BIOTECHCORP
MALAYSIAN BIOTECHNOLOGY CORPORATION

MALAYSIAN BIOTECHNOLOGY
COUNTRY REPORT
2009 / 2010

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Exchange Rate Conversion

	MYR	AUD	RMB	INR	SGD	KRW
USD 1.0	3.5	1.09	6.83	46.45	1.39	1170.18

Executive Summary

Executive Summary

The national interest in biotechnology started as early as the 5th Malaysian Plan (1986-1990) but was given due recognition and emphasis starting from the 8th Malaysian Plan (2001-2005). Consequently, the Malaysian Government identified biotechnology as one of the core technologies to accelerate the transformation of Malaysia into a knowledge-based economy and an industrialised nation by year 2020. For this purpose, the National Biotechnology Policy (NBP) was launched in 2005 to provide a development framework for the industry. The NBP is to be implemented over three phases, namely Phase I – Capacity Building (2006-2010), Phase II – Science to Business[1] (2011-2015), and Phase III – Global Business (2016-2020). Malaysian Biotechnology Corporation Sdn Bhd (BiotechCorp) is the lead agency responsible for the coordinated implementation of the NBP.

Since the launch of the NBP in 2005, the Malaysian biotechnology industry has recorded a total investment of USD 1.3 billion (RM 4.5 billion) by 2009. Out of this investment, 57.8% was funded by the Government while the remainder was funded by the private sector. The contribution of the biotechnology industry towards the Gross Domestic Product (GDP) in 2009 was estimated at 2%. In terms of total employment, it is estimated that 54,000 people were employed in the life-science and biotechnology-related industry in 2009.

The objective of the Malaysian Biotechnology Country Report 2009 / 2010 (Country Report) is to provide an overview of biotechnology industry development in Malaysia since 2005 and set out priority actions moving forward into Phase II of the NBP implementation.

Current State

As at 30 September 2009, a total number of 349 biotechnology companies were identified in Malaysia, a three-fold increase from 117 companies in 2005. Out of the 349 biotechnology companies identified, 41% was involved in the agricultural biotechnology sector followed by the healthcare biotechnology sector with 38.4% and the remaining in the industrial biotechnology sector at 20.6% (see Table ES-1).

Table ES-1: Malaysian Biotechnology Sector Overview

Sector	Number of Companies*	Revenue		Investment	
		USD million	RM million	USD million	RM million
Agricultural	143	57.9	202.7	287.5	1,006.3
Healthcare	134	47.4	165.8	235.1	822.8
Industrial	72	44.8	156.9	297.6	1,041.6
Total	**349**	**150.1**	**525.4**	**820.2**	**2,870.7**

Source:
(1) BiotechCorp (as at 30 September 2009)
(2) SSM (as at 31 December 2008 or latest financial reports available)
** as at 30 September 2009*

The larger representation of agricultural companies in the Malaysian biotechnology industry can be attributed to the country's traditional strength in the agriculture sector. For the healthcare biotechnology sector, there are higher barriers of entry such as extensive product regulations and procedures, while the industrial biotechnology sector requires larger capital investments.

In terms of sectoral contribution, agricultural biotechnology is the largest revenue contributor at 38.6% with the largest number of companies (143 out of 349 companies). Healthcare biotechnology accounted for 31.6% of total revenue followed by industrial biotechnology at 29.8%.

[1] The original term in the NBP is "Lab to Market"

In terms of sectoral contribution, agricultural biotechnology is the largest revenue contributor at 38.6% with the largest number of companies (143 out of 349 companies). Healthcare biotechnology accounted for 31.6% of total revenue followed by industrial biotechnology at 29.8%.

Of the total investment, the industrial biotechnology sector has the highest investment dollars with close to USD 300 million (RM 1 billion). Total investment in agricultural and healthcare biotechnology sectors is USD 287.5 million (RM 1 billion) and USD 235.1 million (RM 822.8 million) respectively. A total of USD 427 million (RM1.5 billion) out of USD 820.2 million (RM 2.9 billion) investment has been approved for BioNexus Status companies. This investment includes contribution from United States (U.S.), United Kingdom, France, Germany, Italy, Belgium, India, China, Hong Kong, Singapore, Thailand, Australia, New Zealand, Japan and Taiwan.

The collective market capitalisation of four BioNexus Status companies exceeded USD 628.6 million (RM 2.2 billion) in 2009. BioNexus Status companies are listed not only on Bursa Malaysia but also on the London Stock Exchange and the Australian Stock Exchange. In 2009, Holista Biotech (Holista), a BioNexus Status company, completed its takeover of Colltech Australia, a listed company on the Australian Stock Exchange.

Sector Focus Development

The NBP has outlined three key policy thrusts supported by specific strategies and actions to develop agricultural, healthcare and industrial biotechnology sectors. Biotechnology is an enabling tool for the development of these three sectors with the view of impacting Malaysia's economy by revolutionising the agriculture, healthcare and industrial sectors. Malaysia's unique biodiversity and abundant natural resources are, inter alia, competitive advantages that are being capitalised on for sector focus development.

Policy Thrust 1 Agricultural Biotechnology Development

Malaysia is a country with abundant natural resources and vast tracts of land that is suitable for agriculture. In the early years, Malaysia relied on its agriculture sector to drive the economy through export of commodities such as rubber, timber and palm oil. Since the 1990s, Malaysia has been moving towards an industrialised economy with the manufacturing and services sector gaining precedence as the key economic drivers. However, the agriculture sector is the third engine of growth and is a strategically important sector as can be seen from two perspectives – GDP contribution and food production. In terms of GDP, the agriculture sector contributed USD 11.4 billion (RM 39.8 billion), which is 7.5% of GDP in 2008[2]. In terms of food production, there is need to provide and produce sufficient food to feed a growing population. In 2008, Malaysia has not yet attained self-sufficiency for major food commodities like rice (70%), beef (25.9%), mutton (9.2%) and milk (4.8%)[3]. This is evident given that Malaysia's food import bill is USD 8 billion (RM 28 billion), with a trade deficit in food items amounting to USD 2.9 billion (RM 10.1 billion) for the same year[4]. This has raised concerns regarding national food security and the balance of trade, especially given the increasing challenges faced in the agriculture sector such as scarcity of land, low crop productivity, increase in frequency of floods, droughts, soil erosion, and high water and energy usage.

In 2004, the Biotechnology Information Centre, Malaysia, recorded that there were nine agricultural biotechnology companies. Since then and the launch of the NBP, there has been a 16-fold increase as at 30 September 2009, there are 143 agricultural biotechnology companies out of a total of 349, representing 41% of the total biotechnology companies in Malaysia. Based on the latest 2008 financial reports available[5], agricultural biotechnology companies contributed total revenue of USD 57.9 million (RM 202.7 billion) which represents 38.6% of the total revenue of the Malaysian biotechnology industry.

Of the 143 agricultural biotechnology companies in Malaysia, 55 companies (38.5% of total biotechnology companies) have obtained BioNexus Status and generated a total revenue of USD 45.5 million (RM 159.1 million) in 2008 as compared to the remaining companies (without BioNexus Status) that generated revenue of USD 12.4 million (RM 43.6 million), which represents 21.5% of total agricultural biotechnology sector revenue size.

[2] Economic Planning Unit Website, accessed on 5 October 2009
[3] Agriculture Statistical Handbook (2008)
[4] MIDA Website, accessed on 22 October 2009
[5] Based on BiotechCorp (as at 31 December 2008) and SSM (31 December 2008 or latest financial reports available)

Total investment of agricultural biotechnology companies was USD 287.5 million (RM 1 billion) based on latest available information[6]. This represents about 34.8% of total investment in the biotechnology industry. A total of USD 167.5 million (RM 586.1 million) investment has been approved for BioNexus Status companies.

As represented by BioNexus Status companies[7] as at 30 September 2009, given Malaysia's traditional focus on agricultural development, a large percentage of agricultural biotechnology companies, are involved in adding value to food and crops by engaging in crop-related biotechnology (47.3%), livestock biotechnology (18.2%) and marine / aquaculture biotechnology (3.6%). The acquisition of a Marker Assisted Selection platform technology from DNA LandMarks, a BASF Plant Science Company will enhance the crop and animal breeding programme. This will further improve the value and productivity of the crops and livestock. In addition, there is a global trend towards the use of biofertilisers as increasing soil degradation is partly attributed to the use of inorganic fertilisers.

One of Malaysia's leading Institutes of Higher Learning (IHLs), University Sains Malaysia (USM) has decoded the first-ever draft of the rubber tree (hevea brasiliensis) genome, thereby positioning Malaysia as one of the likely leaders in rubber research and production. This breakthrough is expected to facilitate significant development in rubber tree breeding and to track development of rubber trees with favourable traits such as disease resistance and improvement of properties of rubberwood, an important export of Malaysia.

The natural products segment, 29.1% as represented by BioNexus Status companies[8], has generated significant interest from local and foreign parties for the extraction of bioactive and novel compounds due to the enormous untapped potential and rich biodiversity of Malaysia's tropical rainforests. However, the challenge has been to achieve standardisation of extracts using chemical and pharmacological profiling. The acquisition of an industrial scale Supercritical Fluid platform technology enables extraction of consistently pure extracts without the use of harmful solvents and produces particles with defined shape, uniform size and controlled morphology that are suitable as active ingredients in a range of products from food ingredients to pharmaceuticals. The acquisition of this technology for the industry players has further spurred interest in the natural products segment.

Policy Thrust 2 Healthcare Biotechnology Development

Healthcare biotechnology is relatively young in Malaysia and has been earmarked for development under the second policy thrust of the NBP. To get started, given Malaysia's comparative advantage in manufacturing and outsourcing capabilities and cost effective resource availability, Malaysia is well positioned to be a strategic outsourcing hub for healthcare biotechnology R&D and manufacturing, namely Contract Manufacturing Organisation (CMO) and Contract Research Organisation or Clinical Research Organisation (CRO). Moving forward, the development of CMO and CRO will provide the foundation for Malaysia to build capacity and capability in drug discovery and development. In addition, Malaysia's tropical biodiversity will provide opportunities for potential botanical drug discovery and development that caters for the needs of tropical countries especially in the areas of neglected diseases (e.g. malaria, dengue and, tuberculosis. Development of natural products is expected to generate greater economic value through progression from extraction of novel bioactive compounds to the development of products with pharmaceutical and health applications.

Due to the heavily regulated nature of the sector, the healthcare biotechnology sector has a longer gestation period and requires greater investment in terms of skills and technologies. For example, any product improvement for pharmaceutical products requires the company to undertake long and extensive product registration procedures. Therefore, Malaysia needs to identify its own niche in developing the healthcare biotechnology sector for the country.

[6] Based on BiotechCorp (as at 30 September 2009) and SSM (31 December 2008 or latest financial reports available)
[7 & 8] Due to unavailability of data for all agricultural biotechnology company in Malaysia

In 2004, the Biotechnology Information Centre, Malaysia, recorded that there were 11 biopharmaceutical companies in the healthcare biotechnology sector. Since then, there has been a 12-fold increase, as there are at least 134 healthcare biotechnology companies out of a total of 349, representing 38.4% of the total biotechnology companies as at 30 September 2009. Based on latest 2008 financial reports available[9], healthcare biotechnology companies contributed a total revenue of USD 47.3 million (RM 165.8 million) which represents 31.5% of the total revenue size of the biotechnology industry.

Of the 134 healthcare biotechnology companies in Malaysia, 51 companies (38.1% of total companies) have obtained BioNexus Status which generated a total revenue of about USD 24.9 million (RM 87 million) in 2008, as compared to the remaining companies (without BioNexus Status) that generated revenue of USD 22.5 million (RM 78.8 million) which represents 47.5% of total healthcare biotechnology sector revenue size.

Total investment of healthcare biotechnology companies was USD 235.1 million (RM 822.8 million) based on the latest available information[10]. This represents about 28.7% of total investment for the biotechnology industry. Total investment of USD 122.3 million (RM 428 million) have been approved for BioNexus Status companies.

As represented by the BioNexus Status companies[11] as at 30 September 2009, 33.3% of the healthcare biotechnology companies is involved in the medical devices / In-Vitro Diagnostics (IVD) segment, followed by biopharmaceuticals / pharmaceuticals at 23.5% and CRO at 19.6%. The therapeutics / stem cells segment represents 11.8% while that of CMO is 5.9%. The biopharmaceuticals segment contributed total revenue of USD 6.8 million (RM 23.7 million), equivalent to 30.5% while the therapeutics / stem cells segment contributed total revenue of USD 6.6 million (RM 23.3 million) in the first nine months of 2009.

Under the National Biotechnology Acquisition Programme, two healthcare platform technologies have been acquired namely, the nanotechnology platform from Nanobiotix S.A of France in 2007 and the DotScan™ antibody microarray diagnostic platform technology from Medsaic of Australia in 2009. These platform technologies can be applied across the healthcare industry, but the immediate applications identified to be developed are in the biopharmaceuticals / pharmaceuticals and medical devices / IVD segments. The selection of these technologies was based on a thorough analysis of the needs of the region and it will benefit the population, serve national interest and further develop the healthcare biotechnology sector. The current need is to attract more research applications for commercialisation of the technologies that have been acquired.

Policy Thrust 3 Industrial Biotechnology Development

There is a growing global concern over environmental issues and increasing emphasis on green and clean technology. The Copenhagen World Summit on Climate Change in 2009 further underscored the international awareness and political will to reduce global emissions and address the issues of climate change. Global chemical companies like DuPont and DSM are switching to biotechnology processes in an effort to go green. Globally, industrial biotechnology contributed around 5% of chemical sales, and this is estimated to reach 20% by 2010, or USD 160 billion[12] (RM 560 billion). In Malaysia, the 2009 contribution of the industrial biotechnology sector is estimated at USD 44.8 million (RM 156.9 million). This is equivalent to 30% of the total revenue of the biotechnology industry. It is expected to be a fast growing sector with Compounded Annual Growth Rate (CAGR) of 10%[13].

As at 30 September 2009, industrial biotechnology companies comprise 20.6% of total biotechnology companies in Malaysia, that is 72 industrial biotechnology companies out of a total of 349 companies. Based on latest 2008 financial reports available[14], industrial biotechnology companies contributed total revenue of USD 44.8 million (RM 156.9 million) which represents 58.3% of the total revenue size of biotechnology industry.

[9] Based on BiotechCorp (as at 31 December 2008) and SSM (31 December 2008 or latest financial reports available)
[10] Based on BiotechCorp (as at 30 September 2009) and SSM (31 December 2008 or latest financial reports available)
[11] Due to unavailability of data for all healthcare biotechnology companies in Malaysia
[12] 6th Annual World Congress on Industrial Biotechnology and Bioprocessing (2009)
[13] Frost & Sullivan Investor Series (2009)
[14] Based on BiotechCorp (as at December 2008) and SSM (December 2008 or latest financial reports available)

Of the 72 industrial biotechnology companies in Malaysia, 20 companies (27.8% of total companies) have obtained BioNexus Status which generated total revenue of about USD 37.9 million (RM 132.6 million) in 2008 as compared to the remaining companies (without BioNexus Status) that generated revenue of USD 6.9 million (RM 24.3 million) which represents 15.5% of total industrial biotechnology sector revenue size.

Total investment for industrial biotechnology companies was USD 297 million (RM 1 billion) based on latest available information[15]. This represents about 36.3% of total investment in the biotechnology industry. A total investment of USD 137.2 million (RM 480.4 million) has been approved for BioNexus Status companies.

One of the key drivers for industrial biotechnology is the presence of an immediate market. In Malaysia, this market is in the oil palm sector as Malaysia is the second largest producer and the largest exporter of palm oil. Hence, industrial biotechnology activities tend to revolve around this sector, as is the case for companies involved in bioremediation (for Palm Oil Mill Effluent), fine and specialty chemicals (oleochemicals and its derivatives from downstream palm oil processing), and biofuel (from olein, crude palm oil, sludge oil and effluent ponds). There is also Intellectual Property (IP) already present from Institutes of Higher Learning (IHLs) and Research Institutes (RIs) for the bioremediation and biocatalyst segments.

Although only 20% of the industrial biotechnology companies are involved in fine and specialty chemicals, this segment alone generated over 94.7% of total revenue in the first nine months of 2009. This was mostly contributed by PureCircle, a public-listed company that produces stevia sugar. The fine and specialty chemicals segment also attracted the largest amount of investment at USD 61.1 million (RM 213.8 million). This is because a large proportion of fine and specialty chemicals that are produced in Malaysia are produced from plant extractions or derived from palm oil. As Malaysia has a large variety of species together with a thriving palm oil industry, the potential in this sector is immense, thus attracting the highest amount of investment into the segment. This is further enhanced by the acquisition of the Supercritical Fluid technology with its applications for extraction and particle formation.

Infrastructure Development

A conducive research and business environment is expected to attract and retain both foreign and local investors, researchers and entrepreneurs. The establishment of appropriate infrastructure will support and strengthen core R&D activities, allow industry linkages between the public sector, private sector and academic institutions, and outline a clear legal infrastructure that governs the orderly development of the biotechnology industry and protects the IP of researchers and companies.

Policy Thrust 4 R&D and Technology Acquisition

There are currently no statistics compiled for the R&D indicators specific to the biotechnology industry in Malaysia. Hence moving forward, a database should be established in order to effectively track R&D indicators in the biotechnology sector. For the purpose of this Country Report, R&D expenditure of BioNexus Status companies has been analysed to provide an overview of the R&D expenditure in the biotechnology industry.

Between October 2008 to September 2009, the total R&D expenditure by BioNexus Status companies amounted to USD 9.3 million (RM 32.6 million). From this, R&D expenditure is highest for healthcare biotechnology companies at 48.5%, followed by agricultural biotechnology companies at 41.1%, while industrial biotechnology companies only recorded 10.4% in R&D expenditure.

While basic and applied research continues as a baseline for developing the Malaysian biotechnology industry, the NBP has recommended adoption of a technology acquisition strategy in accelerating development. The platform technologies acquired for healthcare are the nanotechnology platform from Nanobiotix S.A and DotScan™ antibody microarray diagnostic platform technology from Medsaic; the

[15] Based on BiotechCorp (as at 30 September 2009) and SSM (31 December 2008 or latest financial reports available)

Marker Assisted Selection platform technology from DNA LandMarks for agricultural; and the Supercritical Fluid technology with applications for extraction and particle formation from FeyeCon for the industrial biotechnology sector.

While there is a need for baseline R&D to continue, it is suggested that emphasis should be given to the development component for the purposes of commercialisation. The immediate need for the country is to utilise and adapt the current research and IP for practical use in the industry, and to encourage the take up of applied and developmental research. As part of the NBP implementation, BiotechCorp has put in place a platform, the IGNITE programme, to identify research and IP that are readily available for commercialisation. Under this programme, local R&D was evaluated and assessed by global experts from Cambridge who revealed that more than 80% of the work done was actually business worthy. Another notable programme is the collaboration with the Larta Institute Global Bridge Programme for Commercialisation Assistance Programme which provides commercialisation and innovation expertise, effective training and showcase platforms for IHL spin off companies to connect with investors and industry partners.

Other initiatives implemented include the BioNexus Partner Programme (BNP) which is a network of 37 BNP laboratories in public IHLs and RIs, technology parks, incubators and GLCs to accommodate the needs of the biotechnology industry by giving priority access to the industry, especially BioNexus Status companies. Another notable effort is BiotechCorp's Triple Helix database which is an online portal to encourage cooperation between researchers, biotechnology companies and the government for commercialisable life science projects / products.

Policy Thrust 5 Human Capital Development

Similar to most industries that are knowledge-based or that require specialised skills, the biotechnology industry faces human capital gaps in terms of numbers, skills and expertise. It is estimated that a workforce of 100,000 knowledge workers will be required to support the biotechnology industry, which translates into 280,000 additional jobs supporting the industry by year 2020[16]. The NBP has outlined a number of strategies and actions in addressing these industry needs.

According to Malaysia's Deputy Foreign Minister, 304,358 Malaysians (including 50,000 students) left the country between March 2008 and August 2009; double the number of Malaysians who left the country in 2007[17]. The reasons for their departure and preference to work abroad are multi-faceted, but the most often-quoted reason is the search for better education, career and business prospects.

Besides the brain drain issue faced by the country, retention of talents is also an ongoing challenge as it can be difficult to match job demands and description with the individual's expectations. In the Malaysian biotechnology industry, there is much emphasis on operational, applied or process improvements, and development. Although these may not be the researchers' core interest, such emphasis provides them with generally marketable skills. As a result, they are able to apply these skills to other industries and subsequently leave the biotechnology industry. In a recent survey of biotechnology human capital development, approximately 43% of the respondents indicated that they will select a biotechnology career which is relevant to their interest as this helps create motivation. Furthermore, 16.7% of the respondents indicated that they will not remain in the biotechnology job if it is irrelevant to their area of interest[18].

The NBP highlighted a number of key efforts to develop a highly skilled and motivated workforce. This includes the Government's "Brain Gain" programme which has been designed to attract and retain talents in the country including areas of biotechnology.

[16] National Biotechnology Policy (2005)
[17] The Star Online (4 December 2009)
[18] BiotechCorp

Although IHLs are the key institutions developing human resources for the biotechnology industry, BiotechCorp supplements the effort by implementing programmes to address the lack of critical mass of professionals, scientists and engineers, hands-on skills particularly in lab techniques and equipment, and entrepreneurship within the industry such as the Biotechnology Entrepreneurship Special Training (BeST) programme and Post-Doctoral Research Programme. BiotechCorp has designed several high impact programmes for this purpose:

- National Business Incubation Association (NBIA): Provide comprehensive set of training to enhance skills and gather tools for incubator managers
- California Institute of Quantitative Bioscience (QB3): Provides a comprehensive course in bioentrepreneurship tailored to the needs of professionals in the biotechnology industry
- Office of Technology Licensing, Stanford University: Provide exposure and experience to directors and key personnel from IHLs and RIs technology transfer offices (TTOs) to acquire key competencies

Policy Thrust 6 Financial Infrastructure Development

There is a need to continuously provide adequate and multiple rounds of funding along the value chain of the biotechnology industry. However, one of the critical issues faced by the industry is the lack of financial resources to support the industry development. Current biotechnology and related funds available for the industry are inadequate to meet the developmental goals set out in the NBP. There is a need to promote industry confidence to attract greater private funding participation.

The NBP has outlined a comprehensive and efficient financial infrastructure plan for the implementation of the policy. Both the public and private sectors played significant roles in funding the Malaysian biotechnology industry. Government funding supports the initial stages of pre-R&D and R&D as well as early stage commercialisation while the Venture Capitalists (VCs) and Development Financial Institutions (DFIs) funding support early stage commercialisation or pre-commercialisation (excluding R&D) and commercialisation stage.

The Malaysian Government has made a financial commitment by allocating USD 571.4 million (RM 2 billion) under RMK-9 to fund the development of the industry. Of this amount, close to 46% of the allocation is for physical infrastructure development channeled to all RIs and IHLs through the five-year development budget. The remaining amount is allocated as "soft" infrastructure budget, made available through several public sector bodies in the form of grants, equities and loans to undertake research and related activities but also funding for start-up as well as expansion and growth. In addition, the Government allocated USD 371.1 million (RM 1.3 billion) for biotechnology development under the First and Second Stimulus Package in 2008 and 2009.

Continued Government support in the form of public funding is still required to build industry confidence. However, there is a need to revisit current public funding policies and guidelines so that industry players have access to more public funds for early stage commercialisation and commercialisation funding. In addition, there is a need to have more private funds available for early stage commercialisation and commercialisation funding.

In today's global economic climate, it is becoming increasingly challenging to raise funds via IPO. There was only one biotechnology company listing in the United States in 2008, none in Canada, three in Japan and two in China[19]. In Malaysia, two biotechnology companies have successfully launched their IPOs in 2008, namely Sunzen Biotech and Asia Bioenergy Technologies, raising USD 6 million (RM 20.9 million). As at 31 December 2009, there were 13 life sciences companies (including biotechnology companies) listed on the Main Board and Access, Certainty, Efficiency (ACE) Market of Bursa Malaysia.

In 2008, BiotechCorp undertook efforts to strengthen the availability of funding along the value chain of the biotechnology industry. Prior to the economic crisis in September 2008, private local and foreign investors (corporate and financial institutions) were keen on providing a sizeable fund of close to USD 500 million (RM

[19] Ernst & Young Beyond Border (2009)

1.5 billion) for investment in the industry. The fund size was planned to be integrated with selected local investors and its priority was on BioNexus Status companies. Even though the funds were not raised due to the economic crisis, there is still ongoing discussion to reassess their involvement in funding the biotechnology industry.

BiotechCorp has also continuously engaged the financial and investment communities in the Asia Pacific and Middle East regions to create awareness of the biotechnology industry in Malaysia. The BioFunding Conference was organised in August 2009 and targeted at the financial and investment communities to increase their awareness and understanding of the biotechnology industry.

As part of promoting financial and investment opportunities, BiotechCorp and UEM Land Holdings, a PPP arrangement, signed a joint venture agreement in September 2009 to develop a global biotechnology ecosystem known as Bio-XCell in Iskandar Malaysia, Johor. Bio-XCell is the creation of a dedicated biotechnology park with ready-built and customised commercial scale shared facilities to encourage commercial developments, R&D and production of industrial and pharmaceutical biotechnology products.

Policy Thrust 7 Legislative and Regulatory Framework Development

Malaysia's ranking in terms of IP rights enforcement has improved to number 27 in 2009 compared to number 33 in 2008. Concerted effort and continued focus should be given to the area of IP protection. Awareness in terms of patent protection and recognition of its value and importance has risen in Malaysia and the number of patents in force per 100,000 populations has improved in Malaysia in 2009.

Regulations pertaining to pharmaceuticals in Malaysia are relatively well-developed and stable and are under the purview of the MOH. Active participation of Malaysia in the various regulatory harmonisation initiatives regionally and globally augurs well for industry players in terms of regulatory certainty and ease of export.

Although there are currently no domestic Access Benefit Sharing (ABS) laws, it is anticipated that the national level laws on ABS will be in the pipeline in the near future. This is in view of the developments in the international front for example the progress made in the recent Access Benefit Sharing Working Group 8 (ABS WG8) in Montreal, November 2009 and the importance of this subject to Malaysia.

In ensuring that the country remains competitive and is favoured as a country of choice for research, development and manufacturing activities, Malaysia has adopted and implemented international standards relating to Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and also Good Laboratory Practice (GLP). With regard to GLP compliance, it is also worth noting that Malaysia has been a provisional adherent to the Organisation for Economic Co-operation and Development (OECD)'s Mutual Acceptance of Data (MAD) system since 2008 and is currently focusing her endeavours towards becoming a full adherent to the OECD MAD system.

In relation to biosafety, it is recognised that laws which seek to safeguard public safety could be promulgated whilst also taking into account the developmental goals of the nation as eschewed under the NBP and other related national policies. This balanced approach should be the way forward for Malaysia and constructive engagement between policy and law makers, regulators, industry developers, the industry and all other stakeholders should continue to take place so as to fully realise Malaysia's roadmap towards 2020 and beyond.

Policy Thrust 8 Strategic Development

One of the critical success factors in the development of the biotechnology industry is industry knowledge. Industry knowledge, in this context, refers to general public awareness and knowledge of biotechnology and its applications in the various sectors. Having such knowledge will help to reinforce the needs and expectations of consumers at large, which will in turn drive the demand for greater use of biotechnology.

Attractiveness of market potential will create greater business opportunities for all industry stakeholders.

Besides industry knowledge creation, there is a need for Malaysia to build international recognition of its biotechnology industry and to find a niche in the global biotechnology value chain in order to achieve the overall objectives of the NBP. Building global branding for global market access and foreign direct investment (FDI) participation is one of the strategic imperatives in enabling the implementation of the priority actions identified in the other policy thrusts.

Being the lead agency in implementing the NBP, BiotechCorp has undertaken a number of programmes aimed at achieving global branding and creating public awareness and knowledge. These programmes include BioBusiness Partnering Programme, BioMalaysia, BioCareer, BioUsahawan and Biotech Jom Heboh.

In addition, BiotechCorp participates in the annual BIO conference in the U.S. with the view of showcasing Malaysian biotechnology companies, facilitating business matching and seeking insights into latest developments in biotechnology. Participation in BIO 2008 San Diego facilitated the completion of six international collaborations with total expected investment of USD 0.3 billion (RM 1 billion).

Policy Thrust 9 Government Support and Commitment

Ministry of Science, Technology and Innovation (MOSTI) is the ministry which has overall responsibility for the NBP. BiotechCorp is the lead agency under the purview of MOSTI that is responsible for the coordinated implementation of the NBP. Since 2005, the implementation framework has been implemented through three levels of governance: Biotechnology Implementation Council (BIC), BiotechCorp and the Biotechnology International Advisory Panel (IAP). The BIC and IAP have advisory roles whereas BiotechCorp is the implementation agency.

In addition, the Government has put in place an approach to creating a biotechnology network within Malaysia.

Strategic Direction

In meeting the development goals of the NBP, the overall strategic direction of the Malaysian biotechnology industry that is aimed at wealth creation and social well-being remains unchanged. Biotechnology is the key enabler for the development of agriculture, healthcare and industrial sectors in line with the global trends in green technology. Malaysia's tropical biodiversity and abundant natural resources provide a competitive advantage for the development of the industry. In addition, the industry is expected to develop based on Malaysia's strength in manufacturing and outsourcing capabilities complemented with strong Government support and commitment to continuously improve supporting infrastructure required for the industry.

Moving into year 2010 and beyond, it will be critical to translate scientific results to business performance. The remainder of Phase I in 2010, and beyond in Phase II, is an important period to ensure the success of the NBP implementation. During this period, while efforts should continue to build capacity as outlined in the NBP, highest priority should be given to focus on key actions that would contribute significantly to GDP growth. Priority actions are therefore being identified based on the following critical success factors moving forward:

- Generation of quick results (bringing science to business) through intensification of commercialisation efforts
- Availability of skilled and experienced knowledge workers to meet industry specific needs
- Adequacy and availability of second stage funding growth and expansion
- Effectiveness of globalisation strategy (globalisation of emerging companies and FDI participation)
- Coordinated inter-ministerial development and implementation of Government policies

Priority Actions Moving Forward

Policy Thrust 1: Agricultural Biotechnology Development

Continue effort in developing crop-related biotechnology, livestock biotechnology, marine / aquaculture biotechnology and natural products

Besides addressing domestic needs, there is tremendous regional and global market potential for crop-related biotechnology. There is a need for continued commitment from the Government in building capacity and capability to further develop the agricultural biotechnology sector. Malaysia should continue to focus on the production and utilisation of improved planting materials that are produced through tissue culture, production of organic biofertilisers from palm oil biowaste that epitomises the waste to wealth concept, and the research and utilisation of effective microbes from Malaysia's rich biodiversity.

As part of the NBP's strategy, the acquisition of the Marker Assisted Selection platform technology is expected to accelerate development of capacity and capability in crop-related biotechnology. Models for rice, watermelon and goats are being developed for application in related breeding programmes.

The use of assisted reproductive techniques and the production of animal feed and vaccines should continue thereby improving productivity in the livestock segment. In addition, the way forward is to develop multiplier farms to ensure the continuous supply of selected animals from nucleus farms to commercial farms.

In order to create a sustainable biotechnology ecosystem with its supporting industries that can meet the country's needs and add value to the economy, capacity needs to be built in the marine / aquaculture biotechnology segment. It is proposed that more companies be encouraged to enter the marine and aquaculture segment, particularly in the fish, seaweed and algae sub-segments.

Malaysia has a wealth of traditional knowledge in herbal and medicinal plants, and a treasure trove of flora and fauna which remains largely unexplored. Currently in Malaysia, there are ongoing efforts to discover novel and bioactive compounds from natural resources that can be extracted, formulated, developed and commercialised into ethnic herbal products, food ingredients, functional food, cosmeceuticals, nutraceuticals and botanical drugs. Gearing up towards Phase II of the NBP, Malaysia should continue its efforts in this segment.

The acquisition of the Supercritical Fluid platform technology from FeyeCon is the first step undertaken to address the need to enhance its evidence-based platform in developing natural products.

Implement a suitable business model for commercialisation of applications of newly acquired platform technologies

Moving into Phase II of the NBP, it is critical to generate greater value from the investments of the Malaysian Government in acquiring these platform technologies. Commercialisation of applications and the development of products from the said platform technologies will require adoption of a suitable business model to be in place. BiotechCorp has already proposed a business model for implementation moving forward.

Implement global strategy for home-grown players

In the development of the agricultural biotechnology sector, Malaysian players are well positioned as key global players given Malaysia's reputation and market position in the agriculture sector, especially in primary commodities and the plantation sector. Home-grown players such as Sime Darby, IOI and Felda are major plantation companies globally. Malaysia should therefore leverage on such reputation to develop a global strategy for agricultural biotechnology. Efforts should continue in the development of Malaysia as regional and global player in this sector with emphasis on tropical agricultural biotechnology.

Policy Thrust 2: Healthcare Biotechnology Development

Intensify effort in developing and promoting Malaysia as a regional outsourcing centre for CMOs and CROs

The focus on pharmaceuticals (e.g. production of biosimilars or vaccines), medical devices and diagnostics for CMO initiatives in Malaysia will allow access to complementary technologies and capabilities to build biomedical manufacturing expertise to support future biotechnology growth and to attract global FDIs. In addition, CMOs in Malaysia will enable existing and emerging biotechnology companies to integrate CMOs into their business model to quickly reach commercial scale, reduce capital expenditure, and attain greater overall flexibility.

The opportunities in Malaysia for the growth of its CRO segment lie in its ability to leverage on the country's diverse ethnicity patient pool in the areas of diseases and illnesses. In order for the nation to extensively participate in multinational pharmaceutical companies' clinical trials, there is a need to ensure that the necessary experience, knowledge and infrastructure are present to support the CROs.

Implement research initiatives to develop more applications for commercialisation

In order to continuously develop healthcare biotechnology for greater value creation, there is a need to attract more research applications for commercialisation. In order to capitalise on the enormous potential of stem cell research and therapies, industry players are already undertaking research to develop therapeutics for commercialisation. Besides stem cell research and therapies, there is a continued growing trend for medical devices and IVD given Malaysia's strong manufacturing capabilities and market potential in this segment.

The nanotechnology and DotScan™ antibody microarray diagnostic platform technologies are essentially research tools that can be used as diagnostics and to develop applications for drug delivery, with the emphasis on treating local diseases. However, focused research is still needed before the applications can be developed for commercialisation. Having acquired these platform technologies, the current need is to attract more research applications and development of products of substantial commercial value arising from utilisation of the said technologies.

Leverage on local capabilities to intensify public-private partnership

In order to effectively implement the specific actions identified to develop the various segments, it is proposed that a public-private partnership (PPP) model be adopted through strategic partnerships and collaborations.

Implement globalisation strategy

Unlike the development of the agricultural biotechnology sector, development of the healthcare biotechnology sector requires to attract global players or FDIs into Malaysia.

Policy Thrust 3: Industrial Biotechnology Development

Accelerate development of technology for effective implementation of green chemistry initiatives

Given Malaysia's competitive advantage in the palm oil industry in the international arena, biofuel is another area that has captured the attention of the Malaysian industrial biotechnology community. There is immense potential in biofuel as it is driven by the global trend to reduce greenhouse gas emissions and decrease dependence on the dwindling reserves of fossil fuel. The abundance of biomass from its oil palm sector can also be leveraged on in the production of biofuel. It should be noted that Malaysia is the coordinating country for promoting biofuel for the ASEAN countries.

As a signatory to the United Nations Framework Convention of Climate Change (UNFCCC), Malaysia has ratified the Kyoto Protocol in 2002 and has implemented an institutional framework to support Clean Development Mechanism (CDM) activities. Through the CDM, Malaysia can benefit from investments in the greenhouse gas emission reduction projects, especially in the areas related to the palm oil sector. Furthermore, there are readily available IPs that can be developed for commercialisation, thereby providing opportunities for development of new entrants.

The fine and specialty chemicals segment is expected to leverage on the oil palm plantation sector and Malaysia's rich biodiversity. Malaysia, as a mega biodiversity country, presents opportunities for bioprospecting and the discovery of novel bioactive compounds associated with the medicinal properties of herbs and plants, for nutraceutical and pharmaceutical products. Other end products include food ingredients, cosmeceuticals, flavours and fragrances. The extraction of novel bioactive compounds or Active Pharmaceutical Ingredients (APIs) is aided by BiotechCorp's acquisition of the Supercritical Fluid technology with applications for extraction and particle formation.

Malaysia should also focus on developing its biopolymer segment in order to capitalise on its existing market share, the changing external landscape and the strong push for bioplastics. There is growing demand worldwide for the use of bioplastics and biodegradable plastics in packaging.

Build shared facilities to scale up commercialisation

Some of the key barriers to the development of the industrial biotechnology sector are the lack of know-how and experience in the scaling-up process, limited production capacity and efficiency of infrastructure and the high costs of setting up commercial scale facilities. As part of the initiative to support the development of industrial biotechnology sector, the set up of shared facilities for outsourcing services is equally critical given the amount of investment required to set up such facilities.

The acquisition of Supercritical Fluid platform technology has enabled large scale extraction of novel bioactive compounds or APIs with high purity and uniformity for the purpose of scale up commercialisation.

The development of industrial biotechnology requires significant foreign collaboration for technology and knowledge transfer, and thus the need for concerted effort in attracting global companies to set up operations in Malaysia. The Bio-XCell strategy is to prepare infrastructure in both the form of ready-built and customised commercial scale shared facilities that are available for lease to interested companies.

Leverage on local capabilities to intensify public-private-partnership

Besides FDIs, there is a need to leverage on local conglomerates such as Petronas, CCM, Genting and Sime Darby to drive development of industrial biotechnology. These large home-grown companies should take a leading role in driving green initiatives.

Policy Thrust 4: R&D and Technology Acquisition

Continue acceleration of commercialisation efforts

There is a need to effectively implement the proposed business operating model in order to emphasise on the priority of developing research or new applications for commercialisation of the following four platform technologies.

- The platform technologies acquired for healthcare are the nanotechnology platform from Nanobiotix S.A. and DotScan™ antibody microarray diagnostic platform technology from Medsaic, the Marker Assisted Selection platform technology from DNA LandMarks for agriculture, and the Supercritical Fluid technology from FeyeCon for industrial biotechnology.

Therefore, appropriate allocation of resources, in terms of financial, infrastructure support and human capital must be put in place for effective commercialisation efforts.

There should be continued efforts to expedite commercialisation of readily available IPs of public RIs and IHLs by:

- Building a knowledge sharing infrastructure that enables publication of IPs to attract industry interest in joint collaboration for commercialisation
- Leveraging on the IGNITE programme that enables external validation of the commercial value and business worthiness of research and IP

Leveraging on the Global Bridge Malaysia Commercialisation Assistance Programme with the Larta Institute, U.S.

Continue strengthening TTOs for effective collaboration

Moving forward, TTOs are expected to align their respective policies with the Intellectual Property Commercialisation Policy, taking into account the differing legal status and services offered. It is proposed that MOSTI's involvement would be required to conduct briefing sessions with the TTOs in various RIs and IHLs on how to align their respective policies with the national policy, also considering the feasibility and technicalities of the actual implementation. TTOs are recommended to promote the policy in their respective organisations despite the differing legal status and services offered. As BiotechCorp has already established a link with the TTOs, it should continue to facilitate this initiative.

Policy Thrust 5: Human Capital Development

Continue enhancing higher learning curriculum

While there is ongoing effort to enhance the higher learning curriculum to meet the country's needs, there is currently an urgent need to address gaps in the biotechnology industry. Although BiotechCorp continues to execute its programmes to provide the relevant training required by the industry, it is unlikely that BiotechCorp will be able to train graduates with the speed and volume to match industry needs in the near or longer term.

It is therefore proposed the immediate actions be undertaken to work with selected priority IHLs to develop and conduct training programmes as pre-requisites for graduation. Where possible, the current curriculum should be immediately modified to incorporate certain industry requirements.

Continue strengthening TTOs for effective collaboration

Although the success of the "Brain Gain" programme has yet to be clearly determined, it has been noted that the programme has not been able to fully meet the expectations of those talents who were attracted back to Malaysia. Most talents (including those of overseas returnees) usually have high expectations of infrastructure facilities (e.g. research and laboratory facilities), career progression as well as a progressive living and working environment.

Policy Thrust 6: Financial Infrastructure Development

Continue public investment in physical infrastructure

Government investment into physical infrastructure is important as it demonstrates its commitment towards developing the Malaysian biotechnology industry.

Strengthen public funding for pre-commercialisation and subsequent stages of commercialisation

Ongoing allocation for pre-R&D and R&D funding should continue. However, given the lack of private funding for pre-commercialisation and subsequent stages of commercialisation, there is a need to continue allocation of public funding for these two stages.

It is proposed that the Government continues to support the industry by allocating funds for the provision of soft loans (with no / minimal interest, or based on Islamic principles) to both the Malaysian and foreign biotechnology companies based in the country.

Raising funds through an IPO exercise is an alternative for biotechnology companies but it is an expensive venture. Hence, it is proposed that a dedicated Government fund, e.g. Biotechnology Funding Access Fund, be established to reimburse listing fees / charges for eligible biotechnology companies. The preference of the listing exercise is for the Malaysian capital market.

BiotechCorp is expected to continue to encourage industry players to develop the required skill-sets by providing training grants for eligible BioNexus Status companies.

Intensify public-private partnership

Besides FDIs, there is a need to encourage local large and established companies to drive the development of the local biotechnology industry.

Set up new venture fund with foreign participation

The local VC market continues to develop in accordance to the Financial Services Master Plan. The biotechnology industry requires strong foundation support from the VCs during pre-commercialisation and commercialisation stages.

There is a need to attract greater participation from foreign VCs that specialise in biotechnology industry. In order to attract foreign VCs, it is proposed that a new venture fund be set up by local and foreign VCs which will be matched by Government funding.

Focus on nurturing and developing top performing companies

Showcasing successes will be critical moving forward into Phase II of the NBP, and success tends to be measured on the basis of a company's business performance. It is therefore vital for the lead agency, BiotechCorp, to place emphasis on nurturing and developing potential top performing BioNexus Status companies.

Thrust 7: Legislative and Regulatory Framework Development

Execute plans in the pipeline

It is proposed that plans in the pipeline be executed as part of the continuous enhancement of Malaysia's legislative and regulatory framework to provide a conducive environment for the development of the biotechnology industry.

Thrust 8: Strategic Development

Intensify global branding of biotechnology companies

BiotechCorp complements the globalisation strategy for Malaysia's biotechnology industry through international branding and intensified marketing to reinforce awareness and build Malaysia's biotechnology brand.

Continuously improve public awareness programmes to build industry confidence

BiotechCorp, being the lead agency responsible for the coordinated implementation of Malaysia's biotechnology industry, undertakes relevant programmes (such as BioMalaysia, BioCareer and BioUsahawan) to promote and enhance public awareness and to demonstrate the opportunities and contribution of the local biotechnology industry. These efforts should continue.

Thrust 9: Government Support and Commitment

Continuously improve inter-ministerial coordination

Although a comprehensive implementation framework has been put in place to integrate inter-ministerial coordination, there is a need to continuously improve inter-ministerial coordination in developing the biotechnology industry.

Continuously improve the biotechnology network

There is a need to continuously improve the implementation of the biotechnology network. This will meet the objective of effectively developing and integrating all relevant stakeholders to ensure a vibrant biotechnology community in the country. The key area that needs improvement is essentially the alignment of the biotechnology network development.

Implementation Plan

Moving forward into Phase II of the NBP, it is critical to closely and effectively monitor the implementation of

- Prescribes a mechanism for coordinating the implementation of proposed actions
- Provides broad guidelines for regular implementation monitoring and progress reporting
- Describes the communication programme to disseminate and obtain feedback on the proposed actions and implementation progress

Chapter 1
The Biotechnology Industry in Malaysia

Chapter 1 The Biotechnology Industry in Malaysia

The Malaysian Government has identified biotechnology as one of the core technologies to accelerate the transformation of Malaysia into a knowledge-based economy and an industrialised nation by year 2020. For this purpose, the National Biotechnology Policy (NBP) was launched in 2005 to use biotechnology as an enabling tool to further develop three sectors namely agricultural, healthcare and industrial. From the combined efforts of developing the three sectors, Malaysia's biotechnology industry is expected to contribute 2.5% of the national gross domestic product (GDP) by 2010, 4% by 2015 and 5% by 2020.

The NBP is to be implemented over three phases: Phase I – Capacity Building (2006-2010), Phase II – Science to Business[1] (2011-2015), and Phase III – Global Business (2016-2020). Malaysian Biotechnology Corporation (BiotechCorp) is the lead agency responsible for the coordinated implementation of the NBP. Table 1-1 provides an overview of the key development goals set for implementation of the NBP over the three phases of the implementation period from 2006 to 2020.

Table 1-1: National Biotechnology Policy – The Development Goals (2006-2020)

Development Goals	Phase I (2006-2010) Capacity Building	Phase II (2011-2015) Science to Business	Phase III (2016-2020) Global Business	Progress To-date 2009*
Investment by Government and private sectors				
USD billion	1.7	2.6	4.3	1.3
RM billion	6.0	9.0	15.0	4.5
Total Employment	40,000	80,000	160,000	54,000**
Contribution to GDP (%)	2.5	4.0	5.0	2.0***

Note: Ratio of Government to private sector investment is 70:30 (Phase I) and progressively moves to 30:70 ratio (Phase III)
Sources:
(1) National Biotechnology Policy (2005)
(2) BiotechCorp
(3) JobStreet Malaysia
** Estimated for 2009*
*** Total employment figure covers the life science and biotechnology-related industry*
**** Estimated based on revised assumptions*

Since the launch of the NBP in 2005, the Malaysian biotechnology industry has recorded a total investment of USD 1.3 billion (RM 4.5 billion) by 2009. Out of this investment, 57.8% was funded by the Government while the remainder was funded by the private sector. The contribution of the biotechnology industry towards the GDP in 2009 was estimated at 2%. In terms of total employment, it is estimated that 54,000 people were employed in the life science and biotechnology-related industry in 2009[2]. In tandem with the anticipated increase in private investment in 2010, total employment is also expected to increase to both directly and indirectly support the biotechnology industry.

At A Glance

As at 30 September 2009, a total number of 349 biotechnology companies were identified in Malaysia, a three-fold increase from 117 companies in 2005. Out of the 349 biotechnology companies identified, 41% was involved in the agricultural biotechnology sector followed by the healthcare biotechnology sector with 38.4% and the remaining in the industrial biotechnology sector at 20.6% (see Table 1-2).

[1] The original term in the NBP is "Lab to Market"
[2] JobStreet Malaysia (2009)

Table 1-2: Malaysian Biotechnology Industry Overview

Sector	Number of Companies*	Revenue		Investment	
		USD million	RM million	USD million	RM million
Agricultural Biotechnology	143	57.9	202.7	287.5	1,006.3
Healthcare Biotechnology	134	47.4	165.8	235.1	822.8
Industrial Biotechnology	72	44.8	156.9	297.6	1,041.6
Total	**349**	**150.1**	**525.4**	**820.2**	**2,870.7**

Source:
(1) BiotechCorp (as at 30 September 2009)
(2) SSM (as at 31 December 2008 or latest financial reports available)
** as at 30 September 2009*

The larger representation of agricultural companies in the Malaysian biotechnology industry can be attributed to the country's traditional strength in the agriculture sector. For the healthcare biotechnology sector, there are higher barriers of entry such as extensive product regulations and procedures, while the industrial biotechnology sector requires larger capital investments.

In terms of sectoral contribution, agricultural biotechnology is the largest revenue contributor at 38.6% with the largest number of companies (143 out of 349 companies). Healthcare biotechnology accounted for 31.6% of total revenue followed by industrial biotechnology at 29.8%.

Of the total investment, the industrial biotechnology sector has the highest investment dollars with close to USD 300 million (RM 1 billion) (see Table 1-2). Total investment in agricultural and healthcare biotechnology sectors is USD 287.5 million (RM 1 billion) and USD 235.1 million (RM 822.8 million) respectively.

In terms of ownership of companies, more than 200 of them are owned by Malaysians (see Table 1-3). The agricultural biotechnology sector has the largest number of Malaysian-owned companies (45%). As discussed earlier, this is largely due to the country's traditional strength in the agricultural sector. The healthcare biotechnology companies have a large percentage of foreign ownership (52.9%). This is largely due to the dependency on foreign technology and expertise.

Table 1-3: Ownership of Malaysian Biotechnology Companies (30 September 2009)

Sectors	Domestic*		Foreign**		Total Number of Companies	%
	No. of Companies*	%	No. of Companies*	%		
Agricultural Biotechnology	118	45.0	25	28.7	143	41.0
Healthcare Biotechnology	88	33.6	46	52.9	134	38.4
Industrial Biotechnology	56	21.4	16	18.4	72	20.6
Total	**262**	**100.0**	**87**	**100.0**	**349**	**100.0**

Note:
** Refers to 100% Malaysian-owned companies*
*** Includes companies that are fully-owned by foreigners, partially owned by foreigners as well as listed companies.*
Sources:
(1) BiotechCorp (as at 30 September 2009)
(2) SSM (as at 31 December 2008 or latest financial reports available)

Number of Companies

Prior to the launch of the NBP, 117 biotechnology companies were identified in Malaysia during the Ninth Malaysian Plan (RMK-9). This number of companies was based on a wide definition adopted by the Malaysian Department of Statistics (DOS) during the Census of Establishment and Enterprises conducted in 2005. The definition used was "biotechnology-related companies involved in the biotechnology service and manufacturing sectors such as biotechnology research and development (R&D); biotechnology manufacturing of own biotechnology productions or operations; purchase of biotechnology products or processes from others and sales of biotechnology materials (inclusive of repackaging, distribution and marketing of biotechnology products), and re-use of biology or renewable materials".

The NBP is aimed at increasing business activities in the biotechnology industry. A corresponding increase in the number of biotechnology companies in the country is expected. For the purpose of this Country Report, three sources[3] were used to estimate the current number of biotechnology companies in Malaysia: (a) total number of biotechnology companies granted BioNexus Status[4] by the Malaysian Government, (b) total number of biotechnology companies[5] applying for BioNexus Status, and (c) total number of biotechnology companies that received financial aid (funding and loans) or infrastructure support from the Government such as the Ministry of Science, Technology and Innovation (MOSTI), Malaysian Technology Development Corporation (MTDC), Technology Park Malaysia (TPM) and Malaysia Life Science Capital Fund (MLSCF), as well as other companies identified from secondary published sources[6]. Collectively, companies identified through sources (b) and (c) are known as "non-BioNexus Status" companies. R&D departments residing within the multinational corporations (MNCs) are excluded in the tabulation of the number of biotechnology companies because they are not registered with the Companies Commission of Malaysia (SSM) as a separate business entity.

Based on the three sources described, these biotechnology companies are either involved in pure R&D and manufacturing of biotechnology products or provide support for the biotechnology industry such as sales and distribution of biotechnology products but have the potential of moving into core biotechnology business, the definition of which maps closely to the one adopted during RMK-9.

Out of the 349 biotechnology companies, a total of 126[7] have been granted BioNexus Status as at 30 September 2009. This represents about 36.5% of the total number of biotechnology companies in Malaysia. The growth of BioNexus Status companies has been encouraging from the initial total of seven companies in 2006. The biggest growth is in the agricultural biotechnology sector with 55 companies as at 30 September 2009 (see Table 1-4). The healthcare and industrial biotechnology sectors also experienced significant growth. This growth trend is consistent with the distribution of biotechnology companies in Malaysia as described earlier.

Table 1-4: Growth of BioNexus Status Companies in Malaysia (2006-2009)

Sectors	2006	2007	2008	Sept 2009	Compounded Annual Growth Rate (CAGR) (%)
Agricultural Biotechnology	1	16	37	55	280
Healthcare Biotechnology	4	21	39	51	134
Industrial Biotechnology	2	5	16	20	115
Total	**7**	**42**	**92**	**126***	**162**

Source: BiotechCorp
** As at 31 December 2009, total number of BioNexus Status companies has increased to 151 companies*

The collective market capitalisation of four BioNexus Status companies exceeded USD 628.6 million (RM 2.2 billion) in 2009. BioNexus Status companies are listed not only on Bursa Malaysia but also on the London Stock Exchange and the Australian Stock Exchange. In 2009, Holista Biotech (Holista), a BioNexus Status company, completed its takeover of Colltech Australia, a listed company on the Australian Stock Exchange.

[3] Since 2005, DOS has not conducted a new Census of Establishment and Enterprises, hence three sources were used to help estimate the current number of the biotechnology companies in Malaysia
[4] BioNexus Status companies are those biotechnology companies that have been approved by the Government to be granted with Bill of Guarantees for the development of biotechnology focus areas
[5] Inclusive of companies with minimal biotechnology activities presently
[6] For example, Biofuel Annual Report 2009 and BiotechCorp Website
[7] Inclusive of those pending approval from the Malaysian Government

Revenue

Based on the latest financial reports available for 2008[8], the revenue size of the Malaysian biotechnology industry was estimated at USD 150.1 million (RM 525.4 million) in 2008 (see Table 1-5). The BioNexus Status companies contributed more than 70% of the revenue, led by companies such as PureCircle and All Cosmos Industries.

Table 1-5: Revenue Contribution in the Malaysian Biotechnology Industry (2008)

Sectors	BioNexus		Non-BioNexus		Total Revenue		Percentage (%)
	USD million	RM million	USD million	RM million	USD million	RM million	
Agricultural Biotechnology	45.5	159.1	12.4	43.6	57.9	202.7	38.5
Healthcare Biotechnology	24.9	87.0	22.5	78.8	47.3	165.8	31.5
Industrial Biotechnology	37.9	132.6	6.9	24.3	44.8	156.9	30.0
Total	**108.2**	**378.7**	**41.8**	**146.7**	**150.1**	**525,4**	**100.0**

Sources:
(1) BiotechCorp (as at 31 December 2008)
(2) SSM (as at 31 December 2008 or latest financial reports available)

Amongst the BioNexus Status companies, total revenue contribution was USD 108.2 million (RM 378.7 million) in 2008, and was expected to grow in 2009. In the first nine months of 2009, the BioNexus Status companies recorded revenue growth of 36.9% with USD 101.6 million (RM 355.6 million) compared to USD 74.2 million (RM 259.6 million) during the same period in 2008 (see Table 1-6). 60% of the revenue is generated from export sales. This growth revenue trend is in tandem with the growth in the number of BioNexus Status companies during the same period as discussed earlier. BioNexus Status companies in the industrial biotechnology sector registered the highest revenue growth at 120.8% between the first nine months of 2008 and 2009.

Table 1-6: Total Revenue of BioNexus Status Companies in Malaysia (2007-2009)

Sectors	2008		Jan-Sep 2008		Jan-Sep 2009		Percentage Growth (%)
	USD million	RM million	USD million	RM million	USD million	RM million	
Agricultural Biotechnology	45.5	159.1	34.9	122.2	31.7	110.8	-9.2
Healthcare Biotechnology	24.9	87.0	17.7	61.9	22.2	77.7	25.4
Industrial Biotechnology	37.9	132.6	21.6	75.5	47.7	167.1	120.8
Total	**108.2**	**378.7**	**74.2**	**259.6**	**101.6**	**355.6**	**36.9**

Source: BiotechCorp

The healthcare biotechnology sector also registered a positive revenue growth (25.4%) although at a lower rate compared to the industrial biotechnology sector. This is probably due to the fact that a large number of these companies are still at the R&D stage and have yet to be fully commercialised, such as those that are involved in therapeutics and biopharmaceuticals. Majority of the revenue generated is from healthcare biotechnology companies involved in medical devices and in vitro diagnostics (IVD) segment. On the other hand, the agricultural biotechnology sector registered a decline in revenue of 9.2% in the first nine months of 2009.

[8] Based on BiotechCorp (as at 31 December 2008) and SSM (31 December 2008 or latest financial reports available)

Investment

The Malaysian Government has been instrumental in providing public funding for the biotechnology industry development since the Eigth Malaysian Plan (RMK-8) with USD 164.1 million (RM 574.4 million). The largest public funding was during the RMK-9 period with an allocation of USD 571.4 million (RM 2 billion). This allocation included spending for R&D, commercialisation, business development programmes as well as infrastructure development. In addition, the Government allocated USD 371.1 million (RM 1.3 billion) for biotechnology development under the First and Second Stimulus Package in 2008 and 2009.

Private investment into biotechnology companies can either be direct investment (both local and foreign) via equity capital, reinvested earnings, intra-company loans or capital injection in the form of technology and expertise. Based on sources available, total investment in the Malaysian biotechnology industry was estimated at USD 820.2 million (RM 2.9 billion) as at September 2009 (see Table 1-7) and this is almost equally contributed by the BioNexus Status and non-BioNexus Status companies.

A total of USD 427 milion (RM1.5 billion) out of USD 820.2 million (USD 2.9 billion) investment has been approved for BioNexus Status companies. This investment includes contribution from United States (U.S.), United Kingdom (U.K.), France, Germany, Italy, Belgium, India, China, Hong Kong, Singapore, Thailand, Australia, New Zealand, Japan and Taiwan.

Table 1-7: Total Investment in the Malaysian Biotechnology Industry

Sectors	BioNexus		Non-BioNexus		Total	
	USD million	RM million	USD million	RM million	USD million	RM million
Agricultural Biotechnology	167.5	586.1	120.1	420.2	287.5	1,006.3
Healthcare Biotechnology	122.3	428.0	112.8	394.8	235.1	822.8
Industrial Biotechnology	137.2	480.4	160.3	561.2	297.6	1,041.6
Total	**427.0**	**1,494.5**	**393.2**	**1,376.2**	**820.2**	**2,870.7**

Sources:
(1) BiotechCorp (as at 30 September 2009)
(2) SSM (as at 31 December 2008 or latest financial reports available)

Employment

Employment in the biotechnology industry is relatively small compared to the rest of the economy, for example the manufacturing sector. This is because biotechnology companies tend to be knowledge-based, with many automated processes and highly productive workers. During the 2005 Census of Establishment and Enterprises, a total of 10,200[9] people were employed directly or indirectly in the biotechnology industry. Based on employment data from the BioNexus Status companies, there were 2,067 people that were directly employed by them as at 30 September 2009. This represents a growth of close to 120% compared to 2007 when there were only 940 people employed in the industry. The largest employment share is in the agricultural biotechnology companies at 40.6%, followed by the healthcare biotechnology companies at 34.4% and the industrial biotechnology companies at 25% (see Table 1-8).

[9] Indirect employment in the biotechnology industry is expected to be larger than 10,200.

Table 1-8: Total Number of People Employed in the BioNexus Status Companies in Malaysia (2007-2009)

Sectors	2007		2008		Sept 2009	
	Total Employees	Knowledge Workers	Total Employees	Knowledge Workers	Total Employees	Knowledge Workers
Agricultural Biotechnology	316	143	657	286	840	386
Healthcare Biotechnology	407	184	434	321	710	427
Industrial Biotechnology	217	57	354	101	517	162
Total	**940**	**384**	**1,445**	**708**	**2,067**	**975**

Source: BiotechCorp

Amongst the 2,067 people employed directly by the BioNexus Status companies, 47.2% was knowledge workers. Knowledge workers are defined as those involved directly and indirectly in the technical development and deployment of biotechnology products and services and are equipped with tertiary education and / or industry experience. These would include experts and professionals in disciplines related to biotechnology with not less than five years working experience in legal and regulatory affairs, patent and intellectual property (IP) management, bio-processing, finance and marketing, accreditation of standards related to biotechnology practices such as Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Agricultural Practice (GAP), and other knowledge workers.

The employment trend of knowledge workers is consistent with the focus areas and technology application in each sector. Healthcare biotechnology sector employs the highest number of knowledge workers while employment of knowledge workers in the agricultural biotechnology sector is moderate. On the other hand, the industrial biotechnology sector employs the lowest number of knowledge workers because the sector is highly automated with commercial scale production capabilities.

Strategic Direction

In order to meet the industry developmental goals, the NBP has formulated nine policy thrusts as the comprehensive strategic framework that drives the development of the biotechnology industry. Specific strategies and key actions have been identified for the implementation of each policy thrust (see Table 1-9). The nine policy thrusts are currently being implemented according to the focus of Phase I on capacity building. Details on the implementation of each policy thrust are provided in Chapters 3 and 4.

Table 1-9: The National Biotechnology Policy Thrusts (2005)

1 Agricultural Biotechnology Development

Transform and advance the agricultural sector as well as develop a platform to access the nation's natural resources with commercialisation potential

2 Healthcare Biotechnology Development

Capitalise on the strengths in biodiversity and support activities to commercialise the natural products and to position Malaysia in the healthcare sector

3 Industrial Biotechnology Development

Ensure growth opportunities for the creation of value-added products through the application of advanced biotechnologies

4 R&D and Technology Acquisition Development

Create centres of excellence as a mechanism to bring together multidisciplinary research teams in a coordinated effort for research and commercialisation

5 Human Capital Development

Build the nation's human resource capability in biotechnology through special schemes, programmes, benefits and incentives to increase the number of knowledge workers, particularly scientists and engineers, with the necessary skills and skill-set

6 Financial Infrastructure Plan

Develop and implement a comprehensive funding mechanism from science-to-business with committed participation by the private sector and Government-linked companies (GLCs)

7 Legislative and Regulatory Framework Development

Create a conducive and enabling environment for the development of the biotechnology industry through a continuous review of its regulatory framework and procedures

8 Strategic Development

Develop and implement a benchmarking mechanism and establish a global marketing strategy to build brand and global recognition

9 Government Support and Commitment

Set up BiotechCorp to streamline, coordinate, monitor and manage biotechnology development

Source: National Biotechnology Policy (2005)

In meeting the development goals of the NBP, the overall strategic direction of the Malaysian biotechnology industry that is aimed at wealth creation and social well-being remains unchanged. Biotechnology is the key enabler for the development of the agriculture, healthcare and industrial sectors in line with the global trends in green technology. Malaysia's tropical biodiversity richness and abundant natural resources provide a competitive advantage for the development of the industry. In addition, the industry is expected to develop based on Malaysia's strength in manufacturing and outsourcing capabilities complemented by strong Government support and commitment to continuously improve supporting infrastructure required for the industry.

Moving into year 2010 and beyond, it will be critical to translate scientific results to business performance. The remainder of Phase I in 2010, and beyond in Phase II, is an important period to ensure the success of the NBP implementation. During this period, while efforts should continue to build capacity as outlined in the NBP, highest priority should also be given to key actions that would contribute significantly to GDP growth. Priority actions are therefore being identified based on the following critical success factors moving forward:

- Generation of quick results (bringing science to business) through intensification of commercialisation efforts
- Availability of skilled and experienced knowledge workers to meet industry specific needs
- Adequacy and availability of second stage funding growth and expansion
- Effectiveness of globalisation strategy (globalisation of emerging companies and foreign direct investments (FDIs) participation)
- Coordinated inter-ministerial development and implementation of Government policies

Based on the above mentioned, for benchmarking purposes, Chapter 2 provides a biotechnology industry overview of selected Asia Pacific countries; while Chapters 3 and Chapter 4 provide recommended priority actions for consideration. Chapter 5 outlines the proposed implementation action plan moving forward.

Chapter 2
Global and Asia Pacific Biotechnology Overview

Chapter 2
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Global Biotechnology Landscape

The biotechnology industry was born with the founding of Genentech on 7 April 1976. Since then, the industry has grown from a distinct start-up to a sector that generates revenues of USD 70.1 billion in the U.S. in the year 2008. In 30 years, the industry has provided new therapies for medical needs to improve the quality of life around the world[1].

Similar to the rest of the global economy, the biotechnology industry was affected by the global financial crisis. Biotechnology companies are now faced with challenges as they attempt to navigate through a systemic financial meltdown. Valuations of pre-commercial biotechnology have plummeted, capital has dried up and the landscape is left with companies struggling to survive. This has created extraordinary volatility in the global stock markets and currencies, and has led to the consolidation of the biotechnology industry. The economic crisis during the 2008 period has reduced the number of biotechnology companies and employees by 5%[2].

There was a disproportionate fall in the stock market, impacting the industry's smallest firms and causing their valuations to fall abruptly. Consequently in 2008, 162 public companies, or 44% of U.S. public biotechnology companies, had less than a year's operating cash left[2], while 96 had less than six months of cash left[3] This is supported by the reduction of share of U.S. public biotechnology companies by market capitalisation size as seen from Table 2-1 below.

Table 2-1: Share of U.S. Public Biotechnology Companies by Market Capitalisation Size

Market Capitalisation	1 January 2008	15 October 2008
Less than USD 50 million	35%	52%
USD 50 million to USD 100 million	15%	12%
USD 100 million to USD 250 million	21%	12%
USD 250 million to USD 500 million	10%	9%
Over USD 500 million	18%	16%

Source: Ernst & Young Analysis

Similar declines were seen in other major markets during the year, including a decline in market capitalisation by 35% and 61% in Europe and Canada espectively[4].

The market turmoil led to significant declines in funding in 2008. Overall, the capital raised by biotechnology companies declined by 46% from USD 30 billion in 2007 to USD 16 billion in 2008 and the most dramatic fall was in funds raised from public investors. The amount of capital raised in initial public offerings (IPOs) fell dramatically by 95% from USD 2.3 billion in 2007 to USD 116 million in 2008. Some Asian companies managed to go public in spite of the market conditions, with three IPOs on the Japanese stock exchange and two listings by Chinese firms on the Shanghai Stock Exchange and Hong Kong Stock Exchange. Other funding mechanisms such as follow-on equity transactions, debt offerings and private investments in public equity accounted for the majority of biotechnology industries financing. In 2008, money raised from such financing totalled USD 9.9 billion which was less than half of the USD 20.3 billion raised in 2007[4].

[1] Ernst & Young Beyond Borders (2005)
[2] Ernst & Young Beyond Borders (2009)
[3] Tansey (2008)
[4] Ernst & Young Beyond Borders (2009)

Venture capitalist (VC) financing fell by only 19% compared to a steeper decline in financing for public companies. Venture funding accounted for 37% of total biotechnology financing in 2008, an increase from 25% in 2007. Venture funding fell more sharply in Canada where there was a 41% decrease. Table 2-2 depicts the financing outcome for U.S., Europe and Canada for 2007 and 2008.

Table 2-2 Financing Outcome for U.S., Europe and Canada (2007 and 2008)

Type	2008			2007			% change		
	U.S.	Europe	Canada	U.S.	Europe	Canada	U.S.	Europe	Canada
IPO	6	111	0	1,238	1,010	5	-99.5	-89	-100
Follow-on and other offerings	8,547	1,115	271	14,689	4,880	703	-42	-77	-61
Venture financing	4,445	1,369	207	5,464	1,604	352	-19	-15	-41
Total	**12,998**	**2,595**	**478**	**21,391**	**7,494**	**1,060**	**-390**	**-66**	**-55**

Source: Ernst & Young Beyond Borders (2009)

Despite the worldwide turmoil in capital markets, the global biotechnology industry delivered a solid performance in 2008. The revenues of the publicly traded global biotechnology industry increased by 11.7%, from USD 80.3 billion in 2007 to USD 89.7 billion in 2008. There was also positive growth in global R&D expenditures which grew by 18% in 2008. The global industry's bottom line improved by an impressive 53%. This was largely driven by the U.S. industry, reaching aggregate profitability for the first time in history, followed by Europe, of which net loss declined by USD 1.5 billion. However, as a result of the economic crisis, the number of biotechnology companies and number of employees fell by 5% indicating that the global biotechnology is poised for significant consolidation in 2009. Table 2-3 depicts an overview of the global biotechnology industry from 2003 to 2008.

Table 2-3: Global Biotechnology Industry Overview (2003-2008)

Years	2003	2004	2005	2006	2007	2008	% change
Public Company Data							
Revenue (USD million)	46,553	54,613	63,156	73,478	80,344	89,647	12
R&D expenses (USD million)	18,636	20,888	20,415	27,782	26,881	31,745	18
Net income (loss) (USD million)	4,548	5,304	4,388	5,446	(3,055)	(1,433)	-53
Number of employees	195,820	183,820	173,110	190,500	201,690	200,760	-0.5
Number of Companies							
Public companies	611	641	671	710	815	776	-5
Private companies	3,860	3,775	3,532	3,595	3,984	3,938	-2

Source: Ernst & Young Analysis

The U.S. market, being the biggest biotechnology market in the world, contributed 74% in revenue to the global biotechnology industry. However, the revenue was reduced by the acquisitions of several mature biotechnology companies such as Millennium Pharmaceuticals' acquisition by Japan's Takeda Pharmaceuticals, the purchase of ImClone Systems by Eli Lily and the acquisition of Applied Biosystems by

Invitrogen (since renamed as Life Technologies). The industry revenue would have grown by 12.7% instead of 8.4% after taking into account the three acquisitions. Revenues also fell as the contribution from the largest revenue-generating company, Amgen, grew by only 1.6% in 2008 compared to 27% in 2002 to 2006. This was mainly due to regulatory and reimbursement developments that affected the sale of some of its products[5].

The Europe market revenues for publicly traded companies rose by 26% due to the impact of exchange rate fluctuations as revenues grew by only 17%, when stated in Euros. The increase is due to strong product sales by some of its mature biotechnology companies such as Actelion, Elan, Eurofins Scientific, Qiagen, Shire and Meda[5].

For the Canadian biotechnology market, revenues from publicly traded companies declined by 9% from USD 2.2 billion in 2007 to USD 2 billion in 2008 mainly due to the acquisitions of four significant Canadian firms such as Arius, Aspreva, Axcan and Draxis by foreign companies[5].

In Asia Pacific, revenues grew by an impressive 25%, led by a strong growth in Australia which contributed USD 3.6 billion in revenue in 2008[5].

Table 2-4: Global Biotechnology Industry Performance by Region (2008)

	Global	U.S.	Europe	Canada	Asia Pacific
Public Company Data					
Revenue (USD million)	89,647	66,127	16,515	2,041	4,965
R&D expenses (USD million)	31,745	25,270	5,171	703	601
Net income (loss) (USD million)	(1,433)	417	(702)	(1,143)	(14)
Number of employees	200,760	128,200	49,060	7,970	15,530
Number of Companies					
Public companies	776	371	178	72	155
Private companies	3,938	1,383	1,658	286	614
Total companies	4,717	1,754	1,836	358	769

Source: Ernst & Young Beyond Borders (2009)

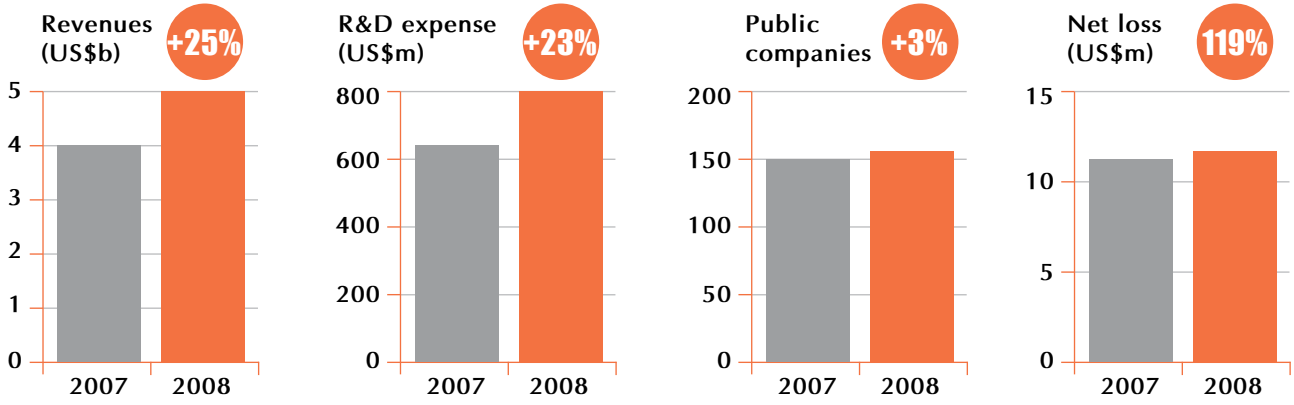
Despite the economic turmoil, the deal environment is expected to remain strong and biotechnology companies need to be vigilant, remain focused and harness creativity in order to sustain its performance in the current economic crisis.

Asia Pacific Biotechnology Highlights

The Asian biotechnology industry continues to grow aggressively given the increasing focus by regional Governments and investors, and the growing numbers of cross-border collaborations. The industry achieved strong double-digit growth, led largely by the fortunes of CSL, which saw very strong product sales growth due to the success of its Gardasil vaccine. In line with the revenue growth, there is also an increase in R&D activities, resulting in R&D growth. The number of public companies also increased slightly during the year.

[5] Ernst & Young Beyond Borders (2009)

Figure 2-1: Asia Pacific Financial Performance (2007-2008)



Source: Ernst & Young Beyond Borders (2009)

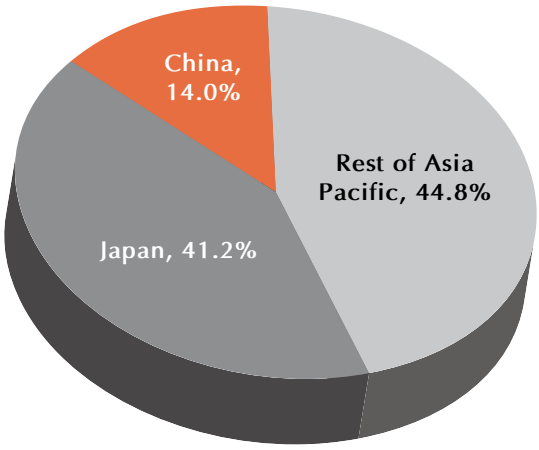
The performance of the market is expected to accelerate slightly, with an anticipated CAGR of 6.8% for the five year period from 2008 to 2013, driving the market to a targeted value of USD 62.8 billion by end 2013. Market value reflects revenues of companies within this industry from product sales, licensing fees, royalties and research funding. In 2008, Japan generated 41.2% of the total Asia Pacific biotechnology market value while China contributed 14%[6].

Table 2-5: Asia Pacific Biotechnology Market Value (2004-2008)

Year	USD billion	% Growth
2004	30.7	-
2005	33.9	10.4
2006	37.7	11.3
2007	42.1	11.6
2008	45.1	7.10
CAGR (2004-2008)		10.1

Source: Datamonitor (2009)

Figure 2-2: Asia Pacific Biotechnology Market Segmentation by Value of Percentage Share (2008)



Source: Datamonitor (2009)

[6] Datamonitor (2008)

The Asian biotechnology industry is different in many aspects from its counterparts in the West, and the impact of the financial crisis differs slightly. While Western companies may have reduced their investments in reaction to tremendous market uncertainty, some Asian companies are expected to grow as companies in the West look for ways to reduce costs by outsourcing more activities to Asia.

Asian economies have the benefit of being cost-competitive; however, being able to compete with the West requires the ability to specialise in higher value-added activities and not compete solely on cost. Strategic plans and national biotechnology policies have been established in some countries to assist in the development of the industry by boosting the R&D, commercialisation, start-up formation, innovative product pipelines and human capital development. To further develop the industry, Governments are revisiting their existing regulations and implementing new rules to promote innovation and commercialisation; fostering home-grown companies to be more competitive in the global market.

Moving forward, Western companies will continue to take the opportunity to invest significantly in Asian countries; however, the growth of the sector may be hampered due to growing unemployment rate and reduced spending power as a result of the economic downturn. As such, companies are expected to reinvent their business and financial models to cater for the unprecedented changes to the global and local economy.

Selected Asia Pacific Country Overview

Australia

Australia is currently the fifth largest biotechnology centre in the world after the U.S., Canada, Germany and the U.K.[7]. In 2008, Australia was also the leading location of biotechnology companies in Asia Pacific with 470 core companies, where 49% were in human therapeutics, 16% in agricultural biotechnology and 13% in diagnostics[8]. The financial performance of the Australian biotechnology industry improved in 2008 as revenues grew 26% relative to 2007 and R&D increased by 32%. The financial performance remained strong largely because of product sales at CSL (the leading Australian biotechnology company). While Australia has the largest core biotechnology industry in the Asia Pacific region, its industry has limited number of established companies like CSL which accounts for a large portion of the Australian biotechnology industry revenue and drives the industry's overall numbers.

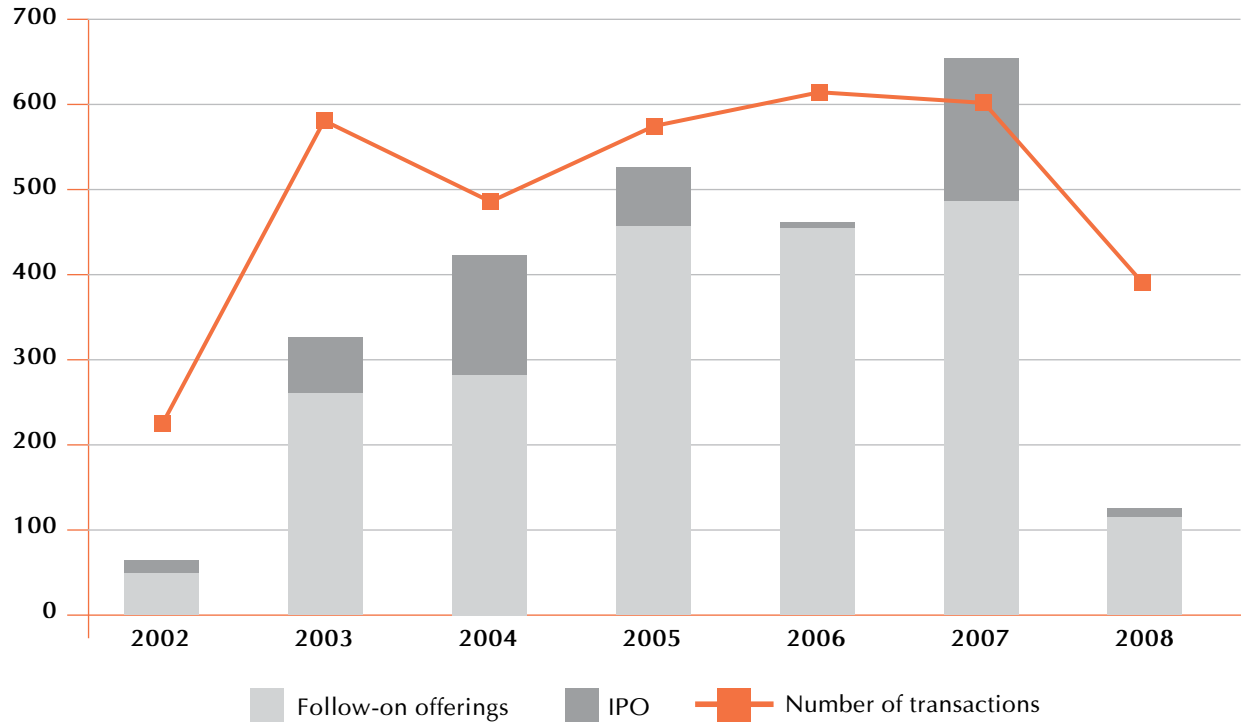
Financing Trend

Australia's publicly traded biotechnology companies can be divided into top-line and bottom-line companies. Top-line companies are companies with advanced pipelines and solid financing (e.g. CSL, Cochlear, Resmed, Sigma Pharmaceuticals), followed by companies that have raised venture funding at an early stage and continue to enjoy support from VC backers. After these two groups, however, come the bottom-line companies (immature) that were compelled to go for listing in the Australia Securities Exchange (ASX) prematurely because of a lack of VCs, and which often continue to struggle. More than 70% of IPOs in this category over the last six years rose to less than USD 8.9 million each[9].

The financing totals in 2008, as in most parts of the world, were down. The IPO market on the other hand has been essentially closed until 2010, with only two IPOs in 2009 getting off the ground. With the termination of the Government's Commercial Ready Grant Scheme and the window to the public markets firmly closed, there is now added pressure for private companies to raise early-stage capital that was previously conducted via the ASX. It will also be challenging for ASX listed companies that had not tapped the markets for follow-on financing over the last few years when money was comparably easy to raise before the economic downturn. As shown in Figure 2-3, "follow-on" funds which tend to significantly exceed capital raised through IPOs fell from a record-breaking USD 380 million in 2007 to USD 99.8 million in 2008[9].

[7] World Report Australia (2007)
[8] Biotechnology Industry Organisation (2008)
[9] Ernst & Young Beyond Borders (2009)

Figure 2-3: Australian Biotechnology Public Equity Raised (2002-2008)



Source: Ernst & Young Beyond Borders (2009)

As of December 2008, approximately 36% of listed biotechnology companies had less than six months of cash on hand, up from 13% a year earlier[10]. The Australian biotechnology industry was largely impacted in 2008 with funding challenges caused by the global economic crisis. As of Q2 2009, 69 biotechnology companies were listed on the ASX with market capitalisation of USD 20.6 billion. However, it is predicted that by December 2009, there would be approximately 20 companies ceasing to be active. This is due to lack of funding, depressing market conditions, as well as mergers and acquisitions. Early-stage funding will be limited as many companies are shelving early-stage R&D programmes to re-focus on their lead drug candidates and near-term projects that are at later-stage trials to reduce losses. Corporate restructuring initiatives, consolidation of companies, and acquisitions by competitors are expected to be significant. Holista Biotech, a Malaysian incorporated healthcare company has taken the opportunity and acquired an Australian public-listed bioindustrial company, CollTech Australia, in a reverse takeover to complement its collagen product development pipeline. Holista is involved in research, development and commercialisation of novel ingredients and formulations as well as the branding, distribution and sale of natural products such as collagen. CollTech, based in Perth, is focused on the development and commercialisation of ovine collagen and collagen-based healthcare products.

The dismal financing environment raises questions about sustainability not just for individual companies that are struggling to remain viable, but also for the Australian biotechnology industry as a whole. Important lessons can be learnt in terms of new start-up formation and financing from the Australian biotechnology industry.

Australia's Institutes of Higher Learning (IHLs) and Research Institutes (RIs) have incentives tied to the number of start-ups generated rather than the quality of those companies. This has resulted in a large number of companies formed around a single compound (e.g. one-drug companies) rather than a complementary group of compounds, and in a larger group of companies competing for the same small pool of funds. Australia's private and public biotechnology funding model grants companies small injections of capital to fund operations for six to 12 months to avoid shareholder dilution. This forces companies to run very lean operations, prolonging product-development times, and creating insolvency risks in difficult

[10] Burill & Company (2009)

economic times. Australia's biotechnology industry needs to restructure university incentives and focus on cutting-edge, readily commercialisable technologies.

Lessons learnt from Australia's biotechnology industry is that building a sustainable industry is about ensuring that the company and the technology are as well funded as possible to either reach commercialisation quickly or demonstrate sufficient value to attract licensors. Companies should be built around a complementary group of products to attract a more sophisticated shareholder base, making them more resilient in turbulent economic climates.

China

The biotechnology industry in China posted revenue of USD 3.5 billion in 2008, an increase of 75% compared to 2000[11]. The industry is expected to account for around seven to 8% of the country's GDP by 2020. The industry is projected to increase to USD 9 billion by 2010, growing at a CAGR of approximately 17%[12]. Nevertheless, China was not spared the impact of the chain of events that began in the U.S. financial markets. The ChinaBio Stock Index, which comprises 15 U.S. listed biopharmaceutical companies, declined 57% during 2008, after rising 70% in 2007[13]. The IPO market slowed significantly as well, both for domestic new issues and for listings in the West. While the Chinese economy has been impacted by the global financial crisis, its prospects may not be as gloomy as in Western markets as China could be an increasingly viable development partner for Western firms that are looking to reduce budgets and eliminate fixed costs.

China has over 25 years of experience in medical biotechnology and generic biologics and is the second largest producer of generic drugs. The biopharmaceutical sector is evolving from companies that were formed in the late 1980s and early 1990s to manufacture therapeutic proteins developed in the West. The new generation of Chinese biotechnology companies is moving to adopt a new business model by creating unique, patent-protected medicines that command higher profit margins than the biogenerics, or biosimilar drugs. In addition, the increasing competition after admission to the World Trade Organisation (WTO) has propelled the local Government entities to invest heavily into modernising the Traditional Chinese Medicine (TCM) industry. The developers of TCM in China, working with Western companies and scientists, are using modern research tools and standards to develop next generation TCM products.

The VC community investing in China is still relatively small, and sums raised are modest compared to those in the more mature markets of the West. Investors active in China continue to favour companies with existing or very near-term revenue streams. Investments in 2008 were made by a handful of local firms as well as established Western players, and recipients included a mix of contract research organisations or clinical research organisations (CROs), active pharmaceutical ingredient (API) manufacturers, distribution companies, research-tool companies, TCM firms, specialty-pharmaceutical companies and novel-drug developers. Hence, the Government remains the main source of funding for R&D and commercialisation and is deeply involved in China's agricultural industry.

Agricultural Biotechnology

A combination of population growth, security of food supply, and the need to raise agricultural worker incomes are the main driving forces for China's agricultural biotechnology to improve food production[14]. China was one of the first countries in the world to begin growing transgenic crops commercially with virus-resistant tobacco plants in the early 1990s. In 2004, China ranked fifth in the world in terms of genetically modified organism (GMO) cultivated acreage. The Chinese Government invests more than USD 292.8 million in transgenic crops each year. This investment is anticipated to increase by 20% per year in the future. In 2006, agricultural biotechnology accounted for nearly 42% of the total Government spending on biotechnology and approximately 37% of total biotechnology market value[15]. Government spending on agricultural biotechnology has resulted in the Chinese Government reaping improved economic and social rewards through bolstering its support for bioagriculture and agricultural biotechnology products that include transgenic cotton, biopesticides, herbicide-resistant rice and animal vaccines with expanded applications.

[11] BioMedex (2008)
[12] Teh (2007)
[13] Ernst & Young Beyond Borders (2009)
[14] Zhang (1999) and BioWorld & General Biologic (2008)
[15] Teh (2007)

Government Role

The Chinese Government is a key investor in the life sciences industry. By 2020, the Government plans to invest 2.5% of GDP in R&D, up from 1.3% in 2005. The country is also implementing a series of healthcare reforms. This includes building more health clinics in rural areas, a zero mark-up policy on drugs prescribed by Government hospitals and clinics and a goal of providing universal healthcare by 2020[16]. In addition, China recently announced a USD 86 billion economic stimulus package that promotes economic restructuring, as well as expanding renewable energy sources (e.g. solar power, wind power, alternative energy sources) and essential green infrastructure. The National Development and Reform Commission (NDRC) will put USD 30 billion into green projects and is also planning to draft another stimulus package to double the China's 2007 output of alternative energy by 2020[17]. This may in turn, provide opportunities for growing innovative companies in China to attract both local and foreign entrepreneurs and companies venturing into related fields.

China's Bioindustry "Eleven–Five" Development Program is aimed at accelerating China's bio-related industries. Major research initiatives and programmes at both national and provincial Government levels were established to fund infrastructure such as RIs and national key laboratories, to promote and train young scientists as well as support in establishing international collaborations. The three main avenues of research in China include Government-funded basic research through IHLs, Government or private-funded academic scientists doing basic or applied research, and in-house private sector research. Currently in China, universities and academic scientists have stronger funding than the private sector. With strong Government backing and increasing private investment, research centres specialising in life sciences are being established all over China and are leveraging on the vast network of state-run academies and specialist universities.

As Western companies grow more comfortable with offshore research and clinical development, China continues to enhance its infrastructure, education and development of a skilled workforce. Chinese citizens are increasingly gaining access to higher education. In recent years, China's population of researchers has increased to 926,000, placing it second behind the U.S. Every year, 40,000 Chinese students receive doctorates[18]. In addition, the Government has adopted various initiatives to attract and retain human capital with advanced degrees and relevant industry experience to boost entrepreneurship and innovation. The country's large pool of scientists and low labour costs make it a prospective location for R&D.

Regulatory Framework

Efforts to improve IP and product safety regimes have escalated after China's admission to the WTO. In recognition of the importance of strong IP regimes in the development of innovative products, China's "third amendment" to its IP law was approved in December 2008, instituting several reforms that are slated to go into effect in October 2009. In addition, after a steady stream of reforms geared at improving product safety in China, the Chinese Government continued its focus on product-safety issues in 2008. In March 2008, it announced that the State Food and Drug Administration would be moved back under the Ministry of Health to improve overall efficiency and oversight. For the moment, the significance of China's regulatory reform is critical and its implications will depend largely on how the law works in practice and how it is interpreted over time. China will continue its IP enforcement in order to boost the confidence level of Western companies and encourage expanded R&D activities into China.

India

Since the establishment of the Department of Biotechnology in 1986, the Indian Government has been increasingly supportive of the biotechnology industry. Indian expertise in the manufacture of generic pharmaceuticals has provided a platform for the sunrise biotechnology industry which is poised to grow into a R&D-led USD 25 billion industry by 2010 with a market capitalisation of approximately USD 150 billion. Combined with rising public interest in this sector, growing investment by traditional business houses, and the tax incentives and significant foreign investment available, the Indian biotechnology industry is poised to emerge as a significant force on the global biotechnology map. The Indian biotechnology industry contributes 2% of the global biotechnology industry[19].

[16] Ernst & Young Beyond Borders (2009)
[17] Tan (2009)
[18] Ernst & Young Beyond Borders (2009)
[19] IBEF (2008)

The industry is segregated into five sectors including biopharmaceuticals, bioagriculture, bioinformatics, bioservices, and bioindustrial, with biopharmaceuticals as the biggest market. The biopharmaceutical sector comprising of vaccines, therapeutics, diagnostics and other biopharmaceuticals such as statins, holds the largest segment in the biotechnology industry, accounting for over 76% of revenues in 2003 / 2004. In 2007 / 2008, sector revenues had already grown to an estimated USD 1.7 billion, accounting for over 67% of total industry revenues. There were over 250 companies in the biotechnology industry in India in 2003 / 2004 and this had grown to more than 325 companies by 2007 / 2008. The number of employees in the biotechnology industry had also grown by over 42% in the year 2003 / 2004 with 9,100 professionals to 119.8% in the year 2007 / 2008 with 20,000 professionals[20]. The availability of a large pool of scientific talent at a moderate cost brings down the overall cost of innovation and drug discovery in the country. Operational costs in India are one-seventh to one-tenth of those in developed markets and are among the lowest in the world, hence reducing R&D costs.

Infrastructure

The Indian Government, in an attempt to promote India as an emerging biotechnology investment destination and transform the latent biotechnology potential into business kinetics, is focusing on the development of biotechnology parks and biotechnology Special Economic Zones (SEZs) which has resulted in biotechnology clusters in several geographical regions in India (e.g. Serum Bio Pharma Park). These parks, with the help of the private sector, focus on specific sub-segments such as health care, bioinformatics, agricultural biotechnology, marine biotechnology and nanobiotechnology. Government initiatives to set up biotechnology parks across the country make available world-class infrastructure to the biotechnology industry where common facilities provided in such parks reduce the cost of discovering, manufacturing, and testing biotechnology products.

In India, R&D infrastructure and efforts were initially restricted to Government-run laboratories and institutes. However, now, private sector companies are also investing in research activities. The Indian biotechnology industry has collaborated with foreign biotechnology companies and institutions since its inception and has aided the growth of U.S. and Europe biotechnology industries. A number of Indian companies entered deals with foreign biotechnology companies. Continuing a trend seen in recent years, domestic players have been active in collaborating with foreign biotechnology companies from Western markets, especially for generic biotechnology products. In the past year, Indian biotechnology companies have increasingly focused on investing in Western companies to strengthen their research capabilities and develop a foothold in U.S. and European markets (e.g. Biocon, and Panacea acquired stakes in Western companies to strengthen distribution base).

A number of Indian biotechnology companies are also venturing into Malaysia. Five biotechnology companies from India have either started operations or signed agreements with BiotechCorp. The five Indian biotechnology companies (i.e. Aurigene, Suvarnarekha, Geneflux, Stempeutics Research and Genzent) have been awarded BioNexus Status and enjoy incentives and privileges awarded by the Malaysian Government. Stempeutics Research, a wholly owned subsidiary of India's Manipal Education and Medical Group, opened its USD 5.7 million groundbreaking stem cell research facility in Malaysia, leading the way for such research to be conducted in Asia[21]. On the other hand, in January 2008, Hovid Berhad (Hovid), a Malaysian diversified pharmaceutical company acquired a controlling stake in an Indian pharmaceutical firm, Biodeal Pharmaceuticals, as part of its overseas expansion plan. This acquisition will enable Hovid to grow its strong R&D capabilities faster with greater development in newer generic products due to production, availability of raw material, human resource and machinery at a lower cost.

Regulatory Reforms

In July 2008, India's Department of Biotechnology drafted new legislation, the National Biotechnology Regulatory Act, which would establish and empower the new single regulatory authority, namely the National Biotechnology Regulatory Authority (NBRA). NBRA has been endorsed as a single regulatory body overseeing all aspects of biotechnology products to provide faster and more efficient clearance in place of previous agencies that approved biotechnology products. This new legislative reform would consolidate biotechnology regulations and improve the business environment for both domestic and global players.

[20] Ernst & Young Analysis
[21] Asia Biomedical Review (12 December 2008)

Furthermore, the Government of India is planning to upgrade the Department of Biotechnology to the status of a separate ministry, in recognition of biotechnology's emergence as a thriving sector.

Patent reforms have exposed domestic companies to foreign competition and spurred innovation. As opposed to the Patents Act of 1970 which did not provide patent protection for products, the reform of the Patents Act in 2005 allowed India to fully enforce product patents and this inspired many Indian companies to go down the innovation route. However, the industry lacks sufficient risk capital to fund this increase in R&D. The Indian Government has responded with a host of programmes (e.g. Biotechnology Industry Partnership Program, Pharma Fund, etc.) to fill the gap. Government funding agencies offer various types of research grants, fellowships and financial assistance through soft loans or equity to conduct advanced research in various biotechnology fields.

Government efforts to reform the regulatory regime and to provide supportive infrastructure and funding are expected to help address some of the gaps and challenges confronting the biotechnology industry in India.

Singapore

Among countries in the Asia Pacific region, Singapore was one of the early entrants into the biotechnology industry, having started its first biotechnology company in 1984. Biomedical sciences were being promoted as a whole along with biotechnology so as to bundle them with other allied industries such as medical devices and pharmaceuticals, of which Singapore is quite strong, to achieve enhanced results. The biomedical sciences sector in Singapore accounted for close to 6% of Singapore's GDP in 2007[22].

The Singapore Government has adopted a "big push" approach with the launch of the National Biomedical Strategy (Biomedical Sciences Initiative) in June 2000 to establish Singapore as a "biotechnology hub" for the region, with a vision to become a global hub for biomedical sciences in Asia with world-class capabilities across the entire value chain, from basic and clinical research to manufacturing and healthcare delivery. The biomedical science sector in Singapore is expected to reach the target of USD 17.9 billion in manufacturing output and 15,000 jobs by 2015[23]. Singapore has already achieved a total manufacturing output of USD 14.1 billion in 2008, despite the decline from USD 17.7 billion in 2006. In anticipation of the global economic recovery, the biomedical industry in Singapore is looking forward to exceeding its target of USD 17.9 billion in manufacturing output by 2015.

Government Role

By 2009, the Government had invested more than USD 3.6 billion in building up industrial, human and intellectual capital, and remains fully committed to developing this sector[24]. The Government's commitment to turn Singapore into a biomedical hub in Asia is demonstrated through its increase in R&D expenditure from USD 213 million in 2001 to USD 757 million in 2006. The Economic Development Board (EDB) is Singapore's lead agency for investment promotion and industry development. Through the EDB and the Biomedical Sciences Initiative, the Government is aggressively building biomedical research capabilities across public-funded research institutes, centres and hospitals. RIs are complemented by a strong health care infrastructure (e.g. National Cancer Center, National Neuroscience Institute and Singapore National Eye Center).

Innovation

Like other Asian economies, Singapore remains optimistic that further outsourcing opportunities can be created as a result of cost-cutting measures in Western companies. However, with the growth of other biotechnology outsourcing hubs in Asia, Singapore is increasingly focused on innovation and building companies focused on discovering and developing novel products. Local companies are encouraged to continue to strive in creativity to access capital and expertise in the current economic environment. As significant sums are necessary to commercialise a biotechnology product, the real lifeblood of an entrepreneurial and innovative biotechnology cluster is a vibrant (and experienced) VC community. Singapore's local VC community is still quite small and companies have little access to additional capital through IPOs on a local exchange. Realising the critical role of start-up funding in developing local entrepreneurship and innovation, the Government has been very active in funding start-ups, as well as

[22] Burrill & Company (2007)
[23] Ernst & Young Beyond Borders (2009)
[24] Economic Development Board Singapore (2009)

developing investment vehicles for the industry through its new venture formation grants and other investment vehicle initiatives such as Bio*One Capital. In 2008, the Technology Transfer Network (TTN) was formed as a result of a collaborative alliance of Technology Transfer Offices (TTOs), to enhance the effectiveness in the transfer of technology to the industry.

Bioclusters

Singapore appears to be successful in attracting investments from Western biotechnology, multinational pharmaceutical and medical technology players and is a destination of choice in the region for manufacturing operations and headquarters because of its access to talent, a modern healthcare system, sophisticated infrastructure and strong regulatory framework.

Singapore's research environment, high quality of life and open immigration policies have been a draw for global and regional talents. Singapore has a well-structured regulatory framework in place across all aspects of biotechnology covering essential modules that comply with international regulatory standards which include compliance to bio-safety via health products legislation and regulation; active promotion of GMP and good clinical practice; good bioethics framework; and rigorous IP framework. In 2008, Singapore was ranked number two in the world for IP protection[25].

Singapore has developed into one of Asia's fastest growing bioclusters that presents strategic partnership opportunities with research institutes, corporate labs and public hospitals to develop new medicine for the regional and global markets. The science parks in Singapore have been developed with the objectives of attracting foreign corporations and providing an environment in which R&D-intensive national firms can grow. Biopolis is an integrated, purpose built biomedical research complex that allows companies to cut R&D costs significantly and accelerate development timeline. Its clustering effect is intended to foster a collaborative culture among institutions and organisations under the same roof.

A coordinated, strategic approach involving multiple Government agencies and sustained investment over a long period have allowed the development of a biomedical cluster. Phase II of the biomedical initiative is to focus on translational and clinical medicine, and the continued efforts to develop competencies and capabilities to continuously support positive results.

South Korea

A large concerted effort to develop biotechnology in South Korea began in 1994 when seven Government ministries collaborated to launch a programme called "Biotech 2000" (1994-2006) as a major initiative to promote R&D, build up the scientific infrastructure and promote commercial applications. South Korea is currently ranked 14th and targets to be placed seventh in world ranking for biotechnology. The Government plans to export USD 25 billion of the total value of USD 61 billion of biotechnology products by 2010[26]. This expected increase in biotechnology exports is due to Korean's innovations gaining patent recognition in the overseas market[27].

In July 2009, agreements were signed between Malaysia's BiotechCorp, Standards and Industrial Research Institute of Malaysia (SIRIM), Ultimate Biotech and Korea's Research Institute of Bioscience and Biotechnology (KRIBB) for collaboration in biotechnology twinning programmes to strengthen cooperation in biotechnology research and related training. The partnership of Ultimate Biotech and KRIBB gives Ultimate Biotech the right to make, use and sell the licensed biofertiliser product, using palm oil mill waste[28].

Pharmaceuticals and healthcare remain the key focus areas in the biotechnology industry with biopharmaceutical representing 32% of the 834 biotechnology companies. South Korea's pharmaceutical market was valued at USD 12.5 billion in 2008 and is considered one of the most promising markets in the world. The country is regarded as one of the most attractive global (being ranked joint ninth, alongside Canada) pharmaceutical markets due to high per capita consumption and strong annual growth of its already sizeable value[29]. The Korean pharmaceutical industry has concentrated mostly in generics but more companies have attempted to venture into the area of innovative R&D. As such, the Government is making

[25] Economic Development Board Singapore (2009)
[26] Promising Report South Korea: Life Science (2008)
[27] Wong, Quach, Thorsteinsdóttir, Singer and Daar (2004)
[28] Bernama (14 November 2009)
[29] Business Monitor International (2009)

plans to improve and expand the infrastructure for the development of drugs, whilst several pharmaceutical companies have increased their R&D budget for novel drugs and medications.

In 2006, the Government launched Bio-Vision 2016 (2006-2016), the Second Framework Plan for Biotechnology Promotion as investors became disenchanted with the lack of profits from the biotechnology industry. Bio-Vision 2016 aims to establish a biotechnology-related economy in ten years, from USD 2.9 billion in 2005 to USD 65 billion in 2016[30]. The plan started out with a budget of USD 720 million for R&D and USD 230 million for infrastructure in 2007, with a projected increase to USD 1.7 billion for R&D and USD 690 million for infrastructure by 2016. The total budget for nine years is projected at USD 15.6 billion[31]. Bio-Vision 2016 is focused on the innovative restructuring of the national biotechnology promotion system, expanding infrastructure for upgrading, achieving globalisation of bioindustries R&D, conducting a regulatory and legal overhaul, and enhancing public acceptance of biotechnology.

Infrastructure

To pursue the strategies and objectives under the Bio-Vision 2016, the South Korean Government is developing the biotechnology industry by fostering and supporting bioclusters. The goal is to develop a regional innovation system and a balanced national development by creating a biotechnology industry complex in each of the region[32]. At present, there are four big bioclusters with 28 biotechnology centres in 13 cities and provinces. South Korea has many established research institutions and universities involved in biotechnology R&D in both the public and private sectors. Under the "2006 Implementation Plan on the Growth of Biotechnology", Government-level investment in biotechnology amounted to USD 1.2 billion in total, of which R&D and infrastructure accounted for USD 954 billion and USD 226.8 billion, up 23.6% and 3% from the previous years[32]. Bio-Vision 2016 will acquire international bio-resources, upgrade infrastructure such as biological resource centres, and expand research facilities for new technology and convergence technology. Efforts by the Government to provide foreign direct incentives such as tax reduction, cash grants, land offering, financial support and research staff support have resulted in major international research institutes such as Pasteur, Battelle and RIKEN locating their its operations in South Korea.

Regulatory Framework

As a result of Government and private investments into both basic and applied research, South Korea has seen a high rate of increase in the number of research projects with 49% in new drug development and 69% in new technology. From 2006 to 2007, 170 patents in biotechnology were successfully registered in the U.S.[33] and South Korea is currently ranked second in Asia and 14th in the world for patents in biotechnology. South Korea is establishing a USD 403 million "invention capital" fund to promote the local IP rights market. This fund will be created by 2011 by Korean Intellectual Property Office (KIPO) using capital from both state and private firms. The fund will be used to purchase and commercialise ideas from local inventors, schools and labs to help local businesses fight challenges from foreign non-practising entities. With this new fund, the country hopes to boost its IP market to fifth in the world and add USD 1.8 billion to its GDP in 2012[34].

South Korea's IP system is very advanced compared to many other countries in Asia and it is a creative filer of patent and trade mark applications for inventions and brands of local companies. The Korean Institute of Patent Information accomplished the fastest patent application processing in the world for December 2006 - in 9.8 months as compared to 17.6 months in 2005. South Korea outran other leading countries in patent examination such as U.S. (22.6 months in 2004), Japan (26 months in 2006) and China (26.1 months in 2004)[35]. KIPO will also open an IP management company to facilitate commercialisation by purchasing ideas, patents and corporate licenses. Currently, South Korea is ranked fourth in the world in terms of number of patent applications and 36th in IP rights enforcement worldwide[36].

[30] Yuan (2009)
[31] Biotechnology Journal (2008)
[32] Promising Report South Korea: Life Science (2008)
[33] Ministry of Education, Science and Technology (2009)
[34] Xinhua and JoongAng Daily (2009)
[35] KOTRA (2009)
[36] IMD World Competitiveness Yearbook (2009)

Country Policy Overview

South Korea established its first national biotechnology policy, Biotech 2000 (1994-2006), in 1994 as a major initiative to promote R&D, build up the scientific infrastructure and promote commercial applications. Consequently, South Korea established Bio-Vision 2016 (2007-2016) as a second national framework plan for biotechnology in 2006. Compared to other countries, South Korea allocated more than ten years to develop its research foundation (1994-2006) via the Biotech 2000 plan. Malaysia and Singapore have only allocated five years for capacity and research building. There were significant achievements during the implementation of Biotech 2000 in terms of R&D, human capital development, infrastructure for biotechnology, international cooperation, science and technology competitiveness and biotechnology market size. The Korean Government has adopted a bold vision for its biotechnology industry by setting a target of being the world's seventh largest biotechnology country by year 2010. It remains to be seen if South Korea will achieve this vision. As of 2008, South Korea is ranked number 14 in world rankings for biotechnology[37].

In the case of Singapore, the biomedical sector has been chosen by the Government to achieve the desired growth rate in terms of manufacturing output. The biomedical science sector in Singapore is expected to achieve a target of USD 7 billion by 2005 and subsequently USD 17.9 billion in manufacturing output and 15,000 jobs by 2015. Singapore's Biomedical Sciences (BMS) Initiative was launched in 2000 to provide approximately USD 1.4 billion in Phase I over five years (2000-2005) to build basic biomedical capabilities. Phase I has enabled Singapore to build academic research infrastructure and provide training in life sciences. By 2005, Singapore's manufacturing output had already reached USD 10.5 billion, exceeding the target by 50%. Subsequently, Phase II (2006-2010) of the BMS provided additional USD 10.4 billion to achieve the development goals of strengthening translational and clinical research expertise. Since then, Singapore has managed to execute several strategies to achieve the above mentioned goals by building biomedical R&D, promoting cross-institutional collaboration; embarking on a clustering strategy (e.g. Biopolis), attracting multinational biotechnology research organisations to set up R&D centres, and offering commercialisation support for potential products derived from biotechnology. By 2008, Singapore had already achieved a total manufacturing output of USD 14.1 billion, putting it on track to exceed its target of USD 17.9 billion by 2015.

Australia's National Biotechnology Strategy (NBS), established in 2000, had a relatively different focus from the other benchmarked countries as it was focused on building on existing strengths, opportunities and capabilities. It was build around six themes that were geared towards safeguarding human health, protecting the environment and capturing the benefits of biotechnology for the country. There was significant involvement from the individual States and Territories resulting in the implementation of state-level initiatives. Potential contradiction between state and national levels had raised concern among stakeholders. The activities funded under the NBS were delivered by Biotechnology Australia. However, Government actions on research, commercialisation, inwards investment and regulation that were undertaken under the impetus of the NBS were implemented by agencies other than Biotechnology Australia. The NBS had been structured against highly broad themes and it lacked clear key performance indicators (KPIs), thus making it difficult to quantify the extent to which they had been met. The NBS was terminated in 2008, with funding and Biotechnology Australia ceasing in June 2008.

In 2005, India drafted its first biotechnology policy, the Eleventh - Five Year Plan (2007-2011). Also known as the National Biotechnology Development Strategy (NBDS), India focused on biotechnology's potential to provide long-term benefits for agriculture, health and the environment. It included a target for the biotechnology industry to generate USD 7 billion by 2012, and the revamping of biotechnology education programmes to create global centres of educational and research excellence. To achieve this target, India has increased funds for biotechnology from USD 362 million during 2002 to 2007 to USD 1.6 billion by 2012[38]. The key elements of the strategy include reinforcing regulatory framework, increasing inter-ministerial coordination, promoting biotechnology, building world-class human capital, and increasing synergy and innovation. The NBDS has taken into consideration all the areas that will affect the Indian biotechnology industry. The Policy has clearly chalked out directions to strengthen India's academic and industrial biotechnology research capabilities; work with business, Government and academia to move

[37] Promising Report South Korea: Life Science (2008)

biotechnology from research to commercialisation; foster India's industrial development; inform people about the science, applications, benefits and issues of biotechnology; enhance the teaching and workforce training capabilities; and establish India as a preeminent international location for biotechnology.

China's Five-Year Plan (The Eleventh Five-Year Program Outline for National Economic and Social Development of People's Republic of China – 2006 to 2010) details a specific biotechnology section, earmarking the industry for accelerated development. As a result of the directives in the above initiative, as well as China's "National Medium to Long-Range Program Outline for Scientific and Technological Development (2006-2010)" programme, in April 2007, NDRC released the "Bioindustry 'Eleven-Five' Development Program" which was created together with the Ministry of Finance, Ministry of Science and Technology and 15 other related Government departments.

China's Eleven-Five Program is the first high-level plan for China's bioindustry (2006-2010). It requires China's Government and related agencies to adopt particular practices aimed at accelerating the development of China's bio-related industries. The Eleven-Five Year Plan emphasises China's increasing industry scale and innovative ability. It also stresses the development of several new biotechnology-related industries according to the future demands of industrialisation, centralisation and globalisation. China will place emphasis on nine specific programmes that include vaccines and diagnostic kits, innovative drugs, modern TCM, biomedical engineering, biotechnology breeding, green agriculture using biotechnology products, bio-energy, bio-based material and organism manufacturing, and ensuring biotechnology safety[39]. Since the launch of the Eleven-Five Program, China has accelerated industry-university research collaborations, increased international cooperation via attracting multinational industries to China (e.g. foreign cooperative projects), and centralised biotechnology zones in Shanghai, Shenzhen and Beijing.

Sector Focus Development

Most of the selected countries being evaluated are focusing or planning to focus on the healthcare biotechnology and the pharmaceutical industries. Biopharmaceutical is the biggest biotechnology industry in South Korea with 32% of the total number of biotechnology companies involved. China has over 25 years of experience in medical biotechnology and generic biologics and is the second largest producer of generic drugs. China's pharmaceutical industry's gross output was USD 81.1 billion in 2006, a growth of 17.9% compared to 2005. South Korea and China's focus on biopharmaceutical is to support the growth rate of local drug consumption. India, on the other hand, has developed expertise in the manufacture of generic pharmaceuticals, providing a platform for the biotechnology industry. The biopharmaceutical sector comprising of vaccines, therapeutics, diagnostics and other biopharmaceuticals such as statins, holds the largest segment of the biotechnology industry in India, accounting for over 76% of revenues in 2003 to 2004. In 2007 to 2008, sector revenues grew to an estimated USD 1.7 billion, accounting for over 67% of total industry revenues and registering 16% in growth[40].

In South Korea, the Government is making plans to improve and expand the infrastructure for the development of drugs. Several pharmaceutical companies have increased their R&D budget for novel drugs and medications after realising the potential high growth of the industry. The Ministry of Science and Technology has also invested USD 76.5 million in R&D to help the pharmaceutical companies with their programmes. This budget is more than double the Government investment made in 2007. The Government also announced the construction of a large medical centre which requires an investment of USD 8.2 billion by 2038.

India and Australia are more focused towards healthcare biotechnology in areas such as human therapeutics and vaccines. India has become an ideal location for vaccine development due to the availability of highly-skilled research scientists, large institutional buyers, and low cost of operations. India has already achieved a leadership position in the global vaccines market, where it accounts for about a third of global vaccine sales and is the largest producer of recombinant Hepatitis B vaccine in the world[41]. Australia has 48% of its Core Biotechnology Companies (CBC) focused on therapeutics. Within the therapeutics sector, areas of significant capability include immunology, oncology, infectious diseases (e.g. Human Immunodeficiency Virus (HIV), Hepatitis B), metabolics and diabetes, allergy and respiratory diseases, stem cell research, infertility, neurology, and nutraceuticals.

[38] Science and Development Network (2009), accessed on 2 October 2009
[39] BioWorld & General Biologic (2008)
[40] IBEF (2008)
[41] Ernst & Young Beyond Borders (2007)

Biomedical science is also another main area of focus for Australia and Singapore. In areas of human therapeutics, the Australian Government has committed USD 423.3 million to enable clinical and research facilities to improve their capacity to undertake quality work into the causes, diagnosis and prevention of disease. The establishment of the Human Genome Project in 2006 resulted in huge amounts of data available to researchers to target disease sources more accurately and to discover its treatments. Singapore, on the other hand, has managed to attract major international players like GlaxoSmithKline, Pfizer, Merck, Sharp and Dohme, Schering-Plough and others, resulting in the strong performance in pharmaceuticals manufacturing in Singapore's biomedical industry, accounting for 85% of total output. Through the Biomedical Sciences Initiative, the Singapore Government is aggressively building biomedical research capabilities and encouraging local companies to continue to strive in creativity to access capital and expertise in the current economic environment.

Countries like Australia and China also focus on agriculture biotechnology as the countries have abundant natural resources. In the case of China, agriculture biotechnology is one of the main focus areas due to the national advantages. The driving factor for China's focus on agricultural biotechnology is the need to improve food production as a result of population growth, security of food supply, and the need to raise agricultural worker incomes. China is also the leading investor in biotechnology rice research and is only surpassed by the U.S. for investment in overall crop biotechnologies. China has been field testing different varieties of genetically enhanced rice for several years, primarily as a means to develop strains with built-in protection from the three devastating pests (stem borers, sheath blight and bacterial blight).

Financial Infrastructure Development

The amount and type of funding available shows strong support for biotechnology development in the region. All five benchmarked countries have invested substantial amounts into their biotechnology industry, with a minimum investment of USD 471 million and a maximum investment of over USD 1 billion.

Singapore is the largest investor in biotechnology with a total biotechnology public funding of USD 10.4 billion allocated for Phase 2 of the National Biomedical Strategy (average per year is USD 2.1 billion per annum). Although Singapore's total private sector funding is the highest compared to the other benchmarked countries, it is still deemed as significantly small because of high risks involved in the investment and long payback times given the significant sums necessary to bring a biotechnology product candidate from discovery to the market. As such, the Government has been very active in funding start-ups and developing investment vehicles for the industry through its new venture formation grants and other investment vehicle initiatives.

Although Australia's private funding availability is higher than public funding, the VC market in Australia is small and unwilling to invest in early stage biotechnology, resulting in many Australian biotechnology companies seeking listing on the stock exchange earlier than their international counterparts to obtain funds from retail and institutional investors.

The selected countries provide examples of many paths to commercialisation. Australia and South Korea present two unique models. In Australia, the "biocreator" model has an investor (financial institution or retail market investor) funding and managing early stage biotechnology projects. When the project has reached the stage of clinical development, the investor will form a company out of the project by infusing a management team and board of directors. The company will then be listed on the stock exchange, with the biocreator retaining a majority shareholding. In South Korea, the 'chaebols' (e.g. Hyundai, Samsung, Daewoo, LG Electronics) play a significant role in the South Korean economy, and this is no different for the biotechnology industry. In recent years, the 'chaebols' have taken the lead in the corporate sector in turning their attention to biotechnology as a new growth area for investment and development. Companies in the Information Technology (IT), semiconductor, food, chemicals and textiles business are also shifting their focus towards biotechnology. However, a series of events has affected the implementation of Biotech 2000. The 'chaebols' have become disenchanted with the lack of profits from the biotechnology industry. As such, the launch of Bio-Vision 2016 is aimed at establishing a biotechnology-related economy in ten years, putting South Korea in seventh place in the global biotechnology market.

The biotechnology industries in these benchmarked countries are also experiencing slow growth in VC interest. As such, the respective Governments have undertaken various initiatives to attract VC financing as a measure to boost the biotechnology industry.

South Korea provides many incentive schemes to attract FDIs. Some of the incentives include tax reduction, cash grant, 'sit' location support and financial support. The Central Government also provides two financial support facilities such as cost of staff education and training and cost of hiring staff.

Singapore also provides a number of tax incentives for biotechnology companies such as incentives for development and expansion, investment, approved royalties and enhanced tax deduction for R&D expenses. In addition, most pro-biotechnology Indian States are trying to compete on the basis of fiscal incentives such as tax holidays, capital subsidies and energy concessions.

In India, the Government is exempting all gains received from investments made by VC funds in biotechnology and has recently granted USD 150 million for joint investment with VCs. Other forms of financing in biotechnology include public equity investments and multiple partnerships and acquisitions which have helped sustain the biotechnology growth in the past year[42].

In China, the Government is investing into quasi-venture capital companies as a method to attract more private sector investment in supporting start-up and growth companies[43]. A quasi-venture capital is characterised by two formats: part of the money available for investment is known as VC investment, while the other part is investment for the development of the company[44].

Research & Development

Asia Pacific's biotechnology R&D expenditure is increasing rapidly but is still behind its global counterparts, and the Government is usually the main fund provider for R&D expenditure. R&D is crucial to the development of the biotechnology industry. In Asia Pacific, the biotechnology R&D expenditure increased by 50% from USD 401 million in 2007 to USD 601 million in 2008. This increase was higher than the increase in global biotechnology R&D expenditure of 14% from 2007 to 2008. However in 2008, Asia Pacific's biotechnology R&D expenditure was only 2% of the global expenditure of USD 31.8 billion.

South Korea has many established RIs and universities involved in biotechnology R&D in both the public and private sectors. Since the publication of the Basic Plan for the Promotion of Biotechnology in 1994, investment has been increasing at an annual average rate of 24%. In 2008, investment in biotechnology R&D amounted to USD 871 million, representing an increase of 16% over the previous year. South Korea also achieved the highest performance in individual sector with more than 77% of the gross expenditure on research and development (GERD) spent and was also ranked the second highest spender in R&D in relation to its GDP at 3.2%. In addition, South Korea possesses the most number of researchers compared to all the benchmarked countries.

Singapore has built a range of biomedical science research capabilities across publicly funded RIs, centres and hospitals to develop core capabilities in bioprocessing, chemical synthesis, genomics and proteomics, molecular and cell biology, bioengineering and nanotechnology, computational biology and immunology. The Government has been active in offering attractive incentives and necessary infrastructure for MNCs to set up facilities in Singapore. Singapore is also the country with the highest IP law enforcement as the country's regulatory framework has essential modules that comply with international regulatory standards such as bio-safety via health products legislation and regulation, active promotion of GMP and good clinical practice, good bioethics framework, and rigorous IP framework.

[42] AusBiotech (2009), Website accessed on 5 October 2009
[43] Nevrivy and Bakin (2009), Website accessed on 1 October 2009
[44] Fredriksen and Klofsten (2000)

Collaborations between the private and public sectors and overseas participants are critical for the industry. Singapore ranked the highest in terms of general university-company research collaboration. Efforts have been made by Australia and India to foster collaboration between industry and RIs. This is done through its Clinical Research Centres (CRCs), Council of Scientific and Industrial Research (CSIR) and research consortia respectively. Research consortium participants need to provide at least 50% of the capital requirement to ensure more commitment from the private sector.

Generally, there is a positive correlation between private sector R&D spending and the intensity of university-company research collaboration among the benchmarked countries. This highlights that collaboration is one of the many ways in which the private sector can contribute to R&D spending.

In 2007, China ranked number one in terms of the total full-time equivalent (FTE) R&D personnel at 1.7 million personnel. A major attraction of conducting R&D in China is the cost factor as R&D in China can be both cheaper and faster than in developed countries. Estimates of savings from local research in China range from 50% to 80% compared to costs in the U.S. or Europe. Salaries of scientists with comparable skills and education are comparatively lower in China.

Both China and India have a strong base of CRO and contract manufacturing organisations (CMO) to support Western biotechnology companies that are increasingly changing their business models to reduce R&D costs. China and India benefit from a large pool of patient candidates, making them ideal locations to conduct clinical trials. Aside from being the top destinations for outsourced manufacturing and R&D due to the large labour pool, Western companies are also increasingly collaborating with China and India because of their increasing innovative capabilities.

In terms of patent processing time, South Korea led the benchmarked countries in accomplishing the fastest patent application processing in the world for 2006, from 17.6 months in 2005 to 9.8 months in 2006. South Korea is ahead of other leading countries in patent examination such as U.S. (22.6 months in 2004), Japan (26 months in 2006) and China (26.1 month in 2004).

South Korea also had the highest number of Patent Cooperation Treaty (PCT) patent applications from 2004 to 2006 followed by Australia with 556. As Singapore became a member of PCT only in 2006, no data was available for comparison. As for patents granted locally, 54% of patents applied were granted in Singapore from 2003 to 2007.

Another R&D indicator is the number of research publication / citation published. Singapore followed by Australia and South Korea rank the highest in terms of productivity per thousand population.

Human Capital

Asia Pacific's number of biotechnology employees is increasing rapidly but the absolute amount is still behind its global counterparts. Human capital is a critical parameter for industries that rely on knowledge and expertise. In Asia Pacific, the number of biotechnology employees in 2008 increased approximately 20% from 2006 to 2008. The number of employees in the global biotechnology industry increased by only 5.3%. The number of companies and employees fell in 2008 – an indication of the industry preparing for significant consolidation in 2009. In 2008, Asia Pacific had only 7.7% of total employees, 15,530, in the global biotechnology industry even though more than one third of the world's population is in the region.

Among the benchmarked countries, Singapore, Australia, and South Korea have higher FTE R&D personnel per thousand population. The number of researchers per ten thousand population ranged from 0.6 to 6.9 in 2007, with Singapore ranking the highest. In terms of absolute number, China's total number of researchers, 1,500,000 in 2006, is significantly higher than India, Australia, South Korea and Singapore. In terms of the state of the current labour force, Singapore is ranked number nine (third in Asia Pacific after Philippines), while Malaysia is ranked 14th (fourth highest in the Asia Pacific region) for the availability of skilled labour[45].

[45] IMD World Competitiveness Yearbook (2009)

In Australia, although there are strong human resources in the area of research, there are still gaps in certain specialised areas such as human capital with strong technical background complemented by business management exposure. Australia has taken an active approach to address this gap. Australia's Biotechnology Entrepreneur Program (BEP) extends business skills programmes to postgraduate students and early scientists, predominantly but not exclusively, within the life sciences and biotechnology fields. This particular competency is crucial given the nature of the biotechnology industry which requires the ability to guide research activities towards commercialisation potential. In the BEP, participants are challenged and guided by high calibre mentors with business / commercialisation knowledge and experience from industry and supporting professions.

To overcome the problem of shortages in human capital, many countries have initiated programmes to attract and develop human capital for the biotechnology industry. Australia, South Korea, Singapore, China and India have all initiated some form of "brain gain" programmes.

Brain Gain Programmes

Australia's Federation Fellowship programme is designed to attract and retain skilled researchers in the fields of business and sciences. Endorsed by the Australian Research Council and reviewed by the office of the Minister of Education Science and Training, Federation Fellowships are worth approximately USD 160,000 per year for a period of five years. At the State level, South Australia has also established the USD 1.1 million BioInnovation South Australia Biotechnology fellowship fund for the appointment of internationally renowned researchers for a minimum five year period for R&D activities in local universities. On the other hand, the International Researcher Exchange Scheme offers fellowships and awards to promote the movement of researchers between Australian research institutions and centres of research excellence overseas.

The Korean human resources in biotechnology have grown to a world-class level due to Government support and the adoption of westernised curriculum and studies by the U.S. South Korea's Brain Korea 21 (BK 21) launched in 1999 by the Ministry of Education and Human Resources Development aims to nurture highly qualified human resources for the 21st century knowledge-based society. BK 21 invests over 70% of total funding for graduate students and post-doctorates, contracting researchers to exert efforts solely on research and study. BK 21 also nurtures specialised regional universities and strengthens industry-university ties by establishing an independent system through raising matching-fund from the industry and local Government, support for commercialising research outputs, and collaborative operation of curricula and projects to nurture human resources relevant to the industry. In addition, the Korean Trade-Investment Promotion Agency (KOTRA) has launched a R&D Human Resource Development Program aimed at retaining human capital in the country. This is conducted by employing Korean research personnel or dispatching training of personnel to Korea to newly established and existing R&D centres.

Singapore's "brain gain" initiatives are mostly linked to strong international networking for active knowledge transfers from the leading global research institutes and scientists for continuous capability enhancement of the local research community. Local human capital initiatives driven by A*STAR scholarship programmes usually involve training in top ranked foreign partner universities and institutes (e.g. John Hopkins University, Imperial College of London, etc.). Two main programmes are administered by the EDB namely, The Strategic Attachment and Training (STRAT) Programme and the "Initiatives in New Technology Scheme" (INTECH). STRAT aims to build up Singapore's manpower capabilities in strategic areas and sectors through overseas training and attachment with leading companies.

With a population of only approximately 4.8 million, Singapore is not only aggressively investing heavily in manpower training but also searching for foreign talent. Singapore's research environment, high quality of life and open immigration policies have been a draw for global and regional talents. Singapore has been consistently ranked as Asia's top city in terms of quality of life and is well known for its ability to attract the world's top scientific and business talents from renowned universities (e.g. U.S. National Cancer Institute, UK Medical Research Council, University of Kyoto, University of California) globally to move to Singapore to head the city-state's research institutes, consortia and laboratories. The increase in foreign citizens in the

R&D workforce has been aided by flexible and liberalised immigration policies in Singapore, whereby skilled immigrants can easily opt to gain permanent residency. Singapore has also launched various programmes aimed at attracting talent, such as company grant schemes to ease costs of employing foreign skilled labour and recruitment missions by Government agencies. In addition, Singapore has launched resilient packages specifically targeted at helping global businesses based in Singapore to retain and enhance their talent base (e.g. Job Credit scheme, EDB's Preparing for the Upturn initiative). The Singapore Government will co-share the cost of wages and training with companies to upgrade the skills of their technical and engineering workforce to ensure they are fully prepared for the eventual economic upturn.

China and India are prospective locations for biotechnology R&D as both countries are able to offer a large pool of human resources at low labour cost. India has a wide spread education infrastructure facilitating the generation of technically qualified English speaking population, while China has the highest total number of researchers compared to India, Australia, South Korea and Singapore.

India's Department of Biotechnology (DBT) human capital initiatives are aimed at supporting approximately 51 specialised academic programmes and courses in biotechnology via several institutions and universities across the country to meet the growing demand for skilled manpower. These include around 24 Masters of Science courses in General Biotechnology, seven in Agricultural Biotechnology and one each in Medical and Marine Biotechnology. It is also supporting four Masters of Technology courses in Biochemical Engineering, Bio-process Technology and Biotechnology, and two Postgraduate Diploma courses in Molecular and Biochemical Technology and Clinical Biochemistry and Biotechnology. The DBT is also supporting overseas associate-ships and short-term training courses for at least 22 to 25 scientists in a particular year to expose Indian scientists to newer trends in R&D. This helps working researchers and scientists to upgrade their knowledge and research areas of interest. In addition, the DBT also offers postdoctoral fellowships and outstanding young investigator grants in biotechnology where, amongst others, salary support, research grants, equipment and opportunities to attend national and international conferences are included.

In the effort to develop and attract human capital, the Chinese Government is looking to admit more talented people from overseas and attract overseas Chinese graduates back to start businesses in China. In order to attract more talented people into this area, administrative departments at different levels have adopted various projects, such as the "Hundred-Talent Project" of the Chinese Academy of Science, the "National Outstanding Young Scholar Project" of the Natural Science Foundation of China and the 'Cheung Kong Scholar Project' of the Ministry of Education[46]. At the local Government levels for example, Shanghai has set up the 'Dawning Project' and "Morning Star Project" which provide good guarantee of research work for talented individuals to return to China after receiving good training abroad. Presently, young talent has become the foundation in promoting the advancement of science and technology in China.

In recognition of the shortage of skilled human capital in highly specialised fields such as biotechnology, many countries including Malaysia have adopted various "brain gain" initiatives to attract, develop and retain talent. Nevertheless, it should be noted that although the various initiatives are necessary to boost human capital for the development of the biotechnology industry in the respective countries, other factors such as a conducive research environment, high quality of life and open immigration policies are driving factors in attracting and retaining local, regional and global talents. Singapore has taken advantage of its world-class infrastructure and standard of living to attract world-class researchers. Drawing from Australia's experience, it should be noted that success in developing strong research and technical capabilities should also be complemented by business management competencies. Business skills programmes extended to postgraduate students and early scientists involved in the life sciences and biotechnology fields are crucial given the nature of the biotechnology industry which requires the ability to guide research activities towards commercialisation potential.

[46] Chen, Wang, Wen and Wang (2007)

Regulatory Frameworks

In the areas of IP Protection, Singapore currently ranks number four in the world[47] as the country has set in place a sound IP protection framework to support the entire spectrum of IP activities from creation through ownership and protection, and eventually exploitation. Special emphasis has also been placed on protection of IP in biomedical sciences to spur innovation and encourage more R&D activities in this area. Singapore has also enforced several other legislations such as Medicines Act, Medicines (Advertisement and Sales) Act and Sales and Drugs Act to regulate health products.

Australia's dedication to IP protection is reflected by initiatives like tailored IP information for small and start-up businesses, a comprehensive IP guide for business and researchers ("IP Toolbox") developed in conjunction with leading industry experts, online IP courses, an IP management training manual, and online application forms. The standard patent term of 20 years applies to all countries considered, but Australia allows a five year extension for pharmaceutical and biotechnology patents. With commercial release of a product typically occurring 12 years after the granting of a patent, such extensions prolong the profitable life of a product by over 60%.

China's IP laws and enforcement challenge the biopharmaceutical industry in particular. Prior to 1993, China patent laws offered no protection for foreign drugs. In response to pressure from the U.S. and later its entry into the WTO, China amended its laws. There are currently ongoing efforts to improve IP enforcement. Australia adopted the Guidance Document and Guidelines for Registration of Biosimilars in 2005 while Singapore and South Korea adopted the guidelines in 2009.

Among the selected countries, Australia, South Korea and India have put in place regulations relating to GMOs. Australia's Gene Technology Act 2000 regulates gene technology and affects the research, manufacture, production and importation of GMOs. South Korea's guidelines focus on risk assessment of genetically modified (GM) agricultural products, labelling of GM food, and gene-recombinant research. India's Ministry of Environment and Forestry has also provided guidelines on regulating GMOs and has ratified the Cartagena Protocol.

China's biotechnology activities in agriculture rely heavily on genetic alteration and does not support restrictions imposed by GMO regulations. Though the Government has set up committees to oversee GMO policies and regulations, the number of GMOs being developed and being considered for approval is not declining. However, starting from April 2008, food products containing Chinese rice will require mandatory certification to prove that they have been tested for the experimental GM variety called Bt63.

In 2005, South Korea established Bioethics and Biosafety Act 2005 aimed at enhancing the health of human beings and the quality of life. The Act covers areas such as embryo production and research, deoxyribonucleric acid (DNA) testing and Gene Therapy. The Act also aims to protect human dignity and to prevent harm to human beings by ensuring that these life sciences and biotechnologies are developed safely and in accordance with the principles of bioethics.

In the area of Biosafety, the mere speed in adopting biosafety laws is not necessarily the measure of success. Biosafety laws can be restrictive (e.g. imposed treatment of GMOs like nuclear waste) while some other regimes may be more accommodative. Due consideration is to be put in place to ensure a balance in biosafety laws so that the adoption of GMO technology is not viewed negatively.

In terms of Good Clinical Practice (GCP), the importance of standard GCP requirements is a result of increasing outsourced clinical trial work from developed markets (typically due to cost issues). The International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) guidelines provide a standard measure for designing, conducting, recording and reporting (drug) trials that involve the participation of human subjects. Compliance with ICH-GCP provides public assurance that the rights, safety and well-being of trial subjects are protected, and that the clinical trial data are credible. The objective of such harmonisation is a more economical use of human, animal and material resources, and the elimination

[47] IMD World Competitiveness Yearbook (2009)

of unnecessary delays in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health. In response to the growing interest in International Conference of Harmonisation (ICH), the Global Cooperation Group was formed as a subcommittee of the ICH Steering Committee in 1999 and has seen participation from all benchmarked countries including Australia, Singapore, India, China and South Korea.

In terms of GMP, all ten Association of Southeast Asian Nations (ASEAN) member countries have signed a Mutual Recognition Agreement (MRA) to harmonise GMP inspections.

Infrastructure Support

All selected countries have biotechnology clusters to facilitate transformation or to develop biotechnology potential into commercial ventures. The clusters or parks generally offer quality infrastructure at a competitive cost and provide an environment where companies can share knowledge, common facilities (e.g. conference room) and equipment (e.g. scientific apparatus). These clusters tend to adopt a "plug-n-play" mechanism, allowing the tenant to immediately commence their activities. Hence, the development of biotechnology clusters or parks allow companies to cut R&D costs significantly, accelerate the development timeline and foster a collaborative culture among institutions and organisations all in one location. Australia, India and South Korea each has more than ten biotechnology clusters across their respective states to promote close partnership between parties engaged in different levels of the biotechnology value chain.

Among the selected countries, Australia has the highest number of clusters at 28 across seven states. These biotechnology clusters are spread throughout the major cities in the country. Biotechnology clusters in Australia centre around a group of small companies with ties to nearby universities, hospitals and medical research institutes, and financial services. Many participants in clusters take advantage of common resources to generate efficiencies of scale and share knowledge (e.g. Bio21 in Melbourne hosts a high-throughput chemical screening facility). Major biotechnology clusters in Australia reveal geographical preferences for established coastal cities, with concentrations in Melbourne (Victoria), Sydney (New South Wales), Brisbane (Queensland), Perth (Western Australia), Adelaide (South Australia), Canberra (Capital Territory), Hobart and Launceston (Tasmania)[48].

Asian countries are placing emphasis on parks which focus on biotechnology and life sciences. The creation of science and technology clusters or parks has become major initiatives for enhancing economic growth. Most parks operate as incubators that assist in providing value-added "one-stop" services such as investment consultation (e.g. raising capital, incentives, business planning), business administration support (e.g. personnel recruitment, industrial and commercial registration, taxation registration, legal and regulatory assistance, municipal administrative coordination), and property maintenance (e.g. security management, environmental management). Similar to Australia, Asian countries like China, South Korea and Singapore centre the majority of the biotechnology clusters and parks in close proximity to universities and Government laboratories.

In China, Shanghai and Beijing have the largest groupings of biotechnology companies as both cities are home to higher learning education institutions. Beijing, in particular, is home to numerous Government agencies and savvy entrepreneurs with links to major national developmental projects in the life sciences field. Several biotechnology parks have emerged in China beginning with the prototype, Beijing Zhongguancun Reseach Park, followed by Shanghai's Zhangjiang and other relatively newer parks like the SuZhou Biobay.

South Korea has adopted a balanced strategy in its development of bioclusters. As part of its objectives under the Bio-Vision 2016 to develop the biotechnology industry, South Korea is supporting bioclusters by creating a biotechnology industry complex in four regional clusters such as the Seoul-Incheon-Gyeonggi Province, Daejeon / Chungcheong Province, Jeolla Province / Jeju Province and Gongwon Province / Gyeongsang Province. As a result, there are now four big clusters with 28 biotechnology centres across 13 cities and provinces. The newest and biggest biocluster, Osong Bio-Technopolis (to be completed in 2010), is surrounded by 16 universities which will create high quality human resources and academic networks.

[48] Biotechnology Australia (2000)

Hence, universities play an important role in providing skilled personnel, research and access to research-support facilities to enforce and foster knowledge-based interaction between industry, academia and research groups.

India has approximately 19 biotechnology clusters which are well spread throughout the country and are spearheaded by the individual State Governments in India. In collaboration with the private sector (e.g. private developers), the Indian Government is aggressively developing biotechnology parks in specific fields such as healthcare, bioinformatics, agricultural biotechnology, marine biotechnology, etc. More biotechnology parks are expected in the country in the next two to three years as several State Governments in India have established or are in the process of establishing more world-class clusters in Gujarat, Kerala, Uttar Pradesh, Punjab and Delhi. Biotechnology clusters in India tend to be larger in scale than those of other countries mainly due to the size of the country (e.g. clusters in the southern region can occupy up to 787 acres of land).

The science parks in Singapore have been developed with the objectives of attracting foreign corporations and providing an environment in which R&D-intensive national firms can grow. The three major science clusters in Singapore with biotechnology-related activities include the Singapore Science Park, Tuas Biomedical Park and Biopolis. The Biopolis, in particular, is a dedicated biomedical science park with the full spectrum of biomedical R&D activities, encompassing basic drug discovery research, clinical development and medical devices research. The biomedical research complex is the hallmark of Singapore's success as it is fully occupied by core public sector research institutes and has managed to attract large pharmaceutical and biotechnology companies, such as Novartis. In order to draw scientists and biotechnology funds to Biopolis, Singapore has adopted a mix of tax breaks, grants and other incentives worth USD 1.3 billion[49].

[49] Ernst & Young Analysis

Chapter 3
Sector Focus Development

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Sector Focus Development

The NBP has outlined three key policy thrusts supported by specific strategies and actions to develop agricultural, healthcare and industrial biotechnology sectors. As described earlier, biotechnology is an enabling tool for the development of these three sectors with the view of impacting Malaysia's economy by revolutionising the agriculture, healthcare and industrial sectors. Malaysia's unique biodiversity and abundant natural resources are, inter alia, competitive advantages that are being capitalised on for sector focus development.

The first wave of biotechnology is agricultural biotechnology, also known as "Green Biotechnology", as it provides the potential for greater productivity as well as environment-friendly solutions and sustainable agricultural development compared to most traditional agricultural practices. Healthcare biotechnology, the second wave, is widely known as "Red Biotechnology" and refers to the interaction between biology and technology for the improvement of medical processes in healthcare. The third wave is industrial biotechnology, which is commonly referred to as "White Biotechnology". This is the usage of life science technologies to support industrial processes and to improve manufacturing of industrial products while reducing the adverse impact of such processes on the environment.

Agricultural biotechnology development was positioned as the first policy thrust of the NBP as traditionally, Malaysia's strength is in the agriculture sector. It is entrusted to create value and wealth in the agriculture sector such as enhancement of crops, natural products and marine life[1]. The long term objective is to enhance national food security, enhance competitiveness and improve the balance of trade in food products. The application of biotechnology can increase crop and livestock productivity, thereby increasing self-sufficiency levels and improving the balance of trade in major food commodities to feed a growing population.

Malaysia is a resource-based country that is rich in natural resources. It is one of the 12 mega biodiversity countries with tropical rainforests that house a high percentage of the world's species. Malaysia can leverage on its abundance of tropical biodiversity for the discovery and commercialisation of natural products. The extraction of bioactive compounds from natural resources can be used in the production of food ingredients, functional food, cosmeceuticals, nutraceuticals and botanical drugs (phytomedicine). Malaysia has also developed a strong agricultural foundation, being a world leader in the production of several commodity crops such as oil palm, rubber, cocoa, pepper and tropical timber. The application of agricultural biotechnology in Malaysia leverages on its natural resources and strong base in the agriculture sector for commercialisation of natural products and the enhancement of food production. .

The healthcare biotechnology development policy thrust is entrusted to contribute towards the advancement of healthcare by exploiting Malaysia's biodiversity for new drug candidates and providing cost-effective outsourcing services for biodrug development[2]. The focus of the policy thrust is to create new value and growth opportunities for Malaysia's healthcare industry and facilitate the development of new drugs, treatments and medical devices for health and wellness. New drugs and therapeutics can be discovered and commercialised from novel bioactive compounds that are extracted from the natural resources and rich biodiversity of Malaysia. Given Malaysia's strengths and capabilities in manufacturing and outsourcing, development of contract manufacturing or clinical research outsourcing services are therefore being considered in the NBP.

[1] National Biotechnology Policy (2005)
[2] National Biotechnology Policy (2005)

The third policy thrust, industrial biotechnology development, is also intended to leverage on the country's strength in manufacturing by way of extending industrial capabilities in the manufacturing of biopolymers, biomaterials, biogenerics and bioenergy (palm oil based)[2]. Global trends are seeing an increasing emphasis on green initiatives that are driven by the rising awareness and concern over environmental issues and a concerted effort by governments worldwide to reduce the carbon footprint and the environmental footprint. Green initiatives are also of increasing socio-economic importance as countries like U.S. and China are looking at clean energy investments to reinvigorate their economies. The growing focus on alternative energy resources that enable environmental protection and energy savings has a huge development potential in global markets. The recent Copenhagen conference in December 2009 has further reinforced the growing focus of governments worldwide to tackle the issues surrounding climate change and to reduce global emissions.

In line with global green trends, Malaysia's progress in industrial biotechnology will result in lesser dependence on fossil fuel, reduced environmental impact from industrial manufacturing, and significant cost savings for industrial processes. Malaysia's strong agricultural foundation in producing commodity crops such as oil palm, provide a comparative advantage to industrial biotechnology. Palm oil waste and waste from other commodity crops supply abundant and readily available feedstock for the application of industrial biotechnology to produce biofuel. First generation biofuel is typically derived from sugar, starch or oil-based crops (food crops), while second generation biofuel is produced from cellulose or hemicellulose that can be derived from oil palm or other agricultural waste. Hence, Malaysia can leverage on the abundance of local biomass to provide a sustainable and viable source of feedstock that can ultimately be converted into an alternative source of energy that will reduce dependency on rapidly depleting fossil fuels.

The following sections provide further details on the current state of each sector focus development and recommended strategies or actions moving forward into Phase II of the NBP: Science to Business.

Policy Thrust 1 Agricultural Biotechnology Development

Agricultural biotechnology is described as a range of biotechnological tools that are applied to various food and agriculture sectors to improve plant and animal varieties, genetic characterisation and conservation, plant and animal disease diagnosis, vaccine development and improvement of feeds[3]. In recent years, agricultural biotechnology has expanded to include genetic engineering and the creation of GM food, crops or products. The development of biotechnology / GM crops is gaining greater acceptance and has been adopted by 25 countries as at 2008[4]. This number is expected to grow as governments worldwide recognise the potential in agricultural biotechnology and are presented with quantitative data on its effectiveness in moving towards agricultural sustainability.

Malaysia is a country with abundant natural resources and vast tracts of land that are suitable for agriculture. In the early years, Malaysia relied on its agriculture sector to drive the economy through export of commodities such as rubber, timber and palm oil. Since the 1990s, Malaysia has been moving towards an industrialised economy with the manufacturing and services sectors gaining precedence as the key economic drivers. However, the agriculture sector is the third engine of growth and is a strategically important sector as can be seen from two perspectives – GDP contribution and food production. In terms of GDP, the agriculture sector contributed USD 11.4 billion (RM 39.8 billion), which is 7.5% of GDP in 2008[5]. In terms of food production, there is the need to provide and produce sufficient food to feed a growing population. As at 2008, Malaysia has yet to attain self-sufficiency for major food commodities like rice (70%), beef (25.9%), mutton (9.2%) and milk (4.8%)[6]. This is evident given that Malaysia's food import bill is USD 8 billion (RM 28 billion), with a trade deficit in food items amounting to USD 2.9 billion (RM 10.1 billion) for the same year[7]. This has raised concerns regarding national food security and the balance of trade, especially given the increasing challenges faced in the agriculture sector such as scarcity of land, low crop productivity, increase in frequency of floods, droughts, soil erosion, and high water and energy usage.

[2] National Biotechnology Policy (2005)
[3] The United Nations Food and Agricultural Organization (FAO)
[4] ISAAA (2009)
[5] Economic Planning Unit Website, accessed on 5 October 2009
[6] Agriculture Statistical Handbook (2008)
[7] Malaysian Industry Development Authority (MIDA) Website, accessed on 22 October 2009

In addressing these issues, the Third National Agricultural Policy (1998-2010) (NAP3) identified biotechnology as the tool to advance the country's agriculture products, particularly in the food and commodity crops segments for the three-fold purpose of national food security, ensuring sufficient and sustainable food supply, and deriving economic gains. At the same time, the RMK-9 also highlighted biotechnology as a key technology that could drive the evolution of the nation into a knowledge-based economy, contributing to economic growth and wealth creation. The application of biotechnology to develop high yield seeds or hybrid seeds for food crops like rice and vegetables will help narrow the gap between local production and domestic demand. Currently, the role of crop breeding in Malaysia is dominated by the public sector, with the exception of oil palm.

Malaysia is also endowed with a rich tropical biological diversity as it is one of the 12 mega biodiversity countries of the world. There are over 12,500 species of flowering plants and 1,100 species of ferns and fern allies; many of which are unique to Malaysia. As such, Malaysia has a competitive advantage in natural products discovery and commercialisation due to its natural resources and biodiversity. There are also over 286 species of mammals, 150,000 species of invertebrates and 8,000 species of fish and countless lower order organisms like microbes, fungi and algae. Hence, there is huge potential in the unexplored biodiversity and a vast gene pool for Malaysia to capitalise on in the natural products, livestock and aquaculture focus areas.

Given the importance of the agriculture sector, agricultural biotechnology development has been positioned as the first policy thrust in the NBP, where the Government aims to transform and advance the agriculture sector, as well as develop a platform to access and commercialise the nation's natural resources. The implementation of the NBP has facilitated creation of awareness and adoption of biotechnology practices amongst the agriculture players.

Current State

In 2004, the Biotechnology Information Centre, Malaysia, recorded that there were nine agricultural biotechnology companies. Since then and the launch of the NBP, there has been a 16-fold increase as there are 143 agricultural biotechnology companies out of a total of 349, representing 41% of the total biotechnology companies in Malaysia as at 30 September 2009. Based on the latest 2008 financial reports available[8], agricultural biotechnology companies contributed a total revenue of USD 57.9 million (RM 202.7 million) which represents 38.6% of the total revenue of the Malaysian biotechnology industry.

Of the 143 agricultural biotechnology companies in Malaysia, 55 companies (38.4% of the total biotechnology companies) obtained BioNexus Status and these companies generated a total revenue of USD 45.5 million (RM 159.1 million) in 2008 compared to the remaining companies (without BioNexus Status) that generated revenue of USD 12.4 million (RM 43.6 million), which represents 21.5% of the total agricultural biotechnology sector revenue size (see Table 3-1).

Total investment of agricultural biotechnology companies was USD 287.5 million (RM 1 billion) based on the latest available information[9]. This represents about 34.8% of the total investment in the biotechnology industry. A total investment of USD 167.5 million (RM 586.1 million) has been approved for BioNexus Status companies.

Table 3-1: Overview of the Malaysian Agricultural Biotechnology Sector (31 December 2008)

Type of Companies	Number of Companies	Total Revenue		Total Investment	
		USD million	RM million	USD million	RM million
BioNexus Status Companies	55	45.5	159.1	167.5	586.1
Non-BioNexus Status Companies	84	12,4	43.6	120.1	420.2
Total	**139**	**57.9**	**202.7**	**287.5**	**1,006.3**

Source:
(1) BiotechCorp
(2) SSM (as at 31 December 2008 or latest financial reports available)

[8] Based on BiotechCorp (as at 31 December 2008) and SSM (31 December 2008 or latest financial reports available)
[9] Based on BiotechCorp (as at 30 September 2009) and SSM (31 December 2008 or latest financial reports available)

Specific strategies and actions have been identified in the NBP for the development of the agricultural biotechnology sector:

- To enhance the initiative on improved and added value crops and foods
- To establish a marine biotechnology initiative
- To facilitate discovery and commercialisation of natural products

While not directly highlighted in the NBP, livestock biotechnology is an area that has tremendous potential to increase yield. For the purpose of this Country Report and in line with the NBP, further analysis of performance has been conducted on crop-related biotechnology, livestock biotechnology, marine / aquaculture biotechnology and natural products.

Given Malaysia's traditional focus on agriculture, a large percentage of agricultural biotechnology companies is involved in adding value to food and crops. As represented by the BioNexus Status companies[10] as at 30 September 2009 (see Table 3-2), 47.3% of the agricultural biotechnology companies are engaged in crop-related biotechnology, 18.2% in livestock biotechnology and 3.6% in marine / aquaculture biotechnology. The acquisition of a Marker Assisted Selection platform technology from DNA LandMarks, a BASF Plant Science Company, will enhance the crop and animal breeding (improvement) programme. This will further improve the value and productivity of the crops and livestock. In addition, there is a global trend towards the use of biofertilisers as increasing soil degradation is partly attributed to the use of inorganic fertilisers.

In terms of revenue contribution for the first nine months of 2009, these three segments had a combined contribution of USD 27.8 million (RM 97.3 million), or about 87.8% of the total agricultural biotechnology revenue of USD 31.7 million (RM 110.9 million). Biofertiliser companies contributed majority of the revenue in crop-related biotechnology. This could be due to the rising price of chemical fertilisers that has resulted in biofertilisers being preferred as an alternative product that is also more environment-friendly. The growing demand for biofertiliser is further intensified given the potential demand by large plantation companies. In terms of knowledge workers, there is a projected total of 810 knowledge workers, with approximately 52.5% being employed by companies involved in crop-related biotechnology.

As represented by BioNexus Status companies[11], 29.1% of the agricultural biotechnology companies are involved in the natural products segment. This segment has generated significant interest from local and foreign parties for the extraction of bioactive and novel compounds due to the enormous untapped potential and rich biodiversity of Malaysia's tropical rainforests. However, the challenge has been to achieve standardisation of extracts using chemical and pharmacological profiling. The acquisition of an industrial scale Supercritical Fluid platform technology enables extraction of consistently pure extracts without the use of harmful solvents and produces particles with defined shape, uniform size and controlled morphology that are suitable as active ingredients in a range of products from food ingredients to pharmaceuticals. The acquisition of this technology for the industry players has further spurred interest in the natural products segment.

Table 3-2: Overview of BioNexus Status Companies in the Malaysian Agricultural Biotechnology Sector (30 September 2009)

Focus Areas	Number of Companies	Total 9 Months Revenue (USD '000)	Total Approved Investment (USD million)	Projected Total R&D Expenses (USD million)	Projected Number of Knowledge Workers
Crop-related	26	26,596.5	114.7	4.9	425
Livestock	10	1,194.3	17.8	4.0	131
Marine / Aquaculture	2	13.2	1.7	0	29
Natural Products	16	3,865.5	33.3	0	217
Others (Food Diagnostic)	1	0	0*	0	8
Total	**55**	**31,669.5**	**167.5**	**8.9****	**810*****

** Equivalent to USD 2,857 (RM 10,000)*
*** Actual R&D expenses for 12 months ending 30 September 2009 was USD 3.8 million (RM 13.4 million)*
**** Actual number of knowledge workers as at 30 September 2009 was 386*
Source: BiotechCorp (based on the latest information available)

[10 & 11] Due to unavailability of data for all agricultural biotechnology companies in Malaysia

Under the natural products segment, there are 16 BioNexus Status companies generating a total revenue of USD 3.9 million (RM 13.5 million) for the first nine months of 2009. A total of 217 knowledge workers are projected to be employed by the 16 BioNexus Status companies involved in the natural products segment. Overall, R&D expenditure by the 55 BioNexus Status companies in the agricultural biotechnology sector remains relatively low. This is partly due to the presence of patents and technology that is already available in the IHLs and RIs given Malaysia's traditional strengths in this area.

From 2004 to 2008, there was a total number of 225 agricultural biotechnology patent applications, which was the lowest number of patents applied when compared to the healthcare biotechnology (819) and industrial biotechnology (530) sectors. Nevertheless, there has been an increasing trend in the number of agricultural biotechnology patent applications especially from 2006 onwards (see Table 3-3). The total number of agricultural biotechnology patents granted was 90, with 88.9% coming from foreign applicants. Based on industry interviews, the low number of patents granted when compared to healthcare biotechnology (344) and industrial biotechnology (323) sectors could indicate that most companies prefer to keep their discoveries as a trade secret rather than go through the process of patenting. Other concerns may be with regard to biosafety, and the exclusion of patentability of plants and animal varieties.

Table 3-3: Number of Local and Foreign Agricultural Biotechnology Patents Applied and Granted in Malaysia (2004-2008)

Patent		2004	2005	2006	2007	2008	Total
Applied	Local	8	10	23	50	16	107
	Foreign	10	22	29	10	47	118
	Total	**18**	**32**	**52**	**60**	**63**	**225**
Granted	Local	0	1	1	5	3	10
	Foreign	23	1	13	25	18	80
	Total	**23**	**2**	**14**	**30**	**21**	**90**

Source: MyIPO (2009)

Table 3-4 provides a summary of current strategic partnerships and collaborations in the development of the agricultural biotechnology sector.

Table 3-4: Selected Strategic Partnerships and Collaborations of the Malaysian Agricultural Biotechnology Sector

Focus Area	Strategic Partnership		Purpose
Crop-related	• Foreign	• Guandong Agriculture Academy of Science, China • Yunnan Agricultural University, China • Beijing Vegetable Research Centre • North Carolina University, U.S. • Korean Research Institute of Bioscience and Biotechnology • DNA LandMarks, Canada • Genetwister Technologies, Holland	• Access to technology • Transfer of technology • Access to markets • Conduct field testing • Collaborative R&D
	• Local	• Malaysian Agricultural Research and Development Institute • Universiti Putra Malaysia • Malaysia Palm Oil Board • Forest Research Institute Malaysia • Universiti Malaya • Standards and Industrial Research Institute of Malaysia	• Access to facilities and equipment • Conduct lab testing • Food Biotechnology Cooperative Centre

Focus Area	Strategic Partnership		Purpose
Livestock and Aquaculture	• Foreign	• Dongtai Bioengineering, Nanjing, China • Animal Breeding Services, New Zealand • GenDocs, Korea	• Transfer of technology
	• Local	• Veterinary Research Institute • Department of Veterinary Services, Universiti Putra Malaysia • Malaysian Agricultural Research and Development Institute – Strategic Livestock Research Centre • Universiti Malaysia Sarawak	• Collaborative R&D • Access to facilities and equipment
Natural Products	• Foreign	• Oak Ridge National Laboratory, U.S. • The Woods Hole Research Center (Ecosystems Centre), U.S. • Rutgers University, U.S. • Vedic Life Science, Mumbai, India • Al-Amin Shanghai Biotech Company, China • Sheng Chang Pharmaceutical Company, Taiwan • Nizo Food Research, Holland	• Conduct product testing • Collaborative R&D • Transfer of technology • Commercialisation of products • Technical assistance
	• Local	• Universiti Malaysia Terengganu • Malaysian Agricultural Research and Development Institute • TPM Biotech Forest Research Institute Malaysia • Standards and Industrial Research Institute of Malaysia • International Islamic University Malaysia	• Commercialisation of research • Access to facilities and equipment • Access to products • Collaborative R&D

Sources:
(1) BiotechCorp
(2) Ernst & Young Analysis

Crop-Related Biotechnology

Crop-related biotechnology involves the application of biotechnology to three main sub-segments (see Table 3-5). The application of biotechnology in agriculture aims to increase productivity and ensure sustainability, which in turn ensures food security and reduces the balance of trade. The areas that are covered under crop-related biotechnology include in vitro technology (e.g. plant tissue culture for planting material production), plant genomics, molecular marker technology and biotechnology / GM crops for plant improvement[12].

Table 3-5: Application of Crop-Related Biotechnology in Malaysia

Sub-Segments of Crop-Related Biotechnology	Example Research Areas
• Crop genetics and planting material – marker assisted breeding and plant micropropagation • Crop nutrition – biofertiliser and soil enhancer • Crop protection – biocontrol and biopesticide	• In Vitro technology / plant tissue culture • Molecular marker technology • Plant genomics • Genetic engineering

Source: BiotechCorp

Based on the secondary data collected, it has been identified that the services that are currently offered or that will be offered in the near future by Malaysian companies comprise the use of tissue culture-based techniques for plant propagation, genetic markers for crop selection and production of biofertiliser. These identified service offerings utilise a variety of technologies for improving crop yield productivity. Specialised skills and expertise required by companies that focus on crop-related biotechnology include molecular biologists, bioinformaticians, tissue culturists, analytical chemists, agronomists, plant breeders, geneticists, plant physiologists, biochemists, microbiologists and chemists.

[12] National Biotechnology Directorate 2nd Edition

Plant tissue culture refers to the production of plants with the same genotype (clones), using the technique of growing plant cells artificially on a nutrient medium. This technique has been highly employed over the years to produce elite planting materials. Companies in Malaysia that are offering tissue culture-based techniques are generally involved in micropropagation resulting in a high multiplication rate of crops. In addition, crops obtained through this method have the potential to be disease free and healthier. Based on the data represented by BioNexus Status companies, there are 15 companies that are involved in tissue culture-based techniques[13]. The range of crops bring propagated by tissue culture companies in Malaysia include oil palm by TSH Biotech, pineapple by Asma Agro, teak by YSG Biotech, orchids by Orchid Life and other ornamentals by Hexagon Green.

In the area of genomics, Asiatic Centre for Genome Technology (ACGT) was the first in the world to completely sequence, assemble and annotate the oil palm genome. It applies genome technology to increase yield, enhance productivity and create added value from oil palm and jathropa. ACGT is a leading genomics centre through its collaboration with the J. Craig Venter Institute in California for technical assistance. Sime Darby has also sequenced and assembled the oil palm genome. This R&D breakthrough is expected to bring multiple benefits to the oil palm industry such as higher yields per hectarage, as well as crops that are disease resistant, drought tolerant and salinity resistant[14]. One of Malaysia's leading IHLs, Universiti Sains Malaysia (USM) has decoded the first-ever draft of the rubber tree (Hevea brasiliensis) genome, thereby positioning Malaysia as one of the likely leaders in rubber research and production. This breakthrough is expected to facilitate significant development in rubber tree breeding and to track development of rubber trees with favourable traits such as disease resistance and improvement of properties of rubberwood, an important export of Malaysia.

In order to encourage the use of marker assisted selection, BiotechCorp acquired the Marker Assisted Selection platform technology from DNA LandMarks. This is in line with the NBP, where the acquisition of new technology is one of the strategies highlighted to accelerate the development of biotechnology. The Marker Assisted Selection platform technology will speed up the plant and animal breeding process by enabling variety development through selection of desired genotypes during the early stage of the breeding programme. DNA LandMarks is a leader in agricultural genomics. Under the terms of agreement, DNA LandMarks will train employees of the custodian, Malaysian Agricultural Research and Development Institute (MARDI), to develop capabilities in high throughput genotyping of Malaysian agriculture crops and livestock, discover and validate genetic markers on these crops and livestock, and effect the general transfer of knowledge, skills and technology that will accelerate and improve the efficiency of plant and animal breeding in Malaysia. The Marker Assisted Selection platform technology enables more precise identification of economically important traits (such as disease resistance, nutritional value and growth rate) in crops and livestock for selection during the breeding programme. In essence, this platform technology significantly reduces evaluation time and increases efficiency of breeding when compared to conventional phenotypic selection.

Models for rice, watermelon and goats are being developed for application in related breeding programmes. Examples of traits that can be selected include disease resistance, drought-tolerance, salt-tolerance and high vigour. This technology acquisition will provide the platform for Malaysia to establish itself as a regional leader in agricultural genomics and a global player in molecular marker technology for tropical agriculture, thereby allowing Malaysia to offer its services as a hub for plant and livestock genetic material improvement in ASEAN using marker assisted selection. Moving forward, the platform technology is expected to enable development of new applications in other crops and livestock, allowing marker assisted selection breeding programmes to be further expanded in the country and in the region.

In Malaysia, Green World Genetics (GWG) is the first private sector company to be involved in seed production for cash crops employing marker assisted selection technology. Its main focus is in the development of hybrid tropical vegetable seeds. The hybrid seeds confer disease resistance against mildew for watermelon, higher yield and palatability for corn, and thermogenic male sterile markers for rice. GWG's target market is 67% foreign, including markets such as Asia Pacific, Middle East and Eastern Europe, with only a 33% domestic focus. Its customers include Government agencies and seed distributors. It aims to be one of the top producers of tropical high value hybrid vegetable seeds for the global market in the coming five years. In 2009, GWG secured contracts to supply seeds to the China market.

[13] Due to unavailability of data for all agricultural biotechnology companies in Malaysia
[14] Sime Darby (2009)

Apart from plant tissue culture techniques, genome sequencing and the use of molecular markers, there are also a number of companies in Malaysia that are involved in research, development, production and commercialisation of microbial-based fertiliser. Biofertiliser has recently gained popularity as it is perceived to be a more sustainable alternative to chemical fertilisers. This is because prolonged usage of chemical fertilisers could cause deterioration of soil fertility. As awareness increases in the ASEAN region and the issues of soil acidity, soil degradation and sustainability become more critical, demand for biofertilisers will continue to grow. Malaysia has a comparative advantage in the production of biofertiliser as it can be produced by the conversion of palm oil biowaste into economically viable and effective organic biofertilisers. Hence, Malaysia can leverage on its strength in the oil palm commodities and plantations sector. As approximately 30 million tonnes of biowaste is being produced annually from the palm oil mills in Malaysia, there is an enormous economic opportunity for companies that are involved in producing organic biofertilisers to convert these wastes into wealth while contributing towards the sustainability of the environment. At the same time, Malaysia has an abundance of microbes from Malaysia's biodiversity areas that could be researched and utilised as effective microorganisms in the biofertiliser segment.

Malaysian Agri Hi-Tech (MYAGRI), a BioNexus Status company, is involved in the provision of a more efficient, effective and environment-friendly solution to challenges faced by the current agricultural and horticultural industry through its production of biofertiliser. MYAGRI is currently expanding its activities to Indonesia. Another example is Ultimate Biotech that is involved in developing biofertiliser from palm oil waste using the technology acquired through a joint ownership agreement with KRIBB. Ultimate Biotech's biofertiliser products are formulated with bioactive compounds for specific growth phases like the vegetative or flowering phase. This is different from most other biofertilisers that are non-specific for different phases in the plant's life-cycle, using the one size fits all approach.

Another key initiative highlighted in the NBP is the development of Agricultural Biotechnology Centres of Excellence that aim to access technology, build needed skill-sets and a knowledge base in agricultural biotechnology. The Agro-Biotechnology Institute (ABI) Malaysia is one of the designated Centres of Excellence for agricultural biotechnology development. Situated in the vicinity of the MARDI and Universiti Putra Malaysia (UPM), ABI is an institute under the purview of MOSTI and was established in 2006 with the objective of improving the productivity and competitiveness of the agriculture sector in Malaysia. It has been tasked to project manage R&D and commercialisation projects relating to agricultural biotechnology in cooperation with various IHLs, RIs and industry players. R&D efforts are focused on increasing food production, producing better quality and higher yield transgenic crops, developing animal vaccines and improving the growth of livestock through advanced reproductive technology. Recently, ABI signed a Memorandum of Understanding (MOU) with Bogor Agricultural University from Indonesia to further develop the expertise and technologies in cultivating Jatropha Curcas as jatropha has been identified as a potential crop that can improve the livelihood of farmers besides being an alternative feedstock for the development of biodiesel.

Livestock Biotechnology

Livestock biotechnology involves the application of biotechnology to animal health, animal feed and nutrition, and animal reproduction. Typically livestock biotechnology covers the poultry, ruminant and swine industry. Under each of these, there are R&D activities in feed and feed additives, animal recombinant vaccines and diagnostics as well as assisted reproductive technologies such as artificial insemination and embryo transfer. The application of biotechnology to the livestock segment is timely to address the growing population resulting in a corresponding increase in the demand for meat and meat-related products. Based on the data represented by BioNexus Status companies[15], 18.2% of agricultural biotechnology companies is involved in livestock biotechnology. Specialised skills and expertise required for livestock biotechnology include chemists, microbiologists, biotechnologists, bioprocessing engineers, molecular analysts and veterinarians.

[15] Due to the unavailability of data for all biotechnology companies in Malaysia

Animal feed additives are basically animal nutrition products such as amino acids, enzymes and probiotics. These are widely used in developing countries especially in a country like Malaysia where there are cattle, swine and poultry production activities. The major animal feed additive markets comprise U.S., Europe and Asia, with the global market dominated by a number of international players. The world animal feed additives market is forecasted to reach USD 15.4 billion (RM 53.9 billion) by 2010[16]. However, Malaysia's animal health products market is relatively small and is estimated to be worth approximately USD 150 million (RM 525 million), with the feed additives market contributing as much as 30%[17].

Similarly, animal recombinant vaccines and diagnostics are used to improve animal health and to increase livestock productivity. Globally, a large number of vaccines have been developed to prevent and treat disease outbreaks such as the Japanese encephalitis (JE), and the avian and swine flu. In addition, early treatment and diagnosis can help lower maintenance cost for farmers and also improve overall animal well-being. In addition, assisted reproductive technologies is being increasingly utilised to facilitate animal breeding programmes. An example of a MNC that is involved in livestock biotechnology is Pfizer Animal Health. It is the world leader in the discovery, development, manufacture and sales of veterinary vaccines and medicines for livestock and pets. Pfizer's annual R&D investment is estimated to be USD 300 million (RM 1.1 billion).

Sunzen Life Sciences (Sunzen) is one of the companies involved in the livestock biotechnology animal health segment. Its activities include the development and production of feed additives and animal nutritional feed supplements. Its main focus is the development of feed additives (organic acids) for both the poultry and swine sectors. One of its current projects is the development of new animal feed additives from a mixture of oil palm, vitamins and other vegetative contents. Since the market for animal health products in Malaysia is relatively small, Sunzen is now planning to expand its market focus towards foreign markets such as Middle East (Iran), South Korea, Vietnam, Thailand, the Philippines and Taiwan. The global trend to ban or discourage the use of antibiotics in animal feed provides the potential for market growth in the use of natural feed additives.

In the nucleus farm (breeding farm) segment, ar-Raudhah Biotech Farm (ar-Raudhah) and Handalas are examples of companies that are involved in the use of assisted reproductive technologies. The ar-Raudhah farm breeds Boer goats via artificial insemination and embryo transfer, while Handalas breeds Jamnapari goats using artificial insemination. Handalas is located in Sarawak, which is recognised by The World Organisation for Animal Health (OIE) as a Foot and Mouth Disease free zone. As such, there is tremendous growth potential for livestock exports from Borneo Island to regions like Europe, U.S. and Middle East. Both farms are working towards employing marker assisted selection technology in their breeding programme. As previously mentioned, the acquisition of the Marker Assisted Selection platform technology will aid in this effort.

Genetic Improvement and Farm Technologies (GIFT) is another company involved in the nucleus farm segment that utilises assisted reproductive techniques. Its principal activities include developing and producing biotechnology products and services for the agriculture, food, biologics and pharmaceutical industries, as well as RIs. It is currently one of the agro-based providers of animal genetics and housing systems for the goat and cattle segments of the agro-based industry. It also provides contract research services to IHLs and RIs. GIFT is one of the producers of specific pathogen-free rabbits for research purposes. There is good potential to export these rabbits in the region.

Marine / Aquaculture Biotechnology

Natural marine habitats are dwindling globally due to environmental degradation. This is exacerbated by the increase in demand for seafood that leads to overfishing and a corresponding decline in wild fish stocks. According to the United Nations Food and Agriculture Organisation (FAO), nearly 70% of the world's commercial marine fisheries species is now fully exploited, overexploited or depleted. With the depleted supply, the interest in aquaculture has increased worldwide.

In Malaysia, the NAP3 highlights the importance of aquaculture production to the economy as fish is one of the most important sources of protein for the population. In line with this, aquaculture has been gaining importance and the fisheries sub-sector is an important component of the overall marine biotechnology focus area. New growth areas of interest to biotechnology companies in Malaysia are algae and microalgae biotechnology.

[16] Thepoultrysite, accessed on 20 October 2009
[17] Industry interviews and EY Analysis

As represented by the BioNexus Status companies[18], 3.6% of agricultural biotechnology companies is involved in the marine / aquaculture biotechnology segment. These companies engage in breeding and cultivation, and the development of disease diagnostic toolkits for aquaculture diseases. The skill-sets required to provide these service offerings include aquaculture biologists, geneticists, microbiologists and chemists. The specialised technologies for breeding and cultivation include the water recirculation system and nano-bubble technology while the infrastructure required are aquaculture laboratories, hatchery and nursery ponds, grow-out ponds and feed cultivation facilities. For the development of disease diagnostic toolkits, quantitative polymerase chain reaction (qPCR) technology is used and the qPCR and Real Time Polymerase Chain Reaction (RT-PCR) equipments are needed.

Borneo Aqua Harvest is Malaysia's pioneer in marine aquaculture where high value and high quality marine fish is bred, hatched, reared and supplied to local and Asia Pacific markets. The R&D involves broodstock management, artificial spawning, egg management, hatchery, production of live feed, larval rearing and juvenile rearing. It produces several species of groupers like the Plectropomus leopardus and Epinephelus lanceolatus, which are in high demand from the overseas market. Borneo Aqua Harvest is ISO 9002 accredited and is the only aquaculture company listed on the Malaysian Exchange of Securities Dealing & Automated Quotation (MESDAQ) market of Bursa Malaysia.

In shrimp aquaculture, Blue Archipelago, a subsidiary of Khazanah Nasional, is the third largest shrimp operator in Malaysia. It is currently planning to develop a 1,000 hectare farm and industrial park with a fully integrated shrimp processing and aquaculture facility to be based in Setiu, Terengganu, which will meet international quality and food safety certification and standards. Blue Archipelago has received certification that allows exports of its shrimp to Europe. Another example is Suvarna Rekha Marine (Suvarna Rekha) that is involved in the cultivation, production and commercialisation of Macrobrachium rosenbergii, better known locally as Udang Galah. Suvarna Rekha undertakes the breeding and cultivation of Udang Galah fry and juvenile, and provides related services. It is dedicated to improving the current breeding techniques and has created an aquaculture laboratory where the technology utilised is in vivo hatching.

Aquaculture biotechnology has also been instrumental in the design of a disease diagnostic toolkit aimed at detecting aquaculture livestock diseases. In Malaysia, Bio-RT is currently developing a qPCR assay to detect slow growing microorganisms from tissue culture assays. Target markets are 80% local and 20% foreign, with foreign markets including Brunei, Thailand, Singapore and Taiwan.

Malaysia is still building capacity in certain focus areas such as marine / freshwater aquaculture, and algae and seaweed. Hence, several companies are being nurtured by BiotechCorp to close the gaps in these areas. An example is BioSatria that is working on drug discovery and proof of concept for anti-viral drugs for shrimps. It has recently signed an MOU with a Belgian conglomerate in animal nutrition and health, where the Belgian conglomerate will purchase drugs from BioSatria and market them overseas. On the other hand, Omni-Gel is involved in the farming of seaweed, production of dried seaweed and seaweed extracts (carrageenan) for the export market, while Bioherbal Extract is focused on the cultivation of microalgae to extract high value compounds that can be used as nutraceutical and pharmaceutical ingredients.

Natural Products

There is a large and steady global health and wellness market of USD 228 billion (RM 798 billion) despite the global economic downturn in 2008. The Nutrition Business Journal reported that the U.S. health and wellness sector grew by 8.3% in 2007, reaching USD 130.5 billion (RM 456.8 billion) in sales, compared to a 3.7% total growth in all food channels[19]. In the health and wellness sector, there has been an increased introduction of products that are organic or all-natural. Hence, there is a large and growing demand worldwide for novel compounds and active ingredients to be used in the production of food ingredients, functional food, nutraceuticals and cosmeceuticals.

[18] Due to unavailability of data for all agricultural biotechnology companies in Malaysia
[19] Burrill & Company (2009)

According to Biotechnology Cooperative Centre (BCC) Research, the world market for nutraceuticals increased from USD 117.3 billion (RM 410.6 billion) to USD 123.9 billion (RM 433.7 billion) in 2008. It is expected to reach USD 176.7 billion (RM 618.5 billion) in 2013, with a CAGR of 7.4%. Large companies and MNCs that are funnelling significant investments into the discovery of nutraceuticals include Monsanto, DuPont, Abbott Laboratories, Johnson & Johnson, Novartis, Metabolex and Genzyme Transgenic. There is also a rapidly growing market for functional food. According to the Nutrition Business Journal, U.S. sales grew 9.4% in 2007 to reach USD 34.3 billion (RM 120.1 billion) (i.e. 5.8% of total U.S. retail food sales). In this arena, energy drinks have been the fastest growing segment recording a 440% growth from 2003 to 2008 with a market value of USD 4.8 billion (RM 16.8 billion). The leading global players for energy drinks are Red Bull and Hansen's Monster Brand, sales of which each surpassed USD 1 billion (RM 3.5 billion). Coca-Cola and PepsiCo are also leveraging on this market to produce healthy beverages by the introduction of low-calorie drinks. Business Insights forecasts that between 2005 and 2010, the oral beauty supplements market in Europe and U.S. will have CAGR of 9%, reaching USD 2.3 billion (RM 8.1 billion). The idea that beauty is from within started in Japan and is still in its infancy stage. However, it has attracted big companies like Nestle, that has developed the Glowelle Beauty Drink (anti-oxidant enriched powder supplement that decreases signs of aging), and Mars, with Dove Beautiful milk chocolate enriched with Vitamin C and E to nourish skin[19].

In 2005, the Malaysian natural products industry was estimated at USD 2.3 billion (RM 8 billion)[20]. The Malaysian pharmaceuticals / nutraceuticals market was worth about USD 400 million (RM1.4 billion) in 2005, and is expected to reach USD 2.9 billion (RM 10 billion) by 2010[21]. Malaysia is one of the 12 mega biodiversity countries in the world with over 12,500 species of fauna, of which only about 100 have been fully investigated for their potential commercial value. As represented by the BioNexus Status companies[22], 29.1% of agricultural biotechnology companies is involved in the commercialisation of natural products. However, the lack of scientific and clinical evidence to support the natural products industry impedes efforts to penetrate and gain acceptance in the global market. Malaysian companies can move forward to produce high quality products supported by scientific evidence and based on standardised formulations.

The potential value that the natural products sector can bring largely depends on R&D efforts. This is because efforts in bioprospecting, identification of novel compounds and the establishment of scientific evidence are required for Malaysia to successfully discover, extract, formulate and commercialise novel compounds. Malaysia's immediate strategy is to establish the scientific evidence for natural products, in order to move up the value chain to nutraceuticals, over-the-counter drugs and ultimately botanical drugs.

The collaboration between BiotechCorp, UPM and FeyeCon will enable a commercial scale Supercritical Fluid technology facility to be established in UPM, which will subsequently be opened for use by the industry. The Supercritical Fluid platform technology utilises carbon dioxide as a solvent to extract the bioactive compounds. This would provide alternatives for the use of solvents and non-halal compounds in the extraction process. Advantages of the platform technology include low temperature extraction of bioactive compounds, thus maintaining the compounds bioactivity, flavour and colour. The Supercritical Fluid platform technology is used to complement the existing extraction methods (water and solvent extraction procedures). The platform technology enables the development of Standard Operating Procedures (SOP) for new extraction recipes and it currently provides 33 extraction recipes that are ready for commercialisation.

Holista Biotech (Holista) is involved in the commercialisation of research for the standardised extracts of Kacip Fatimah. Furley Bioextracts and Nova Laboratories are supporting Holista in supplying the standardised extracts. Holista also has a range of products involving fish oil, probiotics, collagen and a range of healthcare products. In 2009, Holista completed its takeover of Colltech Australia, a listed company on the Australian Stock Exchange, the only company worldwide that has a patented process to effectively extract ovine collagen. There is tremendous potential as ovine collagen is halal certified and sourced from certified and fully traceable livestock.

[19] Burrill & Company (2009)
[20] Burrill & Company (2006)
[21] BiotechCorp
[22] Due to unavailability of data for all agricultural biotechnology companies in Malaysia

Furley Bioextracts is involved in natural products development, where it seeks to develop innovative biotechnology-based products that cater to the health and wellness industry. Its core activity is the extraction of bioactive ingredients from plants using the Supercritical Fluid technology. Furley Bioextracts' expertise is in extracting compounds for nutraceutical ingredients, pharmaceutical ingredients and cosmeceutical ingredients; product formulation and innovation for functional food and beverages, fruit juices and concentrates, and food additives; and also contract manufacturing services. Furley Bioextracts has commercialised a natural antioxidant standardised extract and a natural antioxidant skin whitening standardised extract. It has initiated collaboration with Bionic Life Sciences to co-develop a market outreach and penetration programme for their products in the China market.

Examples of other Malaysian companies involved in the discovery and development of novel compounds are BioTropics Malaysia (BioTropics), Bionic Life Sciences, BioAlpha, TPM Biotech, North Borneo Herbal Biotechnology and Biotech Elite Research and Innovations. These companies are involved in the research, development, extraction, processing and commercialisation of identified biological active compounds from herbs and plants for the formulation of herbal-based health supplement products, food ingredients, functional food, nutraceuticals and cosmeceuticals. Of these companies, BioTropics recently acquired Phytes Biotek and has a strategic stake in Intermed Gmbh to gain access to its library of lead compounds in drug discovery based on natural products and herbs, as it can leverage on the biodiversity of Malaysia's tropical rainforests. Bionic Life Sciences proposes to expand its business by producing halal collagen. It has licensed the technology for production of marine collagen from Al-Amin Shanghai Biotech Company.

Moving Forward

In Malaysia, the agriculture sector has been identified as the third engine of growth and is a strategically important sector in terms of GDP contribution and food production. In the NAP3, biotechnology has been identified as a tool that can enhance the agriculture sector. The current needs of Malaysia suggest that agricultural biotechnology can contribute towards Malaysia's goals of ensuring food security, availability and sustainable food production, and also improving the balance of trade. A continued focus should be maintained in this area as Malaysia's local companies are making inroads by enhancing yield and production of crops, livestock and aquaculture. This will enable Malaysia to meet the current needs of a growing population by increasing self-sufficiency levels of major food commodities and improving its balance of trade by reducing imports and ultimately being a net exporter of food. Furthermore, Malaysia should leverage on its strong commodities sector (e.g. oil palm) to use the waste as a cheap and abundant feedstock to produce biofertiliser; and its rich tropical biodiversity to discover and commercialise natural products. Malaysia is also preparing the groundwork for biotechnology / GM crops.

While efforts should continue to build capacity on a sustainable basis as outlined in Phase I of the NBP – Capacity Building, there is a need to focus on moving forward into Phase II of the NBP – Science to Business, with priority given to commercialisation efforts and activities that will contribute to GDP growth. Moving forward into Phase II, specific priority actions are proposed :

1 **Continue efforts in developing crop-related biotechnology, livestock biotechnology, marine / aquaculture biotechnology and natural products**

Crop-Related Biotechnology

Besides addressing domestic needs, there is tremendous regional and global market potential for crop-related biotechnology. There is a need for continued commitment from the Government in building capacity and capability to further develop the agricultural biotechnology sector. Malaysia should continue to focus on the production and utilisation of improved planting materials that are produced through tissue culture, production of organic biofertilisers from palm oil biowaste that epitomises the waste to wealth concept, and the research and utilisation of effective microbes from Malaysia's rich biodiversity. These activities will ultimately enhance the productivity of the agriculture sector and contribute to Malaysia's GDP.

As part of the NBP's strategy, the acquisition of the Marker Assisted Selection platform technology is expected to accelerate development of capacity and capability in crop-related biotechnology. Models for rice, watermelon and goats are being developed for application in related breeding programmes. This can be achieved by adapting the proprietary methodologies, proven setup and SOP to build a high quality genetic pool. Moving forward, the platform technology is expected to enable the development of new applications in other crops and livestock allowing marker assisted selection breeding programmes to be further expanded and allowing Malaysia to establish itself as a regional hub in molecular marker technology for tropical agriculture.

Livestock Biotechnology

The use of assisted reproductive techniques and the production of vaccines should continue thereby improving productivity in the livestock segment. The challenge for Malaysia is to improve on the success rate and efficiency of the techniques. Further enhancement of the assisted reproductive techniques will be required. The way forward is to develop multiplier farms to ensure the continuous supply of selected animals from nucleus farms to commercial farms. Malaysia should also continue to develop the animal feed segment.

In addition, Malaysia has an advantage given that Sabah and Sarawak are recognised by the OIE as a Foot and Mouth Disease free zone. There is tremendous growth potential as there are no restrictions on export to regions like Europe, U.S. and Middle East. Malaysia should capitalise on Sabah and Sarawak's recognised status as a Foot and Mouth Disease free zone by using it as an export hub for beef, mutton and milk. Generally, livestock breeding should move towards the use of marker assisted selection as this will significantly reduce the time taken to obtain desired traits.

Marine / Aquaculture Biotechnology

Moving forward, there is a need to create a sustainable biotechnology ecosystem with its supporting industries that can meet the country's needs and add value to the economy. Hence, continuing efforts are required to build capacity in the marine / aquaculture biotechnology segment. It is proposed that more companies be encouraged to enter this segment, particularly in the fish, seaweed and algae sub-segments. The involvement of more companies in marine or freshwater fish aquaculture will allow Malaysia to fulfill domestic demand and contribute to the global market. On the other hand, seaweed and algae can be used as food ingredients or for the extraction of natural compounds. Hence, continuing efforts are needed to set up, identify and nurture companies that are involved in these biotechnology activities. Collaborations with other companies, RIs or IHLs must also be encouraged for collaborative R&D, technology transfer, commercialisation of products and access to markets.

Natural Products

Malaysia has a wealth of traditional knowledge in herbal and medicinal plants, and a treasure trove of flora and fauna which remains largely unexplored. Currently in Malaysia, there are ongoing efforts to discover novel and bioactive compounds from natural resources that can be extracted, formulated, developed and commercialised into ethnic herbal products, food ingredients, functional food, cosmeceuticals, nutraceuticals and botanical drugs. Gearing up towards Phase II of the NBP, Malaysia should continue its efforts in this segment.

When compared to developed countries, the Malaysian natural products industry can still be considered in its infancy stage. Majority of the players are small and medium sized companies with limited market and technical capabilities. Malaysia is enhancing its evidence-based platform to encourage the growth of the industry to meet global demands and standards thereby facilitating expansion into foreign markets. The acquisition of the Supercritical Fluid platform technology from FeyeCon is the first step undertaken to address the need to enhance its evidence-based platform in developing natural products. There are already 33 recipes for extraction of natural products such as amaranth, black pepper oil, cardamom oil, ginger oleoresin, vanilla and turmeric that can be commercialised immediately. In addition, the platform technology will be able to scale up commercialisation of extraction and production of novel bioactive compounds that can be used as food ingredients, functional food, cosmeceuticals, nutraceutricals and ultimately phytomedicines. Malaysia's immediate strategy is to establish scientific evidence for natural products, in order to move up the value chain to the production of nutraceuticals, over-the-counter drugs and ultimately tropical botanical drugs.

Key Implementation Considerations

In carrying out the proposed actions, there are several key implementation considerations (that are discussed in detail in Chapter 4) for Malaysia to progress in development and commercialisation of agricultural biotechnology:

- Collaboration and funding mechanisms for commercialisation of applications and development of new applications
- Skill-sets and expertise for development and commercialisation such as assisted reproductive techniques, discovery and validation of markers, know-how to develop SOP for the extraction of other valuable compounds and bioprospecting
- Strategic partnerships and collaborations with foreign affiliates for transfer of technology
- Effective management of Malaysia's biodiversity via the National Biodiversity Policy to ensure sustainability and stability

2 **Implement a suitable business model for commercialisation of applications of newly acquired platform technologies**

Being the NBP's implementation agency, BiotechCorp has taken the lead role in identifying and acquiring suitable technologies as part of Malaysia's biotechnology strategy to accelerate the development of the industry. Upon acquisition, appropriate RIs or IHLs will be identified to be the custodian(s) of acquired technologies or platform technologies. The custodians of the two platform technologies described earlier are MARDI for the Marker Assisted Selection platform technology and UPM for the Supercritical Fluid platform technology.

Moving into Phase II of the NBP, it is critical to generate greater value from the investments of the Malaysian Government in acquiring these platform technologies. Commercialisation of applications and the development of products from the said platform technologies will require adoption of a suitable business model. Moving forward, BiotechCorp has already proposed a business model for implementation.

BiotechCorp, being the owner, will have overall responsibility for the commercialisation of the applications, and the custodian(s) will undertake relevant development and validation efforts to commercialise the applications (see Table 3-6). Briefly, the roles and responsibilities of BiotechCorp and custodian are proposed to be as follows:

Table 3-6: Proposed Roles and Responsibilities of BiotechCorp and the Custodian of the Platform Technologies

BiotechCorp	Custodian
• Plan and monitor progress of the development and commercialisation efforts • Identify new applications for development • Identify, attract and acquire customers • Promote and create awareness to attract new business ventures	• Provide the necessary funding and infrastructure (support and staff) • Develop applications for commercialisation and new applications • Provide development and validation services to meet customer requirements

Source: BiotechCorp

A governance framework has also been proposed to manage the collaboration between BiotechCorp and the custodian. Separate organisations will be set up for BiotechCorp and the custodian to undertake the management and operations required for the collaboration. A Management Committee represented by the senior management of BiotechCorp and the custodian will be set up to oversee the proposed separate organisations. In order to ensure focus on delivering results that is required for the commercialisation of the platform technologies, a dedicated management team should be identified to manage and operate the proposed organisations. Each separate entity is expected to aim at establishing Malaysia as the hub for global or regional markets.

Moving forward, the following key actions are proposed to implement the proposed business model:

- Establish a project team comprising members from both BiotechCorp and the custodian to develop detailed strategies (including marketing and globalisation strategies) for each entity and develop detailed steps to implement the business model
- Set up separate legal entities (if needed) as proposed for BiotechCorp and custodian
- Develop details of governance framework that will form the basis for detailed business operating models, and policies and procedures for each organisation
- Identify funding requirements to develop applications for commercialisation and new applications
- Determine revenue model that will be adopted for each organisation, and where possible, set appropriate financial targets
- Identify management team and personnel to be assigned to the organisation, and where needed, recruit new personnel
- Establish a protocol to facilitate continuous monitoring of progress
- Design and put in place appropriate management and operating processes to operationalise each entity

3 Implement global strategy for home-grown players

In the development of the agricultural biotechnology sector, Malaysian players are well positioned as key global players given Malaysia's reputation and market position in the agriculture sector, especially in the primary commodities and plantation sector. Home-grown players such as Sime Darby, IOI and Felda are major plantation companies globally. Malaysia should therefore leverage on this reputation to develop a global strategy for agricultural biotechnology. Efforts should continue in the development of Malaysia as a regional and global player in this sector with emphasis on tropical agricultural biotechnology. Efforts undertaken by the public and private sectors include:

- Promoting Malaysia as a regional hub for the Marker Assisted Selection and the Supercritical Fluid platform technologies
- Implementing the proposed business model described above to enable the establishment and nurturing of new players in the industry
- Nurturing selected top performing BioNexus Status companies to become global players as described in Policy Thrust 6: Financial Infrastructure Development
- Focusing R&D on commercialisation and accelerating progress in agricultural biotechnology by reprioritising efforts
- Continuously developing agricultural biotechnology by leveraging on Malaysia's strong commodities sector (e.g. oil palm) and moving up the value chain from extraction of novel bioactive compounds to the production of nutraceuticals, over-the-counter drugs and ultimately tropical botanical drugs

While efforts should be continued on the above, the priority for moving into Phase II of the NBP should be the execution of the regionalisation and globalisation strategies for tropical agricultural biotechnology. Hence, the implementation of the proposed business model for the acquired platform technologies is expected to enable regionalisation and globalisation of Malaysian products and services.

Policy Thrust 2 Healthcare Biotechnology Development

The increase in aging population, the emergence of new diseases and the current unresolved illnesses reinforce the need for comprehensive healthcare systems in the world to maintain a respectable quality of life. In 2008, Centres for Medical & Medicaid Services estimated the total global expenditure on healthcare at USD 2.4 trillion (RM 8.4 trillion)[23]. This figure accounts for almost 10% of the GDP of most developed countries. In the same year, the total healthcare market for Asia Pacific was estimated at USD 240 billion (RM 840 billion) and was projected to grow between 8% to 10% in 2009[24] and the CAGR for 2010 to 2012 is estimated at 14%[25]. In Malaysia, the accumulated healthcare spending in 2008 was estimated at USD 7.6 billion (RM 26.6 billion)[26],

[23] Burrill & Company (2009)
[24] BiotechCorp
[25] ASD Reports (2009)
[26] Bernama (5 August 2009)

of which healthcare biotechnology revenue was estimated at USD 2.3 billion (RM 8 billion)[27]. Revenue of the local healthcare biotechnology sector is projected to experience the highest growth amongst the three sectors, with CAGR of 20%[27].

The application of biotechnology in the healthcare industry aims at ensuring the health and wellbeing of the population at large. In recent years, significant advances have been made in the healthcare sector that is attributable to the use of biotechnology. Healthcare biotechnology has been instrumental in developing over 200 new therapies and vaccines, amongst which are medicines for rare or chronic diseases (e.g. Hepatitis C, renal failure, haemophilia, Crohn's disease, Fabry's disease and multiple sclerosis). Besides Japan and Australia, two groups of countries have emerged as new destinations for the healthcare biotechnology industry: emerging markets comprising China, India and South Korea; and new entrants comprising Malaysia and Taiwan[27].

Healthcare biotechnology is relatively young in Malaysia and has been earmarked for development under the second policy thrust of the NBP. To get started, given Malaysia's comparative advantage in manufacturing and outsourcing capabilities and cost effective resource availability, Malaysia is well positioned to be a strategic outsourcing hub for healthcare biotechnology R&D and manufacturing, namely CMO and CRO. Moving forward, the development of CMO and CRO will provide the foundation for Malaysia to build capacity and capability in drug discovery and development. In addition, Malaysia's tropical biodiversity will provide opportunities for potential nutraceuticals and ultimately botanical drug discovery and development that caters to the needs of tropical countries especially in the areas of neglected diseases (e.g. malaria, dengue and tuberculosis). Development of natural products is expected to generate greater economic value through progression from extraction of novel bioactive compounds to the development of products with pharmaceutical and health applications.

Due to the heavily regulated nature of the sector, the healthcare biotechnology sector has a longer gestation period and requires greater investment in terms of skills and technologies. For example, any product improvement for pharmaceutical products requires the company to undertake long and extensive product registration procedures. Therefore, Malaysia needs to identify its own niche in developing the healthcare biotechnology sector for the country.

Current State

In 2004, the Biotechnology Information Centre, Malaysia, recorded that there were 11 biopharmaceutical companies in the healthcare biotechnology sector. Since then, there has been a 12-fold increase, as there are 134 healthcare biotechnology companies out of a total of 349, representing 38.4% of the total biotechnology companies as at 30 September 2009. Based on the latest 2008 financial reports available[28], healthcare biotechnology companies contributed a total revenue of USD 47.4 million (RM 165.8 million) which represents 31.6% of the total revenue size of the biotechnology industry.

Of the 134 healthcare biotechnology companies in Malaysia, 51 companies (38.1% of total companies) obtained BioNexus Status and these companies generated a total revenue of USD 24.9 million (RM 87 million) in 2008, as compared to the remaining companies (without BioNexus Status) that generated revenue of USD 22.5 million (RM 78.8 million), which represents 47.5% of the total healthcare biotechnology sector revenue size (see Table 3-7).

Total investment of healthcare biotechnology companies was USD 235.1 million (RM 822.8 million) based on the latest available information[29]. This represents about 28.7% of the total investment in the biotechnology industry. A total investment of USD 122.3 million (RM 428 million) has been approved for BioNexus Status companies.

Total investment of healthcare biotechnology companies was USD 235.1 million (RM 822.8 million) based on the latest available information[29]. This represents about 28.7% of the total investment in the biotechnology industry. A total investment of USD 122.3 million (RM 428 million) has been approved for BioNexus Status companies.

[27] BiotechCorp
[28] Based on BiotechCorp (as at 31 December 2008) and SSM (31 December 2008 or latest financial reports available)
[29] Based on BiotechCorp (as at 30 September 2009) and SSM (31 December 2008 or latest financial reports available)

Table 3-7: Overview of the Malaysian Healthcare Biotechnology Sector (31 December 2008)

Type of Companies	Number of Companies	Total Revenue		Total Approved Investment	
		USD million	RM million	USD million	RM million
BioNexus Status Companies	51	24.9	87.0	122.3	428.0
Non-BioNexus Status Companies	83	22.5	78.8	112.8	394.8
Total	**134**	**47.4**	**165.8**	**235.1**	**822.8**

Source:
(1) BiotechCorp
(2) SSM (as at 31 December 2008 or latest financial reports available)

For the purpose of this Country Report, further analysis of performance has been conducted on CMO, CRO, biopharmaceuticals / pharmaceuticals, stem cells / therapeutics and medical devices / IVD. The NBP has outlined the following key actions that are required for the development of the healthcare biotechnology sector:

- To implement a biosimilars initiative in opportunistic markets and to develop vaccines for tropical diseases (biopharmaceuticals / pharmaceuticals)
- To implement an initiative to develop molecular diagnostics for diseases (medical devices / IVD)
- To implement the bio-banking initiative to encourage development of personalised medicine (stem cells / therapeutics)

In addition, as provided in Policy Thrust 8: Strategic Development, the establishment of CMO and CRO and the development of bioinformatics initiatives are some of the key strategies and actions for the development of healthcare biotechnology.

As represented by the BioNexus Status companies[30] as at 30 September 2009, 33.3% of the healthcare biotechnology companies is involved in the medical devices / IVD segment, followed by biopharmaceuticals / pharmaceuticals at 23.5% and CRO at 19.6%. The therapeutics / stem cells segment represents 11.8% while that of CMO is 5.9% (see Table 3-8). Several reasons can account for the high involvement of healthcare biotechnology companies in the medical devices / IVD segment. Firstly, there is a shorter gestation period for commercialisation (faster time to market) as it takes only six to 12 months as opposed to the average three to four years for other segments. Secondly, it is easier for these companies to secure funding from financial institutions as there is a better understanding of the medical devices / IVD sector. Thirdly, medical devices and diagnostics are generally less complex when compared to biopharmaceuticals, and are therefore subjected to less regulatory controls as compared to drug approvals. Lastly, Malaysia has strong human capital availability in the engineering field. Hence, the availability of related expertise in engineering which can be applied to the medical devices and IVD sector has been conducive to the development of this area.

Table 3-8: Overview of BioNexus Status Companies in the Malaysian Healthcare Biotechnology Sector (30 September 2009)

Focus Area	Number of Companies	Proportion of Companies in Focus Area (%)	Total 9 Months Revenue (USD '000)	Total Approved Investment (USD million)	Projected R&D Expenses (USD '000)	Projected Number of Knowledge Workers
CMO	3	5.9	0	38.0	0	94
CRO	10	19.6	264.7	8.5	0	177
Medical Devices / IVD	17	33.3	1,782.6	25.5	1,694.6	221

[30] Due to unavailability of data for all healthcare biotechnology companies in Malaysia

Focus Area	Number of Companies	Proportion of Companies in Focus Area (%)	Total 9 Months Revenue (USD '000)	Total Approved Investment (USD million)	Projected R&D Expenses (USD '000)	Projected Number of Knowledge Workers
Biopharmaceuticals / Pharmaceuticals	12	23.5	6,765.1	15.0	1,938.0	258
Therapeutics / Stemcells	6	11.8	6,648.1	23.4	214.9	235
Medical Bioinformatics	3	5.9	6,734.4	11.9	1,832.8	34
Total	51	100.0	22,195.0	122.3	5,680.3*	1,019**

** Actual R&D expenses for 12 months ending 30 September 2009 was USD 4.5 million (RM 15.8 million)*
*** Actual number of knowledge workers as at 30 September 2009 was 427*
Source: BiotechCorp (based on the latest information available)

The 51 BioNexus Status companies generated a total revenue of USD 22.2 million (RM 77.7 million) in the first nine months of 2009. Of these, a large number of them are involved in the medical devices / IVD segment, with a total of 17 companies generating revenue of USD 1.8 million (RM 6.2 million). The high involvement in this segment can be explained by the shorter time to market for the products compared to the other focus areas. This is further highlighted by the significant amount of investment into these companies with a total of USD 25.5 million (RM 89.2 million) being approved. The biopharmaceuticals segment contributed a total revenue of USD 6.8 million (RM 23.7 million), while the therapeutics / stem cells segment contributed a total revenue of USD 6.6 million (RM 23.3 million) in the first nine months of 2009.

Under the National Biotechnology Acquisition Programme, two healthcare platform technologies have been acquired, namely, the nanotechnology platform from France in 2007 and the DotScanTM antibody microarray diagnostic platform technology from Australia in 2009. These platform technologies can be applied across the healthcare industry, but the immediate applications identified to be developed are in the biopharmaceuticals / pharmaceuticals and medical devices / IVD segments. The selection of these technologies was based on a thorough analysis of the needs of the region. These technologies will benefit the population, serve national interest and further accelerate the development of the healthcare biotechnology sector. The current need is to attract more research applications for commercialisation of the technologies that have been acquired.

Total revenue generated by the CRO segment equalled to USD 264,721 (RM 926,525). Although approximately 20% of the companies is involved in CRO, the revenue is relatively small as most are newly established companies. It should be noted that Malaysia has potential to develop this sector given its multi-ethnic population. On the other hand, there is only approximately 6% of companies involved in the CMO segment and there is, as yet, no revenue contribution. Most newly established CMO would take at least three years to be fully operational with the appropriate regulatory approval.

As at 30 September 2009, projected employment of knowledge workers in the healthcare biotechnology sector is evenly spread across the medical devices / IVD, biopharmaceuticals and therapeutics / stem cells segments with the number of knowledge workers standing at 221, 258 and 235 respectively. These numbers are expected to grow as the companies establish themselves within the sector. Based on Table 3-8, the therapeutics segment has the highest number of knowledge workers per company. This could be due to the large number of R&D activities that are being carried out, requiring a large number of specialist knowledge workers in activities related to stem cell therapy, tissue engineering as well as genetic engineering.

In terms of investment, companies that are involved in CMO attracted the highest amount at USD 38 million (RM 133.1 million), accounting for 31.1% of total investment approved in the healthcare biotechnology sector. As Malaysia has been a manufacturing-based economy for the past 15 years, there is sufficient general business experience in manufacturing and an established infrastructure in place to attract foreign investment. Thus contract manufacturing companies have a competitive advantage in that aspect and as a result, it is less risky compared to the other segments.

From 2004 to 2008, there was a total number of 819 healthcare biotechnology patent applications, which was the highest number of patents applied compared to the agricultural biotechnology (225) and industrial biotechnology (530) sectors. Meanwhile, there is generally an increasing trend in the number of healthcare biotechnology patents granted from 2004 to 2008 (see Table 3-9). The total number of patents granted was the highest across all sectors at 344 patents, with 98.5% granted to foreign applicants. Unlike the agricultural biotechnology sector, the healthcare biotechnology sector lacks home-grown technology, thereby necessitating collaboration for the licensing or acquisition of foreign technology.

Table 3-9: Number of Local and Foreign Healthcare Biotechnology Patents Applied and Granted in Malaysia (2004-2008)

Patent		2004	2005	2006	2007	2008	Total
Applied	Local	5	15	14	16	16	66
	Foreign	117	188	165	51	172	753
	Total	**182**	**203**	**179**	**67**	**188**	**819**
Granted	Local	0	0	0	4	1	5
	Foreign	30	23	45	117	124	339
	Total	**30**	**23**	**45**	**121**	**125**	**344**

Source: MyIPO (2009)

Table 3-10 provides a summary of current strategic partnerships and collaborations in the development of the healthcare biotechnology sector.

Table 3-10: Selected Partnerships and Collaborations of Malaysian Healthcare Biotechnology Companies

Focus Area	Strategic Partnership		Purpose
CMO	• Foreign	• Shanghai Fu Yi Bioengineering • CIMAB , Cuba • CEVEC Pharmaceuticals, Germany	• Transfer of technology • Collaborative R&D
CRO	• Foreign	• Veeda South East Asia • Nimura Genetics Solutions • Actis Biologics • Vivo Biotech India • The Cuban Center for Genetic Engineering and Biotechnology	• Strategic partnership • Transfer of technology • Collaborative R&D
	• Local	• Forest Research Institute Malaysia • Universiti Sains Malaysia	• Collaborative R&D • Access to high throughput screening services facility
Biopharmaceuticals / Pharmaceuticals	• Foreign	• Novartis Institutes for BioMedical Research Basel (NIBR Basel) of Novartis Pharma AG • Massachusetts Institute of Technology	• Collaborative R&D • Transfer of technology
	• Local	• Department of Fisheries Malaysia	• Collaborative R&D • Transfer of technology
Stem Cells / Therapeutics	• Foreign	• Institute for Medical Research KPJ Group	• Collaborative R&D • Strategic partnership to provide stem cell therapy services at KPJ

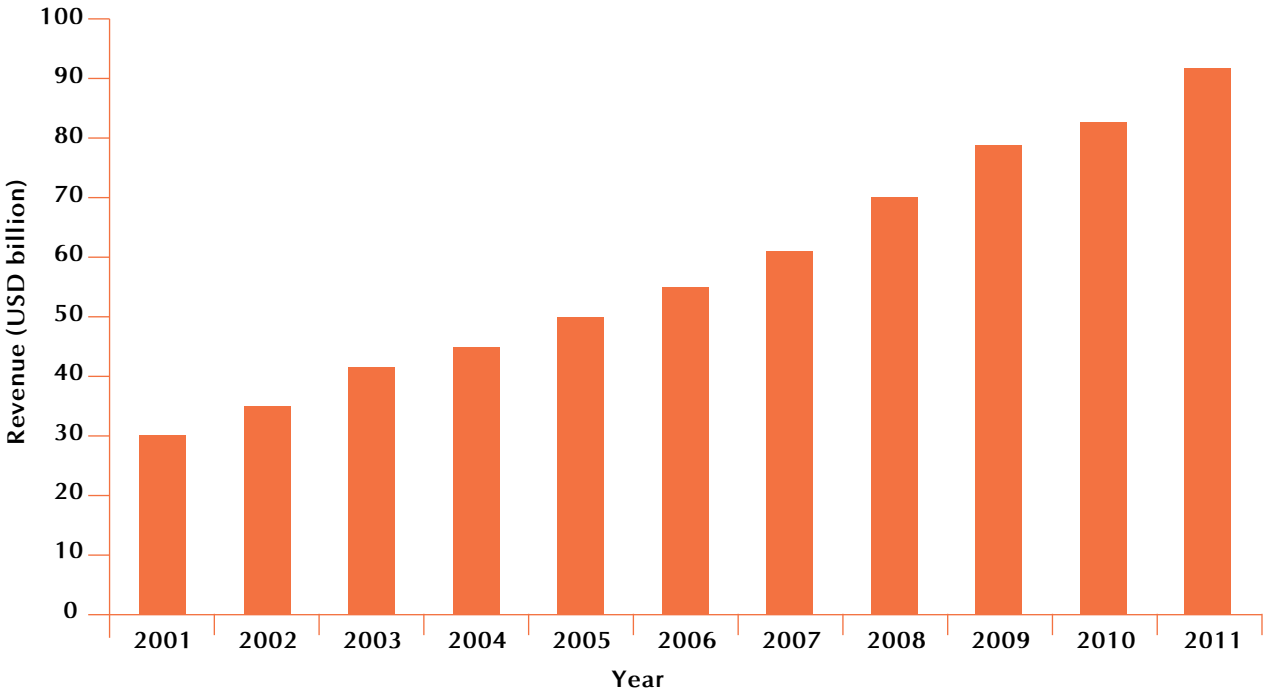
Focus Area	Strategic Partnership		Purpose
Medical Devices / IVD	• Foreign	• GeneNews Canada • National Defence Medical Centre of Taiwan • ReaMetrix India	• Transfer of technology • Collaborative R&D • Access to markets
	• Local	• Universiti Teknologi MARA • Ministry of Health	Collaborative R&D

Sources:
(1) BiotechCorp
(2) Ernst & Young Analysis

Biopharmaceuticals / Pharmaceuticals

In 2004, the biopharmaceuticals market recorded USD 45 billion (RM 157.5 billion) in revenue, witnessing 15% to 17% growth and the market is projected to reach USD 92 billion (RM 322 billion) in 2011 (see Figure 3-1). The U.S. market will remain the dominant market for biopharmaceuticals, where it accounts for 60% of the global share followed by Europe, 20%, which is mostly represented by five main countries, namely U.K., Germany, France, Italy and Spain[31].

Figure 3-1: Global Biopharmaceuticals Market Revenue Forecast (2001-2011)



Source: Pharmaceutical Technology Europe (2006)

It is projected that the Malaysian biopharmaceuticals market will reach USD 132 million (RM 462 million) by 2013 with an aggregated CAGR of 12%[32]. Malaysia has a strategic prospect in the development of biopharmaceuticals. The biopharmaceuticals market will be focused more on catering to local and regional demands. It will avoid entering into direct competition with large and existing global participants as Malaysia will develop biopharmaceuticals that specifically address locally and tropically prevalent diseases. This represents a niche market where emphasis will be placed on the needs of the region, particularly in frequently sought treatments, and the unmet and unresolved illnesses in ASEAN.

[31] Pharmaceutical Technology Europe (2006)
[32] Espicom (2008)

The Malaysia Genome Institute (MGI) and the Malaysian Institute of Pharmaceuticals and Nutraceuticals (IPHARM) were established by MOSTI in 2006. Situated in the vicinity of Universiti Kebangsaan Malaysia (UKM), MGI is expected to carry out studies on tropical bioresources through genome sequencing, comparative and functional genomics and structural biotechnology. To date, MGI has 18 local research projects and three international collaborations such as the study of structural genomics of Burkholderia pseudomallei essential genes with the University of Sheffield. Located within the confines of Universiti Sains Malaysia (USM), IPHARM has been assigned to lead the discovery of functional food and drugs for the future betterment of healthcare. Its focus areas are confined to diagnostics and biomedical, vaccines, nutraceutical, contract research and tropical research. Most projects are still at the R&D stage.

Malaysia has favourable demographics for vaccine development in the ASEAN and Asian economies due to growing urban populations with unmet needs in the emerging disease burdens which are traditionally overlooked by big pharmaceutical companies. MLSCF and MTDC have respectively invested USD 5.7 million (RM 20 million) in Sentinext Therapeutics (Sentinext), a biotechnology company that plans to develop novel vaccines and therapeutics for emerging diseases and tropical infectious diseases. Sentinext is possibly five to seven years away from the development of an antiviral vaccine for Enterovirus 71 (EV71), a hand, foot and mouth disease that can cause death, especially among children globally. A vaccine for EV71 is needed as frequent outbreaks of the disease occur during the summer months in the West and in the tropics. MLSCF funds were invested in Sentinext because it has all the ingredients to become a commercially viable biotechnology company in the near future. Sentinext is also expected to venture into the development of vaccines for JE, dengue and malaria. Other companies that are involved in developing vaccines with different applications (e.g. lung cancer, dengue and JE) include Bioven and Mab Explorations.

Ninebio, a Malaysian Government-owned company, was established in 2003 to undertake R&D and the manufacturing of vaccines, natural products and biologics with a focus on addressing life threatening diseases and emerging regional diseases (e.g. Severe Acute Respiratory Syndrome (SARS), avian flu and nipah virus), as well as bioterrorism. It was also mandated to ensure that the critical vaccine requirements of the country are met in terms of development and supply. A strategic alliance with Emergent BioSolutions has enabled the creation of critical biologics infrastructure and the supply of biodefence countermeasures such as 'BioThrax' (Anthrax Vaccine Adsorbed) to certain Organisation of the Islamic Conference (OIC) countries and countries within Asia. Ninebio was set up to fulfil Malaysia's vision to become self-reliant in vaccine production and security, as well as the development of halal vaccines. Ninebio has been appointed as the technical advisory body to the Department of Islamic Development Malaysia (JAKIM) for halal certification of vaccines and medicinal products (e.g. traditional and complementary medicine, nutraceuticals and supplements). JAKIM's certification for vaccines and medicinal products will promote consistency and confidence in Malaysia's halal logo and certification process to the Muslim world. Ninebio is in the process of seeking collaboration with foreign companies.

The country's position as an international halal hub offers market opportunities to Muslim communities around the globe as there is rising demand for halal certified vaccines in OIC countries. The OIC is promoting emphasis on the use of vaccines that conform to religious dietary restrictions. The market for products approved by Islamic Law is estimated at USD 560 billion (RM 1.9 trillion)[33]. With over 60% of the population in Malaysia practising Islam, Malaysia has enormous potential in producing halal vaccines. At present, most of the vaccines in the country are imported and are not certified by JAKIM[34]. Biotechnology efforts in Malaysia are already underway to develop medicines and vaccines that conform to Islamic regulations. USM and the Finlay Institute in Cuba are developing the meningitis B vaccine that is certified, manufactured and marketed internationally as a halal product to be introduced in the market sometime in 2010 / 2011. The vaccine is critical for Muslims performing Hajj or Umrah as it is derived from plant cell culture instead of animal cell culture[35]. The next stage of this potentially successful two-nation joint effort would be the establishment of a vaccine plant in Malaysia for mass production, warranting the technology transfer from Finlay Institute. This collaboration would make Malaysia the reference and research centre for halal vaccine production in the future and reinforce the nation's efforts to develop into an international halal hub. However, involvement in the area of vaccine production is mainly by GLCs. There is a need to attract private players and global companies as there is currently a lack in critical mass in terms of vaccine producers.

[33] World Security Institute Website, accessed on 3 October 2009.
[34] Sim (2007)
[35] Bernama (5 May 2009)

Drug discovery and drug delivery are other crucial areas in healthcare biotechnology. Drug discovery is the process by which high content screening and research are conducted to assimilate new therapeutic molecules with specific biologic activities in developing drugs for the purpose of providing benefit to a defined patient population. Drug delivery, on the other hand, can be defined as "a method or process of administering a pharmaceutical compound to achieve a therapeutic effect in humans or animals"[36]. Many technologies are involved in drug discovery, ranging from bioanalytical instruments, genomics, combinatorial chemistry and proteomics to emerging new technologies such as nanotechnology and lab on a chip[37]. Presently, U.S. and Europe are the two giant players that dominate the drug discovery technologies. A published report by Global Industry Analysts Inc estimated that both countries comprise 78% of the global market in 2008. However, the market trend is slowly shifting to Asia as companies outsource their R&D to save time and reduce cost, creating a lucrative market for biotechnology firms that can exploit this opportunity.

Based on the data represented by the BioNexus Status companies[38], around 10% of the healthcare biotechnology companies in Malaysia is involved in drug discovery and delivery. Having won the "Most Innovative Biotech Start-Up in Asia Pacific" award, SIOGEN Biotech has positioned itself globally and is attracting strategic partnerships around the globe. The company is equipped with a drug delivery nanotechnology called Siosomes® (based on Silane molecules) that works as a drug carrier and targeting system to ensure the safety and increase the bioavailability of drugs to a user. This platform technology benefits patients as it lowers treatment costs and provides efficient treatment to patients. In addition, the Siosomes® platform offers IP protection to compounds that cannot be patented such as biosimilar products[39]. The company is also focusing on the commercialisation of this proprietary technology for the improvement and development of medical drugs.

The unexplored diversity of natural resources is another key area for the development of the healthcare biotechnology industry. The value in natural products lies in novel discoveries made from the compounds extracted from plants to produce food ingredients, functional food, health and dietary supplements, cosmeceuticals, nutraceuticals and phytomedicines. The development of phytomedicine is a potential focus area as Malaysia can leverage on its rich biodiversity and natural resources for potentially significant achievements in novel compounds, APIs and drug discovery. Malaysia has an estimated 12,500 species of flowering plants and 1,100 species of fern and fern allies, many of which are unique to Malaysia[40]. However, the vast majority of medicinal plants in Malaysia have remained unexplored or are yet to be examined to their full potential, with only about 100 species being fully investigated.

In the state of Sarawak, for example, the rainforest is one of the most diverse ecosystems in the world. In 1997, the Sarawak State Government installed a highly reputable research centre in bioprospecting in the Sarawak Biodiversity Center (SBC). The rich biodiverse ecosystem has attracted Novartis, one of the largest global pharmaceutical companies and a leading company in natural substance research, to sign a tripartite MOU with SBC and BiotechCorp to enhance the development of SBC's capabilities and explore novel bioactive compounds. These bioactive compounds could have medicinal effects which may be developed into medicines in future. The MOU between Novartis, SBC and BiotechCorp is intended to facilitate cooperation, collaboration, consultation and coordination among all three corporations. Novartis also offers support to develop mutually agreed bioprospecting activity and capacity building. Another feature of this partnership is the offer of internships for SBC scientists to work in the Novartis Institutes for Biomedical Research in Basel, Switzerland, which provides opportunities for capability building and knowledge transfer as Novartis is a leader in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and self-medication over-the-counter brands.

One particular company, Nova Laboratories, sees potential in Malaysia's diverse flora and has been developing and commercialising botanical, nutritional and healthcare products derived from local plants. It has a 242,000 square-foot manufacturing facility that is GMP compliant and utilises proprietary extraction technologies such as Nova-PhytoTech Process. This process ensures uniformity in quality and activity from batch-to-batch[41]. The process also assures that the purest and most effective pharmacological components of extract can be obtained for the production of softgels and herbal products in tablet, capsule and oral powder forms. In its efforts to maximise the biodiversity usage, the Sabah Forestry Department has also initiated

[36] Kumar (2006)
[37] Pharmaceutical Technology Website, accessed on 10 October 2009
[38] Due to unavailability of data for all healthcare biotechnology companies
[39] Siogen Website, accessed on 14 October 2009
[40] National Policy on Biological Diversity (1998)
[41] Nova Laboratories Website, accessed 13 October 2009

studies on the distribution and use of medicinal ferns and poisonous plants in Sabah. Another company, Black Gold Petroleum is developing healthcare products using natural products via the production of coenzyme Q10 with improved bioavailability for food supplements from tobacco leaves.

SimuGen is a toxicogenomics company grown from the talents of Cambridge and Oxford in the U.K. SimuGen recently incorporated a sister company in Malaysia (SimuGen Asia), with the aim of launching its first product from Malaysia in the next year. It will be a web-based tool using proprietary dose-response models of gene expression phenotypes from human cell cultures exposed to chemicals. This is to help pharmaceuticals develop safer drugs. This tool has already attracted significant attention and there are future plans to begin collaboration with a large pharmaceutical company.

The Malaysian biotechnology industry has formed important collaborations with local and foreign institutions to tap into their research expertise and infrastructure. In terms of local collaborations, Universiti Malaya (UM) and the Sabah Forestry Department have collaborated with the Centre for Natural Products and Drug Discovery (CENAR) to develop healthcare biotechnology via the development of natural drugs. GeneNews and Ministry of Health (MOH) have collaborated to conduct diagnostics tests for liver cancer, Hepatitis B and nasopharyngeal cancer. In terms of foreign collaborations, two local companies, Melaka Biotech Holdings and Vanguard Creative Technologies, have been in collaboration with Vivo Biotech from India to build a USD 128.6 million (RM 450 million) integrated biotechnology facility in Melaka for the production of drugs for diseases such as diabetes and cancer.

Given that Malaysia is relatively new in healthcare biotechnology, local biotechnology companies do not have adequate technological expertise in developing novel biopharmaceutical drugs. Hence, Malaysia has made significant efforts to acquire technology in this area, as well as support BioNexus Status companies in collaborating with foreign companies to acquire licensed rights to locally produce biopharmaceuticals (e.g. drugs, vaccines) or drug compounds such as APIs. In 2007, one of the platform technologies acquired for healthcare was the exclusive worldwide license for a nanotechnology platform from Nanobiotix of France for the manufacture of nanoparticles and the development of related applications such as drug delivery systems and diagnostics in the non-oncology field. USM is the custodian for this technology, and Malaysia's collaboration with Nanobiotix has enabled three USM researchers to undergo 12 months of training in France to facilitate the transfer of knowledge and technology. These researchers have since returned to Malaysia and will share their training and knowledge with the other researchers and the relevant industry players. Technology acquisitions such as this will allow knowledge transfer to be effected as researchers will be trained accordingly to develop capabilities in the new technologies.

Moving forward, Malaysia should also look into biopharmaceuticals to prevent or treat disease categories that are most prevalent in the region. This may include infectious and neglected tropical diseases like dengue and malaria. The next milestone is to use both these platform technologies to develop applications of commercial value.

Medical Devices / In Vitro Diagnostics

The global medical device market is about half the size of the world's pharmaceutical market, comprising mainly U.S. companies. There are an estimated 20,000 medical devices companies globally and sales were projected at USD 336 billion (RM 1.2 trillion) in 2008[42]. In comparison to pharmaceutical companies, this segment faces lower risk as there is less regulatory approval involved and significantly shorter time for product development. In addition, there is growing demand for better and improved diagnostic kits and imaging tools for more efficient diagnosis and disease detection, accounting for the boost in the medical devices market. Between 2006 and 2007, each of the top ten global medical devices companies, except Phillips Medical Systems which remained stagnant, recorded growth in revenues, totalling USD 119.1 billion (RM 416.9 billion). Table 3-11 provides the summary of revenues generated by the respective companies.

[42] Rosen (2008)

Table 3-11: Top Ten Global Medical Device Companies in 2007

Rank	Company	Country of Origin	2006 Revenue		2007 Revenue	
			USD billion	RM billion	USD billion	RM billion
1	Johnson & Johnson	U.S.	20.3	71.1	21.7	76.0
2	GE Healthcare	U.S.	16.6	58.1	17.0	59.5
3	Siemens Medical Solutions	Germany	11.6	40.6	14.4	50.4
4	Medtronic	U.S.	12.1	42.4	12.9	45.2
5	Baxter International	U.S.	10.4	36.4	11.3	39.6
6	Covidien, (TYCO Healthcare)	U.S.	9.5	33.3	10.0	35.0
7	Philips Medical Systems	Netherlands	8.9	31.2	8.9	31.2
8	Boston Scientific	U.S.	7.8	27.3	8.4	29.4
9	Roche	Switzerland	7.2	25.2	8.0	28.0
10	Becton Dickinson	U.S.	5.8	20.3	6.5	22.8

Source: MX: Business Strategies for Medical Technology Executives, May/June 2008 edition

In Malaysia, the medical devices market was estimated at USD 585.5 million (RM 2.1 billion) in 2008 and was projected to grow by 8% in 2009, reaching an estimated value of USD 669.7 million (RM 2.3 billion) in 2010[43]. There are currently more than 180 medical device manufacturers in Malaysia, employing some 36,500 people. The diagnostics market had a CAGR of 10.5% in 2009, with an allocated expenditure of USD 45 million (RM 157.5 million)[44]. Over 60% of the diagnostics market is made up of three segments – Immuno Chemistry, Clinical Chemistry and Self-Monitoring of Blood Glucose (SMBG). Most Asian countries, including Malaysia, have a growing demand for SMBG devices because of the increasing prevalence of diabetes[44]. This trend creates a market opportunity for the medical devices and diagnostics segment. In recent years, molecular diagnostics, the diagnosis of disease using molecular biology, has been growing in importance. Cytogenetic Analysis that uses In Situ Hybridisation, Oligonucleotide Array Sequence Analysis and pathogenic organism identification analysis of DNA sequences are some of the biotechnology techniques that use this application. One noteworthy company in Malaysia that is set to revolutionise the medical industry is Delphax. It is dedicated to the development of the biomedical device industry with a focus on surgeon-driven solutions through research. Apart from that, the company also emphasises the design and development of treatment for musculoskeletal conditions. Novel inventions include the Orthopaedic (Trauma) and Spinal Fixation Devices, which incorporate the proprietary Fusion and Non-Fusion Technology Platform.

Malaysia is currently focused on identifying potential medical devices and diagnostics companies that produce high-end products that utilise biotechnology applications to bring about greater value-add to medical care. BioNexus Status is granted based on a case by case selective evaluation of the medical devices and diagnostics that comply with the class C and D classification system of medical devices of the MOH's Medical Devices Bureau[45]. Class C and D devices includes In Situ devices such as implantable defibrillators, heart valve, lung ventilators and bone fixation plates[46]. One of the Northern Corridor Economic Region programme initiatives undertaken by the Government is aimed at developing the first medical devices and diagnostics incubator in Malaysia.

In terms of technology acquisition, BiotechCorp acquired a license for the DotScan™ antibody microarray diagnostic platform technology from Medsaic Australia in 2009 to develop relevant clinical applications and accelerate the turnaround time in diagnosing lymphoma and leukemia. This technology enables identification of cell surface proteins, and can be used for haematological malignancies, solid tissue tumours and autoimmune diseases. This will allow researchers to expedite the screening and development of diagnostic tools for local diseases that have been neglected such as lupus and dengue. Additionally, the system will provide local researchers and scientists with a tool to diagnose diseases such as cancer, autoimmune diseases and infections. This will enable clinicians to better understand each patient's condition and as a result, provide better treatment. To-date, the Institute for Medical Research (IMR) has been appointed as one of the custodians for this technology. The nanotechnology platform acquired can also be used for the development of applications in this segment.

[43] Danish Trade Council (2009)
[44] Frost & Sullivan (2009)
[45] BiotechCorp
[46] Medical Device Bureau Website, accessed 3 October 2009

Biotechnology is offering new tools that provide better diagnosis and more effective but less intrusive and uncomfortable testing for patients. Concurrently, diagnostics is receiving growing attention as this critical component is essential to develop academic and R&D capabilities. Malaysia has successfully been making progress in the area of medical diagnostics. During BioMalaysia 2008, Geneflux Biosciences (Geneflux) launched 'MyDENKit', a Polymerase Chain Reaction (PCR)-based molecular diagnostic kit for the detection and stereotyping of dengue. 'MyDENKit' is the first conventional PCR-based molecular diagnostic kit in the world, which is the outcome of the public-private partnership between UM and Geneflux. Geneflux will provide dengue molecular screening services to small clinics, private and public hospitals; and investigation reports will be sent to the concerned clinicians within five to six hours upon receipt of blood samples. The pre-commercial validation of 'MyDENKit' was partially funded by MOSTI. Geneflux has set up a molecular biology laboratory in Malaysia, a bioinformatics centre in India, and a pharmaceutical business centre in Maryland, U.S. This company exemplifies the progress of Malaysian biotechnology in the global arena.

DNA Laboratories is an independent laboratory that commercialised in-house R&D detection kits for genetic abnormalities, cancer and infectious diseases. The company offers technologies such as the Molecular Diagnostic Kit (MDK) which has specific biomarkers to detect genetically inherited diseases. A MDK named 'ThalaCheck' was developed for single gene disorder detection of Thalassemia carrier. The technology to detect diseases at an early stage will increase the survival chances of patients with genetically inherited diseases.

Another company is Malaysian Bio-Diagnostics Research that produces diagnostic kits for tuberculosis, malaria, HIV and typhoid via strategic partnerships with various IHLs and RIs[47]. It has expanded its services into producing other medical diagnostic products that include tests for pregnancy, abuse of drugs and Brugian filariasis. Other foreign collaborations include Venture Technologies with ReaMetrix India to develop Flavivirus diagnostics for the global market.

Small Bone Innovations (SBi), a leading U.S. based specialised orthopaedics company, offers a broad, clinically proven portfolio of products and technologies to treat trauma and diseases in small bones and joints. Khazanah Nasional is investing about USD 25 million (RM 90 million) in SBi. The investment was made as part of a USD 108 million (RM 388 million) series financing round undertaken by SBi, together with other investors including Goldman Sachs Group, Inc, MTDC, the Family Office of Bahrain and Trevi Health Ventures. SBi has decided to set up its Asia Pacific hub in Kuala Lumpur to undertake activities such as biomaterial research, product development, surgeon education and distribution in the region. SBi is also currently exploring the possibility of establishing an Asia Pacific manufacturing base in Malaysia for its products. Its presence is expected to create additional skilled knowledge workers in the areas of new technology and product development for Malaysia's nascent medical devices industry. In particular, the human capital development of the local orthopaedics ecology will benefit from the potential collaboration between SBi and local researchers, entrepreneurs and surgeons.

Overall, Malaysia has progressed in the development of its medical devices / IVD segment since the implementation of the NBP. While sufficient capacity has been built in terms of the number of companies established, there is a need to continuously move the products from the local market to the regional and global markets.

Stem Cells / Therapeutics

Stem cells refer to unspecialised cells in the human body that are capable of developing into specialised cells, each with new specialised cell functions. Stem cell research aims to identify and propagate appropriate stem cells that have great potential to bring modern clinical medicine to the next level by enabling the treatment and cure of various illnesses. For example, understanding and gaining mastery of cell proliferation and differentiation of stem cells would offer the possibility of replacement cells, tissues and organs that are a perfect match for each patient; and treating diseases like Alzheimers, Parkinson's, spinal cord injury, cardiovascular disease, cystic fibrosis, stroke, diabetes, osteoarthritis and possibly even cancer. Therapeutics is defined as the usage of drugs in the remedial treatment or prevention of diseases.

[47] Genetic Engineering and Biotechnology News (2007)

Using conservative estimates, Business Insights reported that the global market for stem cells reached USD 410 million (RM 1.4 billion) in 2008, and is projected to reach USD 2.7 billion (RM 9.5 billion) in 2012 and USD 5.1 billion (RM 17.9 billion) in 2014. On the other hand, Markets and Markets estimates that with a CAGR of 14.8% from 2009 to 2014, the global market for stem cells will reach USD 88.3 billion (RM 309.1 billion) by 2014. This growth is encouraged by the increasing regulatory approval and public acceptance bodies, and the increasing number of patients that are attracted to both the potential and realised benefits of stem cell therapy. The global market for cord blood stem cells alone is projected to reach USD 15 billion (RM52.5 billion) by 2015, at a CAGR of 27.3% from 2006 to 2015.

In Malaysia, guidelines are in place and there is an adequate number of biobanking facilities for stem cells. This provides a good platform for the growing trend in stem cell research, as the importance and potential benefits of stem cells have become more apparent. The stem cell research and therapy market in Malaysia is estimated to be worth USD 157 million (RM 549.5 million), with a year-on-year growth rate estimated at 12%[48]. Government RIs are undertaking research for commercialisation and there are also initiatives to move up the value chain by bringing in companies such as Stempeutics Research Malaysia (Stempeutics), Nichi-Asia Life Science (Nichi-Asia Life) and StemTech International (StemTech) to undertake research and develop therapeutics.

Stempeutics is the first international company in stem cell research and therapeutics to obtain BioNexus Status. Stempeutics has a USD 5.7 million (RM 20 million) stem cell research facility in Malaysia[49]. It concentrates on human stem cells therapeutics research and also in the commercialisation of adult stem cells for therapeutic purposes. The procedure involves stem cell isolation and focuses on up-scaling mesenchymal stem cells (MSC) for cell therapy using its cGMP facility. MSC is prodigious as a potential therapeutic agent for several degenerative diseases that can affect people of all ages.

Nichi Asia Life Science, another BioNexus Status company, has a successful collaboration with GN Corporation in Japan to set up a laboratory facility to develop stem cells to provide Autologous Immune Enhancement Therapy for cancer and also as a Stem Cell Therapy hub for diseases such as liver cirrhosis, heart diseases and neurological illnesses. It also provides research and training for scientists and physicians.

Although there are many controversies surrounding stem cell research, MOH recognises that it is crucial for local scientists and clinicians to be involved in stem cell research provided that these conform to ethical guidelines. It is vital for medical scientists to keep abreast of current advances in science, especially when there is revolutionary potential in the form of cell replacement therapy. Due to the importance of a regulatory framework to govern activities related to stem cell research and therapeutics, MOH has therefore formed the National Stem Cell Committee to provide governance and leadership in this area. BiotechCorp refers to MOH for guidelines to assess companies that are involved in blood-derived products such as stem cells, as these companies are subject to inspection and licensing by MOH.

Given Malaysia's capabilities in stem cell banking, local players have ventured into the regional market to provide such services. However, moving forward, there is a need to undertake research to develop therapeutics in order to move up the value chain of services. Specific skills and expertise will be required to support such efforts.

Contract Manufacturing Organisation

Globally, the healthcare biotechnology sector has a significant dependence on CMOs. CMOs offer manufacturing services with flexible volume capabilities for R&D, pre-clinical and clinical trial purposes and commercialisation, either for pilot-plant production or large scale production. According to a study by Frost and Sullivan, biopharmaceuticals is a large focus area of the world healthcare biotechnology industry, hence contract manufacturing of biopharmaceuticals is set to grow at a CAGR of 14.9% between 2007 and 2014, after having recorded USD 2.5 billion (RM 8.8 billion) in 2007. This is one of the key market drivers of the industry as CMOs are able to provide industry players with access to capacity at lower investments. In particular, smaller biotechnology companies will benefit as they are able to reduce overall operational time to market by sharing the risks of building manufacturing capacities which require a substantial amount of capital. In addition, collaboration between biotechnology companies and CMOs will allow the biotechnology companies to maintain autonomy of their products and focus on product development.

[48] The Star Online (8 April 2008)
[49] Asia Biomedical Review (2008)

While North America is currently the primary destination for contract manufacturing, Asia has been identified as the emerging market for CMOs as Asia Pacific offers reliable manpower, strong implementation of IP laws and competitive production costs that can provide savings from 50% to 80%[50]. The competitive nature of the business and the demand of the industry have pressured CMOs to offer "strategic value-added services such as process development, marketing support, process optimisation and life cycle management" to assimilate the entire supply chain of biotechnology[51].

In Malaysia, while the CMO segment is still small, there is great opportunity for CMOs to flourish. The number is expected to grow as the Government is encouraging the use of generics in its healthcare system and contract manufacturers are targeted to cater mostly to the Malaysian market[50]. Pharmaniaga, the largest integrated local healthcare company in Malaysia, provides contract manufacturing for over 200 types of products for pharmaceutical companies including for U.S. multinationals; while CCM Duopharma has contracts to manufacture more than USD 8.57 million (RM 30 million) worth of generic drugs for MOH per annum. Such contract manufacturing capabilities can be expanded to biopharmaceutical contract manufacturing for local and global markets. Therefore, these leading pharmaceutical GLCs could propel the development of healthcare biotechnology through the expansion of their facilities and services to capitalise on CMO market opportunities. Such outsourcing services will enable the development of emerging biotechnology companies without having to make capital investment into production facilities.

Besides local CMO capabilities, Malaysia has joined the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) that cooperates in the field of GMP. Malaysia's accession to the PIC/S will facilitate exports of pharmaceuticals and medicines as there is greater confidence in products manufactured in countries that are members of PIC/S. This will allow Malaysia to gain further access to member countries like the European Union (E.U.), Australia and Canada. Hence, it is attractive for CMO operations as CMOs will be driven by countries with strong compliances to international standards and accreditation. This will provide a sturdy foundation for the development of Malaysia's life science industry and increase potential exports to global market.

Currently, CMOs for biopharmaceuticals in Malaysia include Inno Biologics, Alpha Biologics and Vivantis Technologies. Inno Biologics and Alpha Biologics are CMOs of biologics from animal cell cultures. Inno Biologics is a GLC with a paid-up capital of USD 21.4 million (RM 75 million)[52]. It is a globally operating CMO and its principal products are monoclonal antibodies and therapeutic proteins. It operates the country's first biopharmaceutical plant of USD 28.6 million (RM 100 million) in Nilai, Negeri Sembilan, and it develops biopharmaceutical products like APIs and antibody drugs. Alpha Biologics, on the other hand, is a contract manufacturer of biologic drugs for use in pre-clinical, Phase I and II clinical trials. It specialises in the production of mammalian cell secreted protein drugs, and provides all of the necessary services required to develop and produce drugs in full compliance with U.S. and E.U. cGMP guidelines. Vivantis Technologies is a research-based biotechnology company dedicated to the production of restriction enzymes, DNA extraction kits, DNA amplification reagents and other related products for molecular biology research. Products stem from in-house research to provide integrated solutions to life science researchers worldwide.

Contract Research and Clinical Research Organisation

CROs refer to Contract Research Organisations or Clinical Research Organisations, which can be commercial or academic and are "contracted by the sponsor to perform one or more of a sponsor's study-related duties and functions"[53]. The primary objective of CROs in the healthcare industry is to carry out medical and scientific studies on a contractual basis, on behalf of multiple clients. This includes clinical trial-related studies, design protocol, laboratory services, safety monitoring, identifying clinical researchers, selection and monitoring of investigations, regulatory report preparation, as well as other regulatory affairs support to both pre-clinical and clinical trial activities. The global CRO market size in 2008 was estimated at USD 20 billion (RM 70 billion) with an expectation to increase to USD 35 billion (RM 122.5 billion) by 2015. Among the global contract research providers, Quintiles is one of the market leaders, with 15% of the global market share[54]. Contract researchers have also played a pivotal role in the R&D of the biotechnology industry. A study that was carried

[50] Ghosh (2008)
[51] ContractPharma Website, accessed on 12 October 2009
[52] Business Times (9 November 2009)
[53] Biotechnology Learning Institute
[54] The CRO Market Outlook: Emerging Markets, Leading Players and Future Trends, Research and Markets, accessed on 15 October 2009

out by Research and Markets revealed that clinical trials conducted by CROs are 30% more efficient than in-house trials by pharmaceutical companies. The lucrative nature of the market encourages R&D expenditure in healthcare biotechnology, thereby creating good prospects for CROs to inflate their market size in the future.

CRO is significant in the development of healthcare biotechnology due to its ability to reach regional patient populations and manage international clinical studies effectively. By facilitating R&D projects, CRO is able to help sponsors economise on time, labour, capital and space. Asia has 14% share of the total registered study sites for the international contract research market. The Asian CRO sector, which generated revenues of USD 1.2 billion (RM 4.2 billion) in 2006, will be worth approximately USD 2 billion (RM 7 billion) by 2010[55]. Malaysia, being a member of Asia Pacific, is recognised as one of the top ten emerging trial countries in the market and is viewed as an ideal location by large pharmaceutical companies to carry out diagnostic and clinical trials for the global market[56]. The importance of CRO is clearly outlined in the Policy Thrust 8: Strategic Development of the NBP as a key service to develop Malaysia's healthcare biotechnology sector.

Malaysia has a multi-ethnic composition, representing a diverse patient pool in the areas of disease and illness that makes it ideal for such value-added trials and propels the development of CRO in pre-clinical and Phase I clinical trials. Despite Malaysia's considerable competitive strengths, Malaysia has traditionally been overlooked by study sponsors seeking to place clinical research in the Asian region. In the past, Malaysia contracted only 40 to 60 clinical trials a year. However, with more aggressive marketing of Malaysia to the industry, as well as concerted actions by the CRC and BiotechCorp, a number of global clinical trials have been brought to Malaysia. CRC under MOH is a one-stop-centre for clinical trials. The CRC's well-established network includes 17 branches that are located at the major MOH hospitals in Malaysia. The number of clinical trials had doubled in recent years (125 in 2008, 64 clinical trials up to June 2009) and more impressively the number of site recruitment had grown to 340 in 2008 targeting an enrolment of 5,000 patients (193 sites enrolling 2,800 patients up to June 2009). This earned the country an estimated revenue of USD 34.3 million (RM 120 million) in 2008. Given the MOH hospital network, CRC is well positioned to become a regional hub that would be attractive to global companies.

Overall, the CRO sector in Malaysia shows considerable progress. In order to continuously build capacity, substantial training programmes have been provided and implemented with regard to CRO. As represented by the BioNexus Status companies[57], 19.6% of healthcare biotechnology companies is involved in this sector. Progenix Research is a company that is partly funded by a U.K. VC and is the pioneer in Malaysia for conducting pre-clinical CRO. IHLs have also started to spin-off companies to provide CRO services, for example, UKM MYCRO is a contract testing laboratory that conducts biological evaluation of medical devices, healthcare, chemicals and cosmetic products to increase the efficiency of the healthcare evaluation process.

The Advanced Medical and Dental Institute (AMDI) has been set up specifically as a post-graduate research institute and clinical trial centre that specialises in selected branches of medicine and dentistry. AMDI is operational and clinical services available include Clinical Research Clinic, Women Wellness Clinic, Oral Health Clinic, Paediatrics Specialist Clinic, Advanced Lab Diagnostic Clinic, Imaging Services and an Advanced Research Centre. The operational structure of AMDI, encompassing both clinical services and administration, will form 12 clusters that will comprise specialists from various disciplines and specialisations. These clusters are the Oncological Science, Cardiovascular Science, Integrative Medicine, Infectious Diseases, Brain Science, Behavioural Science, Immunological Science, Oral Science, Transfusion Medicine, Nuclear Medicine, Clinical Toxicology and Poisoning, and Healthy Lifestyle.

Several noteworthy CROs are Chakra Biotech, InfoKinetics and Aurigene Discovery Technologies (Aurigene). Chakra Biotech offers a full range of neuro-behavioural screening services using its proprietary mouse model for schizophrenia, the chakragati mouse and conditioned animal models of behaviour.

[55] Outsourcing-Pharma Website, accessed 20 October 2009
[56] The Star Online, (17 November 2009)
[57] Due to unavailability of data for all healthcare biotechnology companies in Malaysia

InfoKinetics specialises in clinical trials, bioequivalence studies and laboratory testing. It was set up primarily to serve pharmaceutical companies in planning and conducting pharmacokinetic and clinical trials as well as to provide independent analytical services as part of its drug development programme. Services offered encompass all stages of drug development, from Phase I to IV clinical trials, including bioequivalence and bioavailability studies. The company is capable of rapidly recruiting trial subjects and provides efficient and effective trial coordination in this region.

Aurigene, another CRO in Malaysia, has successful partnerships with ten global collaborative partners. It is involved in the R&D of new drugs and the improvement of existing drugs for human diseases. The proprietary technologies employed are Structural Biology, Target Validation Biology and Fragment-based Drug Design where the main research lies in protein sciences and cell biology. Combined with experienced scientific leadership, Aurigene also provides specialised services in crystallography, peptides and small molecules including absorption, distribution, metabolism and excretion (ADME) assays.

A leading Australian CRO company, Novotech, recently announced that it is expanding its Asian operations through a new regional management hub in Malaysia to serve as a base for expansion in the booming Asia Pacific contract research sector. The company already has operations in India and Korea, and the Malaysian hub will manage its operations in Singapore, Thailand and the Philippines. The reason for the expansion into Malaysia is to improve access to potential study participants. Novotech offers all facets of clinical drug development from first-in-man to large international Phase III clinical trials, and post-marketing support. Most of the clinical trials conducted by Novotech are sponsored by the U.S. and European biotechnology and pharmaceutical companies intended for submission to the Food and Drug Administration (FDA) and European Medicines Agency (EMEA).

Medical Bioinformatics

Bioinformatics is an inter-disciplinary research area which is an interface between computer science and biological science. It involves the use of computing technology for storage, retrieval, manipulation and distribution of information related to biological macromolecules such as DNA, Ribonucleic acid (RNA) and proteins. Bioinformatics is a useful tool for genomic data analysis in sequencing, structural and functional analysis of genes and genomes. Novocraft Technologies, Neopeutics, Semantics BioSolutions and Synamatix Research are some of the companies involved in bioinformatics in Malaysia.

Novocraft Technologies, a wholly Malaysian-owned company, employs extensive international bioinformatics and programming expertise, and is committed to developing Malaysia's best bioinformatics brand to meet global demand. It specialises in the development of fast and accurate tools for comparative genomics and already has numerous software tools applicable in most areas of second generation DNA sequencing analysis such as whole genome sequencing, epigenomics, locus-specific DNA diagnostics and transcriptomics. Focus areas of Novocraft Technologies' products include DNA analysis, agrobiotechnology, medical informatics and DNA-based diagnostics. Novocraft has begun its quest to develop and implement cutting-edge analysis tools for genomics research and production that have already received recognition from the worldwide bioinformatics community, with reputable customers in the E.U., Asia Pacific and the U.S.

Another company, Neopeutics, offers sophisticated knowledge services that will enable pharmaceutical companies to winnow large libraries of compounds down to small lists to screen and identify compounds that are more likely to contain drug candidates. The market for early-stage screening is USD 200 million (RM 700 million) in the U.S alone[58]. Neopeutics combines bioinformatics, genetic interaction mapping and chemogenomic profiling to eliminate the compounds most likely to fail, significantly reducing the cost of screening. Neopeutics will also screen Malaysia's indigenous natural compounds to identify profiles that match the ten most lucrative drugs worldwide and other FDA approved drugs on the market for products of commercial value. Neopeutics will initially be based in Kuala Lumpur, and will eventually develop facilities in both Malaysia and the U.S.

[58] California Institute for Quantitative Biosciences Website, accessed on 8 November 2009

Malaysian Genomics Resource Centre (MGRC) is a wholly-owned subsidiary of Synamatix and is part of the Neuramatix group of companies. It offers online bioinformatics application services and customised services using proprietary workflows. Some of the bioinformatics applications available are SynaBlat, SynaCompare, SynaRex, SynaTate, SynaSearch, SynaBlast, SynaTree, SXOG, SynaHybridise and SynaProbe. The primary goal is to serve individual researchers and scientists who require high throughput applications and new database platforms without the associated resource implications that come with managing and maintaining such technologies in-house. These services are provided free in conjunction with BiotechCorp. MGRC has strategic partners including Beatson Institute for Cancer Research, Washington University Genome Sequencing Center, Synamatix, Hewlett-Packard and Geneworks. In 2008, over 35,000 people in 168 countries or territories used MGRC's application services.

Moving Forward

As described earlier, healthcare biotechnology is a relatively young sector in Malaysia. Hence, there is a need for Malaysia to identify key niches in developing this sector. Malaysia can leverage on its strong existing manufacturing and outsourcing capabilities to develop its focus on medical devices and diagnostics, CMOs and CROs. CMO, CRO, and medical devices / IVD are promising areas for Malaysia as they can be quickly implemented. CRO also requires less intensive capital investment when compared to areas involving drug discovery and therapeutics that require intensive investment and a long gestation period for R&D. Currently, large Malaysian pharmaceutical companies that possess contract manufacturing capabilities can expand their facilities to provide CMO services for healthcare biotechnology. Malaysia is also attractive to CRO as it has a multi-ethnic population that represents a major proportion of the world's population ethnicity.

In recognition of Malaysia's comparative advantage in tropical biodiversity and natural resources, Malaysia should also leverage on this as a starting point for potentially significant achievements in the discovery of APIs and phytomedicines. Furthermore, as Malaysia has a substantial Muslim population, the country has enormous potential in producing halal vaccines for the local and global markets.

Being one of the newest areas in healthcare biotechnology, the stem cells / therapeutics segment is set to revolutionise the medical world in its as yet unharnessed potential to provide cell-based therapies. The stem cell banking services and facilities provide Malaysia with the platform and opportunity to develop this area of R&D.

Given the complexity of this sector, there is a need to focus on certain priority actions for healthcare biotechnology development moving forward into Phase II of the NBP – Science to Business:

1 **Intensify efforts in developing and promoting Malaysia as a regional outsourcing centre for CMOs and CROs**

The focus on biopharmaceuticals (e.g. production of biosimilars or vaccines) and medical devices / IVD for CMO initiatives in Malaysia will allow access to complementary technologies and capabilities to build biomedical manufacturing expertise to support future biotechnology growth and to attract global FDIs. In addition, CMOs in Malaysia will enable existing and emerging biotechnology companies to integrate CMOs into their business model to quickly reach commercial scale, reduce capital expenditure and attain greater overall flexibility.

While the necessary regulations, infrastructure and incentives have been put in place, there are several challenges that hamper the development of a robust CMO segment. These include the lack of specialised and skilled human capital, especially in the area of biopharmaceuticals. Thus, BiotechCorp is actively looking for collaborations that can provide the necessary skills and expertise. As neighbouring countries in the ASEAN region provide similar CMO services, Malaysia needs to differentiate itself to attract companies to select Malaysia as their outsourcing hub. The strengthening of the outsourcing model and improvement in the logistics infrastructure would attract potential partners as Malaysia already has the cGMP facilities in place to provide CMO services.

Key considerations for establishing a strong CMO base in Malaysia include the following (that are discussed in detail in Chapter 4):

- Ensure manufacturing facilities comply with the requirements of international regulators such as FDA and EMEA
- Enforce sound IP protection to eliminate barriers for global biotechnology and pharmaceutical companies to introduce new products for manufacturing in Malaysia
- Build infrastructure, skills and expertise (e.g. bioprocessing engineers, chemists, molecular analysts and microbiologists) for CMO by supporting and expanding existing facilities and capabilities of local CMOs
- Actively collaborate with large multinational pharmaceutical and medical companies to form strategic partnerships for CMO initiatives

The opportunities in Malaysia for the growth of its CRO segment lie in its ability to leverage on the country's diverse ethnicity patient pool in the areas of diseases and illnesses. In order for the nation to extensively participate in multinational pharmaceutical companies' clinical trials, there is a need to ensure that the necessary experience, knowledge and infrastructure are present to support the CROs.

Although there has been a rise in the number of clinical trials and revenue from CROs, there is a need to seek more opportunities as Malaysia has more than sufficient capacity. Efforts need to be intensified to eliminate any impediments that may thwart Malaysia's aim to become a regional hub for pre-clinical and Phase I trials in this lucrative market. In relation to this, it is noted that the development of a skilled workforce plays a critical role in the growth of clinical research to attract study sponsors to Malaysia. Besides human capital development, there is a need to have the appropriate regulations on animals to facilitate development of pre-clinical services.

Key considerations for the successful implementation of a CRO base in Malaysia include the following (that are discussed in detail in Chapter 4):

- Ability to build skilled human capital (e.g. investigators and scientists) or attract skilled personnel from top-ranking RIs to kick-start clinical research initiatives
- Ability to build sound research infrastructure (e.g. RIs, IHLs, bioclusters) to facilitate CRO
- Ability to maintain low cost of conducting clinical trials (e.g. clinical trials performed on humans, animals or cells are estimated to cost only one-tenth in Asia compared to U.S. and Europe)
- Availability of patients for clinical research (e.g. diverse ethnicity)
- Ability to continuously attract and form long-term strategic alliances
- Promote and enforce GCP Standards to ensure proper biosafety and bioethical guidelines for long-term sustainability of CRO
- Appropriate regulations in place on animals for pre-clinical trials

Malaysia is also facing stiff competition in CRO services as China and India have emerged as the top destinations for CRO services. Foreign biotechnology companies look for R&D outsourcing destinations not only to unload labour-intensive jobs but also for a strong base of R&D and innovative capabilities. Singapore, which can be considered a latecomer compared to China and India in CRO, has recognised this importance and invested heavily in R&D. In terms of R&D investments, Singapore's total R&D expenditure for biomedical sciences has grown over 400% from approximately USD 163.5 million (RM 572.3 million) in 2007 to USD 821.3 million (RM 2.9 billion) in 2009[59]. Since 2000, the Singapore Government has invested more than USD 3.4 billion (RM 111.9 billion) to build up its biotechnology industry and human capital. In 2007 alone, Singapore spent approximately USD 1.5 billion (RM 5.3 billion) in R&D expenditure for biomedical sciences[60]. Some of the challenges for Malaysia to successfully move CRO activities forward include the following:

- Significant investments to build sound research infrastructure (e.g. RIs, IHLs, bioclusters) to facilitate R&D
- Availability of an appropriate funding mechanism for Malaysian projects
- Availability of skilled human capital (e.g. investigators and scientists) amidst the current "brain drain" with qualified Malaysian researchers and entrepreneurs leaving the country for better prospects abroad
- Innovative culture and mindset
- Ability to attract skilled personnel from top-ranking RIs

[59] Economic Development Board (2009)
[60] The Edge (8-14 June 2009)

2 Implement research initiatives to develop more applications for commercialisation

In order to continuously develop healthcare biotechnology for greater value creation, there is a need to attract more research applications for commercialisation. In order to capitalise on the enormous potential of stem cell research and therapies, industry players are already undertaking research to develop therapeutics for commercialisation. Besides stem cell research and therapies, there is a continuously growing trend for medical devices and IVD given Malaysia's strong manufacturing capabilities and market potential in this segment.

Given Malaysia's tropical biodiversity richness, novel discoveries for healthcare biotechnology can be made from the ingredients extracted from plants to produce higher value-add in deriving novel compounds for API, phytomedicine (botanical / plant medicine), nutraceuticals, health and dietary supplements, and cosmeceuticals. Nevertheless, drug discovery and drug delivery should be focused on disease categories that will most benefit Malaysia and the surrounding region. This may include areas such as tropical diseases prevalent in ASEAN (e.g. dengue, malaria) or therapies that are in demand locally (e.g. halal vaccines).

The nanotechnology and DotScan[59] antibody microarray diagnostic platform technologies are essentially research tools that can be used as diagnostics and to develop applications for drug delivery, with the emphasis on treating local diseases. However, focused research is still needed before the applications can be developed for commercialisation. Having acquired these platform technologies, the current need is to attract more research applications and development of products of substantial commercial value arising from utilisation of the said technologies.

As described in Recommendation 2 of Policy Thrust 1: Agricultural Biotechnology Development, a similar business operating model will be adopted to develop research of commercial value with emphasis on the following implementation considerations:

- Collaborations and funding mechanisms for research and commercialisation of applications and development of new applications
- Skill-set and expertise for research, development and commercialisation such as chemists, microbiologists, molecular analysts, bioprocessing engineers, toxicologists and clinical researchers
- Strategic partnerships and collaborations with foreign affiliates for transfer of technology

3 Leverage on local capabilities to intensify public-private partnership

In order to effectively implement the specific actions identified to develop the various segments, it is proposed that a public-private partnership (PPP) model be adopted. As described earlier, large GLCs such as Pharmaniaga and CCM Duopharma should expand their existing R&D and manufacturing facilities and services to develop biosimilars, biopharmaceuticals, tropical vaccines and others. A possible PPP model to be considered for partnership between the Government and GLCs is as follows:

- GLCs to supply biosimilars, biopharmaceuticals, pharmaceuticals, vaccines and drugs to MOH hospitals
- GLCs to invest in R&D and manufacturing facilities for healthcare biotechnology development. Capacities will be extended to emerging players for the following possible purposes:
  - Research for commercialisation value
  - Development of applications for commercialisation
  - Provision of contract manufacturing services at competitive pricing
  - Collaboration opportunity to develop product pipelines
  - GLCs to invest in strategic joint venture partnerships to build capabilities and Government to bring technology opportunities to GLCs

In order to implement the appropriate PPP, there is a need to clearly understand and align the objectives of both parties. In addition, there is need to determine the guiding principles and governance framework that will drive the development of the right PPP. Therefore, it is proposed that the following key action items be considered and facilitated by BiotechCorp:

- Identify a working group comprising members from both the Government and GLCs to develop the PPP framework
- Develop overall guiding principles and governance framework based on the objectives agreed by the working group
- Develop the PPP model moving forward and identify priority GLCs for implementation
- Establish detailed governance protocols, policies and procedures for implementation. Key areas to be considered:
  - Funding model and investment arrangement
  - Mutual benefit considerations
  - Partnership arrangement in terms of obligations, roles and responsibilities of each party

4 Implement globalisation strategy

Unlike the development of the agricultural biotechnology sector, the development of the healthcare biotechnology sector requires the attracting of global players or FDIs into Malaysia. As recommended earlier, the promotion of Malaysia as a regional outsourcing centre is intended to attract global players in order to create opportunities for local companies to grow in the same areas of services or complementary areas. Furthermore, the proposed PPP model will facilitate foreign partnership and collaboration for various purposes, such as the transfer of technology or knowledge, research collaboration for speedy commercialisation or strategic business alliances. Current efforts in attracting FDIs should continue and additional incentives should continue to be considered (addressed in Policy Thrust 6: Financial Infrastructure Development).

As the industry development moves into Phase II of the NBP – Science to Business, global market access and speedy time to market for large scale commercialisation will be critical. Specifically, it is proposed that key medical devices / IVD players and stem cell players should intensify globalisation of their products and services. International business development and marketing support will be critical and BiotechCorp has been active in providing such support including facilitating business matching. Financing support will remain critical. Both strategic marketing and financing support will be discussed in Chapter 4.

Policy Thrust 3 Industrial Biotechnology Development

There is a growing global concern over environmental issues and increasing emphasis on green and clean technology. The Copenhagen World Summit on Climate Change in 2009 further underscored the international awareness and political will to reduce global emissions and address the issues of climate change. Global chemical companies like DuPont and DSM are switching to biotechnology processes in their effort to go green. Globally, industrial biotechnology contributed around 5% of chemical sales, and this is estimated to reach 20% by 2010, or USD 160 billion[61] (RM 560 billion). In Malaysia, the 2009 contribution of the industrial biotechnology sector is estimated at USD 2.9 billion (RM 10 billion). This is equivalent to 50% of the total revenue of the biotechnology industry. It is expected to be a fast growing sector with a CAGR of 10%[62].

Across the world, industrial biotechnology is a relatively new sector compared to healthcare and agricultural biotechnology. As such, the industrial biotechnology sector is considered a more level playing field, as it is still a fluid and emerging sector with no single country as the clear leader in the field. The Chinese Government announced a USD 586 billion (RM 2.1 trillion) stimulus package in 2008, where USD 30 billion (RM 105 billion) would be put into green projects to support the growth of a green economy. The Malaysian Government established a fund amounting to USD 0.4 billion (RM1.5 billion) during the Second Stimulus Package in 2009 that aims to provide soft loans to companies that supply and utilise green technology.

[61] 6th Annual World Congress on Industrial Biotechnology and Bioprocessing (2009)
[62] Frost & Sullivan Investor Series (2009)

Industrial biotechnology is a promising new sector that was identified in the NBP in 2005. Malaysia has strong manufacturing and outsourcing capabilities, and is also one of the most developed chemical industries in the world where the country is not only capable of fulfilling local requirements, but also of exporting its chemical products to countries like U.S., Japan, China, Singapore, Hong Kong and Thailand. Malaysia is particularly advanced in the petrochemical and oleochemical segments, as the country is endowed with sizeable petroleum and oil palm resources. As these industries are export-oriented, there is already an established network and market. What is required is the switch from industrial processes to biotechnology processes in the manufacturing sector. Hence, the third thrust of the NBP focuses on industrial biotechnology as Malaysia can leverage on its strong manufacturing industry. SIRIM has been designated as the Environment / Industrial Biotechnology Cooperative Centre to help coordinate biotechnology research, to improve coordination and reduce duplication in research.

Current State

As at 30 September 2009, industrial biotechnology companies comprised 20.6% of the total biotechnology companies in Malaysia, that is 72 industrial biotechnology companies out of a total of 349 companies. Based on the latest 2008 financial reports available[63], industrial biotechnology companies contributed a total revenue of USD 44.8 million (RM 156.9 million) which represents 30% of the total revenue size of the biotechnology industry.

Of the 72 industrial biotechnology companies in Malaysia, 20 companies (27.7% of the total industrial biotechnology companies) obtained BioNexus Status and these companies generated a total revenue of USD 37.9 million (RM 132.6 million) in 2008 compared to the remaining companies (without BioNexus Status) that generated revenue of USD 6.9 million (RM 24.3 million) which represents 15.5% of the total industrial biotechnology sector revenue size (see Table 3-12).

Table 3-12: Overview of the Malaysian Industrial Biotechnology Sector (31 December 2008)

Type of Companies	Number of Companies	Total Revenue		Total Investment	
		USD million	RM million	USD million	RM million
BioNexus Status Companies	20	37.9	132.6	137.2	480.4
Non-BioNexus Status Companies	52	6.9	24.3	160.3	561.2
Total	**72**	**44.8**	**156.9**	**297.6**	**1,041.6**

Source:
(1) BiotechCorp
(2) SSM (31 December 2008 or latest financial reports available)

Total investment of industrial biotechnology companies was USD 297.6 million (RM 1 billion) based on the latest available information[64]. This represents about 36.3% of the total investment in the biotechnology industry. A total investment of USD 137.2 million (RM 480.4 million) has been approved for BioNexus Status companies.

One of the key drivers for industrial biotechnology is the presence of an immediate market. In Malaysia, this market is in the oil palm sector as Malaysia is the second largest producer and the largest exporter of palm oil. Hence, industrial biotechnology activities tend to revolve around this sector, as is the case for companies involved in bioremediation (for Palm Oil Mill Effluent), fine and specialty chemicals (oleochemicals and its derivatives from downstream palm oil processing), and biofuel (from olein, crude palm oil, sludge oil and effluent ponds). There are also IPs already present from IHLs and RIs for the bioremediation and biocatalyst segments.

[63] Based on BiotechCorp (as at 31 December 2008) and SSM (31 December 2008 or latest financial reports available)
[64] Based on BiotechCorp (as at 30 September 2009) and SSM (31 December 2008 or latest financial reports available)

For the purpose of this Country Report, further analysis of performance has been conducted on biofuel, bioremediation, biocatalyst, fine and specialty chemicals, biopolymer and others not classified elsewhere. The NBP has outlined the following key actions that are required to develop industrial biotechnology:

- To implement a green chemistry initiative (biofuel, bioremediation)
- To develop biocatalysts for foods, chemicals and pharmaceuticals (biocatalyst)
- To apply advances in bioprocessing technology for fine and specialty chemicals and biomaterials (biopolymers)

As represented by BioNexus Status companies[65] as at 30 September 2009 (see Table 3-13), 35% of the industrial biotechnology companies is involved in bioremediation. For this segment, local RIs and IHLs have conducted a significant amount of research and some of this has resulted in IPs that are available from the IHLs and RIs. Hence, there are opportunities for commercialisation in this segment.

Table 3-13: Overview of BioNexus Status Companies in the Malaysian Industrial Biotechnology Sector (30 September 2009)

Focus Areas	Number of Companies	Total 9 Months Revenue (USD '000)	Total Approved Investment (USD million)	Projected Total R&D Expenses (USD million)	Projected Number of Knowledge Workers
Biofuel	1	0	48,218.4	0	20
Bioremediation	7	1,164.8	11,171.9	1,838.8	64
Biomaterial / Biopolymer	3	0	12,338.7	51.9	39
Biocatalyst	4	853.1	3,782.8	0	36
Fine and Specialty Chemicals	4	45,224.0	61,094.1	72.3	193
Others	1	502.1	638.2	166.6	31
Total	**20**	**47,744.0**	**137,244.1**	**2,129.6**	**383**

** Actual R&D expenses for 12 months ending 30 September 2009 was USD 1 million (RM 3.4 million)*
*** Actual number of knowledge workers as at 30 September 2009 was 162*
Source: BiotechCorp (based on the latest information available)

Although only 20% of the industrial biotechnology companies are involved in fine and specialty chemicals, this segment alone generated over 94.7% of the total revenue in the first nine months of 2009. This was mostly contributed by PureCircle, a public-listed company that produces stevia sugar. The fine and specialty chemicals segment also attracted the largest amount of investment at USD 61.1 million (RM 213.8 million). This is because a large proportion of fine and specialty chemicals that are produced in Malaysia are produced from plant extractions or derived from palm oil. As Malaysia has a large variety of fauna species as well as a thriving palm oil industry, the potential in this sector is immense, thus attracting the highest amount of investment into the segment. This is further enhanced by the acquisition of the Supercritical Fluid technology with applications for extraction and particle formation.

The four BioNexus Status companies (20%) involved in biocatalyst are relatively new compared to the others, and these companies are mostly involved in enzyme formulations rather than development and production. It should be noted that this is a potentially lucrative segment, providing huge opportunities for these companies to grow.

As for biomaterial / biopolymer, 15% of the industrial biotechnology companies are involved in the development and production of bioplastics. These companies are yet to generate any revenue. This is because while Malaysia is one of the world's biggest manufacturers and exporters of plastic products, the bioplastics / biopolymer segment is yet to be fully developed and is still at a nascent stage. However, with the widespread promotion of bioplastics as an alternative to plastic products by Governments worldwide, this segment is likely to see significant growth in the near future provided the right technologies are acquired.

[65] Due to unavailability of data for all agricultural biotechnology companies in Malaysia

From 2004 to 2008, there was a total number of 530 industrial biotechnology patent applications (see Table 3-14), which was the second highest number of patents applied across the sectors. Of these, 323 patent applications were granted, with 94.7% granted to foreign applicants. Similar to the healthcare biotechnology sector, the large inflow of applications from foreign companies can be attributed to the interest in bringing in technologies so that products can be developed locally, as well as the BioNexus Status requirements for localisation. This is also because unlike the agricultural biotechnology sector, the industrial biotechnology sector lacks home-grown technologies, thereby creating the need to bring in foreign technologies.

Table 3-14: Number of Local and Foreign Industrial Biotechnology Patents Applied and Granted in Malaysia (2004-2008)

Patent		2004	2004	2004	2004	2004	Total
Applied	**Local**	18	15	19	29	28	109
	Foreign	89	84	108	32	108	421
	Total	**107**	**99**	**127**	**61**	**136**	**530**
Granted	**Local**	0	0	3	10	4	17
	Foreign	4	27	61	135	79	306
	Total	**4**	**27**	**64**	**145**	**83**	**323**

Source: MyIPO (2009)

Table 3-15 provides a summary of current strategic partnerships and collaborations in the development of the industrial biotechnology sector.

Table 3-15: Selected Strategic Partnerships and Collaborations of Malaysian Industrial Biotechnology Companies

Focus Area		Strategic Partnership	Purpose
Biofuel	• Foreign	• Rebis srl and Rebis International srl, Europe • Synthetic Genomics, U.S. • Industrial Technology Research Institute, Taiwan	• Access to IP and technology • Access to markets • Collaborative R&D
	• Local	• Universiti Putra Malaysia	• Collaborative R&D
Bioremediation	• Foreign	• Shanghai Jiao Tong University • National Chung Hsing University, Taiwan • Enretech Australasia • Nankai University, China • China Petroleum University (Merlingen) • Fraunhofer-Gesellschaft, Germany	• Collaborative R&D • Access to technology and funding • Access to markets • Joint venture • Access to IP and technology
	• Local	• University Sains Malaysia • Malaysia Agricultural Research and Development • Institute • Universiti Putra Malaysia	• Collaborative R&D • Access to facilities and equipment
Biocatalyst	• Foreign	• Insect Biotech, Korea	• Access to IP and transfer of technology
	• Local	• Universiti Putra Malaysia	• Collaborative R&D • Access to technology • Access to facilities and equipment • Access to IP and scaling up

Focus Area	Strategic Partnership		Purpose
Fine and Specialty Chemicals	• Foreign	• Biozyme Biotech, Taiwan • AT LAB Company • Korean Research Institute of Bioscience and Biotechnology	• Collaborative R&D • Transfer of Technology
	• Local	• Universiti Putra Malaysia	• Access to facilities and equipment
Biopolymer	• Local	• Universiti Sains Malaysia • Standards and Industrial Research Institute of Malaysia • Universiti Putra Malaysia	• Access to IP and transfer of technology • Access to facilities and equipment • Collaborative R&D

Sources:
(1) BiotechCorp
(2) Ernst & Young Analysis

Biofuel

Biofuel is a renewable fuel that is derived from biological materials. Biological materials include plant materials and organic wastes. Biofuel can come in liquid, gaseous and solid forms. Biodiesel and bioethanol are types of liquid biofuel that can be used as transport fuel while biogas is being considered as an alternative to natural gas. Solid biofuel on the other hand, generally involves the direct usage of biomass as a combustible fuel, and hence will not be covered in this Country Report as it does not involve the use of biotechnology.

There is a growing demand worldwide for environment-friendly renewable transport fuel. Biofuel offers a sustainable and viable alternative source of energy that will save on greenhouse gas emissions and reduce dependency on rapidly depleting fossil fuels. Governments around the world have mandated the use of biofuel, providing incentives and setting formal targets (see Table 3-16). The global market for liquid biofuel was USD 30.3 billion (RM 106.1 billion) in 2008 and is expected to increase to USD 42.8 billion (RM 149.8 billion) in 2013 with a CAGR of 7.2%. This is dominated by first generation biofuel that is typically derived from sugar, starch or oil-based crops (food crops).

Second generation biofuel is produced from cellulose or hemicellulose (the woody or non-food part of plants) and is expected to increase from USD 17.1 million (RM 59.9 million) in 2008 to USD 138 million (RM 483 million) in 2013 with a CAGR of 51.8%[66]. Brazil remains the largest exporter of biofuel, and other countries predicted to significantly contribute to the world's production by 2015 are Argentina, China, Colombia, France, Indonesia, Malaysia, the Philippines, and Thailand. Palm oil biodiesel, rapeseed biodiesel and first-generation ethanol are expected to be at the forefront of production. Malaysia's focus is on the production of biodiesel from oil palm. Biodiesel can be used with little or no modification to contemporary vehicle engines.

Table 3-16: Government Initiatives on the Use of Biofuel

Country	Initiatives on Biofuel
E.U.	• E.U. transportation fuel derived from biofuel will reach 5.75% by 2010 and 20% by 2020. Under the Kyoto Protocol, the E.U. has committed to an 8% reduction of carbon dioxide emissions by 2012.
Australia	• Announced a Biofuel Action Plan for achieving the target of 350 million litres of biofuel production by 2010.
Canada	Announced a Renewable Fuel Strategy, which includes a 5% biofuel use target by 2010.
China	• Expand ethanol production as part of the broader effort to raise the share of renewable energy (biofuel, nuclear, hydroelectric and solar power) from 6% to 16% by 2020. • Emphasis on the use of lignocellulosic feedstock such as agricultural and forestry residue, energy crops (e.g. switchgrass) and municipal waste for ethanol production, with commercial production expected to start during 2011-2015. • Existing corn starch production plants are expected to be retrofitted to produce cellulosic ethanol once the technology becomes feasible. The industry is expected to produce an estimated 3 billion gallons of ethanol from lignocellulose by 2015-2020, i.e. one-half of total projected ethanol production from all sources.

[66] Hanft (2009)

Country	Initiatives on Biofuel
Indonesia	• Announced to achieve target of up to 10% biofuel content of diesel by 2010.
Japan	• Long-term intention of replacing 20% of the nation's oil demand with biofuel or gas-to-liquid fuel by 2030.
Korea	• New and renewable energy sources to achieve 5% of the nation's total energy consumption by 2011.
Peru	• The Government hopes to export 1.1 billion litres of ethanol by 2010. A 2005 law promotes the use of ethanol as 5% to 10% additive in petrol.
Philippines	• Plantation biomass could supply 2% to 11% of the economy's projected energy consumption by 2010.
Thailand	• The Biodiesel Promotion Program plans to raise biodiesel production to 3.1 billion litres by 2012, accounting for 10% of expected diesel consumption.
U.S.	• The Energy Policy Act requires the use of 24.8 billion litres of biofuel by 2012 to reduce gasoline usage in the U.S. by 20% in the next ten years. A mandatory fuel standard was set that requires 35 billion gallons of renewable and alternative fuel in 2017.

Source: BiotechCorp

One of the global companies that is involved in the development and production of biofuel is Twin River Technologies. It is the fastest growing oleochemical company in North America. The range of products produced includes fatty acids and glycerine, esters and biofuel. Its biofuel products are biodiesel and bioethanol that is derived from vegetable oil, surpassing industry standards for quality and consistency.

Another company is Mission NewEnergy Limited that develops its Jathropha feedstock for biofuel production in India through its subsidiary Mission Biofuels India, and operates a biodiesel refinery and glycerine purification plant in Malaysia through its wholly-owned subsidiary Mission Biotechnologies. The plant is capable of producing 100,000 tonnes of biodiesel per annum using Palm Fatty Acid Distillate (PFAD) and 99.7% pure refined grade glycerine as a by-product. Expansion plans include construction of an adjacent biodiesel refinery with a capacity of 250,000 tonnes per annum that will also produce 10,000 tonnes of PFAD and 25,000 tonnes of 98% pure technical grade glycerine using second generation transesterification technology developed by Axens, a subsidiary of the French Institute of Petroleum.

Malaysia has installed capacity of close to two million tonnes of palm biodiesel as of 2009 and exported 182,108 tonnes in 2008[67]. Major export markets for local palm biodiesel are U.S. and the E.U. In 2008, U.S. was the largest export market in the world followed by the E.U., respectively accounting for 39.2% and 38.6% of total biodiesel exports[68]. In Malaysia, biodiesel is mainly converted from palm oil through a transesterification process. It can be used as a direct alternative to diesel or as a diesel-biodiesel blend[69]. Malaysia has the experience in producing biodiesel as it is the world's second largest producer and top exporter of palm oil.

The National Biofuel Policy was launched in 2005 with the aim of positioning Malaysia as a major global biodiesel producer. There have been 91 biodiesel licences issued in Malaysia. The Government's commitment is evident given its mandate that all Government diesel-powered vehicles will start using biodiesel in February 2009. Three Government bodies demonstrated their support for the initiative by converting to the usage of biodiesel several months ahead of schedule. In 2010, the Government has projected that 500,000 tonnes of biodiesel per year will be needed upon the full implementation of the B5 programme (5% biodiesel and 95% fossil-fuel diesel)[70]. The Government announced recently that B5 biodiesel would be implemented in 2010[71].

In practice, most companies in Malaysia are currently focused on the production of biodiesel using refined, bleached and deodorised olein or Crude Palm Oil (CPO) as Malaysia has a large volume of palm oil plantations, mills and refineries. Research efforts are also in progress to utilise PFAD, a lower grade of feedstock from palm oil, or feedstock from other crops like jathropa. Another avenue of research that is currently being explored is the use of algae oil as a potential source of feedstock for biodiesel.

[67] The Star Online (12 November 2009)
[68] Malaysian Palm Oil Board (2009)
[69] Hoh (2009)
[70] Biofuels International Industry News (2008)
[71] Business Times (3 February 2010)

Malaysian biodiesel companies that have strategic foreign collaborations and partnerships are performing relatively well due to their access to better technology and foreign markets. As fossil fuel is subsidised in Malaysia, access to foreign markets is important as most of the biodiesel produced is exported. Therefore, the take up of biofuel in the local market is dependent on policy decisions. There is great potential for local market growth as biodiesel becomes more widely accepted and Malaysia's resources of crude oil further depletes. However, it should be noted that the fossil fuel subsidy policy in Malaysia makes the use of biodiesel less competitive. Therefore, there is a need to revisit current policy and other related policies, if any, to ensure a more holistic approach to harmonise all policies for effective implementation of green policies.

SuccessNexus is a company that uses multi feedstock technology to convert oil-based products and waste into biodiesel and glycerine. It is licensed to use a patented technology in the ASEAN region, that converts the typical three-step process of biodiesel production into a two-step process, thereby reducing processing time by 50% and achieving cost savings in terms of power usage and the use of one less chemical. One of its major achievements is its mobile refinery unit that can be transported into remote or rural areas to convert oil-based waste into biodiesel.

Carotech is a company in which biodiesel is the by-product and the extraction of tocotrienol (Vitamin E) is its main activity. Carotech has set up the first and largest integrated plant in the world to commercially extract phytonutrients like tocotrienol, carotene and phytosterols from CPO. The usage of CPO confers a cost advantage to Carotech, as compared to companies that require the use of refined, bleached and deodorised olein for the production of biodiesel. Carotech uses its Molecular Distillation process for the separation of phytonutrients from the other products. Carotech received its GMP certification in 2007, and is the first and only producer of tocotrienol to achieve this certification under the GMP rules for pharmaceuticals or dietary supplements.

Besides biodiesel, Malaysia can leverage on its abundance of biomass as feedstock for the production of bioethanol. Bioethanol is a form of biofuel that is generally produced from any biomass. This is the focus of various R&D and commercial efforts as a palm oil plantation yields 50 to 70 tonnes of harvestable biomass per hectare, and only 10% of the biomass is converted into finished products. Until recently, the remaining 90% (empty fruit bunches, fibres, fronds, trunks, kernels and palm oil mill effluent) was discarded as waste[72]. Bioethanol is a form of biofuel that is generally produced from any biomass. While Malaysia has sufficient biomass feedstock to commercially produce bioethanol, bioethanol production remains commercially insignificant as second generation bioethanol technologies have yet to reach the commercialisation stage[73].

An international company is at the final stage of planning the construction of a bioethanol plant in Malaysia using empty fruit bunches and other cellulosic materials. Another company, AARGYP Scientific (AARGYP) is working with University Malaysia Sarawak (UNIMAS) to set up Malaysia's sago palm bioethanol pilot plant with a daily production capacity of one tonne. Malaysia will be the first country in ASEAN to produce bioethanol from sago palm. Several foreign companies have registered interest in exploring the possibilities of working with Malaysia on the development of second generation bioethanol from palm oil biomass.

Malaysia's natural gas reserves are expected to last for another 36 years[74]. Biogas (methane) can be produced by biodegradable wastes and can be used as an alternative to fossil natural gas. In Malaysia, biogas is generally the by-product of waste treatment or bioremediation (see Bioremediation), and the methane released can be harnessed as a renewable source of energy. A conservative estimate shows that the oil palm biomass derived from Malaysia's plantations is adequate to drive 5% to 10% of the country's total energy requirements[75]. The use of biomass as a source of renewable energy can considerably reduce the energy cost of plantation owners. Under the Small Renewable Energy Programme, small power plant developers that utilise renewable energy sources can sell the electricity to Tenaga Nasional via the distribution grid system. However, the maximum power export is capped at ten megawatts. Biogas can also be used in the transportation sector where it can be blended as a vehicle fuel. Using home-grown technology, Green & Smart is already undertaking projects utilising palm oil mill effluent (POME) for biogassification.

[72] BiotechCorp
[73] Hoh (2009)
[74] Gas Malaysia (2009)
[75] The Star Online (17 January 2009)

Other than palm oil mills, landfills of municipal solid waste (MSW) is also a source of methane. The challenge for the utilisation of local MSW is to separate organic and inorganic waste collected from households. Hence, the Government initiated a pilot project in Putrajaya to segregate the solid waste at source. Other than the production of methane, Jawhara Bioenergie has begun efforts to convert greenhouse gasses into biohydrogen, typically regarded as the cleanest energy source and the most promising energy to be used for home-type fuel cells and transportation. The biotechnological process of producing biohydrogen that utilises agricultural wastes and MSW will significantly reduce the use of fossil fuels and reduce the carbon dioxide that is currently released from current methods of hydrogen production. Researchers from UPM and UKM are pursuing research in the production of biohydrogen using biotechnology methods[76].

Bioremediation

Bioremediation involves the treatment of environmental problems through biological means; using enzymes, cultivated microorganisms and phytoremediation. It is generally regarded as green and safe, with cost and efficiency advantages compared to other methods of remediation as it capitalises on naturally occurring processes, minimises disturbance to the environment, reduces waste, removes or neutralises contaminants and can minimise or eliminate the need for further treatment or disposal. Presently, there is a wide variety of bioremediation technologies that are used for waste treatment purposes.

The global bioremediation market in 2009 was estimated at USD 30 billion (RM 105 billion), which was 20% of the global remediation market of USD 150 billion (RM 535 billion), and its main focus was the issues surrounding petroleum hydrocarbons. In the domestic market, Malaysia's environmental market is estimated at USD 514.3 million (RM 1.8 billion) per annum. Using the same assumption (i.e. the local bioremediation market is 20% of the local remediation market), Malaysia's bioremediation market is estimated at USD 102.9 million (RM 360 million) per annum[77]. Most bioremediation projects that are undertaken and implemented in Malaysia are private sector driven.

In the NBP, bioremediation has been highlighted as one of the key priority areas that can propel Malaysia to become a strong player in the industrial biotechnology sector. Such green initiatives can help reduce the carbon footprint and environmental impact of Malaysia's large manufacturing sector. Bioremediation can also potentially be used to remove contaminants like heavy metals from local bodies of water. This not only helps in remediating contaminated water, but also in maintaining the safety and quality of the aquatic life and Malaysia's fisheries or marine / aquaculture industry. This will help companies to comply with E.U. health standards and practices, as 40 to 50 Malaysian companies currently export frozen seafood to the E.U. The annual value of Malaysian seafood exports to the E.U. is valued at USD 428.6 million (RM 1.5 billion)[78], of which frozen seafood is estimated to comprise USD 171.4 million (RM 600 million)[79].

There are several key RIs and IHLs that are involved in R&D activities related to bioremediation; for example UPM, USM, Universiti Teknologi Malaysia (UTM) and SIRIM. UPM has successfully patented a number of processes and technologies related to effluent treatment. Others have been filed and are still pending as provided in Table 3-17. As described earlier, there are several IPs that industrial biotechnology companies should leverage on to develop applications for commercialisation.

Table 3-17: Bioremediation-Related Intellectual Property of Universiti Putra Malaysia

No.	IP Title	Filing Country	Status
1	System and Apparatus for The Treatment of Organic Effluents	Malaysia	Granted Patent
2	Solid State Bioconversion of Domestic Wastewater treatment Plant Sludge Into Compost	Malaysia	Pending Patent
3	Liquid State Bioconversion of Sewage Treatment Plant Sludge	Malaysia	Pending Patent
4	A Process for Treatment of Palm Oil Mill Effluent and Conversion of the Palm Oil Mill Effluent Into Biodegradable Plastics	Malaysia	Granted Patent
5	A Process for Treating Wastewater	PCT	Pending Patent

Source: Universiti Putra Malaysia Intellectual Property Website, accessed on 21 September 2009

[76] BiotechCorp
[77] BiotechCorp
[78] The Associated Press (19 June 2008)
[79] The Star Online (17 March 2009)

There are several companies in Malaysia that are involved in developing bioremediation technologies for effluent and wastewater treatment, such as sewage treatment system, water treatment system and industrial effluent treatment system. These treatment systems cater to various industries such as palm oil mills, pig farming, breweries, rubber factories, agriculture waste and agro-based industries. However, majority of the bioremediation companies in Malaysia is involved in providing waste management solutions for biodegradable waste like POME, as Malaysia has around 400 palm oil mills and Indonesia has around 600 mills. Most companies conduct some R&D to develop their own cocktail of microorganisms that show high activity in the treatment of industrial biowaste. Currently, specialised facilities and technologies required include bioreactor systems (aerobic or anaerobic), equipment for fermentation and composting facilities[80].

Green & Smart uses anaerobic technology to reduce sludge for effluent treatment. It offers services that include improved anaerobic digestion for palm oil mill effluent, sewage treatment that consumes 50% less energy and produces 45% less sludge, and improved individual septic tanks that reduce sludge production and increase efficiency. For example, its Gas Releasing Anaerobic Sludge System Reactor is an energy efficient and space saving treatment for removing organic matter from effluent. Sludge digestion results in considerable reduction in sludge volume for disposal, and releases methane that may be harnessed as biogas.

Ronser Biotech (Ronser) specialises in treatment of wastewater with high organic content. Services offered include treatment of effluent up to zero discharge and the recycling of treated water. Ronser acquired China-based biotechnology company, Kang Chern Environmental Science & Technology, to own its patented technologies AnaEG and BioAX. The patented technologies are respectively an anaerobic process in the treatment of high organic wastewater and an aerobic process to treat the wastewater for reuse. Current customers in China are China Petrol, China Resources Snow Brewery, Coca-Cola and PepsiCo's operations in China while target markets in Malaysia are palm oil mills and pig farms. Operations in Malaysia are targeted to start in 2010 once its plant is built.

Pollution Engineering is involved in bioremediation and environmental engineering. Its main products and patented technologies include wastewater treatment plants, such as sewage treatment plants and incinerator systems that can be applied across multiple industries such as sugar, textile, paper, palm oil and rubber processing. Examples of these wastewater treatment plants are physio-chemical treatment coarse screening that involves fine screening, micro screening, chemical flocculation and automatic pH regulation; and biological treatment activated sludge that includes aerobic and anaerobic processes. Pollution Engineering has undertaken projects in large scale application of biological treatment to MSW that can be used to generate biogas and organic-based fertiliser. It operates in a number of countries and its customer base includes private as well as public sectors. With such activities, Malaysia is well-positioned to be the hub for the above areas of bioremediation.

Biocatalyst

Biocatalysts are enzymes that activate or accelerate a biochemical reaction, and are naturally produced in living organisms. In industrial processing and manufacturing, biocatalysts are competing with chemical catalysts. Traditionally, the production of biocatalysts is more costly than the production of chemical catalysts. However, the competitiveness of biocatalysts has rapidly increased due to the development of two key technologies – protein engineering and enzyme engineering. Protein engineering allows structural alteration of enzymes while enzyme engineering allows enzymes to operate in a variety of microenvironments[81]. In general, biocatalysts have greater capacity to increase reaction rates, and hence reduce processing time, and in some cases, reduce the number of steps in a given production process. The industrial enzyme market can be broadly segmented into food and beverage enzymes, cleaning product enzymes, ethanol production enzymes, animal feed additive enzymes and other industrial enzymes.

In 2008, the world demand for enzymes was valued at USD 5.1 billion (RM 17.9 billion). North America accounted for 46% of the world demand, followed by Western Europe at 23% and Asia Pacific at 19%. With an expected CAGR of 6.3%, world demand is expected to reach USD 7 billion (RM 24.5 billion) by 2013. Approximately 62.7% of the world demand for enzymes was derived from the global industrial enzyme market, valued at approximately USD 3.2 billion (RM 11.2 billion) in 2008[82]. Within the industrial enzyme

[80] Ernst & Young Analysis
[81] Schmid et al. (2001)
[82] Novozymes Sales and Market Report (2008)

market, the fastest growth is expected in animal feed additives and ethanol production enzymes, while the food and beverage enzymes market will experience moderate growth. Developing markets will contribute greatly to the growth in demand for animal feed additive enzymes as the rising income per capita increases the demand for quality meat as part of the standard diet[83]. Novozymes is the largest producer of enzymes worldwide, capturing 47% of the global market share in industrial use enzymes. Its 2008 revenue of USD 1.6 billion (RM 5.6 billion) encompasses 700 products with sales in 130 countries. In the same year, Novozymes spent over USD 198.3 million (RM 694.1 million) on R&D, and it currently holds 6,000 registered patents[84].

Malaysia is a net importer of enzymes, where total imports doubled over the past five years to reach USD 14.3 million (RM 50 million) in 2008, while the ASEAN market is estimated to be in excess of USD 85.7 million (RM 300 million) per annum, representing a significant potential for import substitution[85]. There is currently no industrial scale enzyme manufacturing in Malaysia or in the ASEAN region. Local players are currently involved only in marketing or enzyme formulation, and they offer their services to help meet local demand. Some of the key barriers to the development of the enzyme industry in Malaysia are the limited know-how and experience in the scaling-up process, limited production capacity and efficiency of fermentation / bioprocessing infrastructure, and the high costs of setting up a commercial scale facility[85]. In view of this, BiotechCorp has facilitated the transfer of technology in the scaling up of enzyme production between Enzyme Technology (a CRO company) and Insect Biotech from Korea, to form MyEnzyme (a CMO company). MyEnzyme aims to be the leading regional CMO for enzyme and enzyme products. Target customers are small start-up companies that are commercialising enzyme, metabolite, and microbes R&D output.

IOI Lipid Enzymtech is investing in a state of the art facility for the manufacture of nutritional lipids and specialty fats. The new facility is in Pasir Gudang, Johor and is expected to be operational by mid-2010. It has successfully brought European technology, know-how and R&D back to Malaysia by acquiring Loders Croklaan, a leading producer of oils, fats and nutritional ingredients. Loders Croklaan has specialised facilities and equipment including R&D laboratories, an enzyme fat modification plant for small scale enzymatic production and a solvent fractionation plant in the Netherlands that is certified ISO14001, Hazard Analysis and Critical Control Point (HACCP) and GMP. Its core business is researching, exploring and developing new applications for palm oil-based fractions and products. It is involved in the research, development, production and commercialisation of enzymatic products. The technology utilised is enzyme modification technology for the production of structured lipids; and separation and purification technology for production of food ingredients for confectionary and infant nutrition. All related enzymatic products are also Halal and Kosher certified.

Fine and Specialty Chemicals

Fine chemicals are chemicals that are produced to customer specifications and are often intermediates or active ingredients for specialty chemicals (e.g. pharmaceutical and agrochemical intermediates); while specialty chemicals are generally formulations that are sold on the basis of their performance. The price of specialty chemicals generally reflects their value, rather than the cost of production[86]. Examples of specialty chemicals include flavours and fragrances, pharmaceuticals and pesticides.

According to Markets & Markets, the world market for renewable chemicals was estimated at USD 45 billion (RM 157.5 billion) in 2009 and is expected to reach USD 59 billion (RM 206.5 billion) by 2014. The E.U. and U.S. respectively accounted for 35% and 30% of the total revenues, driven by Government support and consumer demand for green products. There is also immense market potential in developing countries and emerging economies as their markets for green products are relatively untapped.

The use of industrial biotechnology in this segment allows fine and specialty chemicals to be produced from renewable resources instead of petroleum. Large chemical companies like DuPont, DSM, BASF and Cargill have already commenced using biotechnology processes to replace traditional production processes. For example, DSM's traditional process of producing the antibiotic Cephalexin used to be a ten-step chemical process. Currently, it is produced using a biotechnology process that combines fermentation and an enzymatic reaction that uses less energy and less chemical inputs, is water-based and generates less waste. The environmental impact of using biotechnology in the production of Cephalexin is the savings of 65% in both the materials used and energy consumption, while the economic impact is a reduction of 50% in the variable cost of production[87].

[83] World Enzymes (2009)
[84] Novozymes Annual Report (2008)
[85] BiotechCorp
[86] BiotechCorp
[87] EuropaBio (2003)

In Malaysia, industrial biotechnology in the fine and specialty chemicals segment is focussed on the replacement of traditional chemical processes (petrochemistry) with biotechnology processes that can reduce the negative environmental impact, the production cost and the number of processing steps required. The long established chemical industry in Malaysia is worth USD 11.4 billion (RM 40 billion) and is the second largest contributor to total manufactured exports[88]. E.U. and Japan are some of the major export markets with several guidelines imposed including the 'green chemicals or bio-based chemicals' requirements. As such, many chemical companies are turning to biotechnology processes due to the increasing emphasis on the safety, health and environmental issues concerning the production of fine and specialty chemicals.

The fine and specialty chemicals segment is expected to leverage on the oil palm plantation sector and Malaysia's rich biodiversity. In the oil palm plantation sector, industrial biotechnology is increasingly being utilised in downstream processing and manufacturing of oleochemicals. The derivatives produced from the main oleochemical products are soap and detergent, margarine, shortening and cocoa butter substitutes. The major export markets are the E.U., China, U.S. and Japan. Nutraceuticals like Vitamin A and Vitamin E are also being produced from the palm oil oleochemicals industry. In addition, Malaysia's rich biodiversity provides a valuable resource for the production of herbal based nutraceutical products. This is further aided by the traditional and ethnic knowledge in herbal remedies that has recently gained formal recognition as studies have been undertaken to scientifically identify active and novel compounds associated with the medicinal properties of plants. According to Frost & Sullivan, the phytomedicine market has the potential to reach USD 1.3 to USD 1.4 billion (RM 4.5 to RM 5 billion) per annum, and is expected to reach USD 3.4 billion (RM 12 billion) by 2012, assuming a CAGR of 17.4% (2006 to 2012). Other end products from botanical extracts include cosmeceuticals, flavours and fragrances.

Rapid development in technologies such as protein engineering and microbial pathway engineering has aided in the application and adaption of biotechnology to the production of fine and specialty chemicals. A development of note is biopharming, which is the genetic and metabolic engineering of microorganisms that will enable the production of many platform chemicals used in the industry, for example, the engineering of Esterichia coli to utilise glycerine in the production of formate, succinate and other organic acids. There are efforts underway to develop this technology to improve productivity of existing fermentation, enable cost advantage petrochemical replacements, and produce novel chemicals that were previously unattainable. This is an interesting field for Malaysia to venture into given the apparent advantages and the possibility of producing fine and specialty chemicals at a low cost from renewable resources.

A notable company in the fine and specialty chemicals segment is PureCircle, formerly known as Stevian Biotechnology Corporation. PureCircle, a biotechnology company in Malaysia, is the leader in the production of natural sweeteners and is listed on the London Stock Exchange Alternative Investment Market. Its technology allows the production of enzymatically enhanced natural sweeteners, cyclodextrin and derivative products. PureCircle is the world's leading provider of natural, high intensity sweeteners from plants to the global food and beverage industry. Rebaudioside A (Reb-A), a product of this BioNexus Status company, is a calorie-free natural sweetener produced from stevia that appeals to health conscious consumers. Reb-A is suitable for consumption, especially for diabetics, as it has a low glycaemic index and does not have any caloric or carbohydrate content.

Biopolymer

Biopolymer generally refers to bioplastic and its applications are also seen in the production of biodegradable plastic. There is growing demand worldwide for the use of bioplastic and biodegradable plastic to replace some types of traditional petroleum-based plastic, especially in the packaging industry. Global consumption of plastics exceeded 350 billion pounds in 2003, and is forecasted to reach 500 billion pounds in 2010, at a CAGR of 5%[89]. As plastics are traditionally made from non-renewable sources of fossil fuel and are non-biodegradable, there is increasing concern over the issues associated with waste disposal of plastics and the depletion of fossil fuel. The usage of biopolymer plastics as opposed to traditional petroleum-based plastics may reduce energy consumption by 50% and greenhouse gas emissions by 67% during the production process[90].

[88] BiotechCorp
[89] Research and Markets (2009)
[90] EuropaBio (2008)

Major bioplastics include starch-based, polyhydroxylalkanoate (PHA) and polylactic acid (PLA). The global market for lactic acid and its derivatives is predicted to have a CAGR of 15%. The potential market in bioplastic applications, for instance polylactide, is expected to reach 907,000 tonnes in 2010 and three to five million tonnes by 2020[91]. This estimate is based on the increasing awareness of the environment, health and safety among consumers and businesses. Being natural products, lactic acid and its derivatives can be used safely without threat to the environment.

In line with this, the E.U. and U.S. have started implementing regulations that favour the use of biodegradable plastic. While the general trend is to move from traditional petroleum-based plastics to bioplastics and biodegradable plastics, two E.U. member countries have taken early initiative in terms of local regulations. The French law on the orientation of agriculture in 2006 had an article stating that shopping bags must be biodegradable from 2010, while in Germany, a legal privilege was awarded to certified compostable plastic packaging under the German Packaging Ordinance, effective from May 2005. Certified biopackaging will be exempted from recycling obligation until 2012. Overall, the E.U. has mandated that only biodegradable products be used for packaging from 2010, creating an immediate market of USD 248.3 billion (RM 869.1 billion)[92]. In U.S., the Green Federal Procurement has a major policy directive that designates products made from bio-based plastics as a preferred purchasing item. Disposable cutlery, plastic films (used for compostable bags) and plastic packaging containers are among 20 items on the official list of bio-based products designated as "preference items" for procurement by federal agencies. Worldwide, efforts are being made by the Governments to push and promote the development and usage of bioplastics and biodegradable plastics and this is also true in China and Japan.

NatureWorks LLC (NatureWorks) is the first company to offer commercial production of biopolymers that are 100% derived from renewable resources. Production of these biopolymers generates low carbon emissions, and cost and performance are competitive with petrochemical plastics. Its technology allows natural plant sugars to be processed into proprietary polylactide polymer, which in turn can be used to make a variety of plastics and fibres for various applications. Overall, NatureWorks achieved a 68% reduction in fossil fuel use compared to traditional plastics and a greenhouse gas neutral position in the production of PLA.

Malaysia has a strong traditional petroleum-based plastic industry that is one of the most competitive in Asia. There are more than 1,550 companies producing plastics and plastic-based products, and packaging is the largest market of the plastics industry. Malaysia is a net exporter of plastics with total exports valued at USD 2.7 billion (RM 9.34 billion) in 2008[93]. Main export products are plastic containers, plates, films, sheets, foils, strips and other articles of plastic while major export markets include the E.U., China, Hong Kong, Singapore, Japan and Thailand. Examples of plastic exporters from Malaysia are Toray Plastics, Texchem Group and Polyplastics Asia Pacific. In line with global industry trends, there is a need for Malaysian plastic companies to transform their traditional plastic production to bioplastics and biodegradable plastics in preparation for the enforcement of biopackaging regulations in the E.U. and other developed countries that are key export destinations for Malaysian companies.

TT Biotechnologies was formed to produce organic acids (lactic acid) and bioplastics (polylactide) to capitalise on the growing demand for lactic acid and polylactide worldwide. Its market is not limited to Malaysia and it is expected to expand into the global market with the potential to garner huge returns. TT Biotechnologies plans to commercialise its in-house research on the production of lactic acid and polylactide biodegradable plastics. The lactic acid and polylactide will be produced from palm oil wastes with advanced membrane technologies. The company is now developing a pilot scale plant for the production of high purity lactic acid and polylactide biodegradable plastic from renewable biomass. The ultimate objective is to design and develop a process for producing lactic acid commercially with the proposed capacity of 20,000 to 50,000 tonnes per year by 2013 at the earliest.

[91] BiotechCorp
[92] Industry Interviews and EY Analysis
[93] Malaysian Industrial Development Authority Website, accessed on 10 December 2009

Return 2 Green (R2G) and Bio Green Bags (BGB) are home-grown companies that are involved in the R&D, manufacturing, supply and commercialisation of biodegradable and compostable disposal products made from agricultural waste (bagasse and corn waste) using biotechnology processes. R2G and BGB respectively produce 100% biodegradable food packaging products and biodegradable bags that have obtained international certification for biodegradation and compostability, and product approval from the FDA for food safety. Within 45 to 180 days, their products will organically biodegrade and decompost, turning into organic fertilisers. These companies are looking to further develop products from paddy husks, tapioca stems and pineapple waste. In November 2009, R2G and BGB signed an exclusive partnership agreement with Mega Signet, a Malaysia-based international consulting and marketing company, that gives Mega Signet the rights to market the products in the domestic and global markets. Over the next three years, R2G and BGB plan to invest USD 34.3 million (RM 120 million) to set up five factories in Malaysia and three factories overseas[94].

Others

There are several companies involved in other focus areas of industrial biotechnology such as biohydrometallurgy and bioprospecting. T-BioVenture is involved in developing a cocktail of microorganisms that can be used for biomining and biohydrometallurgy purposes. These microorganisms will aid in the efficiency of recovery and recycling of minerals by at least 10%, which translates into significant economic gains. Current research is looking at improving the recovery in gold mining. The processes used to develop these microorganisms are bacteria isolation, identification and purification; enzyme or protein identification; assays and purification.

Nimura Genetics Solution is involved in bioprospecting for bacteria, fungus and plants that produce novel compounds. Its involvement in bioprospecting aims to leverage on the diverse tropical bioresources of Malaysia.

Moving Forward

The increasing green initiative trends globally offer opportunities for Malaysia to leverage on its strong oleochemicals and petrochemicals manufacturing and outsourcing capabilities for the development of the industrial biotechnology sector. Industrial biotechnology provides the solutions to environmental issues, such as municipal waste management and alternative renewable energy like the production and utilisation of biofuel as compared to fossil fuels. Furthermore, the industrial biotechnology platform facilitates large scale production of environment-friendly fine and specialty chemicals (e.g. food ingredients, functional food, nutraceuticals and pharmaceuticals), biopolymer and biofuel. Malaysia should also leverage on its abundance of natural resources and biomass to further develop industrial biotechnology.

At the Copenhagen World Summit on Climate Change, Malaysia committed to reducing its carbon emission by up to 40% by 2020. To uphold its commitment, the Ministry of Energy, Green Technology and Water (MEGTW) has established a green technology fund and will be expected to intensify its efforts to execute green initiatives in the country. Development of industrial biotechnology sector will be critical to enable the implementation of green initiatives identified. In the past, Malaysia has adopted a broad-based approach to the development of industrial biotechnology that has facilitated capacity and capability building. Moving forward to Phase II of the NBP – Science to Business, there is a need to intensify efforts to implement green chemistry initiatives by capitalising on Malaysia's strengths. The following priority actions are proposed for consideration:

1 **Accelerate development of technology for effective implementation of green chemistry initiatives**

Biofuel

Given Malaysia's competitive advantage in the palm oil industry in the international arena, biofuel is another area that has captured the attention of the Malaysian industrial biotechnology community. The production of biofuel can leverage on Malaysian's oil palm sector. There is immense potential in biofuel as it is driven by the global trend to reduce greenhouse gas emissions and decrease dependence on the dwindling reserves of fossil fuel. It should be noted that Malaysia is the coordinating country for promoting biofuel for the ASEAN countries.

[94] Bernama (17 March 2009)

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The production of first generation biofuel in Malaysia generally utilises refined, bleached and deodorised olein or crude palm oil as feedstock. There are two challenges that are associated with this, namely, the high price of palm oil and the food versus fuel controversy. In order to address challenges in first generation biofuel production[95], R&D initiatives should be intensified to explore the usage of PFAD, a lower grade of feedstock from palm oil, or feedstock from other non-food crops like Jathropa in the production of biodiesel. Another avenue of research is the use of algae derived oil as a source of triglyceride oils for conversion into biodiesel.

Even greater potential lies in the development of second generation biofuels that are derived from cellulose and lignocellulose, which would otherwise commonly be disposed off. The development of second generation biofuels epitomises the concept of turning waste into wealth, and would provide enormous potential for Malaysia given the amount of harvestable biomass that is produced in the palm oil plantation sector. It is recommended that Malaysia should channel resources into either developing or acquiring the technology that is needed to utilise oil palm biomass for the production of bioethanol, or partnering with a foreign company that has sound and promising commercialisable research in this area.

Several foreign companies have registered interest in exploring the possibilities of working with Malaysia to develop the technology for the production of second generation bioethanol from palm oil biomass. Malaysia has the biomass feedstock and is interested in looking for potential partners that can provide the technologies. The current need is to create awareness among the potential players and to bring them together in this field. Palm oil plantation companies are encouraged to play their part in reducing the environmental impact by participating in this scheme.

Furthermore, the trend worldwide is to develop the industrial biotechnology sector by building integrated biorefineries that utilise multi-feedstock and several conversion technologies to manufacture various products. The main product is usually biofuel, with by-products and side-products of biochemicals, biomaterials, heat and power. Integrated biorefineries bridge the gap between the agriculture and chemical industries by integrating the entire biomass chain in a multi-feedstock, multi-process and multi-products facility. Malaysia should also endeavour to move in this direction.

Bioremediation

As a signatory to the United Nations Framework Convention of Climate Change (UNFCCC), Malaysia ratified the Kyoto Protocol in 2002 and has implemented an institutional framework to support Clean Development Mechanism (CDM) activities. Through the CDM, Malaysia can benefit from investments in the greenhouse gas emission reduction projects, especially in the areas related to the palm oil sector. Furthermore, there are readily available IPs that can be developed for commercialisation, thereby providing opportunities for development of new entrants.

Nonetheless, there are several barriers to the development and adoption of bioremediation in Malaysia including the lack of integrated research from multidisciplinary fields, limited funding, and inadequate tools and infrastructure to aid research on bioremediation[96].

[95] Ernst & Young Analysis
[96] BiotechCorp

Fine and Specialty Chemicals

The fine and specialty chemicals segment is expected to leverage on the oil palm plantation sector and Malaysia's rich biodiversity. Malaysia, as a mega biodiversity country, presents opportunities for bioprospecting and the discovery of novel bioactive compounds associated with the medicinal properties of plants for nutraceutical and pharmaceutical products. Other end products include food ingredients, cosmeceuticals, flavours and fragrances. The extraction of novel bioactive compounds or APIs is aided by BiotechCorp's acquisition of the Supercritical Fluid platform technology. This enables the large scale extraction of essential oils and metabolites with high purity and uniformity, as discussed in Policy Thrust 1: Agricultural Biotechnology Development.

In addition, development in technologies such as protein engineering and microbial pathway engineering should continue to improve productivity of existing fermentation to enable the production of many platform chemicals used in the industry in an economical manner.

Biopolymer

Malaysia should also focus on developing its biopolymer segment in order to capitalise on its existing market share, the changing external landscape and the strong push for bioplastics. There is growing demand worldwide for the use of bioplastics and biodegradable plastics in packaging.

As a commodity-based economy, Malaysia generates sufficient feedstock from its palm oil plantations, sago starch and agriculture waste for the production of bioplastics and biodegradable plastics. However, it must be noted that there is a gap where the right technology is needed to convert agriculture waste into bioplastics and biodegradable plastics. Thus, Malaysia needs to collaborate with other countries to obtain the right technologies, resources and leading foreign industry partners to emerge as a hub for the production of bioplastics and biodegradable plastics in the ASEAN region, as currently the bioplastic industry in Malaysia is still in its infancy stage.

Key Implementation Considerations

Effective implementation of green initiatives requires significant Government support and commitment. Key considerations for successful implementation include the following:

- Concerted and coordinated effort by the Government and stakeholders from the private sector, including RIs and IHLs, to support the growth of a green economy. For example, approval of Government budget allocation will be made based on green economy policies and guiding principles. These policies and principles are to be determined by the MEGTW described earlier.
- Government support of green investments, related policies and incentives to boost the development and commercialisation of renewable energy. The drive for industrial biotechnology in Malaysia needs to be policy driven, for example where the Government mandates the use of biofuel or reduces petrol subsidies; or offers incentives for the treatment of solid waste and wastewater using bioremediation; or mandates the use of biodegradable packaging materials.
- Collaboration and funding mechanisms for research and commercialisation of applications and the development of new applications.
- Skill-set and expertise for research, development and commercialisation, for example, specific skill-sets and expertise in bioprocessing, skills and experience in commercial-scale bioreactors and fermentors
- Effective strategic partnerships and collaborations with foreign affiliates for market access or technology transfer
- Ability to build sustainable green infrastructure to ensure cost effective green chemistry initiatives

2 Build shared facilities to scale up commercialisation

Some of the key barriers to the development of the industrial biotechnology sector are the lack of know-how and experience in the scaling-up process, limited production capacity and efficiency of infrastructure, and the high costs of setting up commercial scale facilities. As part of the initiative to support the development of the industrial biotechnology sector, the set up of shared facilities for outsourcing services is equally critical given

the amount of investment required to set up such facilities. As described in Policy Thrust 1: Agricultural Biotechnology Development, a similar business model will be adopted in implementing commercial scale facilities for contract (toll) manufacturing services.

The acquisition of the Supercritical Fluid platform technology has enabled large scale extraction of novel bioactive compounds or APIs with high purity and uniformity for the purpose of scale up commercialisation. The Supercritical Fluid technology comes with SOP and 33 extraction recipes that are ready for commercialisation. These extraction recipes are for the extraction of compounds such as amaranth, black pepper oil, cardamom oil, nutmeg oil, turmeric oil, vanilla, ginger oleoresin, cinnamon and Indian holy basil oil. Therefore, it is possible for the immediate provision of services as contract (toll) manufacturers for the extraction of the 33 compounds.

In addition, the development of a biotechnology ecosystem called Bio-XCell in Iskandar Malaysia, Johor, will include the set up of commercial scale facilities, i.e. commercial scale bioreactors of different sizes. Bio-XCell is a partnership between BiotechCorp and UEM Land Holdings, and is a model for hub expansion within the biotechnology industry. The facilities are purpose-built to create an ecosystem that is focused on bioprocessing and fermentation-based industries. It is planned to attract local and foreign investors that could benefit from Malaysia's value proposition to be clustered around the Bio-XCell industrial complex. Besides local industry development, Bio-XCell has already succeeded in attracting some world-class companies to set up operations in the location, which will aid in establishing Malaysia as an industrial biotechnology hub in the region.

As described earlier, the development of industrial biotechnology requires significant foreign collaboration for technology and knowledge transfer, hence the need for concerted efforts to attract global companies to set up operations in Malaysia. The Bio-XCell strategy is to prepare infrastructure in both the form of ready-built and customised commercial scale shared facilities that are available for lease to interested companies. This is attractive to investors as the facilities and infrastructure are ready for immediate use, thereby significantly cutting down on the initial financial investment and time needed for operationalisation. As such, investors can occupy and use the facilities that are available while paying a nominal leasing or rental fee.

Besides availability of infrastructure and facilities, current efforts to attract FDIs should continue and additional incentives should continue to be considered (being addressed in Policy Thrust 6: Financial Infrastructure Development).

3 Leverage on local capabilities to intensify public-private partnership

Besides FDIs, there is a need to leverage on local conglomerates such as Petronas, CCM, Genting and Sime Darby to drive the development of industrial biotechnology. These large home-grown companies should take a leading role in driving green initiatives. As proposed in Policy Thrust 2: Healthcare Biotechnology Development, a similar approach should be taken in adopting the PPP model, to effectively leverage on local capabilities to implement green initiatives.

Possible PPP model to be considered for partnership between the Government and private sector in implementing green initiatives is as follows:

- Private sector to create the platform for the development and adoption of industrial biotechnology for the supply of green products or services to Government
- Private sector investment in the development of platform technologies for the purpose of:
  - Research for commercialisation value and the development of applications for commercialisation
  - Collaboration opportunities with emerging local biotechnology players to develop product pipelines

The implementation of the PPP model will be based on the proposed approach described in Policy Thrust 2: Healthcare Biotechnology Development.

Chapter 4
Infrastructure Development

Chapter 4 Infrastructure Development

As with the development of any other industry, infrastructure support is of vital importance for the development of the biotechnology industry. A conducive research and business environment is expected to attract and retain both foreign and local investors, researchers and entrepreneurs. The establishment of appropriate infrastructure will support and strengthen core Research, Development and Commercialisation (R&D&C) activities, allow industry linkages between the public sector, private sector and academic institutions, and outline a clear legal infrastructure that governs the orderly development of the biotechnology industry and protects the IP of researchers and companies. As such, Policy Thrusts 4 to 9 of the NBP highlight six essential infrastructure enablers, namely:

- Policy Thrust 4: R&D and Technology Acquisition Development that aims at enhancing the quality of basic research and applied research; focusing on selected priority areas that have commercialisation potential, and fostering public-private R&D partnerships and international collaboration
- Policy Thrust 5: Human Capital Development that addresses the need to bridge gaps in experienced biotechnology sub-specialties and expertise
- Policy Thrust 6: Financial Infrastructure Development that aims at addressing financial resource inadequacy for the development of the biotechnology industry
- Policy Thrust 7: Legislative and Regulatory Framework Development that aims at establishing supportive regulatory framework
- Policy Thrust 8: Strategic Development that outlines the need to develop and maintain an international competitive position
- Policy Thrust 9: Government Support and Commitment that outlines the framework to be put in place to support the implementation of the NBP

Policy Thrust 4 R&D and Technology Acquisition Development

With the formation of the National Biotechnology Directorate in 1996, Malaysia registered interest in the development and promotion of biotechnology. Presently, MOSTI's objective is to champion scientific discovery and transform innovation to achieve a knowledge-based society for sustainable development through R&D planning, funding and commercialisation. Under the RMK-8 (2001-2005), efforts were focused on laying the foundation towards building a competitive biotechnology industry. In 2002, the "Knowledge-based Economy Master Plan" was formulated as part of the country's economic and social development process, reflecting the importance placed on R&D and innovation. During the RMK-9 (2006-2010), concerted efforts were geared towards the implementation of the NBP. These efforts form the basis of Malaysia's involvement in biotechnology R&D, carried out in the agriculture and healthcare sector by RIs and IHLs such as MARDI, SIRIM, Forest Research Institute Malaysia (FRIM), UPM, USM, IMR and TPM.

It is recognised that R&D plays an important role in the development and sustainability of the biotechnology industry. Ongoing R&D ensures a pipeline of competitive and innovative products and services that is critical to the success of the biotechnology industry. As such, the R&D and Technology Acquisition Development thrust aims to ensure that basic and applied R&D is continued (from zero-base until commercialisation). In addition, the implementation of a technology acquisition programme will accelerate the development of the industry by significantly reducing the time needed for commercialisation. This two-pronged approach is suitable as while basic R&D is time consuming with no guarantee of commercialisation; it builds a knowledge base, enables researchers to be familiar with the focus area of interest in biotechnology and enhances their

skill-sets and expertise in research. While R&D is ongoing, the technology acquisition programme will jump start the biotechnology industry, allowing Malaysian companies to be on par with leading biotechnology companies through the acquisition or licensing of targeted technologies that will advance the Malaysian biotechnology industry, with the associated transfer of skill-sets, knowledge and expertise.

Current State

R&D efforts in the biotechnology industry are mainly anchored by MOSTI, as its key responsibility is to harness science, technology and innovation to add value to the agriculture and industrial sectors. This will enable progression to a knowledge-based economy, particularly through the use of ICT and biotechnology. The realisation of a knowledge-based economy requires high investment commitment to R&D from both the public and private sectors.

In general, the 2008 National Survey of R&D showed that the annual GERD in Malaysia experienced an increase from USD 0.8 billion (RM 2.8 billion) in 2004 to USD 1 billion (RM 3.5 billion) in 2006[1], placing Malaysia at 37th in the world. This expenditure is small compared to R&D expenditure of developed countries like the U.S. at USD 0.3 trillion (RM 1.2 trillion) and Japan at USD 158 billion (RM 552.9 billion); and newly industrialised economies (NIEs) like South Korea at USD 25.5 billion (RM 89.3 billion) and Singapore at USD 2.9 billion (RM 10.4 billion). Malaysia's research intensity, as measured by the GERD / GDP ratio[2], was ranked 44th in the world at 0.64, while developed countries like Sweden (3.86) and Japan (3.17), and NIEs like Korea (2.67) and Singapore (2.36) showed greater research intensity.

There are currently no statistics compiled for the R&D indicators specific to the biotechnology industry in Malaysia. Hence moving forward, a database should be established in order to effectively track R&D indicators in the biotechnology sector. For the purpose of this Country Report, R&D expenditure of BioNexus Status companies has been analysed to provide an overview of the R&D expenditure in the biotechnology industry.

Between October 2008 to September 2009, the total R&D expenditure by BioNexus Status companies amounted to USD 9.3 million (RM 32.6 million), see Table 4-1. From this, R&D expenditure was highest for healthcare biotechnology companies at 48.5%, followed by agricultural biotechnology companies at 41.1%, while industrial biotechnology companies only recorded 10.4% in R&D expenditure. The higher spending is partially due to the fact that there is more than double the number of companies in the healthcare and agricultural biotechnology sectors compared to the industrial biotechnology sector. Industrial biotechnology companies, on the other hand, are attracting cutting-edge technologies from foreign companies to produce new products in Malaysia.

Table 4-1: R&D Expenditure for BioNexus Status Companies in Malaysia (2007-2009)

Sectors	Oct 2007 - Sep 2008		Oct 2008 - Sep 2009		Percentage Growth (%)
	USD million	RM million	USD million	RM million	
Agricultural Biotechnology	2.1	7.2	3.8	13.4	86.1
Healthcare Biotechnology	2.3	8.0	4.5	15.8	2.2
Industrial Biotechnology	0.6	2.2	1.0	3.4	54.5
Total	**5.0**	**17.4**	**9.3**	**32.6**	**87.4**

Sources: BiotechCorp

Technology Acquisition Development

While basic and applied research continues as a baseline for developing the Malaysian biotechnology industry, the NBP has recommended adoption of a technology acquisition strategy in accelerating

[1] MOSTI (2008)
[2] The higher the ration, the higher the research intensity; indicating a greater national emphasis or expenditure on R&D in relation to its economy

development. The National Biotechnology Acquisition Programme is to ensure that the technology acquired serves national interest by granting Malaysia entry into foreign markets, access to selective skills and the freedom to operate with proprietary technology. The platform technologies will also enable commercial scale up of specific initiatives in the agricultural and industrial biotechnology sectors.

BiotechCorp has spearheaded the efforts in technology acquisition under the National Biotechnology Acquisition Programme. The platform technologies acquired for healthcare are the nanotechnology platform from Nanobiotix S.A. in 2007 and the DotScan™ antibody microarray diagnostic platform technology from Medsaic in 2009; the Marker Assisted Selection platform technology from DNA LandMarks for agricultural; and the Supercritical Fluid technology with applications for extraction and particle formation from FeyeCon for the industrial biotechnology sector. These acquisitions provide Malaysian researchers with access to world class proprietary technology and the freedom to carry out their development work based on proven platform technologies. The acquisitions are expected to propel Malaysia to the forefront of biotechnology in the region, facilitating the transfer of knowledge and technology, and the development of new applications for commercialisation. Furthermore, the access to these platform technologies will position Malaysia as a regional leader with the potential to access global markets.

While BiotechCorp is constantly on the lookout for other technologies that have broad spectrum applications to serve the needs of the country, the immediate need is to ensure that the platform technologies in the healthcare sector are taken-up for the purpose of enhancing R&D; while for the agricultural and industrial biotechnology platform technologies, immediate commercialisation of applications and development of products are required.

Commercialisation

While there is a need for baseline R&D to continue, it is suggested that emphasis should be given to the development component for the purpose of commercialisation. The immediate need for the country is to utilise and adapt the current research and IP for practical use in the industry, and to encourage the take up of applied and developmental research. Table 4-2 provides a list of examples of Malaysian RIs and IHLs engaged in biotechnology R&D.

Table 4-2: Examples of Malaysian Research Institutions and Institutes of Higher Learning Engaged in Biotechnology Research

Agricultural Biotechnology
Malaysian Agriculture Research and Development Institute, Malaysian Palm Oil Board, Forest Research Institute Malaysia, Malaysia Cocoa Board, Rubber Research Institute Malaysia, Sarawak Biodiversity Centre, Veterinary Research Institute, Universiti Malaya, Universiti Kebangsaan Malaysia, University Putra Malaysia, University Malaysia Sarawak
Healthcare Biotechnology
Institute for Medical Research, Malaysia Nuclear Agency, Universiti Putra Malaysia, Universiti Sains Malaysia, Universiti Kebangsaan Malaysia
Industrial Biotechnology
Standards and Industrial Research Institute of Malaysia, Malaysia Nuclear Agency, University Putra Malaysia

Source: Ernst & Young Analysis

The NBP has identified the three Centres of Excellence to be established, the Agro-Biotechnology Institute (ABI), Malaysia Genome Institute (MGI) and Malaysia Institute of Pharmaceuticals and Nutraceuticals (IPHARM). Several major research projects are currently underway at these Centres of Excellence (see Table 4-3). For example, in MGI, the Microbial Genomics Research for Gene and Natural Product Discovery project is focusing on two model organisms, Burkholderia pseudomallei, a locally important soil pathogen, and Eimeria tenella, a local avian protozoan. The project will gain new insights on virulence, antibiotic resistance, host specificity and infectivity[3]. As outlined in the NBP, SIRIM is also considered a Centre of Excellence for industrial biotechnology. Research projects include development of bioremediation process for industrial waste and biosensor technology for detecting organic contaminants in environment and agriculture.

[3] News Medical.net (21 Februarry 2008)

Table 4-3: Research Areas of Biotechnology Centres of Excellence

Agro-Biotechnology Institute	Malaysia Genome Institute	Malaysia Institute of Pharmaceuticals and Nutraceuticals
• Agricultural Genomics and Gene Discovery • Genetic Engineering • Biopharming • Animal Biotechnology • Food Biotechnology	• Comparative Genomics and Genetics • Structural Biology Systems and Computational Biotechnology • Metabolic Engineering • Protein Expression Systems	• Identification and Development of Bioactive Compounds • Bioprocessing • Pre-formulation for Product Development • Screening of Bioactive Compounds • Advance Drug Delivery Systems
Total R&D Projects = 34	**Total R&D Projects = 18**	**Total R&D Projects = 23**

Source: BIOTEK, MOSTI (as at October 2009)

IP law provides a framework that enables individuals and companies to protect the output of their R&D activities and this includes patents, copyright and trademark, and design rights. In Malaysia, this is administered by the Intellectual Property Corporation of Malaysia (MyIPO). From 2004 to 2008, the total number of biotechnology patents applied was 1,574, while the total number of patents granted was 757 (see Table 4-4). From these, 52% of the patents applied and 45.4% of the patents granted are related to healthcare biotechnology, followed by industrial biotechnology at 33.7% patents applied and 42.7% granted, while agricultural biotechnology recorded 14.3% patents applied and 11.9% patents granted. While the number of patents applied in the agricultural biotechnology sector is relatively low, this could also indicate that companies may have concerns with regard to biosafety, and the exclusion of patentability of plants and animal varieties. Also, companies may prefer to keep their discoveries as a trade secret rather than go through the process of patenting. In general, while the number of patents is one of the indicators of human capital and knowledge creation, it must be noted that the number of patents granted is not necessarily an accurate indicator of the successful commercialisation of ideas and IP. Examples of patents granted to local researchers includes the patenting of the extraction process of palm tocotrienols by Carotech, a subsidiary of Hovid, and the production process for proteins in plant fluids by the Rubber Research Institute of Malaysia (RRIM). International patent applications include the patenting of dietary supplements containing dehydrated cactus fruit juice and ginseng berry juice by E. Excel International of the U.S.

Table 4-4: Biotechnology-Related Patents Applied and Granted in Malaysia (2004-2008)

Patent	Sectors	2004	2005	2006	2007	2008	Total
Applied	Agricultural	18	32	52	60	63	225
	Healthcare	182	203	179	67	188	819
	Industrial	107	99	127	61	136	530
	Total	**307**	**334**	**358**	**188**	**387**	**1574**
Granted	Agricultural	23	2	14	30	21	90
	Healthcare	30	23	45	121	125	344
	Industrial	4	27	64	145	83	323
	Total	**57**	**52**	**123**	**296**	**229**	**757**

Source: MyIPO (2009)

As part of the NBP implementation, BiotechCorp has put in place a platform, the IGNITE programme, to identify research and IP that are readily available for commercialisation. Under the IGNITE programme, local R&D is evaluated and assessed by global experts from Cambridge. This external evaluation revealed that more than 80% of the work done is actually business worthy. In terms of encouraging the take up of applied and developmental research, any increase in R&D funding for biotechnology is recommended to be dedicated to developmental research. Other existing funds such as the TechnoFund may also need to be re-oriented in order to encourage the take up of applied research with the end purpose of commercialisation in mind as Malaysian academicians and researchers have the capability to carry their research and findings beyond the proof-of-concept to commercial applications. However, Malaysia still needs to continuously improve on commercialising available research and IP.

Commercialisation of R&D output by Government agencies and RIs is usually achieved via transfer of technology, licensing or consultancy. In the case of IHLs, interaction and relationship with the industry tends to be less structured. With the launch of the NBP, there has been intensification of efforts to establish TTOs to facilitate more structured approaches to commercialise R&D through strategic collaborations.

While significant progress has been made in establishing TTOs, further improvement should be considered for the standardisation of legal boundaries and the services offered by each TTO. The extent of flexibility given to the researchers, Government agencies, RIs and IHLs for the commercialisation of their R&D output is dependent on the institutions' legal status. Government agencies are not allowed to commercialise their R&D output through a dedicated spin-off company within the institution, or together with the industry players; whereas it is permissible for statutory bodies and IHLs to do so, subject to the approval of the Ministry of Finance (MOF) and the ministry that governs them.

In general, researchers in IHLs have more flexibility in the commercialisation of their research. They are also able to retain a greater level of ownership and management of their research compared to researchers in Government agencies and statutory bodies, based on the legal boundaries and infrastructure (e.g. TTOs) available to support such initiatives. Policies of IHLs and TTOs need to be aligned to the national Intellectual Property Commercialisation Policy that was published in June 2009. Efforts have also been made by BiotechCorp to further enhance the ability of TTOs to support commercialisation efforts, such as the ability to evaluate the commercial aspect of the biotechnology R&D output and a well-established network with the industry to assist in commercialisation efforts.

Collaboration

Biotechnology companies in Malaysia usually have some form of smart and strategic partnership or collaboration, whether local or foreign. Overall, the common theme of local partnerships and collaborations are for the purpose of collaborative R&D or for access to the facilities and equipment located in RIs and IHLs. Local collaborations tend to be on a personal basis first, where the lecturers or researchers are sought after by the industry players for their specialised knowledge or skill-sets, or due to personal relationships; before the formalisation of working arrangements with the institutes, usually in the form of a MOU. The main purpose of partnerships with foreign RIs, IHLs and biotechnology companies is for access to foreign markets, transfer of technology and access to IP.

In the healthcare and industrial biotechnology sectors, much of the technology used is from foreign partners as this strategy has been employed to accelerate the development of the sectors. Another strategy is to attract global healthcare and industrial biotechnology players to partner with local companies to set up a subsidiary in Malaysia. Due to Malaysia's traditional strength in the agriculture sector, R&D and technology in the agricultural biotechnology sector are usually home-grown and often acquired through local RIs and IHLs.

In recent years, there has been an increase in strategic partnerships with local RIs and IHLs, as one of the BioNexus Status requirements is that companies must have some component of R&D in their business activities. This requirement is aimed at fostering R&D in biotechnology and increasing Malaysia's knowledge base. BiotechCorp has been active not only in fostering smart and strategic biotechnology partnerships between businesses, but also between RIs, Centres of Excellence and governments. It has provided the industry with a platform for regional and global collaborations. Table 4-5 provides a list of examples of local and foreign strategic partnerships.

Other collaboration initiatives implemented include the BioNexus Partner Programme (BNP) which is a network of 37 BNP laboratories in public IHLs and RIs, technology parks, incubators and GLCs. This includes a phytochemistry laboratory in FRIM, industrial fermentation and bioseparation laboratory in SIRIM, and DNA sequencing laboratory in UKM. BNP's objective is to accommodate the needs of the biotechnology industry by giving priority access to the industry, especially the BioNexus Status companies. In return, the BNP laboratories will have access to financial initiatives such as infrastructure maintenance and development grants, and non-financial initiatives such as eligibility to be involved in networking programmes with BioNexus Status companies.

Other efforts include the Triple Helix database which is BiotechCorp's online partnership portal to encourage cooperation between researchers, biotechnology companies and the government for commercialisable life science projects / products. As at August 2009, details of 71 commercialisable life science projects / products and 69 services / equipment / facilities have been uploaded by researchers and heads of facilities[4].

Table 4-5: Examples of Local and Foreign Strategic Partnerships in the Biotechnology Industry

Strategic Partnerships	Local / Foreign	Focus Area
Agricultural Biotechnology		
Orchid Life and Genetwister Technologies, Holland	Foreign	Marker Assisted Techniques for floriculture and horticulture products
Biolina and Dongtai Bioengineering, Nanjing, China	Foreign	Production of microalgae in open pond systems
Standards and Industrial Research Institute of Malaysia with Vinetech	Local	The development of specialty vinegars such as pineapple, rambutan and Bario rice vinegar
Malaysian Agricultural Research and Development Institute with Innovax	Local	Value added virgin coconut oil with Antimicrobial Properties
Healthcare Biotechnology		
Venture Technologies with ReaMetrix India	Foreign	Flavivirus diagnostics for a global market
Melaka Biotech Holdings, Vanguard Creative Technologies and Vivo Biotech, India	Foreign	Integrated biotechnology facility in Melaka for production of biotherapeutics for diseases such as diabetes and cancer
Sarawak Biodiversity Centre and Novartis Institutes for BioMedical Research Basel (NIBR Basel) of Novartis Pharma AG	Foreign	Explore novel bioactive compounds with medicinal potential
GeneNews (Malaysia) and Ministry of Health Malaysia	Local	Diagnostic tests for liver cancer, Hepatitis B and nasopharyngeal cancer
Industrial Biotechnology		
Standards and Industrial Research Institute of Malaysia and Korean Research Institute of Bioscience and Biotechnology	Foreign	Perform joint research activities and enhance cooperation in biotechnological research and related training
Asiatic Centre for Genome Technology and Synthetic Genomics, U.S.	Foreign	Genomic approach to discover DNA-based biomarkers in the selection of superior traits in oil palm
Jawhara Bioenergie uses technology developed by Industrial Technology Research Institute, Taiwan	Foreign	Bioremediation to convert municipal solid wastes treatment into biogas and biofertiliser
Forest Research Institute of Malaysia and Halagel	Local	Develop food and pharmaceutical grade gelatine

Sources:
(1) BiotechCorp
(2) Ernst & Young Analysis

Moving Forward

Research should continue as a baseline. Given that 2010 is the Year of Innovation, there will be greater opportunities for biotechnology R&D to complement innovation initiatives undertaken by the National Innovation Centre (MyNIC).

Moving forward to Phase II of the NBP, emphasis is needed for the commercialisation of existing IPs and technologies. As recommended in Chapter 3 - Sector Focus Development, implementation of research initiatives for the development of more applications for commercialisation is required to realise the benefits expected from the acquired platform technologies.

[4] BiotechCorp

Based on the above mentioned, the following specific actions are recommended as priority to strengthen commercialisation efforts:

1 Continue acceleration of commercialisation efforts

As described in Recommendation 2 of Policy Thrust 1: Agricultural Biotechnology Development, there is a need to effectively implement the proposed business operating model in order to emphasise on the priority of developing research or new applications for commercialisation of the following four platform technologies:

- Nanotechnology platform from Nanobiotix S.A., France, for healthcare biotechnology
- DotScan™ antibody microarray diagnostic platform technology from Medsaic, Australia, for healthcare biotechnology
- Marker Assisted Selection platform technology from DNA LandMarks, Canada, for agricultural biotechnology
- Supercritical Fluid technology with applications for extraction and particle formation from FeyeCon, Netherlands, for industrial biotechnology

As the appointed custodians, Government-owned RIs or IHLs will be expected to assume the proposed roles and responsibilities outlined in Recommendation 2 of Policy Thrust 1: Agricultural Biotechnology Development. Therefore, appropriate allocation of resources, in terms of financial, infrastructure support and human capital, must be put in place for effective commercialisation efforts.
Besides focusing on developing new applications as mentioned above, there should also be continued efforts to expedite the commercialisation of readily available IPs of the public RIs and IHLs by:

- Building a knowledge sharing infrastructure that enables the publication of IPs to attract industry interest in joint collaborations for commercialisation
- Leveraging on the IGNITE programme that enables external validation of the commercial value and business worthiness of the research and IP
- Leveraging on the Global Bridge Malaysia Commercialisation Assistance Programme with the Larta Institute, U.S. (see Policy Thrust 5: Human Capital Development)

Key milestones and targets should to be determined in order to measure the effectiveness of the commercialisation efforts. Growth targets could be set for:

- Number of industry accepted applications
- Number of IPs being developed for commercialisation
- Take up rate
- Number of new industry players
- Amount of R&D spending

Acceleration of the commercialisation effort would require an effective strategic partnership and collaboration framework.

2 Continue strengthening TTOs for effective collaboration

As previously discussed, the challenge for TTOs to accelerate the commercialisation of R&D projects is due to its differing legal limitations that could possibly give rise to confusion in forming strategic partnerships or collaborations with the industry.

The Intellectual Property Commercialisation Policy for R&D projects was introduced in June 2009 to establish a common framework to regulate the ownership and management of IP, and to promote and facilitate commercialisation of IP generated from the Government funded projects undertaken by RIs and IHLs. Amongst others, the policy provides precedence for the ownership of IP and guidelines for collaborations between RIs / IHLs and external parties.

Moving forward, TTOs are expected to align their respective policies with the national policy, taking into account the differing legal status and services offered. It is proposed that MOSTI's involvement would be required to conduct briefing sessions with the TTOs in various RIs and IHLs on how to align their respective policies with the national policy, taking into account the feasibility and technicalities of the actual implementation. TTOs are recommended to promote the policy in their respective organisations despite the differing legal status and services offered. As BiotechCorp has already established a link with the TTOs, it should continue to facilitate this initiative.

Having aligned their policies to the national policies, a yearly ranking system for TTOs (that is similar to the ranking system for IHLs) should be implemented to increase the competitiveness of the TTOs. BiotechCorp initiated a study of the TTOs in 2008, and this can be used as a platform to further evaluate the TTOs and to benchmark them against one another. This ranking system will also generate industry confidence and credentialise the TTOs and R&D projects undertaken. Such a system will attract greater participation from the industry, including related stakeholders such as financiers, knowledge workers and entrepreneurs. This will in turn promote greater partnerships or collaborations between the TTOs and the industry.

Examples of the criteria that can be used to rank the TTOs are as follows:

- Range of services offered (e.g. legal, business advisory, marketing, branding)
- Number of patents filed
- Number of patents granted
- Number of spin-off companies
- Number of commercialised applications and products

However, it must be noted that the criteria need to be tailored based on the final policies that are put in place and the legal limitations faced by the TTOs. Furthermore, besides building a local industry network, TTOs should also develop an extensive global network that promotes biotechnology activities. A global network should include a network of governments, foreign investors, global companies, R&D Centres of Excellence, IHLs, agencies, and professionals.

Policy Thrust 5 Human Capital Development

Biotechnology is a knowledge-intensive industry with a range of human resource requirements, ranging from strong management capabilities and a good understanding of related biotechnology activities to lab technicians, research scientists, patent agents and biosafety experts. One of the requirements includes developing individuals who are smart, flexible, educated, proficient and globally aware with the fundamental desire to learn, contribute to society and succeed. A highly skilled, motivated and experienced workforce is important not only for foreign companies investing in Malaysia, but also for the growth and competitiveness of local start-ups, and small and medium size companies on the global front.

Similar to most industries that are knowledge-based or that require specialised skills, the biotechnology industry faces human capital gaps in terms of numbers, skills and expertise. It is estimated that a workforce of 100,000 knowledge workers will be required to support the biotechnology industry, which translates into 280,000 additional jobs supporting the industry by the year 2020[5]. The NBP has outlined a number of strategies and actions to address these industry needs.

Current State

Although there is a growing requirement for mathematics and entrepreneurial development to complement the biotechnology workforce, the primary focus is on science graduates in areas such as biotechnology, engineering, statistics and ICT. The Government's efforts to encourage interest in science and technology start at the secondary school level where the Education Development Plan (2001-2010) outlines a number of initiatives to increase the participation of students in science and technology. The initiatives include the implementation of contextual teaching and learning methods, and the inclusion of new educational elements such as biotechnology and microelectronics to make the learning of science more interesting and relevant[6].

[5] National Biotechnology Policy (2005)
[6] Education Development Plan for Malaysia (2001-2010)

Despite these efforts, it has been a challenge to educate the large number of local human resources required by the industry. As shown in Table 4-6, the number of science graduates reduced in 2007 compared to year 2002. This can be attributed to Malaysians' general lack of curiosity and interest in science and technology. A survey by MOSTI showed that only 50.5% of Malaysians indicate they are interested or very interested in latest inventions in science compared to 92% of Americans[7].

Table 4-6: Number of Science Graduates (2002 and 2007)

Field	Number of Graduates	
	2002	2007
Science	40,706	36,485
Total number of graduates	134,210	137,835
Science graduates as % of total graduates	**30.3%**	**26.4%**

Source: MOHE (2009), accessed on 2 October 2009

There are academic options for individuals who intend to pursue an education in biotechnology. IHLs that offer bachelor degrees in biotechnology include public IHLs such as UM, UKM and UTM as well as private IHLs such as Monash University Malaysia and Universiti Industri Selangor (UniSel). At the postgraduate level, public IHLs offer both masters and PhD courses while the private IHLs only offer masters level studies. Malaysian IHLs have also started developing collaborations with foreign IHLs to tap into their expertise, knowledge and facilities such as the recent MOU between UTM and Delft University of Technology of the Netherlands to collaborate in the development of products involving industrial biotechnology, biorefinery technology and bioproduct development, with future plans to establishing a joint postgraduate programme in this field[8].

Higher Learning Curriculum

Although the number of students who graduated from public IHLs in biotechnology and biotechnology-related programmes for bachelors, masters and PhD studies was almost similar in the 2007 / 2008 and 2008 / 2009 batches (see Table 4-7), closer analysis indicates that there has been a decline in the number of Bachelor of Science (BSc) graduates. This points to a shortage for biotechnology graduates with specialised skills of different disciplines. Based on the focus areas of industrial biotechnology, for example, there is a demand for experienced microbiologists who are able to provide guidance and plan their own research, and for research technicians and bioprocessing engineers to streamline bioprocesses. The larger number of post-graduate students could be attributed to the strong Government support in post-graduate studies, such as the Overseas R&D Management Training Scheme which provides training opportunities to managers who are involved in science and technology R&D, and the Overseas Advanced Research Fellowship that provides the opportunity for scientists or researchers from the local public / corporate RIs and IHLs to obtain hands-on training in an identified scientific research area.

Table 4-7: Biotechnology-Related Graduation Output from Public Institutes of Higher Learning

Area of Study	Graduated					
	2007/2008			2008/2009		
	BSc	MSc	PhD	BSc	MSc	PhD
Biochemistry	69	0	0	139	23	7
Molecular Biology	0	0	0	0	15	0
Microbiology	67	0	0	126	16	0
Plant Biotechnology	40	0	0	65	7	0
Plant Science	0	0	0	138	112	0

[7] MOSTI (2004)
[8] The Star Online (30 November 2009)

Area of Study	Graduated					
		2007/2008			2008/2009	
	BSc	MSc	PhD	BSc	MSc	PhD
Animal Science / Zoology	319	0	0	0	2	0
Food Science	638	0	0	276	96	0
Marine Science	110	0	0	11	29	0
Bioinfomatics	15	0	0	0	0	0
Genetics	26	0	0	0	0	0
Pharmacy / Pharmacology	317	21	5	537	81	0
Biotechnology	38	14	0	201	0	0
Forensic Science	0	0	0	0	0	0
Biomedic	250	0	0	0	0	0
Total	**1,889**	**35**	**5**	**1,493**	**381**	**26**
Grand Total	**1,929**			**1,900**		

Source: MOHE (2009)

Besides the declining number of students, it is also a challenge to sufficiently equipt local students with the skills and knowledge that fully meet the industry's requirements. Biotechnology industry requirements include multiple disciplines and sub-specialties of the science and management fields, for example biochemistry, bioengineering, microbiology, related legal expertise and entrepreneurship. There is a need to balance scientific knowledge with business acumen, and to have a good understanding of legal and commercial requirements, a good command of the English language, communications skills and people management skills.

"Brain Gain" Programme

According to Malaysia's Deputy Foreign Minister, 304,358 Malaysians (including 50,000 students) left the country between March 2008 and August 2009; double the number of Malaysians who left the country in 2007[9]. The reasons for their departure and preference to work abroad are multi-faceted, but the most often-quoted reason is the search for better education, career and business prospects.

Besides the brain drain issue faced by the country, retention of talents is also an ongoing challenge as it can be difficult to match job demands and description with the individual's expectations. In the Malaysian biotechnology industry, there is much emphasis on operational, applied or process improvements, and development. Although these may not be the researchers' core interest, such emphasis provides them with generally marketable skills. As a result, they are able to apply these skills to other industries and subsequently leave the biotechnology industry. In a recent survey of biotechnology human capital development, approximately 43% of the respondents indicated that they will select a biotechnology career which is relevant to their interest as this helps create motivation. Furthermore, 16.7% of the respondents indicated that they will not remain in the biotechnology job if it is irrelevant to their area of interest[10].

The NBP highlighted a number of key efforts to develop a highly skilled and motivated workforce. This includes the Government's "Brain Gain" programme which has been designed to attract and retain talents in the country, including in areas of biotechnology, through:

- Incentives for eligible scientists and researchers residing abroad to undertake applied R&D in partnership with Malaysian researchers from RIs or IHLs, with the purpose of scientific discovery and commercialisable applications
- Industry cluster development support targeted at Malaysians residing abroad to offer their expertise to support local industry cluster development in science and technology, including biotechnology
- Fellowship programme to fund the appointment of renowned researchers for a minimum five-year period for R&D activities in local IHLs
- Special scholarship programmes to train local capabilities at top ranked partner universities and institutes (e.g. John Hopkins University, Imperial College of London)

[9] The Star Online (4 Dec 2009)
[10] BiotechCorp

It should be noted that the "Brain Gain" programme has also been used as a talent retention programme within public RIs and IHLs. There are also concurrent efforts such as offering work passes to non-Malaysian spouses of local medical specialists in an effort to encourage both local and foreign specialists to serve in Malaysian hospitals. The success of these programmes in attracting and retaining the desired talents, particularly in biotechnology, has yet to be determined.

Complementary Human Capital Development Programmes

Although IHLs are the key institutions developing human resources for the biotechnology industry, BiotechCorp supplements the effort by implementing programmes to address the lack of critical mass of professionals, scientists and engineers, hands-on skills particularly in lab techniques and equipment, and entrepreneurship within the industry.

Beginning with undergraduates in the IHLs, BiotechCorp has organised career fairs and talks to educate students on the biotechnology industry and career opportunities available. At the bachelor graduate level, BiotechCorp has implemented the Biotechnology Entrepreneurship Special Training (BeST) programme to equip graduates for entry-level positions in the Malaysian biotechnology industry. The BeST programme provides training aimed at improving communication skills and the command of the English language, preparing young graduates with hands-on lab experience and equipping them with management know-how (e.g. marketing and business). A total of 270 graduates have undergone this programme, with 97% of them obtaining placement in BioNexus Status companies, GLCs and MNCs.

BiotechCorp is currently working on modifying the existing BeST format into a curriculum called Enhanced Best programme (BEST 2012), where instead of obtaining a masters degree, graduates have an alternative to participate in BEST 2012 to learn specialisation in IP, technology transfer and clinical research. The certification programme is being designed to meet industry-specific requirements. India has a similar approach where the Indian Government introduced a Finishing School of Biotechnology, to prepare and equip graduates with the skill-sets that are required in the industry.

At the post-graduate level, BiotechCorp has implemented a Post-Doctoral Research Programme to provide research training to Malaysian graduates and post-doctoral students in life sciences. To-date, BiotechCorp has funded the Post-Doctoral Research of five of USM's researchers at the California Institute of Technology. In addition, BiotechCorp has facilitated a concerted effort to train local talents to become clinical experts. In this respect, BiotechCorp has teamed up with the CRC under MOH to provide their staff with the necessary training in areas such as GLP and GCP. This is part of the NBP's recommendation to identify promising young talents and nurture their scientific career through scholarships, industrial training attachments, appropriate job placements and professional mentoring.

BiotechCorp has also introduced several entrepreneur development programmes that aim at providing biotechnology entrepreneurs with a full array of skills to start, fund and manage new business ventures, by supporting the internal capabilities of its participants and linking them with business networks[11]. One of the programmes is the IGNITE programme which is conducted with the Centre for Entrepreneurial Learning (CfEL), Cambridge University. The programme provides global exposure and experiences to senior researchers and scientists from IHLs and RIs to acquire entrepreneurship competencies while bringing their research findings to commercialisation[12]. Another notable programme is the collaboration with the Larta Institute Global Bridge Programme for Commercialisation Assistance Programme which provides commercialisation and innovation expertise, effective training and showcase platforms for IHL spin off companies to connect with investors and industry partners[12].

BiotechCorp has designed several high impact programmes for this purpose:

- National Business Incubation Association (NBIA): Provide comprehensive set of training to enhance skills and gather tools for incubator managers
- California Institute of Quantitative Bioscience (QB3): Provides a comprehensive course in bioentrepreneurship tailored to the needs of professionals in the biotechnology industry
- Office of Technology Licensing, Stanford University: Provide exposure and experience to directors and key personnel from IHLs and RIs TTOs to acquire key competencies

[11] National Biotechnology Policy (2005)
[12] BiotechCorp

BiotechCorp has also implemented several web-based initiatives, such as BioTalent and BioVoice, aimed at attracting and developing talents for the industry.

Moving Forward

The biotechnology industry in Malaysia will continue to face human capital shortages. The Government is expected to continue its efforts in addressing such issues from the long-term perspective. However, addressing such gaps is one of the critical issues that needs immediate attention moving forward into Phase II of the NBP. Based on the progress of each sector focus as described in Chapter 3, it is anticipated that a number of flagship projects being undertaken will require specific skilled and experienced knowledge workers. Although a number of programmes have been put in place by BiotechCorp to address these gaps, there is a need to put in place a more sustainable approach in address these gaps.

1 Continue enhancing higher learning curriculum

While there is ongoing effort to enhance the higher learning curriculum to meet the country's needs, there is currently an urgent need to address gaps in the biotechnology industry. Although BiotechCorp continues to execute its programmes to provide the relevant training required by the industry, it is unlikely that BiotechCorp will be able to train graduates with the speed and volume to match industry needs in the near or longer term.

It is therefore proposed that immediate actions be undertaken to work with selected priority IHLs to develop and conduct training programmes as pre-requisites for graduation. Where possible, the current curriculum should be immediately modified to incorporate certain industry requirements. It is proposed that BiotechCorp facilitates a working group, that will be represented by industry players and selected priority IHLs to undertake the following key actions:

- Identify specific skills and competencies required – where possible, determine the number of headcounts and skills required based on the projected requirements of flagship projects, as described in Chapter 3
- Determine the extent of changes required in the IHLs' curriculum – this is to help in establishing the amount of effort required and identifying the most appropriate practical approach to make changes for ease of implementation
- Develop appropriate industry training programme details and industrial placement programmes – where possible, take into account the programmes that are currently being implemented by BiotechCorp
- Estimate resources required to implement priority actions – various IHLs, agencies or ministries concerned will be expected to provide resources and support required (e.g. financial, human resources, infrastructure)
- Continuously monitor progress of the milestones that need to be achieved

2 Continuously improve "Brain Gain" programme

Although the success of the "Brain Gain" programme has yet to be clearly determined, it has been noted that the programme has not been able to fully meet the expectations of those talents who have been attracted back to Malaysia. Most talents (including overseas returnees) usually have high expectations of infrastructure facilities (e.g. research and laboratory facilities), career progression, as well as a progressive living and working environment.

It is proposed that the following areas be taken into account for the continuous improvement of the "Brain Gain" programme:

- A conducive working environment with minimal bureaucratic obstacles, provision of easy access to resources and facilities, and extensive institutional support including funding and people support
- Right staffing support is critical. For example, the Biotechnology Human Capital Development report highlighted industry concerns that PhD graduates are not proficient in the latest methods and lab techniques due to the lack of funds needed to maintain and use the equipment[13]

[13] BiotechCorp

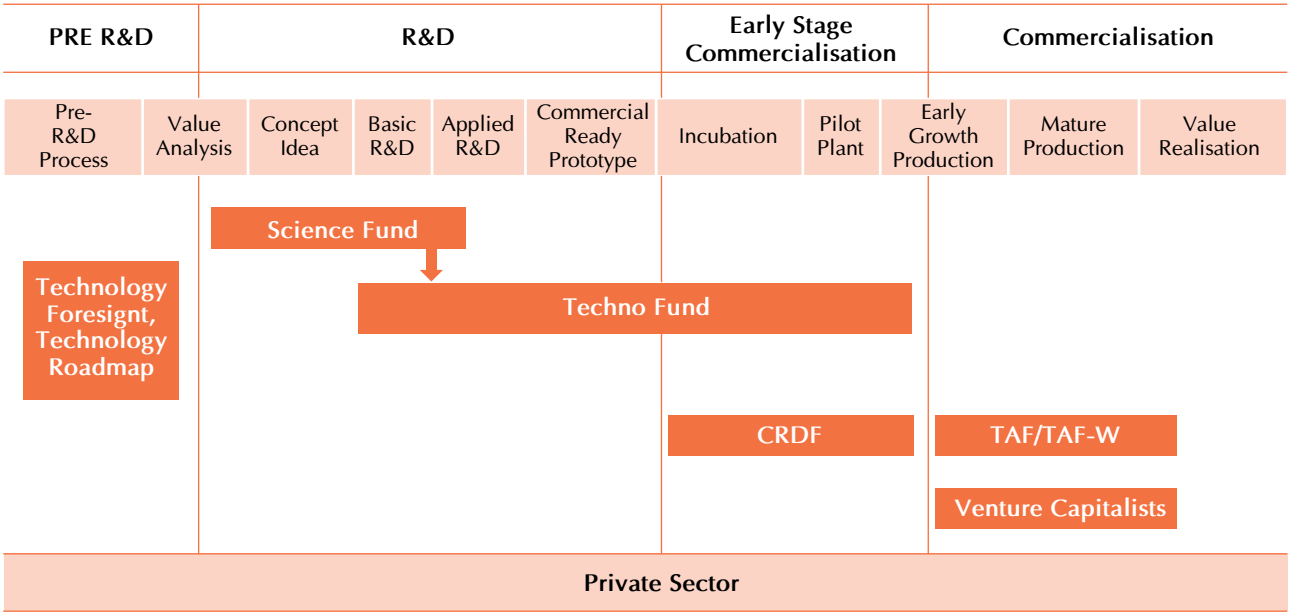
- Where applicable, there is a need for speedy processing of Malaysian work visas for expatriates, to efficiently bring in foreign skills and expertise to address the current human resource needs
- Sufficient mechanism to progress and develop existing talents in the country, especially in terms of R&D, such as infrastructure to allow PhD holders to pursue post-doctoral research which is necessary to improve their expertise in a specialist subject, advance their skills and research methodology as well as gain experience in conducting independent research

In order to effectively implement continuous improvement of the programme, it should be noted that there is a need to secure the commitment of all parties involved in terms of financial budget allocation, human resources allocation and infrastructure support (e.g. policies, processes and systems) enhancement.

Policy Thrust 6 Financial Infrastructure Development

There is a need to continuously provide adequate and multiple rounds of funding along the value chain of the biotechnology industry. However, one of the critical issues faced by the industry is the lack of financial resources to support the industry development. Current biotechnology and related funds available for the industry are inadequate to meet the developmental goals set out in the NBP. There is a need to promote industry confidence to attract greater private funding participation. Figure 4-1 provides an overview of funding availability along the value chain.

Figure 4-1: Funding Availability within the Malaysian Biotechnology Industry



Source: National Biotechnology Policy (2005)

Current State

The NBP has outlined a comprehensive and efficient financial infrastructure plan for the implementation of the policy. Both the public and private sectors have played significant roles in funding the Malaysian biotechnology industry. Government funding supports the initial stages of pre-R&D and R&D as well as early stage commercialisation while the VCs and Development Financial Institutions (DFIs) funding support early stage commercialisation or pre-commercialisation (excluding R&D) and commercialisation stages.

The Malaysian Government has made a financial commitment by allocating USD 571.4 million (RM 2 billion) under the RMK-9 to fund the development of the industry (refer to Table 4-8). In addition, the Government allocated USD 371.1 million (RM 1.3 billion) for biotechnology development under the First and Second Stimulus Package.

Table 4-8: Government Development Expenditure and Allocation for the Biotechnology Industry (2001-2010)

Programmes	RMK-8		RMK-9	
	USD million	RM million	USD million	RM million
Research and Development	**54.3**	**190.0**	**132.3**	**463.0**
• Biotechnology R&D Initiatives	54.3	190.0	103.7	363.0
• Biotechnology Commercialisation Fund	-	-	28.6	28.6
Biotechnology Acquisition Fund	**N/A**	**N/A**	**28.6**	**100.0**
Biotechnology Business Development	**62.0**	**216.8**	**151.4**	**529.8**
• Technology and IP Management	20.0	69.9	28.6	100.0
• Entrepreneurship Development	-	-	14.3	50.0
• Agro-biotechnology Projects	54.3	46.9	22.8	79.8
• Institutional Support and Equity	28.6	100.0	85.7	300
Biotechnology Infrastructure	**47.7**	**167.7**	**265.3**	**928.5**
Total	**164.0**	**574.4**	**577.4**	**2,021.3**

Source: Ninth Malaysia Plan (2006-2010)

Of this amount, close to 46% of the allocation is for physical infrastructure development channelled to all RIs and IHLs through the five-year development budget. The remaining amount is allocated as "soft" infrastructure budget, made available through several public sector bodies in the form of grants, equities and loans to undertake research and related activities but also funding for start-up as well as expansion and growth. For example, the funding requirements at the initial stages of R&D and during R&D are channelled through MOSTI and related Government agencies (e.g. ScienceFund, TechnoFund, InnoFund and Cradle Investment Programme), while early stage commercialisation and commercialisation fundings are channelled through Government agencies such as MTDC (e.g. Commercialisation of Research and Development Fund (CRDF), Technology Acquisition Fund (TAF), Technology Development Fund (TDF)), DFIs such as Malaysian Debt Ventures (MDV), Bank Pembangunan and SME Bank, and MLSCF.

MTDC provides grants to encourage researchers from RIs and IHLs to commercialise their research findings including collaboration with the industry; and incubators and science parks to allow biotechnology companies to operate and manufacture commercial-scale facilities in a contained environment. The DFIs provide loans to support the commercialisation efforts of the biotechnology companies, namely to finance the acquisition and construction of equipment and infrastructure, working capital and contracts / projects. MLSCF, a public VC company is a life sciences venture fund specialising in early stage investments in the areas of agriculture, industrial and healthcare, both in Malaysia and abroad. An example of MLSCF's portfolio includes Chakra Biotech, a BioNexus Status company, which has an exclusive licensing agreement with Roswell Park Cancer Institute for the chakragati mouse, a unique animal behavioural model to test compounds for central nervous system diseases such as schizophrenia and depression.

Pre-R&D and R&D Funding

Public funds are more available for pre-R&D and R&D stages of the biotechnology industry. A summary of the various types of Government funds available for these purposes is shown in Table 4-9.

Table 4-9: Types of Government Funds, Ninth Malaysia Plan (2006-2010)

Public Sector Bodies	Types of Fund	Date Established	Fund Size	Description of Funds
Ministry of Science, Technology and Innovation	Science Fund	2006	USD 276 m (RM 966.5 m)	For strategic basic and applied research to generate new knowledge through basic and applied sciences.
	Agro-biotechnology R&D Initiatives	2006	USD 28.6 m (RM 100 m)	R&D in strategic areas of agro-biotech that will lead to modernisation and transformation of the agricultural sector.
	Genomics and Molecular Biology R&D Initiatives	2006	USD 28.6 m (RM 100 m)	Generate intellectual properties for application in modern biomanufacturing of high value products.
	Pharmaceutical & Nutraceutical R&D Initiatives	2006	USD 25.7 m (RM 90 m)	Develop 'proof of concept' products or service developed by local scientists to comply with the international standards.
	Inno Fund	2006	USD 57.1 m (RM200 m)	For small companies to fund the development or improvement of new or existing products.
	Techno Fund	2006	USD 307.4 m (RM 1,075.8 m)	Pre-commercialisation funding to undertake the development of new and / or cutting edge technologies.
Cradle Investment	Cradle Investment Programme	1995	Up to USD 14,285.7 (RM 50,000)	Pre-seed funding programme for technology, ICT and high growth ideas.
Malaysian Technology Development Corporation	Investments	N/A	USD 142.9 (RM 500 m)	Provide financing for companies involved in life sciences.
	Technology Acquisition Fund	1992	USD 40.6m (RM 142 m)	Grants available to majority Malaysian owned companies undertaking acquisition activities (outlined in the List of Promoted Activities and Products for High Technology).
	Commercialisation of R&D Fund	1992	USD 32.9m (RM 115 m)	Up to USD 526,000 (RM 1.8 million) per R&D project or 70% of R&D project whichever is lower is available to promote the commercialisation of indigenous technology.
	Technology Development Fund (TDF-science parks)	N/A	USD 22.9m (RM 80 m)	Develop a cluster of high technology based companies operating within R&D institution.
	Malaysian life sciences Capital Fund[14]	2006	USD 150 m (RM 525 m)	Early stage investments in the areas of agricultural, industrial and healthcare biotechnology.
BiotechCorp	Seed Fund	2005	USD 28.6 (RM 100 m)	Assist towards the development and commercialisation of Biotechnology projects and R&D findings of priority and core areas.
	R&D Matching-Fund	2005		Matching fund for R&D projects which can develop new or improved products and/or processes and / or technologies.
	International Business Development Matching Fund	2005		Promote the expansion of BioNexus Status companies into the global market.

[14] Co-managed with Burrill & Company

Public Sector Bodies	Types of Fund	Date Established	Fund Size	Description of Funds
Malaysia Debt Ventures	Soft fund	April 23, 2002	USD 457.1m (RM 1.6b)	Financing of project in ICT and biotechnology such as CMO and CRO
	Second Fund (Syariah compliant)	January 2009	USD 714.3m (RM 2.5b)	Debt financing for ICT and biotechnology companies growing beyond the pre-commercialisation stage.
Ministry of Agriculture	Agri R&D Fund (part of Science and Inno Fund)	2006	-	Agro-biotechnology: enhance productivity, quality and disease resistance in agro-products.

Sources:
(1) MOSTI (2009c), accessed on 1 October 2009
(2) Cradle Investment Programme (2009), accessed on 1 October 2009
(3) BiotechCorp
(4) Malaysia Technology Development Corporation (2009b), accessed on 1 October 2009
(5) Malaysian Debt Venture (2009), accessed on 1 October 2009
(6) Ninth Malaysia Plan (2006-2010)

However, there is a need to address certain challenges faced in the provision of Government funds. In order to make Government funds available to a larger community of the industry, funds are being provided with a funding limit per application. However, the amount of funding per application may not be sufficient depending on the nature of the R&D being undertaken by the biotechnology companies. Consequently, funding for pre-commercialisation and commercialisation stages may not be adequate. For example, the ScienceFund provides a maximum grant of USD 0.1 million (RM0.5 million) per proposal for a maximum period of 24 months for non-ICT cluster; TechnoFund provides funding up to a maximum of the total project cost or USD 0.8 million (RM3 million) per company for a maximum period of 24 months; MTDC through TAF provides a maximum grant of USD 0.6 million (RM 2 million) per company; and the seed fund provided by BiotechCorp is capped at a maximum of USD 0.7 million (RM 2.5 million) per company. BiotechCorp also provides R&D matching fund (capped at RM 1 million) as well as International Business Development Fund (capped at RM 1.25 million).

Besides funding limit constraints, researchers or companies are also not allowed to simultaneously apply for more than one type of funding assistance from the Government, even though the fund is to be used for a different purpose. For example, researchers or companies that have funding to scale-up their pre-commercialisation activities via TechnoFund cannot apply for seed fund from BiotechCorp to help set up their biotechnology companies and finance the development and commercialisation of similar or other types of biotechnology projects.

Despite the challenges, public funding continues to be important to build industry confidence. As such, the Government is reassessing current funding limits, application criteria and guidelines without comprising the accessibility of funds to researchers / companies in the areas of biotechnology.

Early Stage Commercialisation and Commercialisation Funding

As described earlier, there is a need to revisit current public funding policies and guidelines so that industry players have access to more public funds for early stage commercialisation and commercialisation funding. In addition, there is a need to have more private funds available for early stage commercialisation and commercialisation. For this purpose, private funds are more available via the capital market, VCs and local / foreign investments, as opposed to traditional financial institutions. This is because most start-up biotechnology companies face difficulties in fulfilling the requirements set by traditional financial institutions.

However, in today's global economic climate, it is becoming increasingly challenging to raise funds via IPO. In 2008, there was only one biotechnology company listing in the U.S, none in Canada, three in Japan and two in China[15]. In Malaysia, two biotechnology companies successfully launched their IPOs in 2008, namely Sunzen Biotech and Asia Bioenergy Technologies, raising USD 6 million (RM 20.9 million). As at 31 December 2009, there were 13 life sciences companies (including biotechnology companies) listed on the Main Board and Access, Certainty and Efficiency (ACE) Market of Bursa Malaysia.

[15] Ernst & Young Beyond Border (2009)

Globally, VCs accounted for 37% of total biotechnology funding in 2008, up from 25% in 2007. However, VCs are becoming more selective in this current challenging environment. In Malaysia, although approximately 38 VCs and Venture Capital Management Companies (VCMCs) indicate biotechnology as one of their focus investment area, only SpringHill BioVentures and First Floor Capital have invested actively in biotechnology companies. Some Government-related VCs like MTDC, MLSCF and Government-related financial institution like Malaysian Debt Ventures (MDV) also invest in biotechnology / life sciences companies. In comparison, Australia has six to seven VCs dedicated to investing in biotechnology ventures such as GBS Venture Partners, Queensland Bio Fund and Innovation Capital Associates.

In Malaysia, the VCs' total cumulative investment increased from USD 342.9 million (RM 1.2 billion) in 2006 to USD 542.9 million (RM 1.9 billion) in 2008[16]. Despite the overall increase, the proportion of investment into life sciences declined from 24.3% in 2006 to 18% in 2008. In total, the VCs have invested close to USD 71.7 million (RM 251 million) in life sciences during the last three years (2006-2008). Of this amount, only 31% (USD 22.6 million / RM 79 million) was invested in Malaysian companies, while the remaining funds was invested abroad. Consequently, sourcing of funds from VCs is still generally considered a challenge for the Malaysian biotechnology companies, especially for second round funding growth and expansion for pre-commercialisation and commercialisation stages.

Complementary Programmes

In 2008, BiotechCorp undertook efforts to strengthen the availability of funding along the value chain of the biotechnology industry. Prior to the economic crisis in September 2008, private local and foreign investors (corporate and financial institutions) were keen on providing a sizeable fund of close to USD 500 million (RM 1.5 billion) for investment in the industry. The fund size was planned to be integrated with selected local investors and its priority was on BioNexus Status companies. Even though the funds were not raised due to the economic crisis, there is still ongoing discussion to reassess their involvement in funding the biotechnology industry.

BiotechCorp has also continuously engaged the financial and investment communities in the Asia Pacific and Middle East regions to create awareness of the biotechnology industry in Malaysia. The BioFunding Conference was organised in August 2009 and targeted at the financial and investment communities to increase their awareness and understanding of the biotechnology industry.

As part of promoting financial and investment opportunities, BiotechCorp and UEM Land Holdings, a PPP arrangement, signed a joint venture agreement in September 2009 to develop a global biotechnology ecosystem known as Bio-XCell in Iskandar Malaysia, Johor. Bio-XCell is the creation of a dedicated biotechnology park with ready-built and customised commercial scale shared facilities to encourage commercial developments, R&D and production of industrial and pharmaceutical biotechnology products. It needs to complement, not compete with Singapore's Biopolis, by providing services that are not / cannot be provided by Singapore such as the population volume and diversity for clinical trials or cheaper labour for medical device manufacturing. This in turn will highlight Malaysia's niche and differentiation factor from the other Asian markets.

In enhancing the exit mechanisms, BiotechCorp has already engaged the Securities Commission (SC) and Bursa Malaysia in strategically developing the BioNexus Status companies as suitable candidates for IPO listing on the ACE market. The plan is to create a life science index within Bursa. Additional efforts have been made with Bursa Malaysia to consider establishing a life science / biotechnology sector classification as well as index that will enhance the biotechnology sector's profile vis-à-vis the capital market. Nonetheless, there is no critical mass at the moment for establishing the sector and index. The viability of raising funds through capital markets will not be attractive until the biotechnology start-up companies have shown records of accomplishment. Moreover, an IPO exercise can be an expensive venture; hence providing relevant incentives to reduce the IPO cost would be beneficial to the BioNexus Status companies.

[16] Securities Commission Malaysia Annual Report (2006, 2007, 2008)

The NBP has provided for the implementation of an incentives package via the Bill of Guarantee in 2005. The tax incentives are targeted at direct investments into companies undertaking biotechnology activities and companies that have obtained approval for their BioNexus Status from the Malaysian Government. This has shown some success as evidenced by the increase in biotechnology companies that have obtained the status. As at 31 December 2009, a total of 151 companies undertaking R&D and commercialisation in biotechnology have obtained BioNexus Status.

Separately, a company that invests in a BioNexus Status company is eligible for a tax deduction equivalent to the total investment made in seed capital and early stage financing, while a BioNexus Status company undertaking merger and acquisition with a biotechnology company is eligible for exemption of stamp duty and real property gain tax within a period of five years until 31 December 2011.

Moving Forward

Adequacy and availability of funds are critical moving forward into Phase II of the NBP. The Malaysian biotechnology industry is still relatively young compared to other industries. Therefore, continued Government support in the form of public funding is still required to build industry confidence. Promotion and awareness programmes should continue to create greater understanding of the industry amongst the financier and investor communities.

The following priority actions are proposed for implementation:

1 Continue public investment in physical infrastructure

The physical infrastructure refers to the basic physical and organisational structures needed for the operation of biotechnology companies or the services and facilities necessary for the development of the biotechnology industry. Government investment into physical infrastructure is important as it demonstrates its commitment towards developing the Malaysian biotechnology industry, and thus will stimulate private investment into the industry.

As described in the other policy thrusts, it is proposed that development budgets be allocated for the following:

- Continual investment into physical set-ups or shared facilities in biotechnology clusters similar to Bio-XCell to allow start-ups to cut costs, accelerate development time and foster a collaborative culture among institutions and organisations in one location (see Policy Thrust 9: Government Support and Commitment)
- Allocate adequate budget to develop the human capital required for the biotechnology industry under Ministry of Higher Education (MOHE) and related Government agencies (see Policy Thrust 5: Human Capital Development)
- Allocate adequate budget to continually conduct basic research and develop applications for commercialisation at the RIs, IHLs, technology custodians and Government agencies (see Chapter 3 – Sector Focus Development and Policy Thrust 4: R&D and Technology Acquisition Development)

2 Strengthen public funding for pre-commercialisation and commercialisation

Ongoing allocation for pre-R&D and R&D funding should continue. However, given the lack of private funding for pre-commercialisation and commercialisation, there is a need to continue the allocation of public funding for these two stages. The following are proposed public funds required:

Government Soft Loan

As discussed earlier, it is generally still a challenge for Malaysian biotechnology companies to raise funds, especially second round funding for pre-commercialisation and commercialisation stages. It is proposed that the Government continues to support the industry by allocating funds for the provision of soft loans (with no / minimal interest, or based on Islamic principles) to both the Malaysian and foreign biotechnology companies based in the country. It is proposed that the soft loan, a convertible loan to grant, be provided for the following areas:

- Development and commercialisation of new applications from new platform technologies
- Development and commercialisation of biotechnology projects and R&D findings of priority and core areas identified in Chapter 3 – Sector Focus Development
- Development of new or improved products and/or processes and/or technologies that lead to further commercialisation of priority sector focus areas
- International promotion of Malaysian biotechnology companies in the global market

In order to increase the level of FDI participation in the Malaysian biotechnology industry, it is proposed that the Government provides a soft loan based on a predetermined ratio of local to foreign capital contribution. The convertible soft loan (convertible to grant) should be extended to eligible foreign companies.

It is proposed the Government soft loan be evaluated and disbursed through existing DFIs or banks. As part of the implementation approach, clear eligibility and evaluation criteria and guidelines must be pre-determined to be in line with the overall purpose of the NBP. Appropriate protocols and governance framework need to be in place to facilitate ease of funding access for the qualified companies.

Key milestones that can be used to monitor and measure the performance of the biotechnology companies are as follows:

- Number of commercialised projects
- Number of commercialised applications
- Number of employees
- Revenue generated from direct production and from royalty / services / sub-licensing fee
- Total FDIs (where applicable)

Biotechnology Funding Access Fund

Raising funds through an IPO exercise is an alternative for biotechnology companies but it is an expensive venture. Hence, it is proposed that a dedicated Government fund, e.g. Biotechnology Funding Access Fund, be established to reimburse listing fees / charges for eligible biotechnology companies. The preference of the listing exercise is for the Malaysian capital market.

Similar to the above, clear eligibility and evaluation criteria and guidelines must be pre-determined together with appropriate protocols and governance framework to reimburse the cost of listing for the qualified companies.

Biotechnology Industry Training Grant

The Malaysian biotechnology industry faces shortage of specialised skills and experienced resources as described in Policy Thrust 5: Human Capital Development. BiotechCorp is expected to continue to encourage industry players to develop the required skill-sets by providing training grants for eligible BioNexus Status companies.

For effective implementation of the training grant disbursements, it is proposed that BiotechCorp determine priority training courses that will be eligible for the training grant applications. There is a need to maintain a database of skills training requirements and recommended certified training courses.

3 Intensify public-private partnership

Besides FDIs, there is a need to encourage local large and established companies to drive the development of the local biotechnology industry. Details have been discussed in Chapter 3 – Sector Focus Development, and specific details on adopting a PPP model have been provided in Policy Thrust 2: Healthcare Biotechnology.

A possible PPP model to be considered for partnership between the Government and private sector in developing biotechnology industry is as follows:

- Private sector to create the platform for biotechnology industry development by supplying products or services to the Government or the general public
- Private sector investment in the use of platform technologies for the purpose of research, research for commercialisation value, and development of applications and products for commercialisation
- Private sector to fund emerging local biotechnology players with the view of collaboration opportunities for the development of product pipelines with commercial value
- Private sector to provide marketing and distribution network access

The implementation of the PPP model is to be based on the proposed approach described in Policy Thrust 2: Healthcare Biotechnology Development.

4 Set up new venture fund with foreign participation

The local VC market continues to develop in accordance to the Financial Services Master Plan. As described earlier, the biotechnology industry requires strong foundation support from the VCs during pre-commercialisation and commercialisation stages.

However, given the limitations faced by local VCs, there is a need to attract greater participation from foreign VCs that specialise in biotechnology industry. In order to attract foreign VCs, Malaysia is currently exploring the possibility of establishing a new venture fund to be set up by local and foreign VCs which will be matched by Government funding. Given the emphasis on the need to attract foreign VCs, it is therefore important to measure how well foreign funds are being raised for this venture fund.

Upon approval by the Government, the investment focus of the new venture fund will need to be determined together with the appointed fund manager(s). The investment focus should be in line with the NBP objectives as outlined in Chapter 3 – Sector Focus Development.

5 Focus on nurturing and developing top performing companies

Showcasing successes will be critical moving forward into Phase II of the NBP, and success tends to be measured on the basis of a company's business performance. It is therefore vital for the lead agency, BiotechCorp, to place emphasis on nurturing and developing potential top performing BioNexus Status companies.

The identification and nurturing of such BioNexus Status companies would be conducted to ensure right quality companies are being nurtured, and that new companies can be continuously developed. The qualities of a top performing company includes amongst others, the potential of producing high value products for the regional and global markets, entrepreneurs with a global mindset, businesses that create multiplier effects and holistic linkages to the economy, the creation of "wealth from waste" and a good management team.

Success built on top performing BioNexus Status companies will boost industry confidence, which in turn would attract more private funding from VCs, angel investors, banks and large corporations domestically and internationally.

Policy Thrust 7 Legislative and Regulatory Framework Development

The NBP rightfully identifies the conduciveness of the regulatory framework as a key factor for the development of the biotechnology sector in Malaysia. It is important for a country which has a clearly stated objective in relation to developing biotechnology as an engine for national growth to then reflect such policies and objectives in its legal and regulatory framework, especially those directly impacting the area of biotechnology.

Current State

The legislative and regulatory framework and IP Rights Management system have been envisaged as an initiative to establish a supportive and conducive regulatory framework which is crucial for the development of the biotechnology industry in Malaysia. The regulatory areas mentioned below have been identified as key contributors to providing a solid bedrock to anchor Malaysia's biotechnology development while enhancing Malaysia's prospects and attractiveness as an investment destination.

Malaysia's ranking in terms of IP rights enforcement has improved to number 27 in 2009 compared to number 33 in 2008[17]. Awareness of patent protection and recognition of its value and importance have risen in Malaysia and the number of patents in force per 100,000 population improved in Malaysia in 2009. Consequently, the establishment of the IP Courts in 2007 demonstrates the Government's commitment to accord the highest standard of protection for IP rights. 15 Sessions Courts with criminal jurisdiction and six High Courts with both civil and appellate jurisdictions were set up to help reduce the backlog of IP cases, to provide for swift and more effective remedies to the owners of IP rights and well as to eradicate IP infringement in Malaysia. Concerted effort and continued focus should be given to the area of IP protection.

Regulations pertaining to pharmaceuticals in Malaysia are relatively well-developed and stable and are under the purview of the MOH. Active participation of Malaysia in the various regulatory harmonisation initiatives regionally and globally augurs well for industry players in terms of regulatory certainty and ease of export.

Although there are currently no domestic Access Benefit Sharing (ABS) laws, it is anticipated that national level laws on ABS will be in the pipeline in the near future. This is in view of the developments in the international front for example the progress made in the recent Access Benefit Sharing Working Group 8 (ABS WG8) in Montreal, November 2009 and the importance of this subject to Malaysia. Upon its promulgation, a formal domestic ABS framework should provide a balanced means to ensure that Malaysia will be able to combat biopiracy besides providing an effective means for Malaysia to leverage on its rich and diverse genetic resources, in line with Malaysia's objective to promote biotechnology development as an engine for growth.

In ensuring that the country remains competitive and is favoured as a country of choice for research, development and manufacturing activities, Malaysia has adopted and implemented international standards relating to GCP, GMP and also GLP. With regard to GLP compliance, it is also worth noting that Malaysia has been a provisional adherent to the Organisation for Economic Co-operation and Development (OECD)'s Mutual Acceptance of Data (MAD) system since 2008 and is currently focusing her endeavours towards becoming a full adherent to the OECD MAD system. To that end, Malaysia has established its GLP Compliance Programme to help test-facilities gain acceptance for their non-clinical health and environment safety studies complying with the OECD Principles into OECD countries and other members adhering to the OECD MAD agreement.

In relation to biosafety, it is recognised that laws which seek to safeguard public safety could be promulgated whilst also taking into account the developmental goals of the nation as eschewed under the NBP and other

[17] IMD World Competitiveness Yearbook 2009

related national policies. This balanced approach should be the way forward for Malaysia and constructive engagement between policy and law makers, regulators, industry developers, the industry and all other stakeholders should continue to take place so as to fully realise Malaysia's roadmap towards 2020 and beyond. The most effective way to ensure a win-win situation for the country would be in the creation of channels for discourse and consultation between the regulators and the industry so that future laws, regulations and rules impacting the development of biotechnology in the country could be formulated in an inclusive and constructive manner. Towards that end, the Ministry of Natural Resources and Environment (MNRE) has taken a progressive move in providing for an avenue for engagement between the relevant ministries, agencies and industry players towards the formulation of regulations on biosafety which will support the existing Biosafety Act 2007.

IP Protection

IP protection in Malaysia is administered by MyIPO, and it includes patents, trademarks, industrial design, copyright, geographical indications and layout designs of integrated circuits. In 2009, the World Competitiveness Online conducted a survey to gauge Malaysia's IP rights enforcement. The survey showed a score of 6 out of 10, indicating that the respondents' believed that Malaysia's IP rights enforcement was slightly above average. With the introduction of the IP Courts it is anticipated that Malaysia will improve its rankings in the near future.

Numerous initiatives have recently been carried out by the relevant ministry and MyIPO together with other related ministries and agencies to resolve issues such as lack of awareness on IP, backlog of patent application files and enforcement of IP rights to improve the IP protection landscape in the country to support the development of the biotechnology sector.

To spur more innovative activity in the agricultural biotechnology sector, the Protection of New Plant Varieties Regulations 2008 was enacted and came into operation on 20 October, 2008 and brings into force the Protection of New Plant Varieties Act 2004. The Act grants an exclusive right to breeders of new varieties to exploit their varieties and has features that are in common with patents for industrial inventions, enabling applications for protection of new plant varieties by breeders, farmers and local communities. With this legislation in place, researchers, plant breeders and local communities are in a better position to acquire protection for newly developed and improved varieties of plants and are encouraged to explore technologies such as genetic engineering.

Malaysia's accession to the PCT in 2006 has added a new and preferred route for foreign applicants to access the local patent system. This change is expected to be more cost efficient and will provide an extended period of time of up to 18 months for applicants to assess the commercial viability of their invention while maintaining entitlement to patent protection at a national level. As at 31 December 2009, MyIPO has received 551 of such applications. Although the numbers are still low, greater awareness on the PCT application is being communicated to the academic, business and industrial community by MyIPO through various awareness initiatives and it is anticipated that the number of filings will increase in the years to come.

The Patents Act 1983 will also be undergoing amendments to include among others, clearer provisions on the definition of microorganisms. Currently, under Section 13(1)(b) of the Patents Act, "man-made living micro-organisms", "micro-biological processes" and "the products of such micro-organism processes" is not excluded from patentability. However, the Act has no clear definition of such terms. With the definitions in place, inventors need no longer be apprehensive on the patentability of their biotech inventions and are encouraged to file patents to protect their innovation. In addition, the Director General of MyIPO has indicated that they are targeting for the Patent Act amendments to be tabled to parliament by early 2011.

There has been a steady increase in the number of patent cases filed in the courts concerning patent rights which suggests that the IP rights landscape in Malaysia will continuously improve. While the development in the ICT sector facilitated the constant review of the Malaysian Copyright Act to be at par with international standards, it is envisaged that the current expansion of the biotechnology industry will also encourage continuous evaluation and assessment of the Patents Act so as to promote innovation in emerging technologies.

There are relatively few cases in the biotechnology or life sciences area which have been filed in the Malaysian courts. An important case recently dealt with by Malaysian courts involved an action filed by Winthrop Pharmaceuticals against Warner-Lambert and Pfizer. In this case, Winthrop sought a declaration that Winthrop's atorvastatin does not infringe the patent for the Warner-Lambert / Pfizer's atorvastatin product – the blockbuster drug Lipitor. On 7 May 2009, Winthrop successfully obtained a declaration that its Winthrop atorvastatin does not infringe the Warner-Lambert / Pfizer atorvastatin patent, allowing it to freely market its product[18].

In June 2009, eight countries from the ASEAN namely, Malaysia, Cambodia, Indonesia, Laos, Philippines, Singapore, Thailand and Vietnam embarked on a regional patent cooperation programme called the ASEAN Patent Examination Cooperation (ASPEC). The objectives of the ASPEC are reduced examination work, faster turnaround time and better search and examination. Once a search and examination report is issued by any of the IP Office of these countries, the applicant may use the report to file an ASPEC request in another member state. The report from the issuing IP Office will be used as a reference. However, the IP Office receiving the report is not obliged to adopt any of the findings or conclusions reached by the issuing IP Office. The ASPEC should make it easier for entrepreneurs, particularly small and medium enterprises (SMEs) and inventors to obtain patents for their innovations in the region and improve the waiting time for the processing of patent applications, and also improve the quality of the search and examination reports amongst the ASEAN IP offices.

The Government in its initiative to drive the nation towards a high-income economy through innovation, creativity and high value added activities has granted tax incentives to SMEs and industries for registration of patents and trademarks during the fiscal year budget for 2010. The tax relief is effective from 1 January 2010 until the year of assessment 2014.

BiotechCorp is cognisant of the efforts made by the Government and MyIPO to increase awareness on IP, and under the capacity building phase of the NBP, has rolled out programmes targeted for various stakeholders (see Table 4-10):

Table 4-10: List of Intellectual Property Training Programmes by BiotechCorp

No	Programme	Description	Outcome
1	Malaysian Institute of Management – Certified Professional Intellectual Property Manager Programme	Certificate course on IP Management attended by BioNexus Status companies and researchers from RIs and IHLs	Value creation through strong intellectual asset portfolios created by BioNexus Status companies / IHLs and RIs
2	FICPI-South East Asian Patent Drafting Course	Patent Drafting course attended by patent agents nominated by MyIPO and IP officers from RIs and IHLs	Improvement in the quality of patents drafted by local patent agents
3	Patent Drafting Workshop for Biotechnology Inventions	Basic patent drafting and patent search workshop for IP officers from BioNexus Status companies, IP officers from RIs and IHLs	Increase the number of biotech patents filed by local applicants
4	IP Commercialisation Workshops	Workshop on the fundamentals of IP Commercialisation attended by BioNexus Companies and researchers from RIs and IHLs	Encourage commercialisation activities
5	IP Clinics / Workshops	One day workshops held quarterly on selected IP topics such as Licensing, Valuation, etc targeted for various stakeholders	Improve overall awareness on IP
6	Certificate Course in IP Law	Certificate course organised with MyIPO specifically for the judiciary, attorney-general chambers officers and enforcement officers	Increase competency in IP law for officers directly involved in the IP Court network

Source: BiotechCorp

[18] Managing IP Magazine, Skrine (200 http://www.managingip.com/Article.aspx?ArticleID=2366035)

To address the issue of patent files backlog especially in the area of biotechnology, BiotechCorp introduced the 'Patent Examiner Attachment Programme" in 2007 to enhance the proficiency of MyIPO patent examiners. The patent examiners were sent for attachments for a period of between 3 to 12 weeks at IP Offices in Europe, South Korea and Australia. Through this programme, 570 biotechnology-related patents were granted between 2007 and 2009. In addition, BiotechCorp will further cooperate with MyIPO in increasing the number of patent examiners by funding ten patent examiners on a contract basis for two years.

Malaysia has not acceded to the Budapest Treaty, which allows "deposits of microorganisms at an international depositary authority to be recognised for the purposes of patent procedure". This treaty was devised to enable applicants who wish to patent their inventions (which involve microorganisms) to comply with the requirement for repeatability and full descriptions of biological materials by depositing a sample of the microorganism at an International Depository Authority (IDA). There are only 37 IDAs in approximately 20 countries worldwide. Currently local inventors need to go to South Korea, China or Japan to deposit their microorganisms at an IDA. If Malaysia forms an IDA, local inventors or inventors from neighbouring countries may deposit their microorganisms in Malaysia for the purpose of patent filing. This can be seen as cost saving for many and will in turn encourage research and innovation.

Pharmaceutical Regulations

As mentioned earlier, the development of regulations in relation to pharmaceuticals in Malaysia are relatively progressive and remain well-developed under the stewardship of MOH. On 4 August 2008, the National Pharmaceutical Control Bureau (NPCB) under MOH adopted the Guidance Document And Guidelines For Registration of Biosimilars. Non-clinical and clinical requirements outlined for biosimilar submission in the guidance document are applicable to biosimilar product registration submissions in line with the GCP Guidelines. It is the NPCB's intention to harmonise as much as possible with other competent regulators and international organisations such as the World Health Organisation (WHO) and the ICH. It is expected that guidance on scientific principles that should be involved in evaluating biosimilars would help harmonise requirements worldwide and lead to greater ease and speed of approval as well as greater assurance of the quality, safety and efficacy of these products worldwide. Malaysia is the second country (after Australia) within the Asia Pacific that has outlined regulations for biosimilar registration (see Table 4-11).

Table 4-11: Asia Pacific Countries with Biosimilar Guidelines

Country	Date of Issue	Description
Australia	May 2005	• Adoption of EMEA guidelines
Malaysia	August 2008	• No product specific guidelines
Taiwan	November 2008	• Four product specific guidelines for 'somatropin', 'recombinant human soluble insulin', 'granulocyte-colony stimulating factor' and 'recombinant erythropoietins'
Japan	March 2009	• Different non-proprietary names given to biosimilar product • No product specific guidelines
South Korea	July 2009	• No product specific guidelines
Singapore	August 2009	• No product specific guideline • Biosimilar product must first be approved for sale in any one of the Health Science Authority's reference agency

Moving forward, Malaysia is actively involved in regulatory harmonisation initiatives which will enhance cooperation between countries and boost trade. An example is Malaysia's active participation in the regional discussions to enhance cooperation amongst ASEAN member states with regard to pharmaceutical regulations, traditional medicines and health supplements and medical devices through the ASEAN Consultative Committee for Standards and Quality.

In the area of traditional medicines and health supplements for example, active work is currently being carried out at the regional level in formulating a mechanism to ensure the safety, quality and claimed benefits of traditional medicines and health supplements marketed in ASEAN. This in turn may bring about the creation of a single market and reduce restrictions to trade in traditional medicines and health supplements through the harmonisation of technical requirements without compromising the safety and quality of traditional medicines and health supplements.

Active engagement in forums such as the International Regulatory Cooperation for Herbal Medicines (IRCH) also ensures that the country is in tune with discussions between agencies which regulate herbal medicine with the overall aim of supporting the safety and quality of herbal medicines across the world.

Access Benefit Sharing

The Convention on Biological Diversity (CBD) has a total of 190 member parties and Malaysia ratified the same in 1994. The CBD deals with the fair and equitable sharing of benefits arising from access to genetic resources as well as transfer of technologies. Currently, work on formulating the international regime for ABS is being carried out, in line with the third objective of the CBD which provides for the fair and equitable sharing of the benefits arising out of the use of genetic resources.

Article 15 of the CBD recognises the sovereign rights of states over their natural resources. Thus access shall be based on mutually agreed terms (MAT) between the user and the provider and be subject to the prior informed consent of the Contracting Party pro viding such resources. MATs are to provide for the sharing of benefits arising from the commercial or other utilisation of these genetic resources with the Contracting Party providing such resources.

While there is currently no domestic ABS laws to date, in view of the developments in the international front for example the progress made in the recent ABS WG8 (Montreal, November 2009) and the importance of this subject to the country, it is anticipated that the national level laws on ABS will also be in the pipeline in the future.

Upon its promulgation, a formal domestic ABS framework should provide a balanced means to ensure that Malaysia will be able to combat biopiracy besides providing an effective means for Malaysia to leverage on its rich and diverse genetic resources in line with Malaysia's objectives to promote biotechnology development as an engine for growth.

International Accreditations (GxP)

Malaysia has adopted and implemented international standards such as GMP, GLP and GCP to ensure Malaysia's competitiveness in relation to other countries with similar biotechnology initiatives.

Good Manufacturing Practice

In terms of GMP, Malaysia and Singapore are moving towards harmonised GMP inspections as in April 2009, all ten ASEAN member countries signed a MRA to harmonise GMP inspections. Under the MRA, member states are obliged to establish inspection services for conducting GMP audits and issuing reports / certificates, as well as accept and recognise GMP certificates / reports issued by listed inspection services of another member state. GMP certificates are in accordance to the PIC/S GMP Inspection Framework. This means that drug companies marketing products in all ASEAN member countries should implement PIC/S GMP guidelines. Singapore and Malaysia are already PIC/S members, and are both Chair and Co-Chair of the ASEAN inspection task force respectively. The MRA benefits regulators and the industry in several ways:

- Avoids duplication of GMP Audits within member countries
- Saves time, resources and costs for regulators and industry
- Facilitates trade in medicinal products across ASEAN
- Quicker access of medicinal products by ASEAN patients
- Increased competitiveness of Asia vis-a-vis India, China and other bigger industrialised countries

Good Laboratory Practice

With regard to the implementation of the OECD GLP framework which is applicable to the non-clinical health and environment safety studies for the testing of test items contained in pharmaceutical products, pesticide products, cosmetics products, veterinary drugs as well as food additives, feed additives, and industrial chemicals; the Government of Malaysia had designated the NPCB and Department of Standards Malaysia (Standards Malaysia) as the Malaysian Compliance Monitoring Authorities (CMAs). NPCB is the CMA for the non-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs and food additives and Standards Malaysia is the CMA for the non-clinical safety testing of test items contained in industrial chemicals, pesticides, feed additives, and biotechnology (non-pharmaceuticals). NPCB and Standards Malaysia enjoy close co-operation and may conduct joint inspection of the test facility at its request.

The GLP Compliance Programme which is intended to certify whether test facilities adhere to the OECD Principles of GLP and Compliance Monitoring have been initiated by the CMAs. Test facilities requesting for verification and certification of compliance to the said Principles of GLP, and subsequent inclusion into the CMAs GLP Compliance Programme are required to submit application to the relevant CMAs. With GLP recognition, the non-clinical health and environment safety studies conducted locally will enjoy greater access to international market.

The GLP Compliance Program includes Pre-Inspection, Inspection, Surveillance and Extra Ordinary Inspections. Pre-inspection is conducted first to familiarise the CMA with the test facility and verify that the test facility has the requisite resources to undertake GLP studies. The Inspection combines inspection of the test facility's facilities and study audit on its ongoing and/or completed studies. Surveillance Inspection will be conducted within two years after the last Inspection. Extra Ordinary Inspection shall be carried out in situations not covered by Pre-Inspection, Inspection and Surveillance Inspection. Test facilities found complying with requirements of the OECD Principles of GLP and Compliance Monitoring shall be listed in the Master Register of the GLP Compliance Programme. BiotechCorp is working with the CMAs to assist in the certification of test facilities through provision of funding for numerous capacity building initiatives including identification of potential test facilities for GLP compliance.

Good Clinical Practice

Malaysia is the ideal clinical research destination in Asia. In addition to its large multi-ethnic population, the nation boasts excellent healthcare infrastructure, GCP-trained clinical researchers who are mostly English-literate, strong government support and efficient regulatory process. Malaysia offers pharmaceutical, biotechnology, medical devices and CRO companies with plenty of opportunities to conduct their research. The Government-backed National Institutes of Health, through MOH CRCs promotes, supports and conducts quality and ethical research to improve patient outcomes. There are now 17 CRCs located in all major public hospitals in the country.

MOH ensures each trial proposal goes through a rigorous review and the trial itself is strictly monitored and regularly audited. The Clinical Research and Compliance Section of the NPCB plays an important role in issuing Clinical Trial Import License and ensuring compliance with GCP. The obvious benefit of GCP is acknowledged by Malaysia's Drug Control Agency as Malaysia becomes a more active participant in international drug research.

In regulating clinical trials involving human subjects (to ensure that the data and reported results are credible and accurate; and that the rights, integrity and confidentiality of the trial subjects are protected), guidelines applicable in Malaysia include:

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - Guideline for GCP
- Malaysian GCP Guideline
- Guidelines for Ethical Review of Clinical Research or Research Involving Human Subjects
- Guidelines for Application of Clinical Trial Import License and Clinical Trial Exemption in Malaysia

BioSafety

Malaysia is a signatory of the Cartagena Protocol on Biodiversity (the Protocol), which is the first legally binding international agreement governing transboundary movement of living modified organisms (LMOs). The Protocol which came into force on 11 September 2003 was crafted to ensure the safe handling, transfer and use of LMOs. The Protocol establishes rules and procedures with a view to regulate the movements of these LMOs from one country to another.

The regulator in relation to biosafety laws in the country is the MNRE and biosafety related matters are administered by its Biosafety Core Team. In 2007, Malaysia enacted the BioSafety Act 2007 to regulate the release, importation, exportation and contained use of LMOs. Under this Act, the National Biosafety Board will be established to monitor activities relating to LMOs and products of such organisms. The Biosafety Act 2007 came into force on 1 December 2009.

The coming into force of the Biosafety Act provides certainty to the industry and also ensures that a process is in place to handle the release, importation, exportation and contained use of LMOs. Currently, a set of biosafety regulations which will support and help operationalise the Biosafety Act is also in its final leg of completion. Towards that end, MNRE has shown that they are progressive and open in their approach by providing an avenue for engagement and consultation between the relevant ministries, agencies and the industry players towards the formulation of the aforementioned biosafety regulations, which is currently still in draft form.

In furthering the objectives of the NBP, Malaysia needs to ensure that Biosafety policy and laws not only protect biodiversity but also provide room for the development of biotechnology in the country. This balancing act remains the biggest challenge in a scenario where there are multiples stakeholders and the most effective way to ensure a win-win situation for the country would be the creation of channels for discourse and consultation between the regulators and the industry so that future laws, regulations and rules impacting the development of biotechnology in the country could be formulated in an inclusive and constructive manner.

Moving Forward

Malaysia is cognisant of the fact that a solid and conducive regulatory framework will be the cornerstone for the development of a robust and competitive biotechnology sector. Malaysia has already put in place well-measured and sound plans to ensure that the country's regulatory framework is conducive towards the continued development and advancement of business, research and innovation.

Moving into the next phase of the NBP, it is important to establish a supportive regulatory framework and environment for the development of biotechnology in Malaysia. This involves the following key priority actions:

1 Execute plans in the pipeline

It is proposed that plans in the pipeline be executed as part of the continuous enhancement of Malaysia's legislative and regulatory framework to provide a conducive environment for the development of the biotechnology industry and towards supporting Phase II of the NBP – Science to Business:

- Continue constructive engagement with regulatory stakeholders to provide an avenue for discourse and alignment towards national policies
- Engage with IHLs, RIs and BioNexus Status companies to further support and harness potential R&D initiatives for commercialisation
- Support MyIPO in its quest to provide world class services by enhancing its capacity in terms of human capital
- Support NPCB and Standards Malaysia (being the CMAs for Malaysia) for Malaysia to achieve OECD GLP MAD full member status in 2011
- Assist identified facilities for GLP accreditation in terms of capacity building, training and attachments
- Participate and contribute in the development of Pharmaceutical regulations
- Provide input and feedback with regard to the development of national biosafety and ABS laws
- Support the development of capacity in terms of international accreditation such as GCP and GMP

Policy Thrust 8 Strategic Development

Biotechnology is one of the fastest growing industries in the world and is one of the major areas of investment by most Governments worldwide. Malaysia has also identified the biotechnology industry to be one of the key growth engines for the country's economy. As described in the NBP, Malaysia will leverage on its strengths and capabilities to position itself as one of the key players in the global biotechnology industry. For this purpose, strategies and actions have been identified for each policy thrust to drive the implementation of the NBP.

One of the critical success factors in the development of the biotechnology industry is industry knowledge. In this context, industry knowledge refers to general public awareness and knowledge of biotechnology and its applications in the various sectors. Having such knowledge will help to reinforce the needs and expectations of consumers at large, which will in turn drive the demand for greater use of biotechnology. Attractiveness of market potential will create greater business opportunities for all industry stakeholders.

Besides industry knowledge creation, there is a need for Malaysia to build international recognition of its biotechnology industry and to find a niche in the global biotechnology value chain in order to achieve the overall objectives of the NBP. Building global branding for global market access and FDI participation is one of the strategic imperatives in enabling the implementation of the priority actions identified in the other policy thrusts.

Current State

Being the lead agency in implementing the NBP, BiotechCorp has undertaken a number of programmes aimed at achieving global branding and creating public awareness and knowledge:

- BioBusiness Partnering Events - Platform for BioNexus Status companies, local VCs, distributors, importers, exporters and traders to meet their counterparts
- BioMalaysia - Malaysia's premier and largest biotechnology conference and exhibition
- BioCareer - Create awareness among students and the general public on the emerging and available career opportunities in the biotechnology industry
- BioUsahawan and Biotech Jom Heboh - Create awareness for the local biotechnology industry

In addition, BiotechCorp participates in the annual BIO conference in the U.S. with the view of showcasing Malaysian biotechnology companies, facilitating business matching and seeking insights into latest developments in biotechnology. Participation in BIO 2008 San Diego facilitated the completion of six international collaborations with total expected investment of USD 0.3 billion (RM 1 billion).

Other programmes undertaken by BiotechCorp to enhance Malaysia's readiness for global market positioning:

- BNP (details provided in Policy Thrust 4: R&D and Technology Acquisition Development)
- Triple Helix (details provided in Policy Thrust 4: R&D and Technology Acquisition Development)
- Bio-XCell (details provided in Policy Thrust 9: Government Support and Commitment)

In addition, the Government has set up Centres of Excellence with the view of positioning Malaysia's capabilities in biotechnology R&D (as described in Policy Thrust 4: R&D and Technology Acquisition Development).

Global Branding

Global networks are integral to provide a window into the global life science industry and access to competitive intelligence to prospect for international investment opportunities and identify targets for collaborations[19]. BiotechCorp has taken the lead to build and promote Malaysia's biotechnology industry, especially at the international level as global branding is critical to strengthening global market access.

BiotechCorp also facilitates business matching and business development between foreign companies and local enterprises to increase access to facilities, equipment, technology, IP, funding and markets.

[19] National Biotechnology Policy (2005)

Public Awareness

The objectives of the promotional efforts are to increase the public's awareness of biotechnology, develop this knowledge-based industry in Malaysia as a platform for the creation of jobs, wealth and social well-being, and attract major international biotechnology players to invest in the country and form smart partnerships, collaborations and alliances[19].

Key Government agencies like MIDA have been instrumental in building Malaysia's profile as a key investment destination through intensive foreign trade missions. BiotechCorp has complemented these efforts by building a brand for Malaysia's biotechnology industry via conferences, exhibitions, road-shows, press releases and tailored media campaigns. The key aim is to create awareness of the importance of biotechnology as the enabling tool to accelerate the development of the agricultural, healthcare and industrial sectors in Malaysia.

The local promotional and publicity efforts include BioMalaysia, BioCareer, and BioUsahawan and local nationwide outreach programmes include Biotech Jom Heboh, as described above. The success factors lie in BiotechCorp's ability to promote Malaysia as a destination for biotechnology activities, and how effective BiotechCorp is in its role and function to develop strong and successful biotechnology companies by showcasing the success stories of BioNexus Status companies. A key measurement of success of these efforts is reflected in the media value generated by BiotechCorp from 2007 to 2009, which is valued at close to USD 20.6 million (RM 72.3 million).

Moving Forward

Moving into Phase II of the NBP, the priority strategy is to accelerate commercialisation for global market opportunities. Hence, emphasis needs to be placed on globalising local companies and attracting global companies to set up operations in Malaysia. Chapter 3 outlines the globalisation strategy implementation for each sector.

The following priority actions are proposed to intensify global branding and public awareness to increase industry confidence:

1 Intensify global branding of biotechnology companies

BiotechCorp complements the globalisation strategy for Malaysia's biotechnology industry through international branding and intensified marketing to reinforce awareness and build the power of Malaysia's biotechnology brand.

For this purpose, BiotechCorp organises regular international partnering programmes and spearheads Malaysia's participation in international biotechnology conferences and dialogues. These programmes have been notable in increasing the prominence of the local biotechnology industry by solidifying international collaborations and should continue with the following emphasis:

- Intensify business matching between the local biotechnology industry and potential foreign counterparts and investors to improve access to foreign funds, markets and technology. Potential top performing BioNexus Status companies can leverage on such opportunities.
- Focus on attracting FDIs to Bio-XCell. As a dedicated biotechnology park with ready-built and customised facilities, Bio-XCell should be heavily promoted among foreign companies to encourage commercial developments, R&D and production of industrial and pharmaceutical biotechnology products.
- Position platform technologies and applications globally. The newly-acquired platform technologies particularly the Marker Assisted Selection and Supercritical Fluid platform technologies will help to position Malaysia as a regional hub for such platform technologies.

[19]National Biotechnology Policy (2005)

2 Continuously improve public awareness programmes to build industry confidence

BiotechCorp, being the lead agency for Malaysia's biotechnology industry, undertakes relevant programmes (such as BioMalaysia, BioCareer and BioUsahawan) to promote and enhance public awareness and to demonstrate the opportunities and contribution of the local biotechnology industry. These efforts should continue with the following emphasis:

- Promote top performing BioNexus Status companies - Policy Thrust 6: Financial Infrastructure Development highlights the importance of developing top performing BioNexus Status companies that have the potential to produce high value products for regional and global markets. Moving forward, there is a need to leverage on existing promotional platforms to develop suitable marketing campaigns and promotional efforts for these companies to and provide them the visibility needed to attract international attention, collaboration and funding.
- Support intensification of PPP - As proposed above, BiotechCorp should intensify business matching efforts for the local biotechnology industry. These collaborations (both local and foreign) should be heavily publicised to create more understanding and acceptance of the biotechnology industry as a whole and to demonstrate the industry's potential. PPP models proposed are further described in Chapter 3 and Policy Thrust 6: Financial Infrastructure Development.
- Continuously engage the investor community - Investors are one of the industry's key stakeholders who need to be constantly engaged through events such as Bio Funding to publicise the industry's successes and viability. This will provide investors with the confidence needed to become increasingly involved in the local industry, which includes raising funds for the industry and recommending innovative funding options.

Policy Thrust 9 Government Support and Commitment

The Government's stewardship is crucial in promulgating a successful and innovative biotechnology industry. Continued Government support and commitment is key towards effectively and efficiently developing the three major sectors, namely agricultural, healthcare and industrial biotechnology, as well as establishing the right infrastructure enablers. The Government has therefore developed a comprehensive NBP to drive the development of the biotechnology industry in Malaysia.

Current State

MOSTI is the ministry which has overall responsibility for the NBP. BiotechCorp is the lead agency under the purview of MOSTI that is responsible for the coordinated implementation of the NBP. Since 2005, the implementation framework has been implemented through three levels of governance: Biotechnology Implementation Council (BIC), BiotechCorp and the Biotechnology International Advisory Panel (IAP). The BIC and IAP have advisory roles whereas BiotechCorp is the implementation agency. In addition, the Government has put in place an approach to creating a biotechnology network within Malaysia.

Implementation Framework

The BIC is chaired by the Prime Minister and comprises Ministers from the various relevant ministries. The BIC sets policy direction and priorities for the growth and development of Malaysia's biotechnology industry as the engine to accelerate the national economy. The council also integrates inter-ministerial coordination in biotechnology and oversees development to ensure the achievement of the developmental goals set out in the NBP.

At the working level, in order to better coordinate the various efforts and initiatives as well as strengthen the linkages between the public and private sectors, six Cluster Working Groups (CWGs) were formalised by the BiotechCorp's Board of Directors. The six CWGs cover areas of Agriculture, Healthcare, Industrial, Legislative and Regulatory Framework, Human Capital Development and Financial Support. Each CWG is headed by a member of the Board and it serves as the forum for BiotechCorp and its stakeholders to discuss issues relating to the implementation of the NBP.

The Government has appointed IAP members comprising industry experts from global organisations (financial institutions, MNCs, professional services organisations, RIs and academia). The IAP's primary role is to advise the Government in strategising, shaping and promoting the development of the industry, vis-à-vis the development of the biotechnology industry at the global front.

Established on 13 May 2005, BiotechCorp is the lead agency overseeing and coordinating the execution and implementation of the NBP with the following mandate:

- Act as a one-stop-centre serving the Malaysian biotechnology companies
- Nurture and accelerate growth of the Malaysian biotechnology companies
- Create a conducive environment for biotechnology
- Actively promote FDIs in biotechnology

As a one-stop-centre, BiotechCorp provides support, facilitation and advisory services for the establishment of biotechnology companies in Malaysia. In this respect, BiotechCorp is usually the first point of contact for companies that intend to apply for BioNexus Status.

Biotechnology Network

The biotechnology network is a group of specialised companies and institutions that can support each other to create Centres of Excellence in terms of physical assets, human resources, entrepreneurship and exchange of ideas. This network provides important infrastructure to allow start-ups to cut costs, accelerate development time and foster a collaborative culture among institutions and organisations within the network.

Since the launch of the NBP, BioNexus Status has been granted to 151 qualified biotechnology companies as at 31 December 2009. Three Centres of Excellence have also been set up (as described in Chapter 3 and Policy Thrust 4: R&D and Technology Acquisition Development).

In addition, TPM's wholly-owned subsidiary, TPM Biotech operates one of the two biotechnology clusters: Herbal Biotech Centre in Kg. Ulu Sungai, in Raub, Pahang. The centre is GMP certified and it undertakes all aspects of herbal processing, extraction and finished products through CMO. The other biotechnology cluster is Inno Biologics' Bio Innovation Centre in Nilai, Negri Sembilan which is due to be completed in April 2010. The objective of the centre is to provide seamless integration of services for its partners in biotechnology manufacturing and foster synergies across the biotechnology value chain.

BiotechCorp and UEM Land Holdings, a PPP arrangement, have collaborated to develop a biotechnology ecosystem called Bio-XCell in Iskandar Malaysia, Johor for USD 157.1 million (RM 550 million). It is a model for hub expansion within the biotechnology industry. Bio-XCell is designed to create a vibrant, dedicated, productive and custom-built ecosystem with a special focus on industrial biotechnology, particularly those involved in green technology, and healthcare biotechnology. The infrastructure is comparative to the Virginia Biotechnology Research Park, which consists of a 14-hectare land area and has approximately 3,000 researchers. Bio-XCell will play a complementary role to the advanced R&D parks in Singapore, namely Biopolis and Tuas Biomedical Park. Additional incentives are also being proposed to encourage individuals to work and live in Iskandar Malaysia. During the announcement of the 2010 national budget, the Prime Minister of Malaysia proposed that income tax on employment income for both local and foreign knowledge workers be capped at 15% compared to 26% for the rest of the country.

Moving Forward

As the implementation of the NBP moves towards Phase II, continuous Government support and commitment will be critical. Greater integration and coordination of efforts by all parties will be required to ensure the achievement of the desired results.

Besides specific Government support and resources recommended in the other policy thrusts, the following priority actions are recommended for consideration in reinforcing Government support and commitment.

1 Continuously improve inter-ministerial coordination

Although a comprehensive implementation framework has been put in place to integrate inter-ministerial coordination, there is a need to continuously improve inter-ministerial coordination in developing the biotechnology industry.

A new working group may be established with the objective of aligning and harmonising all related Government policies in the development of the industry. The working group should be guided by the principle that all policies and regulations should maintain a balance between developing Malaysia's economy as a whole and preserving social values and responsibilities. The working group members should be represented by senior Government officials of all ministries. BiotechCorp is proposed to be the secretariat for the group.

Following are the proposed terms of reference for consideration by the new working group:

- Identify all related Government policies of all ministries
- Determine areas of overlaps / duplications / conflicts
- Review areas of concerns to determine extent of industry impact
- Propose alternatives / changes for consideration with appropriate justifications
- Present findings and recommendations to BIC for review and approval to proceed with policy changes

2 Continuously improve the biotechnology network

There is a need to continuously improve the implementation of the biotechnology network. This will meet the objective of effectively developing and integrating all relevant stakeholders to ensure a vibrant biotechnology community in the country. The key area that needs improvement is essentially the alignment of the biotechnology network. Besides Bio-XCell being developed for the industrial and healthcare biotechnology sector, the following economic corridors have also published the intent to develop certain sectors of biotechnology industry:

- Northern Corridor Economic Region, Kedah - Natural products
- Eastern Economic Corridor Region, Pahang - Crops, livestock and fisheries
- Sarawak Economic Corridor Region - Livestock and aquaculture
- Sabah Development Corridor – Natural products and aquaculture

In order to have a coordinated approach in developing the biotechnology network, it is proposed that early involvement of various parties concerned be required. It is also proposed that BiotechCorp works with other relevant parties like economic corridor authorities, ministries, IHLs and RIs to effectively implement relevant programmes / initiatives to ensure the growth and development of the industry, and to further align the Government's initiative in developing a biotechnology network within the economic corridors.

In addition, MOSTI is currently undertaking a comprehensive study on the implementation of the MyNIC, which is targeted to be launched in early 2010. MyNIC's focus is on innovation across critical sectors in the economy including biotechnology, agriculture and ICT. This centre will provide an ecosystem to improve the commercialisation of existing R&D. Alignment of this centre within the biotechnology network will also be required.

The following is a list of possible areas to be considered for alignment to the NBP and priority actions moving forward into Phase II of the NBP:

- Sector focus development (agriculture, healthcare, industrial)
- Key anchor tenants' or MNCs' requirements (global market access, global brand)
- PPP requirements (investments, partnership arrangement)
- Pipeline of resources (raw materials, supporting industry and specialist business services such as patent agents, lawyers, recruitment and property advisors)
- Environment conduciveness (quality living conditions, access to basic facilities such as schools and hospitals)
- Unique shared facility requirements (for example, cold rooms, bio-hazard waste management systems, relevant laboratories and scale-up facilities)

Chapter 5
Implementation Plan

Chapter 5 Implementation Plan

Moving forward into Phase II of the NBP, it is critical to closely and effectively monitor the implementation of the proposed actions. The proposed implementation plan:

- Prescribes a mechanism for coordinating the implementation of proposed actions
- Provides broad guidelines for regular implementation monitoring and progress reporting
- Describes the communications programme to disseminate and obtain feedback on the proposed actions and implementation progress

Implementation Structure

BiotechCorp, being the lead agency responsible for the coordinated implementation of the NBP, will continue to leverage on existing governance structure (as described in Policy Thrust 9: Government Support and Commitment) to oversee the implementation of the priority actions. A dedicated Action Management Team (AMT) is proposed to be set up according to the nine policy thrusts in order to closely monitor the priority actions recommended.

To provide a timely, pragmatic and systematic response to new developments and changing circumstances in the Malaysian economy, the Country Report's objectives and recommended actions will need to be regularly reviewed and updated to ensure their continued applicability.

On an annual basis, a comprehensive review and update of the Country Report will be required.

Implementation Monitoring

Implementation monitoring is essential in achieving the priority goals moving forward and can be measured in terms of:

- The timeliness of the implementation
- The effectiveness of the implementation

Upon approval of proposed recommendations, detailed activities and timeframes will need to be determined for each proposed priority action for proper monitoring. Proper monitoring is aimed at ensuring that priority actions outlined in the report are implemented within their stipulated timeframes. Any delays will need to be carefully reviewed to take into account their effects on other dependent or associated recommendations.

Communications Programme

A coordinated communications programme for the recommended actions and progress of implementation is particularly important given the need for broad awareness and understanding of the direction and objectives of the priorities of Phase II of the NBP.

The main objectives of the communications programme are to:

- Create awareness among the relevant parties of the recommendations
- Establish clear communication and feedback channels that have been set up within the current governance structure
- Ensure that information about the recommendations and updates on the progress of implementation are disseminated in a timely and consistent manner
- Enhance the transparency of the implementation process and ensure the accountability of the parties involved

The AMT will continue to undertake consultation with the relevant parties, where appropriate, on an ongoing basis to obtain their feedback and input throughout the course of the recommended implementation.

Abbreviations and Acronyms

Abbreviations and Acronyms

A

ABI	Agro-Biotechnology Institute Malaysia
ABS	Access Benefit Sharing
ABS WG8	Access Benefit Sharing Working Group 8
ACE	Access, Certainty and Efficiency
ACGT	Asiatic Centre for Genome Technology
ADME	Absorption, Distribution, Metabolism, and Excretion
AMDI	Advanced Medical and Dental Institute
AMT	Action Management Team
API	Active Pharmaceutical Ingredient
ASEAN	Association of Southeast Asian Nations
ASPEC	ASEAN Patent Examination Cooperation
ASX	Australia Securities Exchange

B

BCC	Biotechnology Cooperative Centre
BeST	Biotechnology Entrepreneurship Special Training
BEST 2012	Enhanced BeST Programme
BGB	Bio Green Bags
BIC	Biotechnology Implementation Council
BiotechCorp	Malaysian Biotechnology Corporation
BK 21	South Korea's Brain Korea 21
BMS	Singapore's Biomedical Sciences
BNP	BioNexus Partner Programme
BSc	Bachelor of Science

C

CAGR	Compounded Annual Growth Rate
CBC	Core Biotechnology Companies
CBD	Convention on Biological Diversity
CDM	Clean Development Mechanism
CENAR	Centre for Natural Products and Drug Research
CfEL	Centre of Entrepreneurial Learning
CMA	Compliance Monitoring Authorities
CMO	Contract Manufacturing Organisation
CPO	Crude Palm Oil
CRC	Clinical Research Centre
CRDF	Commercialisation of Research and Development Fund
CRO	Contract Research Organisation or Clinical Research Organisation
CWG	Cluster Working Groups

D

DBT	Department of Biotechnology
DFI	Development Financial Institution
DNA	Deoxyribonucleic Acid
DOS	Department of Statistics

E

EDB	Economic Development Board
EMEA	European Medicines Agency
Ernst & Young	Ernst & Young Advisory Services
E.U.	European Union
EV71	Enterovirus 71

F

FAO	Food and Agriculture Organisation
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FRIM	Forest Research Institute Malaysia
FTE	Full-time equivalent

G

GAP	Good Agricultural Practice
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GERD	Gross Expenditure on Research and Development
GIFT	Genetic Improvement and Farm Technologies
GLC	Government Linked Companies
GLP	Good Laboratory Practice
GM	Genetically Modified
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
GWG	Green World Genetics

H

HACCP	Hazard Analysis and Critical Control Point
HIV	Human Immunodeficiency Virus

I

IAP	International Advisory Panel
ICH-GCP	International Conference on Harmonisation – Good Clinical Practice
ICH	International Conference of Harmonisation
ICT	Information and Communication Technology
IDA	International Depository Authority
IHL	Institutes of Higher Learning
IMR	Institute for Medical Research
INTECH	Initiatives in New Technology Scheme
IP	Intellectual Property
IPHARM	Malaysian Institute of Pharmaceuticals and Nutraceuticals
IPO	Initial Public Offering
IT	Information Technology
IVD	In Vitro Diagnostics

J

JE	Japanese Encephalitis
JAKIM	Department of Islamic Development Malaysia

K

KIPI	Korea Institute of Patent Information
KIPO	Korean Intellectual Property Office
KPI	Key Performance Indicator
KRIBB	Korea Research Institute of Bioscience and Biotechnology

L

LMO	Living Modified Organism

M

MAD	Mutual Acceptance of Data
MARDI	Malaysian Agricultural Research and Development Institute
MAT	Mutually Agreed Terms
MDK	Molecular Diagnostic Kits
MDV	Malaysia Debt Ventures
MEGTW	Ministry of Energy, Green Technology and Water
MESDAQ	Malaysian Exchange of Securities Dealing & Automated Quotation
MGI	Malaysian Genome Institute
MGRC	Malaysian Genomics Resource Centre
MLSCF	Malaysian Life Sciences Capital Fund
MLTM	Ministry of Land, Transport and Maritime Affairs
MNC	Multinational Corporation
MNRE	Ministry of Natural Resources and Environment
MOF	Ministry of Finance
MOH	Ministry of Health
MOHE	Ministry of Higher Education
MOSTI	Ministry of Science, Technology and Innovation
MOU	Memorandum of Understanding
MIDA	Malaysian Industrial Development Authority
MRA	Mutual Recognition Agreement
MSc	Masters of Science
MSC	Mesenchymal Stem Cells
MSW	Municipal Solid Waste
MTDC	Malaysian Technology Development Corporation
MYAGRI	Malaysian Agri Hi-Tech
MyIPO	Intellectual Property Corporation of Malaysia
MyNIC	National Innovation Centre

N

NAP3	Third National Agricultural Policy
NBDS	National Biotechnology Development Strategy
NBIA	National Business Incubation Association
NBP	National Biotechnology Policy
NBRA	National Biotechnology Regulatory Authority
NBS	Australia's National Biotechnology Strategy
NDRC	National Development and Reform Commission
NIE	Newly Industrialised Economies
NPCB	National Pharmaceutical Control Bureau

O

OECD	Organisation for Economic Co-operation and Development
OIC	Organisation of the Islamic Conference
OIE	The World Organisation for Animal Health

P

PCR	Polymerase Chain Reaction
PCT	Patent Cooperation Treaty
PFAD	Palm Fatty Acid Distillate
PHA	Polyhydroxylalkanoate
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PLA	Polylactic Acid
POME	Palm oil mill effluent
PPP	Public-Private Partnership

Q

QB3	California Institute of Quantitative Bioscience
qPCR	Quantitative Polymerase Chain Reaction

R

R2G	Return 2 Green
R&D	Research and Development
R&D&C	Research, Development and Commercialisation
Reb-A	Rebaudioside
RIs	Research Institutes
RMK-8	Eighth Malaysian Plan
RMK-9	Ninth Malaysia Plan
RRIM	Rubber Research Institute of Malaysia
RT-PCR	Real Time Polymerase Chain Reaction
RNA	Ribonucleic acid

S

SARS	Severe Acute Respiratory Syndrome
SBC	Sarawak Biodiversity Centre
SBi	Small Bones Innovations
SC	Securities Commission
SEZs	Special Economic Zones
SIRIM	Standards and Industrial Research Institute of Malaysia
SMBG	Self-monitoring of blood glucose
SME	Small and Medium Enterprise
SOP	Standard Operating Procedures
SSM	Suruhanjaya Syarikat Malaysia (Companies Commission of Malaysia)
STRAT	Strategic Attachment and Training

T

TAF	Technology Acquisition Fund
TCM	Traditional Chinese Medicine
TDF	Technology Development Fund
TPM	Technology Park Malaysia
TTN	Technology Transfer Network
TTO	Technology Transfer Office

U

U.K.	United Kingdom
UKM	Universiti Kebangsaan Malaysia
UM	Universiti Malaya
UNFCCC	United Nations Framework Convention of Climate Change
UNIMAS	Universiti Malaysia Sarawak
UniSel	Universiti Industri Selangor
UPM	Universiti Putra Malaysia
U.S.	United States
USM	Universiti Sains Malaysia
UTM	Universiti Teknologi Malaysia

V

VCMC	Venture Capital Management Companies
VC	Venture Capitalist

W

WHO	World Health Organisation
WTO	World Trade Organisation

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Malaysian Biotechnology Corporation (BiotechCorp) is a central contact point for biotechnology and life science companies in Malaysia. BiotechCorp is the industry's one-stop-centre providing support, facilitation and advisory services.

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