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Review of the human therapeutics industry's economic value to New Zealand

David Moore, Preston Davies and Andre Bate

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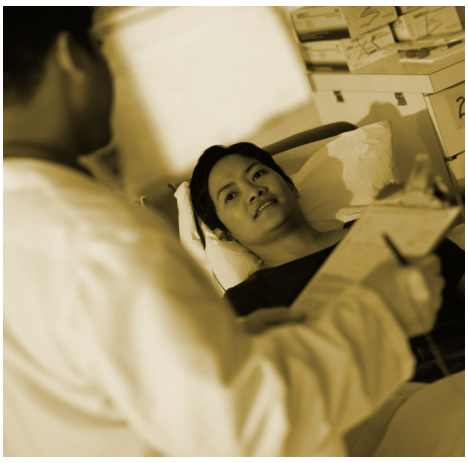

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WELLINGTON

Level 9, Axon House, 1 Willeston Street
PO Box 587
Wellington 6001
Ph: (64 4) 915 7590
Fax: (64 4) 915 7590

AUCKLAND

Level 17, West Plaza Building
3-7 Albert Street
Auckland 1010
Ph: (64 9) 913 6240
Fax: (64 9) 913 6241

For information on this report please contact:

Name: David Moore
Telephone: (04) 472 0590
Mobile: 021 518 002
Email: DMoore@lecg.com

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Executive Summary

The Foundation for Research, Science and Technology (FRST) and New Zealand Trade and Enterprise (NZTE) asked LECG to identify the contribution that the human therapeutics discovery industry (the industry) brings to New Zealand.

FRST and NZTE asked LECG to calculate:

- The GDP that the industry generates for New Zealand.
- The employment that the industry generates for New Zealand.
- Better ways for the agencies involved to invest for the benefit of New Zealand.

The New Zealand human therapeutics sector has relatively strong foundations, is developing and has attributes similar to other emerging sectors

Relative to the recent past, the human therapeutics sector is spending more, employing more people, and generating more revenue. The sector now generates revenues of $200 million, which is a four-fold increase from 2000. The sector employs nearly 900 people, almost three times as many people as in 2000.The compound annual growth rate for the sector between 2000 and 2009 was 16.3% (6.3% for the 2005-2009 period).

- A measure of the success of the New Zealand industry is the increase in the number of drugs in phase II and phase III. In 2000, there was only one drug candidate in phase II. By 2008, there were 7 in phase II and two in phase III.
- A number of human therapeutic companies have taken alternative, faster and lower risk routes to market, for instance by manufacture of pharmaceutical intermediates, providing elements of other compounds, making lesser therapeutic claims (e.g. Blis) and participating in the diagnostic market.
- Niche manufacturing is increasing. One niche manufacturing company has become considerably larger.
- Two companies, Douglas Pharmaceuticals (Douglas) and NZ Pharmaceuticals (NZP), generate over 90% of the sector's revenue.
- The sector has attracted an increasing amount of funding, peaking at $130 million in 2007. Some of this funding is from grants (10%) and nearly 50% is from overseas private investors. The sector spent over 60% of its money in New Zealand between 2000 and 2009.

Firms in the sector use a relatively wide range of business models. A loose grouping framework applied to the participating firms results in four basic groups: - those that are manufacturing based (both new versions of older drugs and intermediates/ingredients); classical drug discovery firms; firms based on platform technology models; and firms employing a hybrid model, which either form international partnerships and combine

inputs to build new drugs or use the IP and drive of a single person/idea and serendipitously move into other areas.

Commercial end points are achieved via royalties, trade sales, alliances and public listing. Companies occupy different parts of the value chain. The drug discovery firms largely start at the preclinical stage, intending to move through to phase II. AFT Pharmaceuticals is at the distribution and sourcing end, and moving to add value through a portfolio of intellectual property. Douglas Pharmaceuticals is in niche manufacturing but has significant competencies which assist in the drug development part of the value chain.

Economic contribution of sector

In contrast to other industry sectors, human therapeutics may be active and profitable from an economic perspective even though classic indicators of sector health, such as revenue and bottom line profits, are absent. Foreign investment is an important feature of the sector. In addition to providing valuable capital, foreign investment is also of value in terms of establishing and strengthening external links (which promote knowledge transfer and increase New Zealand's world wide exposure). Moreover, foreign investment has an indirect role in signalling investment merit. All else equal, a sector that continues to attract foreign investment would appear to have strong prospects.

Other messages are:

- Clear economic contributions (measured in terms of impacts to output, GDP and employment) arise from the human therapeutics sector. These contributions are largely as a result of the profitability of two key firms, but also as a result of the expenditure of foreign-sourced funding in New Zealand.
- The sector has generated (on a cumulative basis) almost $337 million in output, $833 million in GDP and 19,000 jobs between 2000 and 2009. On average, the sector generates around $38 million in output, $85 million in GDP and 2,000 jobs across the economy (i.e. including multiplier effects) in a year. The most recent year of activity is slightly better than average- indicating positive recent performance.
- The performance of individual firms varies widely within the sample, with much of the responsibility for the economic performance of the sector centred around two firms: - New Zealand Pharmaceuticals and Douglas Pharmaceuticals.
- Government grant funding has been instrumental to the achievement of economic performance in the sector over the period of study. Even excluding the two big contributors mentioned above, the economic "return on investment" to the Government has been positive (i.e. over $1 back for every dollar in) over the 2000-2009 period.
- While there are examples of historical returns driving current results (i.e. poor recent performance relative to historical performance clouding the outlook somewhat) a clutch of firms has also demonstrated better recent performance than their historic averages.

- The economic contribution of the sector is not limited solely to attracting overseas capital - significant employment effects (in terms of quality and quantity) are also generated.
- Significant potential exists for future returns from the sector, which will only add to the positive picture emerging from this analysis. That is, "breakthrough" results will add to the economic contribution measured here, rather than replace it. The estimates in this paper may significantly underestimate the quantum of the economic contribution.
- Many other positive effects from the sector cannot be quantified but nonetheless add to the richness of the story and "value" derived from the sector.

- We are not able to assess the likely future value of the industry with any precision or degree of confidence. Assuming something close to a one in ten success rate, then on average, we would expect the sector to contribute around $200 million to the New Zealand economy annually from revenues, licensing deals and milestone and royalty payments. Relative to the current estimate of around $90 million annually in terms of value-added contribution the New Zealand economy, **this suggests that a sector contributing around $300-$450 million per year to the economy (with a balance of new start-up and existing, mature firms) is comfortably feasible within the next five to ten years.**

Investment in the early stages of the value chain (up to phase IIA clinical trial) should be the focus for Government

The sector has a number of points along a "value chain" where the Government can invest- running from the "pure" research aspects of candidate screening and selection, through pre-clinical and clinical stages, to manufacturing, marketing, distribution and sales. At the moment, most of the industry activity in New Zealand is occurring in the earlier stages, although clearly there are some prominent manufacturing interests.

- Matching funding structure to particular business models would be highly difficult given the disparate range and highly fluid nature of business models and strategies currently in use by firms in the sector.
- An assessment of the potential investment points was undertaken using the following framework:
  - *Relevance*- the stage/s in the chain where Government investment is being contemplated.
  - *Role*- a brief functional classification of Government involvement.
  - *Route*- describes the pathway of interest in terms of the stages above.
  - *Recipients*- identifies who the funding/support is transferred to.
  - *Rationale*- considers the reasoning behind the investment/support.
  - *Rate*- discusses the possible level of Government support/investment.

- The assessment suggests that early stage investment was most likely to support the current articulation of the Government's science and research investment priorities. Early stage investment is most logical for a number of reasons, including: likely returns versus magnitude of investment, relative need, existing and burgeoning strengths in New Zealand, and the degree to which it complements other public science investments.
- Early stage investment is not necessarily restricted only to start up firms. It may mean assistance to existing, mature firms with early stage activities. For those companies, although the sources of finance may be internal, the risk profiles, barriers faced, and the profile of benefits to New Zealand, are likely to be similar for early stage activities.
- The assessment was unable to determine optimal investment amounts. Nevertheless, there was nothing to suggest that the current arrangements were wildly inappropriate, insufficient or mis-specified. Indeed, the general direction and quantum of Government investment in human therapeutics research seems appropriate, though some modification might be fruitful for future/further development. One possibility requiring further thought is the prospect of taking some form of option over future revenues, recognising that this is controversial to industry and to policy makers.
- Relevant information from overseas was limited, making benchmarking in a precise manner difficult. However, we are able to conclude in a general sense that the sector in New Zealand has progressed well in the recent past and seems at a reasonable state of maturity given what we know about industry development and international patterns. It is best characterised as a clearly evolving sector that has not yet taken off but is stretching its wings and is poised for flight.
- The industry has the potential to contribute between $300 million and $450 million annually to GDP in the near future, perhaps significantly more. Given this, regular updates of this work would be beneficial: - perhaps biennially. Regular reporting allows for the evolution of the sector to be better captured, key learning to be incorporated and government funding arrangements to be reviewed in a timely fashion.
- Foreign investment will also mean foreign ownership. The first is to be encouraged and the important test is whether the money will be spent in New Zealand. Grant conditions may need to be sharpened as later returns may not accrue to New Zealand.

1 Introduction

The Foundation for Research, Science and Technology (FRST) and New Zealand Trade and Enterprise (NZTE) asked LECG to identify the contribution that the human therapeutics discovery industry (the industry) brings to New Zealand.

1.1 Our brief

FRST and NZTE asked LECG to calculate:

- The GDP that the industry generates for New Zealand.
- The employment that the industry generates for New Zealand.
- Better ways for the agencies involved to invest for the benefit of New Zealand.

In our report we also describe the qualitative benefits, and potential that the industry has for New Zealand, from our interviews with participants in the industry. We understand that the findings from this report will be used by FRST and NZTE to understand how best to support the industry. In particular, the findings will enable FRST and NZTE to determine how much they 'invest' and how they structure this investment in order to generate the greatest benefit to the industry and to New Zealand. Thus the report is also intended to give some indication of where on the value chain it might be wise to invest.

The focus of the brief is on companies involved in human therapeutics and excludes neutraceuticals, health supplements, bioengineering and medical devices.

1.2 Rationale for involvement

A New Zealand network of firms that span the range of human therapeutics activities provide an array of opportunities by building upon existing and developing strengths (research, niche manufacturing, international collaborations). These opportunities include:

- Maximising economic growth potential from innovative and skill-biased activity.
- Attracting and retaining world-class knowledge workers.
- Maintaining international competiveness by focussing on "weightless" economy possibilities, particular around exports.

1.3 Approach

The approach included three major elements, as follows:

- Framework and rationale.

- Data collection.
- Analysis.

The first element was a review of the rationale for government involvement in the sector and a brief examination of the nature of human therapeutics operations, and the funding and regulatory settings in selected international jurisdictions. The desk-based review was undertaken prior to other elements in the process. This not only allowed us to gather information to better prepare for the other elements of the analysis, but also provided a form of benchmarking. The jurisdictions examined were Victoria and Australia, as well as Finland.

The second and most intensive element was a series of interviews with firms involved (directly and indirectly) in human therapeutics in New Zealand. Arranging the interviews, preparation of the interview questions and the actual interviews themselves all involved assistance from staff at NZTE and FRST. Wherever possible a face-to-face interview was conducted, though a small number of interviews were conducted by telephone.

While the interviews were semi-structured they tended to be more conversational in nature and moved relatively freely across a range of subjects.

Topic areas covered in the interview included:

- Data on the financial performance and structure of the company.
- An indication on specific points in time where value may be created and other major company events take place.
- Information on employee numbers and major New Zealand suppliers over time.
- Qualitative information on the history, profile and effects of company activities.
- The role that government-provided funding played at different times in the company's lifetime (where relevant).
- Why the company is New Zealand based.
- What the firm and the sector might look like in the future.
- Thoughts on the funding and general environment in which they are doing business.

Prior to each interview, a dossier of web-based publicly available material and copies of NZTE and FRST funding application forms for each company were put together. Following the interviews a reconciliation process took place where we looked to match the information we had been given in the interview to the information we had assembled on each company. Where discrepancies arose, we followed up through FRST and/or NZTE.

As a result of this process, we were able to track over time a reasonable amount of information that could be used to calculate direct economic impacts. Following a series of arithmetical translations, we are able to determine direct economic effects and apply existing information about multiplier effects to these estimates to derive measures of economic value for the industry. To this we add observations around non-financial and intangible effects and some comments and reflections.

1.4 Caveats/limitations

This section sets out a range of issues that should be considered in relation to both the undertaking of the analysis and interpretation of the subsequent findings. We note that these caveats and limitations are implicit in most studies, and are explicit in some.

Historical focus
The major limitation in this exercise is that the main calculations are essentially measuring what has happened, (the period of analysis is generally 2000-2009), rather than what can or may happen in terms of economic impact. To the extent that we can, we look at what might happen into the future.

Given the nature of drug discovery, with exponential returns as progress is made through different stages, this may mean we substantially under-estimate the actual impact of the sector. The sector is all about potential, however difficult to achieve.

Parameters of "government investment"
The emphasis on the effective "return on government investment" involves potentially significant boundary issues. In particular, the question arises as to the parameters of government investment.

We have focussed on a relatively small subset of FRST and NZTE grants, but are aware that funding from the Heath Research Council and the Marsden Fund for instance are significant in terms of the research work undertaken through the development of compounds for eventual commercialisation. In many respects the boundaries are porous and attribution is difficult. Nevertheless, the possibility still exists that impact measures based on an artificially small subset of funding will bias the results upward.

1.5 Study strength

In addition to developing a robust method by which to express the economic contribution of a sector with only limited actual sales, a particular strength of the report is that it captures a full ten years of granting history. It does so with both qualitative and quantitative data, at a firm level, for all firms in the sector. The level of disclosure is relatively high and the financial analysis is relatively fine-grained.

1.6 Acknowledgements

We acknowledge the very considerable contribution of FRST and NZTE staff to the analysis, and to the considerable effort from companies/ researchers in providing information and attending interviews.

1.7 Organisation of report

The main body of this report is organised as follows:

- **The New Zealand human therapeutics sector -** describes the attributes of the sector, the industry building blocks and development path, as well as outlining the particular development paths of firms.
- **Economic contribution of human therapeutics sector** - presents estimates of the economic return to New Zealand.
- **Comments and implications for investment** - includes some discussion of where in the "value chain" it might be best for government to invest.

A series of appendices are also included, covering material on:

- **The global human therapeutics sector** – some background material on the sector from a global perspective.
- **A framework for Government assistance** - explores reasons for government intervention in the sector and sketches out the current involvement of the New Zealand government in human therapeutics.
- **Methodology** – the tools and techniques used in the study and some of the limitations around these.
- **International examples** – discusses the environment and key policy settings in selected overseas jurisdictions.

2 The New Zealand human therapeutics sector

In this section, we first set out brief industry fundamentals before discussing the financial performance of the New Zealand human therapeutics sector. We make the following introductory comments:

- In contrast to other industry sectors, human therapeutics may be active and profitable from an economic perspective even though classic indicators of sector health, such as revenue and bottom line profits, are absent. Value is generated as a company moves the compound through the research and development pipeline.
- New Zealand is characterised by pockets of world-class research capability in several areas of biological science and the chemistry underpinning human therapeutics research. This includes areas of high healthcare expenditure such as cardiovascular disease and oncology and also in the processing of carbohydrates. Niche manufacturing is also increasing.
- New Zealand also has excellent conditions for the growth and harvesting of antibodies and other biological materials from animal herds because of its disease free status.
- A number of human therapeutic companies have taken alternative, faster and lower risk routes to market, for instance by manufacture of pharmaceutical intermediates, by providing elements of other compounds, or making lesser therapeutic claims (e.g. Blis) and participating in the diagnostic market.
- The sector is spending more, employing more people, and generating more revenue. The sector now generates revenues of $200 million, which is a four-fold increase from 2000. The compound annual growth rate for the sector between 2000 and 2009 was 16.3% (6.3% for the 2005-2009 period). The sector now employs nearly 900 people, which is a three-fold increase from 2000.
- A measure of the success of the New Zealand industry is the increase in the number of drugs in phase II and phase III. In 2000 there was only one drug candidate in phase II. By 2008, there were seven in phase II and two in phase III.
- Two companies, Douglas Pharmaceuticals (Douglas) and NZ Pharmaceuticals (NZP), generate over 90% of the sector's revenue.
- The sector has attracted an increasing amount of funding, peaking at $130 million in 2007. Some of this funding is sourced from grants (10%) and nearly 50% is from overseas private investors.
- The sector spent over 60% of its money in New Zealand from 2000 to 2009.
- We are not able to assess the likely future value with any precision or degree of confidence. Assuming something close to a one in ten success rate, then on average, we would expect the sector to contribute around $200 million to the New Zealand

economy annually from revenues, licensing deals and milestone and royalty payments.

- Relative to the current estimate of around $90 million annually in terms of value-added contribution the New Zealand economy, this suggests that a sector contributing around $300-$450 million per year to the economy is feasible in the short-medium term (i.e. within the next five to ten years).
- The interviews are clear about the capabilities and competencies of the industry now versus then years ago. However, the New Zealand human therapeutics sector is an emerging industry.

2.1 Idiosyncrasies of human therapeutics industry[1]

In contrast to other industry sectors, human therapeutics may be active and profitable from an economic perspective even though classic indicators of sector health, such as revenue and bottom line profits, are absent.

These idiosyncrasies reinforce the emphasis in public investment on direct economic effects associated with the journey to commercialisation, as opposed to a single focus on post-marketing revenue returns.

The idiosyncrasies that we have identified are listed below:

1. Technical uncertainty - biomedical research and development, including human therapeutics, is inherently uncertain. The biological sciences include all of the uncertainties of the physical sciences, which are further amplified by dealing with complex living systems.
2. Long lead times - products typically result from long term research and development activities. Following a discovery, large amounts of scientific data must be generated to validate findings, substantiate patent claims and demonstrate safety and efficacy.
3. Demanding regulatory requirements - products are highly regulated to ensure safety and efficacy. The regulatory pathways and standards are well established and generally require a series of clinical trials. The process is time consuming and requires significant investment.
4. Requirement for specialist infrastructure and skills - research and development requires access to specialised and expensive equipment and highly skilled well

[1] Sourced from: "The Growth of New Zealand's Biomedical Sector and Future Requirements" a joint paper prepared by SIGHT, FRST, and the Ministries of Research Science and Technology and Economic Development.

paid staff. While many knowledge-intensive opportunities, such as those seen in ICT, might originate from a garage start-up, pharmaceutical ventures typically require significant resources for sustained periods of time.

5. Need for collaborations, alliances, partnerships - very few New Zealand or even international companies have the resources to successfully take a therapeutic candidate to market. International partnering is fundamental, and there are many opportunities for niche businesses to be very successful in differentiated areas of the value chain.

6. Intellectual property – securing intellectual property rights is crucial due to the long development times and the need to ensure that investors have the opportunity to make a good return.

7. Capital investment - as a consequence of the previous characteristics, development requires access to large amounts of capital. Companies typically raise finance via multiple funding rounds, often involving investor consortia which specialise in each funding stage.

These global industry characteristics mean that establishing a competitive position for NZ firms is challenging. At face value overcoming these characteristics may appear daunting but the upside is that meeting these standards allows entry into a sector that is high margin, high value, high growth and often establishes a position which can be maintained for a long period of time.

The company interviews we carried out emphasised the comparison between present and past industry capability. Ten years ago the industry consisted of a handful of companies with little or no experience in biomedical commercialisation. The industry now has a number of individuals who have been involved in a series of therapeutic commercialisation projects in New Zealand and overseas. Consequently, domestic regulatory, clinical and commercialisation skills are deepening. There are now pilot processing facilities for small batch manufacture and some drug formulation capability. Crucially, there are substantially better and deeper links to smart capital.

2.2 Generating value

For most industries, the value of the industry is the value of the companies, which in turn is the value of capitalised profits. This is true for part of the human therapeutics industry. The value that drug discovery attracts is unrelated to immediate revenue, which is generally nil, and more related to the possibility of future, large revenue streams post commercialisation.

Value is generated as a company moves the compound through the research and development pipeline. Of over-riding importance, apparent from the interviews, is the accumulation of high quality data to meet regulatory requirements. Achievement of another step in the drug development pipeline represents a point of value inflection – data meeting regulatory requirements and value are inextricably linked. The compound becomes exponentially more valuable as it achieves milestones in the drug development

programme; first proving that it is safe, and then proving that it is efficacious. A major point of value inflection is where there is sufficient information for completion of phase II clinical trials.

We set out the phases of trials and the likelihood of success in the table below.

As a drug is developed, additional capital is generally needed. The extent to which value can be retained by the inventor or early stage investors differs but the final return is likely to be substantially diluted. Thus, as drug development markets mature, there is a general progression up the ladder of what value can be captured.

Phases of drug development[2]	
Discovery	Generally includes the activities of target identification, target validation, lead generation, lead optimisation and candidate selection
Preclinical	Undertake the animal and toxicological studies that are needed to establish that there is a compound that warrants testing in humans. The Food and Drug Administration (FDA) stipulates a variety of tests, often disease and compound specific. All preclinical work is then submitted to the FDA for investigational new drug approval (IND). **Starting development gives a probability of success of 10%** **Successful completion increases probability to about 20%**
Phase I	The compound is tested in humans. The dose may not be efficacious, but it will affirm or deny preclinical testing. **Probability of success increases to close to 30%**
Phase II	These are crucial tests of efficacy, of how the compound performs, in humans, for particular diseases (or indications). The trial will give good information for comparison with other compounds and, also, valuable information into how it might perform in phase III trials. For some compounds, when at this stage, there is enough evidence to gain market approval. **Probability of success increases to about 60%**
Phase III	These are definitive multi centre trials that are also the first stage of commercialisation. The capital involved in running phase III trials is very substantial. The success or failure at this stage depends on the extent of marketing, degree of innovation, number and type of competitors, etc

[2] Adapted from "The Business of Healthcare Innovation", edited by Lawton Robert Burns, Cambridge University Press 2005.

2.3 New Zealand firm strategies

The firms respond to this with different business models. A loose grouping framework applied to the firms under study results in four basic groups. Those that are:

- Manufacturing based- both new versions of older drugs (Douglas) and intermediates/ingredients (NZP).
- Classical drug discovery firms- spin-outs with and without overseas operations (CoDa, Pathway, Proacta).
- Platform technology models- (LCT, KODE).
- Hybrid groups which either form international partnerships and combine inputs to build new drugs (IRL) or used the IP and drive of a single person/idea and serendipitously moved into other areas (Innate, perhaps LCT).

These patterns are not unexpected and can be further extended into end points through royalties, trade sale, alliances and public listing.

Further, companies occupy different parts of the value chain. The drug discovery firms largely start at the preclinical stage, intending to move through to phase II. AFT Pharmaceuticals is at the distribution and sourcing end, and moving to add value through a portfolio of intellectual property. Douglas is in niche manufacturing but has significant competencies which assist in the drug development part of the value chain.

A number of themes that emerged in interviews with New Zealand companies (these themes find parallels in human therapeutic firms elsewhere):

- De-risking – business models are adapted that are highly situational to the point on the value chain. Management and boards work closely to select managerial strategies to maximise the chance of success and deal with the risk of adverse consequences. Those providing the money in private equity and venture capital settings release money on achievement of milestones.
- Close attention to regulators – relationships with regulators and regulatory strategy define the market place that the therapeutic innovation can participate in. The market place defines the margins and the value that the innovation attracts.
- Ability to persist in the face of adverse consequences – ability to move forward with other indications or other related compounds, or to survive in the face of failure.

2.3.1 Industry achievement

The most concrete measure of achievement is the increase in the number of drugs in phase II and phase III (see figure below). In 2000, there was one drug candidate in phase

II. In 2008, there were seven in phase II and two in phase III[3]. One compound, DMXAA, appears to be on the brink of coming to market. The royalty flow back to New Zealand will be substantial relative to other activities in New Zealand, despite "our" equity investment stopping at the pre-clinical stage.

A number of human therapeutic companies have taken alternative, faster and lower risk routes to market, for instance by:

- Manufacture of pharmaceutical intermediates.
- Providing elements of other compounds.
- Making lesser therapeutic claims (e.g. Blis).
- Participating in the diagnostic market.

Many of the small companies developing these compounds have come from, or collaborate with, universities:

- Otago Innovation- responsible for commercialising research coming out of the University of Otago; and
- Uniservices- responsible for commercialising research coming out of the University of Auckland.

The rate of development of new compounds appears to be increasing. Eleven out of the eighteen companies in the sector that we examined were founded after 1998. Seven of these companies are created out of, or collaborate with, the University of Auckland, and three from the University of Otago.

The linkages in the clinical development process appear to be widening and deepening. Whilst a number of small firms were created out of, or are based on research from New Zealand universities, a number also build on research from other research institutions. For example, a number of companies spun out of the University of Auckland come from collaborations with other universities or research institutions (University College, London for Coda Therapeutics, Stanford University for Proacta and the Auckland Cancer Society Research Centre for Pathway Therapeutics).

Niche manufacturing is also increasing. There are two types of pharmaceutical manufacturing in New Zealand –manufacture of pilot quantities for the research process (very limited, Glycosyn) and manufacture of intermediates (NZ Pharmaceuticals) or final products (Douglas).

[3] SIGHT 2009: The importance of New Zealand's Human Therapeutics Sector in Future Economic Growth, NZBIO Special Interest Group for Human Therapeutics.

What were two small niche manufacturing companies have become considerably larger and have moved considerably up the value chain. One new entrant has launched into the market a patented compound with a potential valuation of hundreds of millions.

Figure: Companies and phase development over time

Company	Product	Stage at Oct 2000	Stage at Oct 2001	Stage at Oct 2002	Stage at Oct 2003	Stage at Oct 2004	Stage at Oct 2005	Stage at Oct 2006	Stage at Oct 2007	Stage at Oct 2008
Antipodean	Mitoquinone						Phase I	Phase II	Phase II	Phase II
Anzamune	Chitin microparticles								Phase II	Phase II
CoDa	Nexagon									Phase I
Genesis R&D	AVAC			Phase I	Phase II	Phase II				
	PVAC	Phase II	Phase II	Phase II	Phase II					
Living Cell Technologies	DiabeCell								Phase II	Phase II
Neuren	Glypromate					Phase I	Phase II	Phase II	Phase III	Phase III
	NNZ-2566								Phase I	Phase I
Proacta	PR-104							Phase I	Phase I	Phase I
Protemix	Laszarin					Phase I	Phase II	Phase II	Phase II	Phase II
Innate Therapeutics	PEHRG214					Phase I	Phase II	Phase II	Phase II	Phase II
Industrial Research Ltd	Fodosine							Phase II	Phase II	Phase II
	BCX-4208						Phase I	Phase I	Phase II	Phase II
	MT-DAD Me-Immucillin-A									
The University of Auckland	XR-11576			Phase I	Phase I					
	MLN-944				Phase I	Phase I				
	DMXAA (ASA404)			Phase I	Phase I	Phase I	Phase II	Phase II	Phase II	Phase III
	CI-1033 (Canertinib)			Phase I	Phase II	Phase II				

Source: SIGHT 2009 "*The Importance of New Zealand's Human Therapeutics Sector to New Zealand's Future Economic Growth*." Report of the NZBIO Special Interest Group for Human Therapeutics.

2.4 Industry highlights

The sector is spending more, employing more people, and generating more revenue. We show headline industry statistics in the table below, then identify some summary points that describe how the industry is developing. We have obscured firm level data to protect commercial sensitivity.

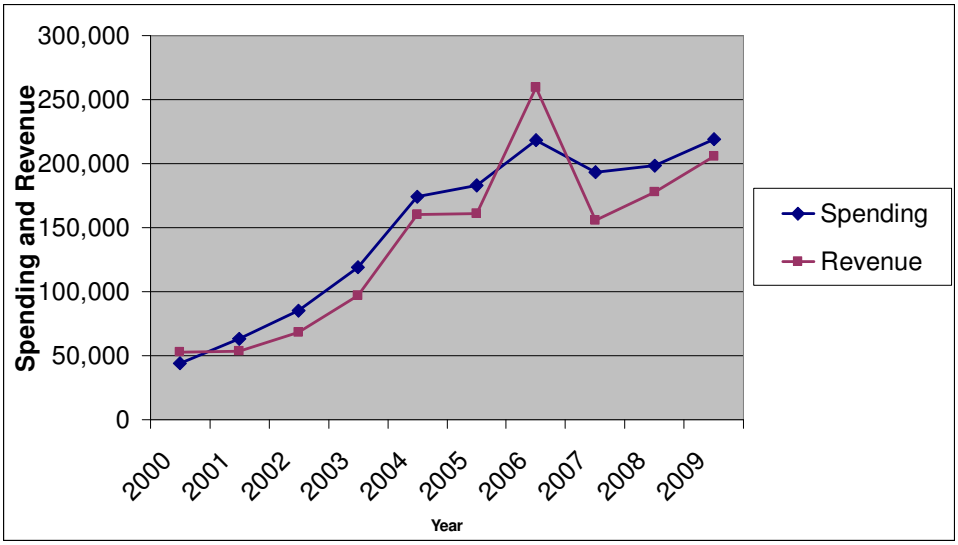
Key industry statistics (NZD, 000s)			
	Total 2000-2009	Average 2000-2009	2009
Funding	626,451	62,645	14,845
Spending	1,497,871	149,787	219,313
Revenue	1,391,836	139,184	205,769
Employment	6,042	604 FTE	883 FTE

There are some encouraging summary points. In general:

1. The sector is generating increasing levels of revenue with several participants coming from positions as manufacturers. The sector now generates revenues of $200 million, which is a four-fold increase from 2000. The sector is generating increased revenues from organic growth in larger firms, and from more small firms joining the sector. The sector now employs nearly 900 people,[4] which is a three-fold increase from 2000. The compound annual growth rate for the sector between 2000 and 2009 was 16.3% (6.3% for the 2005-2009 period).

[4] Note that this is total industry employment, including Douglas Pharmaceuticals and New Zealand Pharmaceuticals, which combined accounted for over two-thirds of the employment. This figure does not include indirect or induced employment (i.e. does not include multiplier effects).

Figure: Sector spending and revenue[5]



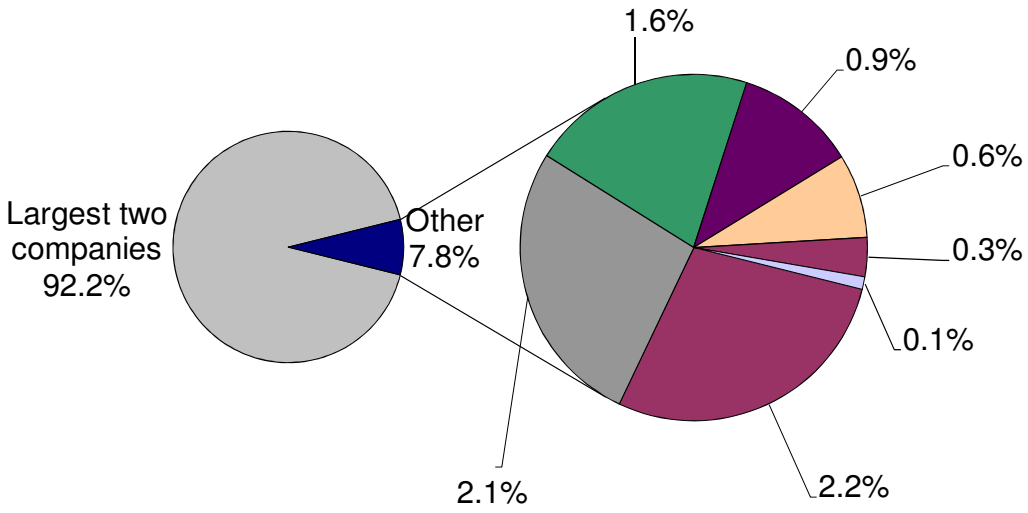
2. Douglas Pharmaceuticals (Douglas) and NZ Pharmaceuticals (NZP) generate over 90% of the sector's revenue and nearly 70% of the sector's spending. The remainder of the sector is made up of small companies developing and commercialising from clinical development projects. The one major exception AFT Pharmaceuticals. We include only AFT Pharmaceuticals' non-distribution business in the analysis.

3. This increase in revenue is largely due to Douglas and NZP increasing their sales[6]. The remainder of the sector is also increasing its sales, though these are small compared to Douglas and NZP. AFT Pharmaceuticals is also a sizeable entity but much of its revenue still comes from distribution, at present, and that portion is excluded.

[5] Spending includes capital and operating expenditure and excludes interest and tax. The drop in revenues and spending in 2007 is because the revenues and spending from Douglas Pharmaceuticals' subsidiary, Douglas Pharmaceuticals Australia, is excluded after it is sold in 2006.

[6] Except where revenue fell in 2007. This was because spending from Douglas Pharmaceuticals' subsidiary, Douglas Pharmaceuticals Australia, is excluded after 2006, because it was sold.

Figure: Revenue – by company, companies not labelled, 2000 to 2009[7]



4. Niche manufacturing firms and firms with royalty arrangements are heavily export focussed. Douglas Pharmaceuticals has increased the proportion of its revenue from exports from just over 10% in 2000 to just over 60% in 2009.

5. The sector has attracted an increasing amount of funding. The sector raised an average of nearly $63 million per year from 2000 until 2009, including grants. The sector secured funding of over $30 million per year from 2000 to 2004, increasing to over $85 million per year from 2005 to 2008, with nearly $130 million raised in 2007. Funding for 2009 is much lower, at nearly $15 million[8]. The increase in funding in 2007 comes from five companies raising over $10 million each. The drop in funding for 2009 reflects the difficult economic climate during that year.[9]

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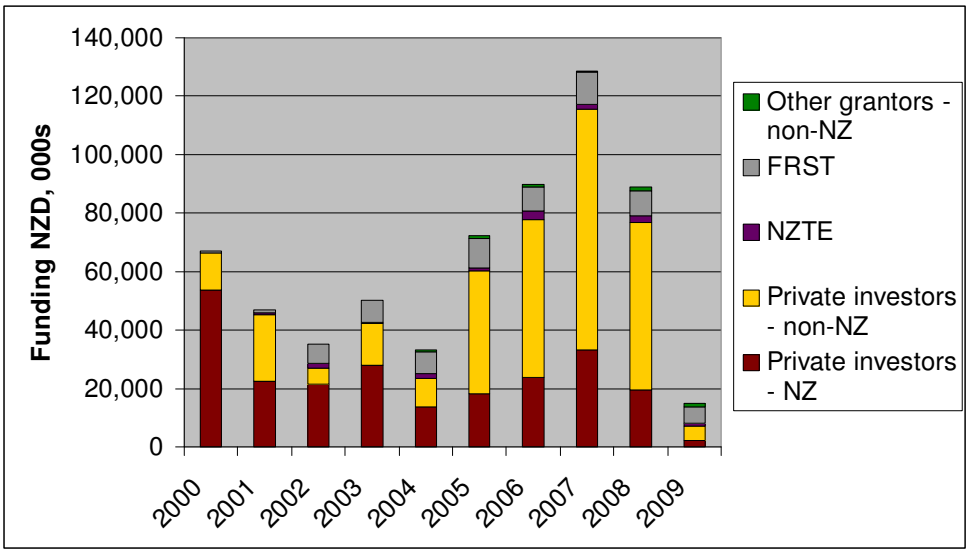
[7] We have not shown in the above graph companies with revenue of less than NZ$1 million from 2000 to 2009, since their contribution to industry revenue is comparatively insignificant. A total of nine companies were excluded, which together accounted for only around 0.1% of total revenue. Hence their exclusion has no material effect on the graphic.

[8] The average funds raised over more than one year are more accurate than for one particular year, since we have had to assume the timing of capital raising for a small number of firms where they did not provide us with timing information. This is also the case for spending and revenue figures.

[9] The 2009 funding figure may be understated if companies sourced funding in the 2009 financial year after we contacted them for this study.

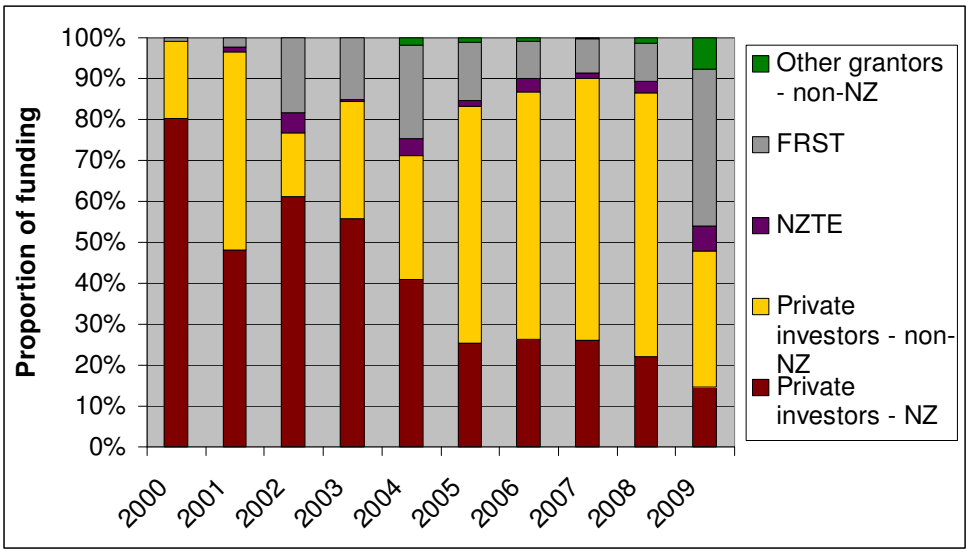
Figure: Sector funding sources – by year



6. The sector attracts significant foreign investment. The sector is funded nearly 40% from New Zealand private investors, nearly 50% from overseas private investors, and just over 10% from grants. The sector has increasingly sourced its funding from overseas since 2000, though this has reduced substantially in 2009. The sector has gained increasing New Zealand grant funding up until 2005, and it has gained a reasonably constant grant funding since 2005.[10]

[10] We have excluded grants from NZ government agencies other than NZTE and FRST (e.g. we have excluded Health Research Council grants and any funding from universities). One implication of this treatment of funding has been to restrict the consideration of activities undertaken by IRL to those relating to Glycosyn only.

Figure: Sector funding sources – by year - % of total



7. International partnering is a feature of some companies. Small firms in the sector are partnering with larger companies from overseas. For example, one firm reported that it is partnering with a fast moving consumer goods company to develop a product that combats illness in infants.

8. Firms in the sector are also commercialising intellectual property developed overseas. AFT Pharmaceuticals has acquired a number of over-the-counter pharmaceutical products from abroad and is actively looking abroad for suitable acquisitions. NZP bought Dextra Labs this year. Pacific Edge acquired an Australian biotech company partly to find a path to market.

Figure: Sector revenue – by year

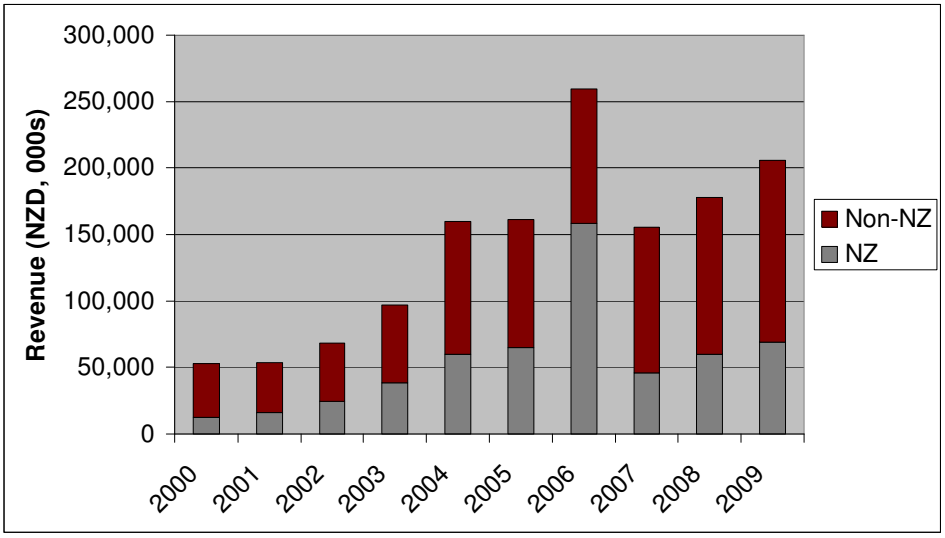
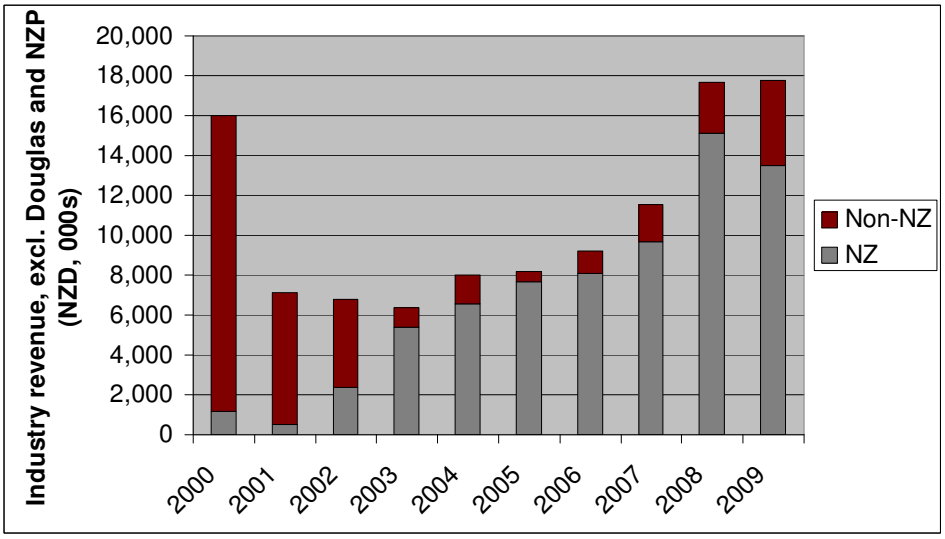


Figure: Sector revenue – by year – excluding Douglas and NZP



9. A number of companies are advancing in the development process to the point that they are profitable[11]. Currently, only three companies are profitable. One more company is approaching profitability.

2.5 Application of funds

We analysed closely where the money intended for research is spent particularly for the purpose of the calculations of the impact of the industry on New Zealand. Our findings are the following:

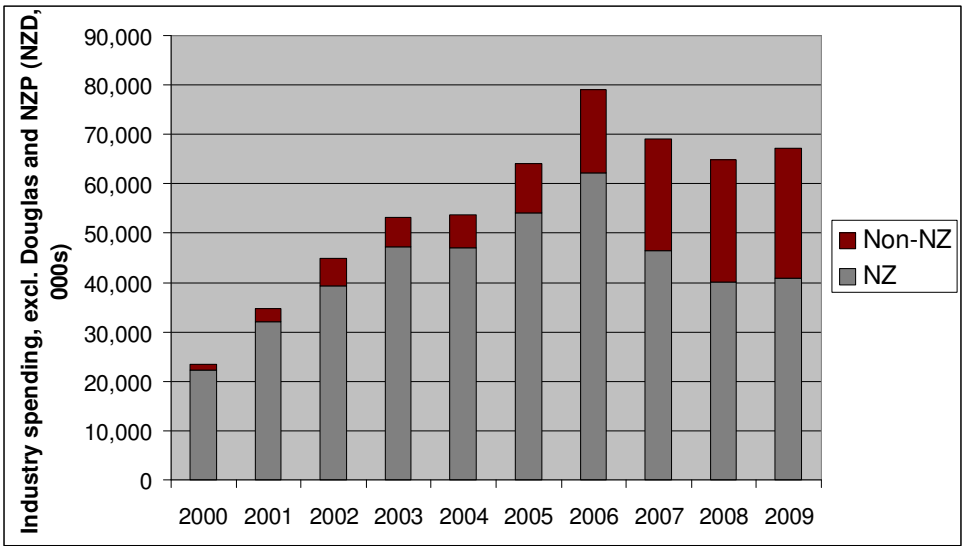
1. The sector spent over 60% of its money in New Zealand from 2000 to 2009.
2. As a whole, from a purely financial perspective, the sector has generated 93 cents in revenue for each dollar it has spent. If Douglas, NZP, and AFT Pharmaceuticals are excluded, the sector has generated 20 cents for each dollar it has spent. This reflects the reality that most of the small drug development companies are a number of years away from proving their products' efficacy and securing their products' regulatory approval. However, the process of drug development is intensive and we highlight in the next chapter the economic benefits of that spend.
3. The sector is increasing its spending for two reasons[12]. First, Douglas and NZP are generating increasing profits and are spending this on growing their businesses. Second, small companies are raising capital and spend in New Zealand to make their way down the development pipeline[13].

[11] We have defined profits as revenue (excluding grants, including contracted research), less operating and capital expenditure (excluding tax and interest).

[12] Spending includes capital expenditure and operating expenditure and excludes interest and tax.

[13] Spending fell in 2007 because spending from Douglas Pharmaceuticals' subsidiary, Douglas Pharmaceuticals Australia, is excluded after it is sold in 2006.

Figure: Sector spending – by year – excluding Douglas and NZP



Where companies spend their money is very dependant on the adopted business model. Some companies, like Antipodean, spend mainly in New Zealand. Others, like Neuren, now do most of their clinical work overseas.

Inevitably, regulatory approval and sources of funds mean that a number of firms that lead their research and development from New Zealand have their commercial bases overseas (largely in the US).

2.6 Industry capability has developed greatly

The interviews are clear about the present capabilities and competencies of the industry relative to the past. Ten years ago, there were large deficits; there were few firms: two small niche manufacturers and one large research company. There was little in the way of skills – early challenges for the industry identified in the interviews were a lack of skills in collecting and preparing data for regulators, a lack of investors who understood the industry, and a lack of scientists or clinicians able to participate in the discovery process and in the drug development pipeline.

The interviewees draw a fundamentally different picture of today's industry. Particular aspects of the industry that are highlighted in interviews include: much stronger drug development and commercialisation skills; ability to organise data to the required regulatory standards; some pilot processing facilities for small batch manufacture; some drug formulation capability; and substantially better and deeper links to smart capital.

Relative to other emerging industry sectors, such as health IT and medical devices, the industry structure and level of success does not appear to be orders of magnitude different. In both of these other emerging technology sectors, one or two companies have grown considerably and dominate sector revenue.

2.7 Future industry value

We are not able to assess the likely future value with any precision or degree of confidence. However, if we consider the number of compounds under development and apply a range of assumptions around likelihood of success, market share and structure of any deals we are able to get a "ballpark" estimate of possible future values for the sector. Of course, these estimates are highly speculative and to that end should best be considered in "orders of magnitude" terms rather than as industry forecasts as such.

Based on company assertions
Indicative estimates sourced from analysis undertaken by firms in order to support their applications for funding from NZTE and FRST suggest that an upper bound estimate of the contribution of the sector could be over $2 billion a year in around ten years' time.

This indicative estimate assumes that almost all of the compounds under development are successful and market share estimates are borne out. Clearly it is not realistic to assume that kind of success rate, but it is not clear what the best alternative assumption should be.

Alternative assumptions
We rely on judgement as much as science in suggesting alternative assumptions. Given the development of the sector, the nature of activity being undertaken (i.e. the main indications being targeted), the calibre of people involved and the lessons learned from recent history, we could safely assume relatively good success rates across the stock of compounds in development.

Assuming something close to a one in ten success rate, then on average, we would expect the sector to contribute around $200 million to the New Zealand economy annually from revenues, licensing deals and milestone and royalty payments. Such revenues are feasible within the next five to ten years.

Relative to the current estimate of around $90 million annually in terms of value-added contribution the New Zealand economy, this suggests that a sector contributing around $300-$450 million per year to the economy is feasible. This amount is comprises:

- "projected" milestone and royalty payments associated with DMXAA of between $50 million and $100m annually;
- $100 million-$150 million in GDP per year (which is a rough projection of the $90million/year generated currently, accounting for organic growth and possible new firm entry); and
- $200 million from royalties, milestone payments and licensing deals.

Despite obvious difficulties in comparing across different methodologies, these figures compare favourably with the Medical Technologies sector, given the relative sizes of the respective sectors. There is obviously the potential for significant upside benefit.

3 Economic contribution of the human therapeutics sector

We set out in this section an analysis of the benefit that has come from the granting activity to the sector. This requires a view to be formed about the "additionality" of the human therapeutics sector to the New Zealand economy. (By "additionality" we mean including only "new" or additional effects in our analysis. What we are measuring is the extent of "injections" into the economy as a result of the activities of the human therapeutics industry.)

An appendix sets out the methodology in some detail and provides a worked example to assist interpretation.

3.1 Umbrella observations

We understand that this is the first time that FRST/NZTE has applied such a detailed lens to a particular industry sector. Studies of other sectors (e.g. medical devices or health IT) have not taken the same approach as that adopted here. Therefore, direct comparisons with other studies are problematic. To undertake an "apples with apples" examination of respective sectors would require the application of the "additionality" focus used in this study.

In terms of the human therapeutics sector, there are some important and surprising outcomes from the analysis. One revealed aspect of the industry is that the drug discovery process destroys value more easily than it generates success. However, in economic terms, this "destruction" may not be negative as the process may still create additionality to the wider economy. For instance, adverse events that appear to indicate substantial loss, such as a failed phase II clinical trial, in fact generate economic additionality through the activities involved in applied endeavour in the discovery process. Thus, a major conclusion is that net economic value to New Zealand may arise from (financially) loss-making activities for firms.

3.2 Nature of benefits

Expenditure undertaken by firms in drug development is the main form of (gross) economic benefit that we are measuring. The following types of benefit accrue to New Zealand as a result of drug-discovery firm expenditure:

- Clinical and pre-clinical research.
- Employment (wages and salaries).
- Rents and/or purchases of buildings.
- Associated operating expenditure for fit-outs, incidentals and the like.

- Inter-sector expenditure (i.e. second round expenditure for inputs into firms' production).

Expenditure is not the only relevant effect. Profits are also important from an economic value-added perspective. Where firms are able to make sales at a price that exceeds the cost of production, profit occurs and resources available in the economy are increased as a result. Royalties and milestone payments fit within this general profit rubric.

3.3 Quantum of benefits

The objective of this section is to present and quantify the economic and financial effects of the human therapeutics sector in New Zealand.

Deriving additionality
The most relevant effect for this industry (at this time) is attracting off-shore investment. Such injections of offshore funding lead directly to positive economic effects of interest, while investment of existing (domestic) resources into the industry represents diversion (i.e. a transfer of existing resources) rather than the creation of new resources for the economy. Accordingly, we exclude transfers of existing resources from our calculations on the basis that these resources have effectively already been accounted for in the GDP statistics. Moreover, we assume that if they had not been expended here, in this sector, the resources would have been expended elsewhere in New Zealand. That is, the investment and expenditure by New Zealanders into domestic human therapeutics firms does not represent additonality for the domestic economy.

All of the final measures of the key metrics used in the study include indirect and induced (i.e. multiplier) effects. The table below outlines:

- The metrics used.
- Their standard definition.
- An explanation of the calculations for each of the metrics.

Key metrics explained			
	Standard definition	**Calculation basis for this study**	**Rationale**
Output	The total amount of economic activity generated by expenditure in the sector in New Zealand.	The amount of spending undertaken by firms in New Zealand where funding originates from outside New Zealand.	Economic effects arise from "injections" of "new" resources. Activity funded solely by New Zealand-based investors does not create new resources as such.
GDP	The total value of goods and services produced in an economy in a given time period, adjusted for intermediate consumption (i.e. output adjusted for the possibility of double counting some expenditure - a measure of "value added").	GDP/value-added arises in two ways: • Funding from overseas sources that is spent in New Zealand, converted into a GDP equivalent. • From "profit" (i.e. revenue from sales that exceeds the cost of production) accruing to New Zealand. The sum of these two components represents the measured value-added/GDP contribution of the sector.	The majority of firms in the human therapeutics sector do not generate profits as such- but still contribute to GDP. Wholly New Zealand-owned firms who make profitable sales should have that economic contribution recognised. To the extent that profits are repatriated to overseas owners/shareholders, these should not be counted as an economic impact to New Zealand.
Employment	Being in paid work- often expressed as a rate (i.e. the proportion of the labour force or working age population who are employed).	Total number of people employed in New Zealand (i.e. excluding employees based off-shore). No distinction is made between full-time and part-time employment (i.e. it is a measure of job numbers). Total employment numbers across time represent a cumulative annual total (i.e. this is not a measure of job creation). No "additionality" rule is used. That is, we assume (unlike the flow measures above) that no employment would exist in the absence of human therapeutics firms.	Given the relatively fluid nature of the sector, a high degree of firm turnover is expected. The ability to maintain employment levels over time should be highlighted.

Note that total employment is cumulative. Rather than representing an annual employment number, it is the sum of all effective annual employment across all years. Thus, if the industry has 100 employees every year for 10 years, then this would register as employment of 1,000 in the ten-year period under study.

Multiplier effects
Work undertaken for NZTE previously has calculated multipliers for employment, output and value-added in relation to the biotech sector. The relevant sector multipliers are 2.03 (output); 1.95 (GDP) and 3.41 (employment) and are interpreted as representing the economy wide effect of a one unit change in the metric of interest, inclusive of the unit change. In the case of employment, this means that the total effect on the economy of an additional unit of employment in the biotech sector is 3.41 units of employment (i.e. the additional unit of employment in the human therapeutics sector and 2.41 units of employment elsewhere).

Expenditure analysis
By definition, expenditure analysis focuses heavily on tangible, monetary flows.

Intangible impacts and other effects that are difficult to place a monetary value on or measure with any precision (e.g. the economic effects of research and reputation, and the role of demonstration effects and knowledge spillovers) are less able to be included in the estimation and measurement process. Given the interaction between the human therapeutics sector and universities and pure research, these issues are very relevant and the inability to be specific in quantifying (and monetising) the impacts means we may be less accurate than otherwise.

Other relevant factors in relation to expenditure are that:

- Taxes and interest are excluded as they represent transfers rather than actual economic effects.
- Expenditure on capital equipment is included alongside operating expenditure and is "collapsed" into a single period effect.
- Funding is not measured as an economic activity as such, but spending is.
- Expenditure (e.g. on research) is taken as a proxy for output and converted to GDP (value-added) using previously determined industry relationships (as described further above) rather than being firm-specific.
- We only count expenditure that is funded by overseas or external sources, meaning that the contribution of predominantly New Zealand owned and funded firms' is substantially lessened.
- The figures used in the analysis are nominal- in the sense that they have not been adjusted for inflation.

In relation to profits, we use the basic definition of total (offshore and onshore) revenue (from human therapeutics) less expenses and capital expenditure (excluding tax and interest). Where we have "negative" profits, we assume a zero value in terms of economic effect. In terms of real economic activity, expenditure is what matters. Even in a situation where expenditure exceeds income/revenue (i.e. a technical loss) spending has still taken place, with real economic effects. In addition, netting of economic losses would be the equivalent of "reverse expenditure" and this process does not take place (i.e. there is no refund process for expenditure exceeding income/revenue for any firm), and therefore the assumption of nil economic effect (i.e. the effect is an accounting/transfer one) is reasonable. The basic point is that economic activity and effects may still be generated in a loss-making situation.

For our purposes we include only the notional proportion of firm profit that accrues to New Zealand (proxied by ownership). For instance, if a firm is 30% foreign owned and makes a profit of $1 million in a particular year, then we assume that $700,000 of that profit would accrue to New Zealanders.

3.4 Results – sector aggregates

This section presents estimates at a sectoral level, using the process outlined above to calculate the respective metrics. The sector aggregates include indirect and induced effects.

Sector totals over time			
	Output ($000's)	**GDP ($000's)**	**Employment**
Total	336,970	832,792	19,311
Average per year	37,694	85,322	2,010
Latest year	36,305	90,259	2,757

The table shows that the sector generated the following (on a cumulative basis) between 2000 and 2009:

- Almost $337 million of output/expenditure.
- $833 million of value-added (GDP).
- Over 19,000 jobs.

Not all of the companies have been in existence for all of that time (in fact most have not). On average, in a given year, the sector generated over $37 million of output/expenditure, $85 million in GDP and around 2,000 jobs. Perhaps encouragingly, the most recent year of data shows the sector contribution to GDP and employment as being above historical averages, while output is around historical average levels. Profitability in a small number of firms is the reason for this result.

There are two firms which are both New Zealand-owned and material to the analysis- Douglas Pharmaceuticals and New Zealand Pharmaceuticals. Being New Zealand-owned means their contribution to output would be classified as zero. Both are profitable, which means they contribute substantially to the GDP figure in the table.

These two firms are largely responsible for the seeming divergence between output and GDP. If we were to remove the GDP contribution of these firms from the overall figure, we are left with a total sector GDP contribution of around $170 million in the period under study. Thus, the contribution of these two firms is very large (which is not an unusual finding) but, also, that the contribution to GDP of smaller firms is substantial.

3.5 Individual company highlights

In addition to sector-wide aggregates, we calculated individual company figures for the main categories (output, GDP and employment). While the results are commercially sensitive, a number of interesting points arose, which we summarise in this section. Firstly, there was considerable variance present in terms of company performance, despite a relatively small number of firms under study. For instance, in terms of GDP across the period under study, the contribution of the highest ranked firm was over 5,000 times that of the lowest ranked firm.

Secondly, there are entities which have provided employment opportunities but, according to our methodology, have not contributed otherwise (in any material sense) to economic activity. The majority of these entities are university-based, where either their economic effects are picked up by spin-out companies, or due to their sources of funding being domestic, we have not counted any economic effect from their activities (there are still financial effects, considered elsewhere). Notwithstanding this, there is a clear linkage between employment and the other economic indicators. That is, the economic importance of the sector is not restricted solely to attracting foreign investment.

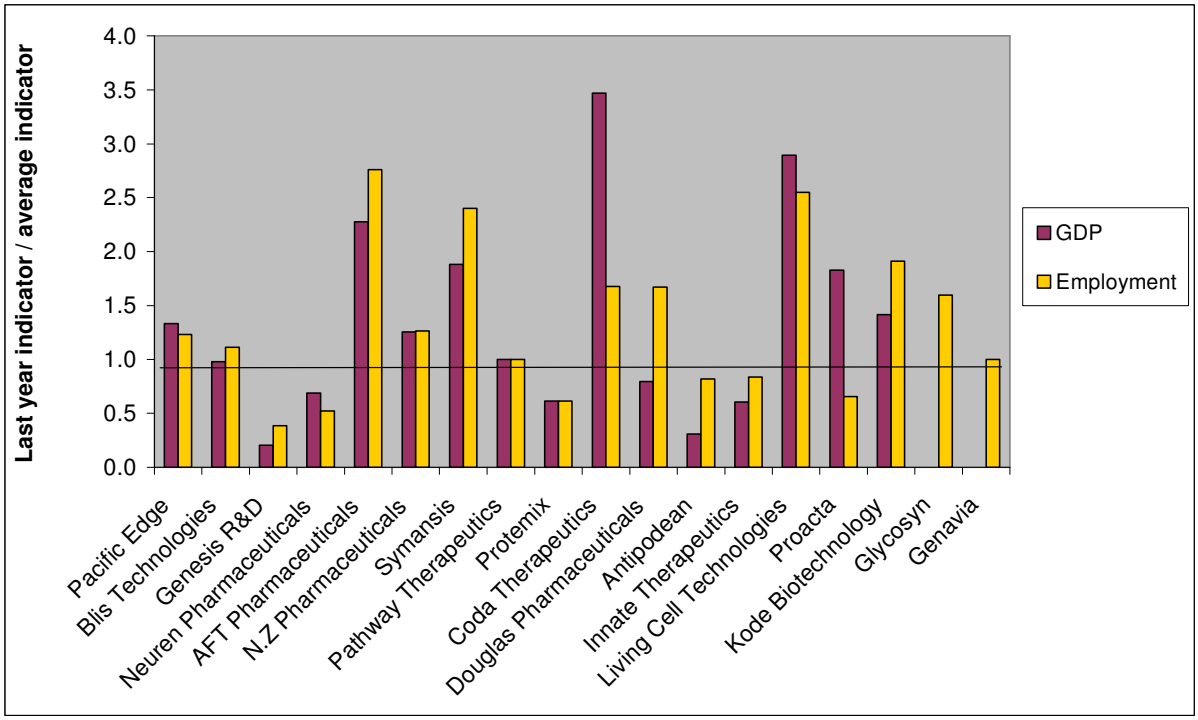
The strong contribution of manufacturing based companies Douglas Pharmaceuticals and New Zealand Pharmaceuticals is also readily apparent.

Accounting for company tenure (through examining individual results on an average annual basis) still results in considerable variation across entities. That is, age or longevity does not appear to be a major explanatory factor for economic performance in this sector.

Data on the latest year of activity shows that, relative to historic averages, the sector overall enjoyed positive recent times. The chart below shows the ratio of the most recent year's numbers to the historical average for each company where we have reliable data, in terms of output, GDP and employment. A ratio above one indicates that the most recent year exceeds the historical average for the company over its lifetime.

Of the 18 entities in the chart, 11 have at least one dimension where their performance in the most recently reported year exceeds their historical average. Firms where all recently measured indicators exceed historical averages are:

- AFT Pharmaceuticals.
- Pacific Edge Biotechnology.
- Symansis.
- CoDa Therapeutics.
- Living Cell Technologies.
- KODE Biotechnology.



3.6 GDP contribution without profit

There is a contradictory result in terms of the results for calculation of GDP for companies that are not yet generating revenue.

Firms that are not involved in developing IP (or for which IP development is a small aspect of the business) tend to be more profitable. Moreover, these firms are privately owned. Publicly-owned companies tend to be less profitable. In general, this pattern is repeated in terms of the economic contribution of individual firms, with one or two exceptions.

The possibility of non-profitable companies featuring prominently in the "economic performance" comparisons used in this study (and vice versa) highlights a key difference between economic contribution (as measured here) and financial profitability. The industry takes a long time to develop a product, but economic activity is not restricted to specific points in time. Indeed, there may be a great deal of activity generated by capital inflows outside of "starting" and "finishing" years. Also, the financial valuation is highly volatile depending on success in the development pipeline.

3.7 Benefit for cost of granting activity

In this section, we attempt to account for the "cost" side of the equation and calculate the probable "benefit for cost". The cost element that we refer to is the cost to the Government of FRST and NZTE grants.

This is very much a partial assessment of some of the key metrics assessed against obvious costs, rather than representing a full economic cost-benefit analysis. A full economic cost-

benefit analysis would require considerably more data than we have available and would include consideration of opportunity costs, alternative uses and counterfactuals, appropriate discounting techniques and the relevant time period.

For this exercise we have largely collapsed these aspects into singular considerations. In calculating the effective return on Government grants, we first needed to ascribe to each company a value that they placed on receiving NZTE and FRST grants – basically how important the grant(s) appeared to be to each company. Failure to do so would likely result in serious misspecification of the effective "return on investment" to Government.

We use this informal assessment of impact as the basis of attribution of benefit to the grants. As can be seen from the table below, the estimates vary widely from high (i.e. fundamental to the company) to low (i.e. probably had little effect). These estimates are based on reported statements on the importance of grants obtained by firm interviews, analysis of the general company situation and the structure and history of granting application behaviour over time. To that end, they are akin to expert opinion, rather than scientific fact.

Our estimate of funding impact

Company	Funding impact	Company	Funding impact
Pacific Edge	70%	Coda Therapeutics	13%
Blis Technologies	13%	Douglas Pharmaceuticals	1%
Genesis R&D	70%	Antipodean	13%
Neuren Pharmaceuticals	13%	Innate Therapeutics	13%
AFT Pharmaceuticals	0%	Living Cell Technologies	50%
N.Z Pharmaceuticals	50%	Proacta	45%
Symansis	50%	Kode Biotechnology	50%
Pathway Therapeutics	45%	Glycosyn	70%
Protemix	70%	Genavia	70%

3.8 Results post attribution

The table below sets out the calculations of return for every $1,000 of Government grant, by individual company and in terms of an industry average. On average, the sector has generated around $4,200 of output, $10,500 in GDP and 0.2 of a job (i.e. around 242 jobs per million dollars) for every $1,000 of Government input. When we exclude Douglas Pharmaceuticals and New Zealand Pharmaceuticals the output number remains unchanged (as both are domestic firms), but the GDP number reduces considerably to around $2,100 (for every $1,000 of Government input) and the employment effect reduces to 0.09 (i.e. around 90 jobs generated per million dollars).

Total "return on Government investment" by individual company			
Company	**Output ($000s) / Government grants ($000's)**	**GDP ($000s) / Government grants ($000's)**	**Employment / Government grants ($000's)**
Pacific Edge	0.3	0.2	0.1
Blis Technologies	0.3	0.2	0.1
Genesis R&D	13.0	6.5	1.1
Neuren Pharmaceuticals	1.0	0.5	0.0
AFT Pharmaceuticals	0.0	0.0	0.0
N.Z Pharmaceuticals	0.0	102.6	0.8
Symansis	0.1	0.0	0.0
Pathway Therapeutics	2.5	1.2	0.1
Protemix	6.9	3.4	0.1
Coda Therapeutics	1.9	1.0	0.0
Douglas Pharmaceuticals	0.0	155.2	5.0
Antipodean	0.8	0.4	0.0
Innate Therapeutics	5.5	2.7	0.1
Living Cell Technologies	2.5	1.3	0.1
Proacta	0.8	0.4	0.0
Kode Biotechnology	0.1	0.0	0.0
Glycosyn	0.0	0.0	0.0
Genavia	-	-	-
Average	**4.2**	**10.5**	**0.2**

Some care should be exercised in interpreting these numbers due to the wide range of funding amounts received across firms. Some companies have received very little funding from the Government sources included in this study, meaning that the "effective return" from that Government funding may be artificially high. Moreover, looking at such measures as a means of making funding decisions may be misleading. The high apparent return from Government may seem like a signal to invest further, when in fact it may also be a signal

that Government investment is not needed or beneficial. The logic is that if the firm is making a positive contribution to GDP with little current Government support, it has revealed itself as being able to compete and perform without Government assistance. The returns will accrue to the economy even in the absence of Government assistance and therefore further assistance might be considered "deadweight" in nature.

In the case of Genesis R&D, we see that since 1994, the company has generated thirteen dollars of economic output/activity for every dollar of Government grant funding received. The next column shows that Genesis R&D contributed over six dollars of value-added (GDP) for every dollar of Government grant funding received.[14]

There are seven entities that appeared to deliver a "neutral" or better return (in terms of GDP generated) per dollar of grant funding. Three of these firms (i.e. those marked with an asterisk) were also identified above in respect of producing above average recent performance:

- Genesis R&D.
- NZ Pharmaceuticals*.
- Pathway Therapeutics.
- Protemix.
- Douglas Pharmaceuticals*.
- Innate Therapeutics.
- Living Cell Technologies*.

Benefits may flow into the future depending on whether the company continues to be a success. If granting ceases, then clearly the return gets larger. If granting stops, then the picture we draw is complete- within the limitations of the analysis.

The statistics above effectively double count as they include the economic impact from the companies spending the grant money they receive. In addition, the effects of spending from private funding that companies would have received without the grants is also included in the numbers. Once these effects are excluded[15], we revealed that the industry generated the following activity (on a cumulative basis) between 2000 and 2009:

- Over $63 million of output/expenditure.
- $181 million of value-added (GDP).

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[14] These figures depend crucially on the assumption that 70% of the output and GDP derived from the company's activities were attributable to grant funding. In other words, Government grants were very important to the company.

[15] We exclude the direct, rather than the induced effects of Government grants. Economic activity is scaled down by our estimate of the funding impact (as outlined in the previous section).

3.9 Economic potential may be underestimated

We set out a number of reasons why our estimates of economic impact may be understated.

Estimates only an approximation, for the following reasons:

- First, we are unable to quantify and monetise the entire range of economic effects likely to emanate from the sector. This is not unique to the human therapeutics sector, but is at least as acutely felt here as elsewhere.
- Second, rather than using official data sources, we have relied on data sourced from primary and secondary sources. While there are likely to be measurement errors in any exercise such as this, the possibility is greater when relying on such data sources. We are not able to indicate which way the bias might run (i.e. whether our numbers under-estimate or over-estimate reality), but are almost certain that some bias is present.
- Third, we have had to make assumptions and judgements regarding some important parameters. This too, may have the effect of biasing the estimated effects away from the true effects.

Measures the "journey", not the "destination"

Perhaps most importantly, the numbers reflect a measure of the economic effect of "the journey" rather than "the destination" for most of the companies involved in human therapeutics in New Zealand.

To date, we are yet to see any significant transaction being concluded involving a New Zealand firm and large players off-shore. While the DMXAA deal involving Novartis was substantial, it involved something of an "intermediary" in Antisoma (via the British Cancer Research Trust). This arrangement is common in the drug discovery field – hence the complexity and value of licensing and sub-licensing contracts.

It is difficult to place a value on the returns that would have accrued to New Zealand had there been greater New Zealand-sourced capital and other backing for DMXAA. As it is, New Zealand stands to gain as much as $50m-$100m a year for 8-9 years once the drug reaches the market (estimated to be 2-3 years away).

One approach therefore, would have been to estimate the probability of New Zealand companies producing other successful compounds and to estimate the potential economic return that would accrue to New Zealand using similar figures as existing deals that have been struck. Given the idiosyncrasies of the sector which add up to considerable uncertainty and risk, we decided against this and to concentrate more on the money that is actually being attracted to and spent in New Zealand. While we believe that this is a more robust approach, we do concede that it results in substantially lower estimates of economic effects than the alternative. Further, the results may be misleading. A number of companies have established themselves with licensing transactions. The money from those transactions then flows through to other compounds, which the entity can then afford to progress. It would be risky for us as outside observers to make judgments on firm-level strategies from this perspective.

Deals with additional activity only
Finally, the estimates we have derived deal with "additional" activity only. That is, they net out activity that is funded by New Zealand sources and measure only "new" activity coming from overseas. Undoubtedly, there is economic activity associated with expenditure that is funded solely from onshore sources. We have assumed that such activity would have occurred in New Zealand anyway (i.e. if not in the human therapeutics sector then elsewhere) and should not therefore be counted as having an economic effect as such. In short, it is trade diverting (rather than trade creating) in nature and does not alter the resources available in the economy for consumption or investment. To the extent that an alternative view is taken and the effects of activities associated with New Zealand-sourced funding are taken into account, this would result in larger impacts.

3.10 A job is a job is a job?

We have focussed on employment as one of the key economic activity indicators. What has not been mentioned is the quality of employment associated with the sector. While precise figures are not available, the prevailing view is that many (perhaps most) of the employment in the human therapeutics sector is high quality in nature. Moreover, in terms of industry multiplier effects, the employment multiplier (i.e. the degree to which an additional job in the sector generates employment elsewhere in the economy) is 3.41. This means that for each new job in the sector, 2.41 jobs are created elsewhere. This is a relatively large employment effect (though not uncommon in capital-intensive industries with above-average salaries).

Thus, from a national perspective, the sector contributes disproportionately in terms of job quality and quantity.

3.11 Other benefits

In addition to the "harder" benefits from the sector discussed above there are also other "softer" benefits. While difficult to estimate with any precision, and often not able to be monetised, these benefits are nonetheless real.

3.11.1 Demonstration effects

The idea here is that firms which undertake a certain activity reduce the cost of undertaking such activity for other firms, usually proximate ones without the latter having to compensate the first mover.

There is an established literature on knowledge spillovers associated with exporting or other "first-mover" activity. That is, empirical evidence supports the notion that other exporters can reduce the cost of foreign market access for a firm contemplating making the jump into

exporting.[16] To the extent that export markets are a specific target of companies in the sector, then the work of Douglas Pharmaceuticals and NZ Pharmaceuticals may be beneficial to these firms. There may also be beneficial discovery-based lessons available from other firms such as Proacta who have successfully secured the support of overseas-based investors.

Perhaps more relevant to the human therapeutics sector is the possibility of demonstration effects in relation to partnering. With the recent growth in the number of firms looking to secure licensing deals and other formal collaborations, there is likely to be significant benefit from observing "the play of the game" from the first company to successfully complete a deal. In addition, there may be demonstration effects in relation to the ability to conduct pre-clinical work and perhaps even clinical trials in New Zealand which encourage other firms to locate such work in New Zealand.

To the extent that such observation opportunities are available, there will be efficiency gains (in terms of avoiding or minimising pitfalls and reducing transactions costs) and commercial technology transfer (i.e. making "sharper" deals) which act to reinforce the work done in drug discovery. It is possible that such lessons will also cross-over into other sectors which may be involved in related activities (e.g. agricultural and horticultural product developments that have some commonality with processes and/or players involved in human therapeutics).

These effects appear strongest in the case of multi-national enterprises, but are likely to apply equally to domestically-based firms. The mechanism is relatively simple: domestic firms learn from or copy new technologies, processes, or market development techniques that are used by foreign-owned affiliates. If domestic firms can successfully implement this new knowledge, resulting in enhanced efficiency or increased revenues, these effects represent externalities. Market access spillovers in particular appear to be strongest when firms are located in close proximity to each other.[17]

In terms of quantification of these effects, it is not yet clear whether sufficient activity of this nature is being undertaken. This is very much a case of needing to be aware of the possibility of such effects arising, monitoring the situation and in future, developing and adopting a process to capture effects in the wider analysis.

3.11.2 Network effects

The other major category of externality that may be relevant concerns network effects. Network externality has been defined as a change in the benefit, or surplus, that an agent

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[16] Aitken, B, Hanson, G H and Harrison, A (1997) "Spillovers, foreign investment and export behaviour" *Journal of International Economics*, volume 43.

[17] Jordaan, J A (undated) "Determinants of FDI-induced externalities: New empirical evidence for Mexican manufacturing industries." London School of Economics. Available at: http://www.lse.ac.uk. Refer also Jaffe, A B (2005) "The Importance of "Spillovers" in the Policy Mission of the Advanced Technology Program", revision of published article available http://www.atp.nist.gov/eao/jtt/jaffe.htm.

derives from a good when the number of other agents consuming the same kind of good changes. Strictly speaking, network effects should not properly be called network externalities unless the participants in the market fail to internalise these effects.[18]

The most relevant consideration here is the possibility of costs being lowered due to a network of firms being able to share information and/or interact in ways that were not possible previously. Such pecuniary externalities arise in addition to other, less tangible effects such as "feel good" effects and "bandwagon" effects that drive sectors to increase output due to confidence gained from sectors approaching critical mass. In concept, there are likely to be benefits associated with network-based activities related to innovation that add to the analysis.

The growing cadre of experienced people with relevant expertise will no doubt assist New Zealand in a network sense. The diaspora effects of Genesis R&D illustrate the extent to which such effects can materialise. Such a process is essentially a "virtuous circle" and can occur in both a formal and a tacit sense.

3.11.3 Reputational effects

Reputation has been identified as one of the few, strong factors that give firms (and by extension countries) distinctive capabilities, which in turn leads to competitive advantage, when matched with appropriate markets. Reputation is particularly important in markets where product quality matters but can only really be assessed over a long time period. In such markets reputation can be difficult and costly to develop, but once established, can yield substantial added value.[19]

The benefits we are talking about here accrue both to individuals and to the country as a whole. They arise due to the stream of publications that often accompany significant drug discovery work. As well as raising the standing of the author(s) of the publication, it also enhances New Zealand's reputation internationally in terms of the scientific community, which may lead to commercial outcomes in time as work is directed this way. At the very least, it may lead to overseas scientists wishing to spend time in New Zealand to work with and for leading scientists. There is anecdotal evidence of such occurrences having taken place already.

3.12 Effects on related industries

There is strong convergence across medical supply markets generally; diagnostic markers are used in conjunction with cancer pharmaceuticals, algorithms derived with the assistance

[18] Liebowitz, S J and Margolis S E (undated) "Network Externalities (Effects)." Available at: http://www.utdallas.edu/~liebowit/palgrave/network.html

[19] See Kay J (1995) "Why Firms Succeed." Oxford University Press.

of bioengineers are integrated with information technology, and medical devices may include a pharmaceutical component. Human therapeutics has a leading role to play.

Health system related areas are going to need the skills developed in and for the human therapeutics industry. At present, there is an increasing demand for medical devices in medical assessment processes to be credentialed. For example, the information packs that may be needed for future registration of medical devices could look similar to the information packs required of pharmaceuticals.

3.13 Chapter summary

The following messages summarise the chapter.

- Clear economic contributions (measured in terms of impacts to output, GDP and employment) arise from the human therapeutics sector. These contributions are largely as a result of the expenditure of foreign-sourced funding in New Zealand, but also as a result of concentrated pockets of profitability.
- Financial success/profitability of firms is not necessary for such economic contributions to the country to result.
- The sector has generated (on a cumulative basis) almost $337 million in output, $833 million in GDP and 19,000 jobs between 2000 and 2009. On average, the sector generates around $38 million in output, $85 million in GDP and 2,000 jobs a year. The most recent year of activity is slightly better than average- indicating positive recent performance.
- The performance of individual firms varies widely within the sample, with much of the responsibility for the economic performance of the sector centred around two firms- New Zealand Pharmaceuticals and Douglas Pharmaceuticals.
- Government grant funding has been instrumental to the achievement of economic performance in the sector over the period of study. Even excluding the two big contributors mentioned above, the economic "return on investment" to the Government has been positive (i.e. over $1 back for every dollar in) over the 2000-2009 period.
- While there are examples of historical returns driving current results (i.e. more recent performance has been much worse than across the life of the firm and therefore clouds the outlook somewhat) a clutch of firms has also demonstrated better recent performance than their historic averages.
- The economic contribution of the sector is not limited solely to attracting overseas capital - significant employment effects (in terms of quality and quantity) are also generated.
- Significant potential exists for future returns from the sector, which will only add to the positive picture emerging from this analysis. That is, "breakthrough" results will add to the economic contribution measured here, rather than replace it. The estimates in this paper may significantly underestimate the quantum of the economic contribution.
- Many other positive effects from the sector cannot be quantified but nonetheless add to the richness of the story and "value" derived from the sector.

- The methods used to measure the economic impacts of the sector have not been used elsewhere to date, and thus cross-sector comparisons are not valid.
- Foreign investment will also mean foreign ownership. The first is to be encouraged and the important test is whether the money will be spent in New Zealand. Grant conditions may need to be sharpened as later returns may not accrue to New Zealand.

4 Comment and implications for investment

The previous chapter presented a range of figures that, put together, constitute an approximation of the economic contribution of the human therapeutics sector to New Zealand. This chapter discusses aspects of the findings, with a focus on implications and explanations.

4.1 No natural groupings or business model clusters emerged

At the outset of the project, it was hoped that we would be able to construct a taxonomy of business models or approaches that might prove useful in thinking through Government funding approaches. The motivation for attempting this was to consider whether funding approaches were directed at those companies (or business models) that would most likely result in the greatest return to New Zealand. In other words, what is the best "value for money" approach to supporting drug discovery in New Zealand?

Our assessment of the companies involved in the sector did not reveal any natural groupings as such. While it would be a stretch to say there were as many different business models and approaches as firms, this is not far from the truth. Moreover, in terms of key factors that would enable a set of clusters to be constructed, little real information was forthcoming. For example, in relation to possible exit strategies or plans for the future, a common response was "it depends." Most participants did not specifically differentiate between a trade sale, licensing arrangements, or other partnering approaches. That is, nothing was ruled in or out at this point in time. This is to be expected in a dynamic, discovery-driven industry.

4.1.1 A loose framework?

Applying a loose grouping framework to the firms being studied results in the identification of four basic groups of firms. Firms are generally:

- Manufacturing based- developing both new versions of older drugs (Douglas) and intermediates/ingredients (NZP);
- Classical drug discovery firms- spin-outs with and without overseas operations (CoDa, Pathway and Proacta);
- Organised around platform models- (LCT and KODE); or
- Hybrid groups who either form international partnerships and combine inputs to build new drugs (IRL) or used the IP and drive of a single person/idea and serendipitously moved into other areas (Innate, perhaps LCT).

It is difficult to think about matching funding strategy to these groupings as such, as the key dimensions (e.g. exit strategy, nature of indications targeted, structure and objectives) are disparate. In addition, it is important to consider the purpose of the funding. Where there is a clear purpose and rationale for the funding, it is much easier to be clear about the types and scale of support and who it should be directed towards. To a certain extent the purpose of the

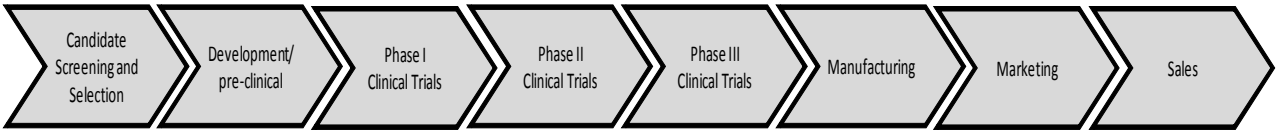
funding will reflect an implicit view of the role that the Government is playing in the industry.

What emerged from this process has been added to industry insights and other thinking in order to provide comment on the most appropriate investment strategy, given what appear to be Government objectives for the wider research, science and technology system. This section sets out the basis of our assessment.

4.1.2 Where are the points to invest?

The figure below outlines the basic structure of a "value chain" for human therapeutics.[20] Brief descriptions of the activities at each stage are as follows:

- *Candidate screening and selection*- this stage involves a range of sub-steps, including gene sequencing, target identification (e.g. look for proteins or mRNA expressed (or not expressed) in a disease state), target validation (i.e. verify the involvement of the protein in the diseased state and understand the relevant protein pathways and interactions), and lead discovery (i.e. where evaluation of "leads" to cure problems takes place).
- *Pre-clinical*-this stage involves animal tests of toxicity and efficacy of therapy.
- *Clinical phase I trials*- typically involve a small group of healthy volunteers to determine safety and toxicity. Some members of target group may be included in trial.
- *Clinical phase II trials*- typically a larger group (i.e. in the 100's) of patient population to determine efficacy, dosage, and safety.
- *Clinical phase III trials*- typically involve 1000's of patients and healthy volunteers to determine efficacy, dosage, safety, side effects and interactions.
- *Manufacturing*- while there is a manufacturing component associated with trial-based quantities, this stage is effectively about scaling up to make commercial quantities.
- *Marketing*- use of advertising and other channels to highlight awareness.
- *Sales*- use of distribution channels and relationships in a direct (to consumer) and indirect (through GP's and/or insurers) manner to generate sales.



[20] This material draws heavily from "Strategies in Drug Development" Dan Kalish's talk as presented by Doug Brutlag. 2002. Accessed through http://cmgm.stanford.edu/biochem118/Papers/Drug%20Discovery/Pharmaceutical.pdf

In broad terms, these stages can be broken up and bundled into potential investment points for Government. The motivation for doing so is to address the question of where it makes most sense (in terms of return to the economy) for Government to invest. Matching possible Government roles to the stages allows a high-level investment options assessment to be mapped out. A description of the categories of interest follows.

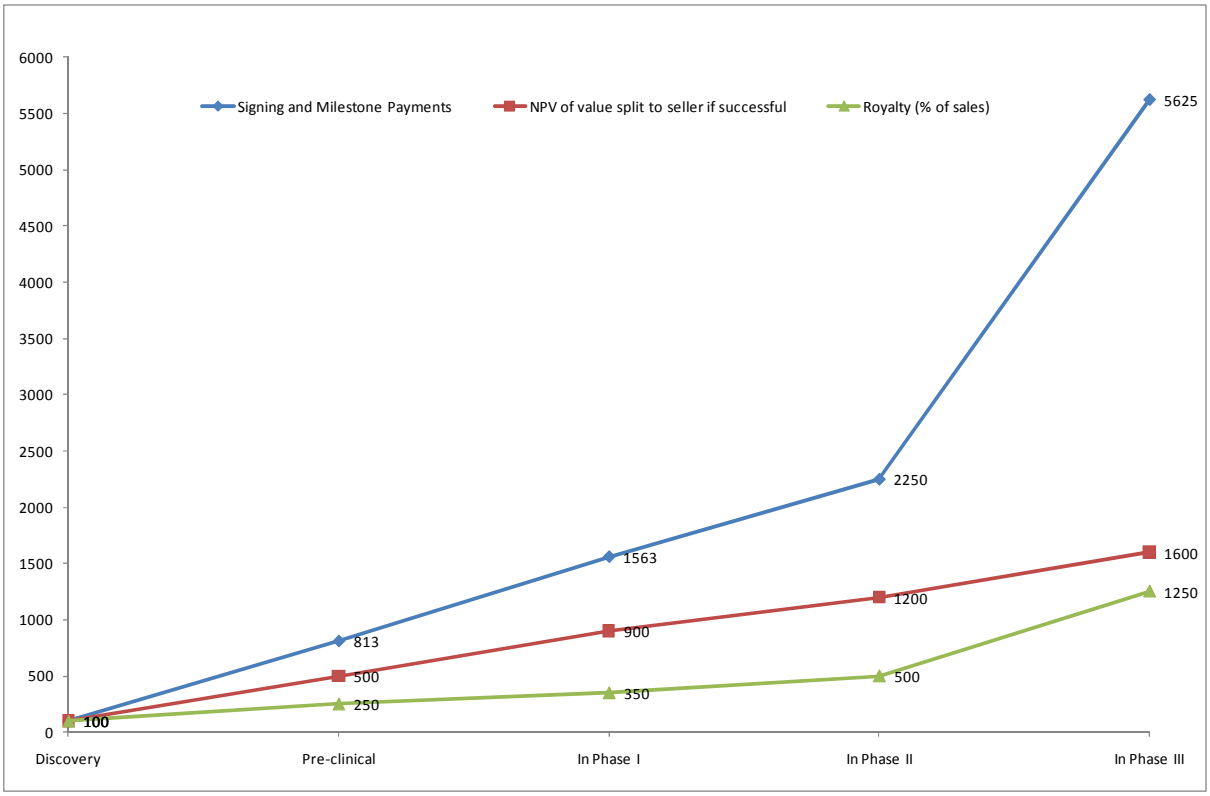
- *Relevance*- the stage/s in the chain where Government investment is being contemplated.
- *Role*- a brief functional classification of Government involvement.
- *Route*- describes the pathway of interest in terms of the stages above.
- *Recipients*- identifies who the funding/support is transferred to.
- *Rationale*- considers the reasoning behind the investment/support.
- *Rate*- discusses the possible level of Government support/investment.

4.1.3 Towards an optimal investment strategy

In thinking through what an optimal investment strategy might be, we need to consider both the scale of possible returns and their likelihood. In the absence of specific details relating to particular companies or compounds, deals done in the past provide a useful guide. The figure on the following page indexes industry averages in terms of value gained at different stages of investment.[21] In the figure we plot three series- a combined signing and milestone payments category, the value split that accrues to the seller in total if successful (expressed as a net present value) and the royalty amount (expressed as a percentage of sales).

The upward-sloping nature of the returns through progression is clear. It is most stark in relation to the combined milestone and signing payment line. From discovery to "in phase III" the value of deals grows by a multiple of around 56. However, the greatest "between-stage" gain occurs between discovery and pre-clinical, where the value increases by over 700%. Across all series, there is also a noticeable change in slope between phase II and phase III. On the face of it, this would suggest that two investment points stand out in terms of optimising returns- the pre-clinical stage and the phase II clinical trial stage.

[21] This material is sourced from Burns L R (2005) "The Business of Healthcare Innovation" p.95.



There are important differences in the particular stages. It may not be possible for the Government to invest at the "in phase III" stage for the following reasons:

1. These are industry averages and there is a great deal of attrition- getting to that stage in the process requires significant time and resource.

2. There is a great deal of interdependence- existence at the later stage (i.e. survival) is often conditional on garnering sufficient support at the earlier stages.

3. There may be efficiency and equity reasons why Governments would choose not to invest at this point despite the apparent high returns (i.e. questions of relative need, the role of Governments at this stage of investment and the possibility of deadweight expenditure and subsidisation).

These arguments may be especially strong when clinical trials are being completed overseas.

In our view, complementary investment from other sources and the apparent returns available would suggest that the transition from discovery to pre-clinical stages would be most beneficial. To a large extent that is where Government investment flows presently.

4.2 Possible investment points

The table at the end of this section summarises our assessment of possible investment points using the categories outlined above. Implicit in the content of the table is the relationship between potential return and cost/risk associated with different points in the chain. What is

not detailed to any degree is the mechanism by which these returns may be achieved (e.g. trade sale, licensing agreement, joint venture, etc).

Naturally, the mechanism used to generate returns will have significant influence on results and therefore on points of investment, but it is difficult to be certain which mechanism is preferable and/or possible. In other words, building an investment strategy based around activation mechanisms (as opposed to stages in the process/chain) is not recommended.

No template for funding efficiency…
There is no simple answer or template for "funding success" in an environment of such uncertainty. While potential returns appear to be greatest between the commencement and completion of phase II trials, focusing solely (or even heavily) on that particular stage is not recommended. In simple terms, there may not be sufficient opportunity to invest at that stage (i.e. firms and/or ideas may not survive past the initial stages or may have moved offshore by that stage). In addition, the nature and quantum of Government support at that stage is not straightforward, particularly when partnering arrangements might see diminished local opportunities to undertake key work.

…however, early stage investment preferred, based on…
Our high-level assessment is that the focus of Government investment should be at the earlier stages in the chain- discovery and pre-clinical investigation, moving through to early stages of the development pipeline (phase I and IIA clinical trials). Investing at these stages is most logical for a number of reasons (e.g. likely returns, relative need, existing and burgeoning strengths in New Zealand, and the degree to which it complements other science investments), which we outline in more detail below.

…greater spillover rates at early stage…
As mentioned elsewhere, early stage investment gives rise to greater spillover rates (benefits) than later stage activities. Given exploitation of such spillovers is a major reason for Government intervention in the human therapeutics/drug discovery sector, it makes sense to target support at the stage that provides these external benefits. At this early stage, it is less likely that individual firms would be able to fully appropriate the surpluses that might accrue from the innovation, relative to investment in later stages. This means that the prospect of deadweight expenditure (i.e. effective subsidy transfers from Government to private interests) is lessened at the early stage.

…budgetary constraint considerations…
Budget constraints also provide support for concentrating Government investment at relatively early stages of discovery. Two major aspects are important. First, limited budgets require an assessment of effective return, with areas that provide greatest return standing out as obvious targets for support. The return to Government involves more than just direct (financial) considerations and the spillover benefits provide one element of justification. An additional consideration however, is that the financial support is more effective (i.e. "goes a lot further") at the early stage than later on in the process- increasing the effective return. The second major aspect is related to this last point- the amounts required at later stages are simply much larger in scale than at the early stage and the Government will have to back relatively fewer projects. Budget constraints therefore restrict the ability to invest at the later stages at the required levels, even if the will to invest in what are effectively higher risk-profile projects is there.

*… **and wider changes in structure of industry***

A further argument in support of early stage investment hinges on movements in the global pharmaceutical model. In the recent past "Big Pharma" has adjusted its activities towards later stages and sought to reduce (and minimise) involvement at early stage discovery processes. In part this is a specialisation strategy- reflecting expertise in deal structuring, distribution and marketing channels as opposed to discovery elements (skills which may be lacking in public entities). It also reflects cost containment objectives- most science expertise is housed in Government-supported education institutions and it is costly for private interests to independently obtain and retain the skills and the supporting infrastructure.

The research side of the human therapeutics sector is thus less appealing to Big Pharma. On the other hand, most Governments retain an active interest in basic research and provide significant resources for such pursuits. It is this complementarity which supports early stage Government investment. In effect, there are two forces at work which act together- the "crowding out" effect of Big Pharma investment at later stages and the "crowding in" effect of basic research support provided by Government which is best used at early stages. The bridging element is need. Given the "flight" of Big Pharma from early stage development activity, something of a funding vacuum develops between basic research and commercialisation, which Government involvement seems well suited to fill.

In large part the current arrangements in New Zealand are targeted correctly
Our assessment of the funding arrangements for the sector suggests that, in large part, existing Government investment is already aimed at the early stages. However, we believe that in terms of optimising investment and aligning incentives, the addition of some funding support/investment in later stages would also be beneficial. This is consistent with observed practice in overseas jurisdictions.

An option for possible further development could be that, as part of providing support at the discovery and pre-clinical stages, specific commitment could be made to provide further support if/when success in phase I and/or phase IIA trials is achieved. That is, introduce options into the system of support that rewards achievement (and encourages further efforts towards such achievement) but also provides support at the crucial early stages.[22]

[22] We do concede that such "letter of comfort" arrangements create difficulties in terms of accounting and cash flow management around future liabilities.

Relevance	Role	Route	Recipients	Rationale	Rate
Candidate screening and selection	Researcher/scientist and industry cheerleader	Ideas genesis; target/compound pipeline.	Universities/CRIs and start-up companies	Support at the basic level is important to incentivise the search (and discovery) of new knowledge. Given the inherent risk and cost in getting to commercialisation, waiting to invest has substantial opportunity costs (i.e. it might be too late by then).	Up to 50% of required funds.
Development/ pre-clinical	Catalyser/ developer	Precursors to commercialisation	Firms (domestic) and Universities (indirectly)	Real returns accrue at this stage if activity takes place in New Zealand. Significant knowledge, relationships and experience are gained at this stage which enhances future prospects. Complementary to strengths in science/backward linkages.	Fixed payments based on scale, etc.
Clinical trials	Investor	Commercialisation entry points	Firms (domestic and off-shore)	Increased potential return to New Zealand from expenditure and licensing and other deals (with concomitant cost burden as well). Possibility of establishing reputation, although limited by distance, cost and numbers of people/patients. Incentives are better aligned in terms of performance/success (i.e. targeting funding support to areas with more chance of success).	Proportional payments based on scale, etc.
Manufacturing	Investor	Scaling up	Firms (domestic and off-shore)	Existing strengths (at least in respect of generics).	Up to 25% of required funds.
Marketing	Investor	Notification, awareness	Firms (domestic and off-shore)	Not strong, despite currently available support from NZTE for market development/exporting.	Up to 50% of required funds.
Sales	Investor	Sales	Firms (domestic and off-shore)	No strong rationale (i.e. evidence of barriers or market failures) for Government investment. Any Government involvement in the sales process for human therapeutics would represent a significant change in policy direction.	To be determined given goals.

4.3 Lessons from other countries

Governments around the world have designed initiatives similar to those being pursued in New Zealand for outcomes in the human therapeutics drug discovery sub-sector.

The growing sectors in Victoria and Finland generally come from similar fundamentals as New Zealand – a relatively small home market, a stable regulatory and institutional environment, a modest but high quality professional labour force, a growing entrepreneurial culture characterised by key individuals, relatively immature venture capital structures, and modest but high quality research institutions. We set out our reviews of these countries in an appendix.

Governments in both jurisdictions have implemented targeted funding, financing and other support to foster R&D and commercialisation of technology-based sectors such as biotechnology, and in some cases human therapeutics specifically.

Recognising the complex factors impacting Government policy development, the jurisdictions do not appear to have focussed solely on either traditional economic spillover and externality effects or addressing innovation system imperfections as explicit design principles. Support is provided across various elements of the value chain, albeit with some initiatives targeting different elements.

While specific initiatives have been designed appropriate to the specific circumstances of the jurisdiction, a number of generic elements might be discerned:

- Strategic analysis and/or planning to identify major challenges facing the sector and possible considered approaches to address those challenges, developed by Governments, Governments with sector representatives, or sector representatives with Government assistance.
- A portfolio approach to funding support distributed through a number of initiatives and agencies, recognising the different actors, drivers and contexts at different stages of innovation development and commercialisation.
- Grant funding for research entities and early stage commercial research, rather than more complex instruments such as loans.
- Funding to foster a deeper venture capital environment that supports innovation development and commercialisation, typically by Government investment in or contribution to commercially-run funds (including some specific to biosciences) rather than direct equity holdings in specific companies.
- Initiatives to support network development, partnerships, shared resources or services and more efficient regional or national processes.
- Support and advice to manage complex development paths, including disseminating knowledge about previous successes and failures.

Over the longer-term, it might be generally expected that Government support for human therapeutics drug development would be mainstreamed into programs to support research, development and commercialisation generally. This would be a logical and sustainable outcome if sector-specific initiatives have helped to address systemic issues impacting the efficiency and competiveness of the sector. In short, the trends in Government involvement in the two jurisdictions offer little more in the way of insight- New Zealand is already well advanced in terms of the mainstreaming of funding policy.

4.4 Other observations

We have a number of other observations on the industry, as follows.

Regular updates useful
During the course of our study we were made aware of the importance of timing. While we have reiterated a number of times that ultimately, the industry has long lead times which influence the long-run nature of investment, there is also a degree of within-period dynamism. Three firms mentioned that significant developments were underway at the time of our investigation but were not able to be fully discussed due to commercial sensitivity. The impacts of the developments would most likely be felt in 12-18 months' time and could be significant.

Thus, we see merit in using this study as a basis for regular updates, rather than as a "one-off." Not only would this allow for inclusion of dynamic effects mentioned, but it would also assist in signalling the interest in strengthening the relationships of Government agencies with participating firms. To the extent that updates focus on incremental or marginal changes, then the participatory burden on firms would reduce each time. It seems to us that bi-annually would be the best interval, perhaps with different focus areas each time.

Future focus difficult, but important to consider
The major limitation of this study was the emphasis on historical performance. There are positives that arise as a result of concentrating on what economic benefit has actually accrued to New Zealand. However, in many respects it is only a partial look at the sector.

As we have mentioned a number of times, the industry is inherently risky and therefore, it is important that we use this as context rather than as a barrier to estimating future prospects. However speculative, insights into sector potential are nonetheless useful.

The assumptions set out in section 3 led to an estimate of a sector contributing around $300-$450 million per year to the economy in future. We suggest that such a sector could be a reality within 5-10 years time, given the platform that now exists. Getting the precise timing right is probably less important than understanding that such potential exists. This is especially important given the prospects on offer in other sectors (including traditional mainstays of the New Zealand economy) are somewhat limited. While it is possible that it might take longer for the sector to reach the scale we are talking about here, it is also possible that our estimate will be dwarfed- possibly by orders of magnitude. That is the nature of the industry. Recognition of such possibilities

(no matter how uncertain) is a possible explanation for continued public and private participation in the industry the world over.

The sector is clearly evolving

The number of companies involved in human therapeutics and the core institutional knowledge contained within the sector (often embodied in the individuals operating within the sector) has grown in the last decade or so. As this process of evolution continues, it makes the experiences of previous years less relevant. That is, viewing the sector in terms of the events of the last ten years would be unfair in terms of what might happen in the next ten years, as the base platform and development work means that it may be an entirely different proposition.

Relationships between and across firms and key individuals in New Zealand and overseas have developed and the necessary "industry infrastructure" is now largely in place. The product pipeline is also growing. While there may still be some deficiencies in terms of access to finance, other supporting mechanisms (e.g. IP expertise) have arisen as a result of recent activities. While by no means sunk costs, these developments suggest that downing tools and abandoning the sector now may come at considerable cost to the sector (both actual and opportunity costs).

While we were not able to locate any publicly available information that would have been useful in determining how the evolution witnessed in New Zealand compares to the situation overseas, what little we have been able to discern makes us comfortable that New Zealand does not appear to be an outlier. Despite having no real comparison (or more general concept of industry evolution for human therapeutics) it is apparent to us that a sound platform for the sector does exist.

Government funding mechanisms could be usefully tweaked

As mentioned above, thinking through an "optimal" Government funding strategy requires thinking through Government objectives and what role Government is and could be playing in the process. Notwithstanding this, some observations can be made in respect of current funding design, mechanisms and operation in New Zealand.

- Funding decisions do not appear to consider the spending intentions of firms in New Zealand. Inclusion of such spending (actual and/or intended) would increase the economic impact of NZTE and FRST funding as well as further developing the New Zealand industry.
- The granting nature of the current Government intervention raises interesting issues in relation to incentives and effects. They essentially provide non-diluting capital to firms (often at a particularly important time in their development), the benefit of which may be largely felt by other investors. There is essentially no direct relationship between the subsequent performance of the firm and the grant funding arrangements, which does not necessarily strengthen the incentives on firms in terms of future performance and sustainability.
- Firms that are judged more likely to be successful would attract funding from private sources and potentially Government as well- essentially a subsidy to private

investment in the current granting form. In addition, such funding would be less influential from a behaviour change perspective – it supports activity that would most likely have taken place anyway and as such is "deadweight" in nature. This is perhaps unavoidable in a system designed to de-risk projects to encourage private sector investment that might not otherwise happen.

- Available options that might address this issue all have their own shortcomings. Equity stakes for Government require a fundamentally different set of skills in public servants and entail a significant increase in monitoring and oversight, with attendant transactions costs. Other "clawback" mechanisms may suffer from similar problems as the current arrangement in terms of somehow "short-changing" the public purse (i.e. in general the arrangement would see only the grant funding being returned to the Government rather than including a time value of money and opportunity costs as well).
- Performance-based support, such as funding based on milestones associated with clinical trials, for example, while creating useful incentives, may also see firms that perhaps need the most support (i.e. at the early stage of their life) unable to access this funding. In addition, from a public policy perspective, spillovers associated with the sector generally occur at the early (discovery and pre-clinical) stages of development so the rationale for Government support on the basis of market failures is often strongest at this point.
- Funding decisions should also be cognisant of the share of the risk/cost being assumed. Anecdotes suggest that New Zealand incurred around 1% of the costs associated with getting DMXAA to market. If this is the case, then a return of around $10 million to date seems reasonable and the royalty projected flows of between $50m and $100m look very positive.

In summary, if a major concern exists that "New Zealand Inc" is not receiving a share of any spoils commensurate with its inputs into the success, then better aligning funding to directly relate to the precise aspects of concern (i.e. sharp practice negotiation) may be a useful tool.

4.5 Chapter summary

The following messages summarise the chapter.

- Firms in the sector use a relatively wide range of business models, with no natural clusters or groupings apparent. Matching funding structure to particular business models would be highly difficult as a result.
- The sector has a number of points along a "value chain" where the Government can invest- running from the "pure" research aspects of candidate screening and selection, through pre-clinical and clinical stages, to manufacturing, marketing, distribution and sales. At the moment, most of the industry activity in New Zealand is occurring towards the earlier stages, although clearly there are some prominent manufacturing interests.

- An assessment of the potential investment points was undertaken using the following framework:
  - *Relevance*- the stage/s in the chain where Government investment is being contemplated.
  - *Role*- a brief functional classification of Government involvement.
  - *Route*- describes the pathway of interest in terms of the stages above.
  - *Recipients*- identifies who the funding/support is transferred to.
  - *Rationale*- considers the reasoning behind the investment/support.
  - *Rate*- discusses the possible level of Government support/investment.
- The assessment suggests that early stage investment was most likely to support the current articulation of the Government's science and research investment priorities. Early stage investment is most logical for a number of reasons, including: likely returns, relative need, existing and burgeoning strengths in New Zealand, and the degree to which it complements other public science investments.
- The assessment was unable to determine optimal investment amounts. Nevertheless, there was nothing to suggest that the current arrangements were wildly inappropriate, insufficient or mis-specified. Indeed, the general direction and quantum of Government investment in New Zealand seems appropriate, though some modification might be fruitful for future/further development.
- Relevant information from overseas was limited, making benchmarking in a precise manner difficult. However, we are able to conclude in a general sense that the sector in New Zealand has progressed well in the recent past and seems at a reasonable state of maturity given what we know about industry development and international patterns. It is best characterised as a clearly evolving sector that has not yet taken off but is stretching its wings and is poised for flight.
- The industry has the potential to contribute between $300 million and $450 million annually to GDP in the near future, perhaps significantly more. Given this, regular updates of this work would be beneficial- perhaps biennially. Regular reporting allows for the evolution of the sector to better be captured, key lessons to be absorbed and acted upon and Government funding arrangements to be reviewed in a timely fashion.

Appendix One - The global human therapeutics industry

We set out in this section an overview of the global therapeutics industry as background and context for analysis of industry assistance to the New Zealand human therapeutics industry.

1.1 Conclusions from the industry review

Our conclusions from the review of the global industry of relevance to the New Zealand industry are as follows:

1. The global industry is large, growing and displays margins that are dramatically higher than many other industries. However, the industry also displays a high entry cost, with high risk of failure, and large regulatory barriers that are exceptionally costly to overcome.

2. The structure of the industry has changed over the years to be sharply "disinter mediated". Large and established global companies control and manage most marketing, sales and distribution. Manufacturing may be outsourced. Research and development is more likely to be outsourced rather than based around largely unproductive and inflexible internal capacity.

3. Deal structures have emerged that reward the discovery and development process based on quality of result and timeliness. These deal structures reflect significant value increments as the drug development process gets closer to market. Substantial capital investment may be needed to complete the final stages and large transactions increasingly share a portion of the risk of an adverse outcome.

The conclusions tend to support our suggested focus for New Zealand on discovery and drug development (i.e. relatively early stage) processes. There will be occasions where companies are able to expand downstream (i.e. at later stages such as advanced clinical trials and manufacturing) but the key message to us is that, as a generalisation, New Zealand is likely to be more successful in early stage development and will not be able to build the marketing, sales and distribution capacity of large private interests (i.e. "Big Pharma").

1.2 An overview of human therapeutics

In this context, the human therapeutics sector includes:

- Pharmaceutical intermediates.
- Pharmaceuticals (chemical or biological therapies).

- Research development tools.
- Reagents and diagnostics.

For the purposes of this report, the focus has been on pharmacology (chemical and biological), reagents, intermediary pharmacological products and biotechnology. Biotechnology has played an increasingly important role in the sector since its origins in the 1970s with the development of key tools such as recombinant DNA and monoclonal antibody technologies.

Global markets

The global market for pharmaceutical drugs in 2008 was estimated by one research firm to have reached US$615 billion at ex-factory prices (wholesale). The sale of cardiovascular pharmaceuticals accounted for 19.8% of the market estimate and the United States accounted for 51.9% of the value of global sales estimate.[23]

In 2007, the global market for pharmaceuticals was estimated at US$693.6 billion by another research firm, who included the categories of branded prescription drugs (US$525.1 billion with a CAGR of 6.0%), generic prescription drugs (US$78.5 billion with a CAGR of 11.3%), and over-the-counter products (US$90.0 billion with a CAGR of 7.1%). On the basis of these CAGR the market for these three categories of pharmaceuticals was forecast to grow to US$1 trillion in value by 2013.[24]

These sales figures do not include reagents and diagnostics, some intermediates and nutraceuticals, medical devices, or development tools. Therefore, sales resulting from (or accruing to) the entire human therapeutics sector are far larger. However, the attribution of figures outside pharmaceuticals is difficult; for instance, an OECD expert was unable to develop or reference robust estimates of the value of health biotechnology in 2008.[25]

The OECD therefore developed its own framework for assessing biotechnology and released its first report on this in 2009. The report set out that one or more FDA/EMEA-approved bio-therapies were developed by firms in 12 OECD and 3 non-OECD countries. Firms based in the United States developed 66.3% of the 138 bio-therapies

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[23] The global market being comprised of the Americas, Asia-Pacific, and Europe. Research and Markets (2008) *Pharmaceuticals: Global Industry Guide*.

[24] BCC Research (2008) *Global Pharmaceutical Markets*.

[25] McKelvey, M (2008) *Health Biotechnology: Emerging Business Models and Institutional Drivers*, OECD International Futures Project. Lawton Robert Berns presents the 2002 annual revenue of all publicly listed biotechnology firms active in therapeutics as US$41 billion. Burns, L R (Ed) (2005) *The Business of Healthcare Innovation*. Page 154.

that received marketing approval between January 1989 and January 2009; European firms contributed a further 15.6% and Japanese firms 7.6%.

As with the previous OECD reports, no global market or sales estimates were given, partially reflecting the stage of development of biotech firms, which are primarily in R&D rather than market sales. Of the four countries that reported biotechnology sales by sector (Belgium, Canada, Germany, and Poland), 57% of all sales accrued from health applications.[26]

Research and development

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the largest global pharmaceutical research and biotechnology companies (therefore not including generics manufacturers). PhRMA reports its members spending US$50.3 billion in 2008 researching and developing new medicines and estimates industry-wide research and investment reaching a record $65.2 billion.[27]

The priority of international pharmaceutical research is often to find 'blockbusters': products that can generate revenues in the tens of billions of US dollars for over five to ten years. In general, the only markets that can generate such returns are management of chronic conditions in relatively wealthy populations.

Human therapeutics research is usually classified into discovery, pre-clinical investigation, and then four phases of clinical trial before it is approved for market use:

- In phase I clinical trials, researchers test a new drug or treatment in a small group of healthy people (20-100) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- In phase II clinical trials, the study drug or treatment is given to a larger group of affected people (20-500) to see if it is effective and to further evaluate its safety. A Phase IIA clinical trial is specifically designed to assess dosing requirements (how much drug should be given); whereas a Phase IIB clinical trial is specifically designed to study efficacy (how well the drug works at the prescribed dose(s)).
- In phase III studies, the study drug or treatment is given to large groups of people (300-5,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

[26] van Beuzekom, B and Arundel, A (2009) *OECD Biotechnology Statistics 2009*.

[27] http://www.phrma.org

- In phase IV studies, the post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.[28]

During September 2009 the database at ClinicalTrials.gov contained publicly available information on 78,991 clinical trials. These trials were sponsored in 171 countries around the world and were public, private, and NGO-funded.[29]

Some phase II and most phase III drug trials are designed as randomised, double blind, and placebo-controlled. Success in phase I and II trials does not guarantee market success; for example a 2008 study showed that only 25% to 50% of new cancer drugs that successfully completed phase II clinical trials during 1995 to 2000 subsequently had their clinical efficacy confirmed in larger phase III studies.[30]

PhRMA states that only one of every 10,000 potential medicines investigated by its members eventually make it through a research and development pipeline and receive FDA approval for market use. It estimates that only one in fifty compounds that enter preclinical testing will make it to clinical trial and that the average cost of development is US$800 million over 15 years.[31] This figure is disputed by many as it also includes the clinical cost of unsuccessful trials and post-approval expenses for successful products. Other estimates of the cost of drug development range widely, from US$100 million for an extensively trialled drug (including the cost of failures also carried out by the company) - to US$34 million when marketing expenses and the costs of failed developments are not included and smaller sized trials are undertaken (for a new indication rather than new chemical entity the average cost reduces to US$11 million).[32]

Irrespective of which figures are used - as a result of the long lead-times for drug development, focus on blockbuster drugs, high costs, and high failure rates - the

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[28] http://www.clinicaltrials.gov/ct2/info/understand and http://www.phrma.org

[29] http://clinicaltrials.gov/

[30] http://caonline.amcancersoc.org/cgi/content/full/58/4/194

[31] http://www.phrma.org/index.php?option=com_content&task=view&id=382&Itemid=118

The National Institute of Cancer explains that a new cancer drug candidate has, on average, at least six years of research behind it before it even makes it to clinical trials, and then a further eight years before a successful drug candidate will receive FDA approval for market use.

[32] GAO (2006) *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*; PERI, "Project Management in Pharmaceutical Industry: A Survey of Perceived Success Factors 1995-1996."; and Love, J (2003) "Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines." *Consumer Project on Technology*.

numbers of truly innovative human therapeutics introduced each year are very low (therapeutics applying a new chemical entity or biologic). For instance in calendar year 2008 the FDA only approved three new biologic applications and 17 new drug applications, up from two and 16 approvals respectively in the calendar year 2007. There has been a decrease by almost a half in the number of new therapeutics being approved in the past decade.[33]

There are also usually a number of competing therapeutics under development for the treatment of a condition; once one or more reach the market the development of alternative treatments without indications of greater efficacy usually stops.[34]

Capital raising and investment

The table below shows capital raising for pharmaceutical companies. Our reading of the situation is that there is capital available for human therapeutics and that, although there is pressure on the money, the flow of activity has recovered from the recent financial crisis.

[33] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/default.htm

[34] For instance, in May 2009 there were record numbers of oncology (861) and diabetes (183) therapeutics under development as there is significant unmet market need. http://www.phrma.org/

Global capital raising: private pharmaceutical & biotech companies		
Month	**Number of firms**	**Capital raised**
August	14	US$230.4 million
July	21	US$429.5 million
June	15	US$264.0 million
May	16	US$468.7 million
April	12	US$219.3 million
March	13	US$287.7 million
February	Not disclosed	US$273.9 million
January	Not disclosed	US$211.2 million

Source: compilation by LECG of SCRIPT monthly reporting; biotech only includes human therapeutics firms and the capital raised is primarily but not exclusively from private sources.

The table below shows the approximate values that are gained depending on the stage of investment. Clearly, the more developed the data file, and the further down the pathway of clinical development, the payments become significantly larger.

Pharmaceutical molecule deals from 2002 to 2004 (primary indication)					
Stage of development	**Signing payment (US$ million)**	**Milestone payments (US$ million)**	**Royalty % sales (US$ million)**	**NPV of value split to seller at time of deal (est.)**	**NPV of value split to seller in total if successful (est.)**
Discovery	1-3	0-5	1-4	~75	~5
Pre-clinical	5-15	25-50	6-10	~75	~15-25
In Phase I	15-25	60-100	10-14	~75	~25-45
In Phase II	40-60	80-120	15-20	~85	~45-60
In Phase III	100 or more	200-300	50/50[35]	~90	~65-80

Figure averages. When Phase II is successfully completed this is the equivalent to "In Phase III".
Source: Burns, L R (Ed) (2005) *The Business of Healthcare Innovation*.

Industry trends

Following is a bullet point summary of major industry trends.

Overview

There are several high-level scientific, demographic, and economic trends that will continue to affect the global industry in the next few decades. These include:

- An aging population profile in most countries combining with increasing obesity, diabetes, and lifestyle diseases will result in increased demand for most therapeutics (a high lifestyle disease burden is already present in developed countries and is increasing everywhere). Growing affluence in developing countries is also driving the growth of therapeutics markets.

  According to IMS Health, another consultancy, the seven biggest emerging markets will account for more than half of the industry's total sales growth this year.[36]

- Declining research and development productivity in big pharmaceutical companies (more being spent but less market approvals being given) is resulting in a trend towards partnering activity.

[35] Typically a profit split as shown for USA market, and 10% royalty elsewhere.

[36] *The Economist*, Aug 2009.

According to CMR International, a consultancy, in most years in the 1990s the industry spent roughly $35 billion – $40 billion on research and development and produced 35 – 40 new drugs. By 2004 spending had swept past $50 billion, but the number of new drugs had fallen below 30. Now annual spending exceeds $60 billion, but the number of new drugs has still to grow. [37]

Similarly, a United States Government Accountability Office (GAO) report on pharmaceutical research between 1993 and 2004 found that although reported research and development expenses (adjusted for inflation) increased from US$16 billion to US$39 billion, a 147% increase, the number of new drug applications increased by only 38%, and the number of applications for innovative drugs had increased by only 7%.[38] *Most of the recent dramatic advances in human therapeutics have come from academic labs and biotechnology start-ups rather than industry research centres.*[39]

- A focus by large companies on developing blockbuster drugs.

  The US General Accounting Office also found that, in the 10 years to 2006, large pharmaceutical companies had concentrated on the development of blockbuster drugs that will realise over US$1 billion in annual sales to the detriment of other areas of research. Many research projects were curtailed as a result of increased level of agglomeration over this period in which 'big pharma' has merged to create 'mega pharma'[40].[41]

- Many existing blockbuster drugs are coming off patent.

  Evaluate Pharma, an industry consultancy, estimates that about half of the $383 billion-worth of patented drugs to be sold in the world this year will lose patent protection within five years.[42]

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[37] *The Economist*, Jan 2007.

[38] GAO (2006) *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*.

[39] *The Economist*, Jan 2007.

[40] As mentioned on the following page in the trend on industry consolidation and specialisation.

[41] GAO (2006) *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*.

[42] *The Economist*, Aug 2009.

Pressure on drug company profitability

- Unsustainable healthcare costs in developed countries resulting in increased pressure on the prices of publicly funded drugs.

  Governments are looking for improved cost-effectiveness in their drug purchasing. Some are establishing drug purchasing agencies similar to PHARMAC, such as the National Institute for Health and Clinical Excellence (NICE) in the UK, that analyse the costs and benefits of new drugs. Governments are increasingly purchasing lower-cost generic drugs.

- Governments are also placing pharmaceutical companies under greater levels of regulatory scrutiny in order to try and reduce costs.

  In the past few weeks regulators in America and the European Union have announced separate crackdowns on anti-competitive practices, including "pay-for-delay" deals, whereby big drug makers pay generics firms to delay the launch of competitors to drugs coming off patent.[43]

- Unsustainable healthcare costs in developing countries resulting in increased pressure on the prices of drugs.

  A decade ago Britain's GlaxoSmithKline (GSK) got a bloody nose in South Africa when it tried too vigorously to defend patents on an HIV drug. More recently Novartis, a Swiss firm, lost a bitter battle in India over patent protection for Gleevec[44]*, a profitable cancer drug. In Thailand the government has invoked compulsory licensing for some drugs. And next week the industry can expect another drubbing over patents harming "innovation for the poor" at the World Health Organisation's annual assembly.*[45]

Industry consolidation and specialisation

- Large pharmaceutical companies have been merging and acquiring each other and moving into related fields, such as biotechnology or into over the counter drugs and diagnostics.

  Fifteen years ago, the ten largest companies commanded 25% of the global market; today their market share is over 50%.[46]

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[43] *The Economist*, Aug 2009.

[44] The chemical name is imatinib mesilate, and the brand name in New Zealand is Glivec.

[45] *The Economist*, May 2008.

[46] '*Innovation in the Pharmaceutical Industry – Future Prospects*' Roche Chairman and CEO, Dr Franz Hummer, (2005).

- At the same time many large companies have been moving from conducting all activities in their value chain (vertically integrated) to focusing on the parts of the value chain that they are strongest at (outsourcing aspects of R&D or manufacturing):

  Many activities can be put out to the growing legion of biotechnology start-up firms, contract research organisations, independent drug development firms and freelance sales organisations. [47]

The increasing prominence of biotechnology

- Biotechnology firms are joining the ranks of 'big-pharma'.

  Although most of the biotechnology sector outside of the USA is composed of many small local enterprises, the top-tier companies such as Amgen, Biogen Idec, and Genzyme are developing into traditional global companies. In other cases major biotechnology companies focus on their domestic market and are putting in place marketing and distribution agreements with established pharmaceutical companies for foreign markets (which are often too small to justify the cost of developing an independent distribution channel).[48]

- Biotechnology contribution to future human therapeutics will increase.

  The biotechnology sector in healthcare is developing at a far greater rate then the rest of the industry. Global pharmaceutical companies are placing ever greater reliance upon biological products as sources of future innovation; over 70% of all life sciences deals between January 2008 and June 2009 were in relation to small-molecule agreements between pharmaceutical and biotechnology companies.[49]

- Generic biologics will become prominent in the future.

  There is already significant pressure on profit margins from generic and 'patent-busting' drugs. The issue of the development of generic biologics has not yet been addressed by regulation, and it is likely that this will become a pressing issue in the near future.[50]

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[47] *The Economist*, Jan 2007.

[48] Burns, L R (Ed) (2005) *The Business of Healthcare Innovation*.

[49] Chan, P "Commentary: 10 pro-innovation biopartnering trends", *SCRIP World Pharmaceutical News*, 01 September 2009.

[50] Burns, L R (Ed) (2005) *The Business of Healthcare Innovation*.

Changes in the licensing environment

- Less licensing is occurring but the value of transactions is higher.

  The average value of licensing transactions in 2008 for compounds that have completed proof-of-concept (Phase II) was US$350 million (sometimes including multiple assets); although this was a doubling in value from 2006, the number of transactions decreased by a third over the same period.[51]

- Licensing deals are increasingly 'back-loaded'.

  Large companies need to fill their product pipelines, yet are increasingly averse to paying large amounts of money upfront in order to secure licensing opportunities for unproven compounds. A change in the risk environment has led to a notable increase in deals in which the headline value is split between developmental and commercial milestones ('back-loading'). The consideration of risk is no longer limited to getting drugs to market; there is also growing scrutiny of both post-marketing safety and a changing pricing and reimbursement environment. This has changed the ability of the innovator to realise the great percentage of the overall value of their development simply by successfully completing Phase II trials (as shown in Table 2 above). Over the 18 months to August 2009, 37% of all clinical-stage deals have included contingent payments based on the commercial performance of products once they reach market.[52]

[51] Chan, P "Commentary: 10 pro-innovation biopartnering trends", *SCRIP World Pharmaceutical News*, 01 September 2009.

[52] Chan, P "Executive Briefing - Biopartnering 2.0", *SCRIP World Pharmaceutical News*, 27 August 2009.

Appendix Two - A framework for Government assistance

We first set out in this section a framework and context for how LECG thinks about Government assistance to the biotech industry from a public policy perspective. The appendix is for discussion rather than being in any way prescriptive or directive in nature.

In this appendix, we discuss:

- The role of Government in industry development and its current involvement
- The nature of market failure in human therapeutics
- Some suggested policy issues.

2.1 The role of Government in industry development

A New Zealand network of firms that span the range of human therapeutics activities, building upon existing and developing strengths (research, niche manufacturing, international collaborations), provides an array of opportunities. These include:

- Maximising economic growth potential from innovative and skill-biased activity;
- Attracting and retaining world-class knowledge workers;
- Maintaining international competiveness by focussing on "weightless" economy possibilities, particular around exports.

The table on the following page provides a high-level explanation for government support of research and development, much of which is relevant to drug discovery and human therapeutics.

Possible reasons for public support of research and development

Australian Productivity Commission (1995) "Research and development" Industry Commission Inquiry Report:

- *Externalities*: External benefits from R&D accrue to those other than the innovator without adequate recompense. These are spillovers under another name and are characterised by the same attributes of non-rivalry and non-appropriability. They can result in inadequate incentives for private investment in R&D.
- *Risk and uncertainty*: R&D is claimed to be an activity which will be avoided by private investors because of its high risk and the difficulties in determining likely outcomes from investment in research and development.
- *Information*: Trading in the results of R&D (knowledge) is limited by the fact that to be fully informed in advance about a purchase is to acquire the R&D itself. The seller of information necessarily has information that the buyer cannot have.
- *Indivisibilities*: Many research projects require large investments to produce results. This is thought to discourage investment in R&D, especially if the research has applicability to many firms.
- *Evolutionary theories*: R&D is seen as a process of evolution to different products and processes. Evolution requires the creation of diversity and a principle of selection. Evolutionary theorists argue that governments can assist in these processes to obtain a better evolutionary path.
- *New growth theory*: Stressing the role of R&D in assisting nations to achieve their path of maximum growth.

Australian Productivity Commission (2007) *Public Support for Science and Innovation*:

- *Institutional theory:* Public support of scientific research creates an institutional form for the conduct of science that maximises agglomeration benefits, cumulative knowledge generation, and variety.

Below we consider the rationale for public investment from a policy perspective. We cover more orthodox "market failure" arguments that suggest a role for government as well as canvassing innovation-based arguments. While we draw on principles of good policy design in the discussion we wish to emphasise that there are two major constraints. The first is the lack of strong empirical/evidential support. Given the relatively "young" age of the industry in New Zealand and the long lead times and uncertainty of commercial outcomes characteristic in the industry, the evidence base is not strong.

Secondly, there is often no clear and crisp "problem definition" as such. That is, rather than looking for policy to "remedy" a particular problem, or a problem which is well-defined, discrete and measureable, policy in this area is more about looking to maximise opportunities which themselves may be speculative or subject to significant risk. There is no linear chain from problem to solution via options as is often the case in other policy areas. These two constraints have the effect of raising the risks associated with the proposals put forward by the sector, but also in some ways lowers the effective thresholds for intervention.

2.2 Current involvement of the New Zealand Government

A number of government agencies are involved in funding (and other means of support) for biotechnology generally and human therapeutics specifically. Government support

spans a range of activities, even within the same agency. Here we only briefly sketch out the nature and volume of government support for the sector.

Foundation for Research, Science and Technology (FRST)

FRST is the government's main investor in research, science and technology, spending around $500 million annually. Relevant FRST funds and areas of support are:

- New Economy Research Fund- supporting basic and basic- targeted research.
- Pre-seed Accelerator Fund- supporting commercialisation of research.
- Technology New Zealand- supporting technology development, commercialisation and business growth.

Health Research Council (HRC)

HRC is the Crown agency responsible for the management of the Government's investment in "public good" health research. Ownership of the HRC resides with the Minister of Health, with funding being primarily provided from Vote Research, Science and Technology. The statutory functions of the HRC include:

- Advising the Minister and administering funds in relation to national health research policy.
- Fostering the recruitment, education, training, and retention of those engaged in health research in New Zealand.
- Initiating and supporting health research.
- Undertaking consultation to establish priorities in health research.
- Promoting and disseminating the results of health research to encourage their contribution to health science, policy and delivery.
- Ensuring the development and application of appropriate assessment standards by committees or subcommittees that assess health research proposals.

NZTE

NZTE is the government's economic development agency, responsible for improving the international competitiveness and sustained profitability of New Zealand businesses through access to people, knowledge and opportunities. In terms of funding, relevant NZTE areas of support are:

- Market development funding- this source of funding has now been closed. Existing recipients will continue to receive assistance to develop international markets. It can help a business enter a new market or undertake new activity in an existing market.
- International Growth Fund

- Australia New Zealand Biotechnology Partnership Fund (ANZBPF) - ANZBPF is designed to support and speed up trans-Tasman collaborations in biotechnology, thereby giving companies in both countries better access to global opportunities. Eligible New Zealand biotechnology companies can apply for four different types of funding through the ANZBPF:
  - People and Skills Development
  - Bio-Market Development
  - Market Acceptance Projects
  - Collaborative Projects

Ministry of Economic Development (MED)

MED has a wide array of functions, but is basically the policy Ministry responsible for fostering economic development and prosperity for all New Zealanders. In addition to the various regulatory, industry and regional development roles it has, MED also administers two relevant funds focussed on commercialisation and support for firms:

- Seed Co-investment Fund (SCIF) - aimed at small to medium sized businesses with strong potential for high growth, particularly in the technology area.
- New Zealand Venture Investment Fund (NZVIF) - a Crown Owned Company responsible for implementing the New Zealand Government venture capital programme.

Tertiary Education Commission (TEC)

TEC manage government's $3 billion annual investment in the tertiary education system: a national strategic asset critical to New Zealand's economic and social wellbeing. TEC have three initiatives of relevance:

- Centres of Research Excellence (CoRE) - primarily, but not exclusively, inter-institutional research networks, with researchers working together on a commonly agreed work programme. Each Centre of Research Excellence is hosted by a university and comprises a number of partner organisations including other universities, Crown Research Institutes and wananga. The first CoREs were established in 2002.
- Partnerships for Excellence (PfX) - a framework that aims to increase private sector investment in tertiary education and foster better links between tertiary education institutions, industry and business.
- Performance Based Research Fund (PBRF) – funding that flows directly to Universities which they then use to support health research (in part).

Royal Society of New Zealand (RSNZ)

RSNZ was created to advance and promote science and technology in New Zealand. It manages the Marsden Fund, supports research excellence in science, technology, engineering and maths, social sciences and the humanities. The Fund's objectives are to:

- undertake investigator-driven research
- enhance the research knowledge base in New Zealand
- contribute to the global advancement of knowledge
- broaden and deepen the research skill base in New Zealand.

In addition to these specific support initiatives there are also agencies that impact on the sector in a regulatory sense (e.g. PHARMAC) and from a policy and focus perspective (e.g. the previous Growth and Innovation Framework). Finally, government plays a role in supporting industry-led development, such as assisting in the development of the sector group NZBIO.

In terms of public funding/investment of human therapeutics, FRST is the largest contributor, followed by HRC, then closely following is TEC (CoRE) and finally the Marsden Fund.[53]

2.3 Market failures in human therapeutics

As their name suggests, market failures are situations where the market alone may not provide the socially optimal amount (or quality) of a particular good or service. Government intervention to correct this "failure" by the market to provide may be feasible and desirable (i.e. efficient).[54] The most common forms of market failure are summarised below.

- *Public goods*- goods that are non-rival in consumption and non-excludable, making attempts to allocate the good via market means difficult due to free-riding and overuse possibilities.
- *Externalities*- an economic cost or benefit that is the by-product of economic activity but that is allocated outside of the market system. This means that the producer of the externality has no incentive to take account of the external cost or

[53] Sourced from NZBIO SIGHT Report. Relates only to projects where new therapeutics is a target outcome.

[54] It should be noted that government intervention is no guarantee of efficiency or optimality- "government failure" may be as much an issue as "market failure."

benefits that are being generated, resulting in too much or too little of the activity being produced, relative to the socially optimal amount of the good or service.

- *Market power*- where participants have a form of market power, it can lead to imperfect competition, where output is restricted and prices are raised.

While there does not appear to be a single market failure driving government involvement in the sector, externalities and public goods appear relevant. The former is relevant in a direct sense, while the latter has indirect relevance/importance.

Externalities

There are three main arguments associated with externalities (particularly in relation to small firms). Firstly, larger firms are more fully able to internalise the spillovers that R&D generates, meaning that the divergence between social and private rates of return is much less.[55] One of the main goals of government support to private R&D is to bridge the gap between the two rates of return. Without government support there is a possibility that small firms will do too little R&D relative to the socially desirable level. Therefore, government support encourages firms to increase the amount of R&D- equalising private rates of R&D spend with social rates. All else equal, the more a company is able to internalise the spillovers the less it requires government funding.

Secondly, R&D is essentially about risk and risk taking. This includes:

- The degree of risk of an R&D project from an economy-wide point of view may be lower than that perceived by private firms- a problem with asymmetric information (i.e. lack of knowledge of what the benefits might be).
- The degree of risk aversion by private investors may be higher than the social rate of return. As a result, the market may provide for too little risk taking in R&D, and hence government support would encourage firms to move in the socially desirable direction.

In this respect there may be major differences between small and large firms and this may be exacerbated in the New Zealand case by the distance from markets. Asymmetric information will normally be more acute with younger/smaller firms, and the risk premium that smaller firms are required to pay is often much higher. Also, R&D projects undertaken by small firms, all other things being equal, may be riskier than if done by larger firms, even if they are exactly the same in terms of technological goals. This is because smaller/younger firms are potentially disadvantaged relative to large firms as they might lack the wide range of competencies and experience that are complementary to R&D i.e. in marketing the innovation, pure management, in know

[55] The social rate of return on R&D is defined as the gain in consumption associated with innovation.

how etc.. Thus, there is more room to subsidise risk taking by small firms relative to large ones.

Thirdly, imperfections in capital markets usually impact on smaller firms' more than larger firms. The availability of internal financing – which is important in the R&D context – is normally less constrained for older/larger firms than for smaller ones. Also, access to global capital markets is easier/cheaper for larger firms.

Earlier drug discovery activities are likely to have greater spillover rates than later activities. For example, the Australian Productivity Commission has noted that:

> *…while clinical trials may generate benefits associated with introducing new technologies and methods to clinicians, these benefits are likely to be greatest for the first of a set of trials, rather than all trials*[56]

Activities such as regulatory compliance with toxicology requirements and phase III and IV clinical trials were especially noted as not likely to be major sources of spillovers. The table below outlines and compares sources of spillovers in pharmaceutical drug discovery.[57]

[56] Productivity Commission 2008, *Public Support for Science and Innovation*, Commonwealth of Australia, pp.10-11

[57] Adapted from content in Productivity Commission 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, Research Report, Commonwealth of Australia, Canberra, January.

Sources of spillovers in pharmaceutical drug discovery		
Stage	**Extent of spillovers**	**Scaling**
Discovery/basic research	Strong spillovers as innovations are least appropriable by the researching firm	High
Pre-clinical trials and early stage clinical trials	Enabling role for discovery/basic research. Agglomeration benefits through forming an integral part of the 'critical mass' of pharmaceutical capability required for the sector to prosper. Location of trial stage influences location of subsequent stages	Medium
Late stage clinical trials	Marginal net gains to consumers – balancing patients getting access to the newest drugs earlier with potential for unforseen and costly consequences Potential spillovers to clinicians and other parties, to the extent that clinicians, researchers and consultants are exposed to new technologies/approaches which might not otherwise be available in routine practice. Some aspects (Phase IV trials, post-marketing studies, cost effectiveness studies, meta-analysis, co-prescription studies, and epidemiology studies) may not involve significant additions to knowledge that have benefits outside the firm.	Low

Consistent with higher spillover rates for earlier R&D activities, in reference to the specific Commonwealth investment program in Australia at the time the Productivity Commission found that:

> *…payments for R&D are likely to have generated* [social] *benefits that exceed the costs, while subsidies for value added activity are likely to involve a net* [social] *loss.*[58]

While the existence of spillovers may justify government intervention, whether the drug discovery sector merits special treatment over other sectors is a different issue:

> *…The [pharmaceutical] industry conducts a large amount of R&D and is an important source of collaboration and expertise to the biotechnology sector. This is likely to produce significant knowledge spillovers for other firms. But overall there is no evidence to suggest that spillover rates in the pharmaceutical industry are greater than in other industries.*[59]

[58] *Evaluation of the Pharmaceutical Industry Investment Program*, Productivity Commission, Australia, Jan 2003, p.xxii

[59] *Evaluation of the Pharmaceutical Industry Investment Program*, Productivity Commission, Australia, Jan 2003, p.xix

However, there may be an argument that drug discovery is different because the wide-scale adoption of its outputs can have substantial public benefits into the future, different to the more private and immediate impacts of other sectors:

> *…the application of biological knowledge to other sectors of the economy will provide major benefits, including …improved health outcomes and reduced social costs through major advances in the prevention, diagnosis and treatment of major debilitating chronic diseases.*[60]

Public goods

In considering the rationale for government intervention, it would seem natural to consider why it is that government should/would assume many of the risks associated with the sector.[61] That is, are there public good arguments that could be used in support of government intervention?

It has often been claimed that knowledge is a public good- once produced, it is hard to exclude people from consuming it, and one person's consumption of knowledge does not reduce the amount of that knowledge available for consumption by others. Therefore, standard economic reasoning suggests that the prospect of "free-riding" dampens incentives for individuals to produce new knowledge in a "market-like" situation. Government involvement raises the level of knowledge being produced to somewhere nearer the socially optimal amount. Thus, intervention based on the notion that research is a public good has a reasonably solid grounding.

However, things become less clear in respect of government involvement in the commercialisation of research- the activities of companies set up to take the research to market. Pure public good arguments dissolve and questions arise as to why we would not expect a form of voluntary, market-based alternative to develop. For example, clubs are one form of alternative examined in the economics literature in the context of impure public goods. To a certain extent, "clubs" of like-minded individuals have formed, with GBS Venture Partners being a visible example. The key feature of clubs is that there is some element of excludability.[62] The strongest argument against the possibility of clubs forming (and taking on the entire role of investing in human therapeutics with no government involvement) is the somewhat blurred interface between research and

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[60] Victorian Government 2007, *Action in partnership: Building our biotechnology future, Victorian Biotechnology Strategic Development Plan*, p.6

[61] In reality, due to the granting nature of public funding, the government does not actually assume risk, but it could be argued that there is an implicit transfer of risk from private investors to the public through the granting mechanism. At the very least, the grants system reduces the financial risk to private investors.

[62] Mechanisms for exclusion can include voting procedures; institutional rules (e.g. granting power to a leader, or excluding the lowest contributors); and a selection rule.

commercialisation in human therapeutics. There is no clear separation as such as the commercialisation opportunities take place while scientific inputs are still feeding into the development process.

Innovation system and industry development

The New Zealand drug discovery innovation system has some attributes that make the R&D effort particularly challenging. These include the long lag from the initial research to successful commercial applications and consequent financing issues in a small economy distant from major decision-makers.

Government can be – and some would say should be – an active contributor to overcoming barriers to the human therapeutics innovation system in order to support industry and national economic development.

The policy/program implementation role focuses on improving systematic imperfections in the interactions between innovation system actors. These systemic imperfections relate to:

> *…the absence or inappropriate functioning of specific elements in the innovation system, with specific emphasis on R&D funding, public-private partnerships, intellectual property rights, product regulation, and the configuration of public health care systems.*[63]

Potential examples of this include a lack of biotechnology expertise in technology transfer offices, inappropriate models for attributing the ownership of and returns from intellectual property between the researcher and the research organisation, inadequate public-private linkages, the shortage of risk capital, and lack of availability of specific expertise in human resources.[64]

The Table below outlines OECD perspectives on actions to enhance national innovation systems for pharmaceutical biotechnology through more effective policies. In the New Zealand context, all can be influenced positively by FRST and NZTE funding programs, with the exception of issues around the regulatory framework.

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[63] Organisation for Economic Cooperation and Development (OECD) 2006, *Sectoral Case Studies in Innovation: Pharmaceutical biotechnology*, <http://www.oecd.org/document/29/0,2340,en_2649_34273_15709661_1_1_1_1,00.html>, accessed 8 July 2009

[64] Organisation for Economic Cooperation and Development (OECD) 2006, *Innovation in Pharmaceutical Biotechnology: Comparing National Innovation Systems at the Sectoral Level*, OECD Directorate for Science, Technology and Industry

OECD integrated innovation policy approach for biopharmaceuticals	
Issue	**Response**
Coherent and consistent innovation policies	Combine objectives such as improving international competitiveness through innovation policies towards pharmaceutical biotechnology on the one hand, and a high-quality and affordable public health care system on the other hand.
Public governance	Facilitate a more active role of patients and/or their organisations in innovation processes, clinical trials and market access; potentially important sources of innovation remain untapped.
Promote co-operation and networking	Create network linkages throughout the biopharmaceutical innovation system, especially between actors in science and the business system.
Support for an innovative industry	Develop instruments that provide incentives for private financers to invest in biopharmaceutical firms.
Regulatory framework	Develop transparent and stable regulations with short application procedures and good information on procedures and the development of an adequate system for protecting biopharmaceutical innovations.
Technology transfer	Stimulate the exploitation of public sector biopharmaceutical research, include intellectual property rights indicators in review and evaluation procedures, establish qualified supportive infrastructure for start-ups (legal, business, marketing expertise, incubator and technical facilities).
Stimulate sound science systems	The persistence of market imperfections associated with basic research requires a role for government research policies and research funding.

Source: *Innovation in Pharmaceutical Biotechnology: Comparing National Innovation Systems at the Sectoral Level*, OECD, 2006

However, smoother pathways for New Zealand-based basic research is not necessarily the sole goal, especially when greater benefit might result from directing resources towards imitating or adapting overseas innovation.[65] The concept of open innovation, especially with international linkages, may be more relevant to a small country like New Zealand, which only undertakes about 0.2% of research and development in the OECD and is therefore reliant to a greater extent upon foreign innovation to drive domestic productivity improvement.[66]

[65] Australian Productivity Commission (1995) "Research and development" *Industry Commission Inquiry Report*.

[66] OECD (2009) *OECD Economic Surveys: New Zealand*.

With open innovation, firms harness widely distributed knowledge, buying or licensing processes or inventions (e.g. patents) from other companies to supplement their own research. In addition, internal inventions not being used in a firm's business should be taken outside the company (e.g. through licensing, joint ventures, or spin-offs on commercial terms).[67] This may involve an active search for new technologies and ideas outside of the firm, but also cooperation with suppliers and competitors in order to create customer value.[68]

Irrespective of the source of the basic science, a critical mass of research and commercialisation capability may be important to a country's ability to absorb ideas from abroad[69] and to maximise the returns from public innovation investment.[70] This may provide a rationale for an industry development focus distinct from spillover rationales.

With a similar framework in the context of the industry's global trends and local advantages, Australia's recent Pharmaceuticals Industry Strategy Group[71] found that "the thrust of pharmaceuticals industry policy should be to:

- Provide the knowledge and research skills base that underpins the sector and wider innovation system.
- Support the industry to develop technology and innovation to a later stage of development before out-licensing and to shift its profile to develop areas that deliver a specialised and sustainable competitive advantage.
- Encourage the industry to seek to compete internationally on quality and distinctive capability rather than on the basis of lowest cost."[72]

These principles – particularly support to develop to a later stage of development – are generally transferable to the New Zealand context, recognising New Zealand's track

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[67] Chesbrough, H (2003) "Open Innovation: The New Imperative for Creating and Profiting from Technology".

[68] Ibid. (OECD)

[69] Ibid. Refers to the work of Jaumotte, F and Pain, N (2005) "Innovation in the Business Sector", *OECD Economics Department Working Papers*, No. 459.

[70] Australian Productivity Commission 2007 *Public Support for Science and Innovation*.

[71] A specially appointed group providing advice to the Australian Government

[72] McNamee B, Pennifold C et al 2008, *Pharmaceuticals Industry Strategy Group Final Report – Executive Summary*, pp.xvi, Commonwealth of Australia, December

record in early stage R&D but less strength in moving through the innovation system to commercialisation.

Summary

In summary, we make the following summary comments (rather than recommendations):

1. While there is not a strict, technical rationale for government intervention in respect of classical market failures, there are reasons why market (or private) solutions might not be sufficient. There are valid externality arguments that suggest a role for government in a New Zealand context, particularly in relation to smaller firms, and particularly given the serendipitous nature of the discovery and development process in this industry.

2. While we are saying that there is something of a justification for government intervention, we are not saying that the current form of intervention is right or optimal. Sharpening the underlying incentives and/or a re-assessment of the basis and nature of that intervention and being specific about what we want to achieve might still be beneficial. Such a consideration may lead to development of a strategy which may present an international opportunity for better organisation than we currently observe.

3. While intervention to address the external effects of spillovers may focus on support for early-stage R&D, interventions based on a conception on systemic failures in innovation systems might take a broader focus with a particular interest in the exploitation and commercialisation of knowledge at later development stages. We have not seen any evidence of systemic failures although opportunities for better co-ordination across agencies (perhaps under the banner of a unified industry and sector strategy) do appear available.

Appendix Three - Methodology and components of analysis

In this section we set out the major components of the analytical task. Any estimation exercise involves the bringing together of a combination of hard and soft "edges." By this we mean there will be areas where there are robust and quantifiable effects that are amenable to enumeration with relatively little interpretative or judgement-based support. On the other hand, there are also areas where effects are less amenable to enumeration, inherently speculative or ambiguous. To be most useful, an analysis of economic value should contain both perspectives. In the case of "hard edges" we expect this to be manifest in terms of information and/or data, while the "soft edges" are generally expressed in terms of qualitative discussion and judgements related to magnitude and likelihood of occurrence.

By way of reference to the previous section on the rationale for government intervention, obviously where such intervention is premised on "correcting" market failures, then we are interested in market-based transactions and exchange. Clearly, input factors such as labour are available on the market and market prices are paid, so it is relatively easy to account for these things in the analysis. However, research is not as readily traded in markets (while the process of publication of research is highly competitive, in general there is less of a competitive market in the production of basic research). Therefore, such factors are difficult to conceive of and capture in the framework used to describe intervention logic above.

3.1 Overview of method

We have calculated the economic return that the sector generates, using a hybrid/mixed methods approach, involving aspects of expenditure analysis economic impact modelling analysis and timing concepts used in value chain analysis. In part such an approach reflects the somewhat fluid nature of the objectives and outcomes sought from the project (which ultimately meant no "off the shelf" or single model was fit for purpose). In addition, it also reflects the nature of the data and information available. Given the relatively young age of the sector it was always going to be difficult to develop a time series of information. In addition, commercial sensitivity dictated that even where data did exist, access to such was not guaranteed.

We have sought to measure economic returns where they can be measured, and have used assumptions where we have sufficient information and basis. Some forms of economic returns, such as experience developed, are harder to measure and require more subjectivity. We have described these economic returns, rather than attempting to estimate them.

We have performed these calculations for each human therapeutics company that we consider, and we have summed the economic return across all these companies to yield a figure for the whole sector. Our calculation of economic return from each company uses

information we have retrieved from public sources, financial accounts sent by companies, grant information provided by NZTE and FRST, and comments that interviewees made when we interviewed them.

We have analysed the sector beyond these direct calculations of economic value. We have described the human therapeutics sector, and how Governments support it, for both New Zealand and some overseas jurisdictions. We have done this using information that we sourced from websites and previous reports on human therapeutics industries.

In this report, we consider the economic benefit that human therapeutics companies based in New Zealand bring to the country. We do not include the costs or benefits of research into human therapeutics that does not result in a human therapeutics company. We have chosen to exclude companies that discover or produce nutraceutical products, or therapeutics for animals. Where companies that discover and/or produce human therapeutics also perform other activities outside of this area, we have excluded these costs and benefits from our analysis.

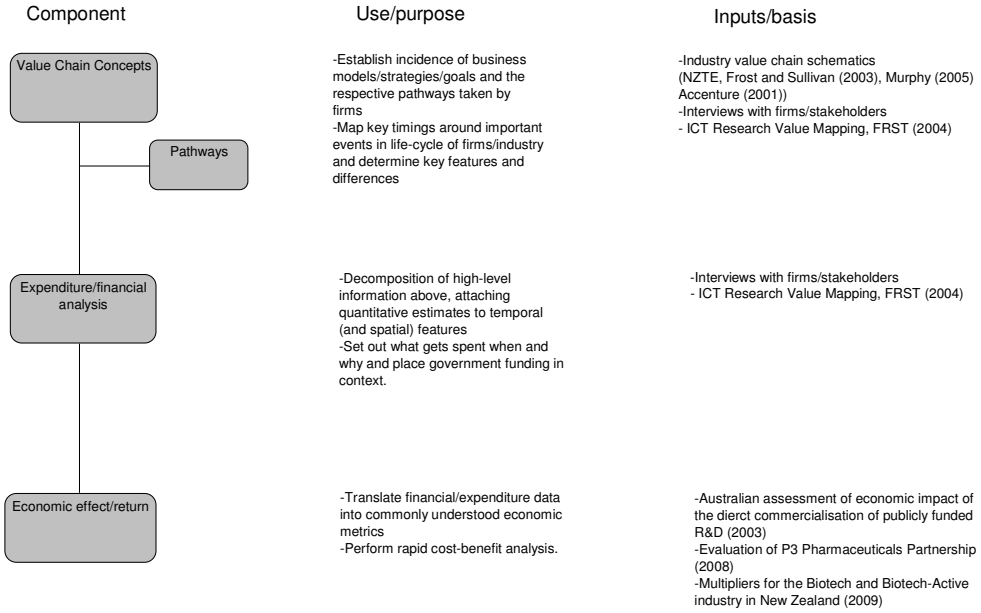
3.2 Framework

The original intention was to use Value Chain Analysis (VCA) to construct the equivalent of a value chain for the human therapeutics sub-sector in New Zealand. Such a concept was thought useful in demonstrating the economic return to New Zealand from the sector. However, further consideration of the practical difficulties associated with VCA and the intention of the study resulted in a change of focus away from VCA and more towards economic impact analysis (EIA).

There is a relatively well-known and frequently utilised framework for EIA. The objective is generally to measure the impacts of expenditure by a particular sector on the wider (often national, but sometimes regional) economy. Impacts are generally measured in terms of employment, output, value-added (i.e. GDP) and household incomes. EIA is usually expressed in terms of direct, indirect and induced impacts, with direct impacts being estimated by use of surveys or other engagement tools, while the indirect and induced effects are obtained through specific models.

The organising framework we put together for use in this project is essentially a hybrid-using elements of VCA and EIA. The hybrid model is necessitated by the lack of an “off the shelf” model or workable algorithm that would adequately capture the types of effect we are interested in.

Figure 1 Organising framework



Value chain concepts and pathways

The VCA component is useful for tracing out the different pathways taken by firms to undertake drug discovery and development activities and ultimately create economic value. This is important in terms of better understanding the role that timing plays and the influence of business models on value points and quantum.

Expenditure analysis

The expenditure/financial analysis component is needed to estimate the direct effects of firms' activities. These effects largely relate to the dollars spent in New Zealand. In measuring this effect we are careful to separate expenditure that is "new" to New Zealand or that would not have otherwise occurred in New Zealand if the firm was not based here (i.e. trade creation), from "domestic" expenditure, which has no real economic effect attributable specifically to the firm/sector (i.e. trade diversion).

By way of example, consider a firm that raises $10 million in series A funding, with $8 million coming from overseas investors and the remaining $2 million from domestic sources. If all of the funding gets spent in New Zealand (i.e. with no import component) then we would count the $8 million only as representing the direct economic effect to New Zealand (the indirect and induced effects would be calculated separately and added to the direct effect to estimate the economic impact). We assume that the $2 million raised from New Zealand sources does not have any real economic impact attributable

solely to the presence of the firm. It is effectively a transfer rather than newly created activity. All else equal, the $2 million already formed part of the New Zealand economy and in the absence of the firm would most likely have been invested elsewhere in New Zealand.[73]

Economic metrics

The final component is the translation of financial information into commonly-used metrics associated with EIA, as well as the addition of indirect and induced effects to the direct effects. Indirect effects arise largely due to inter-industry linkages- when expenditure takes place in one industry/sector; it effectively triggers spending in another industry/sector. Induced effects capture the effects of increased household spending as a result of the employment being provided by the industry/sector in question. It is largely a mechanical exercise, provided the necessary modelling has been completed. For this study, we made use of recently completed work estimating the degree of inter-industry linkages for the biotech and biotech-active industry in New Zealand.

3.3 A note on attribution

An important part of ascribing economic effects to the human therapeutics sector component is attribution. By this we mean establishing the linkage between funding and return. Given firms in the human therapeutics sector obtain funding from both government and non-government sources, we need a method of attributing economic effects specifically to the government sector. In particular, we need to know how and to what extent government funding contributed to the economic effects we estimated. Two examples illustrate the importance of this point. Firm A raises $10 million in funding from overseas sources and intends to spend all of this money in New Zealand. It also applies for and receives grant funding of $1 million. Firm B raises $1 million in funding from overseas sources and intends to spend it all in New Zealand. It too, is successful in receiving grant funding of $1 million.

However, firm A indicates that the government funding, while welcome, is not material in their business decisions or in their ability to raise funds. In other words, government funding had little to no effect on them- they would have done exactly the same in the absence of the grant as they did with it. Meanwhile, firm B indicates that were it not for government funding, they are unlikely to have been able to secure the overseas funding and hence may have ceased trading as a result. In this situation, the economic

[73] This is, of course, an assumption. To the extent that there is strong evidence that New Zealand investors would definitely have invested the $2 million overseas were it not for the firm being in existence, then there may be a case that some economic activity should be counted as a result of avoiding "losing" that $2 million overseas. The analysis undertaken here does not allow us to be definitive.

contribution of the two firms attributable to government funding may actually be very similar despite the sizeable difference in the amount of expenditure.

Leaving aside the direct effect of the $1 million in grant funding, we might attribute, say, 10% (at best) of the expenditure impact of firm A to the grant funding. For firm B however, the attribution is likely to be close to 100%. Thus, despite there being a $9 million difference in the expenditure between the firms, the amount of the expenditure attributable to grant funding is roughly the same (i.e. $1 million) for both firms. While this is an extreme (and perhaps unrealistic) scenario, it does illustrate the role that attribution and judgement plays.

In the absence of detailed information that would allow us to definitively estimate the proportion of expenditure that could be specifically attributed to grant funding, judgement is required. We utilised a broad sliding scale to do this, based on timing, relativity and expressed opinions of importance gained in the interview process. Firms that placed a relatively low importance on grant funding were assigned percentages in the 0%-20% interval. Most firms were assigned values in the 35%-50% interval while a small number of firms were assigned values in the 65%-75% interval.[74] While it would have been especially useful to assign measures of importance to particular time periods in the history of each company, the availability of accurate data that would allow us to do this was not available. Therefore, we assigned a single value for the entire period under study.

3.4 Interviews

Following are the groups and persons that were interviewed.

[74] This method of attribution was loosely based on the method employed in "Australian Assessment of Economic Impact of the Direct Commercialisation of Publicly Funded R&D" a report prepared by Allen Consulting, for the Australian Institute for Commercialisation, September 2003. An alternative method would have been to use the ratio of grant funding to private funding as a means of attribution, but there is some endogeneity inherent in such an approach as the amount of private funding received may be related to grant funding and vice versa.

Groups interviewed		
Organisation	**Name**	**Title**
AFT Pharmaceuticals	Hartley Atkinson	Founder and Managing Director
Auckland Cancer Society	Bill Denny	Director
Otago Innovation Ltd.	Colin Dawson	CEO
Protemix	Garth Cooper	President and Chief Technical Officer
Proacta Therapeutics Ltd	Kate Parker/Nel Molinyawe	Director of Operations, New Zealand/Accountant
Innate Therapeutics	Simon Wilkinson/Peter Bradley	Director and CEO/Chief Business Development Officer
Genesis R&D	Stephen Hall	CEO
Uniservices	Will Charles	General Manager Technology Development
Living Cell Technologies	Paul Tan/John Cowan	CEO/CFO
CoDa Therapeutics	Brad Duft	President and CEO
Pathway Therapeutics	Nicole Fowler	CEO
Symansis	Peter Foster	CEO
Kode Biotechnology	Steve Henry	CEO
Pacific Edge Biotechnology	Dave Darling	CEO
IRL Glycosyn	Richard Furneux	Science Group Manager
New Zealand Pharmaceuticals	Selwyn Yorke	Business Development Manager
Blis Technologies	Barry Richardson	CEO
Douglas Pharmaceuticals	Rod De Spong/Andrew McLeod	Chief Financial Officer/Director, Research and Development
Genavia Therapeutics	Peter Bradley	CEO

3.5 A worked example of the calculation of additionality

The best way to demonstrate the calculation process is by (hypothetical) example. Consider three firms, A, B, and C.

Core details for illustrative examples			
	Firm A	**Firm B**	**Firm C**
Finance raised	$10m	$10m	$10m
New Zealand	0	$10m	$5m
Overseas	$10m	0	$5m
Expenditure in New Zealand	$10m	$10m	$10m
Sales	0	$20m	$20m
Profit	0	$5m	$5m
Life of company	2000-2009	2005-2009	2007-2009
Employment latest year	10	10	20
Employment first year	10	10	10
Employment intervening years	10	10	15

Applying our calculation process to the figures above generates the following summary statistics for each company. Despite being fairly similar in total the calculation process for each of the firms is quite different. For instance, firm A sourced the entire $10m of its expenditure from overseas and thus, all of their expenditure is counted as a new "injection" of resources that the New Zealand economy would not otherwise have had. Applying the sector ratio of output to value-added to this figure gives the GDP/value-added contribution of firm A as $5.2m. This is the total amount of value-added that firm A is responsible for as it does not generate profits.

Firm B on the other hand, spent the same amount in New Zealand as firm A, but raised all of its finance through domestic sources. Our assumption is that these resources already existed in New Zealand and were they not supplied to firm B they would otherwise have been applied in New Zealand and therefore do not generate economic effects as such. Therefore, the impact on economic activity (or output) is zero. It follows that the impact on GDP/value-added from this source is also zero. However, firm B

makes sales and generates profits of $5m from those sales, contributing to value-added correspondingly.

Meanwhile, firm C raises $10m from both overseas and domestic sources. It also spends the entire $10m in New Zealand, but the effect on output in New Zealand is only counted as $5m, due to half of the funds being sourced domestically. Applying the sector ratio of output to value-added to this figure gives the GDP/value-added contribution of firm C as $2.6m. To this must be added the value-added that accrues to New Zealand as a result of firm profits. Assuming that half of the profit figure goes off-shore (in accordance with the respective sources of finance shares) we are left with $2.5m. Adding this to the expenditure driven source of value-added, we are left with a contribution to GDP/value-added of $5.1m for firm C.

In terms of employment totals, these are simply annual counts summed across the length of time that the firm has been in business. Firm A has been in business for 10 years (inclusive) and employed 10 people each year, so is responsible for 100 jobs in its lifetime. Firm B has been operating for five years and employed 10 people each year, so is responsible for 50 jobs. Firm C has been operating for three years, started with 10 people employed, moved to 15 the next year and in its latest year has 20 people employed. It is therefore responsible for 45 jobs in its lifetime.

Firm totals over time (excluding indirect and induced effects)

	Output	GDP	Employment
Firm A	$10m	$5.2m	100
Firm B	0	$5m	50
Firm C	$5m	$5.1m	45

The figures in the table above relate solely to the contribution of the firms themselves. There are flow-on effects to other sectors of the economy as well. These so-called multiplier effects take the form of indirect effects (e.g. purchases from other sectors in the production process) and induced effects (i.e. impacts from household spending as a result of wages and salaries earned from the specific sector and related sectors). This means the total economic effects associated with the human therapeutics sector will exceed just the direct impacts measured above.

Multiplier effects

Work undertaken for NZTE previously has calculated multipliers for employment, output and value-added in relation to the biotech sector. The relevant sector multipliers are 2.03 (output); 1.95 (GDP) and 3.41 (employment) and are interpreted as representing the economy wide effect of a one unit change in the metric of interest, inclusive of the unit change. In the case of employment, this means the total effect on the economy of an

additional unit of employment in the biotech sector is 3.41 units of employment (i.e. the additional unit of employment in the human therapeutics sector and 2.41 units of employment elsewhere).

In the table below, these multiplier effects are applied to the original direct impact numbers to derive total economic effects. If we assume that these three firms represent the entire sector, then the sum across all firms would give sector aggregates for the respective metrics.

Firm totals over time (including indirect and induced effects)			
	Output	**GDP**	**Employment**
Firm A	$20.3m	$10.15m	341
Firm B	0	$9.75m	171
Firm C	$10.15m	$9.95m	153

Appendix Four - International benchmarks

In this section we review what two other countries have done to encourage the human therapeutics sector; Australia and Finland.

4.1 Introduction

If governments or their agencies make a choice to implement a funding program, the program should be designed to achieve the maximum benefit for the funding involved, consistent with the program's objectives.

Governments often aim to encourage a higher level of socially valuable activity than would be undertaken in the absence of public support. However, for discretionary reasons governments also sometimes try to pursue other objectives such developing national or regional innovation systems. These goals are not always complementary, so trade-offs are sometimes required.

The table below outlines some of the principles that are usually taken into account when a funding program is designed.

Design Principles for Business Programs
Target the source of the problem (objectives/rationales)
Inducement (additionality)
Contestability
Consistency
Funding duration
Avoidance of risks (adverse interactions with other programs, unforeseen liabilities for government, strategic behaviour by firms)
Administrative and compliance efficiency
Accountability and transparency
Cost effectiveness
Compliance with international obligations
Evaluation, monitoring and reporting

Source: Productivity Commission 2008 adapted from Lattimore R, Martin B, Madge A. and Mills J 1998, *Design Principles for Small Business Programs and Regulation*, Australian Government Productivity Commission Staff Research Paper, August

The ways in which other jurisdictions have balanced these principles, and the outcomes they have achieved, are relevant to understanding implications for program design in New Zealand.

The following section outlines and analyses some frameworks for supporting human pharmaceutical drug discovery in other jurisdictions similar to New Zealand.

Two jurisdictions are the focus:

- The Australian state of Victoria (and national frameworks, to the extent they support or reinforce Victoria-specific activities).
- Finland.

For each jurisdiction, we:

- Explore the size, structure and nature of the local human therapeutics drug discovery sector and the firms within it.
- Describe the nature, justification and outcomes of any funding and other support that is provided by government agencies to the sector – considering a small number of initiatives in detail.
- Identify any critical perspectives on the strengths and weaknesses of this government support.

From this information, we draw comparisons to the New Zealand sector and experience, and identify whether there are any lessons learned or potentially local applications.

4.2 Victoria (Australia)

Profile of local human therapeutics drug discovery sector
Victoria has similar attributes to New Zealand. It is a small open economy with strong and stable institutional structures, is relatively cost competitive with other advanced economies but not with emerging economies, and has a similar population.

In a broad Australian context relatable to Victoria, the Australian Government's recent Pharmaceuticals Sector Strategy Group considered that:

> *…Excellence in scientific and clinical research while retaining the highest possible safety standards has made Australia a competitive location not only for R&D, but also for clinical trials, particularly in the earlier phases. Australia has a competitive advantage as a location for Phase I and Phase II clinical research…*

The following table outlines the attributes and environment of Victoria's pharmaceutical discovery sector.

SWOT Analysis for Victorian Pharmaceuticals Discovery Sector	
Strengths	**Weaknesses**
R&D Quality medical research Cost competitive compared to North America, Europe and Japan Many biotechnology companies Extensive and unique biological diversity Legal certainty for investment in biodiscovery and strong and effective IP laws *Clinical trials* Quality infrastructure Ethnically diverse population High volunteer rate for Phase I trials Well established track record and high number of ongoing trials for population size Globally recognised clinicians (and translational medicines capabilities) Fast-track approval system for Phase I trials Strong and effective IP laws Southern hemisphere location	*R&D* Limited pool of experienced management that can attract investment and guide commercialisation Some biotechnology companies having difficulty attracting funding Intellectual property capture and storage Infrastructure gaps Lack of critical mass Shortage of locally trained bench research staff *Clinical trials* Small, geographically dispersed population: results in higher numbers of sites and less patients per site compared to emerging markets, can also prolong recruitment period Capacity to supply patients in some therapeutic areas is already stretched due to the number of trials ongoing — improved referral patterns and volunteer rates would increase capacity further Significantly more expense for Phase II and III trials than emerging markets Appear less efficient—multi-centre clinical trials require approvals from each institution—creates time and cost delays
Opportunities	**Threats**
Ageing global population: increasing demand for therapies Increasing wealth and health-consciousness of global population and growing markets in Asia Global pharmaceuticals companies moving to outsource early stage R&D to fill product pipelines: partnering and out-licensing arrangements for biotechnology companies; utilising biodiversity for drug discovery Venture capital funds that are looking globally for investments Growing interest in personalised medicine as a means to improve health outcomes and cost-effectiveness Better and cheaper 'omics' technologies: opportunities for R&D and personalised medicine Development of new therapies, particularly biologics Different distribution and delivery models for new therapies Rising demand for products with a reputation for quality	Small market, with low growth compared to emerging markets Sector consolidation Distance from global headquarters—low visibility to key global investment decision makers Ageing population: governments seeking to reduce the cost of healthcare Rising costs of drug discovery and increasing competition from low-cost clinical trial centres Global rationalisation of pharmaceuticals activities Increasing scientific capability and reputation in lower cost countries such as China and India: competition for investment Global credit crisis affecting investment in biotechnology Workforce inadequate in number and skills, increasing global and regional competition for competent specialised bio/pharmaceuticals staff at all stages of the value chain

Source: Adapted from McNamee B, Pennifold C et al, *Pharmaceuticals Industry Strategy Group Final Report*, pp.23-24, Commonwealth of Australia, December 2008. Developed for Australia generally, the table is relatable to the Victorian context.

Victoria's human therapeutics drug discovery sector is significantly larger than New Zealand's.

At 31 December 2008, 48 Victorian life science companies were listed on the Australian Stock Exchange (ASX), with a combined market capitalisation of around $22.7 billion. This includes CSL, one of world's ten largest biotechnology companies by revenue.[75] A substantial high-quality infrastructure of universities and other medical research centres is clustered in inner Melbourne.

More than any other Australian state, the Victorian Government has been focussed over the last ten years on enabling the human therapeutics drug discovery and other parts of the life sciences and biotechnology industries through infrastructure, direct funding, workforce development and network development. The Victorian sector has also been able to benefit from initiatives at the Commonwealth level.

The Victorian Biotechnology Strategic Development Plan (*Action in partnership: Building our biotechnology future*, Oct 2007), although broader than human therapeutics drug development, provides a framework for the Victorian Government approach to the sector's development.

It builds progressively on two previous Strategic Development Plans, in 2001 and 2004, and previous funding programs and other strategic initiatives:

> *The 2001 Plan put in place the fundamentals needed to build a successful biotechnology sector, including strengthening Victoria's R&D foundations and facilitating industry growth through new start-up companies, R&D partnerships and clinical trials.*
>
> *The 2004 Plan focused on building international alliances and filling gaps in the discovery-to-market pipeline, with the aim of building a critical mass of infrastructure, people and companies in Victoria's areas of excellence.*
>
> *The 2007 Plan reflects changes in the industry over the last three years and adopts an outcome-focused and partnership approach. The Plan focuses on building substantial and sustainable firms, forging closer collaboration between researchers and firms and integrating developments in biotechnology into the broader Victorian economy* [76]

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[75] Victorian Government 2007, *Action in partnership: Building our biotechnology future*, Victorian Biotechnology Strategic Development Plan, p.8

[76] Victorian Government 2007, *Action in partnership: Building our biotechnology future*, Victorian Biotechnology Strategic Development Plan, p.6

Government interventions and support
With Australia's federal system, initiatives to support human therapeutics drug discovery are at both the Australian Government (federal) and State Government level.

Initiatives by the Australian Government have included:

- Direct grant funding through the former Pharmaceuticals Partnerships Program (P3); and
- Publicly sourced capital for venture capital firms through the Innovation Investment Fund.

Initiatives by the Victorian Government have included:

- VicStart, supporting commercialisation resources, capabilities and networks for Victoria's innovative science and technology businesses.

This is just a sample of some main initiatives – there are a range of other programs in multiple portfolios designed for science, innovation and industry development outcomes that are potentially beneficial to the Victorian human therapeutics drug discovery sector.

In addition, the Victorian Government has funded platform technologies such as the Australian Synchrotron, the National Neuroscience Facility and the Monoclonal Antibody Technology Facility, and supporting public and collaborative initiatives such as Monash University's Centre for Drug Candidate Optimisation, RMIT Drug Discovery Technologies, Swinburne University/CSL's Biopharmaceutical Formulation Centre, the not-for-profit clinical research Nucleus Network, and the Neuroscience Trials Australia clinical trials cooperative group.[77]

(Former) Pharmaceuticals Partnerships Program (P3)
The Commonwealth's former Pharmaceuticals Partnerships Program (P3) was a competitive grants program. It provided grants to companies to increase their pharmaceuticals R&D in Australia. P3 had three funding rounds with total funding of approximately $150 million over five years.

The Commonwealth aimed to promote:

- Additional, high-quality pharmaceuticals R&D in Australia throughout the pharmaceuticals value chain, including biotechnology, originator and generic medicine companies
- The development of medicines for global markets.

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[77] Business Victoria 2009, *Biosecurity Bridges Fact Sheet*, <http://www.business.vic.gov.au/BUSVICWR/_assets/main/LIB60215/VIS%20FACT%20SHEET%20-%20BIOTECH.PDF>

- Partnerships and collaborations between multinational firms and local companies.

Companies from all stages of the pharmaceuticals R&D chain, including biotechnology firms, originator and generic medicine companies, were eligible to apply, provided they undertook pharmaceuticals R&D activities for at least three years prior to the round's start date[78] and proposed to increase their level of pharmaceuticals R&D expenditure in Australia for each year of their participation in the Program.

Eligible pharmaceutical R&D activities included basic pharmaceuticals research through to clinical trials needed for drug registration, as well as supporting activities directly related to the conduct of R&D activities. Companies were required to forecast expenditure on projects they proposed to undertake in Australia during the period of their participation in P3, and would be paid in arrears based on actual expenditure (see the table below for details).

Proposals were assessed by a Government-appointed expert advisory panel, the Pharmaceuticals Committee of Innovation Australia, against four criteria:

- The applicant's track record and capabilities.
- The scope and nature of the applicant's partnerships and collaborations.
- The technical merit of the proposed activities.
- The level of benefit to the Australian economy.

The table below outlines the outcomes and design of the grants over the three rounds.

[78] For Rounds 1 and 2, a minimum of three years R&D activity in Australia was required. For Round 3, this was broadened to Australia or overseas.

P3 Funding Rounds				
Round	**Commencing**	**Approved grants**	**Number of companies funded**	**Basis of grants**
Round 1	1 July 2004	$AU87.1 million	11 (from 26 proposals)	Taxable grant of 30 cents in the dollar for R&D expenditure above a base level, calculated as an average of the past three years eligible R&D expenditure, paid in arrears. Allowable expenditure cap for IP protection of $0.1 m. Total grant capped at $10 m per company.
Round 2	1 July 2005	$AU46.8 million	6 (from 13 proposals)	As above
Round 3	1 July 2007, for up to 2 years	$AU28.1 million	5 (from 8 proposals)	Level of taxable grant increased to 50 cents in the dollar. IP protection expenditure cap increased to $0.2 mi. Previous recipients can reapply, with $10 m cap across all 3 rounds. Assessment placed greater emphasis on partnerships and collaborations, and the subsequent benefits to the industry and Australia.

Source: Derived from Deloitte Insight Economics 2008, *Evaluation of the Pharmaceuticals Partnerships Program (P3) – Final Report* for the Australian Government Department of Innovation, Industry, Science and Research, May

As shown below, over the three rounds ten Victorian-based companies were funded (italicised), compared to nine in New South Wales and five in Queensland. A number of successful applicants withdrew from the program, some because they were acquired by larger companies during the course of the funding period.

A wide range of R&D activities were funded, from discovery research through to clinical trials.

Successful applicants from P3 Funding Rounds		
Round 1	**Round 2**	**Round 3**
Acrux DDS (VIC)	Alchemia (QLD) withdrawn	Peptech (NSW) now Arana Therapeutics.
ChemGenex Pharmaceuticals (VIC)	Alphapharm (NSW) withdrawn	Janssen-Cilag (NSW)
Zenyth Therapeutics (VIC) withdrawn	CBio (QLD)	Progen Industries (QLD)
CSL (VIC)	Peplin Limited (QLD)	Tissue Therapies (QLD)
Eli Lilly Australia (NSW) withdrawn	Pfizer Australia (NSW)	*Vital Health Sciences (VIC)*
Janssen-Cilag (NSW) now a Round 3 participant	*Prana Biotechnology (VIC) declined*	*GlaxoSmithKline Australia (VIC)*
Mayne Pharma (VIC) now Hospira	*Starpharma (VIC)*	
Merck Sharp & Dohme Australia (NSW)		
Novogen (NSW)		
Pharmaxis (NSW)		
Servier Laboratories (VIC) withdrawn		

Source: Derived from Deloitte Insight Economics 2008, *Evaluation of the Pharmaceuticals Partnerships Program (P3) – Final Report* for the Australian Government Department of Innovation, Industry, Science and Research, May

The Australian Government has not continued P3 beyond June 2009 and has concentrated on a range of other initiatives to address to support R&D and commercialisation infrastructure generally and in priority areas.

Innovation Investment Fund

The Australian Government's three main general funding programs for supporting R&D and commercialisation across industries are:

- The Pre-Seed Fund (PSF) program introduced in 2001, with $AU104.1 million to support projects or companies created from universities or Australian Government research agencies through four industry-delivered venture capital funds[79].
- The Innovation Investment Fund (IIF) program, a long-standard initiative to promote the commercialisation of Australia's research through the establishment of

[79] One of the four PSF funds, delivered by GBS Venture Partners, specialises in life sciences including human therapeutics. Two others, by Starfish Ventures and SciVentures Investments, have wide scope including human therapeutics investments.

new fund managers (or funds) to provide equity finance to small, early stage companies[80].

- The Commercialising Emerging Technologies (COMET), supporting business planning and management skills development to enhance small new start-up company commercialisation prospects.

This section focuses on the Innovation Investment Fund– the largest of the initiatives – with particular reference on how it supports the human therapeutics drug discovery sector.

The Innovation Investment Fund program provides an Australian Government capital commitment and ten-year licences to chosen private fund managers. IIF venture capital funds invest in early stage companies commercialising Australian R&D. Investment decisions by IIF venture capital funds are made on a commercial basis. By demonstrating the returns achievable from investing in such companies, IIF aims to encourage additional private sector investment.

In Rounds 1 (1998) and 2 (2001), the Australian Government invested $AU221 million in nine fund managers. Private sector fund managers were required to provide at least one third of the funding through privately sourced capital, resulting in $AU354 million available for investment. For Round 3 since 2006, the Australian Government will invest $AU200 million and appoint up to ten new fund managers over five years. Up to $20 million in capital will be provided to each venture capital fund, which must be at least matched with privately sourced capital. Three fund managers have been selected to date.

The following Table outlines the successful funds. A number of these funds are investing in human pharmaceutical drug discovery in Victoria and elsewhere – many of the funds have a specific focus on life sciences. As at the end of 2007, 87 companies have found capital through the IIF scheme, across all sectors.[81]

[80] Australian Government Department of Industry, Innovation Science and Research, <http://www.innovation.gov.au/Section/Innovation/Pages/InnovationInvestmentFund.aspx>

[81] Cutler T 2008 et al, *Venturous Australia: building strength in innovation*, Review of the Innovation System for the Australian Government Department of Industry, Innovation, Science and Research, p.122

Venture Capital Funds under Innovation Investment Fund			
Round	**Fund Manager**	**Capital commitment ($AUm)**	**Preferred Investment**
Round 1, 1998	Allen & Buckeridge Investment Management (NSW)	41.25	Electronics, IT and telecommunications (IT&T), electronic commerce, entertainment services
	AMWIN Management (NSW)	41.25	General (expertise in IT&T, industrial engineering and multi-media)
	CM Management (Qld)	41.25	IT&T, software, biotechnology, life sciences
	Momentum Funds Management (VIC)	31.00	General
	GBS Venture Partners (VIC)	42.50	Life sciences
Round 2, 2001	Start-Up Australia (NSW)	39.21	Life sciences
	Four Hats Capital (NSW)	50.00	General (focus on manufacturing, IT&T, medical devices and born global companies)
	Neo Technology Ventures (NSW)	31.70	IT&T and media
	Stone Ridge Ventures (WA)	35.69	General
Round 3, Tranche 1, 2007	Cleantech Australian Management Fund (Vic)	50.00	Clean technologies
	Brandon Capital Management (NSW)	40.00	Life sciences
Round 3, Tranche 2, 2008	Andover Venture Partners, Yuuwa Capital, IB Australian Bioscience Fund		

Examples of human pharmaceutical investments include:

- GBS Venture Partners (Vic)[82], which through its $42.5 million Australian Bioscience Trust and other funds invests at the seed, start-up or early expansion

[82] GBS Venture Partners, <http://www.gbsventures.com.au/>

stage (including a range of firms focussed on human therapeutics and a number of New Zealand drug discovery companies), for example:

  - Antipodean, a New Zealand-based early-stage clinic ready pharmaceutical company developing treatments for neurodegenerative diseases such as Parkinson's Disease and Friedreich's Ataxia that are associated with mitochondrial dysfunction;
  - Proacta, an oncology drug development company focusing on novel therapies for hypoxic (oxygen-starved) solid tumours, headquartered in San Diego with operations in Auckland and Melbourne;
  - CoDa Inc, a San Diego based developer of anti-sense therapies to aid wound healing based upon technology from the University of Auckland;
  - Pathway Therapeutics

- Brandon Capital Partners (NSW)[83], which through its $40 million Brandon Biosciences Fund 1 has invested in, for example:
  - Melbourne based Fibrotech Therapeutics, which is developing compounds for the treatment of fibrosis associated with diabetic nephropathy
  - Melbourne based Spinifex Pharmaceuticals Pty Ltd, which undertakes drug development activities leading to the commercialisation of potential new drug candidates for the treatment and management of pain.
- Start-up Australia (NSW)84, a specialist venture capital company with a $39.2 million IIF fund to invest in innovative life science companies with high growth prospects and a human therapeutics portfolio including:
  - Alchemia, developing new and efficient process for the preparation of synthetic heparin, a generic version of GSK's drug Arixtra® (fondaparinux);
  - Arana Therapueutics Limited (formerly Peptech), developing next generation biopharmaceutical products for improving the lives of patients with inflammatory diseases and cancer.

VicStart

The Victorian Government's VicStart technology commercialisation initiative facilitates the development of new export-oriented technology businesses, products and services. VicStart is delivered by 13 partner organisations that specialise in technology commercialisation, including Melbourne Ventures, Pyksis and Starfish Ventures. The

[83] Brandon Capital Partners, <http://www.brandoncapital.com.au/portfolio.htm>

[84] Start-Up Australia <http://www.start-up.com.au/index.htm>

key aspect of the program is specialised advice and contacts to help technology companies link with existing opportunities.

Since 2004, VicStart partners have facilitated access to over $127 million in grants and private investment and 250 new partnering and business relationships for Victorian companies. A number of biotechnology firms have been supported by VicStart, including the University of Melbourne's start-up biotechnology company Velacor Therapeutics, Fibrotech Therapeutics, Neuprotect, Radical Biotechnology, and Benitec (which is currently developing novel HIV gene therapy).[85]

4.3 Finland

Profile of local human therapeutics drug discovery sector
Finland is a small open economy that is relatively remote and with a similar population (5.3 million) to New Zealand. The Finnish economy generates substantial exports from resources (forestry and forest-related industries in particular), complemented by a high technology manufacturing sector including communications company Nokia.

The Finnish pharmaceutical sector is modest in size, employing around 6,185 people with production valued at €869 million ($1.76 billion). Industry association Pharma Industry Finland currently has nearly sixty members. Orion Pharma is Finland's largest pharmaceutical company, with market share of approximately 8.8 per cent.[86]

The following table outlines the attributes and environment of Finland's pharmaceutical discovery sector.

[85] Government of Victoria 2009, *Victorian Biotechnology Strategic Development Plan Year 1 Progress Report*, May

[86] Espicom Business Intelligence, <https://www.espicom.com/Prodcat.nsf/Search/00000340?OpenDocumentm>, accessed 30 Sept 2009

SWOT Analysis for Finland Pharmaceuticals Discovery Sector	
Strengths	**Weaknesses**
Excellent science base with international networks Opportunistic approach. E.g. no core scientific areas to discover drugs have been defined Universities have established scientific training and offer degrees that are specifically suitable for pharma industry Science parks, premises, and infrastructure exists Established track record to discover, develop, and commercialize drugs (also internationally) Patients are willing to participate clinical trials Collaboration and networking with the universities and within industry Organized & high level health care in Finland TEKES funding for biotech and pharma industry (but still a considerable basic turnover is needed)	Small domestic pharmaceutical market unable to support innovative Finnish pharma industry Many small providers of domestic specialized services are dependent on companies located in Finland Clinical work & clinical research have been diverted from each other in university hospitals Too limited strategic & operative outsourcing Limited international and commercial networking of Finnish pharmaceutical industry Shortage and underutilization of existing managerial talent Exit opportunities are practically nonexistent in Finland Finnish society does not support entrepreneurship and risk taking Lack of uniform view on the direction among the decision makers
Opportunities	**Threats**
Orphan and niche markets exist that can support small to medium sized Finnish pharma industry Pharmacogenomics, gene therapy, nanotechnology, stem cells, individualized therapeutic options may produce quantum leap changes in the industry The number of drug candidates in development is all time high Collaboration between academia and industry is reorganized to produce commercial results and sufficient incentives for both parties Opportunities for synergies through domestic cooperation between established pharma and start-ups Low cost of excellent infrastructure and highly trained professionals may attract international pharma companies	Domestic pharma market & industry is seriously affected by global mega trends of pharma industry (continued M&As and concentration, global clinical trials will decrease Clinical drug development is moved to eastern Europe (Poland Czech, Russia) and to Asia (China, India, Malaysia) and South America, where cost level remains still low compared to Western world Clinical development atmosphere is interpreted hostile and costly Europe as a whole continues to lose ground to USA Exit opportunities do not develop favourably in the whole Europe

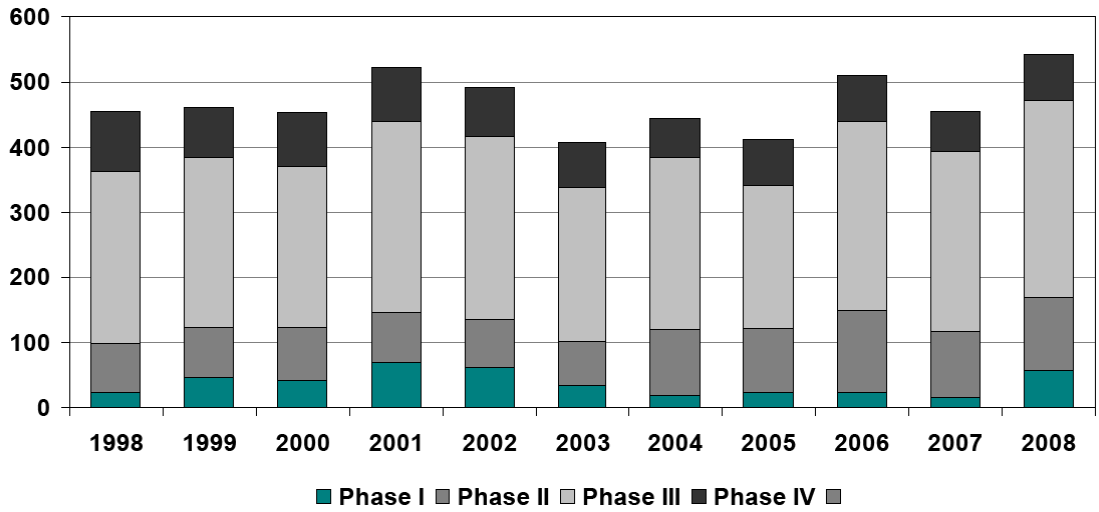
Source: Adapted from Brnnback M, Jalkanen M, Kurkela K, Soppi E 2005, *Pharma Development in Finland Today and 2015*, Technology Review 179/2005, TEKES

The Finland pharmaceutical industry spent approximately €239 million ($485 million) on pharmaceutical R&D in 2007, equivalent to 27.5 per cent of production by value. This quantum is slightly higher than Ireland (€200 million), about half the Netherlands (€505 million) and a tiny share of Germany (€4,662 million).[87]

A 2004 OECD report suggested there were about 12 companies developing drugs in Finland including three large pharmaceutical companies. [88] A different 2004 survey pointed to the high proportion of small-to-medium bio-pharmaceutical companies in Finland, and that three quarters of these have patents or patents pending (compared to 6 per cent of SMEs generally).[89]

Finland appears to have a relatively strong capacity at later stage pharmaceutical R&D. For example, the number of pharmaceutical clinical trials in Finland has stayed strong and relatively stable over recent years, between around 400 and 550, with most Phase III trials. There has been recent growth in vaccine trials in Finland.

Figure 2: Number of ongoing pharmaceutical clinical trials in Finland, 1998-2008



Source: Pharma Industry Finland, 2009

[87] *The Pharmaceutical Industry in Figures* – Key Data 2009 Update, European Federation of Pharmaceutical Industries and Associations

[88] von Blankenfeld-Enkvist G, Brannback M, Soderlund R, Petrov M 2004, *OECD Case Study on Innovation: The Finnish Biotechnology Innovation System*, Turku School of Economic and Business Administration Research and Development Centre, January

[89] Hermans R 2004, "Finance of Small Bio-Pharmaceutical Industry in Finland – Descriptive Analysis", Research Institute of the Finnish Economy, <http://www.etla.fi/files/710_dp888.pdf>

Government interventions and support

The Finnish Government has a general commitment to supporting pharmaceutical research and development through its *Pharmaceutical Policy 2010* policy which states that:

> *The development of new medicinal products and pharmacotherapies is promoted by supporting pharmaceutical research in various ways, e.g. by funding research and securing education and training, and the operational prerequisites for pharmaceutical industry.*[90]

Government interventions and support for the human therapeutics drug discovery sector come from a range of agencies, aim to address different changes in the innovation process. These include:

- The Academy of Finland, the prime funding agency for early stage scientific research with a focus on universities and other research institutions
- Tekes, the Finnish Funding Agency for Technology and Innovation, which finances research, development and innovation including in the private sector
- Sitra, the Finnish Innovation Fund, is an independent public foundation that amongst other activities supports venture capital funds and other investment mechanisms

The relevant activities of these last two agencies are detailed below.

TEKES

The main source of funding for applied R&D in Finland is Tekes, the Finnish government funding agency for technology and innovation. Through grants, loans and risk capital, each year Tekes finances around 1,500 R&D projects for Finnish-based and registered companies and almost 600 public sector research projects at educational institutions and research institutes, across all sectors. Research, development and innovation funding is targeted to projects that create in the long-term the greatest benefits for the economy and society.[91]

The current TEKES program for specifically supporting pharmaceutical R&D and innovation is the *Pharma – Building Competitive Edge* program, one of our thirty sector-specific TEKES programs. *Pharma* aims to promote the international competitiveness of the Finnish pharmaceutical industry through direct funding and expert services for the pharmaceutical industry, service companies and research organisations.

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[90] Finland Ministry of Social Affairs and Health 2003, *Pharmaceutical Policy 2010*, p.7

[91] Tekes 2009. "About Tekes", <http://www.tekes.fi/en/community/About%20Tekes/339/About%20Tekes/1279>

It spans the four years from 2008 to 2011, with a total budget of €58 million, averaging €14.5 million a year (or $118 million, averaging $29.5 million a year).[92]

The main focus areas for Pharma are:

- Models and tools accelerating and supporting the product development process.
- Chemical production technology and innovative medical formulations.
- Developing a national operational model for clinical research (centres of excellence).
- A network of business activities through all the areas.

A key focus of the programme is intensifying networking with the industry, including between pharmaceutical R&D, diagnostics, and clinical research. In addition to funding, the programme also provides expert advice to support business competence in (small) pharmaceutical companies.[93] Drug development paths themselves are explicitly out of scope. Examples of possible activities are given in the table below.

[92] However, only half of this (€29 million) is funded by government – the other half is contributed by participating companies/entities through project co-funding. In essence, it is a €29 million government programme.

[93] Tekes 2009, "Pharma – Building Competitive Edge", <http://akseli.tekes.fi/opencms/opencms/OhjelmaPortaali/ohjelmat/Laaketeollisuus/en/etusivu.html>

Tekes *Pharma - Building Competitive Edge* program themes	
Theme	**Examples of possible activities**
Predictive models and methods accelerating and supporting the drug development process	Patient samples and registry data to support research Identifying and exploiting biomarkers Understanding pathogenetic mechanisms as well as pharmacokinetics and mechanisms of action
Chemical production technology and innovation medical formulations	Solutions for synthesis and development of cost effective synthetic pathways New production technologies for promising drug candidates and generic medicines Innovation drug formulations for children, the elderly and for veterinary use Drug delivery technologies
Development of a national operational model for clinical drug research	Reformation and harmonisation of clinical processes and operations Development of therapy-specific clusters
Networked business models	Developing business skills Productisation of innovations and access of new products to the market

Private companies can apply to the program at any time. As at September 2009, the program has funded 18 private sector R&D projects for 15 companies. Examples include:

- Funding to Santen Oy to increase the efficacy and safety of new drugs in the treatment of glaucoma, with the results of the study guiding the finalisation of clinical study protocol for conducting pharmacokinetic study in healthy volunteers.
- Funding to Hormos Medical Oy for new productive and predictive technologies to bring a new SERM from research to successful clinical development, developing the drug discovery platform so that the results translate efficiently to clinical results.

The program has phased calls for proposals for research organisations, typically once or twice a year. As at September 2009, the program has funded 15 public research projects since 2008, mainly to universities, with government funding of €5.94 million ($12 million). Examples include:

- €311 007 funding for the University of Kuopio Department of Pharmaceutical Chemistry to develop of disease models with altered steroid metabolism, evaluate drug effects on steroid levels, and combine mass spectrometric data with metabolomic data analysis methods, to predict clinical responses of new drugs on steroid metabolism and body functions.

- €393 000 funding for the University of Turku, Turku Center for Disease Modeling, to develop in vivo prostate cancer models that mimic the human PCa development better than the existing models for drug development, enabling the evaluation of drug efficacy in earlier phase of drug development than the conventional models and methods.

In addition, TEKES is establishing a network of Strategic Centres for Science, Technology and Innovation. The Strategic Centres are aimed offering leading research institutes and businesses a new way of engaging in close, long-term cooperation. The focus is strategic planning for a 5-10 year timeframe, aimed at solving the challenges of practical application. A Health and Well-being Strategic Centre, the sixth, was launched in April 2009. This may provide future opportunities for the human therapeutics drug discovery sector.[94]

SITRA – venture capital funding

Sitra, the Finnish Innovation Fund, is an independent public fund which under ownership of the State of Finland. Amongst other activities supporting new technology to generate wellbeing, Sitra is a major source of venture capital funding to the human therapeutics companies undertaking drug discovery activities. Sitra's operations are funded with endowment capital and returns from capital investments.[95]

One of Sitra's four current programmes, consistent of various projects and measures, is Health Care. In making venture capital investments to create and develop competitive and profitable businesses, Sitra seeks to make the health care sector more effective and to create better services.[96]

Examples of Sitra's current direct venture capital investment in Finland-based pharmaceutical companies include:

- €15.5 million in Biotie Therapies Oyj, a drug development biotechnology company with a focus on dependence disorders, inflammatory diseases and thrombosis.
- €5.1 million in Ipsat Therapies Oy, a company developing and licensing beta lactamase, a drug used that alleviates the side effects of antibiotics.

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[94] Tekes 2009, "Strategic Centres boost innovation", <http://www.tekes.fi/en/community/Strategic%20Centres%20for%20Science_%20Technology%20and%20Innovation/360/Strategic%20Centres%20for%20Science_%20Technology%20and%20Innovation/1296>

[95] Sitra 2009, "This is Sitra", http://www.sitra.fi/en/About+Sitra/sitra.htm

[96] Sitra 2009, "Health Care Programme methods", <http://www.sitra.fi/en/Programmes/health_care/implementation/implementation.htm>

- €4.1 million in Juvantia Pharma Oy Ltd, a drug discovery company specialising in neurological and cardiovascular disorders including the motor disorder related to Parkinson's disease.97

Sitra has also invested in international venture capital funds concentrated in early-stage technology enterprises in Europe and the USA, and in fifteen Finnish venture-capital funds. This includes, for example, the Finnish venture capital funds Bio Fund Ventures I Ky, Bio Fund Ventures I Jatkosijoitusrahasto Ky, Bio Fund Ventures II Ky, Bio Fund Ventures II Jatkosijoitusrahasto Ky and Bio Fund Ventures III Ky, managed by Bio Fund Management Oy, which has invested directly in Finnish pharmaceutical companies undertaking human therapeutics drug discovery activities.

4.4 Critical perspectives on government support

A number of international evaluations have considered the effectiveness of the various government initiatives to support pharmaceutical and other R&D in Victoria, Finland and similar jurisdictions.

In general, these evaluations have found that government programs can support industry development. For example, a literature review of Tekes program evaluations in Finland indicated some positive impacts from R&D funding on outputs and financial performance of funded companies – that Tekes' clients have experienced more rapid growth than companies in general; that Tekes funding is positively associated with patent activity; and that nearly two in three companies perceived Tekes funding to have helped increase net sales. The literature review also canvassed findings that public R&D funding in Finland shows a strong additionality to companies' own R&D investment.[98]

Government support can be designed to be focused on activities with greater spillover benefits or discretionary innovation system outcomes, although there can be trade-offs between different efficiency and effectiveness in program design.[99]

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[97] SITRA 2009, "Sitra's venture-capital investments", <http://www.sitra.fi/en/Corporate+funding/vemtures/investments.htm>

[98] Tekes presentation "Results and impact of R&D investment", February 2009. However, there has been criticism of evaluation activities and their weak influence on ongoing program design – see for example Oksanen T, Vuorela T, Sarpakunnas J 2008, *R&D evaluation activities*, performance audit 157/2008, National Audit Office of Finland

[99] For example, competitive grant programs may allow governments greater ability to select projects with particular preferred attributes than market-based schemes such as tax concessions, but they can often by more costly to implement.

The value of these programs as an appropriate use of public monies, both of themselves and relative to generalised support across industry sectors, is a different issue.

For example, in assessing the effectiveness of Australia's P3 program, Deloitte found the program made a positive contribution in relation to its objectives, although in some cases only modestly. It found that the program:

- Tended to fund projects at an earlier stage of development in the pharmaceuticals value chain than the industry average.
- Resulted in increased pharmaceuticals R&D in Australia (including by multinational corporations with existing Australian R&D operations) and potentially induced additional investment into recipient firms.
- Had a low to moderate impact on new collaborations and partnerships, although some partnerships with universities and medical research institutes were further developed.
- Had a modest impact on developing medicines for global markets, although did assist participants to gain new IP (acknowledging this objective may take some time to realise).

Deloitte also undertook an economic cost-benefit assessment of P3. It found that the public cost-benefit of the program is likely very close to neutral[100], with the balance of probability towards a small negative impact. However, Deloitte acknowledge that this is only a partial analysis of benefits and costs over a limited time horizon, and does not include spillover and other non-market benefits that the R&D activities might create and other public benefits over the long-term.[101] Alongside this public net benefit, the program generated a private net benefit for pharmaceutical R&D firms exceeding $100 million.

4.5 What can we learn?

There are a number of points that emerge from looking at Australia and Finland. First, these countries tend to exhibit the same strengths and weaknesses that New Zealand does – for instance, an inability to build a pharmaceutical industry from an internal market, but particular strengths in early discovery.

[100] Mid-point impact estimates ranged from -$AU23.8 million to +$AU9.8 million.

[101] Deloitte Insight Economics 2008, *Evaluation of the Pharmaceuticals Partnerships Program* – Final Report for the Australian Government Department of Innovation, Industry, Science and Research, May

There is nothing that stands out that these countries are doing that we are not. Australia and Finland appear to approach their industry development in broadly the same way, with broadly the same interventions that New Zealand has adopted, with a close focus on drug discovery and early stage drug development.

Industry growth beyond the incremental growth that we are seeing in Australia, Finland and in New Zealand is, in our view, likely to be serendipitous.