

Approaching the Japanese Biotechnology Market

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Overview

- Current and Predicted Market
- Drivers of the Industry
- Sectors
- Comparison with Australia
- Opportunities for Australia
- Approaches to the Japanese Market
- Case Study - Diagnostics

Background

- **1999 - 2001 Bureaucratic Reform**
- **2002 Government Decision to Promote Biotechnology**
 - Biotechnology Strategy Council
 - Tax incentives to stimulate R&D
 - Large clinical trials network to be established
 - Public funds for medical start ups
 - Academics to work with industry

JAPANESE BIOTECH MARKET 2001/2010

[Source: METI 2002 Units: AUD billion]

SECTOR	2001	2010	CAGR
Human Health	7.00	109	36%
Agri-Food	4.77	82	37%
Bioprocess	3.17	47	35%
Environment & Resources	0.04	8	80%
Bioutil	1.82	40	41%
Bioinformatics	0.38	29	62%
Services & Other	0.34	10	46%
Total	17.47	325	38%

JAPANESE BIOTECH MARKET

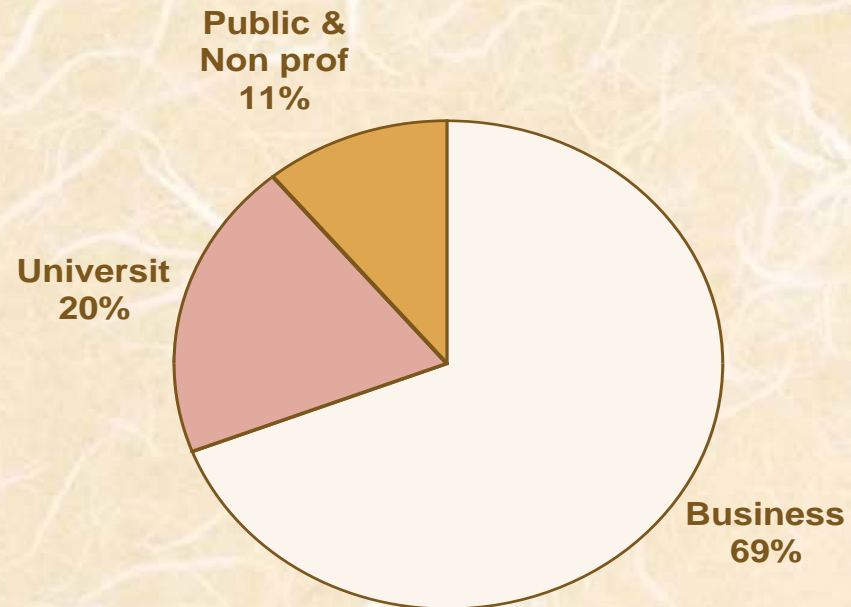
Sectors

- **Almost entirely internal market with few exports**
- **Human Health(40%)** - EPO, C-GSF, MAbs, GH, Insulin
- **AgriFood (27%)** - maize, functional food, special health foods
- **Bioprocess (18%)** - enzymes for food & detergents
- **Biotoools (10%)** - biosensors, analytical equipment
- **Bioinformatics (2%)** - complete cDNA cloning
- **Environment** - bioremediation
- **Services (2%)** -

JAPANESE BIOTECH MARKET Drivers

- FY2001 GERD AUD215 billion
- 3.3% GDP
- 69% business
- Breakdown
 - Basic 15%
 - Applied 23%
 - Dev't 62%
- Life Sciences 10% approx.

R&D Expenditure



JAPANESE BIOTECH MARKET

Drivers - Government

National Government Ministries

- Ministry of Economy, Trade and Industry - METI
- Ministry of Education, Culture, Sports, Science and Technology - MEXT
- Ministry of Agriculture, Forestry and Fisheries - MAFF
- Ministry of Health, Labour and Welfare - MHLW

JAPANESE BIOTECH MARKET

Drivers - Government

- **METI (~AUD 350M)**
 - Links to broad industry sectors
 - Research institutions such as NIAIST and NIBHT
 - Links to Japan Bioindustry Association (190 companies) and Research Association for Biotechnology for priorities
- **MEXT (~AUD 900M)**
 - Regulation of university sector
 - Research institutions such as RIKEN as well as university research groups and associations
 - 32 Technology Licensing Organisations

JAPANESE BIOTECH MARKET

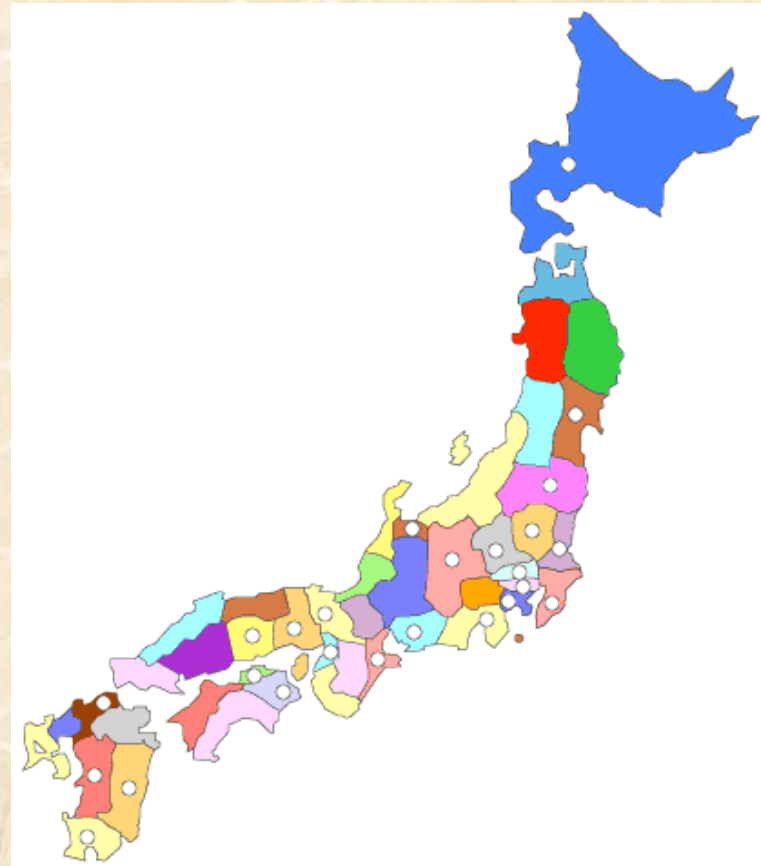
Drivers - Government

- **MAFF (~AUD 300M)**
 - Regulation of all agriculture activities
 - Research institutes
 - Links to Japan Society for Techno-innovation of Agriculture, Forestry and Fisheries (160 companies)
- **MHLW (over AUD 1,600M)**
 - Regulation of all health matters including pharma, medical devices and diagnostics
 - Links to Japan Health Sciences Foundation (154 companies)

JAPANESE BIOTECH MARKET

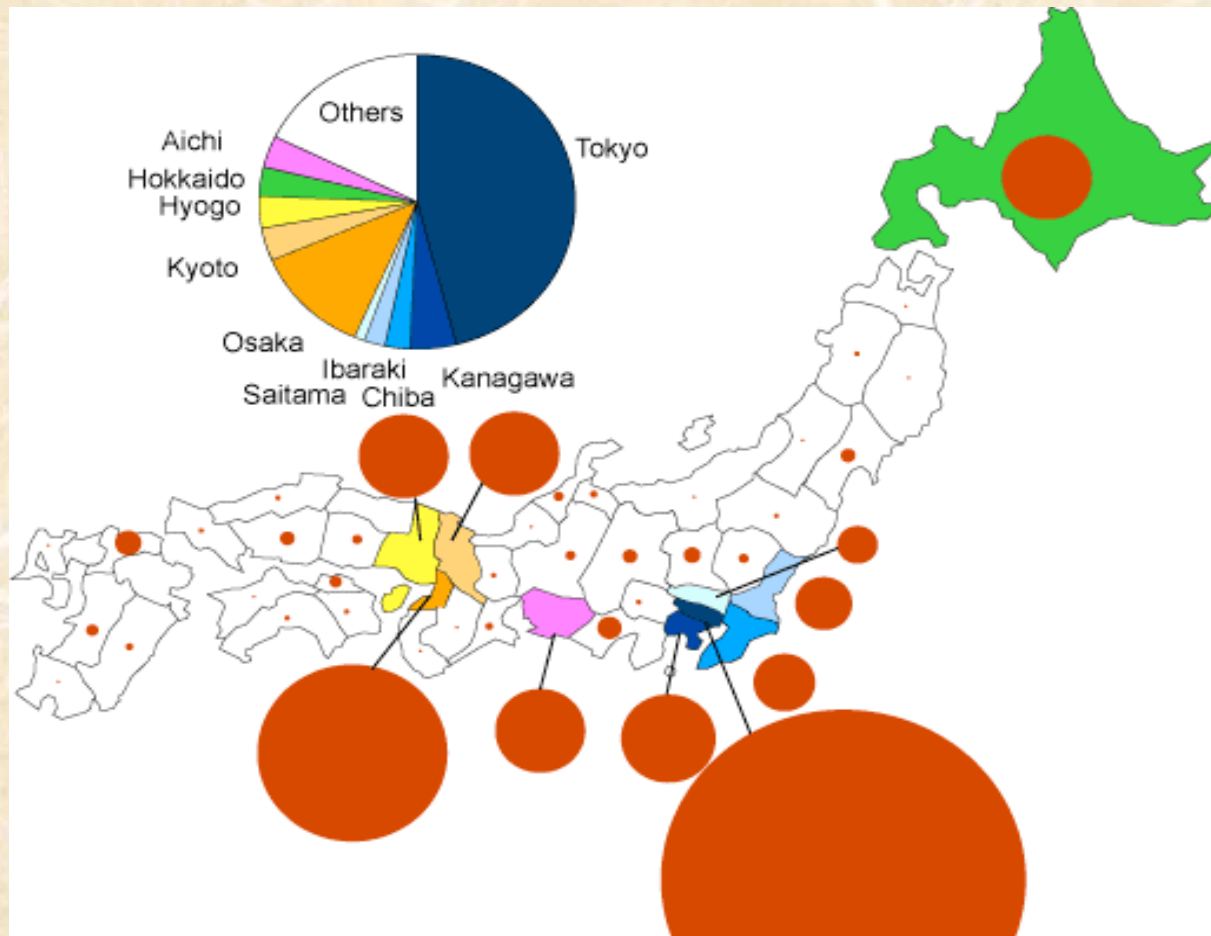
Drivers - Local Government

- Promote industrial clusters
- Promote public private partnerships
- Fund regional institutes with industry
- Main focus Tokyo, Osaka and Hokkaido



JAPANESE BIOTECH MARKET

Drivers - Industry

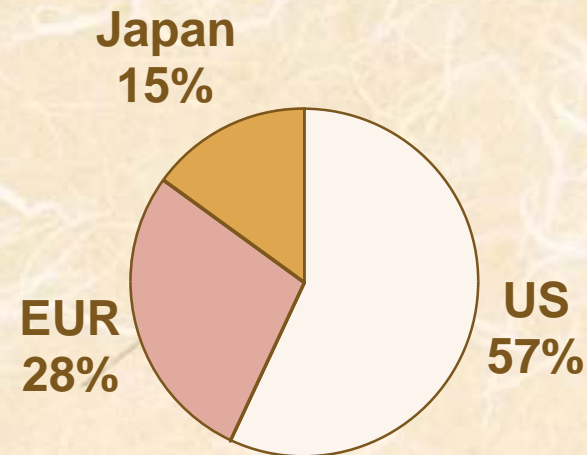


Japanese Market - Sectors

● Pharmaceuticals

- 50% controlled by domestic companies
- 20% by Japanese companies under foreign licence
- Increasingly looking to foreign markets with major companies having >40% of sales O/S
- Establishing O/S R&D and marketing operations
- Commercial incentive for new products

AUD 480 Billion

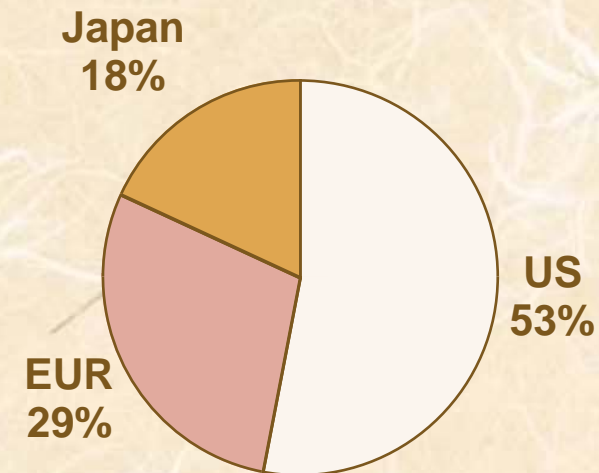


Japanese Market - Sectors

- **Medical Devices**

- 57% sourced domestically
- Major import demand for biomedical transplantation devices and surgical equipment
- Easier access to market from 2005

AUD 200 Billion

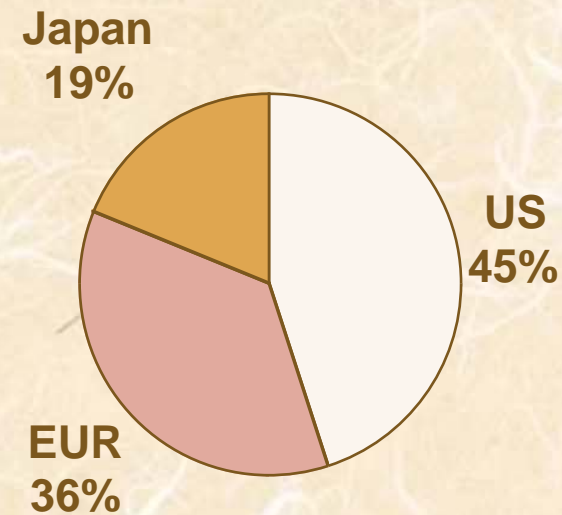


Japanese Market - Sectors

● In Vitro Diagnostics

- Thin margins
- Large distribution costs
- 50% of immunoassay products imported but other products almost entirely local
- Local producers of instrumentation strong

AUD 30 Billion



Japanese Market - Sectors

● Agriculture

- Relatively underexploited due to highly protected nature
- Strong emphasis on seed industry with focus on rice and then vegetables
- Major corporate players are from pesticide, seed, beverage and brewing industries as well as agricultural cooperatives

Japanese Market - Sectors

● Food & BioProcess

- Strong highly competitive industry reliant on imported material
- Long history of fermentation to produce food with adaptation to other industries rather than extension in existing industries
- New category - Special Health Foods - focus of considerable market attention

Japanese Market - Sectors

● **Biotoools**

- Area of significant government support
- Building on strong electronics and laboratory equipment base and relying on increase in local demand
- Interest in nano-medical device development

Japanese Market - Sectors

● **Bioinformatics**

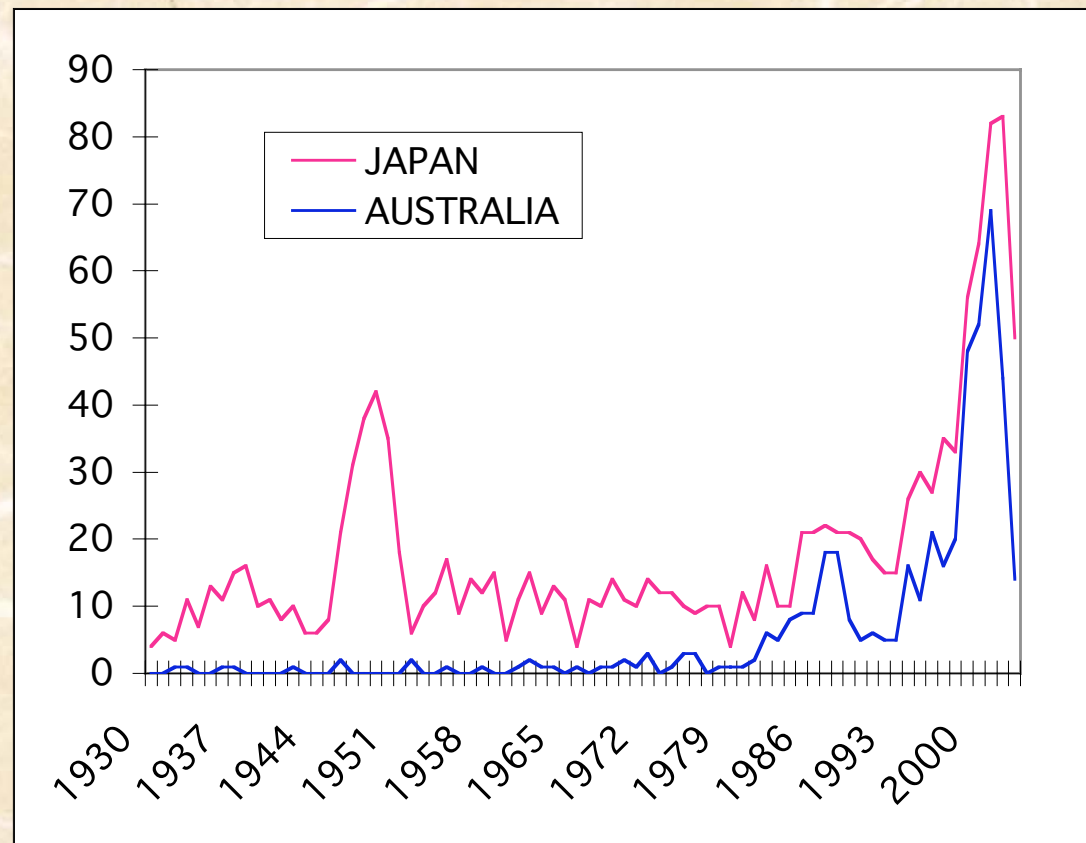
- Relatively under-developed and hence focus of Government push
- RIKEN's Genomic Sciences Centre
- Helix Research Institute Inc. funded by industry and government
- Significant strategic patent approach

Japanese Market - Sectors

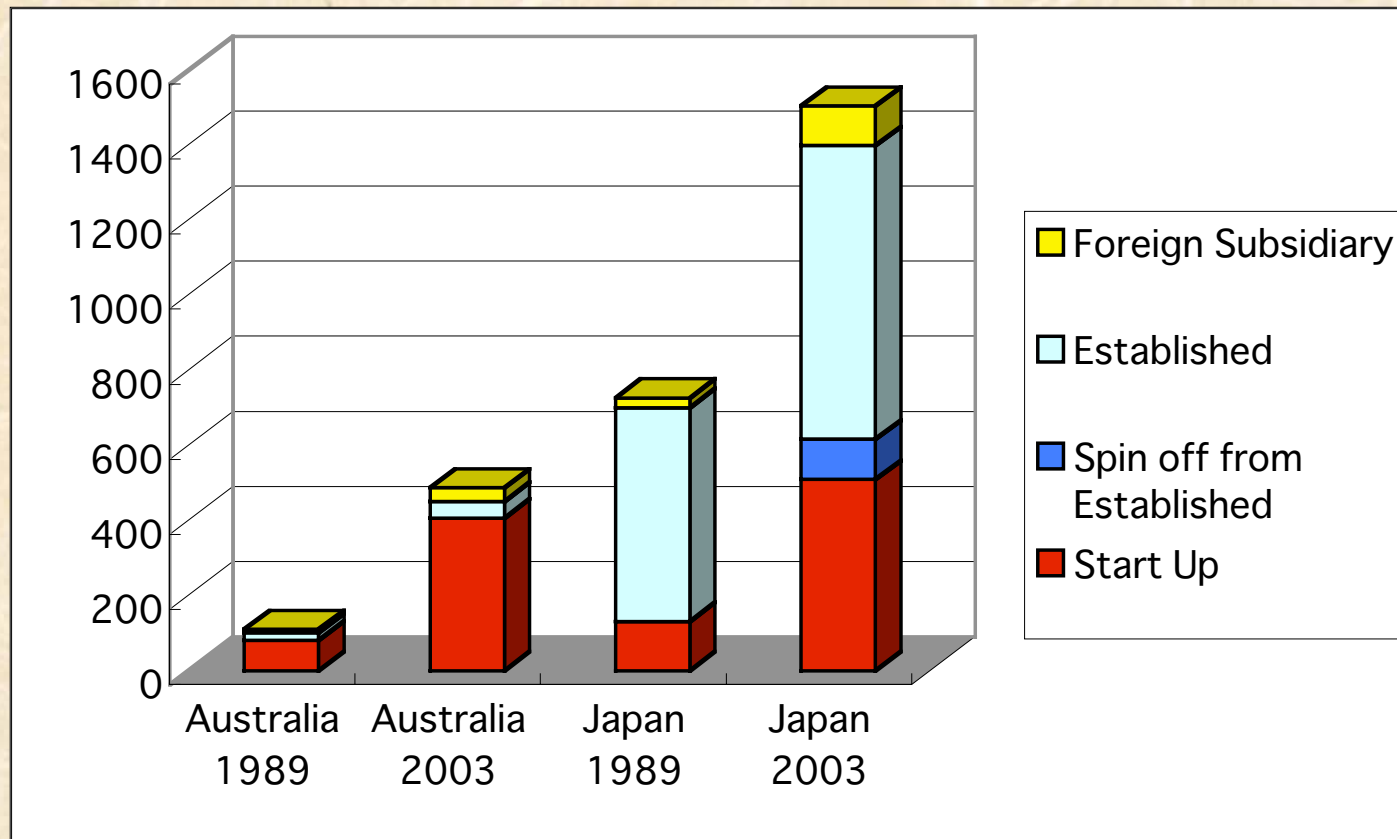
● Environment

- Market over AUD 300 billion and growing at 3.7%pa
- Expecting rapid growth in
 - *Soil and water remediation*
 - *Pollution prevention services*
 - *Energy saving and management*
- Industry highly competitive particularly in industrial pollution control but opportunities in soil and water remediation and associated services
- Major sector is wastewater treatment

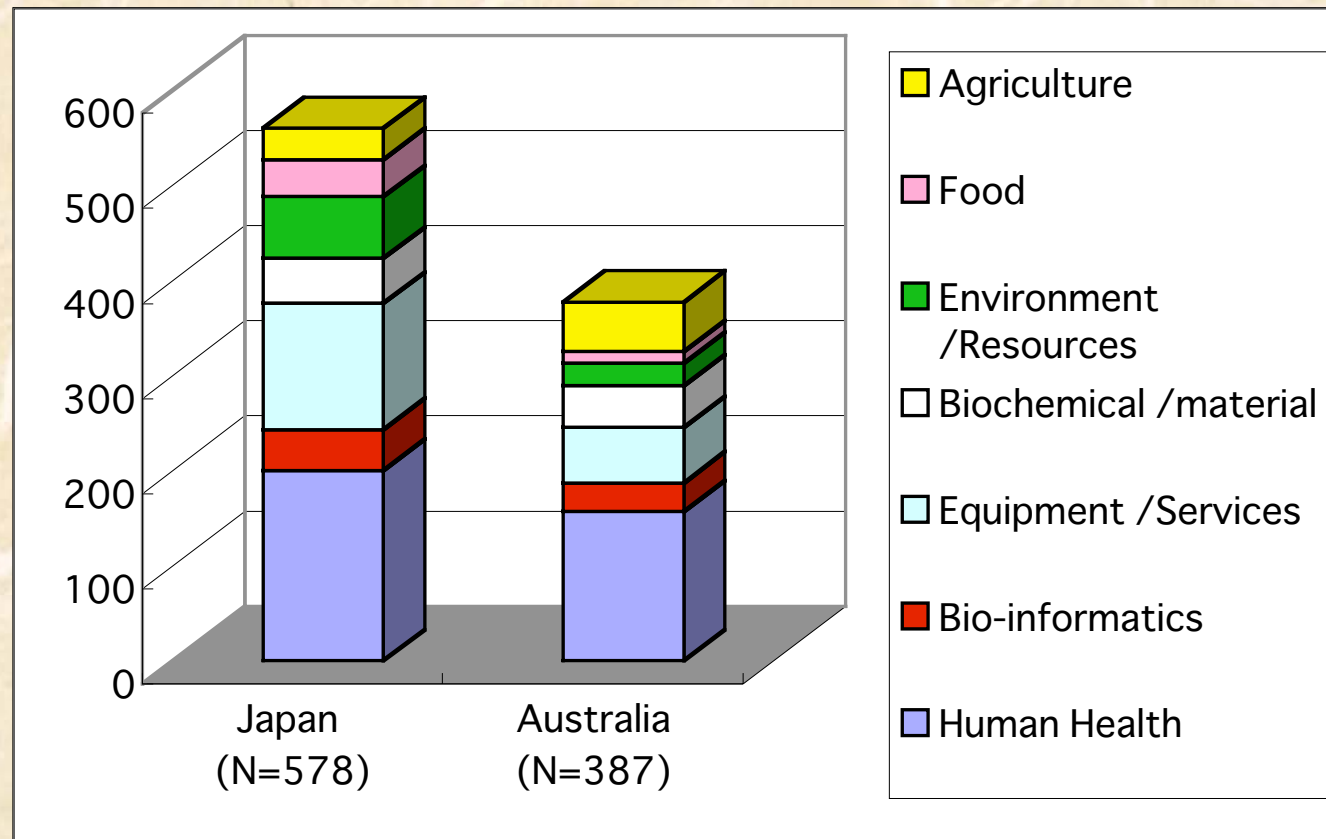
Comparison with Australia



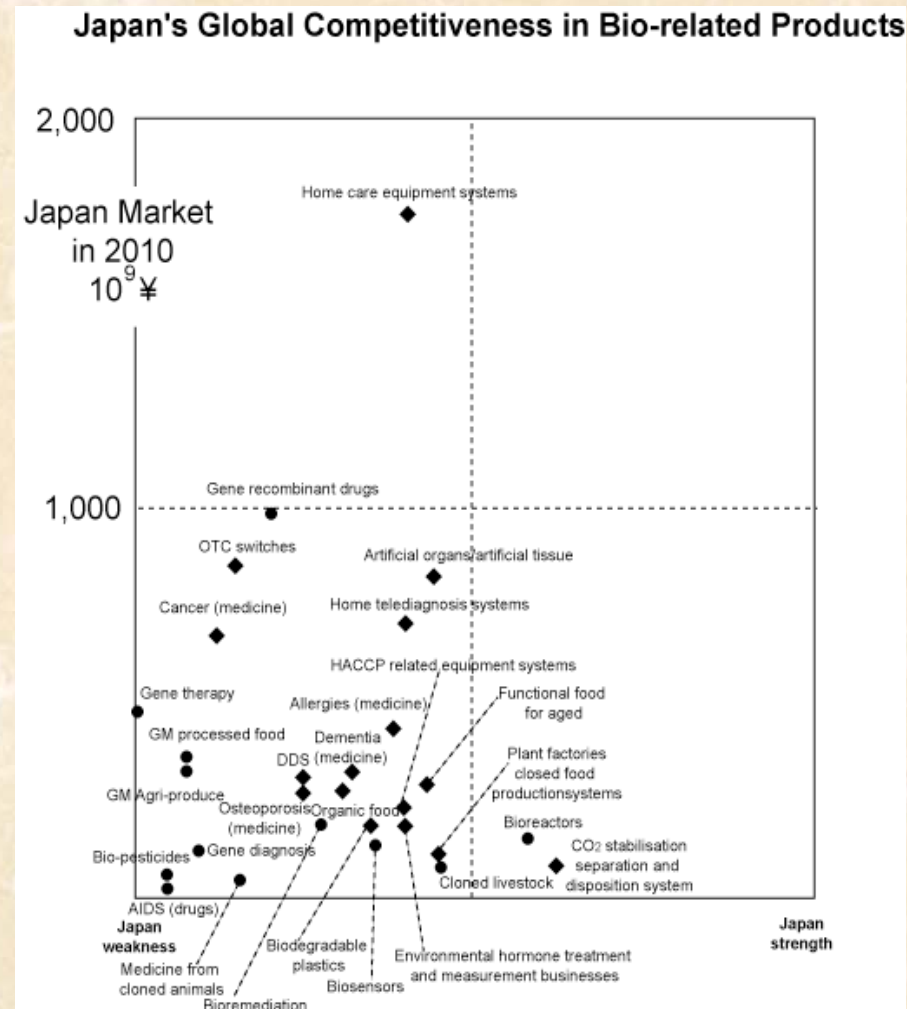
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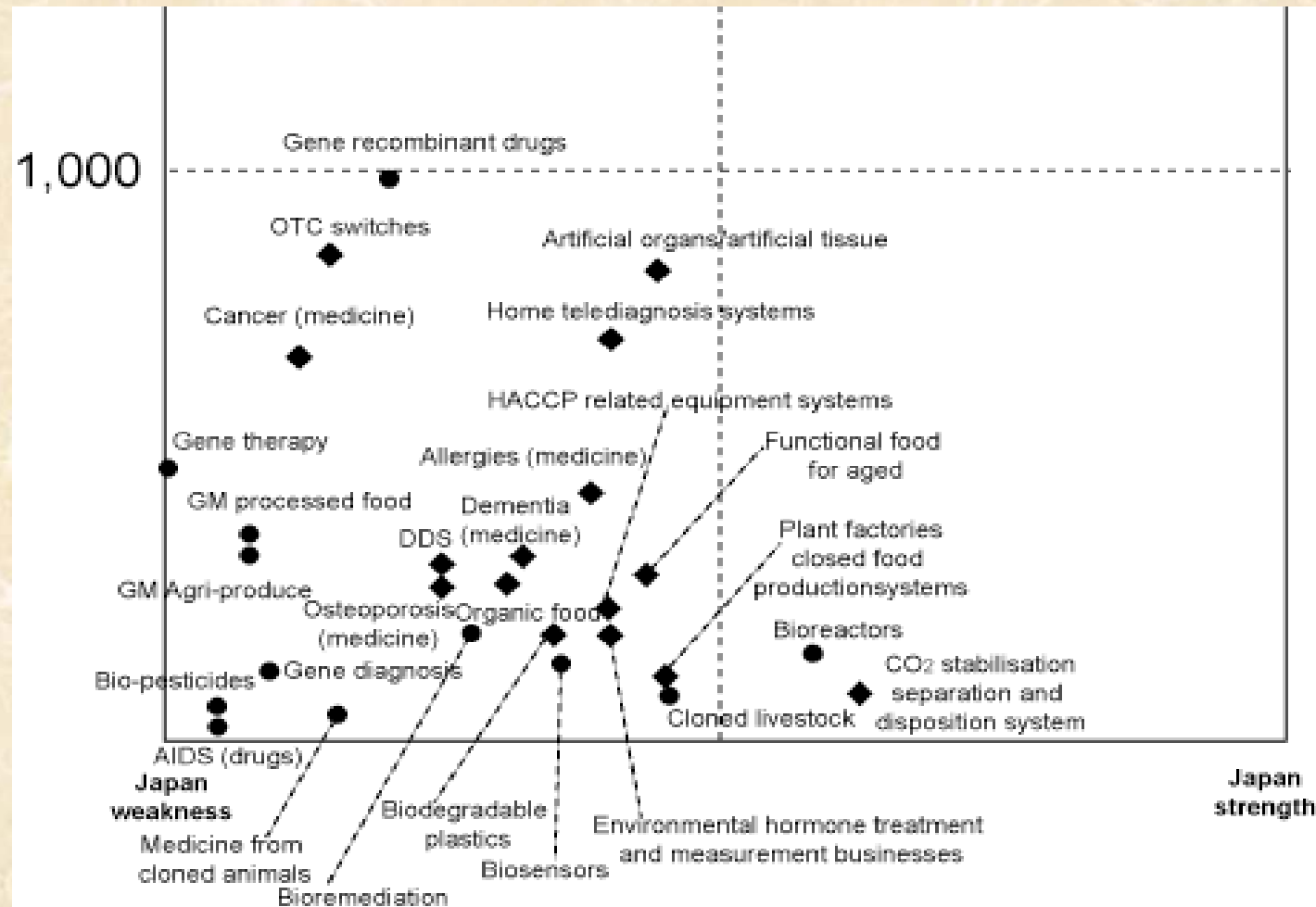
Comparison of Start Ups - Sectors



Opportunities



Opportunities



Australia Japan Activities

Products/Equipment

● Equipment

- Corbett Research
- Vita Medical
- Vision Biosystems
- Axon/Molecular Devices
- Cryologic
- Riancorp
- Optiscan
- ResMed
- Compumedics

● Biologicals

- CSL/JRH
- Moregate
- SC Botanicals
- Herbworx
- Thermo Trace
- GR Davis

● Other

- Genetic Solutions
- Ozgene
- Mimotopes

Australia Japan Activities

Regulated Products

- **Diagnostics**

- Life Diagnostics
- PanBio
- Biota
- Cellestis

- **Other**

- Cochlear
- BioProperties
- Atcor Medical

Australia Japan Activities Technology Licensing

- **Chemgenex Pharmaceuticals**
- **Byron Australia**
- **Mayne Pharma**
- **Food Science Australia**
- **Optiscan**
- **Virotec**
- **Environmental Solutions**
- **SciGen**

Australia Japan Activities R&D Collaboration

- **AMRAD**
- **Cerylid Biosciences**
- **RMIT**
- **St. Vincent's Institute Medical Research**
- **Animal Reproduction Co.**
- **Centre for Animal Biotechnology**
- **Children's Medical Research Institute**

Australia Japan Activities Joint Ventures

- **Stem Cell Sciences**
- **Proteome Systems**
- **Bioproperties Australia**
- **Waste Technologies Australia**

Australia Japan Activities Investments

- **Florigene (Suntory)**
- **Bioclone (Hitachi)**
- **Biocontrol (Shinetsu Chemical)**
- **Cerylid Biosciences (JAFCO/Starfish)**
- **Optiscan (Asahi Optical)**
- **Shimadzu**

Australia Japan Activities Marketing in Japan

- **Neurosciences Victoria (Nissho Iwai)**
- **Institute for Molecular Bioscience (Itochu)**
- **Food Sciences Australia (Itochu)**
- **Proteome Systems (Itochu and Shimadzu)**

Approaching the Market

- **Homework** (low \$)

- Gather information on target market and industry
- Critically evaluate appropriateness of offering (*why would they be interested?*)

- **Strategy** (low \$)

- Targeting the entry point - *creating opportunities*
- Trading Co > Importer > Marketer > Distributor > Specialist > Consumer

Approaching the Market

- **Creating Opportunities** (low to mod. \$)
 - Trade Fairs - oriented to established products
 - International Conferences - low success rate - hit or miss - like with like
 - Government support
 - *Austrade - more active - can be counterproductive*
 - *JETRO - more passive - first step only*
 - *Global Venture Forum - high focus but requires preparation*
 - Academic linkages
 - *Provides introductions only*
 - *Opens and closes doors - limitations*

Approaching the Market Linkages

- **Trading Companies**

- Provides ready access
- Route to market must be clear, rapid and provide good return
- Additional intermediary and margin

- **Investment Companies**

- Good potential
- Variable track record

Approaching the Market Linkages

- **Company Matching/ Individuals**

- Selection
- Terms of arrangement
- Need for continuing contribution
- Need for parallel official and non-official channels
- Need for advice on interaction

Regulatory Requirements

- **Pharmaceuticals, Medical Devices and Veterinary Medicine** - Pharmaceutical Affairs Law, GMP, GLP, GCP
- **Foods** - Food Hygiene Law
- **Agriculture** - Guideline for Release of Recombinant Plant /Organisms
- **Environment** - Environment Law

Case of Company C

Background

- Newly established Australian company with limited financial capacity
- Novel *in vitro* diagnostic for detection of disease
- Some IP protection
- Japan still has high infection rate
- Japanese market is monopolized by one company
- Protocol of diagnosis is specified by special law

Objective

- Selection of partner - interested in distribution and capable to obtain an import permit of the test

Process

- **Identification/Assessment of key factors**

Influential government organization in Japan

Resistance force in Japan - Monopoly company

Likely distributors - Fujirebio, Kyowa Medex, Chugai,
Monopoly company

- **Approach**

Introduction through respected person/organization -
JETRO, Austrade and/or personal connection

Process

- **Selection of a Partner**
 - Nichirei, why?
 - Terms and conditions on distribution and clinical trials
- **Modification of product to meet market requirements**
 - Second generation kit
- **Building up working relationship**
 - Generation of clinical & non-clinical data in Australia/Japan
 - Human factor, product champion

Conclusion

- Homework
- Strategy
- Selection
- Process