

Bold Steps – New Horizons

An External View of New Zealand Biotechnology and its Future in the Global Arena

A Summary Report

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Preamble

The Channel Group (TCG) was engaged by Industry New Zealand to develop and author an independent, external, Unites States-based perspective on the current state, needs, and future directions of New Zealand's nascent biotechnology industry. This summary report is a reflection of our own several decades-long experience within the United States and international biotechnology communities, and a more recently acquired knowledge base relative to New Zealand that was enhanced over the course of two extensive trips to the country during the past nine months. During this time we met with a significant number of New Zealanders who advocate the growth of the biotechnology sector.

The Channel Group's directive from Industry New Zealand for producing this report has been to provide an independent view of the prospects and potential for New Zealand's biotechnology industry. In concert with this goal, the report both discusses and proposes a number of ideas for achieving growth within the New Zealand biotechnology sector. Although this report was developed independently of the work of the New Zealand Biotechnology Sector Taskforce, it contains input from a wide range of members of the community within New Zealand and from a number of well-known individuals from the Unites States biotechnology industry. The Channel Group has enjoyed significant access and support from many individuals from government, academia, the biomedical community and others in the biotechnology industry,

1. Introduction

1.1 Market opportunities

New Zealand's young biotechnology industry, built on a backbone of world-class science emanating from the country's academic centres and government-sponsored Crown Research Institutes (CRIs), is at a crossroads. To date, despite the enthusiastic support of a significant cadre of industry advocates and government, the industry has not developed sustainability or a major international commercial success. Nonetheless, New Zealand has in place many of the capabilities requisite for building a successful industry. New Zealand's biotechnology industry holds great promise. The industry and its innovative profile can support the country's goal of building a high-value knowledge-based economy to propel it into the top half of the OECD nations.

The biotechnology industry in its broadest sense requires a vision that is quite different from that which drove the primary industry sectors, and, consequently, requires skills, experience, and investment horizons that are different. A paradigm shift from focus and dependency on the traditional biology-based industries of New Zealand will necessitate a new view of commercial horizons, government investment, physical infrastructure, and human resources. To bring about such a shift will require partnerships amongst government, academia, industry, and many support organisations. Currently the government-industry ratio of investment into research and development in New Zealand sits at 65:35 percent. Within the OECD countries it is reported that increasingly industry's investment in research is greater than that of government and is now responsible for more than 50 percent of research expenditures. The creation of an innovative commercial biotechnology industry will fuel the type of research spending within New Zealand that the OECD suggests is an economic driver of the future. Initiatives must be put in place to encourage significant global investment in New Zealand's biotechnology industry, both directly and through commercial partnerships. In addition, the status of current regulatory policies, tax policies, and government investment policies, as barriers or gateways to building a successful industry, must be reviewed.

New Zealand will be able to build a broad-based biotechnology industry grown from its unique assets and the overlap of biomedical and primary sector research. Current investment within New Zealand has resulted in the creation of several important biotechnology sectors, reviewed in this report, that The Channel Group believes have great potential for further development. They include:

- Biopharmaceuticals
- Agriculture biotechnology
- Transgenic animals and plants
- Industrial and environmental
- Biomanufacturing
- Marine
- Bioactives
- Nutraceuticals
- Clinical trials and research

The **biopharmaceutical industry** represents the largest portion of the international biotechnology industry and the one that attracts the greatest amount of investment into research and development and infrastructure. It is important that New Zealand fosters the development of a biopharmaceutical sector, although the amount of investment and focus should be balanced within the overall needs of the industry. To do so will support the objective of global investment into New Zealand's economy, and will attract the requisite experienced, knowledgeable, and talented people who will drive all sectors of this industry in New Zealand.

Agricultural biotechnology represents the most obvious and short-term opportunity for New Zealand to establish global leadership in innovation. The development of **transgenic animals** for the production of pharmaceuticals, biomaterials, and for use as research models, is a logical outgrowth of the country's outstanding animal health status and vast experience in breeding.

New Zealand's unique **marine** biology and well-developed agricultural sector has the capability to develop an initiative to identify and characterise **bioactive** materials that can be employed in several biotechnology sub-sectors, including pharmaceuticals, industrial processes, and bio-remediation. The country's extensive knowledge base in agriculture, animal husbandry, forestry, and the biodiversity of its plants and sea, will serve as a foundation for the development of important commercial products used in **industrial and environmental** applications, in addition to the development of new and enhanced sources of nutrition. TCG believes that the **biomanufacturing** sector could represent a significant opportunity and play an important role in establishing New Zealand's presence on the global biotechnology landscape.

Finally, the **nutraceutical** sector is potentially a very important growth opportunity for the country. However, the level of investment in research, the development process, scientific validation, and regulatory controls associated with the nutraceutical sector are vastly different from those found within the biotechnology industry. Consequently, this report recommends that the nutraceutical sector in New Zealand be supported and developed separate from the mainstream biotechnology initiative.

The country's academic medical centres are contemporary in their knowledge of **clinical trial** design and implementation. New Zealand has several advantages over other regions that are working in this area, including seasonal (Southern Hemisphere) differences, cost, regulatory harmony and potentially ease of patient recruitment, and thus speed. Although this sector might represent a major opportunity, the country's policy regarding public funding of pharmaceuticals via PHARMAC might be a barrier for major biotechnology and pharmaceutical companies to establish facilities, invest, form partnerships, or conduct trials within New Zealand. The conduct of such trials represents a clear opportunity for the biotechnology industry and the country that should not be missed. Every effort should be made to establish conditions in New Zealand that will welcome the presence of the international pharmaceutical industry.

1.2 The New Zealand science baseline

Global biotechnology has been built on a foundation of world-class science that has been translated into powerful intellectual property that thereby has conferred on its owners the rights to produce and sell proprietary products. A nation's capability to grow its own biotechnology sector can only be enhanced by retaining and attracting the best of the world's scientists. The quality of an industry depends on the quality of its individuals, and frequently on the absolute quantity of those people.

Although New Zealand has a distinguished scientific community that has generated high-quality scientific output, it has not as yet demonstrated a sufficient and broad-based commercial orientation for transforming scientific concepts into commercially viable products. Evidence for this assertion is based on the dichotomy of the excellent publication track record of New Zealand academics relative to their publication rates (top third of OECD countries) and their surprisingly low performance in patent production. New Zealand patent production is less than 20 percent of the aggregate average of the OECD countries and near the lowest third of all countries in the issuance of United States and/or European patents. Rectification of this situation, fostered through government initiatives, will allow New Zealand to capitalise on its academic assets.

1.3 Some key issues and recommendations

To provide an added jump-start to the biotechnology sector, this report suggests that New Zealand should develop a **recruitment programme to bring world-class scientists and business people to the country** through the enhancement of its infrastructure. At the core of this proposal is the suggestion that two new institutes be created as the centrepiece for the research sector of the biotechnology industry. The Institute for Agricultural Biotechnology and the Institute for Biomedicine and Biotechnology Development could be showcased and would form a major part of an inducement for expatriate life sciences luminaries to return to New Zealand. However, that effort will require more than the construction of an institute. Significant long-term funds will be required, great flexibility and research freedom will need to be offered, and incentives to allow such scientific leaders to grow their personal economic base while in the country will be needed. In addition, this report suggests that New Zealand should consider attracting a cadre of experienced and market savvy ex patriates and international executives from North America and Europe.

In New Zealand today, there is not one obvious site where young companies can develop and grow within the environment of a supportive academic centre. In the United States most major biotechnology clusters have developed in proximity to the most distinguished academic centres whose scientists have provided the core intellectual property for the creation and initial growth of the companies at those sites. TCG suggests herein that New Zealand **consider the development of a significant Science Park** that would house the proposed Institute for Biomedicine and Biotechnology Development. This campus would contain government-supported incubator space, offer a wide range of shared services, provide availability of technology and equipment at the academic center, offer significant computational capacity and contemporary communications technology, and provide meeting facilities to hold scientific and business symposia. The Science Park should be located at a site having sufficient space for the construction of biotechnology companies, infrastructure, and an expanding academic research laboratory environment. In short, it will become a showplace for New Zealand innovation and progress.

Access to significant capital is essential for developing a vibrant biotechnology industry. Without pioneer venture capitalists and public capital markets offering capital to high-risk research-based companies there would be no biotechnology industry. Financial capital is the lifeblood of biotechnology, and the availability of sustaining capital is a very significant limitation for the growth of biotechnology within New Zealand. TCG suggests that government develop a grant system providing funding for future scientific entrepreneurs to develop their ideas into business plans. TCG further suggests ***the creation of a biotechnology specific Venture Investment Fund (VIF) fund for seed stage investments*** that should be run by managers who have significant experience in the creation and management of biotechnology companies.

New Zealand clearly has the potential to be an integral part of the global biotechnology community. To achieve that goal, there are many fundamental national issues that must be addressed, including resource allocation, focus, positioning, and most importantly, expectations. New Zealand's positioning relative to global biotechnology will determine to a large extent the potential for attracting international investment and participation in the local industry. New Zealand's current and future policies on intellectual property, regulatory harmonisation, taxation, pharmaceutical reimbursement, and domestic and foreign investment will serve as important bell wethers for the future of the industry in the country.

1.4 Global investment and market opportunities

International investment in New Zealand's biotechnology companies is less than optimal. Foreign fund managers view New Zealand's distance, and lack of local fund management partners who can cooperate in the vetting of projects, as barriers to entry. Although New Zealand's current biotechnology industry is not driven by the development of pharmaceuticals, the overwhelming majority of global investment in biotechnology is focused on the creation and ultimate marketing of pharmaceuticals and biotherapeutics. New Zealand's policy toward the procurement of pharmaceutical products through the PHARMAC agency and the introduction of generics has had a cooling effect on corporate investment in New Zealand. Furthermore, these policies affect the interest of international companies toward using New Zealand's clinical trial resources. These are important issues both for the short-term and long-term economic status of the country, and the country's current policy should be reviewed relative to its impact on the development of the industry.

The government can continue to play an active role in the growth of biotechnology, through the development of international cooperative investment programmes, such as the BIRD Foundation, to encourage cross-border collaboration and investment. This matching grant programme provides capital resources for funding bi-national research and commercial collaboration. New Zealand should seek out opportunities to establish such collaborative engines with countries such as Australia, United States, Canada, Israel, various Western European nations, Singapore, Malaysia, Taiwan, and China. New concepts such as a "not for profit" foundation aimed at accessing international research funds should be an important part of the international collaboration paradigm.

Ultimately, New Zealand's biotechnology industry will be driven by its ability to export products and services and to form collaborative multinational partnerships. International business development activities require sufficient capital and manpower resources these appear generally to be insufficient today and for the foreseeable future in the majority of the current New Zealand biotechnology companies. It has been proposed that a way for New Zealand to rectify that situation will be to establish

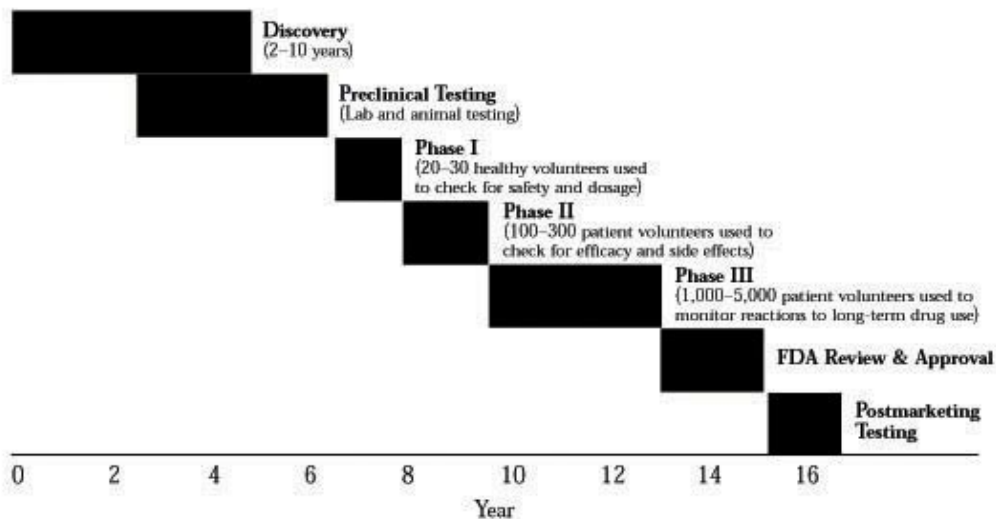
a bi-portal economic development initiative to support market access and collaboration. This idea is well-founded and should be expanded to become a source of competitive intelligence, human resources, and the promotion of New Zealand's biotechnology industry and academic centres in the United States.

2. Sector Opportunities

2.1 Biopharmaceuticals

In order for New Zealand to be a meaningful player in worldwide biotechnology, it must develop a significant drug discovery sector. Growing drug discovery companies within New Zealand will need and want to partner with international pharmaceutical companies. The basis for such collaborations is not only financial, but is based on the need of the biotechnology company to access the internal capabilities of the large drug companies in order to usher their drug candidates through the approval processes. The graph below illustrates the timeline for the process of drug discovery:

Biotech Drug Discovery Process



Source: Ernst & Young LLP, *Biotechnology Industry Report: Convergence*, 2000

It takes approximately a decade and hundreds of millions of dollars (including all overhead costs and drug failures) in investment for a biotech company to reach the point at which it can apply for regulatory approval for its first product. However, the bulk of biotechnology companies in the United States and Europe engaged in the development of biotherapeutics are finding that it is most cost efficient for them to bring those products to Phase IIa, which many companies consider to be the stage at which proof of principle is achieved, and then to partner with pharmaceutical or large biotechnology companies. In fact, many pharmaceutical companies are unwilling to invest in earlier stage products and feel the requisite need to take over the development process at this point in the clinical trial process. Such a strategy for drug development minimises risk on the part of the biotechnology company and allows smaller companies, wherever they might be located in the world, to participate

in the process. Thus, New Zealand biotechnology companies should be no more advantaged or disadvantaged than their counterparts in other locations relative to infrastructure, regulatory and clinical trials experience.

The process of growing a successful biotechnology company is lengthy. Underlying that timeline is the need for exceptional science, technology, intellectual property, as well as management that can secure the necessary financing to allow a company sufficient time to bring to market its first product and to develop a technology platform that will sustain the development of additional products.

Assets and opportunities in New Zealand for continued growth of biopharmaceuticals

- Strong, broad basic research efforts in scientific institutions (universities, hospitals, CRIs)
- Researchers with abundance of good ideas and novel ways of approaching research questions
- Creative and novel approaches toward product concepts
- Available infrastructure, including developed communication system
- Well-educated researchers and well-educated population
- Core group of biotech companies, including Genesis Research and Development Corporation Ltd, Proacta Therapeutics, Pacific Edge Biotechnology Ltd, Protomix Corporation Ltd, Antipodean Biotechnology Ltd, NeuronZ Ltd and Virionyx Corporation Ltd.

Needs for the growth of the drug development sector in New Zealand

- Experienced management has been the *sine qua non* for the growth of the best biotechnology companies in the United States. In order to effect alliances with strategic partners, particularly in the United States and Europe, it will be necessary to develop rapidly a core group of experienced biotechnology managers having scientific and business skills and, most importantly, relationships with pharmaceutical companies and the larger biotech companies.
- Smart, patient money with deep pockets and associations with United States, European, and Asian venture capital firms will be necessary for funding the later development and commercialisation stages.
- Development of critical mass of personnel in carefully planned areas of strength, eg diabetes, obesity, heart disease, and cancer.
- Careful selection of focused areas of research to build a meaningful sector. It is not likely that all sectors of health care can be covered.
- Cultivation of global strategic partners in order to finance the later stages of development and to market ensuing products.

Conclusions and recommendations

It is important that New Zealand foster the development of a biopharmaceutical sector although the amount of investment and focus should be balanced within the overall needs of the industry. To do so will support the objective of global investment in New Zealand's economy and will attract requisite experienced, knowledgeable and talented people who will drive all sectors of this industry in New Zealand.

It is recommended that amongst New Zealand's initiatives in this sector are the following:

- The creation of a focused development consortium leveraging the skills and knowledge of New Zealand's leading academic institutions to achieve critical mass in several key disease areas of importance to the people of New Zealand and with great promise for investment return. This effort ought to be financed initially via government grants. Its presence will make it possible to attract pharmaceutical funding for projects and for the development of new companies.
- Each consortium focused on a specific disease or group of diseases should develop a web of international partnerships with other research groups.
- The consortia should be able to spin-out companies, following the achievement of key milestones and the attainment of critical mass, using a combination of venture capital and pharmaceutical financing. Pharmaceutical alliances will validate for the venture capital investors that the technology underpinning the company has commercial potential. Similarly, the pharmaceutical company will be guaranteed that it will not be the sole source of financing for the spin-out company. In any event, pharmaceutical companies would never be willing to shoulder the task of managing a small company. Their interest in striking such strategic alliances is to fund research teams and ultimately to procure a commercial product(s) that they will manufacture and market.
- The securing of pharmaceutical strategic alliances and the concomitant funding associated with such deals is one of the highest priorities for growing the drug development sector. It has been suggested by several parties and reports, including one published in June 2002 by the New Zealand Institute of Economic Research entitled "*Bio-pharmaceuticals – A Pathway to Economic Growth?*," that if the bio-pharmaceutical industry is to become an important industry within New Zealand it will need pharmaceutical company funding.

Although pharmaceutical discovery is a long-term process from early concept stage through regulatory approval, there are a myriad of strategies that can be employed to shorten the time to market. Because the area of human health care is the primary focus of the largest biotechnology companies, it is important that there should be a real focus to develop a 'winner' in the shortest time possible within New Zealand. That company will signal to the world that New Zealand is a meaningful global player in biotechnology. Amongst the paradigms for reducing development times and inherent risk are the following:

- Product focus on existing products with new uses and indications
- The development of drug delivery technologies

- Development of modifying technologies that can alter untoward effects of currently marketed drugs
- Licensing of products that are under development yet have little opportunity for continued financing
- Acquisition of products that no longer fall into the strategic portfolio of the innovating company.

2.2 Agricultural Biotechnology

New Zealand's unique disease-free animal populations represent a significant asset for the country, as does its world-class wine production and extensive knowledge in the breeding of animals and plants. The country's innovation also is visible in its leading industry sectors that include wool, beef, and pulp production. To support these sectors several of New Zealand's Crown Research Institutes, including Forest Research, HortResearch, and Crop and Food Research, and its leading academic centres in Auckland, Canterbury, and Otago have invested millions of dollars each year in applied research to improve the financial outcomes of these important industries. It is clear that New Zealand has a great deal at stake relative to the adoption and success of agricultural biotechnology on a global basis. It could be argued that biotechnology will have a significant impact on New Zealand's future either as a result of the country's continued innovation and leadership or through innovation driven by external sources.

New Zealand's economic roots are deep in agriculture and biology. The country has benefited significantly from its diversity of climate, expansive open lands, and remoteness to build success and innovation in animal, plant, and forest-based industries. These industries have had and will continue to have a significant impact on New Zealand's economy and her people. Agriculture contributes 17 percent of New Zealand's Gross Domestic Product and, according to Statistics New Zealand, there are more than 170,000 New Zealanders employed in agriculture, horticulture, and forestry. Agricultural exports totalled \$20.6 billion, and amounted to about 66 percent of the total of New Zealand's exports.

In addition, New Zealand has completed a thorough and thoughtful review of the issues surrounding genetic modification. The results of this important work were reported in the *"Report of the Royal Commission on Genetic Modification"* issued in 2001. A significant amount of study was focused on issues affecting crops, field use, and food production. Specifically, the study analysed the effect of genetic modification on New Zealand's unique environment and biodiversity and the risks and safety associated with genetically modified crops and foods. New Zealanders take great pride in their values relative to the uniqueness of the environment of New Zealand and the uniqueness of their cultural heritage. These values will form the cornerstone of the report and will ultimately be an important foundation for New Zealand's agricultural biotechnology strategy. From this careful study, and the current moratorium, should come a well thought out, scientifically supported and valid set of new directions for the acceptance of agricultural biotechnology and genetically modified plants and animals that could lead the way in the development of international protocols. This approach should be supported by clear, balanced regulations that establish a path towards development in concert with the ethics and sensitivities of the New Zealand people.

Although agricultural biotechnology is clearly important to the country and its existing economic drivers, global agricultural biotechnology has been dominated primarily by a number of very large, yet consolidating, corporate players who control the vast

majority of existing product sales. As a result, there are a limited number of potential strategic partners and investors currently associated with this sector. The industry has been undergoing consolidation for the past five years, during a period when the issues of genetically modified organism regulation and product labelling were working their way through North America, Europe, and Asia. In 1995, according to Burrill & Company there were 11 corporate players in the crop protection sector, whereas today this list totals 4-5 large corporations.

A similar situation also exists within New Zealand. The agricultural output of the country is controlled to a significant extent by large cooperatives that consolidate the interests of farmers and distribute the profits broadly. These cooperatives have played an important role in building and maintaining New Zealand's position in the dairy, meat, wool, wood, and fruit industry sectors. Recognising the importance of these cooperatives for the country's economy, the New Zealand government has supported their efforts, through significant research and development support monies that ultimately flowed to the CRIs and currently through funding mechanisms such as Foundation for Research, Science and Technology (FoRST). The aggregate investment has been significant over a great number of years, and it has yielded important results for the cooperatives.

Conclusions and recommendations

New Zealand's current biotechnology effort in this sector is still largely internally driven by its large industry-specific strategic research and development activities. This approach is important for sustaining the innovation profile of these industries. However, such investment is largely focused on improving products for commodity markets where the return on investment dollars might be relatively modest. In reality, significant government investment into commercially directed research should be reduced somewhat and re-directed to provide the economic base for basic research and innovation in emerging market sectors. Government and industry should be mutually supportive of a goal to focus commercial research and development investment on product development to allow for a greater government investment in research innovation that should ultimately yield true high-value innovation. Government and industry should maintain their important existing partnership in research investment and collaboration while establishing balanced investment funding.

2.3 Transgenic animals and plants

Dairy farming and animal husbandry are marvellously developed businesses in New Zealand. The underpinning for those commercial arenas has been basic research on cattle that has been supported by government and private industry, and that assuredly will continue to be supported heavily. In addition, the country can boast the 'cleanest' animals on the earth. Based on currently available assays, there is no evidence of prion or transmissible spongiform encephalopathy contamination of livestock. To that end, the use of transgenic animals to generate large amounts of human-protein-based drugs is a natural fit for New Zealand.

The advantages include:

- Ability to produce significantly greater amounts of protein with higher expression levels and output volumes than observed with traditional cell culture techniques
- Ability to express novel proteins in milk of transgenic animals because of the unique nature of the mammary gland, including the ability to synthesise properly folded and assembled complex proteins
- Ability to modify proteins post-synthesis to correctly mimic proteins made in humans, including proper glycosylation and gamma carboxylation
- Ability to isolate proteins in a multi-step process that combines methods used to recover proteins from cell culture supernatants with processes from the dairy industry
- Potential for flexible scale-up of protein manufacturing to meet increasing production needs throughout the product development process
- Potential for significant reduction in cost per unit weight of protein because animals are the ultimate bio-reactors requiring less raw materials and less complex monitoring, significantly less investment in plant and equipment and the support systems than customary validated recombinant cell culture production or biopharmaceutical fermentation systems

Transgenic animals such as cattle or sheep represent important potential models for the study of human diseases and biomedicine. In addition, a great deal of research is underway to develop humanised organs in animals that could ameliorate the critical shortage of kidneys, livers and other organs. For example, pigs have historically been a source for valves for cardiac implant. Furthermore, there is a significant on-going study on the use of transgenic pigs as a source of islet cells to be used in xenotransplantation in order to reduce or eliminate the need for exogenously administered insulin by diabetics.

Conclusions and recommendations

The development of transgenic cattle represents an enormous opportunity for New Zealand. It will be important to develop further this platform technology and to consider harnessing it for the production of the following types of products:

- Antibodies, including fusions of antibodies and enzymes
- Vaccines
- Human serum proteins
- Designer milk and nutraceuticals
- Expression of protein used in biological manufacturing
- Large animal models for research applications
- Organ transplant
- Islet Cells

Serious focus and the development of research depth in these areas should allow the growth of a meaningful biotechnology sector.

2.4 Biomanufacturing

It has been widely reported that the global biopharmaceutical industry is facing a major and ongoing shortage of manufacturing capacity. There are currently more than 300 biopharmaceutical drugs in the pipeline and many more are anticipated as an outgrowth of genomics and proteomics research.

In a recent study by High-Tech Business Decisions, more than 40 percent of biomanufacturing company responders indicated that capacity would not meet demand for at least 7 to 10 years, and 23 percent of respondents suggested that capacity requirements might never be met. Another factor that has caused additional demand for more contract manufacturing capacity has been the relaxation of Federal Drug Administration (FDA) manufacturing requirements.

Opportunities for New Zealand in biomanufacturing

New Zealand has a number of important advantages that lend credence to developing a meaningful biomanufacturing initiative, including:

- significant cost advantage relative to countries in North America or Europe;
- significant experience in stainless steel engineering and fabrication skills which are a direct outgrowth from the dairy industry;
- a world leader in the extraction of specialist high value dairy proteins and animal-derived biologicals;
- good capabilities for the production of small quantities of drug compounds necessary to conduct clinical trials;
- existing long-term investment in the development of manufacturing processes through Crown Research Institutes such as Industrial Research Ltd.

Establishing a manufacturing base in New Zealand has important implications for the future of the country's biotechnology industry. Expanded biomanufacturing capacity will promote further biotechnology development, support the use of transgenic initiatives and potentially answer a significant future demand for vaccines to combat infectious diseases.

If New Zealand were to build a base of expertise in the development of biopharmaceuticals and the conduct of clinical trials, the ability to manufacture clinical trial materials in a GMP manufacturing facility will become critical. Technology New Zealand recently recognised the importance of building clinical trial capability in New Zealand through the awarding of its largest research and development grant to Antipodean Biotechnology. Antipodean Biotechnology is currently developing a treatment for Friedreich's ataxia and Huntington's disease.

2.5 Marine Biotechnology

One of the unique opportunities in New Zealand for biotechnology development might lie in the marine biotechnology sector. The seas around the country are replete with organisms and micro organisms which have great genomic variety, prolific breeding habits, and short life spans that make them useful subjects for significant research opportunities and commercial endeavours.

While the work of marine biology is important to the economy of New Zealand, the future holds far more promise than simply the fishing and hatchery industries. It is possible that contemporary marine biotechnology will be one of the next frontiers in biomedical research. Recent research also has suggested that marine biotechnology can be used to develop new biomaterials. Indeed, worldwide research efforts have indicated increasingly that the sea is a rich source of new and potentially improved products in many arenas, including:

- pharmaceuticals
- enzymes
- biomolecular Materials
- biomonitors
- biopesticides
- biomass for Energy Production
- bioremediation
- bioprocessing

The country has identified its marine-based biodiversity as a national treasure of great importance. The value of that biodiversity must be realised through properly the orchestrated commercialisation. To that end, government should assure that intellectual property realised from the discovery of new marine organisms or compounds from those organisms will be made available through exclusive licenses to committed commercial organisations, in order to productively exploit and to commercialise products derived from the surrounding ocean waters.

2.6 Clinical trials and research

New Zealand is a logical location for the conduct of clinical trials by international pharmaceutical companies or clinical research organisations (CROs) for the following reasons;

- high calibre of investigators who generally have trained in New Zealand and worked in the United States or Europe;
- New Zealand investigators have a reputation for delivering on time and budget;
- New Zealand laboratories are of a good standard;
- trials can be conducted in a cost-effective manner in comparison with the United States and most European countries.
- the research output of New Zealand investigators is rated highly.

The increasing number of compounds in the research and development pipelines of biotechnology and pharmaceutical companies, and the need by such companies to develop drugs faster to maximise patent protection and secure marketplace advantage means they are often outsourcing a portion of their drug development effort to CROs. By accessing CROs for the drug development process, pharmaceutical and biotechnology companies have reduced a portion of the inherent

risk in drug development. In turn, the CROs are constantly seeking worldwide sites for aspects of their work. New Zealand should be able to market itself favorably as a site for a number of CROs to carry out their work.

2.7 Industrial and environmental biotechnology

Industrial biotechnology is a term broadly describing the application of biotechnology techniques and tools for industrial manufacturing processes. These include waste treatment, environmental remediation, production of renewable energy sources, and replacement of certain chemically synthesised materials. One of the primary applications of industrial biotechnology is environmental management through the deployment of micro-organisms and enzymes.

Many companies are attempting to find cost-effective approaches for the treatment of both organic and toxic wastes. For environmental remediation to be successful, contemporary technologies will have to meet the expectation of improved performance over current methods concomitant with minimal incremental cost. New biotechnological processes have identified naturally occurring microbes that can live on toxic waste and could be bioengineered to degrade harmful compounds.

Environmental biotechnology uses bio-remediation to introduce nutrients to stimulate the activity of bacteria already present in the soil at hazardous sites or to introduce new genetically modified bacteria that render hazardous wastes into harmless by-products. Some bio-remediation methodologies also use naturally occurring micro-organisms to process and filter wastes before they are re-introduced into the environment.

One of the most promising applications of biotechnology in industry is the use of biomaterials for the development and production of renewable energy sources. Manufacturing processes worldwide rely heavily on petroleum, a non-renewable resource that generates considerable pollution and solid waste. Fuels derived from biomass provide a potential alternative to petroleum-based products. These alternative fuels, such as ethanol, represent an opportunity to produce 'sustainable' sources of clean fuels.

New Zealand is in a strong position to establish a leadership role in the development of industrial applications of biotechnology. The country has a significant base of knowledge in the understanding of forestry and the structure and genetics of plant materials. New Zealand's largest biotechnology company, Genesis, has established a foundation of knowledge in plant genomics that ought to be readily exploited in this sector. New Zealand's research centres possess, in addition to their body of knowledge in plant physiology, an established foundation in the identification and study of extremophiles (micro-organisms that live in inhospitable environments). This collective body of knowledge and expertise represents an important foundation for the establishment of new industrial biomaterials and processes.

2.8 Nutraceuticals

Nutraceuticals are bioactive chemicals from natural sources that are thought to have health promoting, disease prevention, or medicinal properties.

New Zealand is well positioned to become a competitive market player in this financially significant sector. The country has a long history of food research as an outgrowth of its dairy, crop and meat industries. In addition, it possesses great diversity in its horticulture and among its sea-based organisms that can be used for identifying and developing new nutraceuticals. Research centres have developed significant expertise in understanding food functionality and structure. Furthermore, the country's animal health status provides an important distinction relative to its ability to provide animal-sourced raw materials for the nutraceutical sector. In addition, New Zealand has several established companies that have experience in the extraction of active ingredients from animal sources.

2.9 Bioactives

The bioactive market is often described as a subset of the nutraceutical sector. The key distinction is in the extraction of the active ingredient from the biological source, either synthetically or through a manufacturing process.

New Zealand with its unique marine biology and well-developed agricultural sector, has the capability to develop an initiative to identify bioactive materials that can be employed in several biotechnology sub-sectors, including pharmaceuticals, industrial processes, and bio-remediation.

3. Conclusion

This report has probed the issues surrounding the growth of the biotechnology industry within New Zealand to assess how it can be a significant player in the global biotechnology effort of the 21st century. Our conclusion is that New Zealand clearly has the potential to be an integral part of the global biotechnology community. To achieve that goal, there are many fundamental national issues that must be addressed, including resource allocation, focus, positioning, and most importantly, expectations.

New Zealand has already many of the capabilities requisite for building a successful industry. This holds great promise. TCG believes the industry and its innovative profile can support the country's goal of building a high-value knowledge-based economy to propel it into the top half of the OECD nations. New Zealand's well-established industries and research organisations, well-educated population, disease-free animals, and emphasis on a knowledge-based economy offer the country a clear, competitive edge in biotechnology. In addition to its important biology-based primary industries, New Zealand has a long history of academic excellence, investment in research, and now has a growing sector of support services that are essential for the growth of the biotechnology industry. New Zealand also has a government that is scientifically knowledgeable and supportive of the concept of building a significant commercial biotechnology sector.

The government's sector team and its leadership are experienced, informed and committed to building a significant economic presence for the industry. The components to achieve success are in place, the strategy is evolving, yet New Zealand will need to take bold steps to emerge from its status as an internally driven biology-based country to that of a global player in biotechnology.

Appendix

International Observations

“New Zealand is in a solid position to grow its biotechnology community. With world-class expertise in agriculture and livestock, disease-free animals, a well-educated population sustaining top-notch researchers and facilities, and established export markets, the country has an excellent foundation for reaping the benefits that biotechnology holds”.

Carl B Feldbaum, LLB: President of the Biotechnology Industry Organization (BIO)

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centres and related organisations in all 50 United States states and in 33 other countries. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

“The agricultural economy of New Zealand has potential to benefit greatly from biotechnology, which can yield wide impact for both plant and animal agriculture”.

Mr W Steven Burke: Senior Vice President, Corporate Affairs and External Relations, North Carolina Biotechnology Center

Mr Burke is responsible for those activities and programs with which the North Carolina Biotechnology Center - a private non-profit corporation working for economic gain to North Carolina - addresses governmental, policy, regulatory, ethical, societal and international issues. Mr Burke serves as Vice Chair of the Board of Directors of the recently constituted Biotechnology Institute, a non-profit corporation working for strengthened biotechnology education. He also is founding Chairman of the Board of the Institute of Forest Biotechnology, a private non-profit corporation addressing the scientific, industrial and societal issues of forest biotechnology worldwide.

“As for New Zealand, it has a bright future in biotech. A long history of successful international business, a strong position in the agricultural world, especially in animal breeding, forestry, and natural products, a population interested in nutrition, wellness and improved health, and a young, but growing biotech industry. New Zealand has the opportunity to be a world player in biotech in the 21st century. No doubt biotech will revolutionise the world, redesigning everything from drug discovery/development to personalised medicine, to wellness, to improvements in the environment and energy supply, plus the creation of new biomaterials and bioprocess...its here to stay...and New Zealand will play an important role”.

G Steven Burrill: CEO, Burrill & Company

Mr. Burrill is founder and CEO of Burrill & Company, a San Francisco-based merchant bank focused exclusively on the biotechnology industry, other medical related technologies, nutraceuticals and wellness products, agricultural biotechnology, and the biomaterials/bioprocess (industrial biotech) segments. He

was recognised recently by Scientific American as being among the top 50 leaders in science and technology worldwide and was labelled a 'biotech visionary'.

“There has been increasing focus in recent years on the need to direct resources toward applied (“translational”) research. It is worthwhile pointing out, as noted by the great Argentinean physiologist Bernardo Houssay, that without basic research there will be no research findings to apply. In thinking about the future of biotechnology, it seems important to keep this admonition in mind. For that reason, as New Zealand grows its biotechnology industry, it will be important to increase continuously the level of spending for basic research, the ultimate engine of innovation for biotechnology”.

Stanley N. Cohen, MD: Chairman and Professor of Department of Genetics, Stanford University School of Medicine

Dr Cohen was co-author with Dr Herbert Boyer of the famous Cohen-Boyer patent for the use of recombinant DNA to produce proteins. It is the seminal patent underlying the formation of the biotechnology industry. Dr Cohen co-founded Cetus, one of the earliest biotechnology companies that later merged with Chiron. He also is the co-founder of Functional Genetics Inc. Dr Cohen is a member of the National Academy of Sciences and recipient of numerous international awards.

“New Zealand’s well-established industries and research organisations, well-educated population, disease-free animals, and emphasis on a knowledge-based economy offer the country a clear, competitive edge in biotechnology.”

Raymond Fersko, JD: Managing Member, Ferskos LLC

Ferskos LLC is an international law firm with a concentration in biotechnology. Mr. Fersko is an adjunct law professor of biotechnology law, and lectures at the National Institute of Health (NIH). He was counsel for the company involved in two landmark cases, which established the first Cooperative Research and Development Agreement (CRADA) with Dr Robert Gallo and Dr Anthony Fauci. This landmark agreement was for the development of an AIDS vaccine, which resulted in the first clinical trial, conducted by the NIH.