

New Zealand Biotechnology¹ Overview

New Zealand has one of the fastest growing biotech industries the world. Its biotechnology sector comprises six public and 47² private core biotechnology companies. Almost 50 percent of these 47 companies were created in the last three years. There are 28 research institutes, of which 9 are Crown Research Institutes (“CRIs”) and are primarily funded by the New Zealand Government.

New Zealand’s geographic isolation and strict quarantine standards contribute to the best animal health rating in the world, uniquely positioning the country as a global leader in agricultural biotechnology research and application. This leadership position is greatly assisted by the R&D capabilities of sector leaders such as Fonterra, the CRIs, and the universities that undertake R&D specifically targeted at the primary industry sector.

Biotechnology Income and Expenditure

Biotechnology income in New Zealand for the 2004 financial year was valued at \$675 million, while biotechnology expenditure was valued at \$430 million for the same period.

New Zealand biotechnology companies export to more than 60 countries. Major export markets are the USA, Europe and Australia. Because many New Zealand biotech products are animal or plant derived, products must comply with New Zealand Government legislation and other countries’ protocols must be fulfilled, particularly for the USA and the EU.

Annual export earnings are predicted to reach \$1 billion by 2014.

New Zealand’s Biotechnology Strengths³

Large-Animal Based Biotechnologies

New Zealand’s long history of large-animal farming (sheep, dairy, beef and deer) has led to the development of world-class science and technologies. This includes genomics, reproductive and cloning technologies, large animal models of human diseases, and using molecular approaches to solve animal health issues and to enhance human health. The convergence of agriculture and biomedicine is a defining and unique feature of New Zealand’s biotechnology sector.

Plant-Based Biotechnologies

New Zealand has extensive knowledge of the biology of industrially significant plants, grasses, trees and crops (both arable and horticultural). This includes access to some unique germ plasm and expanding genomic databases. For nearly three decades, propagation of plants in culture from tiny tissue samples has been a niche business in New Zealand.

¹ The OECD defines biotechnology as “the application of Science & Technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.”

² Ernst & Young 2005 “Beyond Borders”.

³ NZ’s biotechnology research strengths adapted from Ministry of Research, Science and Technology (2005) “Biotechnologies to 2025”

Biomedical Science and Drug Discovery

Around one third of New Zealand's public research effort in biotechnology is in the area of health. While this is small compared with global research in this area, it includes research in areas that could be described as "lifestyle diseases" (eg CNS, cardiovascular disease, asthma, diabetes, cancer, osteoporosis and bone health).

Bio-processing Technologies and Bio-manufacturing

This predominantly involves the extraction of bioactives from meat and fish waste, as well as the retention of biological activity in unstable valuable compounds such as enzymes. From this research, New Zealand is developing bio-processing technologies to manufacture and market high-value molecules.

Innovative Foods and Health

Functional foods and nutraceuticals are a very important part of the New Zealand biotechnology sector. Much work is being undertaken in the identification of valuable bioactive compounds in food, the development of food and dietary supplements and nutraceuticals. A key and emerging sector is food safety and in particular food traceability

Bio-control, Bio-security and Bioremediation

New Zealand's economy is based on primary production with a range of unique and sometimes endangered plants and animals. It is therefore very vulnerable to bio-security threats and environmental contamination. New Zealand scientists are developing bio-control and detection technologies, and are seeking to reduce environmental damage through bioremediation which is the use of selected or modified bacteria or fungi to detoxify or degrade waste.

The key strengths listed above result from New Zealand having:

- Strong intellectual capital in the biological sciences, particularly in the animal sciences, horticulture, marine and biomedical industries
- High calibre internationally measured research and development which can be delivered at a cost of up to 40% lower than international levels
- A fertile biotech environment with export focused biological industries
- A pristine environment and unique natural resources with unique genetic and geological diversity – a fertile source of genetic information and natural compounds
- A clinical trials environment to exacting FDA standards
- Geographic isolation and quarantine standards that provide safety and security – New Zealand has the best animal health status in the world. It has no history of any List A (OIE) diseases and is one of only five countries in the world to achieve a category one rating from the European Union for BSE-related risk

Research

New Zealand's biotech research efforts are centered around its nine CRIs and the academic research resources of the tertiary education institutes. Five of the CRIs – Forest Research, Crop & Food Research, HortResearch (horticulture), AgResearch (agriculture), and Industrial Research – support private companies in addition to undertaking strategic, public good science in the biotechnology sector.

Likewise, university medical schools and science facilities have a long history of pioneering research. The focus on commercialization of new technologies by these research institutions is reflected in the rapid growth in the number of spinout biotechnology companies. Auckland University's commercialisation vehicle, Auckland Uniservices Ltd, is at the forefront of biotechnology spinouts in New Zealand.

General Trends / Opportunities for NZ

Biotechnologists are merging discoveries from the primary sector and research organisations to create new applications in the bio-medical and agricultural bioscience industries. One practical application of R&D in the agricultural biotechnology sector is in functional foods and nutraceuticals.

Similarly, biotech has a close relationship with developments in other technology sectors, like information technology, and increasingly in nanotechnology. Beyond increasing synergies between technology platforms, there are also growing convergences between biotechnology industry sectors. For example, the personalization of treatment through genomic medicine is forecast to be mirrored in developments in the food and nutrition sector through advances in nutrigenomics.

In its recent publication, the Ministry of Research Science and Technology⁴ noted trends in genomic medicine are indicating that:

- Diagnostics will become more *predictive*;
- Therapeutic interventions will become more *preventive*; and
- Healthcare (including diet) will become more *personalised* and tailored to the individual

Personalised medicine, where each individual will have their own biomarker status identified and an appropriate preventative therapy directed toward that disease, is becoming a reality.

This trend should be of benefit to the New Zealand life sciences sector. Personalised medicine will in no small way be based on pharmacogenomics, which is the ability to identify SNPs (single nucleotide polymorphisms) in the genomes of individual patients. This will make it possible to not only identify the specific genes responsible for diseases, but also to tailor drugs to an individual's particular needs, and will result in drugs with increased efficacy and reduced side effects.

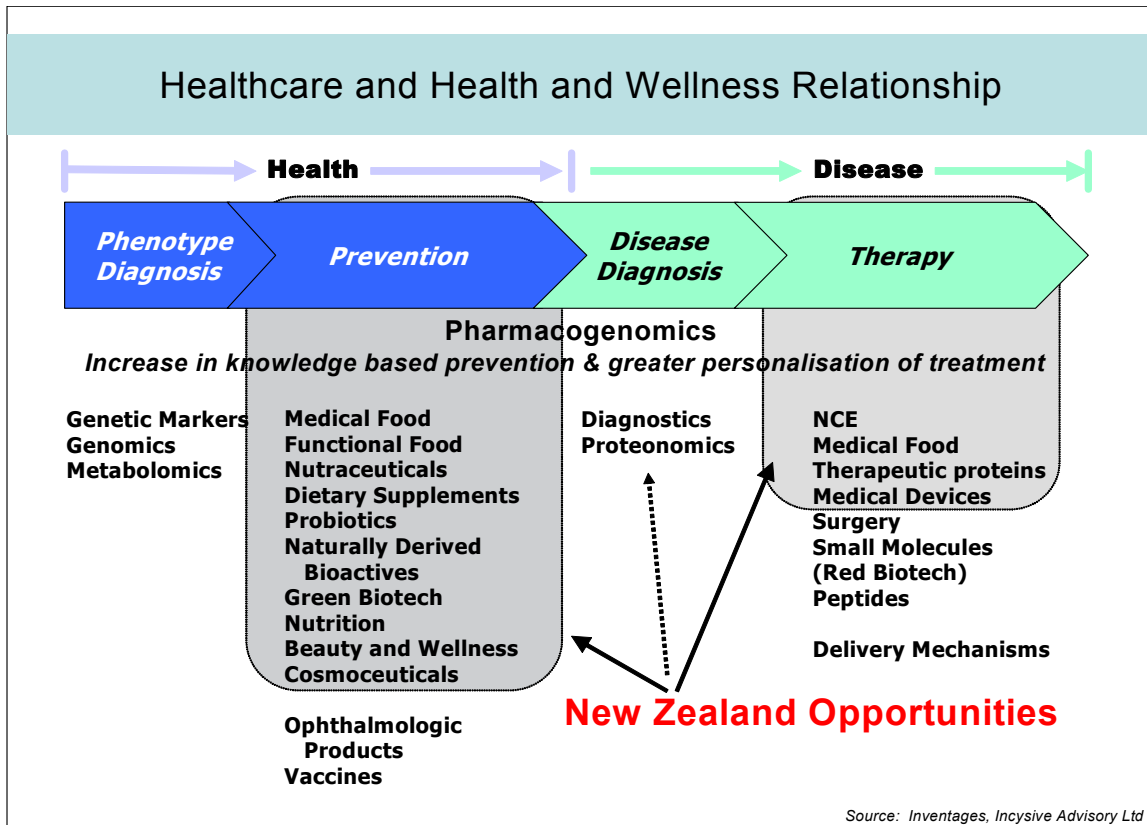
The importance of pharmacogenomics is evidenced by the opening of a new dedicated research centre at the Christchurch School of Medicine and Health Sciences.

⁴ Ministry of Research Science and Technology (2005), "Biotechnology to 2025"

The Carney School for Pharmacogenomics aims to shed new light on metabolic interactions between genes and drugs, improve treatment and avoid negative side effects on patients.

The Health and Wellness relationship to the health bioindustry described above can be demonstrated in Figure 1.

Figure 1⁵ **New Zealand Opportunities – Health and Wellness**



As shown in Figure 1, there is significant focus in the prevention section which mainly revolves around medical and functional foods, nutraceuticals and related products. This would appear to be the area where New Zealand has a key competitive advantage based on access to high quality raw materials from innovative farming systems, strong science platforms and well established supply chains.

Nutrigenomics

An integral component of Figure 1 is nutrigenomics. Nutrigenomics is described as nutrition customised to an individual’s genetic makeup to benefit their health and enhance normal physiological processes. Nutrigenomics uses genomics, proteomics and metabolomics approaches. It will lead to the development of new foods for individualised health and nutritional benefit. Just as pharmacogenomics has led to the concept of “personalized medicine” and “designer drugs”, so will the new field of nutrigenomics open the way for personalized nutrition. In other words, by understanding our nutritional needs, our nutritional status, and our genotype,

⁵ Reprinted with permission of NZTE.

nutrigenomics should enable individuals to better manage their health and well-being by precisely matching their diets with their unique genetic makeup.

Nutrigenomics New Zealand was recently established to concentrate initially on gut health. The founding partners include three CRIs: AgResearch, HortResearch and Crop & Food Research, and the University of Auckland. This is the first time a major university and CRIs have put together a multi-disciplinary team for the benefit of New Zealand health and the New Zealand food industry.

Functional Foods / Nutraceuticals

Consumers are increasingly interested in the health benefits food and drink products can offer, and manufacturers have responded to that challenge by developing a global dietary supplement market estimated to be worth around USD\$190 billion per year.

Health-targeted products ranging from traditional dairy products through to new generation nutraceuticals and functional foods are being developed. World leading research and development into functional foods is being carried out in New Zealand, both by the CRIs and large private companies such as Fonterra, and fruit processing company ENZAFOODS.

HortResearch, for example, is studying the health components in berryfruit, kiwifruit and pipfruit, while ENZAFOODS is identifying how compounds rich in phytonutrients can be extracted from by-products of the apple juicing process. Long term, the goal is for New Zealand to be known around the globe for its work in foods that promote health and performance.

Other examples of functional food development include:

- Lactopharma, a partnership between Fonterra, the world's largest exporter of dairy products, and Auckland University, producing functional food products, specialty ingredients, nutraceuticals and pharmaceuticals from milk and colostrums
- BioProducts NZ Ltd, which produces a range of high quality extracts sourced from natural raw materials. Currently the majority of extracts are sourced from deer products but extractions from other natural products, including plants, are also under development
- Removal of bitterness from milk protein hydrolysates for nutraceuticals and infant formula
- Production of new high activity antioxidants from natural sources
- Large scale production of hyperimmune milk
- Production of polyunsaturated fatty acids from fish oil for pharmaceutical and nutraceutical applications

Bio-Medical

Biomedical companies are typically being developed as spin-offs from medical research at leading universities. Key examples of New Zealand biomedical discovery companies are:

- Neuren Pharmaceuticals Limited, an ASX-listed biopharmaceutical company with a unique product pipeline applicable to two of the world's largest and

fastest growing therapeutic markets: neuroprotection and metabolism. The pipeline comprises compounds which mimic innate CNS protection and repair mechanisms and those which regulate growth and metabolism. Key indications include acute and chronic neurodegenerative conditions such as stroke, head injury, Parkinson's disease, cognitive impairment and multiple sclerosis, as well as disorders of growth and metabolism. The company has five families of compounds in various stages of development for neurological and metabolic disorders, and has just announced that one of its drugs, glypromate, has been granted permission by the FDA to skip phase IIb trials and proceed to phase III testing.

- Protemix has a pipeline of diabetes-related drugs, including one compound currently undergoing Phase II clinical trials and a number of promising pre-clinical drug candidates. In what may be a first for a New Zealand company, the US Food and Drug Administration (FDA) has recently granted fast track status for Protemix Corporation's lead compound, LaszarinT (trientine) for treatment of heart failure in people with diabetes.
- Proacta is a drug development company focusing on novel physiologically targeted therapies, including hypoxic (oxygen-starved) tumours. The portfolio is based on technology from Stanford University and the University of Auckland. Tumour hypoxia is a condition that exists in the majority of solid tumours and makes treatment with conventional chemotherapy and radiotherapy less likely to succeed. Proacta has developed a unique portfolio of molecules which are selectively active in hypoxic tissue.
- Living Cell Technologies is an advanced biotechnology company currently listed on the Australian Stock Exchange. The company's focus is on market-driven encapsulated living cell products, for the treatment of Huntington's disease, haemophilia and insulin-dependent diabetes.

AGRICULTURAL BIOTECHNOLOGY

Extensive knowledge and innovation in research and development in New Zealand is supporting low-cost, sustainable and environmentally friendly farming and forestry systems. Key examples of R&D in this sector are:

- The development of solid-state reproductive and milk-residue sensors at HortResearch and Sensortec
- Work by the Dexcel-led team to combine sensors and fractionation technologies in milking machines to detect and separate the biologically valuable proteins and peptides from whole milk
- ViaLactia, which identifies, discovers and commercializes genes that are important to the dairy industry, including those affecting pasture grasses, milk production and animal health. It is a subsidiary of the world's largest milk products export company, Fonterra
- Clonal afforestation through the development of micropropagation techniques to select superior tree variants for large scale forestry
- Genetic manipulation of flower colour
- The world's first enteric bacteria-based bioinsecticide, for the control of grass grubs

- The development and commercial production of vaccines to prevent sheep abortion and deer tuberculosis, and to promote fertility in sheep
- The extraction of complex lipids from milk and brain tissue

Clinical Trials

The research output of New Zealand's investigators is rated highly internationally. New Zealand has several advantages in clinical trials including lower cost, high ethics and regulatory standards, a UK/US style medical system and excellent patient recruitment.

Genomics

Gene mapping in animal and plants that can be leveraged into improved farming, forestry, food and health. For example, Genesis, New Zealand's largest biotechnology company, has built a technology platform to identify new molecules that regulate the distribution of information during cell to cell communication common to all life systems, from microbes to plants and animals.

Bio-Prospecting

New Zealand's unique biodiversity offers opportunities from bioactives. Key examples of such research include:

- Biodiscovery Ltd, which is undertaking high throughput screening of microbes for their ability to destroy plant pests and crop diseases. The company is looking for novel bioactives, in particular peptides and proteins for use in organic pesticides
- Crop and Food Research have a good understanding of seafood composition. It's combined seafood biochemistry and bioprocessing skills (including the ability to scale up from lab bench to pilot plant) mean that it is developing marine extracts obtained from seafood processing discards. Fish enzymes, protein and mineral extracts, and biomolecules extracted from fish collagen or lipid sources, promise a wide range of unique biological, chemical or physical functionalities

Biosecurity / Traceability

Funding for the establishment of a National Centre for Emerging Diseases and Biosecurity at Wallaceville, Upper Hutt, has been provided in Budget 2005. The new centre will add significantly to the country's capability to safeguard human and animal health and to protect the economy. It will comprise new state of the art Environmental Science and Research laboratories and new staff with existing Ministry of Agriculture and Forestry National Centre for Disease Investigation and AgriQuality facilities.

Biotechnology patents

In the year ended 30 June 2004, 117 biotechnology-related patents were granted to New Zealand organisations. This compares with the 56 patents reported in the previous biotechnology survey.

In the last five years, 348 biotechnology-related patents have been granted to New Zealand organisations. This compares with the 156 patents reported over the five year period ended 30 June 1999.

Biotechnology employment and qualifications

In 2004, the biotechnology sector employed 2,464 people in New Zealand. A large proportion of employees in the biotechnology sector are highly qualified. Thirty-eight percent of biotechnology employees hold a doctorate, while a further 42 percent hold a postgraduate or undergraduate qualification.

NZBio

Following recommendations made in the Biotechnology Taskforce Report in 2003, NZBio was established as the single industry body to represent the interests of the New Zealand biotechnology sector. NZBio's mission is to assist the expansion of the sector by working strategically with members, the Government, domestic and international partners to create opportunities and remove barriers to growth. Early activities have focused on improving the investment and tax environment, and extending national and international networks. More recently, special interest groups have been established to address the needs of the agbio and medical device sub-sectors. NZBio enjoys strong support from over 80 companies within the industry.

New Zealand Government and the Biotech Sector

The New Zealand Government has identified biotechnology as one of three industries that will make a major contribution to the country's future economic growth.

In 2002, New Zealand's Growth and Innovation Framework committed the country to moving back into the top half of income rankings among countries of the Organisation for Economic Cooperation and Development. Biotechnology was identified as a growth industry that could help the nation achieve its goal. The Government created a Biotechnology Taskforce, made up of ten industry leaders, to develop plans for boosting New Zealand's biotech development and international competitiveness.

The Taskforce issued recommendations in early 2003 in its report 'A Framework for Action', focusing on people, funding institutions, infrastructure, regulations and global participation. The 10 year growth plans calls for:

- Tripling the number of organisations involved in biotechnology to more than 1,000
- Increasing biotech industry employment more than fourfold to 18,000
- Increasing fivefold the number of core biotechnology companies to more than 200

- Quadrupling export earnings from biotech to more than \$647 million per annum

The Government subsequently released its 'New Zealand Biotechnology Strategy', supporting the Taskforce's recommendations and setting out a vision and direction for the development of biotechnology in New Zealand.

Current R&D budget

Government support for the biotechnology sector has been evidenced by an increase in funding over the past three years. In the year ended June 2004, New Zealand allocated an estimated NZ\$170 million in public funds for biotechnology research. This is approximately 15% of the total government R&D budget allocation.

Government funding is administered by three agencies: the Foundation for Research, Science and Technology, the Health Research Council, and the Royal Society of New Zealand.

Capital

Capital continues to be a major constraint for the development of the biotech sector in New Zealand, particularly for early stage companies or entities. The venture capital market continues to be a slow investor in the sector although this is improving on the back of the introduction of the New Zealand Venture investment Fund (VIF), a government vehicle set up in 2002 to invest venture capital in emerging New Zealand firms.

Within the last few months a specialist biotech fund has been announced. Inventages Venture Capital has partnered with Direct Capital and AgResearch to establish a NZ\$150 million life sciences investment fund for companies doing business in New Zealand and Australia. Called BioPacificVentures, it had its first close in March with NZ\$100 million invested. Further investments of up to NZ\$50 million are to be accepted on a first-in basis.

BioPacificVentures will invest exclusively in life sciences, with a focus on prevention, nutrition and agri-biotech. This includes naturally derived bioactives, beauty and wellness products, medical food, plant health, traits and therapeutics (pharmaceuticals, vaccines, medical devices), for human, veterinary and companion animals, as well as commercial applications eg. food safety, novel food packaging.

The sector faces significant challenges at the "proof of concept" and early venture capital stage. NZBio has been actively engaging with the Government and private sector to address this issue. NZBio and the NZX are currently discussing how the two parties might work together to create a more favourable investment environment for biotech companies in New Zealand to access capital.

The Australia New Zealand Biotechnology Partnership Fund

The Australia New Zealand Biotechnology Partnership Fund (ANZBPF), administered by New Zealand Trade and Enterprise, is designed to facilitate and accelerate trans-Tasman biotechnology industry collaboration. Developing greater regional critical mass will give Australian and New Zealand biotech companies better access to global market opportunities.

The Fund consists of \$12 million dollars to be distributed by 30 June 2007. The Fund will support a number of activities, including the Australia-New Zealand Biotechnology Alliance <http://www.biotechalliance.org/> The majority of the Fund will be available to industry in the form of grants.

New Limited Partnership Regime

The New Zealand Government has recognized the unique capital requirements of the biotech sector and the importance of international investment. To attract international investors, non-residents are exempted from tax on investments in small unlisted New Zealand shares. This exemption will be available to non-residents who are tax exempt in their countries and thus cannot claim a credit in their jurisdiction for tax paid in New Zealand.

A new limited partnership regime designed to help encourage the flow of venture capital investment into New Zealand was recently announced by the Government. Standard features for limited partnerships include: flow-through tax status, limited liability for investing partners and separate legal personality.

The new limited partnership regime will complement the venture capital tax reforms enacted last year to remove tax barriers to New Zealand companies attracting private equity and venture capital from institutional investors in specific countries. Legislation will be introduced in 2006.

Biotechnology use in New Zealand

In 2004, 129 organisations indicated they had used one or more biotechnologies in the last three years. Of the biotechnologies used by these organisations, 61.8 percent were used as part of a production process and 14.6 percent as part of products sold. The applications are set out in Table [1].

Table 1 **Biotechnology Use in New Zealand⁶**

Area of Biotechnology	Developmental Stage (Number)	Percent
DNA – The coding	147	20%
Proteins and Molecules	183	24%
Cell and Tissue Culture and Engineering	168	22%
Process Biotechnologies	165	22%
Sub-cellular organisms	24	3%
Other	63	8%
	750	100%

Area of Application	Overall	
	Number	Percent
Human Health – Bio	81	20%
Bioinformatics	27	7%
Ag-bio	87	22%
Innovative health and Human Nutrition	72	18%
Aquaculture	33	8%
Mining / Energy / Petroleum / Chemicals	15	4%
Forest products	12	3%
Environment	54	13%
Other	21	5%
	402	100%
No of organizations using biotechnology in the last three years	129	

Summary

The New Zealand biotech market continues to thrive. In the area of biomedical research and development there has been significant progress made by two of the leading companies in their dealings with the FDA. This should provide a very positive impetus to other companies in the sector.

There has been strong growth in patents in recent years. A significant test for the sector is to see how many of these patents can be taken through to commercialisation.

Health and Wellness is an emerging market that is very much in evidence around the world when participants speak of biomedical and related research and development. The term not only implies the development of drugs but also, and more importantly for New Zealand, implicitly involves the development of preventative products, particularly functional foods, dietary supplements and nutraceuticals. New Zealand is well placed to take advantage of this given the strong focus on the primary sector and food development.

⁶ It is important to note that these figures are not the number of organisations utilising each process / area of application, but are figures of overall biotechnology use and application. This is because firms may use multiple types of biotechnology, in a variety of different applications.

The New Zealand Government has continued to support the sector through funding for research and development and its support of the Venture Investment Fund. In addition, it has moved to bring New Zealand into line with globally accepted investment rules and regulations. The success of the industry will continue to be measured against the biotechnology strategy plan introduced in May 2003.

Of key importance is the need for the industry to work together to continue overall growth. International collaborations, alliances and direct investment will be increasingly critical for the ongoing development of the sector.

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