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APPENDICES

Appendix1 – Driving Forces Analysis

1.1 Political Driving forces

- Political stability
- Visibility of biotechnology as source of economic growth
- Australia's investment in integrated drug development pipeline concept
- Perception of capability gaps
- Lack of a strategic and integrated inter-governmental approach
- Government averse to direct incentive packages for companies
- NZ alliance with state governments for biotech development

Driving Forces	Critical Success Factors Created
Political stability	• Australia is recognised as a stable first world country. • Various state governments have been visible supporters of strategic biotechnology industry development.
Biotechnology as source of economic growth	• Receptiveness to support the sector.
Australian investment in integrated drug development pipeline	• Scale-up facility marketability is enhanced by quality of upstream and downstream resource.
Perception of capability gaps	• To optimise benefits of other initiatives need all steps in chain to be covered. • Receptiveness to support well-structured proposal • Need to quantify local market opportunity and flow-on effects.
Lack of integrated inter- governmental approach	• Need to align efforts between Federal and the various State governments.
Government averse to direct incentive packages	• Big pharma doesn't regard Australia as a location for major investment due to lack of tax breaks and other incentives
Australia NZ Biotech Alliance	• Opportunity to gain critical mass by leveraging NZ capability into equation.

1.2 Economic Driving Forces

- Currency stability and economic management credentials
- Costs of drug development
- High failure rate in pipeline
- Impact of long times for clinical development
- Competitors in CMO space
- Limited competition in Asia-Pacific
- Opportunities arising from existing CMO capability

Driving Forces	Critical Success Factors Created
Currency stability and economic management credentials	• Australia is recognised as a first world economy with advanced capital markets and business acumen.
Costs of drug development	• Outsourcing to CMOs offset risk and time to market.
High failure rate in pipeline	• Desire to access more drug candidates.
Impact of long times for clinical development	• Bottlenecks in in-house capability of major pharma companies.
CMO competitors	• Capital cost is a barrier to entry in favour of established large CMOs. • Large CMO services are very expensive; creates opportunity. • Production-oriented CMO's may not deliver full range of drug development services. • Must have a clear strategy leveraging local strengths. • Must identify market niche as the target customer base. • First to market in Australia will create barrier to entry for others.
Existing CMO capability in Australia	• Timelines reduced if infrastructure exists already. • Fragmentation may create impediments to effective management. • Capability may have key gaps.

1.3 Social and Cultural Driving Forces

- Aging population
- Increasing cost of health services
- Disease control opportunities in underdeveloped markets
  - Lack of IP protection
  - Profit margins lower
- Internet and ease of communications
- Liability and litigation
- Regulatory processes
- Medicines derived from GMO processes are acceptable

Driving Forces	Critical Success Factors Created
Aging population	• More opportunity for new drug targets. • Size of market increasing rapidly for degenerative diseases.
Increasing cost of health services	• Cost burden limits government support and customer access.
Disease control in (less profitable) underdeveloped markets	• Creates niche outside global pharma interest.
Ease of communications	• Diminishes tradition of country-based parochialism in favour of best overall package to meet market need. • Asia-Pacific time zone difference remains an issue for US and European clientele.
Liability and litigation	• Reinforces interest in diversity of new products to offset risk of failure in the market. • Heightens focus of CMO client on quality processes and technical sophistication.
Regulatory	• Compliance costs rising continuously. • Compliance process slows drug development pipeline at every step. • Highest standard GMPs an absolute requirement for a CMO. • Trend to global harmonisation.
GMO derived products accepted by the consumer	• Unlike foods, GMO issue does not impede development.

1.4 Technological Driving Forces

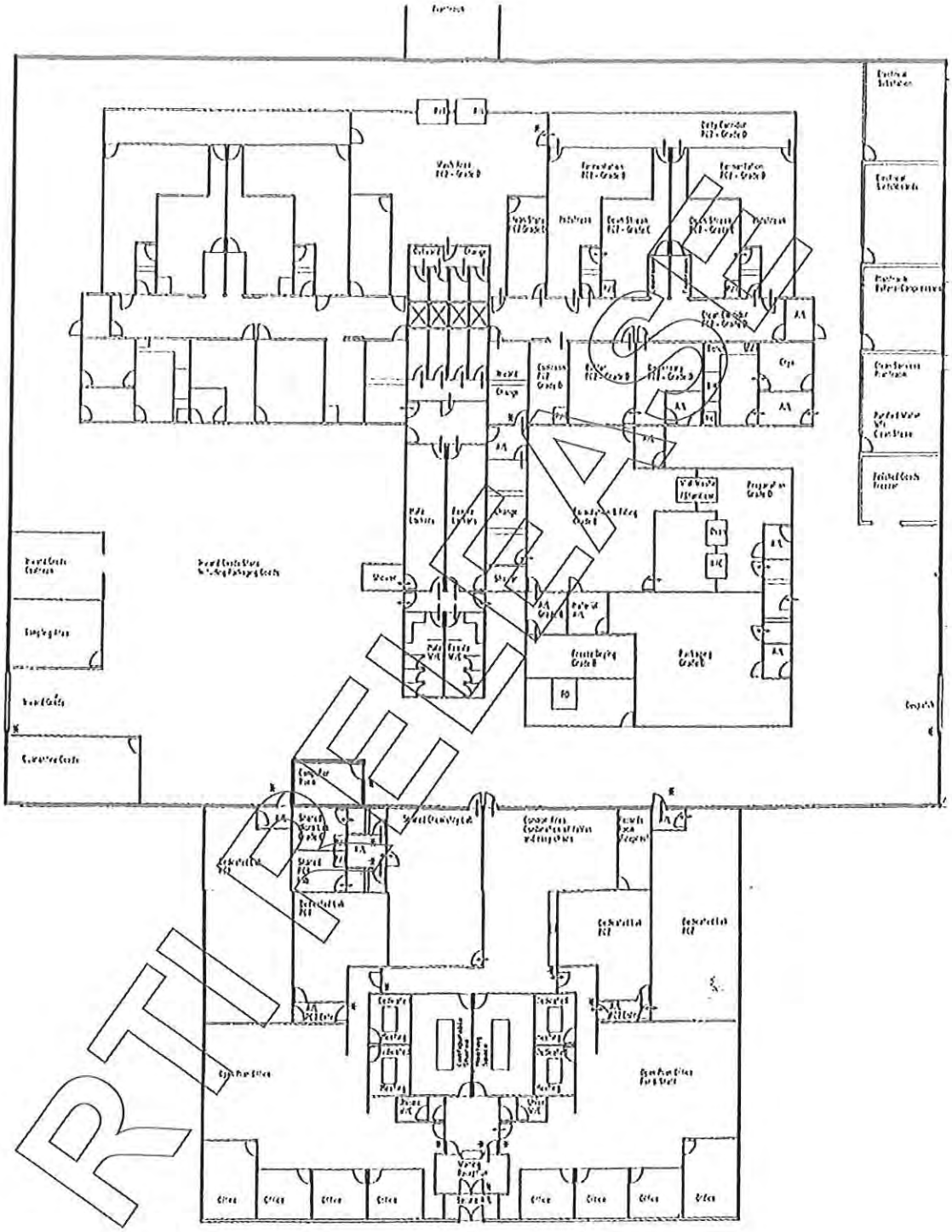
- GMO route to new products
- Challenges posed by viruses and prions
- Chronic metabolic diseases hard to solve
- Accelerated screening technologies
    - Genomics/Proteomics
    - New technologies and automated methods
    - Molecular screening *in silico* (computer modeling)
- World class research and development resources concentrated in Queensland and Victoria in particular

Driving Forces	Critical Success Factors Created
GMO route to new products	• Provides new and faster routes to identification of new drug leads
Removal of viruses and prions	• Increases focus on CMO to provide watertight GMP and technical consistency at cutting edge.
Chronic metabolic diseases hard to solve	• Multiple routes to treatment create opportunities for more discovery companies and potential CMO clients. • Development costs escalate.
Accelerated screening technologies	• Opportunity for CMO to offer linkages into cutting edge R&D providers.
Development of local R&D strength; people and institutions world class.	• Leverage intellectual capital and technical resource.

1.5 Global Driving Forces

- Corporate growth by acquisition
- Big pharma focus on marketing and distribution
- Emphasis on partnering
- Outsourcing of production by big pharma and discovery start-ups
- Matching demand and supply for production capacity
- Biotherapeutics are a growth industry

Driving Forces	Critical Success Factors Created
Corporate growth by acquisition	• Drug market access becoming restricted to fewer and fewer bigger players
Big pharma focus on marketing and distribution	• Receptiveness to partnering for new CMO facilities and CRO providers for drug lead discovery and process development
Emphasis on partnering at all stages in the drug development pipeline	• Opportunities created for long term commercial deals • Highlights dependency on third party capabilities
Outsourcing of production	• Emphasizes need for best in class quality processes • Creates advantage for CMO where leverage points exist
Capacity demand/supply equation	• Long lead times for drug candidates creates CMO demand timing uncertainty • Failures in clinical trials and on-market create demand uncertainty • Regulatory processes delay construction of new capacity and create unpredictability regarding availability of suitable facilities • Big pharma may take key CMO products in-house
Biotherapeutics are a growth industry	• Environment generally conducive to further investment



Appendix 2 - Plan - Proposed Scale-up Facility

Site and Building Layout

Overview

In order to accommodate the building footprints required including services plant and waste handling, and to provide staff and delivery vehicle access and circulation, together with car parking, a site of approximately 100 metres width and 100 metres depth (10,000m2) would be ideal.

In determining the building type to best accommodate this type of facility it is important to consider the plan for multiple stages of construction whilst maintaining good GMP and providing adequate builder access and separation. A typical light industrial office/warehouse type construction would provide the most economical approach with separation of the GMP areas from the office and laboratories. Each area can then be developed using the most economical building methods appropriate to the usage.

The office and laboratory area plan provides for a 2-stage "mirror-image" development which will enable the support area to expand proportionately to the manufacturing capability. Importantly, the plan allows the facility to be expanded without interruption to ongoing operations.

The GMP area and associated support functions would be accommodated within a typical medium rise warehouse structure consisting of concrete slab on ground, portal frame structure, metal deck roof and tilt slab walls. The GMP area would then be fitted out using steel framing, steel stud and plaster board partitioning and trafficable sandwich panel ceiling. HVAC and clean services to the GMP modules would be located above the ceilings on steel support structures whilst central plant items would be located in fire isolated plant rooms to one side of the facility in a manner that accommodates the expansion and staging requirements set out above.

The warehouse section housing the GMP manufacturing and associated support areas has a building footprint of approximately 70 metres wide by 45 metres deep (3150m2). The structure would have a mezzanine level to accommodate the HVAC plant above the GMP rooms

The GMP manufacturing facility plan is based on a shared central core of personnel amenities and change facilities, flanked by mirror- image production modules to either side in dedicated 'wings'. The two GMP modules in each wing are set out between clean and dirty corridors to facilitate unidirectional movement of staff and materials and also to allow staged construction and external viewing.

The GMP modules would each comprise separate fermentation/midstream lab and downstream purification lab. In the development of the first wing, one GMP lab would be dedicated to bacterial-derived products, the other to mammalian cell. Each of the wings would be also provided with cool room, buffer preparation, raw materials weigh station, and cell propagation laboratory to support the GMP production labs.

The plan would call for the first stage to include some areas which would be shared once the second wing had been completed. These common areas would be for:

- wash and waste handling;
- formulation, filling, freeze drying;
- packaging facilities;
- inward and outbound goods;
- raw materials storage and handling;
- electrical switchrooms;
- services room providing steam, air ;
- pure water and pure steam generation;
- finished goods storage.

The capital cost and description above assumes 4 GMP modules or trains, all dedicated to biologicals. A variant option to this would be to dedicate a module to small molecule drug production. This would affect the cost estimates for equipment, but the costing for buildings and infrastructure would be largely unaffected

The sterile fill and packaging functionality in the scale-up facility could be available to customers with API's, bulk intermediates or clean non-therapeutics made elsewhere.

Floorplan Detail

The bottom section of the plan above (forming the vertical section of the squat T-configuration) illustrates the front office / laboratory building comprising approximately 40 metres width and 25 metres depth (1000m2). This area includes 4 development labs as well as a QC lab, a Micro Lab and a PC 3 Lab. Office facilities for 20 staff are incorporated together with meeting and amenities areas suitable for 20 staff.

The office/laboratory plan has been drawn with a two phase development in mind. Depending on the availability of funding, and the number of locked-in supply contracts to justify facility development, the right hand side only need be fitted out initially, leaving the left hand wing for expansion at a later time.

The first wing would comprise office facilities for about 10 people, with two dedicated development labs, as well as the QC lab, micro lab and PC3 lab. The "mirror image" design concept provides for the expansion to be conducted without compromising activities in the right wing.

The top section of the floor-plan above (forming the horizontal section of the T design), comprises an attached warehouse of approximately 70 metres width and 45 metres depth (3150m2) incorporating within it the fit out of approximately 1700m2 of GMP manufacturing space in 4 modules, formulation, filling, freeze –drying, spray-drying and packaging areas, as wells as support functions.

The back end of the facility is also configured to allow for phased construction. The right wing (1st phase) would comprise 2 GMP suites as well as the fill and finish area and all support services sized for the fully developed facility. There are generous storage areas for inbound raw materials warehousing which could potentially comprise expansion area for more GMP production space.

Clean Rooms & Containment

The cleanliness and containment requirements have been determined in accordance with the Australian Code of GMP Annex 1 and the OGTR Guidelines and are as follows :

- Cell expansion area Grade D – Contained, PC2, with Biological Safety Cabinet protection where cell lines/banks are opened.
- Cell bank unclassified/Grade D – Contained, PC2
- Dispensing area Grade D
- Buffer & Media preparation Grade D
- Clean Goods Store Grade D
- Wash Area Grade D – Contained, PC2
- Fermentation and mid-stream processing Grade D – Contained, PC2
- Downstream processing Grade C – Contained, PC2, with laminar flow protection where product is open.
- Formulation, filling and freeze-drying Grade B, with Grade A laminar flow where product is exposed.
- Packaging Grade D

Contained clean rooms are to be run at relative negative pressure to their immediate surroundings, but must still meet the cleanliness criteria for the nominated class. PC 2 requires a net inward airflow to the area.

Factors Affecting Location

Physical resources

- Ease of road access for inbound and outbound deliveries. Preferably there should be unidirectional traffic flow in both cases to separate clean and dirty materials.
- Ease of road access and parking for service providers such as maintenance contractors.
- Availability of parking for staff and visitors.

- Availability of any existing infrastructure which can reduce capital costs and/or reduce timeframes.
  - Land and buildings
  - Mains water
  - Electricity
  - Sewerage
  - Plant services such as steam, chilled water, PFW etc

  However, it is worth noting that refits to existing buildings can involve considerable time and expense:
  - Demolition
  - Design constraints arising from the existing structures inevitably add to design and installation costs.

Human and Technical Resources

- Ready access to graduates and skilled labour
- Proximity to biomedical and biotech clusters and centres of academic excellence
  - Availability of suitable R&D linkages
  - Skilled support services such as instrumentation, software, aseptic design engineering etc
  - Specialist suppliers of consumables
- Availability of pharmacokinetic drug-development lab expertise
- GMP training and auditing to international standards
- Ready access to regulatory affairs advisers
- Proximity to clinical trials facilities for in man studies.

Financial/other facilitation

- Tax breaks
- Utilities discounts
- Subsidised land and infrastructure
- Streamlined approvals
- Single point of contact for red tape reduction

Appendix 3
Equipment List Proposed Scale-up Facility

CAPITAL ITEMS LIST

Description	Qty		Supply Cost	Installation Cost	Total Cost
OFFICE/LAB INFRASTRUCTURE					
Chilled water	1				20,000
Switchboards	1				40,000
SubMains	1				31,500
Heating water	1				17,500
FIP	1				25,000
PABX	1				30,000
					164,000
DEDICATED LAB 1 (CELL CULTURE)					
- Biological Safety Cabinet Class II	1	Off	14,000	520	14,520
- CO2 Incubator	2	Off	10,000	520	21,040
- Roller bottle Apparatus	1	Off	9,200	520	9,720
- Shaking Incubator	1	Off	35,000	260	35,260
- Inverted Microscope	1	Off	10,283	130	10,413
- Bench Scale Fermenters	6	Off	27,833	1,040	173,240
- Fridge	1	Off	3,000	260	3,260
- Freezer	1	Off	19,775	260	20,035

Sub-Total					**287,488**

DEDICATED LAB 2 (PURIFICATION)

(incl. Formulation & Freeze Dryer Cycle Development)

- Chromatography System	1	Off	110,000	1,040	111,040
- Concentration/Diafiltration Systems	1	Off	38,028	1,040	39,068
- Filtration Systems	1	Off	38,028	1,040	39,068
- Analytical HPLC	1	Off	60,000	260	60,260
- Freeze Dryer	1	Off	22,550	1,040	23,590
- Laminar flow hood	1	Off	9,000	520	9,520
- UV/Vis spectrophotometer	1	Off	14,525	260	14,785
- pH meter	1	Off	4,250	130	4,380
- Conductivity meter	1	Off	2,323	130	2,453
- Fridge	1	Off	3,000	260	3,260
- Freezer	1	Off	19,775	260	20,035
Sub-Total					**327,459**

QC LAB

- 96 well Plate washer	1	Off	10,000	130	10,130
- 96 well plate reader	1	Off	25,000	130	25,130
- UV/Vis spectrophotometer	1	Off	14,525	1,040	15,565
- Electrophoresis equipment	1	Off	19,650	1,040	20,690
- Gel scanner	1	Off	42,000	1,040	43,040
- Fluorescent plate reader	1	Off	65,000	520	65,520

- HPLC/MS	1	Off	260,000	260	260,260
- Balances	1	Off	6,300	130	6,430
- pH meter	1	Off	4,250	130	4,380
- Conductivity meter	1	Off	2,323	130	2,453
- Osmometer	1	Off	15,750	130	15,880
- Metabolite analyser	1	Off	74,000	520	74,520
- TOC analyser	1	Off	49,350	520	49,870
- Particle counter (environmental monitoring)	1	Off	21,150	260	21,410
- Air sampler	1	Off	9,650	130	9,780
- Cell counter / viability analyser	1	Off	70,000	1,040	71,040
- Filter integrity tester	1	Off	28,000	520	28,520
- Fume cupboard	1	Off	23,000	520	23,520
- Particle size analyser	1	Off	65,000	260	65,260
- Agilent 2100 Bioanalyser (lab-on-a-chip)	1	Off	42,000	1,040	43,040
- Fridge	1	Off	10,550	520	11,070
- Freezer	1	Off	19,775	520	20,295
- Analytical capillary electrophoresis	1	Off	50,000	520	50,520
- Isothermal calorimeter	1	Off	120,000	520	120,520
Sub-Total					**1,058,843**
MICRO LAB					
- Laminar Flow Cabinet	1	Off	9,000	520	9,520
Incubator	1	Off	10,000	520	10,520
Sub-Total					**20,040**

PC3 LAB					
- Biological Safety Cabinet Class II	1	Off	14,000	520	14,520
Sub-Total					**14,520**
BUFFER PREP					
- Mixing tanks	2	Off	8,000	1,040	18,080
- Stirrer	2	Off	2,000	520	5,040
- Peristaltic Pumps	2	Off	4,100	260	8,720
- pH meter	1	Off	4,250	130	4,380
- Conductivity meter	1	Off	2,323	130	2,453
Sub-Total					**38,673**
DISPENSARY					
- Balances	3	Off	6,300	130	19,290
- Biological Safety Cabinet Class II	1	Off	14,000	520	14,520
- Fridge	1	Off	10,550	520	11,070
- Freezer	1	Off	19,775	520	20,295
Sub-Total					**65,175**
FERMENTATION / MIDSTREAM					
- Laminar flow hood &/or sterile tubing welder	2	Off	24,250	520	49,540
- 500/1000 L fermenter	2	Off	600,000	6,400	1,212,800
- 50 L seed fermenter	2	Off	75,000	2,560	155,120
- Biological Safety Cabinet Class II	2	Off	14,000	520	29,040
- CO2 Incubator	2	Off	30,000	520	61,040

- Roller bottle Apparatus	2	Off	11,287	520	23,614
- Shaking Incubator	2	Off	35,000	520	71,040
- Inverted Microscope	2	Off	10,283	520	21,605
- Fridge	2	Off	10,550	520	22,140
- 1° Clarification equipment : centrifuge or filtration	2	Off	75,000	1,040	152,080
Sub-Total					**1,798,019**
DOWNSTREAM					
- Chromatography Skid	2	Off	250,000	4,160	508,320
- Bioprocess chromatography columns	8	Off	11,034	520	92,432
- Concentration/Diafiltration Systems	2	Off	43,641	520	88,322
- Filtration Systems	2	Off	43,641	520	88,322
- Peristaltic pumps	4	Off	4,100	260	17,440
- Laminar flow hood &/or sterile tubing welder	2	Off	24,250	520	49,540
Sub-Total					**844,376**
CELL BANK					
- Cryogenic storage tanks	4	Off	23,000	1,040	96,160
- Controlled rate freezer	1	Off	25,000	520	25,520
Sub-Total					**121,680**
CELL BANK EXPANSION					
- Biological Safety Cabinet Class II	1	Off	14,000	520	14,520
- CO2 Incubator	1	Off	31,875	520	32,395
- Roller bottle Apparatus	1	Off	2,438	260	2,698

- Shaking Incubator	1	Off	41,667	260	41,927
- Inverted Microscope	1	Off	10,283	130	10,413
- Fridge	1	Off	10,550	260	10,810
Sub-Total					112,762
FORMULATION & FILLING (OPTIONAL)					
- GMP Autoclave	*1*	*Off*	*200,000*		*200,000*
- Peristaltic pump	*1*	*Off*	*4,100*	*260*	*4,360*
- Programmable, low volume batch dispensing pump	*1*	*Off*	*10,000*	*260*	*10,260*
- Laminar Flow hood	*1*	*Off*	*55,000*	*2,000*	*57,000*
- Vial washer steriliser	*1*	*Off*	*500,000*		*500,000*
- Dry heat oven	*1*	*Off*	*125,000*		*125,000*
- Vial packing line	*1*	*Off*	*600,000*		*600,000*
- filler capper	*1*	*Off*	*500,000*		*500,000*
- Freeze Drier	*1*	*Off*	*1,135,600*		*1,135,600*
Sub-Total					*2,932,220*
CORE SUPPORT PLANT AND EQUIPMENT					
- Purified water system					300,000
- WFI system					350,000
- Pure steam					250,000
- Decontamination autoclave					150,000
- Waste Handling					150,000
- Boiler set					125,000
- Chilled water					180,000

- Chilled Piping	24,000
- Substation and Switchboards	60,000
- 415v switchboards	40,000
- Submains	31,500
- compressed air, supply and reticulation	48,000
- Hot water boiler and piping	71,000
	1,779,500
TOTAL Office/Lab Infrastructure Services	164,000
TOTAL Fill and Finish Lab	2,932,220
TOTAL Shared Labs/Office	1,093,403
TOTAL Dedicated Laboratory Each Wing	614,946
TOTAL Plant Infrastructure Services	1,779,500
TOTAL GMP processing Each Wing	2,980,685
GRAND TOTAL Facility stage 1 First Wing	9,564,753
Grand Total 2 wings	13,160,384

Appendix 4 – Survey Methodology

A selection of Australian biotechnology companies were interviewed to establish the current and future demand in Australian for mammalian cell expression technology as indicated by the number of recombinant proteins, monoclonal and diagnostic antibodies progressing through research and clinical development. In addition, companies were also asked to provide the location of current and future manufacturing with the aim of gaining an understanding of the number of companies taking their manufacturing requirements offshore.

From data collected in previous surveys and subsequent in-house research, fifty-four biotechnology companies were identified as potential users of mammalian cell expression technology. Companies were subsequently invited to participate in a phone interview. The interview updated data previously collected and was based on previous questionnaires designed by Innovation Dynamics.

Fifty-seven companies were contacted by phone. One company was unable to be contacted. Twenty-seven (47%) companies failed to respond or were unavailable. Thirty (53%) companies completed the survey. A list of the companies contacted can be seen below. Data on the twenty-seven companies who failed to respond was gleaned from other sources including company press releases, investor presentations and the internet.

The information gained from the survey is a good indication of the current demand in Australia for mammalian cell manufacturing services, and at least as comprehensive and current as any other study. However, the survey only targeted companies developing products and does not include products in discovery in research institutions (that sector was regarded as beyond the scope of the report).

Because of the stated limitations in responses and the restricted target groups the survey's accuracy must be qualified to some extent.

SCOPE OF SURVEY: COMPANIES WITH PRODUCTS IN DEVELOPMENT

	Phase Of Development							
Company Name	1	2	3	Clinical Trials	Develop ment	Disco very	Preclin ical	Grand Total
				1				1
					1			1
						1	3	4
	1						10	11
				1	2	1		4
				1	2	1		4
					1			1
						1		1
	1	2	1			1		5
					1			1
					1			1
						4		4
						2	1	3
						1		1
					1			1
					1			1
					1			1
						2		2
						1	3	4

		1				1		2
							1	1
					1	1		2
				1	1			2
							1	1
Grand Total	2	3	1	4	13	17	19	59

Appendix 5 – Scenario modeling and sensitivity analysis

Table 1 "Best-case" Operating Scenario – Projects and revenues

Project type	$M/project	Projects / GMP suite 1	2	3	4	DEVELOPMENT LABS 1	2	TOTAL $M
small preclinical/clinical	0.5*					2	2	2
major process development	1.5					2	2	6
preclinical/phase 1	2.0	2	2	2	2			16
phase 2	2.0	1	1	1	1			8
phase 3	7.5	1	1	1	1			30
		4	4	4	4	4	4	62

Numbers in bold type represent changed assumptions vs those given in Tables 6 and Table 7.

Appendix5 Table 2 NEW SCALE-UP FACILITY CASHFLOW STATEMENT "BEST CASE"

Year			2006 0	2007 1	2008 2	2009 3	2010 4	2011 5	2012 6	2013 7	2014 8	2015 9	2016 10	2017 11
Net Revenue		stage 1	0	0	11,962	25,133	39,565	41,543	43,620	45,801	48,091	50,496	53,021	55,672
		stage 2				0	0	20,771	43,620	45,801	48,091	50,496	53,021	55,672
		TOTAL	0	0	11,962	25,133	39,565	62,314	87,240	91,602	96,182	100,991	106,041	111,343
Cost of Goods Sold		0.4	0	0	5,981	12,567	15,826	24,926	34,896	36,641	38,473	40,397	42,416	44,537
		0.5												
Gross Profit			0	0	5,981	12,567	23,739	37,389	52,344	54,961	57,709	60,595	63,625	66,806
Overheads		0.4	0	0	4,785	10,053	11,869	18,694	21,810	22,901	24,046	25,248	26,510	27,836
% of sales		0.3												
		0.25												
EBITDA			0	0	1,196	2,513	11,869	18,694	30,534	32,061	33,664	35,347	37,114	38,970
		%sales			0.10	0.10	0.30	0.30	0.35	0.35	0.35	0.35	0.35	0.35
CAPEX	stage1	28,034	12,000	16,538	1,197									
	stage2 - second wing fitout	36,301					10,551							
CASH MOVEMENT			-12,000	-16,538	-1	2,513	1,319	18,694	30,534	32,061	33,664	35,347	37,114	38,970
CUMULATIVE CASH MOVEMENT			-12,000	-28,538	-28,538	-26,025	-24,706	-6,012	24,522	56,583	90,247	125,594	162,708	201,678

INFLATION	5%
NPV	49,176
COST OF CAPITAL	15%
IRR	34%

Notes assumes

62 sales in 2005$ for 100% operation, year 6 (Stage2)
10.333 sales in 2005$ in year1 of operation (2008) at 50% capacity (Stage1)
20.677 sales in 2005$ in year 2 of operation at 50% capacity (Stage 1)
15.5 sales in 2005$ year 1 of second wing

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APPENDIX 5 TABLE 3 **CASHFLOW STATEMENT - base case ($30 million at full capacity) ÷ Government**

Year			2006 0	2007 1	2008 2	2009 3	2010 4	2011 5	2012 6	2013 7	2014 8	2015 9	2016 10	2017 11
Net Revenue	stage 1		0	0	5,788	12,161	19,144	20,101	21,107	22,162	23,270	24,433	25,655	26,938
	stage 2					0	0	10,051	21,107	22,162	23,270	24,433	25,655	26,938
	TOTAL		0	0	5,788	12,161	19,144	30,152	42,213	44,324	46,540	48,867	51,310	53,876
Cost of Goods Sold		0.4	0	0	2,894	6,081	7,658	12,061	16,885	17,729	18,616	19,547	20,524	21,550
		0.5												
Gross Profit			0	0	2,894	6,081	11,487	18,091	25,328	26,594	27,924	29,320	30,786	32,325
Overheads		0.4	0	0	2,315	4,864	5,743	9,046	10,553	11,081	11,635	12,217	12,828	13,469
% of sales		0.3												
		0.25												
EBITDA			0	0	579	1,216	5,743	9,046	14,775	15,513	16,289	17,103	17,959	18,856
		%sales			0.10	0.10	0.30	0.30	0.35	0.35	0.35	0.35	0.35	0.35
CAPEX	stage1	28,034	2,000	16,538	1,197									
	stage2 - second wing fitout	36,301					10,551							
CASH MOVEMENT			-2,000	-16,538	-618	1,216	-4,807	9,046	14,775	15,513	16,289	17,103	17,959	18,856
CUMULATIVE CASH MOVEMENT			-2,000	-18,538	-19,156	-17,940	-22,747	-13,701	1,073	16,586	32,875	49,979	67,937	86,794

INFLATION	5%	Notes	assumes	30 sales in 2005$ for 100% operation, year 6 (Stage2)
NPV	16,599			5 sales in 2005$ in year1 of operation (2008) at 50% capacity (Stage1)
COST OF CAPITAL	15%			10.005 sales in 2005$ in year 2 of operation at 50% capacity (Stage 1)
IRR	27%			7.5 sales in 2005$ year 1 of second wing
				10 SM Govt Grant subsidises capex spend

APPENDIX 5 TABLE 4

CASHFLOW STATEMENT - low revenue ($16million at full capacity)

Year			2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
			0	1	2	3	4	5	6	7	8	9	10	11
Net Revenue		stage 1	0	0	3,087	6,486	10,210	10,721	11,257	11,820	12,411	13,031	13,683	14,367
		stage 2				0	0	5,360	11,257	11,820	12,411	13,031	13,683	14,367
		TOTAL	0	0	3,087	6,486	10,210	16,081	22,514	23,639	24,821	26,062	27,365	28,734
Cost of Goods Sold		0.4	0	0	1,544	3,243	4,084	6,432	9,005	9,456	9,929	10,425	10,946	11,493
		0.5												
Gross Profit			0	0	1,544	3,243	6,126	9,649	13,508	14,184	14,893	15,637	16,419	17,240
Overheads		0.4	0	0	1,235	2,594	3,063	4,824	5,628	5,910	6,205	6,516	6,841	7,183
% of sales		0.3												
		0.25												
EBITDA			0	0	309	649	3,063	4,824	7,880	8,274	8,687	9,122	9,578	10,057
		%sales			0.10	0.10	0.30	0.30	0.35	0.35	0.35	0.35	0.35	0.35
CAPEX	stage1	28,034	12,000	16,538	1,197									
	stage2 - second wing fitout	36,301					10,551							
CASH MOVEMENT			-12,000	-16,538	-888	649	-7,488	4,824	7,880	8,274	8,687	9,122	9,578	10,057
CUMULATIVE CASH MOVEMENT			-12,000	-28,538	-29,426	-28,777	-36,265	-31,440	-23,561	-15,287	-6,600	2,522	12,100	22,157

INFLATION	5%	Notes	assumes	16 sales in 2005$ for 100% operation, year 6 (Stage2)
NPV	-12,029			2.6667 sales in 2005$ in year1 of operation (2008) at 50% capacity (Stage1)
COST OF CAPITAL	15%			5.336 sales in 2005$ in year 2 of operation at 50% capacity (Stage 1)
IRR	7%			4 sales in 2005$ year 1 of second wing

APPENDIX 5 TABLE 5

CASHFLOW STATEMENT - low revenue ($16million at full capacity) + Government Grant

Year			2006 0	2007 1	2008 2	2009 3	2010 4	2011 5	2012 6	2013 7	2014 8	2015 9	2016 10	2017 11
Net Revenue	stage 1		0	0	3,087	6,486	10,210	10,721	11,257	11,820	12,411	13,031	13,683	14,367
	stage 2					0	0	5,360	11,257	11,820	12,411	13,031	13,683	14,367
	TOTAL		0	0	3,087	6,486	10,210	16,081	22,514	23,639	24,821	26,062	27,365	28,734
Cost of Goods Sold		0.4	0	0	1,544	3,243	4,084	6,432	9,005	9,456	9,929	10,425	10,946	11,493
		0.5												
Gross Profit			0	0	1,544	3,243	6,126	9,649	13,508	14,184	14,893	15,637	16,419	17,240
Overheads		0.4	0	0	1,235	2,594	3,063	4,824	5,628	5,910	6,205	6,516	6,841	7,183
% of sales		0.3												
		0.25												
EBITDA			0	0	309	649	3,063	4,824	7,880	8,274	8,687	9,122	9,578	10,057
		%sales			0.10	0.10	0.30	0.30	0.35	0.35	0.35	0.35	0.35	0.35
CAPEX	stage1	28,034	2,000	16,538	1,197									
	stage2 - second wing fitout	36,301					10,551							
CASH MOVEMENT			-2,000	-16,538	-888	649	-7,488	4,824	7,880	8,274	8,687	9,122	9,578	10,057
CUMULATIVE CASH MOVEMENT			-2,000	-18,538	-19,426	-18,777	-26,265	-21,440	-13,561	-5,287	3,400	12,522	22,100	32,157

INFLATION	5%	Notes	assumes	16 sales in 2005$ for 100% operation, year 6 (Stage2)
NPV	-2,029			2.6667 sales in 2005$ in year1 of operation (2008) at 50% capacity (Stage1)
COST OF CAPITAL	15%			5.336 sales in 2005$ in year 2 of operation at 50% capacity (Stage 1)
IRR	13%			4 sales in 2005$ year 1 of second wing
				10 SM Govt Grant subsidises capex spend

Appendix 6 National Biomanufacturing Centre

The UK National Biomanufacturing Centre in Liverpool will open in 2006. Funded by a £30 million grant by the European Regional Development Fund, the Northwest Development Agency and the UK Department of Trade and Industry, the facility is the centerpiece of a government policy designed to develop Merseyside (which includes Liverpool and surrounding suburbs) as a key biomanufacturing centre. This policy was developed following a study carried out by the Bioscience Innovation and Growth Team (comprising the BioIndustry Association, DTI and the Dept of Health).

The NBC has been designed to cater for both mammalian and bacterial drug production and also has the capacity for viral processing and specialty products. Its 3 GMP suites each contains separate upstream and downstream rooms which can run different products and be turned around independently (49). The mammalian suite has 2x300L plus 2x30 L fermenters, while the bacterial suite has 2x200 L plus 1 x 30L capacity. The suites each have their own air handling systems and the equipment inside each suite is skid mounted to improve flexibility. Disposable technologies are used in order to minimize downtime. In parallel to the GMP suites, on the other side of the building are three process development and scale up areas, an analytical/QC lab (divided into microbiology, molecular biology, biochemistry and immunochemistry), teaching areas, controlled storage and administration.

In October 2003 Eden BioDesign won the tender from the Northwest Development Agency to operate the facility and has been closely involved in its design. AMEC has been responsible for construction. Following its selection, Eden BioDesign raised £5 million in equity finance to provide working capital for the project(50). Between 2003 and the end of 2005, the company assisted up to 30 local drug developers to design their manufacturing processes. The cost of this consultancy has been partly supported by the Northwest Development Agency and partly by the company.

When the NBC comes on line in Q1 2006, local Merseyside and UK biotech SMEs will be able to access grants of up to £60,000 each to pay for scale up manufacturing and process development. A total of £3,000,000 is available for this support. Merseyside companies also qualify for additional assistance through MerseyBIO. MerseyBIO itself is funded through the Objective 1 Programme for Merseyside and supported by the University of Liverpool, Liverpool John Moores University and NHS Trusts(51).

Another key component of the centre will be training. The Biotechnology and Biological Sciences Research Council (BBSRC) has established a Working Group which identified challenges for further bioprocessing research(52). The BBSRC, the Engineering and Physical Sciences Research Council (EPSRC) and industry have launched a Bioprocessing Research Industry Club. The Club will support innovative bioprocessing-related research projects and is being managed by bioProcessUK, the DTI-funded Knowledge Transfer Network. Bioprocess UK will disseminate research outputs and promote networking. The Club will support industrially-relevant research projects from a joint fund in excess of £10 million (£1 million of which comes from industrial membership subscriptions).