needed for speech understanding, compared with simply hearing a sound. This was instrumental to his future insistence on developing the multiple-channel device. However, the electrical currents short-circuited through the fluid in the inner ear and did not reach the nerve fibres. Furthermore there are 10,000–20,000 hearing nerve fibres taking speech signals from the inner ear to the brain in normal hearing, and it would be impossible to put a tiny fraction of this number of electrode wires into the inner ear. In addition it was feared that an implant in the inner ear would damage the very nerves it was hoped to stimulate, and because of the deafness there would be too few residual hearing nerve fibres in the inner ear to transmit essential speech information. Every solution towards furthering the understanding of auditory brain functioning led to new problems, demonstrating the path dependence of technological development in this groundbreaking industry. In all cases the

scientific/technological problems required teams of people with complementary scientific skills to take the technological development to a successful demonstration of proof of concept.

The solutions to the technological problems were also extended over very long gestation periods. Hadley and Kahl, for instance, faced ten years of developing seed for Australian conditions. However, in agriculture the initial problems were not as urgent as in the other sectors of the industry. Only six years after CSD began operations, the government-funded CSIRO entered the breeding program and focused on breeding varieties with a significant commercial fit in northern NSW and south Queensland. As well as being compatible with Australian weather and soil conditions, the program focused on fibre quality that put Australian cotton at number one position in the local market. CSD therefore mobilised their resources early and began to generate resources soon after the first Australian seed was available. It is, however, important to appreciate the assistance that government funding provided to this company. If CSD had needed to find the financial resources to maintain the research program at CSIRO, its growth path would clearly have encountered many more obstacles.

The technological development in all cases required the conversion of many sceptics. Scientific entrepreneurs without the skills or aptitude to lead multidisciplinary teams of technologists have little chance of turning their inventions into innovations. It would be prudent for them to seriously consider licensing or selling their inventions rather than developing and trying to commercialise their own technology.

For the four nonagricultural companies, the development period was fraught with obstacles that added to the scientific challenges outlined above. Possible scientific development was blocked by lack of resources such as suitable instruments, essential basic ingredients, facilities and, most of all, funding to support the researchers and their work. Long periods of gestation require substantial funding for salaries, equipment and experiments that may not always give the expected results. In agriculture, the main problems revolved around weather conditions such as hail and drought or pests such as weeds and insects. These challenges were greatly reduced for CSD through the life-long experience in dealing with such challenges that Hadly and Kahl had brought with them from California.

In all cases resource leverage was a critical strategy for progressing the research on which the development of the product depended. Resource leverage was achieved through using students, adapting basic facilities and promoting the research to inspire the public and funding agencies. These activities were clearly path-dependent throughout the development of the technology.

This study, as in those covered by Hugo and Garnsey (2005), found that a key feature of the response to adversity was cognitive. These entrepreneurs always viewed the situation they faced as a soluble problem which they could address proactively and on which they could have some impact. That is, they continually displayed a 'problem solving can do' philosophy. Recurrent problem solving of this kind enabled these firms to build capability on a cumulative basis.

6.1.3 External environment

A firm entering a new market with a new product will commonly encounter highly uncertain markets, creating the classic problem of the early entrant unable to appropriate the returns of pioneering innovation. In this study, in all cases, the entrepreneur was confronted with a risk-averse culture, suggesting that biotechnology is still a pioneering industry. In part the riskiness of their ventures is attributed to the lack of maturity of the market, giving the firms the problem of the early entrant with pioneering technology.

On the one hand such a position in the market is an advantage. There was already a single-channel cochlear device on the market through 3M. However, the first really effective multi-channel device that provided speech recognition was that of Cochlear. In the water monitoring industry, tests were already available but they took up to a week to be completed. The BTF technology provided a reliable system that took three minutes to do the same test. Similarly, PSL technology enabled researchers with PhDs to be replaced by lab assistants to do diagnostic tests in a much shorter time. For Novogen, the isoflavone compound provided the ability for surgeons to target cancer cells without the harmful toxicity of other drugs. For Hadley and Kahl, the ability to greatly improve the quality and yield per acre by replacing US seed with seed suitable for Australian conditions enticed others to join them.

Clearly, this leading-edge position can provide a competitive advantage for the firm. On the other hand, however, it also poses funding problems, problems with government support and public acceptance critical to the progress of technological development. PSL encountered such a difficulty when DAS ended its association with the company due to adverse public reaction to genetically modified agricultural products. In contrast, CSD had no such problems with their genetically modified seeds. Cotton seed has not been perceived as harmful for human consumption, because it is not generally known that the oil produced by the cotton seed is used in cooking potato chips that are consumed by millions of people worldwide on a daily basis.

6.1.4 Financial constraints

Schumpeter (2004) highlights that for entrepreneurs, convincing funding providers of the prospects for their venture is the key to openings beyond their own immediate means. Their success in so doing depends not only on their skill and persuasiveness but on chance contacts and occurrences. Individual entrepreneurs show varying ability and desire to raise funds in similar circumstances. However, overall, funding is influenced by factors such as state of the national economy, government policy and incentives for investment, and by structural arrangements such as stock market and banking facilities. Financial institutions such as these drive the selection process in a market economy and make available the additional capital which fuels extensive firm growth.

Funding is an issue for any small firm, but particularly so for new biotechnology firms due to the nature of the business. In the biotechnology industry, the time from company formation to first revenue (resource generation), much less profit, can be very long. For the Australian biotechnology industry several intertwined sources of funding have been available to would-be biotechnology entrepreneurs. These include private investors or high worth angels, government grants and loans, and the Australian Stock Exchange. The findings of this study show that, despite the challenges posed by institutional financial frameworks, all the entrepreneurs demonstrated creative problem solving by seeking alternative venues for finance such as telethons, global corporate partners and overseas financial markets, such as London's Alternative Investment Market (AIM). Their very long-term commitment ensured a focus that went well beyond the technical.

They were willing to travel overseas and were determined to gain what they saw as realistic valuations when the local market could not be convinced of the value of their inventions and remained sceptical of the technological possibilities. The emphasis on developing global financial perspectives is critical to the survival of the Australian biotech market given the risk-averse and immature structure of the Australian financial environment in this industry, as demonstrated by the actors in this study.

The scientists in the study also discovered that the availability of funding was bound to an opportunistic timing factor that was, in three of the cases, tied to government policy. The manoeuvring of strategies through the complex combination of these factors was risky, made more difficult because alternatives consisted of simply responding to opportunities as they arose. Clark, for instance, wrote to both 3M and Nucleus as he searched for a commercial partner. 3M were not particularly interested in the multi-channel implant, taking the position popular in the market at the time that the single-channel device it was already producing was all that was possible in the cochlear implant market. 3M eventually exited the cochlear implant market and Nucleus (through its various transformations) took on the role of carrying the banner for the device. The outcome could have been very different if 3M had accepted Clark's invitation and later disbanded the project as it dropped out of the cochlear implant market.

But long before he could even think about looking for a commercial partner, Clark first had to clearly define the major objections to his proposal so he could address them. To substantiate his findings Clark urgently needed funding for the research. Melbourne University provided the initial funds of $5,000 to all departments, regardless of their size. However, a few years later when the rules changed, and funding was now dependent on the number of students a department could attract, Clark needed to find other means to fund the research. He also managed to obtain a total of $5,214 from the NHMRC. Creative thinking was needed to apply for such grants: "How could I frame an application on electrical stimulation of the hearing nerves when I knew that my scientific and surgical colleagues who would review the application believed it wouldn't work and was a waste of time?" (Clark, 2000:56). In this example, Clark demonstrates why perhaps Kelly was unsuccessful with his early applications for funding from the NHMRC. Although Clark was successful on the first occasion (he framed his application on the need to promote further understanding of hearing rather than as research to develop the device), subsequent funding was not forthcoming. He learnt that

the application had been voted against by colleagues and peers due to its emphasis on electrical stimulation of the hearing nerve. He was advised to change the title of his application and reduce the emphasis on electrical stimulation so that it could go to another review panel. Choosing to ignore the advice and undaunted by peer rejection, Clark approached the Apex Club of Melbourne. He found that the members were all young and enthusiastic and he could relate to them best. An invitation to speak at a joint meeting of the Apex and Lions clubs of Melbourne led to a public appeal that eventually netted $15,000, providing the means with which to purchase a computer. It was during the handing over of one of the Apex cheques that Sir Reginald Ansett, owner of the channel 0 (now channel 10) television station, saw the event on the news and considered a telethon to give his station a competitive advantage against other stations. Several telethons were undertaken by the station and netted close to $500,000, providing Clark with the source of funding to develop the expensive engineering that was necessary to produce the multi-channel implant prototype. Such innovative public promotion goes well beyond the job description of a research scientist but highlights the 'can do' philosophy of a driven entrepreneur. The strategy also promoted the device and raised public awareness with an additional advantage of delivering the first patients to Clark. Public enthusiasm provided the means to positively promote the device to possible commercial partners.

Individual entrepreneurs show varying ability and desire to raise funds in similar circumstances. In obtaining funding Clark exhibited many personality traits of a sales person, qualities often considered contrary for those with a scientific orientation. Vesey, commenting on scientists he has hired, has stated that "the challenge to get people to stop thinking about the technical challenge and start thinking about commercial challenges, is difficult". He notes that this will often mean creating a cultural shift from being 'pin heads', to sales people. Scientists are not often exposed to the business environment; they often do not understand it. Accepting invitations to talk to Apex clubs and the media on the technical challenge was an exercise in straddling the two camps and not one that comes easily to the scientist, nor is it a challenge that many scientists welcome. It is, however, critical for overcoming many of the challenges to commercialisation of the technology at this formative stage of the firm's emergence.

6.1.5 Summary of Phase I: Resource Access

Although Hopper and Thorburn note in their 2003 Review that the Australian biotech industry has now reached the stage of being severely over-surveyed, they do explain that the data for the Review is drawn from industry databases and questionnaires. The limits of such studies were addressed in Chapter 4. Other studies (Vitale, 2004) attempt to redress the criticism of broad-based surveys of the sector by looking at critical success factors and barriers to successful commercialisation of SMEs in the Australian biotechnology industry. However, these studies do not reveal the processes of firm growth, especially the feedback element central in Penrose's original conception. Such a perspective has underpinned this study in an effort to accommodate the way entrepreneurs adapt and modify their business ideas in a path-dependent process of learning and response to internal and external influences. Quantitative research has studied firms following their establishment; however, in biotechnology, growth processes begin to take shape long before the firm is established and determines it has a need to build its competency at the formative stage of the innovation. Entrepreneurial perspectives developed at this stage of the innovation process are critical to how possibilities, as well as problems, are viewed at later phases of growth.

The Resources Access Phase of the firms in this study demonstrates some key features, especially the nature of the Schumpeterian entrepreneur and his perception of opportunities and solutions to critical problems that block the pursuit of perceived opportunities. Furthermore, if government funding such as BIF operates with an objective to enable biotech firms to access funding for development by going to IPO too early, founders may do so without the necessary skills and aptitude to succeed. The founders of a firm wishing to access BIF funding may follow a strategy of trading off long-term ownership of their firm and taking a one-off chance to access the money whilst it is available. They can thus obtain capital funding for development and gain some commercial skills before selling off developed technology and justifying listing early. If, however, the expected results are not forthcoming in the short term, as they often are not, but the investment market wants profits and doesn't get them, then even late listing (as in the PSL case) will not assist with additional funding. Such a strategy is full of danger for a company wishing to follow a long-term growth path into uncertain markets. This study therefore supports Vitale (2004) in his assessment that many small Australian biotechnology firms become firms when they are really still research

projects. This may also explain other findings (Hopper & Thorburn, 2003) that show many small biotechnology firms that do list early often fail to reach maturity. BIF funding, therefore, could be better used.

As early entrants, none of the above firms in this study was able to access NHMRC funds and so their entrepreneurs pursued other avenues. Neither were any of these firms recognised by their research institutes as worthy of support, either during their research phase or later when they attempted to commercialise their technology. Clearly conditions have changed in the commercialisation arms of universities since the above entrepreneurs attempted to access funding and recognition. The relative ease with which BTF obtained a license from Macquarie University, compared with PSL, is an example. However, what is more significant is that in every case the entrepreneurs in this study followed creative strategies and were prepared to use whatever powers of persuasion they had to encourage students, associates, friends, commercial partners and sponsors to share their vision. These efforts were linked in a dynamic process of problem-solving that required strategic relations with others, and this behaviour was path-dependent and highly interactive. Development of these skills was instrumental to the progress of the technology to commercialisation and thus a critical solution to the financial problem in this phase.

Although luck and timing also played a major role in their success, their ability to see the opportunities and seize them was the critical activity that enabled all firms to reach a stage where they were able to demonstrate a proof of concept of their invention, enabling them to progress to the next stage of growth.

6.2 Phase II: Resource Access/Mobilisation Crossover

Resource Access Phase for the five firms in this study has followed Garnsey's (1998) model where founders have gone through a preparatory searching phase of identifying and matching resources and opportunities. Having demonstrated a proof of concept they should be ready to embark on a viable course of action to set up a resource conversion process with revenue potential. In the Garnsey (1998) model, this set of problems dominates the Resource Mobilisation Phase. However, in a number of cases this could not be viewed as a smooth transition and this thesis has added an additional step to the

growth process. The material for this phase has been summarised in tables 5.5 (Cochlear), 5.12 (Novogen) and 5.18 (BTF). The data from these tables are summarised in Appendix 7.

The crossover between Phase I and Phase II of the Garnsey (1998) model is represented as the crossover between the first and second circle in the Sparling & Vitale (2003) model and a move from discovery to development stage in the Kapeleris et al. (2004) biotechnology value chain. In Garnsey's (1998) model, a business plan that outlines strategies for converting accessed resources for revenue generation denotes the move from the Access Phase to the Mobilisation Phase. The case studies in this thesis demonstrate that there are various business plan options available to the scientist, but the scientist with limited commercial experience does not always accurately assess and choose options that best ensure the successful growth of the firm.

In the Cochlear case, although Clark and his researchers had developed a prototype and had clearly demonstrated revenue potential, there was no appreciation of the extent of the market, and possible commercial partners were not willing to undertake the expensive Mobilisation Phase. Manufacture of the prototype was not considered commercially viable, with redesigning considered necessary to ensure reliability and an economic return. Clark was yet again fortunate with timing. The Australian Government saw benefit in providing financial and administrative support for the redesign and global market study to determine the commercial viability of the device.

During this two-year period neither the inventor nor the commercial partner controlled the process of growth. However, this Crossover Phase was a critical element missing in the growth paths of many Australian biotechnology firms. This phase enabled the project to determine that indeed there was an extensive global market and identify the critical networks that would ensure successful marketing of the invention. Furthermore, it enabled a commercial partner to patent a commercially manufacturable design for the device without leaving itself open to extensive financial risk. The Australian Government could focus on this area to provide meaningful support to fledgling biotechnology companies before they spend many years developing products that, although highly worthwhile, will never provide a financial return to investors because the market is just not big enough.

Once these two challenges have been addressed and overcome then meaningful business plans can be developed. PSL is an example of a company that could have used such assistance. There was obviously a demand for the instruments that PSL had the expertise to develop. Such a demand was demonstrated by the willingness of corporate giants to form joint ventures with the small Australian company. But the extent of that demand and the willingness of customers to pay amounts that would cover development costs were never clearly determined, leaving PSL with a flawed business plan and still a long way from break-even point, despite earning revenue in excess of A$61 million.

BTF and Novogen also did not move smoothly from proof of concept to business plan and the foundation of a business enterprise. Both of these companies continued to manufacture their products while still at the university. BTF initially manufactured their water products for Sydney Water at the university under licence to the university. Kelly continued to develop products at Sydney University in partnership with Blackmores, even when his veterinary company Norvet took out the patent for the isoflavone OTC products. In all these instances, although the resources had been accessed and were in the process of being mobilised, the divisions between the phases were blurred with no clear business plan in place. After 13 years Novogen has still not reached break-even point despite, like PSL, earning millions of dollars in revenue. With cervical cancer drugs coming onto the market in recent times, there remains a possibility that Novogen faces a similar fate to PSL, despite strong commercial skills.

6.3 Phase III: Resource Mobilisation

Four key variables have been used through which to view growth paths in this phase: business plans, access to long-term financial resources, manufacturing issues and company structures to enable growth to take place. This strategy has been used to highlight the critical challenges that will need to be overcome for the firm to reach Garnsey's (1998) Resource Generation Phase. The material for this phase has been summarised in tables 5.6 (Cochlear), 5.13 (Novogen), 5.19 (BTF), 5.24 (PSL) and 5.29 (CSD). The data from these tables are summarised in Appendix 8.

The findings in this section illustrate that Australian biotech firms have in many cases set up resource conversion processes that generate revenue while still in the Mobilisation

Phase, and these firms are not totally dependent on transfer payments while developing their destination products. However, the enormous costs involved with very long gestation periods of taking the development through the regulatory approval process prolong the mobilisation of resources in this industry. All but two firms are still unable to reach break-even point despite earning substantial amounts of revenue.

The majority of companies in this sector are dealing with platforms of technology, not just a single product, and the temptation to overextend business plans is a serious problem. The evidence provided by the case studies suggests that developing a realistic business plan is very difficult in this industry, given the range of possible growth directions for technology platforms and the uncertainty of markets for revolutionary technology. Past experience in similar companies provided considerable benefits to two of the companies, demonstrating the benefits of path-dependent learning.

6.3.1 Business plans

Having determined that a global market existed for the implant device and that it could be commercially manufactured at a pre-determined price, Cochlear's Money was able to outline a reasonably accurate business plan. Clark, having no interest in commercial issues and being made aware of his limitations regarding leakage issues of his prototype, chose to licence the IP to the Nucleus group of companies rather than attempt to commercialise the device himself. However, to facilitate the transfer of essential tacit knowledge, a number of his key people moved to join the commercial group.

The business plan was able to predict with reasonable accuracy when break-even point would be reached and at what cost. Trainor, Nucleus Chairman, was not prepared to provide the A$5 million that the business plan had calculated it would cost to mobilise resources to break-even point. He undertook a global roadshow to determine a valuation for the company in a market that was experienced with biotechnology issues, rather than attempt the exercise in Australia. The Bear Stearns/Fred Adler valuation was able to establish a realistic valuation for the company and thus enable the company to raise A$3 million of the required A$5 million in exchange for 27.5% equity to cover developmental costs to take it to break-even point while reducing his risk exposure.

CSD was also able to develop and follow a well-focused business plan. Once research had determined the best area to grow irrigated cotton, and strategies to cover costs of harvesting and ginning through cooperative activities with neighbours were determined, the two entrepreneurial farmers were able to not only grow their businesses but lead the successful development of the whole industry in northern NSW.

The Mobilisation Phase of these two firms fits the Garnsey (1998) model of small firm growth. The founders, as described by the model, have embarked on a viable course of action to gain use of the acquired resources and set up a resource conversion process with revenue potential. Their linear progression through this phase, however, can also be explained by factors other than path-dependent learning. Companies with technology platforms have a number of direction choices, as seen with Novogen and PSL. Cochlear, on the other hand, was a single device with a single use and, despite the additional complication of the regulatory approval process it needed to overcome, it is more aligned to the engineering model than companies looking to manufacture drugs from various compounds. Similarly, CSD focused on the steady development of one product in a known market without the complication of a regulatory process to hinder its progress to resource generation.

BTF differed from the other firms in that it had a resource generation process in place with an established customer when it spun off from Macquarie University. Not being a drug company, it was able to follow a focused business plan as per the Garnsey (1998) model. The two entrepreneurs understood the water market niche and knew most of the labs operating globally in the field. They could have stayed in this small niche but took advice to broaden their product line. This action complicated their initial growth path by changing resource requirements very soon after becoming established. They were, however, still very clear about their strategy. There was the opportunity to undertake a more diverse research and product development path by developing DNA technology as well as their water and bacterial products. They chose to stay focused and, unlike PSL, did not overstretch themselves. According to Nanyang Ventures, the company's venture capitalist, they are on the brink of becoming profitable.

PSL and Novogen attempted to follow plans that anticipated the firms becoming major pharmaceutical companies. Novogen began with veterinary products as well as their initial OTC isoflavone products. Despite generating resources in various forms it was

required to continually return to its Access Phase for additional resources in the form of finance, labour, IP and land as it changed direction with some opportunities not coming to fruition and new unexpected opportunities becoming available. PSL had the most far-reaching business plan, expecting to develop very expensive and complex protein instrumentation, and use those instruments and consumables for diagnostics to further research proteins to eventually develop drugs to cure various diseases. Despite having a good deal of expert commercial advice and attracting the attention of a number of global companies such as IBM, who were happy to become joint partners, the company's business plan was flawed on several counts. Although the instrumentation was excellent in its design and implementation, the demand was not nearly as extensive as the company estimated. For instance, they had expected that Australian universities would be their first customers for their computer products. But overseas competitors managed to hold on to the Australian customer base making it an impossible market to penetrate, especially given the huge cost involved for institutions wanting to absorb the PSL products. Another unfortunate problem for the PSL business plan was the unexpected exit of DAS from the genetically modified agricultural market. Although having provided PSL with solid references as to its commercial abilities, it removed an essential financial source leaving the company dependent on commercial partners, many of whom did not provide the expected long-term benefits of downstream expertise. Furthermore, by attempting to stretch across the whole spectrum of the protein market, the company grew very quickly but staff were often stretched too far and experienced burnout and loss of direction. Development costs continued to rise. Despite earning A$61 million, the company failed to reach break-even point. When it attempted to go to an IPO it was only able to raise a small fraction of what it had expected and Williams, its scientific entrepreneur, resigned in favour of a commercial expert who immediately reduced the range of company activities.

The actions of BTF, PSL and Novogen have not followed a linear growth path in setting up a resource conversion process with revenue potential. Apart from CSD, the firms were all mobilising resources to add value to their inventions, but were also generating resources in that they were all selling some products as they returned to accessing additional resources. In this way they were demonstrating a more circular growth path throughout the Mobilisation Phase more in line with the Garnsey (2003) diagram outlined in Chapter 3. They demonstrated problems confronting firms with

revolutionary platforms of technology facing uncertain markets with long gestation periods. These problems have required these firms to go through continual 'loops' of additional search activities for finance, R&D and labour that could meet the changing skill needs as the company as it moved down the value chain.

6.3.2 Long-term financial resources

A critical problem is the lack of sufficient financial resources to develop the research to manufacturing and distribution stage. In a recent study, Vitale (2004:24) found that "every company interviewed (in that study) nominated, without prompting, funding as their biggest issue". The experience of the firms in this study concurs with those findings. Because biotech firms increase their employee numbers before they achieve economic independence, increasing R&D expenditure on salaries and other costs increases losses, the cash burn rate of investment funds has been evident in the four non-agricultural firms. Costs include scientific staff to develop and validate the technology, the cost of plant and equipment and legal and commercial expertise that is required to patent, structure and promote the company throughout the Mobilisation Phase. As outlined above, Cochlear's product development through clinical trials to gain USA FDA approval and other regulatory approvals, and to begin sales in major markets, required A$5 million (in 1982 terms). Novogen has obtained approx A$141.5 million from various sources over a period of 12 years, and has still not managed to reach break-even point. Typical timeframes within which the biotechnology sector operates can be 5–30 years. Providing sufficient funds for such a long gestation period is a serious problem for the development of a potential product.

Several sources of funding were available to the firms for commercialisation of their technology. These sources included government sector loans and grants, Initial Public Offerings (IPO), business angels, partnership arrangements and Venture Capital as well as the resource-generating activities outlined above. These funds are available on a local as well as a global scale. In some cases where the local market was not prepared to provide essential financial resources, firms took their financial search overseas. For instance, Novogen and BTF both sought Australian VC funding and both described it as a 'horrendous experience'. Novogen abandoned the Australian venture capital market

and took its fundraising activities overseas. BTF was eventually able to begin dealing with an Australian VC company that took on the role of finalising an investment deal and bringing sound business management skills to the table. The interviewees in this study concurred with other studies (Hopper & Thorburn, 2003; Vitale, 2004) that a sophisticated financial market that understands the industry is not yet fully established in Australia. The Novogen and BTF funding experiences highlight two points. First, their experiences confirm other findings regarding the lack of sophistication in the Australian venture capital market. The second is the demonstrable benefit of experience. Trainor did not even attempt to go to the Australian financial sector until he already had a US valuation for the company. Having secured a commitment from the US venture capitalist, he was able to leverage this offer to obtain Australian capital.

Hine and Griffiths (2004) have identified an additional problem for the Australian biotech entrepreneur operating in an unsophisticated financial market in terms of venture capital funding. The biotechnology industry suffers from being grouped with other high-technology industries such as IT, particularly where investors are concerned. While market capitalisation is important to this industry, so too is its scientific base, but the same investment criteria are applied throughout this industry without considering the differences. "Most IT products require R&D cycles which are quite short when compared with products such as pharmaceuticals and medical equipment" (Hine & Griffiths, 2004:147). The volatility in the Australian biotechnology industry, as described in Chapter 2, is an indication of a market that is yet to understand such concepts.

All companies in the study received government sector transfer payments. This funding included START Grants, SPIRT, concessional loans from the IR&D Board and a Section 39 Public Interest Project Grant from the Department of Productivity to Cochlear (then Telectronics). None of the firms was successful in obtaining support funding from NHMRC to support their research. Other studies (Thorburn 2000; Vitale 2004) found that BIF and START grants were available to firms before they had the competencies to develop their firms.

The five firms in this study gained a much-needed benefit from the availability of the above grants, but this occurred only at the Research or Early Development stage. The government had very little to offer at this key Mobilisation stage. Novogen, for instance,

was able to gain $10 million from three grants as its research discovered additional opportunities. BTF began with a START grant and then received an additional START grant to develop their Bioball technology. A concessional loan from the IR&D Office, which was eventually paid back, provided additional funds to take the development of the technology to marketing stage. For PSL getting started with its technology program was supported by Shimadzu, but was also subsidised by a much needed START grant, and for the cotton entrepreneurs, subsidies and protection from overseas interests with trade barriers helped put the fledgling industry on its feet. Government assistance to identify the possibility and extent of market demand, as in the Cochlear example, would clearly benefit many firms before they embarked on this expensive phase, and would enhance their chances to more accurately outline realistic business plans.

This study concurs with Vitale's (2004) findings that highlighted the survival and adaptation of Australian biotechnology firms. These findings were three-fold. First, the firms adopted a 'hybrid' business model, which included some sort of short-term cash generating activity to fund the long-term discovery process. Second, they focused on the global market from the outset, concentrating on market intelligence, branding and customer service offshore, while seeking to capture value for the Australian operation. Third, three out the five firms concentrated on niche markets and products to maximise returns from limited capital. The founders all needed to approach overseas interests to promote their products to tap into a much bigger market potential outside the local sphere. They were also required to meet financial and consulting resource shortfalls through overseas contacts because the local market was unable or unwilling to provide the necessary resources at a price they could afford.

6.3.3 Manufacturing challenges

The biotechnology supply chain demonstrates a complex pattern of interactions and is diagrammatically described in Appendix 11. Manufacturing issues requiring access to stakeholders along the supply chain include services such as tax, financial and legal consultants, and research contract firms. Additional suppliers such as packaging firms, chemical and hard- and software companies also provide valuable resources. Public research institutions such as CSIRO or local universities can supply essential knowledge

transfer, access to facilities and advice regarding the latest research. Additional suppliers of equipment, facilities, research and vital access to trial patients are clinics and hospitals. Support in terms of funding, legal and business management, distribution and marketing is provided by specialist agencies and firms such as KPMG or PWC. All these firms are impacted on by regulatory bodies and political actors who also play a major part in determining the environment in which the firm must operate. These external associations add considerable complexity to the skill requirements of biotechnology firms compared with the in-house production of engineering firms. The ability to opportunistically manoeuvre the firm through such complex requirements complicates the linear growth path demonstrated in Garnsey's (1998) model.

An additional challenge not found within engineering and IT sectors is the restraint on access to customers. In most cases the producer is not permitted to distribute the product directly to customers. Doctors, surgeons, clinics and pharmacies are the distributors of the final products, hence supplying essential distribution services. However, promotion to this sector is expensive and faces competition from well-resourced large pharmaceutical companies.

This is an extraordinary web of stakeholder relationships that need to be managed and coordinated by the growing firm. It demonstrates why it can be so difficult for the initial scientific entrepreneurs to negotiate their way through this complex web without assistance and expert advice both within and outside the firm.

Problems with supplies experienced by the firms in this study were varied. BTF needed appropriate packaging to ship their EasySeed technology to the US. But none of the packaging companies they approached was interested because BTF was just too small. But not servicing the US market would have been a major loss in their strategic plan. Eventually – by pure luck – they met with a sales representative working for NorthWest Packaging who agreed to supply the packaging and who still works for them today.

In terms of consulting advice, BTF found that,

> *"In Australia there are a lot of people who say they are there to help with the process but there are not a lot of people who actually know or have experience in how to do it".*

The process referred to includes the ability to manage applications and trials through the FDA, marketing and sales strategies that will maximise exposure and revenue potential. It also includes accounting expertise that assists with acquiring finance and with structuring the company in the most appropriate way, as in the Novogen example. The compounded difficulty lies in the immediate market for the small biotech firm being global. There is little opportunity to develop competencies on a local level before facing a much more hostile global environment. In fact, in the PSL example, strong local competition from overseas competitors meant that the company had much better chances of selling its product in the USA and Japan than in its own home market. Had PSL concentrated on the Australian market first, its survival would appear to have been doubtful. This difficulty is further compounded by the nature of the science. Because it is cutting edge and because it has to be so to capture the market, there are no role models. Most products are prototypes, making it difficult not only to market but to find sales people who understand the product to negotiate sales for the company.

PSL found that the best strategy was not to recruit a sales and marketing force. It would have taken 12–18 months to train anybody to understand proteomics technology. They considered that an executive of the business had to handle the first sale. They believed that it was an absolutely necessary to combine an understanding of what they were actually selling with the needs of the customer. They were convinced that was the reason CRL chose PSL for the job, rather than because PSL products were the best in the field. CRL were most interested in the commitment of the staff to the success of the proteomics program. Williams considered that one of PSL's closest competitors was probably a well-trusted brand with no risk to the customer. But CRL rightly questioned what knowledge base did they have around proteomics? Were they going to be able to support the CRL program? Given the cutting edge nature of the PSL product, the 'sale' became a joint venture but not with the assistance of an Australian consultancy firm.

Chris Naughton found Australian consultants very expensive and often lacking in experience. He noted that the mechanics of how to structure the company to allow commercialisation to take place was difficult and complex. But he found a lack of sound advice in the local market and considers this the reason why many companies are forced to go offshore. For a small company without a team of lawyers and accountants and specialist people to draft applications, even grant applications are challenging. The application itself is very lengthy because it has to include all the company audited

statements and reports, all the IP position or patents, as well as a written explanation as to how this is going to contribute to Australia's R&D success. Much work is involved and Novogen's Husband did the bulk of it himself. He obtained some assistance from other people, but small companies lack the financial resources or the luxury of a department to write grants for them.

An additional complexity and expense for a firm attempting to progress through the Mobilisation Phase is the cost of obtaining regulatory approval and downstream marketing experience, especially when it needs to be on a global scale. This cost can be prohibitive. Hence the experience of small biotech firms worldwide is to develop the initial concept and then license the intellectual property to large pharmaceutical firms with downstream resources when they reach Phase II trial stage. But Ernst & Young (2004) note that Australia does not have a pharmaceutical industry. Therefore for Australian firms this requirement presents an additional problem. Given that at least 40% of the market for most biotech products is in the USA (E&Y, 2004), FDA approval is absolutely essential to receive world-wide acceptance of the product. But, apart from CSL, there are no Australian pharmaceutical companies ready to undertake the mantra of the Australian biotech entrepreneur. Peter Barnes, Business Manager for Aventis Australia, echoes other anecdotal evidence when he notes that:

> *"Overseas pharma companies see themselves as distributors on the Australian scene and should an Australian company approach an international pharma company in Australia to develop its concept, it is unlikely to receive the attention that is given to its USA or UK counterpart".*

Novogen CEO, Chris Naughton, who has had extensive experience in the northern hemisphere biotech industry, agrees that international pharmaceutical companies are in Australia as a sales office to sell existing products and extend their global business, but they are not often engaged in primary research in this country. In Australia, although the ideas come from what have been called the 'ideas factories' such as the hospitals, universities, CSIRO and similar places as demonstrated in this study, downstream development is inhibited through the lack of a supporting structure that local pharmaceutical companies would have been able to provide. Such challenges reduce the opportunity for scientific entrepreneurs to contribute to the growth of the Australian biotech industry as a whole. Exit from a company with credentials of having successfully grown a firm to its Mobilisation Phase should be a positive outcome. The

scientist, having weathered the experience, should then be able to assist with establishing other small firms in the industry. This strategy is in operation in other countries, especially the USA. In Australia, the perception of failure when the scientist leaves, such as in the case of Williams with PSL, limits a country's potential for industry growth.

6.3.4 Company structure

Cochlear and Novogen demonstrated differences in their search for development funds and these differences were due in part to the structures underpinning the two companies. Novogen was struggling to set up distribution outlets in overseas markets to grow company brand and to gain understanding of the experience required for working in important overseas markets. Cochlear, on the other hand, was part of Nucleus, a holding company for its group of medical device companies such as Telectronics (pacemakers), Domedica, (kidney dialysis) and Ausonics (diagnostic ultrasound), among others. As explained in the Cochlear case study, Telectronics had a global structure in place that designed, manufactured and distributed cardiac monitors and implantable cardiac pacemakers. The company had been established by Trainor, who thoroughly understood the medical device market, and had grown it to global scale. He stated that he was convinced that the Cochlear project was eventually successful for two main reasons:

1 The company knew from previous experience in developing implantable devices that the whole project, from prototype to accepted medically approved (FDA) implant, would take at least ten years.

2 The company understood that concurrently with the research and development on the implant there would be clinical trials, documentation, payment of fees to audiologists world-wide, back up clinical research, submissions to the FDA etc. and no one else had experience in such a project before, especially on a global scale.

In other words, the company understood the product and its market and could strategically plan for it. They were not grabbing at opportunities without realising that there may be consequences from pursuing such opportunities. It was important that the company made an early assessment that the R&D, clinical trials, pre-market FDA

approval trials, documentation and good manufacturing practice would last a decade and would cost (in 1982 terms) around $A5 million. That Nucleus had the legal, commercial and manufacturing infrastructure in place to facilitate such a major development is one of the major contributions that Trainor and his team made to the success of the company as we know it today. For instance, Hirshorn was able to rent space in Telectronics offices in the USA, London and other overseas destinations from which to establish his subsidiaries. It was also the purchase of the Telectronics import licence in Japan when Telectronics moved to another country that enabled Cochlear to trade in Japan. Finally, legal and commercial skills were always available to leverage if necessary; these cannot usually be afforded by start-up companies. The lack of such infrastructure would clearly impede any successful progress of superior science that Australian scientists are able to deliver.

Despite the difficulties, Novogen and PSL aspire to being future Australian pharmaceutical companies. BTF will also be looking to an Australian listing to give its venture investor an exit, and CSD's structure protects it from being taken over by its corporate partner BayerCorp Science. The strong determination of each company to stay Australian is of particular interest to the Australian biotechnology industry, perhaps reflecting a national characteristic of independence. However, although such nationalistic perspectives are admirable they do not promote successful outcomes in an industry without appropriate entrepreneurial culture and structure.

Corporate structures also call for a clear understanding of the collaboration, cooperation and network building that are essential to enable small biotech firms to extend and leverage their limited resources. Novogen's experience highlights the extent of such connections and their value to the growth of the firm. Novogen has undertaken significant research projects jointly with various groups both in Australia and overseas. In Australia, anti-cancer drug trials have been conducted at the Royal Prince Alfred Hospital (Sydney), St George Hospital (Sydney), the Royal North Shore Hospital (Sydney), Royal Women's Hospital (Melbourne) and Sir Charles Gardiner Hospital (Perth). Overseas, anti-cancer drug trials have been conducted at Cleveland Clinic (Ohio, USA), and Yale-New Haven Hospital (Connecticut, USA). Research collaborations are in place in the USA with the National Institutes of Health, Medical University of South Carolina, Yale University, Purdue University, John Wayne Cancer Institute and the University of Birmingham at Alabama. In Australia, research collaborations are in place

with the Hansen Institute (South Australia), University of New South Wales (NSW), Wollongong University (NSW) and Newcastle University (NSW).

There are some essential benefits to such collaborations and Novogen's association with Yale Medical University provides an excellent example. As a renowned American company, Yale enhances Novogen's chances of obtaining FDA approval for its drugs. Furthermore, to maintain its level of public grants, endowments and large donations, Yale needs to keep on producing high profile news. Also, Yale, as a powerful organisation, has graduates in all fields of business and their connections with all facets of industry are likely to be highly influential. It could be surmised that they are well represented in the US government and will be recognised by powerful interests. Novogen has done well to secure these ties with Yale and other universities, research institutes and hospitals. Once these connections have been established, they can become the overseas infrastructure that was not available to Novogen when Kelly began his research but which can facilitate the company's growth, as did Cochlear's relationship with Telectronics. American connections are important, particularly if any trial successes are declared. Although essential, such collaborations need to be monitored so as not to repeat the PSL experience.

6.3.5 Leading cultural change

Growth prospects appear to be very positive for the firm that has been successful in acquiring the appropriate human, financial, technical and physical resources. However, in line with the Garnsey (1998, 2003) models, it is at this Mobilisation Phase that leadership problems emerge. The charismatic leader of a close-knit legendary team struggling against the odds requires a very different set of skills to the one who oversees clear documentation of routines and procedures. The entrepreneurial flair that kept the vision alive is no longer sufficient for dealing with the level of commercial and legal interests that are now imperative in taking the company forward. This is the cultural change referred to earlier in the section. Kelly of Novogen eventually resigned as Managing Director, handing the reigns over to Chris Naughton. Kelly notes that, in starting companies, the greatest talent you can have as a company founder is to know how to align yourself with people who can plug your missing knowledge gaps.

In all of the cases, a change of company leadership was required to promote the necessary change in culture that then facilitated the multiple rounds of financial resource-seeking that, in turn, prolonged the Resource Mobilisation Phase. The need to change the company's focus from a technological to a commercial perspective was critical to the survival of each company. The inability of the entrepreneurial scientist to fully understand that focus created, in some instances, serious problems for the company. Williams always believed that if a person can manage a lab, they can manage a global company. The complexity of the industry and its supply chain, as discussed above, demonstrates the fallacy of Williams's logic. BTF continues to maintain the scientists as its business leaders but they are supported by a venture capitalist with extensive experience in both the domestic and global biotech market.

The Garnsey (1998) model does not incorporate such leadership changes. It refers to successful firms being founded by teams rather than individuals and founders with qualifications and relevant business experience. This study illustrates the complexity of qualifications and experience required for the firm as it moves down the value chain. It is a challenge for enthusiastic entrepreneurs to hand over the leadership. Their entrepreneurial personality, as outlined by Schumpeter in 1934, and their 'can do' philosophy limit such behaviour. For the firm to proceed to its next phase of growth, such an exit for the founder, either out of the firm or to another role, is critical during this phase of the firm's growth.

6.4 Phase 4: Resource Generation

In Garnsey's (1998) model, the firm is now in the position where it has mobilised and deployed sufficient resources to allow a production cycle to take place, in an effort to become self-sustaining and allow the build-up of competence. Problems throughout this phase revolve around assimilation of new members, building key relationships with customers and distributors and putting systems in place for effective production and market feedback. The material for this phase has been summarised in tables 5.7 (Cochlear) and 5.30 (CSD). The data from these tables are summarised in Appendix 9.

In the biotechnology industry, resource generation depends on the ability to sell drugs or medical devices to customers and usually begins with the conclusion of successful Phase III trials and the granting of regulatory approval, preferably from the FDA. Novogen's phenoxodiol is being developed as a therapy for late-stage, chemo-resistant prostate, ovarian and renal cancers. These therapies are at various stages along the clinical trial pathway. However, phenoxodiol is still an investigational drug and, as such, is not able to be marketed. Novogen therefore continues to be within the Mobilisation Phase of its growth path.

Proteome Systems continued to develop its revolutionary technology in protein identification and characterisation, winning the prestigious Frost & Sullivan Award for Technology Innovation for its ChIP product in 2005. Stephen Porges, the newly appointed PSL CEO, has extensive experience in Australia, Asia and the US in implementing strategic management for early stage companies. In July 2005 he announced that the company had appointed Sage Healthcare Group in the US to develop partnering deals for the company's portfolio of technology and informatics products. This association was initiated so that the company can now focus on its next business plan horizon of developing diagnostics and therapeutic product programs. Although significant partnerships and funding have already been achieved on these next level horizons, the company is still at the early stages of this area of development. PSL's technology program will now be used as one source of revenue to assist in these second and third horizons of its growth path. These areas, however, are still at the Resource Access and Resource Mobilisation phases of growth.

BTF have also made major inroads into their growth; however, they have not yet achieved break-even point. As outlined above, Gauci acknowledges that break-even depends on spending as well as revenue raising. The company is not interested in just surviving and therefore it continues to reinvest returns in an effort to grow the business to eventually obtain worthwhile profits. Therefore, although significant progress has been made into the commercialisation of the BTF products the company still sits within the Mobilisation Phase of its growth.

Cochlear, having mobilised its resources to develop a manufacturable product with definable production processes in place and being on the cusp of receiving FDA approval, was now moving into Garnsey's Resources Generation Phase of its growth.

The entrepreneurs of CSD, having saturated the domestic market that was capped by the availability of water, were not interested in growth and the company remained on a plateau for close to fifteen years. A changing environment required some quick changes in culture and the company was forced to remobilise its resources to meet the new conditions. The final section in this chapter focuses on two companies, Cochlear Limited and CSD. These are the only two companies that have managed to overcome problems in the Mobilisation Phase and put in place sustainable production processes to generate resources for continued growth.

6.4.1 Cochlear

The problem with people

In the move from Access to Mobilisation Phase, one of the major problems for the firm was the change of leadership. The technological challenges that were met in the first phase depended on skill sets that did not meet those required for the next phase, where an understanding of legal and commercial issues from a much wider perspective was critical for growth. These skills were beyond those acquired by any of the original scientific entrepreneurs in the study and the firms thus looked to a new leader to drive the firm through the Resource Mobilisation Phase. Similar problems with changing skill set requirements were experienced as the firm moved to the Resource Generation Phase.

From 1982 to 1984, Dianne Mecklenburg worked to bring the pivotal study to a successful conclusion. Hirshorn joined Mecklenburg in mid-1982 and was charged with the responsibility to promote the Melbourne/Nucleus device to a market that did not always recognise or necessarily trust Australian scientific excellence: "There was always the problem of not being American". Selling the concept of the multi-channel device and its benefits added a layer of problems for Cochlear to overcome at this early stage of reaching into the US market. Furthermore, the US competition, especially the 3M/House device, was promoted by the very eminent and respected Bill House himself, who spoke at conferences and had personally trained many of the ENT surgeons. Clark, however, refused to travel to the US, thus constraining the Cochlear team's promotional efforts. An even bigger challenge was to develop the protocol that all the surgeons, audiologists and clinics would adhere to for the equivalent of Phase III trials, a pivotal

study that would provide data for the ultimate FDA approval. To have brought together such a diverse group and provided training for a totally new form of technology that was in competition to a national product was an extraordinary achievement.

Certain personality characteristics were necessary for this kind of successful outcome. Colleagues described Hirshorn as very bright, sincere and with a very high level of integrity but very much the opportunistic business entrepreneur driven to succeed. Although working as a consultant, Mecklenburg was very committed to the project. Her task was to organise the protocol, collect the data, run training workshops and trouble shoot technical problems around the country. She gave workshops and wrote papers so that she and her colleagues could talk about Cochlear implants although, without data, which was still being collected, it could be embarrassing. They were given the freedom to travel to conferences all over the country and ask questions as an opportunity to talk about multi-channel Cochlear Implants and the Melbourne device.

She and Judy Brimacombe, her first employee, were always there for the first programming of a patient. They trained every clinician who had ever programmed a patient in the US and slowly built up a team of audiologists. She flew to wherever there were problems and would phone Patrick so they could work through various strategies to solve any technological problems. Patrick would fly over for some of these cases to ensure that the service was always first-class. Nucleus offered the service at no cost to the patient, and the team would go anywhere they were needed, using whatever man-hours were required. Replacement units would arrive as special delivery with no expense spared. This Cochlear team were very professional, very confident and were fast responders. This kind of service made their chief competitor look very sluggish and slow. It also proved to the American specialists that there was no issue with a device that was not made in America.

The team were also very strict about the protocol to ensure that FDA approval was not held up by unreliable data. That level of control was justified during the approval process, because the study had to be done according to the protocol, but once the clinical trials were completed a different orientation was required. West, Cochlear's first US CEO, and Dianne found it difficult to reach compromises as he tried to put commercial systems in place and build up customer relationships. Hirshorn also had difficulty in letting go. West gave him three going away parties before Hirshorn finally

moved onto his next assignment setting up a European subsidiary. His reluctance to go illustrates the entrepreneurial difficulty of understanding the changing skill needs of a growing company, especially when they have done an excellent job to this point.

Garnsey's (1998) model speaks of a lack of appropriate skills and commitment from new members being a problem for the growing firm at this stage. In the Cochlear case, new team members were dealing with old members who had had a great deal of freedom, total control over processes and very successful outcomes. Mecklenburg and Ginger Minelli (later Whellock), Hirshorn's executive assistant and the first US employee, were soon finding it difficult to fit into the new growing team and left. Hirshorn went to Europe to start the process again and Dianne eventually joined him there. As new members joined it became easier for West to establish effective routines.

Structure problems for the new president

As the new leader of the new subsidiary, West was charged with growing sales for the company to meet its current business plan objectives. Experienced in the US medical devices market, he was a crucial element in the firm's business plan in building local business know-how in the US market. However, there were a number of serious problems for him in taking on this role in addition to having to deal with the existing team.

West was sceptical that the Cochlear device could be dominant in the US market place. But he had experienced and was impressed with other Nucleus technology. He was also not convinced that the business plan's predictions could be achieved; he was worried that the company as a start-up would be undercapitalised but was pacified that the start-up was part of the Nucleus Group. The options he was used to were not negotiable and when he tried to employ senior staff who needed to be paid US salaries, Nucleus refused, leaving him with less-qualified people. His board was not always cooperative and production problems added to his troubles. Since all the manufacturing was done in Australia, he had no influence over what he considered important marketing issues. For instance, the only colour available was beige, which was not a problem in Australia, but greater ethnic diversity in the US required cosmetic changes to the device. His concerns were mostly ignored.

Several events did, however, provide him with solutions. David Money, the new CEO of the Australian Cochlear company, strongly believed that nationals knew their own market best and as long as they were producing the results he did not interfere with their procedures. West believed that the US team always had a good working relationship while Money was the CEO. Another beneficial factor was that 3M had been in the market already for a year so the concept was no longer new. He and Brimacombe were the first US sales team and, being very opportunistic, they visited all the firms working with the 3M device because these people already knew what they were talking about. They developed a video showing how the patient received speech recognition and this proved to be very effective. Their first sale to such a contact produced desperately needed revenue that was equivalent to the entire income for the previous year. When 3M began to make a series of critical mistakes, Cochlear was able to eventually take over the competitor, giving itself a very dominant market position. Furthermore, once FDA approval was established, the professional reputation of the company ensured easier access for approval into the children's implant market, which was the next critical development when the company moved to the Resource Regeneration Phase of growth.

The European subsidiary

In Europe Hirshorn repeated the process of finding an office, hiring a CEO and establishing a market. As in the US, he visited surgeons that Cochlear had made contact with earlier, specifically Professor Ernst Lehnhardt, who was operating in Hanover. Hirshorn initially set up an office in London, renting a part of the Telectronics building. He eventually established a Head Office in Basel, Switzerland, in order to suit his replacement executive, reach German and European markets more easily and to avoid an extremely high German tax regime. He hired Dr Monika Lange (later Lehnhardt) to lead the new subsidiary. She proved to be the perfect candidate, speaking five languages fluently, stylish with a strong presence and with a knowledge of the medical industry. These traits provided the basic characteristics to overcome many of the cultural issues that Hirshorn anticipated. He introduced her to Professor Lehnhardt, who she later married. In 1984 Mecklenburg joined Lange and her assistant, Ulrike Trautmann, and "we literally hit the ground running".

The job for this team was the same as it had been initially in the US. They needed to go out to centres in different hospitals and train people in all aspects of rehabilitation and programming, giving lectures and workshops. Mecklenburg did not have a language problem as "most of the work was done in English", and most European people know some English. She also knew some German and French, so she understood what patients were saying. Her main problem was working with cultural issues. In the US she was able to bring the various disciplinary groups together to determine a protocol that everyone agreed to. In this part of the world, disciplinary systems were considerably more hierarchical and Lehnhardt was not impressed that he should be told to adhere to what some audiologist had agreed to. Considering the relationship between Dr Lange and Professor Lehnhardt, the relationship between Mecklenburg and Lange very soon broke up and Dianne reluctantly went to work for the opposition.

Sue Roberts joined Hirshorn in the UK and colleagues speak of her as very spontaneous, jumping in and taking a risk at everything. She would get on a plane and go to another opportunity without hesitation. Roberts established the market in the UK and France, and then began to sell to customers in the Middle East, often taking serious risks being a woman in Moslem countries. Given the drive for success that this team had, sales continued to mount despite the strong competition in Europe. Hirshorn was careful to introduce the European and US groups in an effort to develop camaraderie and a team spirit between the two Cochlear groups.

The problem for the groups was the lack of coordination between the production team in Australia and the sales that the subsidiary teams had made. The subsidiary teams felt that part of their Head Office was demanding growing sales but the other half was unable to deliver the product. Eventually Hirshorn moved back to Australia and took over the manufacturing. The manufacturing function was carried out by two divisions. One was responsible for manufacturing the implant, the other for the non-implant parts such as the speech processor. The divisions shared common warehousing, transport and administration, and their heads were at 'war' with each other.

Hirshorn's task was to bring about harmony. There was a serious need to coordinate all the elements, and he made it clear that the important thing for him was the shipping schedule. Such coordination made a huge difference to the sales team. In Australia there

was no competition and the operations in Head Office did not seem to appreciate that the subsidiaries had competitors, people who were halving Cochlear's price.

6.4.2 The Cotton Story

Having mobilised its resources, CSD was able to generate resources for its members much faster than the other firms in this study. The company had a dominant market position in Australia with a couple of leading varieties of cotton seed. A new variety would come to market every 4–5 years, so there was little pressure to streamline production processes. The company also had approximately $40 million of shareholder funds. They were a very strong company and didn't borrow a lot of money. Everything they had was built on the premises and funded out of cash. Such conditions gave the company an enviable position, even in the drought. Being a company limited by guarantee, and a research company, CSD was also able to secure a tax-free status.

Additional benefits were secured from the partnership with CSIRO, who were at the cutting edge of cotton seed technology. Furthermore, in Australia the cotton growers' networks were very strong and Hadley and Kahl personally knew all the distributors. The company was established by farmers, for farmers and, not surprisingly, it became grower-focused rather than profit-focused. With subsidies, they received a good price for the seed and any profits were reinvested back into R&D or capital equipment. Growth and expansion were not a consideration and the company stayed on a plateau for several years.

In Garnsey's (1998) terms, the firm was financially self-sustaining with production cycles in place and the company was definitely within the Resource Generation Phase. It is in this phase that Garnsey identifies some critical problems. One is that new members assimilated into the firm will not have the commitment and perhaps the appropriate skills to drive the company forward. Lack of growth orientation eventually produced a culture whereby CSD employed only permanent people who were related to those already working for the company. This closed shop environment made things very difficult from an operational perspective, especially if the company tried to sack anyone. It is a small community and everyone sees what is happening.

Such lack of commitment meant that effective practices were not implemented. Financial information was not maintained and contracts were handed out with a handshake. The practice of debt collecting was never put in place and, before the recent company restructure, more than 100 people owed the company money. CSIRO research was conducted in the same community and employed similar family members, locking in the culture even further and detracting from any systems that could produce effective market feedback. There was no capacity to adapt to a changing industrial environment when it did eventually come about.

Two safeguards kept the company solvent. Formal alliance with CSIRO ensured that the company always had a great product, and its structure ensured that it could not be taken over, which is a threat to most other firms in such situations. The environment in which the company operated changed dramatically in the mid-1980s due to two factors. First, the industry itself was threatened by the overuse of chemicals. Over 300 insects that live in a cotton crop and a large number of weeds made spraying necessary on a large scale. This practice was environmentally unsustainable. Second, the market position that CSD had was being threatened by a new competitor who was developing new biotechnological products that could mitigate the environmental issues domestically. Overseas, competition was also growing with several countries now growing Australian seed to commercial quantities for distribution. The only advantage CSD could maintain was being a few years ahead. However, that could be sustained only for a short period and therefore, under threat of extinction, the company began to remobilise its resources on several fronts. However, these activities move the firm into the Growth Reinforcement Phase, which is beyond the scope of this study.

6.4.3 Summary of Generation Phase

The two firms that have reached this phase of their growth were potentially self-sustaining with production cycles in place. For both firms assimilating new members was a critical problem. For Cochlear, the problem was both cultural and professional. In both cases as the firm grew, or was forced to grow to survive, solutions had to be found, but they were not without pain and led to original members leaving the firm. Competencies built in previous phases were used to maintain or extend key

relationships with customers and distributors. However, to ensure that appropriate systems were in place, routines needed to be overhauled to improve stability of production fluctuations. The capacity to adapt to a changing industrial environment, including the challenge from competitors, was a problem experienced by both firms. These growth problems are consistent with the Garnsey (1998) growth model.

6.5 Chapter summary

The growth patterns demonstrated by the five firms in this study approximate the composite account of Garnsey's (1998) model, with some modifications. Three clearly defined phases were demonstrated by the growth paths of the five firms, although the transition of firms from Resource Access to Resource Mobilisation proved to be unclear and this thesis included another Resource Access/Mobilisation crossover? Phase for clarity. Only two of the five firms reached the Growth Generation Phase described by the model. The critical problems identified within the firms' growth phases were aligned to the Garnsey (1998) model in the first and third phases.

The second phase, the Mobilisation Phase, was less clearly defined. Two firms that were more closely aligned to the engineering industry, having single products targeting single markets, did fit the Garnsey (1998) model to a certain extent. The remaining three firms with long gestation periods and revolutionary technology platforms faced uncertain markets that created major problems for the firms. The substantial financial and IP resources that were required forced all three companies to continually return to Resource Access Phase, even though they were already generating resources through the sale of products. That is, in their Mobilisation Phase these three firms were simultaneously experiencing problems of all three phases while attempting to reach break-even point. All three remain in the Mobilisation Phase despite earning substantial revenue and all have had to reassess their strategic directions in an effort to maximise opportunities and remain viable.

The study has been able to answer the research question by demonstrating the very difficult path that Australian biotechnology entrepreneurs must negotiate to achieve commercial success. The obstacles to successful commercialisation of Australian biotechnology research are clearly numerous and difficult to overcome. Those problems

are due to the inherently difficult nature of the scientific firm with revolutionary technology and external factors such as national infrastructure and cultural perspectives. The two firms in this study that have been able to achieve growth to resource generation stage have done so with the assistance of government protection and subsidies in one case and an established global infrastructure to support their growth ambitions in the second case. Entrepreneurial tenacity and very creative problem solving skills have been a major contribution to the survival of all firms in the study.

7 Conclusions

This research has investigated the anomaly that the world-class standard of Australian biotechnology science is not reflected by numbers of companies established or products launched. The industry has been identified as a significant element of sustained economic growth and as such it has attracted a great deal of government interest and financial support on a global scale. In Australia there has been comparatively little commercial success in the industry except for two medical device companies and one pharmaceutical company. The aim of this thesis was to document the growth of a sample of Australian biotechnology companies in an effort to better understand the obstacles encountered by Australian biotechnology researchers as they attempt to commercialise their research discoveries.

A qualitative focus has been undertaken with a view of making a contribution to the growing body of quantitative research already available to the Australian biotechnology industry. In doing so the thesis has asked the question, do the growth paths of Australian biotechnology firms compare with Garnsey's (1998) small firm growth model? More specifically, how have Australian biotechnology firms overcome obstacles to the growth paths of their firms?

7.1 Comparison of findings with Garnsey's (1998) model

Garnsey's (1998) model of small firm growth, discussed in Chapter 3, takes the form of a composite account of typical growth phases. This account, set out as a narrative, has been used throughout the thesis as a framework to gain insight into the research question and to develop a structure on which to present the research findings. This model originated with reference to engineering firms with in-house production and did not account for the additional complexities associated with commercialising discoveries in the biotech industry. The uncertainty that surrounds biotech products in terms of public acceptance and regulatory requirements results in long and expensive time lags that draw out the growth dynamic. Taking these differences into account, Garnsey

modified her model in 2003. The Garnsey (2003) model, however, begins at the foundation stage of the firm and therefore does not represent the early Resource Access Phase carried out in research institutions by scientists before the idea takes on a business perspective. Garnsey's more recent high tech growth models (Lim et al., 2006; Maine & Garnsey, 2006) focus on development cycles and process innovation. They do not enhance understanding of the entrepreneurial process, illustrated by the first phase in the Garnsey (1998) model. Therefore, this thesis has proposed that the earlier model still holds for the biotech industry, although once past the initial Resource Access Phase, the model requires modifications in order to reflect the specific problems of the biotech industry just described.

7.1.1 Access Phase

In the biotechnology industry, the research undertaken before a company is established constitutes the reason for the firm's existence. Studying the firm after establishment leaves out an important element and takes no note of the essential corporate learning and problem solving that is reflected in future events. In line with the model, the thesis has described the early beginning of each firm as the Access Phase. The study clearly identified four critical elements within this first phase: the entrepreneurial scientist, unique technology, financial support and environmental settings. This phase of the firms' growth adhered relatively well to the Garnsey (1998) model.

7.1.2 Crossover Phase

The second phase, the Mobilisation Phase, was described in line with the model as beginning with the establishment of a firm and a business plan where research and commercial activities are combined to develop technology with revenue potential. The study was able to demonstrate that the progress of the firm's growth between the first two phases was blurred. In one of the cases investigated, neither the scientist nor the commercial partner controlled the growth process for a period of two years. To account for the anomaly, an additional Crossover Phase has been proposed. The thesis demonstrates that this Crossover Phase is a critical element missing in the growth paths

of many Australian biotechnology firms. Australian Government assistance in this phase enabled this particular company to determine that there was indeed an extensive global market demand for its product. The market survey also simultaneously identified critical networks that would ensure successful market penetration of the invention. Furthermore, it enabled a commercial partner to patent a commercially manufacturable design for the device without leaving itself open to extensive financial risk.

7.1.3 Mobilisation Phase

In all five cases, a change of company leadership was required during the Mobilisation Phase. The need to change focus of the company from a technological to a commercial perspective was critical to the survival of each company. The inability of the entrepreneurial scientist to fully understand that focus created, in some instances, serious problems for the company. In identifying the complexity of the industry and its supply chain the thesis has demonstrated the complexity of qualifications and experience required of company leaders as the firm moved down the value chain. When a change of culture was required within this phase, it was often challenging for entrepreneurial scientists to hand over the reigns, given the entrepreneurial personality described by Schumpeter (2004).

Two firms, with single products targeting single markets, did fit the Garnsey (1998) model to a certain extent throughout their Mobilisation Phase. The remaining three firms with long gestation periods and revolutionary technology platforms faced uncertain markets that created major problems for these firms. The substantial financial and IP resources required forced all three companies to continually return to the Resource Access Phase even though they were already generating resources through the sale of products. That is, in their Mobilisation Phase these three firms were simultaneously experiencing problems of all three phases while attempting to reach break-even point. All three remain in the Mobilisation Phase despite earning substantial revenue and all have had to reassess their strategic directions in an effort to maximise opportunities to remain viable. The thesis proposes that the ability of a firm to simultaneously straddle so many problems across the three phases demonstrates

significant creative problem-solving abilities. However, it also explains the enormous difficulties of commercialising biotechnology research.

Once the company reaches break-even point and is able to make profits, it moves into the third phase, the Resource Generation Phase. Very few Australian companies have reached this phase of their growth and the above discussion provides an insight into this phenomenon.

7.2 Limitations of the study

By studying five firms that have survived the growth process, the research is unavoidably limited by a survivor bias. Additional studies into firms that have not survived growth challenges, and have folded, would provide a valuable comparison to the competence-building experienced by the entrepreneurs in this study. Continuing the research by following the companies in this study would provide a more informative comparison between the three firms currently still in the Mobilisation Phase of their growth and the two companies that are already generating profits. Similar research into additional firms in each sector in this study would also provide a wider comparison of their growth patterns and assist in better understanding the industry as a whole in this country.

7.3 Contributions of the research

The contributions of this research fall into two broad categories. In the first category are outcomes that expand upon aspects of the Garnsey (1998) model. Second are findings that have wider implications by shedding light on the complex nature of the Australian biotechnology industry and the types of obstacles faced by small firms trying to establish a foothold.

The identification by this study of a Crossover Phase spanning the Access and Mobilisation phases of the model has contributed to the literature in two ways. First, it has identified an element in the growth process for the biotechnology industry that differs from the in-house technology development of the engineering industry described

by Garnsey (1998). It has also provided an insight for improving government policy. Assistance from the Australian Government at this phase of a biotechnology company's growth could provide meaningful support to the fledgling firm before they spend many years developing products that, although highly worthwhile, will never provide a financial return to investors because the market is just not big enough for that to happen.

When the extent of markets is understood then business plans setting realistic courses of action can be developed. This thesis has demonstrated that biotechnology companies operate with technology platforms rather than single products and therefore they have several choices of direction when developing business plans. Understanding market demand provides an additional source of information on which to develop a sustainable course of action.

The finding that very few Australian companies reach the Resource Generation phase of their growth also contributes to the literature by challenging the linear perspective taken by many small firm growth models. For instance the models of Sparling and Vitale (2003) and Kapeleris et al. (2004), discussed throughout this thesis, suggest a linear progression of growth that is clearly not visible in at least three of the five firms studied. The Garnsey (2003) model, it is proposed, provides a better understanding of this phase of firm growth in the biotechnology industry. This thesis also adds to the Garnsey (2003) model by identifying the path-dependent nature of corporate learning undertaken by entrepreneurial scientists that can severely hinder progress.

The study has shown how the nature of the Australian institutional environment can create difficulties for scientific entrepreneurs. Although in the case studies the universities provided basic facilities and access to students to assist with the research, support with patenting and other commercial issues was generally available to only a very minor level, if at all. Australian universities have improved their assistance to scientists who wish to commercialise their research in recent years but such help is not consistent across Australian universities. The research illustrated how these scientists needed to go to extraordinary lengths to produce results that eventually developed their technology.

In addition, the study has highlighted the existence of a long history of national policy that does not sustain development in the industry. It is proposed that such actions have

limited the growth of crucial commercial knowledge and infrastructure. A possible consequence of the demise of the penicillin industry, described in Chapter 2, is a lack of pharmaceutical or medical companies with international infrastructures to take on the downstream marketing and legal services that are so vital for product development. US entrepreneurs emerged from three sources: local venture capital firms with experience in the high-tech boom, business leaders from previously successful biotech firms that had been sold to large pharmaceutical firms, or large pharmaceutical companies. In Australia these sources have not been generally available and critical mass for the industry is limited. The one company that began under the umbrella of a group of similar companies successfully leveraged the available knowledge and infrastructure from that group to become one of the country's leading medical device companies.

The study has demonstrated that government policies were not always well targeted and in some cases were actually in conflict with each other. The experiences of firms in this study concur with other findings outlined in Chapter 2, with examples such as the Commonwealth Department of Industry, Tourism and Resources using the Biotechnology Investment Fund (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. Also 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. This study provides qualitative support to the findings of other quantitative studies that challenge many government taxation policies on issues such as options, capital gains tax and employee share acquisition scheme.

By examining issues of small firm growth through a long term, historical perspective in a particular Australian industry, this research has expanded knowledge of the small firm sector. In choosing to focus on problems that must be solved for firm growth, it provides important micro-level information for an economically important industry to add to quantitative information already available. Furthermore, it has studied firms in Australia, outside the developed economies of US, UK, Western Europe and Japan. Overseas studies usually do not include the Australian context and if used for Australian policy settings could exacerbate instead of solving ABT problems while wasting

valuable public resources. This research has produced findings directly relevant to the Australian biotech industry.

Finally, Australia has traditionally relied on agriculture, mining and, more recently, service industries, but this study demonstrates that these traditional sectors are undergoing revolutions of their own. The traditional slow-paced Australian agricultural industry, originally with safe markets and distribution links, has been required to make major overhauls to agricultural and distribution strategies in alignment with other sectors of the biotechnology industry. This study of the ABT sector demonstrates how these agricultural sectors have been impacted by the biotech industry and thus provides an insight into a high tech input into traditional industry perspectives.

The sample of five firms in this study demonstrated entrepreneurial tenacity and creative problem solving throughout their growth phases. They always saw such problems as solvable. They provide evidence that Australian biotechnology firms face a hostile commercial environment with little support from governments in their mobilisation phase, lack of supporting infrastructure or industry clusters, unsophisticated financial markets and hostile professional assessments. Yet in the face of these difficulties, certain outstanding companies survive, indeed flourish. But a country cannot build an industry on exceptions. It is essential to ensure that a more favourable climate greets the commercialisation of biotechnology scientists in the future. This thesis has mapped out some of the issues that such a new pathway will need to address.

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