



**BIOTECHCORP**  
MALAYSIAN BIOTECHNOLOGY  
CORPORATION

# RMK-9 INDUSTRY SCORE CARD REPORT





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## Project Background and Objectives

Biotechnology has been identified as one of the new economic growth engines that will drive Malaysia towards advanced nation with a high-income by the year 2020. The country has rich biodiversity, cost-competitive skilled labour, good transportation networks, Information and Communication Technology (ICT) infrastructure, and a cost effective platform for doing business. These combined characteristics provide Malaysia with opportunities to develop new enterprises, new industries and new bases in the local biotechnology industry.

To pursue excellence in this sector, a biotechnology policy was developed under the Eighth Malaysia Plan (RMK-8) led by the Ministry of Science, Technology and Innovation (MOSTI). The aim was to formulate “a comprehensive and coordinated approach for the advancement of biotechnology as a strategic technology in the development of the economy”. The biotechnology policy focuses on key contributors that lay the foundation towards building a competitive biotechnology industry namely:

- Human resource development to create skilled workers;
- Research and Development (R&D) in priority areas; and
- Enhanced technological infrastructure and facilities to foster innovation and industry development.

A significant milestone was achieved with the launching of the National Biotechnology Policy (NBP) in 2005, which states Malaysia’s vision “To position biotechnology as the new economic engine to enhance prosperity and wellness of the nation by 2020”. Amongst others, the policy identifies specific actions in the areas of agriculture, healthcare and industrial biotechnology development. This policy encompasses nine thrusts which underline the direction and measure offered by the Government towards developing the local biotechnology industry. The implementation of the NBP consists of three development phases:

- Phase 1 (2006-2010): Capacity Building;
- Phase 2 (2011-2015): Science to Business; and
- Phase 3 (2016-2020): Global Business.

Each development phase outlines the milestones and strategies to be adopted, starting from capacity development to commercialisation and finally, placing Malaysia as a competitive, leading edge biotechnology hub at the global level by 2020. Each phase is tied to four performance indicators set by the Government as a measurement of the progress and impact of the NBP implementation, which are Investment, Employment, Revenue and Contribution to Gross Domestic Product (GDP).

The development of biotechnology targeted to contribute 2.5 percent of national GDP by 2010, 4.0 percent by 2015 and 5.0 percent by 2020. Furthermore, it is estimated that the local biotechnology industry will create a total of 280,000 new jobs – both directly and indirectly – by 2020.

The Malaysian Biotechnology Corporation Sdn. Bhd. (BiotechCorp) was established on 13<sup>th</sup> May 2005 as a dedicated and professional one-stop development agency with the objective to develop the country's biotechnology industry, under the purview of MOSTI. The Ninth Malaysia Plan or *Rancangan Malaysia Ke-9* (RMK-9) announced on 31<sup>st</sup> March 2006 further defined and detailed out the goals of the Malaysian government in relation to the biotechnology sector. The Government had allocated a total funding of RM2.0 billion to support the development of physical and soft infrastructure in the local biotechnology sector. BiotechCorp was allocated a sum of RM265 million by the Government to undertake six Developmental Programmes in Phase 1-Capacity Building of the NBP. In order to measure the success of the Programmes implementation, the Economic Planning Unit (EPU) has set a list of targets for BiotechCorp to monitor and achieve.

As the implementation of Phase 1 NBP ended on 31<sup>st</sup> December 2010, BiotechCorp is keen to benchmark and assess the achievements of its Programmes. Therefore, BiotechCorp had engaged Frost & Sullivan to undertake "The RMK-9 Industry Scorecard Report", with the aim of providing a formal, independent stakeholder-based management report on BiotechCorp's overall RMK-9 Programme achievements for the 2006-2010 period. The report will serve as an important and insightful tool for BiotechCorp's planning and implementation of future Malaysia Plans, including those outlined in *Rancangan Malaysia Ke-10* (RMK-10).

### Information Sources

Frost & Sullivan used three levels of information to develop this report. These have been highlighted below:

1. Secondary Sources	<ul style="list-style-type: none"><li>• MOSTI Bio-Indicator Report 2009/2010</li><li>• BiotechCorp Developmental Management Report</li><li>• BiotechCorp Annual Reports</li><li>• Websites of beneficiaries of the Programmes</li></ul>
2. Frost & Sullivan Knowledgebase and Expertise in Biotechnology sector	<ul style="list-style-type: none"><li>• Database from previous projects conducted for BiotechCorp</li><li>• Database from previous projects conducted in the biotechnology sector</li></ul>
3. Primary Research	<ul style="list-style-type: none"><li>• Interviews with Government Representatives for each Programme</li><li>• Interviews with beneficiaries of the Programmes</li><li>• Interviews with industry experts</li></ul>

A half-day project initiation workshop with BiotechCorp was also conducted on 26<sup>th</sup> January 2011. The prime objective of the workshop was to understand the perspective of Programme Owners on the overall success and achievement of the RMK-9 and their vision for the RMK-10.

## Executive Summary

Malaysia has identified the biotechnology sector as a key investment area that can generate tremendous business opportunities and social benefits. Under the NBP, the biotechnology sector in Malaysia is projected to generate annual revenue of RM100 billion by 2020. With a strong base developed over the past five years by the Government and BiotechCorp, coupled with strong growth shown over the years, Malaysia's biotechnology cluster has the potential to be among the leading Asia Pacific biotechnology clusters. However, this would require that the current concerted efforts are further intensified by both public and private sectors.

The Malaysian government enacted the NBP in 2005. The focus was to lay down a comprehensive framework to guide the development of the industry, through conducive R&D environment and industry development whilst leveraging on the strengths of the country. Malaysia has a well-defined framework and action policies for the local biotechnology industry to leverage on and grow.

Successful biotechnology clusters had long gestation period. Biotechnology market takes a relatively longer period to mature compared with most other industries due to its detailed processes and standards that are required to be fulfilled. For example, the Boston and California biotechnology clusters had five decades of experience. Biotechnology discoveries only started to generate returns after funding injection worth billions of dollars over the last two decades.

It is noteworthy that in Malaysia, a strong biotechnology industry base was developed over the past five years during the Capacity Building phase of the NBP under the leadership of BiotechCorp. Malaysia's Biotechnology cluster has also shown the potential to grow aggressively in areas like agriculture, healthcare and industrial biotechnology, as well as peripheral industry. This would form a strong engine of growth for the economy.

### RMK-9 Performance

BiotechCorp's Programmes have been crucial in unlocking the potential of the Malaysian biotechnology industry. Industry revenues grew at a Compounded Annual Growth Rate (CAGR) of approximately 39 percent over the 2006–2010 period. This was made possible largely due to the support provided by the Government and private sector participation. It is worth mentioning that when the Programmes of BiotechCorp are evaluated as a whole, it is evident that these Programmes had brought economic and social benefit by handholding both entrepreneurs and companies throughout the value chain.

Furthermore, other initiatives have been undertaken to improve the image, capabilities and ecosystem of the overall Malaysian Biotechnology industry. These include initiatives such as:

1. **Bio-XCell cluster in Iskandar Malaysia, Johor** -This has attracted substantial Foreign Direct Investment (FDI) from leading global players such as Biocon Ltd (Biocon), Metabolic

Explorer SA (METEX) and Glycos Biotechnologies Inc. (GlycosBio) with a total approved investment of RM1.146 billion.<sup>1</sup>

2. **International Collaborations** – In the area of human capital development, strategic collaborations which were formed with LARTA Institute (LARTA), California Institute for Quantitative Biosciences (QB3) and Korea Research Institute of Biotechnology & BioScience (KRIBB) are a few successful examples. The purpose of these initiatives was to accelerate the commercialisation of bio-innovations, nurture local scientists, researchers and bio-entrepreneurs and form strategic alliances for potential technology transfers, business ventures and talent development.
3. **Participation in International Fairs/Conferences** such as BioMalaysia, Bio-Europe, Bio-Investor etc. – Participation and establishment of strategic communication platforms that leads to effective collaborations between global and local biotechnology industry fraternities.
4. **Public Outreach** through BioIndustry Dialogue and Exhibition in conjunction with “*Karnival Jom Heboh*” – TV3, BioUsahawan etc. Public awareness on biotechnology and its economic and business potential is essential for the overall successful implementation of NBP. With accurate facts that are accessible to the general public, the *Rakyat* (Malaysia citizen) will be aware of the benefits of such initiatives. This can in turn generate support for the government’s efforts and assist in developing biotechnology as one of the country’s economic growth engines.
5. **BioFunding Conference** – Knowledge from a business and investment perspective is pivotal for the commercialisation of any technology. Such conferences provided participants i.e. investors/funders with a better understanding of the biotechnology industry from a business and investment perspective, as well as its enormous economic potential. Through the conferences, the BioNexus status companies were provided with the knowledge on how to attract investors/funders to invest in their businesses. The conference also provided an avenue for them to network with the investors/funders.
6. **Biotechnology Business and Investment Matching** – Active engagements with various local and foreign investors such as private VCs, corporations, financial institutions and angel investors to increase the access of funding and business opportunities for Malaysia’s biotechnology companies and bio-entrepreneurs.

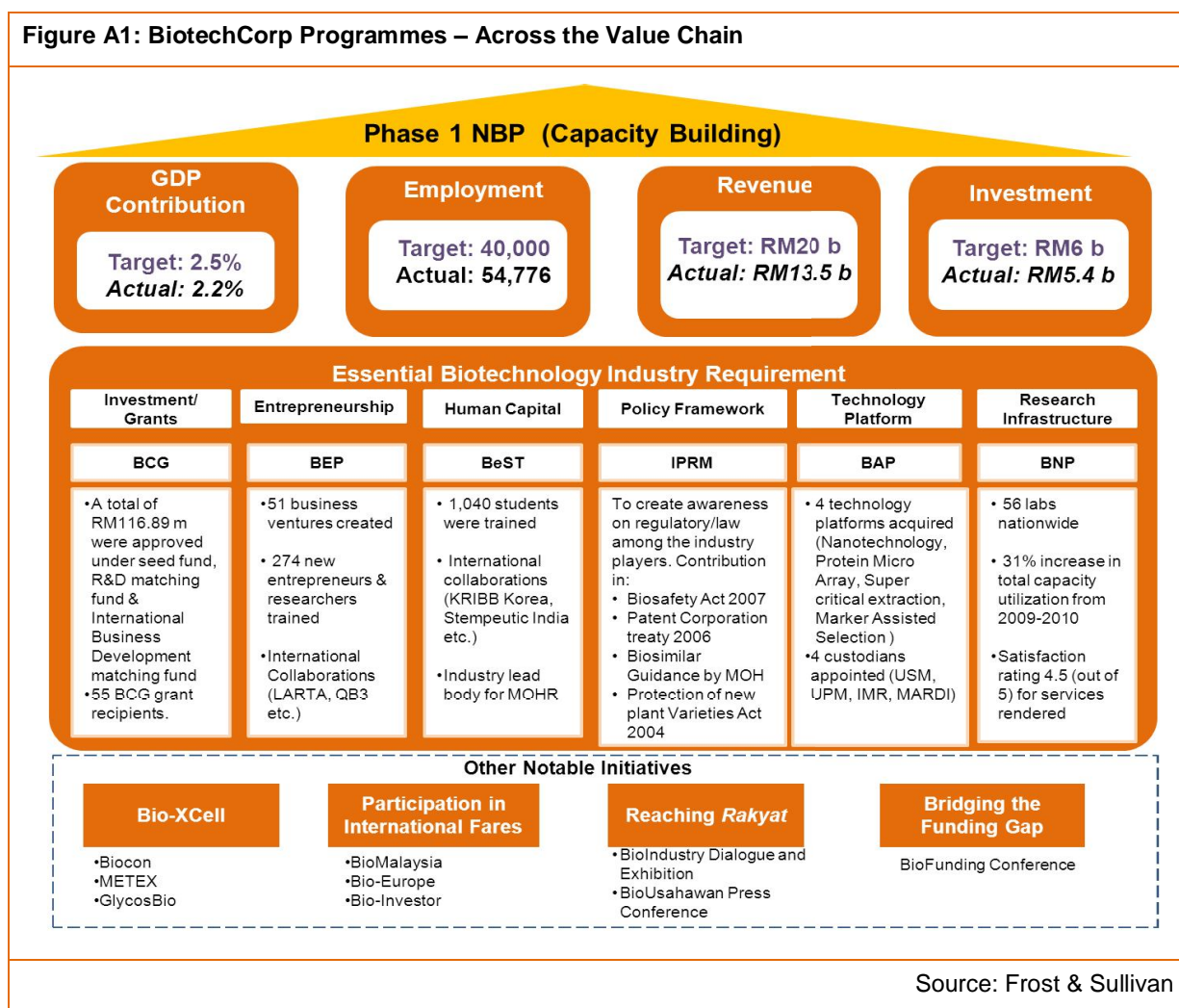
The results of these programmes are reflective of the initiatives taken by the Government. Several programmes with clear measurable benefits are discussed in this report.

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<sup>1</sup> Source: BiotechCorp



**Figure A1: BiotechCorp Programmes – Across the Value Chain**



In order to have measurements of the biotechnology industry performance, Key Performance Indicators (KPIs) were set at the beginning of the Programmes, as per the table below:

Indicators	Actual	Target
<b>Investment by private sector and government</b>	RM5.4b	RM6.0b
<b>Employment</b>	54,776	40,000
<b>Total revenue</b>	RM13.5b	RM20.0b
<b>Contribution to GDP</b>	2.2 percent	2.5 percent

### **Six Focus RMK-9 Programmes under BiotechCorp**

Over the RMK-9 period, BiotechCorp has implemented six focus Programmes that have been the driving force towards reaching Phase 1 NBP objectives. The summary of the activities and achievements on these six programmes is as below:

#### **Biotechnology Commercialisation Grant (BCG)**

BCG has been the key driver providing funds to encourage and facilitate deserving local biotechnology companies with commercialisation capabilities. Fifty five BioNexus status companies have been awarded Seed Fund, R&D Matching Fund and International Business Development (IBD) Matching Fund amounting to RM116.89 million.

The overall fund assessment shows that there is a stronger demand for funding by local biotechnology companies. Many have indicated that continuity of such funding is critical in ensuring the growth of their R&D and hence, commercialisation. Many companies have indicated that the BCG is an excellent effort by the Government and BiotechCorp to help nurture companies at different business stage: from seed level to global presence. The grant recipients expressed appreciation as they have obtained seed level support in order to grow their business and sustain their R&D activities.

BiotechCorp is on the right direction with disbursement of much needed grants to create the critical mass throughout Malaysia's biotechnology industry value chain. The funding strengthens the deserving BioNexus status companies which make them to be more confident to move on aggressively with their business activities.

#### **Biotechnology Entrepreneur Programme (BEP)**

Malaysian biotechnology companies have been mentored to widen their business horizons and to equip themselves with required business expertise and knowledge transfer. BiotechCorp had initiated and completed:

- Mentoring Programmes with US-based QB3, BioPark, Association of University Research Parks (AURP), National Business Incubation Association (NBIA) and LARTA, UK-based Centre for Entrepreneurial Learning (CfEL) of Cambridge University (IGNITE Programmes); Executive-in-Residence (EIR) programmes;
- International conferences and dialogues; and
- Biotechnology entrepreneur workshops.

A total of 16 mentoring Programmes were carried out. These mentoring Programmes were conducted with 35 local researchers with global potential bio-business ideas presenting value propositions to international Venture Capitalists (VCs) and industry experts.

In addition, 14 International Conferences were held during RMK-9 such as Conference on Science to Business – Exploring Entrepreneurship Opportunities in Biotechnology, Industry Dialogue - Double Helix: Decoding Biotech Start-ups and Investment Options in Malaysia, BioFunding and Technology Commercialisation. More than 700 industry participants attended the conferences and dialogues.

A total of 274 new entrepreneurs and researchers were trained from the 31 Biotechnology Entrepreneur Workshops during the RMK-9 period. As a result, 42 ventures (commercialisation projects and technology licensing) and nine spin offs were created from these BEP programmes.

### **Biotechnology Entrepreneurship Special Training Programme (BeST)**

The BeST Programme is designed to bridge the gap between the education provided at the Institutes of Higher Learning (IHLs)/Research Institutes (RIs) and industry requirements. BeST is a six-month intensive and structured re-tooling Programme for graduates from all disciplines, wishing to enter the biotechnology industry and other related industries in general. Combining classroom-based learning, laboratory work and industry internship, the Programme is aimed at equipping graduates with essential skills and knowledge for entry-level positions within biotechnology companies or biotechnology-related companies.

Through the BeST Programme, the participants have widened their skills and knowledge on biotechnology as well as gained appreciation of bio-entrepreneurship. The success of this programme was well demonstrated with actual job placement estimated at 75 percent. In addition; BiotechCorp was awarded as Industry-Lead Body (ILB) for human capital development in Malaysia by the Ministry of Human Resource (MOHR) in April 2011<sup>2</sup>.

### **Intellectual Property Research Management (IPRM)**

The IPRM programme played an important role in carrying out advocacy; capacity building and regulatory review initiatives to promote the development of the local biotechnology industry. The Programme has been instrumental in assisting the relevant policy makers in devising regulatory policies and created public awareness among industry players on regulatory issues.

- The IPRM programme has supported policy makers in their decisions, especially in relation to technology, environment, legal and social implications of the proposed laws and regulations in the Biotechnology Industry. Notable contributions have been contributions to:
  - Accession to the Patent Corporation Treaty on 16 August 2006;
  - Biosafety Act passed by Parliament on 11 July 2007;

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<sup>2</sup> Industry Lead Body (ILB) is an appointed agency/body which is responsible for defining, maintaining and improving human capital training standards under MOHR

- The Biosafety Regulations which came into operation on 1 November 2010;
  - Protection of New Plant Varieties Act 2004 that came into force 1 January 2007;
  - Protection of New Plant Varieties Regulations 2008 which came into operation on 20 October 2008;
  - The Biosimilars Guidance document issued by National Pharmaceutical Control Bureau (NPCB), MOH in August 2008;
  - The Good Clinical Practice (GCP) Inspection Programme issued by the Director of Pharmaceutical Services, MOH in 2010;
  - The Data Exclusivity Directive introduced in 2011;
  - Malaysia became a Provisional Member of the Organisation for Economic Cooperation Development (OECD) Good Laboratory Practice (GLP) Mutual Acceptance Data (MAD) system in 2008; and
  - Target for full adherence to the OECD GLP MAD system by 2012.
- Over 5,000 participants from BioNexus status companies, industry players, IHLs, RIs and government agencies have attended conferences, seminars and workshops during the last three years. Through these conferences, seminars and workshops participants were enlightened and updated about the developments in areas such as Intellectual Property (IP), biosafety, pharmaceutical regulations and international accreditation such as GCP, Good Manufacturing Practice (GMP) and GLP under IPRM.
  - There has been improvement in terms of protection of IP. According to the Intellectual Property Rights Index 2010, Malaysia has moved up six positions to 31<sup>st</sup> from 37<sup>th</sup> in 2009 for the Protection of IP Rights. According to the World Economic Forum's IMD Global Competitiveness Report 2010-2011, in terms of IP protection, Malaysia has moved up four places to 33<sup>rd</sup> from last year's ranking of 37<sup>th</sup>.
  - The patent processing time has now improved from 60 months in 2003 to 43 months in 2010 and the backlog of patent files is currently being addressed; and
  - IPRM has helped to enhance the engagement levels amongst relevant stakeholders such as Intellectual Property Corporation of Malaysia (MyIPO), NPCB, Department of Biosafety, STANDARDS MALAYSIA and Clinical Research Centres (CRC).

### **Biotechnology Acquisition Programme (BAP)**

The BAP plays an important role in jumpstarting the R&D processes and commercialisation activities. With the acquisition of four advanced biotechnology platforms, the Programme is a key driving force in terms of actual know-how and technology transfer to open new possibilities to discoveries in Malaysia's biotechnology and life science sector. The four technology platforms acquired are described below:

- **French Based Nanotechnology platform in non-oncology applications:** Focused on healthcare and immediate applications identified to be developed are in the biopharmaceuticals/pharmaceuticals and medical devices/*in vitro* diagnostics (IVD)

segments. Other potential applications include tissue engineering, nanofiltrations, nanobatteries with supercapacitors, quantum computers, etc.;

- **Australian based DotScan™ Antibody Microarray technology:** Development of immunoassay reagents and therapeutic monoclonal antibodies;
- **Canadian based Marker Assisted Selection (MAS) in plant and animal breeding technology:** Potential new varieties in commercial and food crops, livestock, forestry and aquaculture with desirable economical traits can be produced much faster through targeted breeding methods than the conventional breeding approach; and
- **Dutch based Supercritical Fluid Extraction (SFE) platform technology:** Extraction of high valued flavour/fragrances, food ingredients, nutraceuticals, active pharmaceutical, cosmeceutical ingredients and specialty industrial chemicals on areas that SFE had proven its efficacy and commercial viability. Other potential applications include material treatment and pollution abatement, which are in R&D stage.

To-date, three projects/applications have been approved by the Steering Committee to be developed using the nanotechnology platform:-

**Two projects/applications from *Universiti Sains Malaysia (USM)*:-**

- Drug Delivery System (DDS) for Tuberculosis. Using Nanosilica-based platform to develop new silica based particles as carriers for therapeutic molecules/biomolecules in DDS application. Tuberculosis has been chosen as the disease to be treated in the DDS proof-of-concept (POC); and
- Gold-conjugated antibody for diagnostic applications.

**One project/application from *Cerebro Sciences Sdn. Bhd*:-**

- Neuron specific delivery of gonadotropin-releasing hormone (GnRH) in small interfering ribonucleic acid (siRNA) for drug delivery.

It is expected that the acquisition of the four platform technologies will improve industry performance in a shorter time-frame and create new business opportunities through various applications, thus driving the overall growth of the industry.

**BioNexus Partners Programme (BNP)**

BNP allows local and foreign biotechnology companies to access laboratories and infrastructure in local IHLs/RIs to undertake product testing and research to enhance productivity of the companies. Through the BNP Programme, 56 laboratories and units owned by IHLs<sup>3</sup>/RIs have been opened up for access to biotechnology industry. Out of these BNP laboratories/units, 87.5 percent have been utilised by the industry as at the end of the RMK-9

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<sup>3</sup>All in Public Universities in Malaysia.

period. Primary research showed that the industry players gave an average score of 4.5 (on a scale of one to five, with five being the highest) for their level of satisfaction with BNP labs/units services. This reflects the quality of BNP services rendered and acceptance by the industry players.

### **Strategic Recommendations:**

#### **Strategies to Attract Foreign Direct Investment (FDI) and Encourage Domestic Direct Investment (DDI) into the Malaysian Biotechnology Industry:**

##### **1. Market Guided Funding Mechanism to Encourage Growth of a Venture Economy**

In tandem with Phase 2 NBP (Science to Business), which emphasises on entrepreneurial activities and commercialisation, there is a requirement to develop a conducive biotechnology ecosystem and funding accessibility. This should take into consideration a broad view and address not just the availability of capital but also other components of the ecosystem. The Government can consider providing matching funds through Public Private Partnership (PPP) as a de-risking mechanism for both private and public sectors. There is a need to develop industry-led technology foresight focusing on niche areas, which then needs to be supported by matching funds.

##### **2. Increase Seed Funding From Government Sector**

Seed funding is one of the critical elements to build the critical mass to form a solid foundation within the Malaysian biotechnology industry. Financial support is needed to create critical mass to enable integrated service and equipment in biotechnology development throughout the value chain.

#### **Strategies to Create Value-Added and Quality Employment:**

##### **3. Building Global Reputation of IHLs and RIs**

In line with global standards in technology commercialisation, Technology Licensing Office (TLO), especially in IHLs/RIs need to be more “inventor and investor friendly”. There should be less emphasis on maximising licensing revenue, and greater focus on deployment of Malaysian technology to the marketplace. Most technologies in Malaysia do not grow from Proof Of Concept (POC) to commercialisation stage. Malaysian bio-entrepreneurs and scientists need to be aligned to global best practices, where R&D is more market driven.

To foster biotechnology commercialisation, there is a need to introduce apprenticeship programmes in IHLs’ syllabus at undergraduate and postgraduate levels. Additionally, building a network of bio-entrepreneurs, VCs and angel investors by Technology Transfer Offices (TTOs) will further spur commercialisation activities.

While initiatives for accreditation and developing research labs has already been undertaken by the Government, there is also a need to provide funding support for maintaining and operating these state-of-the-art laboratories, to ensure greater usage in the interest of promoting biotechnology in the country. In addition, engagement of international service companies to

establish new facilities and/or collaborate with local laboratories in upgrading existing facilities will build credibility of these laboratories and attract international investors to invest in local technologies.

#### **4. Tapping into Global Biotechnology Experts**

BiotechCorp could tap the top brains from around the world to form a network of experts in niche biotechnology areas. This network could be made up of Malaysians living abroad and/or foreign overseas experts. Local biotechnology companies would then get connected directly through these link-up programmes to get mentoring or specific expertise not available previously.

#### **Strategies to Increase Total Revenue of Malaysian Biotechnology Companies:**

#### **5. Create Opportunities for Bio-innovation through Government Procurement**

The adoption of local innovation by governments will give confidence to potential foreign buyers as it serves as an informal certification on the quality of these innovations. Engaging suppliers early, managing their expectations and increasing the transparency and accessibility of the process will support more bio-innovations from local biotechnology companies.

#### **Strategies to Increase GDP Contribution through the Biotechnology Industry:**

#### **6. Positioning Malaysia as a Global Biotechnology Hub**

BiotechCorp has initiated efforts to promote the Malaysian cluster globally. These efforts need to be sustained and intensified in view of the competition between clusters for investments and funding. Malaysia needs to be positioned as a strong and distinct biotechnology hub with a vibrant and sustainable ecosystem.

#### **7. Launching Innovation-Focused Missions**

It is important to apply biotechnology to both developmental and operational activities at working levels (e.g. community, farm and enterprise level). The approach will focus on Malaysia specific issues and serve as an organised framework that rallies specific knowledge and other resources (e.g. biomass management, tropical diseases management, food security and natural resource management).

#### **8. Conduct Industry-led Technology Foresight Exercises**

A long-term industry-led scientific and technological forecast is needed and should be integrated into the unified system of long-term strategic management of the Malaysian economy. It should include the maximum possible applications of selected methodologies to implement biotechnology development priorities, in both applied and fundamental research based on the industry needs.

#### **9. Review of Strategies within the NBP**

Innovation and industry performance can be used as important feedback to direct existing and future policies. Successful bio-innovation policies should be tailored to our strength and niches, with specific market-driven adaptive policies in place to encourage continuous industry growth.



Current strategies within the NBP need to be aligned with technology and market development, taking into consideration current and future national needs.

### **Conclusion**

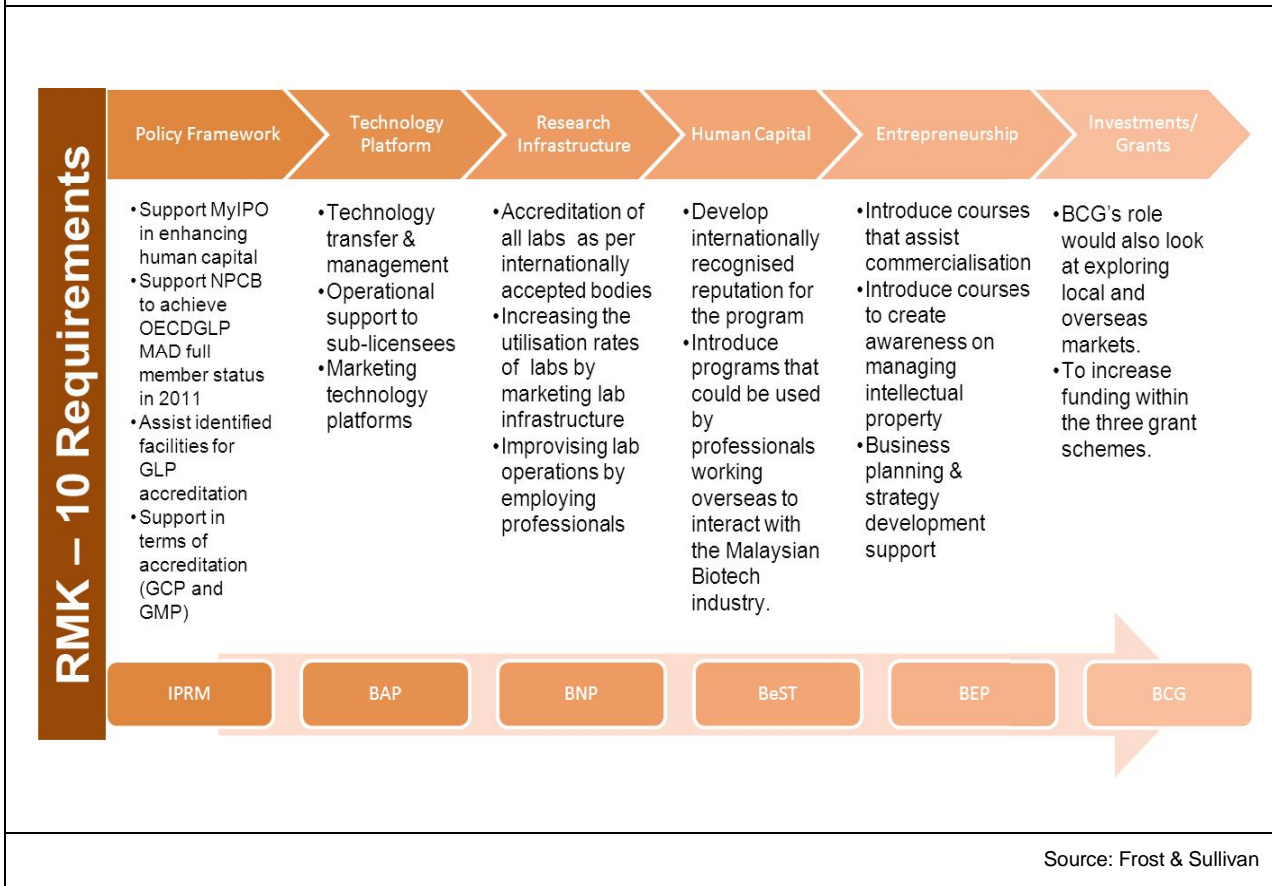
Phase 1 NBP was well-linked to the Government's economic goals and has been adequately supported by specific Programmes initiated by BiotechCorp. While the critical elements of vibrant biotechnology ecosystem are present in Malaysia, continuous effort and public sector support is needed to strengthen these building blocks in Phase 2 NBP:

- Due to its inherent nature, the biotechnology industry takes longer to mature and requires more funding in comparison to other industries;
- Continuous investment from both public and private sectors is essential to create the critical mass leveraging on BioNexus status companies;
- The funding gap to create critical mass need to be addressed to build a strong and sustainable industry base;
- While the fundamental talent pools are present in Malaysia, specialised skills are required in Phase 2 NBP across the value chain of local biotechnology industry; and
- Most of the BioNexus status companies are in the start-up and growing stage, such that the priority will be to grow and develop these companies via targeted collaborative programmes. This will require further nurturing activities while building momentum on revenue generation from these companies.

Recognising these industry gaps, continuance of the Six Programmes (under BiotechCorp) is essential for the Malaysian biotechnology industry to continue to grow. The role of the Programmes need to be revised, enhanced and re-strategised to be more market-oriented to address the commercialisation needs of Phase 2 NBP.



**Figure A2: Requirement of Biotechnology Sector in Phase 2 NBP (During RMK-10)**



Looking at the performance of BiotechCorp within the last five years, the biotechnology industry has managed to make 2.2% contribution towards the GDP, attract RM5.4 billion worth of investments from both private and public sectors, acquired a total of RM13.5 billion in revenue and provided 54,776 jobs in spite of the global financial crisis.

As a result of the initiatives from the Government and BiotechCorp, the biotechnology industry sector has witnessed significant growth compared to pre-NBP era. An enabling environment for biotechnology industry has been built, where Malaysia's society at large can start to receive positive impacts from these efforts. New innovations and technologies were adopted, new specialised and high value jobs were created, public and private collaboration creating value added to local IP and products that attracted investments-all create impacts on Malaysia's economy. With effective execution strategies from the Government and BiotechCorp, the biotechnology sector has shown its potential to drive Malaysia towards a high-income and knowledge-based economy by year 2020 as per national aspirations envisioned in the New Economic Model (NEM).



**RMK – 9  
and the National  
Biotechnology  
Policy**

### 1.1. Three Development Phases

Malaysia has identified biotechnology as one of the new engines of growth for the national economy and it is expected that the sector will generate US\$75 billion (RM270 billion) in revenues by the year 2020. In order to fully realise this potential, the Government has identified the need to create a strong supporting framework to facilitate the long term growth of the sector.

#### National Biotechnology Policy (NBP)

In 2005, the Malaysian government enacted the country's NBP that provides a comprehensive framework to guide the development of the overall development of the local biotechnology industry, with the ultimate vision for Malaysia to be a competitive global player and a leading edge technology business hub in the field of biotechnology.

The policy outlines vision statement, objectives, nine focus areas (or nine policy thrusts) and key recommendations which are critical in creating of a sustained and successful biotechnology sector in Malaysia:

Table 1.1: Highlights of the National Biotechnology Policy	
<b>Brand statement</b>	Biotechnology for Wealth-Creation and Social Well-Being
<b>Policy Statement</b>	Innovation to create wealth by utilising and advancing biotechnology for socio-economic benefits of the nation in accordance with established social and ethic norms.
<b>Vision</b>	Position biotechnology as the new economic engine to enhance prosperity and wellness of the nation by 2020.
<b>Objectives</b>	1. To generate a new engine for growth for the nation by creating value that is competitive, innovative and consistent with the aspiration of Vision 2020.
	2. To formulate an economic, legislative and regulatory framework that will support the development in Agricultural, Healthcare and Industrial Biotechnology.
	3. To identify strategies as part of the implementation plan with the objectives of establishing Malaysia as a competitive nation with the capacity to develop leading edge business.
	4. To develop biotechnology to provide better healthcare and medical support that ensures a better quality of life for all Malaysians.
	5. To create greater value from agriculture and the nation's natural resources utilising our unique biodiversity and natural environment; and
	6. To broaden and expedite the applications of biotechnology throughout various economic sectors for maximum benefits.

Source: National Biotechnology Policy, 2006

In the NBP, nine policy thrusts are established to serve as markers for monitoring and benchmarking the progress of biotechnology development.

Table 1.2: The Nine Thrusts of the National Biotechnology Policy		
1	Agricultural Biotechnology	Transform and enhance the value creation of the agricultural sector through biotechnology.
2	Healthcare Biotechnology	Capitalise on the country's biodiversity for commercialising the discoveries of health related natural products and bio-generic drugs.
3	Industrial Biotechnology	Leverage on the country's strong manufacturing sector to increase opportunities for bio-processing and bio-manufacturing.
4	Research & Development, Technology Acquisition	Establish centres of biotechnology excellence, through research & development, as well as technology acquisition.
5	Human Capital Development	Build the nation's human capital through education, training and research activities, with the aim of producing knowledge generation capabilities.
6	Financial Infrastructure	Provide the right financial support via competitive Science to Business funding and incentives to encourage committed participation from academia and the private sector, including Government-linked companies.
7	Legal & Regulatory Framework	Create an enabling environment through continuous review of the country's regulatory framework and procedures in line with global standards and best practices.
8	Strategic Development	Build international recognition for Malaysian biotechnology and find a niche in the global technology value chain.
9	Government Support & Commitment	Realise the execution of policy through the establishment of a dedicated and professional Government agency to spearhead the development of the biotechnology industry with the incorporation of BiotechCorp.
		<i>Source: BiotechCorp, 2008</i>

In planning to turn Malaysia into a global player in biotechnology by the year 2020, the NBP had outlined three development phases that can be summarised as follows:

<b>Table 1.3: Targets as per the NBP</b>		
<b>Phase 1 NBP (2005-2010): Capacity Building</b>	<b>Phase 2 NBP (2011-2015): Science to Business</b>	<b>Phase 3 NBP (2016-2020): Global Business</b>
Provide Biotechnology Development Incentives	Intensify FDI Participation	Consolidate Strengths and Capabilities in Biotechnology Development
Improve Human Capital & Skill Development	Expand Pool of Knowledge Workers	Intensify Expertise And Strength in Drug Discovery And Development
Improve Job Creation	Intensify Spin-off Companies	Create Leadership in Innovation And Technology Licensing
Intensify R&D	Develop Expertise in Drug Discovery And Development Based on Biodiversity and Natural Resources	Create Greater Value Through Global Malaysian Companies
Accelerate Development in Agricultural, Healthcare And Industrial Biotechnology	Improve New Products Development	Strengthen Branding of Malaysia as a Global Biotechnology Hub
Legislative and Regulatory Framework	Intensify Technology Acquisition	
Develop Bioinformatics	Develop Capability in Technology Licensing	
Develop BioNexus Companies	Create Global Brands	

Source: BiotechCorp, 2010

### 1.2. Phase 1 NBP (2006-2010): Capacity Building

Phase 1 NBP developments involved adoption of policies, plans and strategies by the Government. On 13<sup>th</sup> May 2005, BiotechCorp was established as the leading developmental agency that facilitates the development of the local biotechnology industry. Wholly owned by Ministry of Finance (MoF) and under the purview of MOSTI, BiotechCorp works under the supervision of Biotechnology Implementation Council (BIC) and advice by the International Advisory Panel (IAP).

The main objective in Phase 1 NBP is to build a strong foundation for biotechnology, focusing on the key success factors for the industry: human resource, regulatory and institutional development.

Initiatives that were carried out in Phase 1 NBP include:

- Capacity building in R&D where steps were taken to establish technology development/ acquisition and programme to boost research productivity and shorten the time required to bring products to the market;
- Capacity building in three major sectors of the industry, which are agricultural, healthcare and industrial biotechnologies. It is envisaged that each of these sectors will present niche areas for Malaysians to explore and expand;

Sector	Focus area
Agricultural	Crop, livestock, marine and aquaculture, natural products
Healthcare	Contract Research Organisation, Contract Manufacturing Organisation, drug delivery and discovery, medical devices and diagnostics, vaccines, therapeutics, genomics, stem cell therapy
Industrial	Biofuel, biopolymer, enzyme, bioremediation, fine, bulk and specialty chemicals

- Provide competitive incentives to sustain growth of the industry. Biotechnology projects face high risks, long gestation periods, substantial upfront capital investment and stringent regulatory compliance. Therefore, a comprehensive funding structure and incentive schemes need to be put in place to address gaps in financing as well as project the government’s commitment to support the industry;
- Development of human resource capital and improvement of skill sets as Malaysia need to increase and retain adequate number of competent knowledge and skilled workers;
- Improve existing legislative and regulatory framework to foster innovation and safeguard investment;
- Set up a Biotechnology Business Accelerator Programme to expedite corporate and business development;
- Leverage on the convergence of ICT and biotechnology to grow the nascent bio-informatics industry. Bio-informatics plays an important support function to gather, store, classify, analyse and distribute biological information derived from sequencing and functional analysis projects; and
- Develop BioNexus status companies as a means of projecting a firm commitment by the Government and to facilitate the marketing of the biotechnology industry. BioNexus status Companies is a group of specialised companies that can support each other to create centres of excellence. Incentives are provided to encourage participation of local and foreign companies.

Through these initiatives, it was anticipated that the level of expertise will increase and more jobs will be created to build an optimistic market prospect for the industry.

### **1.3. Phase 2 NBP (2011-2015): Science to Business**

Phase 2 NBP emphasises more on turning scientific progress into tangible products that provide return of investment to both investors and researchers. The target for Phase 2 NBP is to generate an economic return of about four percent of GDP through various strategies that lead to greater competitiveness for Malaysian companies.

Following are the strategies that will be adopted in Phase 2 NBP:

- Intensify FDI participation through appropriate incentives that may include customised incentives areas critical to the development of the biotechnology industry such as Contract Research Organisation (CRO) and Contract Manufacturing Organisation (CMO) businesses.
- Increase number of knowledge workers in view of high reliance on intellectual capital and knowledge intensive applications;
- Generate “spin-off” companies at the rate of five per year through projects, for instance, business accelerators and technology-based entrepreneurship development Programmes;
- Develop expertise in drug discovery through human resource and R&D development programmes;
- Strengthen basic and applied research on biodiversity and natural resources to create new products;
- Acquire technologies through acquisition of companies and FDI;
- Increase capability in technology licensing as it will strengthen the development of IP rights and strengthen commercialisation of R&D activities; and
- Develop local and global brands through availability of grants and specific trade missions for promotion and marketing.

### **1.4. Phase 3 NBP (2016-2020): Global Business**

For Phase 3 NBP development, the goal is to place Malaysia as a competitive leading edge global biotechnology player. To established the local biotechnology industry as a global business, Phase 3 focuses on:-

- Consolidating the strength and capabilities in technology development;
- Further develop expertise and strength in drug discovery and development;
- Develop biotechnology as a leading edge business;
- Maintain the nation’s leadership in innovation and technologies through projects like technology acquisition and licensing biotechnology;
- Produce at least 20 global Malaysian biotechnology companies in Phase 3 NBP to spearhead the value creation process and growth of the industry; and

- Promote “BioNexus Malaysia” brand to position Malaysia as a global hub, as well as leverage on the consolidated strengths, capabilities and expertise.

It is envisaged that the implementation of strategies under Phase 1 to Phase 3 NBP will ultimately move the country economy up the value chain, create employment and investment opportunities as well as generate wealth and social wellbeing for Malaysian. This is in line with the main objective of the New Economic Model (NEM) by the Prime Minister of Malaysia to achieve high income status nation by the year 2020.





**Placing  
Malaysian  
Biotechnology  
Industry on  
the World Map**

## 2.1. The Beginning of NBP

Biotechnology is identified as the new economic engine that will drive Malaysia towards a high-income advanced nation by the year 2020. The country has rich biodiversity, cost-competitive skilled labour markets, good transportation networks, high-end Information and Communication Technology (ICT) infrastructure, and a cost effective platform for doing business. These combined characteristics provide Malaysia with opportunities to develop an industry base in biotechnology.

To pursue excellence in biotechnology, a biotechnology policy was developed under the RMK-8 led by MOSTI. The aim was to formulate a comprehensive and coordinated approach for the advancement of biotechnology as a strategic sector in the development of the economy.

Malaysia conceptualised and developed the NBP in 2005 with an agenda of creating a strong high value service based industry. Nine thrust areas were identified and initiated to build strong and sustainable biotechnology ecosystem that is fully integrated into national economy. Initiatives under the NBP include clear direction and industry roadmaps to achieve its goal.

Activities and strategic goals that have been executed within the Capacity Building Phase of the NBP aims to lay a strong foundation of infrastructure, policies and more importantly creation of a biotechnology environment. The result is an astounding increase in numbers of quality BioNexus status companies, a brand by itself to propel the Biotechnology industry to be one of the proud wealth-creation pillars of the nation as per the aspirations of RMK-9. The duration has been over a short period of five years but the results have a deep long term positive effect.

Malaysia has a reserve of untapped potential within the Biotechnology sector. The next phase will be the ultimate test of delivery i.e. to build on this strong foundation, to create and commercialise Science to Business.

### **Current Status**

BiotechCorp has received support and recognition for its importance in carrying out its role as the leading development agency for the local biotechnology industry. BiotechCorp's support is crucial as it provides support and catalyst mechanism that leads to the following industry impacts:

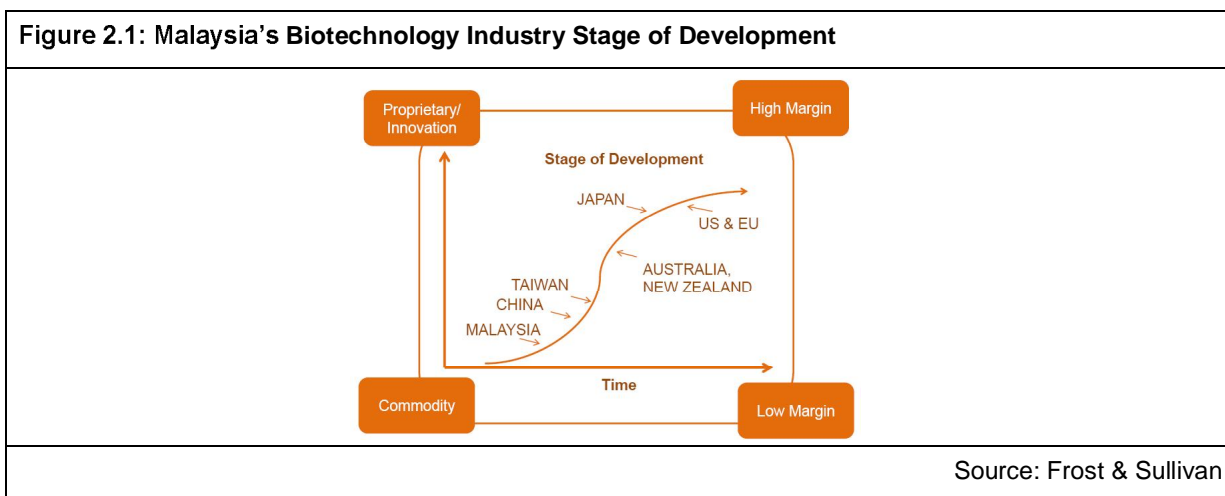
<b>Table 2.1: Current State Analysis (Phase 1 NBP)</b>	
<b>Goals</b>	<b>Current State</b>
Adoption of Policies, Plan and Strategies	Under Phase 1 NBP, the emphasis was on capacity building to lay the foundation for industry growth. The results on broad based economic and social implications are covered in Chapter 3. Programmes based on specific action plans and industry needs are covered in Chapter 4.
Establishment of Advisory and Implementation Councils	Biotechnology Implementation Council (BIC) and International Advisory Panel (IAP) were established comprising key policy makers, industry players, world renowned scientists and entrepreneurs.
Establishment of BiotechCorp	BiotechCorp has played a vital role to act as one-stop centre for biotechnology companies, attract FDI, encourage DDI and create conducive biotechnology industry environment.
Capacity Building in Research and Development	R&D activities are well established in IHLs/RIs. However, entrepreneurial culture and commercialisation activities are limited within the academic community. To address this gap, BiotechCorp has actively created communication platforms, implemented international best practices mentoring and training programmes that bring both industry players and academia through collaborative approach.
Industry Technology Development	Technologies used in the Malaysian biotechnology sector mainly focus on applications like bioprocessing, cell/tissue culture, DNA/RNA sequencing, genomics and fermentation using bioreactors. There is limited use of advanced applications of biotechnology like cell signalling, proteomics, gene vectors and bioinformatics. The focus is to widen research applications to deliver high value products and services across biotechnology sector.
Develop Agricultural, Healthcare and Industrial Biotechnology Initiatives and Projects	The biotechnology industry had attracted total investment of RM5.4 billion, generated revenue of RM13.5 billion and created 54,776 job opportunities in biotechnology (Refer to Chapter 3).
Strengthen Legislative and Regulatory Framework	The following laws, regulations and directives were introduced on biosafety, access benefit sharing, compliance to international standards and guidelines (Refer to Chapter 4).
Business and Corporate Development Programmes	The industry is seeing initial success where two thirds of biotechnology firms are revenue generating. In addition, 52 percent of firms also anticipate commercialisation or projects or products in the next two years. Biotechnology R&D in RIs and IHLs however is still slow to adopt an effective business culture and model, therefore rationalisation and integration between firms and RIs and IHLs can further accelerate this process. Technology transfer is also limited to a handful of collaborations, mainly Memorandums of Understanding (MOUs).

Table 2.1: Current State Analysis (Phase 1 NBP)	
Goals	Current State
Skills Development	One of the major issues faced by biotechnology firms is the availability of strong human capital. Amongst others, BiotechCorp together with various stakeholders e.g. government agencies, IHLs and private sectors had initiated various Programmes such as entrepreneurship, regulatory, specialised biotechnology skills and soft skills
Job Creation	A total of 54,776 jobs were created. The next step is to create specialised job opportunities to cater for Phase 2 NBP needs.( especially human capital for commercialisation).
Regional Biotechnology Hubs	Development of incubation infrastructures with a central location within the region and potential identification of core incubation areas which are attractively located regionally throughout Malaysia. Notably, Bio-XCell, the envision biotechnology ecosystem in Iskandar Development Region, Johor, has attracted more than RM1.0 billion FDI to date.
Develop BioNexus Malaysia as a Brand	The BioNexus Malaysia is a well-recognised brand locally with firms seeing the benefit of the Status. It has been one of the key drivers of the establishment of biotechnology firms in Malaysia. The next step will be further developed at international level to attract investment into Malaysia biotechnology industry.

## 2.2. Placing the Malaysian Biotechnology Industry on the World Map

The global Biotechnology market takes a longer period to mature due to its extensive processes and standards required to be fulfilled. Countries like US and EU lead the industry with vast experience of three to four decades. Other countries that have joined the bandwagon are now reaping huge benefits despite economic challenges and uncertainties. Each country is finding its own niche, for example, Japan is a world leader in bio-food processing technologies. This breakthrough had created a tidal impact that revolutionised the biotechnology business landscape in Japan.

Figure 2.1: Malaysia’s Biotechnology Industry Stage of Development



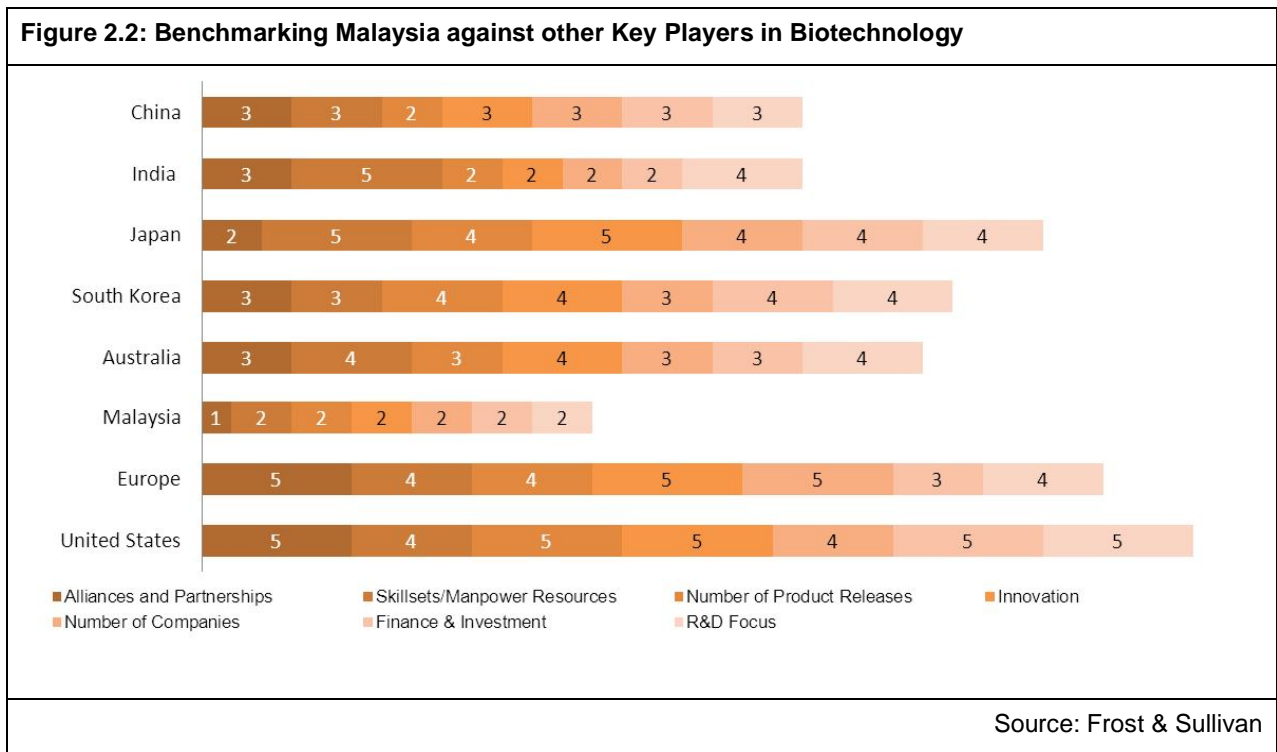
Source: Frost & Sullivan

OECD countries in Asia Pacific that have higher number of biotechnology firms than Malaysia are Australia and South Korea. These countries started biotechnology plans and strategies much earlier and have a relatively more mature sector. South Korea and Australia have between 500 to 800 biotechnology firms respectively, compared to 187 BioNexus status companies in Malaysia that experienced praiseworthy growth.

An analysis of economies that are well-established and emerging in biotechnology, demonstrates that Malaysia has achieved a level of credibility and an industry base within biotechnology. However, Malaysia has to advance further before it is considered a strong contender in all aspects of the benchmarked indicators.

A competitive benchmarking of Malaysia vis-à-vis other countries in biotechnology, on key aspects of alliances and partnerships, manpower, biotechnology products, innovation, biotechnology companies, investment in the industry, as well as R&D focus, shows that Malaysia is still a very new developing nation in biotechnology.

In a study conducted in 2009, Malaysia was seen as a new and emerging biotechnology industry player. Figure 2.2 illustrates the aggregated scores by country or region for Malaysia and other key Asian economies, as well as Europe and US.

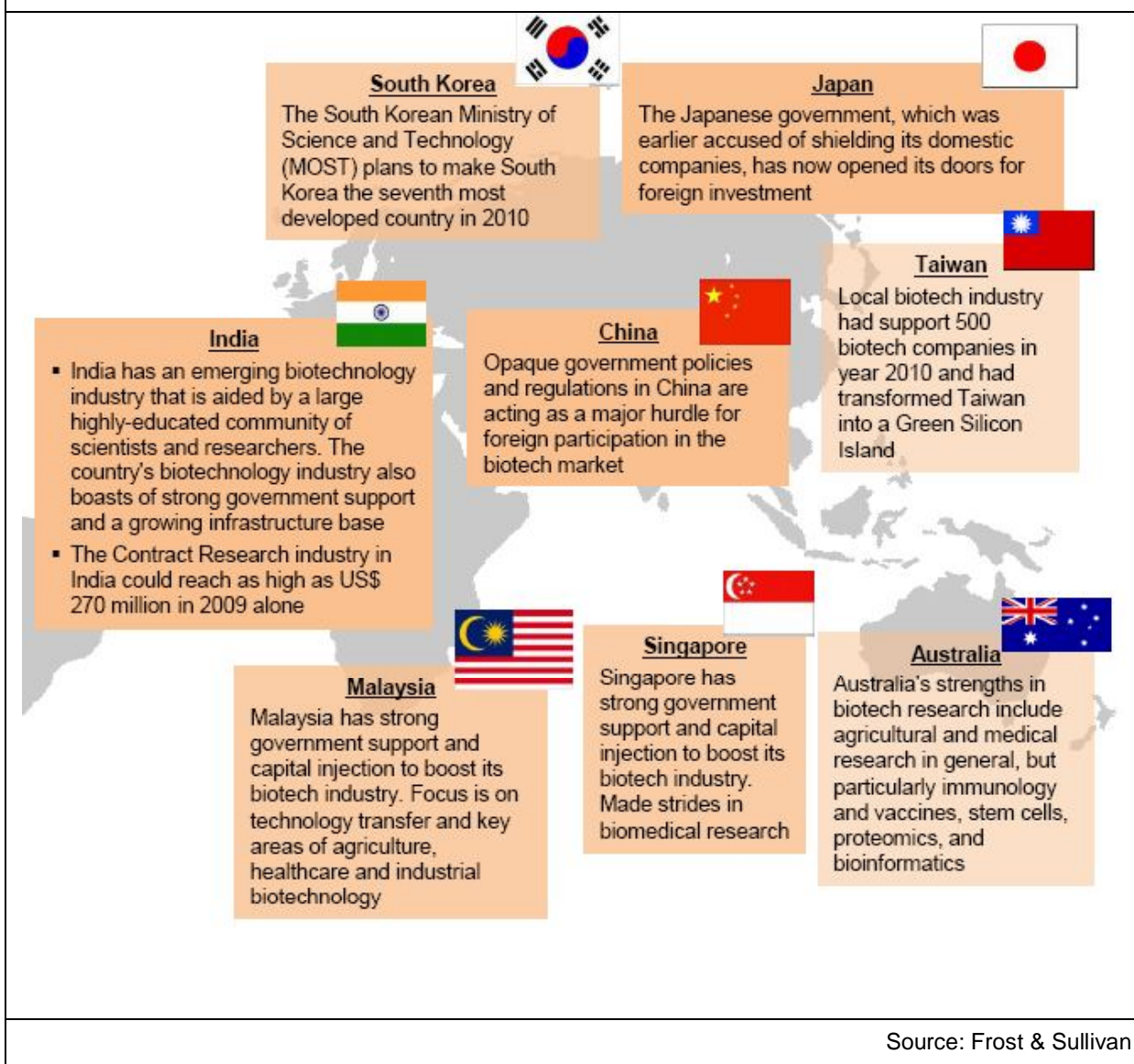




### Asia Pacific (APAC) Benchmarking At a Glance

Taiwan, India and Korea are examples of the fastest growing clusters globally. Taiwan has a strong base of 500 Biotechnology companies whilst India has a large base of professionally experienced scientists. Asian countries are beginning to catch up within the value chain and are already making inroads with the private sector through collaborations to conduct contract research of high value.

**Figure 2.3: Biotechnology Industry Development in APAC**



### 2.3. Benchmarking against the Evolution of Other Biotechnology Clusters

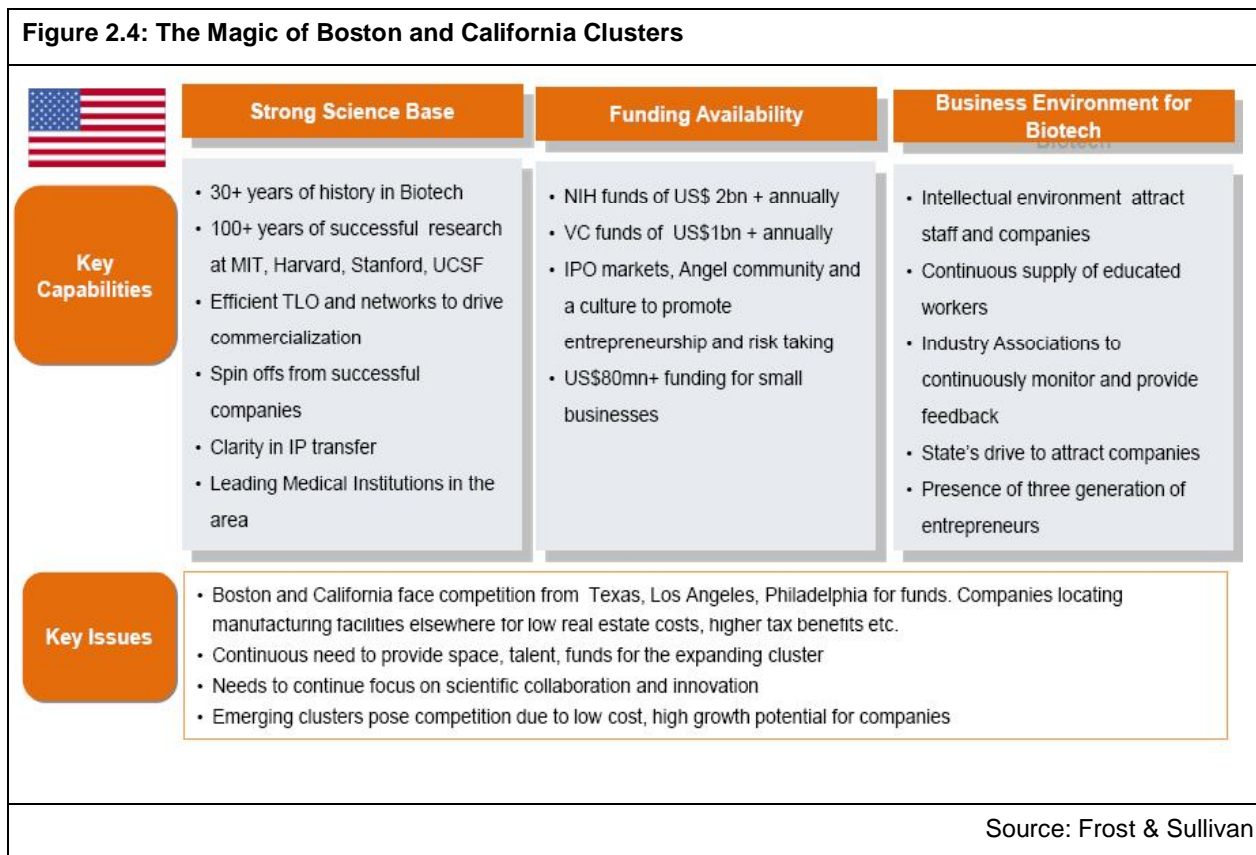
Malaysia's biotechnology industry is relatively new compared to the global biotechnology industries. The key advantage that Malaysia has lies in its natural biodiversity, mature commercial agriculture industry, availability of biomass and trainable human capital.

Table 2.2: Global Major Biotechnology Clusters						
	California	Boston	Medicon Valley	Korea	Singapore	Malaysia
<b>Year Started</b>	1978	1978	1995	Initial: 1982 Phase 1: 2000	2000	2005
<b>No. of companies</b>	2,000	1,300	500	700 pharma, 600 biotech, 2000 medical devices	Over 130 global biomedical companies	187 BioNexus status companies
<b>Sector size and growth</b>	Lifesciences contributed \$ 75bn in 2008, a growth of 2% over 2007	Biotechnology annual growth rate of 7% during 2003-2007	N/A	Pharmaceutical was US\$14bn in 2007 growing at 10% during 2001-2007. Biotech was US\$3.3 bn in 2006 growing at 18% during 2001-2006	Biomedical sector was US\$15bn (S\$20.7bn) in 2009 a CAGR of 14% during 2000-2009	US\$ 4.5bn growing at CAGR 39% over period of 2006-2010 period
<b>Venture Capital Funding (Private Funds)</b>	US\$3.4 bn in 2009	US\$1.1 bn in 2006	US\$940 mn in 2006	N/A	US\$100 mn in 2009	US\$ 1.98bn in 2010
<b>Research Institutions</b>				>100	17	43
<b>Direct Employment</b>	274,000	72,000	40,000	63,000	16,000	13,690
<b>Population</b>	7.4 mn (SF Bay Area) 2.7 mn (San Diego)	4 mn (Greater Boston)	3.2 mn	48 mn	4 mn	27mn
<b>Region Area (sq km)</b>	18,000 (SF Bay Area) 840 (San Diego)	12,105 (Greater Boston)	1,788 (Zealand) 10939 (Scania)	98,480 (country area)	682	2,500 (5 economic corridors)

Source: Frost & Sullivan

California and Boston lead the race after having been established more than 30 years ago. Combined, they boast a strong number of 3,300 companies. California has a workforce of over 274,000 dedicated to the biotechnology industry with huge capital investments flowing in each year.

**Figure 2.4: The Magic of Boston and California Clusters**



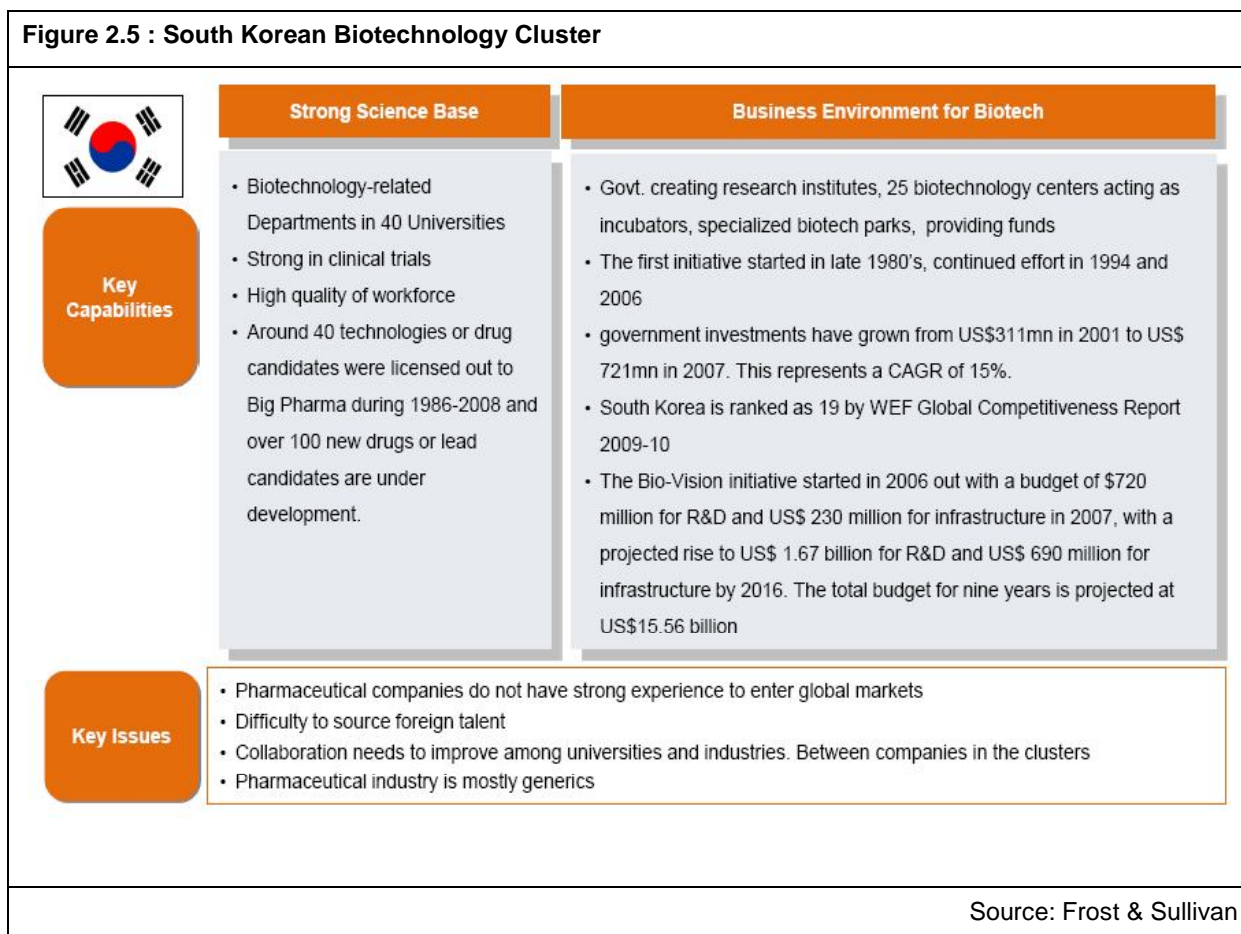
*Analysis*

A mature industry with strong science base, funding availability and business environment

- It has taken over 30 years for the industry to mature with successful research with leading education hubs;
- Focus has been on having clear guidelines on transferring IP and know-how;
- Strong domain expertise and over 100 years of research;
- VC funds make up half of overall US\$3.8 billion funds received annually;
- Strong advisory panel that monitor and provide valuable feedback to industry; and
- Over three generations of entrepreneurs with strong skill sets.



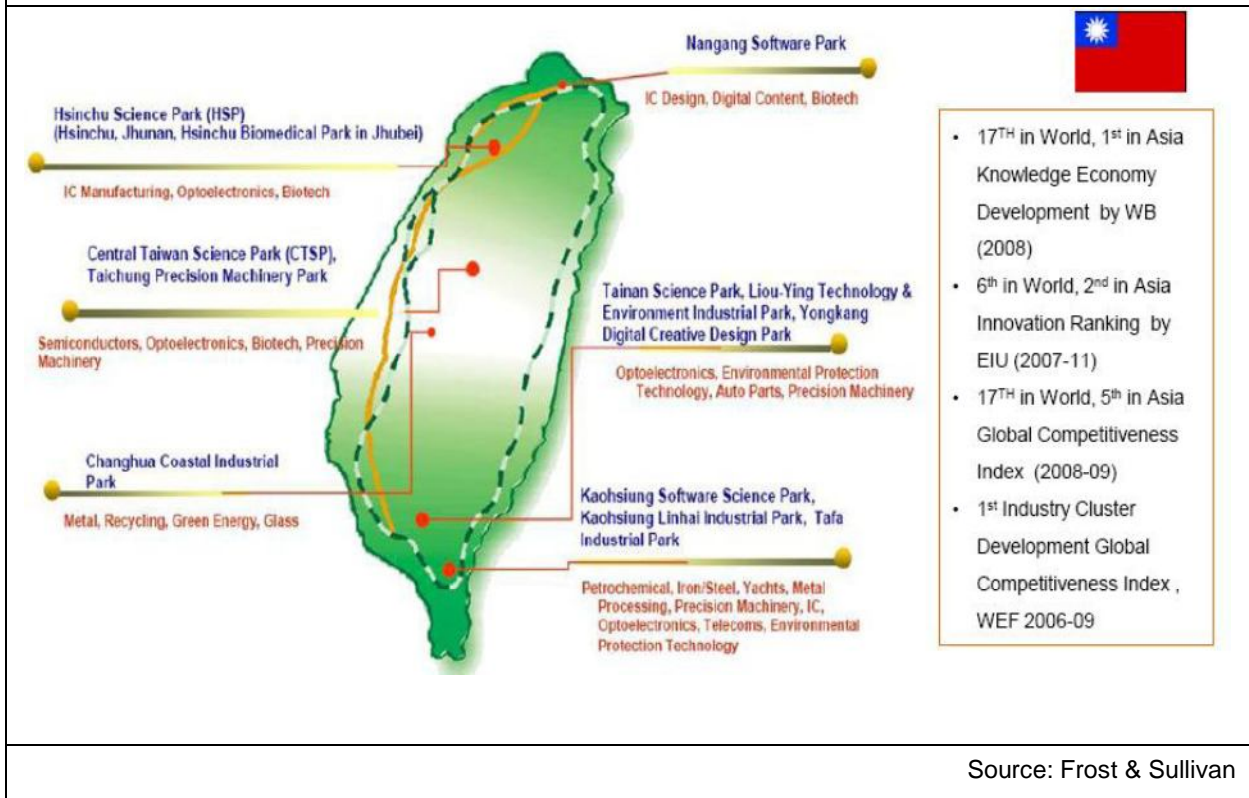
**Figure 2.5 : South Korean Biotechnology Cluster**



**Analysis**

- Very strong domain expertise mobilised out of IHLs/RIs;
- Expertise in conducting clinical trials;
- Over 40 technologies were licensed out being the key activity leading to commercialisation;
- Over 25 strong incubators with effective nurturing activities from Korean government;
- South Korea is ranked 19<sup>th</sup> by WEF Global Competitiveness Report 2009-2010;
- Over three decades of experience; and
- Total government allocation of US\$15.56 billion under Bio-Vision initiatives is projected for nine years till 2016.

**Figure 2.6: Taiwan Hi-Tech Cluster**



*Analysis*

- Taiwan has strong industry clusters, e.g. Hsinchu Science Park (HSP) and Tainan Science Park;
- It has dedicated Biotechnology clusters and is first in Asia in the Knowledge Economy;
- Taiwan is working on becoming the next green Silicon Valley; and
- Over 500 Biotechnology companies have been developed.

## 2.4. Highlights of Malaysian Biotechnology Industry during RMK-9

Malaysian biotechnology industry has witnessed excellent growth during the RMK-9 period. While some of this success can directly be attributed to the government initiatives, others are indirect results of long term planning by the Government. Some of these successes have been highlighted in this section.

### 2.4.1. BioNexus Status Companies on the Global Map

#### *About BioNexus Status*

BioNexus status is a designation awarded by the Malaysian Government through BiotechCorp to qualified local and foreign biotechnology companies, making these companies eligible to privileges under the BioNexus Bill of Guarantees, grants and tax incentives.

The brand BioNexus is promoted to market Malaysia's biotechnology initiative to investors and potential partners. BioNexus leverages on the strengths of existing institutions and ecosystem.

Malaysia is a new entrant in global biotechnology industry. Looking back at the past five years, we witnessed global financial market meltdown due to subprime crisis in US, and rising food and oil prices that triggered riots. Despite many challenges during the first phase of the NBP (2005-2010), several BioNexus status companies have successfully crafted their niche market, with widely recognised products, high profile Initial Public Offerings (IPOs) and reverse take-over exercises, in both local and overseas bourse market.

Brief overviews of some of the key BioNexus status companies are provided below:-

#### **PureCircle Ltd**

PureCircle Ltd<sup>4</sup> is a world leading provider of natural sweeteners to the global food and beverage industry. A Malaysian home grown company, PureCircle specializes in a natural high-intensity sweetener known as *rebaudioside-A* or *reb-A*, which is derived from the *Stevia rebaudiana* plant, known as 'honey leaf' in its native South America. The PureCircle Group currently operates on a regional basis from eight offices, including:

- Americas (USA, Paraguay)
- Europe Middle East Africa-EMEA (Switzerland, Russia)
- Asia Pacific (Japan, Australia, Malaysia, China)

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<sup>4</sup>Official Website of PureCircle Ltd: [www.purecircle.com](http://www.purecircle.com)

The Group operates a B2B business model and has a consolidated supply chain positioning. The Group currently operates from the world's largest stevia extraction and refinery located in China and Malaysia respectively. Reb-A's growing acceptance by global food and beverage companies as an additive or even replacement for sugar has been accelerated by regulatory approvals, with Australia, New Zealand, Switzerland and the US all approving in the second half of 2008. This resulted in the launch of several global brands containing Reb-A including PepsiCo's Sobe LifeWater, Coca-Cola's Sprite Green and Cargill's Truvia table top sweetener.

PureCircle is listed on the London Stock Exchange AIM market with current market capitalisation of RM1.8 billion (February 2011). PureCircle raised US\$50m (£31m) when it was floated in late 2007 and has since rapidly developed its supply chain and manufacturing capability, as well as promoting its high-intensity natural sweetener in international markets, where a series of regulatory approvals have led to a rapid growth in potential demand. It is noteworthy that significant amount of investment and income has been generated by its BioNexus status company; PureCircle Sdn. Bhd. PureCircle's achievements have been recognised by the readers of the Financial Times Investors Chronicle who in 2009 voted PureCircle as AIM International Company of the Year.

#### **Holista CollTech Ltd**

Holista CollTech Ltd<sup>5</sup> is a research-driven Biotechnology company, a result from a strategic reverse take-over of CollTech Australia Ltd by Malaysian BioNexus status company, Holista Biotechnology Sdn. Bhd. The Group is dedicated to deliver first in class natural ingredients and wellness products. It is the only company producing sheep (ovine) collagen using its patented extraction methods and is on track in nano-nising and liposome encapsulating the Ovine Collagen. The company researches, develops, manufactures and markets "health-style" products to address the unmet and growing needs of natural medicine and wellness. Some highlights of achievements are:

- Development of various products based on its patented technology: Pristine™ (Toxic-free fish oil), VavAlert™ (Extract of Belgian chocolate and green tea that is clinically proven to improve alertness, concentration and memory), Lacto-5™ (locally cultured probiotic bacteria ensuring better adaption to Malaysian gastro-intestinal tract), NarcoX™ (Natural pain relief solution) and other value added applications in cosmetics and medical healthcare.
- Joint venture with an Indian company, Hi Tech Biosciences India Ltd of India (HTBS) to set up a plant in Pune, India, to produce herbal extracts for export. HTBS, which has developed a proprietary process that can expedite herbal extraction and cut manufacturing costs. HTBS will continue to conduct R&D, procure the herbs and extract them to the specification.

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<sup>5</sup>Official Website of Holista CollTech Australia Ltd: [www.holistaco.com](http://www.holistaco.com)

- Complete patented solution for “4S Tsunami” of Salt, Sugar, Starch and Saturated Fat that threatens the fast food industry due to the shift of consumer preference:
  - i) Patented low fat chip: Pre-soak process that would reduce the fat pull into the chip by 40 percent, giving consumers potato chips that are less oily, less in calorific value and crispier;
  - ii) Final stage of low sodium technology that would allow a 40 – 60percent reduction in sodium without compromising the “saltiness” or leaving a “metallic after taste”.

Holista CollTech Ltd continues to work with local and international companies and research institutions to further enhance and diversify the current product portfolio. With its current estimated market capitalisation of RM57 million (February 2011), Holista CollTech is a fine case where a Malaysian biotechnology company has found its unique niche in the global market.

#### **Malaysian Genomics Resource Centre Bhd.<sup>6</sup>**

First-of-its-kind Asia Pacific bioinformatics applications services company being listed in Malaysian ACE market, Malaysian Genomics Resource Centre Bhd. (MGRC) specialises in bulk processing and complex analysis of large volumes of genomic data generated through high throughput DNA sequencing technology, translating these data into meaningful biological information for post-genomic work. The Genomic Data Access Services enables the local and international life sciences community to access MGRC’s online bioinformatics applications services at no cost pursuant to the arrangement with BiotechCorp.

The IPO of MGRC attracted attention from local and foreign investors as seen by a 28.7 times oversubscription on its shares. The company successfully raised RM18.5 million from the IPO exercise. The market capitalisation was estimated at RM67 million (February 2011).

In June 2011, MGRC had launched a range of comprehensive genetic screening services and all-in-one test for a multitude of infectious diseases. These services will be made available through hospitals and other primary care facilities around Malaysia. Access to information from the results of a genetic screening test can help to reduce the threat posed by both genetic and infectious diseases, through early detection and treatment.

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<sup>6</sup>Official Website of Malaysian Genomics Resource Centre Bhd.: [www.mgrc.com.my](http://www.mgrc.com.my)

### *Emerging BioNexus Status Companies*

#### **Myagri® Group<sup>7</sup>**

Myagri® Group of Companies is a group of biotechnology companies dedicated to providing more efficient, effective and environmentally friendly solutions to agricultural and environmental management challenges. Myagri® Principal activities consist of identifying, isolating, and propagating beneficial microorganisms that are aimed at improving crop productivity, land rehabilitation, bio-remediation of wastes and long term sustainability of agriculture.

To date, Myagri® had successfully commercialised several products that are in demand from the Plantation and Agricultural Industries e.g. MYCOgold® (premier product containing a concentrated mixture of several species of Arbuscular Mycorrhiza fungi), TRICHOfgold® (Plant defence booster containing Trichoderma sp. TRICHOfgold® will protect the plants by acting as fungal antagonist and mycoparasitic against pathogenic fungi, METAXORB® (Fungal based solutions for the problem of Rhinoceros Beetle Problem in the Oil Palm Sector) and aGricare®.

Bio-Organic is a premium mature green waste compost with key beneficial microbes such as Bacillus Megaterium (Free Living Nitrogen Fixation Microbes), Mycorrhiza and Trichoderma. Besides these products, Myagri® also offers land rehabilitation consultancy services such as for ex dumping area, highway green lung maintenance, green biosciences technology transfer program and advisory on product development."

#### **Hopematic Sdn. Bhd<sup>8</sup>**

Hopematic Sdn. Bhd. (HOPEMATIC) is a research-driven company fully equipped with commercialisation and marketing units, which specialises in herbal preparation, health and functional foods. It is one of the subsidiaries of INS Bioscience Bhd., among the pioneer biotechnology companies listed on the Bursa Malaysia ACE market.

By harnessing the country's abundant natural biodiversity, HOPEMATIC focuses in R&D of novel herbal based products that provide medical and health benefits, including prevention and management of diseases such as hypertension, diabetes, cardiovascular and liver disease. The core products range from home care, nutraceuticals to modern traditional herbal medicine and phytochemical products. With their in house R&D capabilities, international collaborations, compliance with GMP and ISO 17025 standards, the Company has successfully formulated winning global products.

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<sup>7</sup> Official Website of Myagri® Group of Companies: [www.myagrigrp.com](http://www.myagrigrp.com)

<sup>8</sup> Official Website of Hopematic Sdn. Bhd.: [www.hopematic.com](http://www.hopematic.com)

### **InQpharm Sdn. Bhd.<sup>9</sup>**

InQpharm is a biopharmaceutical company that engages in the acquisition, R&D and commercialisation of unique natural compounds with nutritional and therapeutic properties for the nutritional, animal health and medical device/pharmaceutical markets.

As a bio-pharmaceutical incubator, InQpharm acquires exploration and commercialisation rights of novel biological therapeutic compounds, usually from small scale innovators and research institutions.

InQpharm adds value to such compounds through strong branding and conceptualisation, IP, raising production standards to a pharmaceutically acceptable standards and conducting industry standard safety and proof of principle studies (both pre-clinical and clinical), before making a decision on how it is going to commercialise each technology. InQpharm distributes its products in more than 35 markets at present. InQpharm's current compounds/technologies cover anti-microbial, immuno-modulating, anti-inflammatory and anti-obesity applications. InQpharm's medical device technologies cover obesity, allergic rhinitis, insomnia, migraine and erectile dysfunction.

### **Nova Laboratories Sdn. Bhd.<sup>10</sup>**

Nova Laboratories Sdn. Bhd. is a private Malaysian company that is involved in development and marketing of high quality animal health products. They then moved into R&D and manufacturing of herbal based supplements and novel phytopharmaceutical products. Its long term commitment in the area is further reflected in the establishment of a GMP compliant facility at its headquarters in Sepang which is complete with advanced scientific extraction facilities.

The Company currently has 26 herbal products currently being marketed in the Malaysian market and hopes to double its product offering. To date, the company has received approval from MOH to market another 22 other products while another 10 are pending approval. The greatest achievement is the development of Hepar-P, a phytopharmaceutical product, that contains active compound extracted from a local plant called “*Dukung Anak*” or scientifically known as *Phyllanthus nirur*. The product is said to possess a cure for Hepatitis B and is currently undergoing clinical trials at Selayang Hospital.

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<sup>9</sup> Official website of InQpharm Sdn. Bhd.: [www.inqpharm.com](http://www.inqpharm.com)

<sup>10</sup> Official website of Nova Laboratories Sdn. Bhd.: [www.nova.com.my](http://www.nova.com.my)



## **Return 2 Green Sdn. Bhd<sup>11</sup>**

Return 2 Green Sdn. Bhd. is involved in R&D and manufacturing of bio-degradable, eco-friendly packaging products made from biomass agricultural waste.

The Company's inventions comply with and have passed European Regulation, USA Regulation and other related regulatory standards at international level on biodegradation and compost ability. A 4-acre factory was set-up at Prai Free Trade Zone (Penang) with state-of-the art technology and facilities. Mass-production commenced in April 2010, catering for the international market.

### **2.4.2. Bio-XCell in Iskandar Johor: Custom Built Biotechnology Ecosystem**

Malaysian Bio-XCell Sdn. Bhd. ('Bio-XCell') was incorporated on 30 October 2009 to develop a comprehensive, state-of-the-art biotechnology ecosystem in Malaysia with the objective of reinforcing Malaysia's efforts in developing the local biotechnology industry. More than a Biotechnology park, Bio-XCell aims to build a conducive Biotechnology ecosystem to support manufacturing and R&D for the industrial and healthcare Biotechnology sectors. It is a platform where Malaysia pools the soft infrastructure – financial incentives, human capital development, business and operational set-up, advisory and services and attractive leasing models, along with the hard or physical infrastructure that will enable companies to springboard their Biotechnology business and commercialisation activities.

Bio-XCell is a joint venture between BiotechCorp and UEM Land Holdings Berhad ('UEM Land'). The Bio-XCell project entails the development of a 72.53-acre biotechnology park in Iskandar Malaysia, Johor. The biotechnology park will be developed in three phases over a span of six years, to provide an estimated 1.125 million square feet of dedicated, purpose-built space and facilities for biotechnology companies.



To date, Bio-XCell has clinched some RM1.146 billion million investments from deals with three companies, namely India's Biocon Ltd, French group Metabolic Explorer (METEX) and Houston, Texas' group Glycos Biotechnologies (GlycosBio).

Biocon would focus on R&D and production of high-end biosimilars and other biopharmaceutical products in Bio-XCell. The investment is the largest for the Malaysian biotechnology sector thus far. In the first phase, Biocon proposes to invest around RM1.0 billion in this facility which is targeted to be operational by 2014.

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<sup>11</sup> Official website of Return 2 Green Sdn. Bhd.: [www.return2green.com.my](http://www.return2green.com.my)



GlycosBio plans to invest RM46.2 million to set up an industrial biochemical plant and biotechnology research and development facility at the Park. Targeted to start operation by 2012, the plant will produce 20,000 tonnes of bioethanol by end of 2013.

METEX will invest RM100 million to set up a plant to produce glycerine-based 1, 3 propanediol (PDO), commonly used in textile fibre and paints, among others. Malaysia is METEX's first commercial plant, which marks an important milestone in METEX's business expansion plan.

With these foreign investments and international collaborations, it is a vote of confidence to Bio-XCell's capability to be a regional hub for industrial and healthcare biotechnology.



### 2.4.3. Capacity Building through International Collaboration

In Phase 1 NBP initiatives that would accelerate the commercialisation of Malaysian biotechnology companies, were actively rolled-out to prepare local scientists and bio-entrepreneurs. Various Programmes on the nature of business incubation, technical know-how and expertise transfer were initiated to popularise, drive and create new bio-business opportunities in Malaysia.

#### **Strategic Collaboration with South Korea**

The Malaysian-Korean Business Summit 2009 was officiated on 7<sup>th</sup> July, 2009 by YB Datuk Seri Dr. Maximus Johnity Ongkili, Minister of MOSTI. The three-day event was participated in by 25 delegates from South Korea and 50 Malaysian delegates. Three important collaboration agreements were signed:

- BiotechCorp and Korea Research Institute of Bioscience and Biotechnology (KRIBB) to collaborate on technical training;
- SIRIM Berhad and KRIBB for collaboration on talent exchange programme; and
- Ultimate Biotechnology Sdn. Bhd. and KRIBB for collaboration on development of bio fertilizers using palm oil mill waste.

The signal from South Korea to the Malaysian biotechnology industry is clear. Korean biotechnology companies are looking at Malaysia not only in terms of exploring and enhancing business ties, but also as a springboard to the vast ASEAN market which is already a free trade area. Malaysia can play an important role in creating better market access for South Korea's biotechnology companies to penetrate into the 10-nation market of 600 million people with a combined GDP of US\$1.4 trillion.

Malaysia is also seen by the Korean biotechnology companies as an important hub for the global *Halal* market. With an estimated 1.8 billion Muslim consumers worldwide, the value of the current global market for *Halal* food and non-food products is estimated to be around US\$2 trillion annually. The Korean biotechnology companies are keen to collaborate with Malaysian industry players to access the global *Halal* market.

Malaysia can provide South Korean companies with a cost-competitive location for R&D and manufacturing operations. In return, Malaysia will benefit from the capital, technology and market access that the South Korean companies bring into the country.

### 2.4.4. Global Industry Engagement

Malaysia can no longer stay as a low-cost operator or a “me-too” (follower) industrial player. Instead, Malaysia needs to excel at enhancing knowledge based economy through superior innovations with unique competitive advantages. This will call for international collaborations engaging both local and global players.

Recognising this challenge, BiotechCorp has actively involved itself in creating and participating in strategic communication platforms that will create effective collaborations among global and local biotechnology industry players.

### BioMalaysia: Meeting Point of Global Biotechnology Players

BioMalaysia is Malaysia’s largest international biotechnology conference held annually in Kuala Lumpur. In 2010, more than 50 world renowned international and local biotechnology experts shared their knowledge, experience, insights and inspirations, updates and



developments affecting the biotechnology industry. The conference featured insightful keynote address, plenary and parallel sessions from world renowned biotechnology scientists, key policy makers, and captains of the biotechnology industries. The event covered the latest biotechnology trends, policy issues, technological innovations, and commercialisation opportunities. The BioMalaysia Conference has attracted over 1,400 delegates each year with constant growth in participation, making BioMalaysia the meeting point of choice for biotechnology in the region. BioMalaysia 2010 had attracted more than 8,000 trade visitors.

BioMalaysia is also the platform to launch and announce some of the most ground breaking developments for Malaysian biotechnology industry. Some of the significant developments announced during BioMalaysia over the years were:

#### BioMalaysia 2007

Announcement by BiotechCorp and Bioven Sdn. Bhd.	A significant breakthrough on cancer therapeutics. Bioven Sdn. Bhd. is a local biotechnology company involved in the advancement of breakthrough cure for cancer.
Launch of Technology Acquisition by BiotechCorp	BiotechCorp and Nanobiotix S.A signed a MoU to acquire exclusive worldwide licence for the manufacture of nanoparticles with the rights to use them in any non-oncology applications.

#### BioMalaysia 2008

Exchange of Documents between <ul style="list-style-type: none"> <li>• <i>Unit Perancang Ekonomi</i> (UPEN) Kelantan</li> <li>• USM</li> </ul>	The exchange of documents between UPEN Kelantan and USM was for the commercialisation of the innovation by the USM researchers using the solid state fermentation process to produce industrial enzymes.
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<p>Exchange of Documents between</p> <ul style="list-style-type: none"> <li>• Insect Biotech (Korea);</li> <li>• Enzyme Technologies Sdn. Bhd.</li> </ul>	<p>The collaboration between BiotechCorp and Insect Biotechnology of Korea announced at Bio San Diego in June 2008 has resulted in the partnership with a Malaysian counterpart Enzyme Technology Sdn. Bhd. to establish an industrial enzyme manufacturing facility in Malaysia.</p>
<p>Exchange of Documents on Technology Transfer between</p> <ul style="list-style-type: none"> <li>• ABCAR Asia</li> <li>• Global Sunshine Biotechnology Sdn. Bhd.</li> </ul>	<p>This collaboration resulted in the transfer of technology agreement between the two parties for a post-harvest extraction technology significant for nutraceuticals and cosmeceuticals products. At the same time, the technology could be used to enhance the drying process of the agricultural products.</p>
<p>Launch of the BioNexus Partner Programme</p>	<p>This involves the opening of the extensive resource and talent of 20 labs in public IHLs and RIs for collaboration with BioNexus, international and local life sciences companies in Malaysia.</p>

### BioMalaysia 2009

<p>Award of the ISO9001: 2008 certification by Moody International Certification to BiotechCorp</p>	<p>The scope of the certification covers five key business processes which are the BioNexus Status Application process, BioNexus Monitoring Processes, Commercialisation Grants Application and Disbursement Processes and Technology Acquisition Process.</p>
<p>MOU between</p> <ul style="list-style-type: none"> <li>• BiotechCorp</li> <li>• Sarawak Biodiversity Council (SBC)</li> <li>• Novartis Pharma AG</li> </ul>	<p>This significant initiative involves a global pharmaceutical company, Novartis, research institution and a government agency to enhance Malaysia's scientific capability in exploring bioactive compounds from natural sources in Sarawak.</p>
<p>Exchange of Documents between</p> <ul style="list-style-type: none"> <li>• BiotechCorp</li> <li>• LARTA Institute</li> </ul>	<p>BiotechCorp has embarked on an ambitious project called the Global Bridge: Malaysia Commercialisation Assistance Programme (CAP) for the Promotion of Science to Business in partnership with a non-profit Organisation in California, LARTA Institute, whose mission is to uncover innovations from around the world. The project has identified 12 potential innovators to mentor in commercialising their innovations</p>
<p>Exchange of Documents between</p> <ul style="list-style-type: none"> <li>• BiotechCorp</li> <li>• DNA LandMarks (DLM)-BASF subsidiary</li> <li>• MARDI</li> </ul>	<p>Engagement of MARDI as the custodian and main beneficiary of the Molecular Assisted Selection (MAS) technology. MAS is a leading platform technology in the improvement of crop varieties and livestock breeds.</p>

**BioMalaysia 2010**

<p>Memorandum of Collaborations (MoC) between</p> <ul style="list-style-type: none"> <li>• BiotechCorp</li> <li>• CNI Holdings Berhad</li> <li>• Universiti Putra Malaysia (UPM)</li> </ul> <p>And</p> <ul style="list-style-type: none"> <li>• BiotechCorp</li> <li>• Amway (Malaysia) Sdn. Bhd.</li> <li>• UPM</li> </ul>	<p>This initiative will focus on the development and commercialisation of products using Supercritical Fluid Extraction (SFE) platform technology for both Amway and CNI. The MoC involves product development, which includes identification of targeted new specialty ingredients to include into Amway's and CNI's product portfolios, contract manufacturing services at SCF Centre for commercial production and entrepreneur development which will see local entrepreneurs and companies participate in Amway's and CNI's supply chain for the targeted specialty ingredients.</p>
<p>Exchange of Definitive Agreement between</p> <ul style="list-style-type: none"> <li>• Bio-XCell</li> <li>• Glycos Biotechnologies Inc.</li> </ul>	<p>The agreement was on GlycosBio's participation in the BioXCell ecosystem. GlycosBio based in Houston, Texas is an emerging biochemical company pioneering metabolic engineering and microbiology innovations to produce sustainable biochemicals. The company will establish an industrial biochemical plant and biotechnology R&amp;D facility in Bio-XCell Malaysia. GlycosBio's CEO, Richard Cilento said their initial R&amp;D efforts will be on creating isoprene to support Malaysia's rubber industry. Their long term strategy include further expansion and forming joint venture partnerships with existing petrochemical, oleo chemical, and biofuel producers and to partner with end market players in the development of advanced biochemicals.</p>
<p>Exchange of Definitive Agreement between</p> <ul style="list-style-type: none"> <li>• Bio-XCell</li> <li>• Metabolic Explorer S.A (METEX)</li> </ul>	<p>METEX which is based in Clermont-Ferrand, is a green chemical company that specialises in the development of bioprocesses for the production of chemical compounds used in a wide range of everyday products including textile fibres, paints, solvents, animal feed supplements, adhesives, etc. METEX will establish its first PDO (1, 3 propanediol) manufacturing plant in Bio-XCell on an 11 acre site as part of its strategic expansion into South East Asia. METEX aims to be the leading PDO manufacturer in this region.</p>

<p>Exchange of Co-Production Agreement between</p> <ul style="list-style-type: none"> <li>• BiotechCorp</li> <li>• Biotechnology Industry Organisation (BIO)</li> </ul>	<p>BiotechCorp and BIO will co-produce the international Bio Pacific Rim Summit on Industrial Biotechnology and Bioenergy in 2011 in conjunction with BioMalaysia 2011 which is scheduled for 21<sup>st</sup>-23<sup>rd</sup> November 2011. BIO is the largest biotechnology industry organization in the world. Since the inaugural Bio Pacific Rim summit in 2006; this will be the first time the summit will be held outside the US. This collaboration will help place Malaysia on the global map of industrial biotechnology and highlight Malaysia's competitive advantage in industrial bioprocessing and biomanufacturing.</p>
<p>Exchange of MoU between</p> <ul style="list-style-type: none"> <li>• Holista CollTech (Australia) Limited</li> <li>• <i>Universiti Sains Malaysia</i> (USM)</li> </ul> <p>And</p> <ul style="list-style-type: none"> <li>• Holista CollTech (Australia) Limited</li> <li>• Uni-Amla International Co Ltd</li> <li>• Furley Bioextracts Sdn. Bhd.</li> </ul>	<p>The MoU with USM is to further research on the world's first 'Halal' food-grade sheep collagen towards facilitating easier human digestion, and the second MoU with BioNexus status company Furley and Uni-Amla, China's 10th largest Multi-Level Marketing (MLM) company is towards the formulation and commercialisation of ovine collagen product for the Chinese market.</p>
<p>Exchange of Agreement between</p> <ul style="list-style-type: none"> <li>• Aurigene Discovery Technologies Limited</li> <li>• University of Malaya (UM)</li> </ul>	<p>The agreement was on Drug Discovery Joint Development Programme. There were three (3) proposed programmes that cover the areas of oncology, inflammation (rheumatoid arthritis or osteoarthritis) and anti-infectives.</p>
<p>Collaboration between</p> <ul style="list-style-type: none"> <li>• Massachusetts Institute of Technology (MIT)</li> <li>• <i>Universiti Teknologi Malaysia</i> (UTM)</li> </ul>	<p>The collaboration was on critical topic of 'Sustainability' and 'Value Creation' – specific research topics includes – Biopolymers from palm oil mill effluent; microbial consortium for CO<sub>2</sub> reduction in wastewater biodegradation and treatment; microbial bioreactor for self-sufficient electricity generation for waste biodegradation; and design and modelling of microreactors.</p>
<p>Announcement by Malaysian Genomics Resource Centre (MGRC)</p>	<p>MYGenome Project - a collaboration between MGRC, MOSTI and Malaysia Genome Institute (MGI), will be the world's first multi-ethnic human genome study involving Malaysians. Downstream analysis of the resulting genomic data will pave the way for better healthcare and open the door to personalised medicine for Malaysians.</p>
<p>Announcement by Malaysian Genomics Resources Centre (MGRC)</p>	<p>Proboscis Monkey Project - Collaboration between MGRC, MOSTI and <i>Universiti Malaysia Sabah</i> (UMS), will involve the first complete sequencing and assembly of the genome of the endangered Proboscis Monkey. This will place Malaysia among the few countries globally undertaking sequencing and assembly of iconic species.</p>



Meanwhile, the trade exhibition in BioMalaysia has been successfully attracting participation from more than 180 companies including participations from USA, UK, Netherlands, Switzerland, Singapore, Norway, Taiwan, China, Germany, Japan and Korea. Participants were presented with refreshing and cutting edge developments that signify the advancement of the biotechnology industry.



### **BioEurope 2009 - Milan, Italy - March 16-18**

The highlight of this event was the networking sessions with a diverse group of Biotechnology experts from Europe and the rest of the world, where participants could openly share their insight and opinion on industry developments and the important issues. New business development leads were initiated during the three days event.

### **BIO International Convention 2005 – 2010**

BIO is a biotechnology organization based in the U.S. providing advocacy, business development and communications services to its members. BIO organizes the BIO International Convention annually in the U.S. - featuring the largest and most diverse gathering of biotechnology experts and participants from all over the world.

In order to keep up the pace and provide insights on the latest development in the biotechnology sector, BiotechCorp participated in BIO International Convention from year 2005-2010 which was held in Philadelphia, Chicago, Boston, San Diego and Atlanta. BiotechCorp played a role as the lead agency and a one-stop facilitation centre for the development of biotechnology industry in Malaysia and represented Malaysia's competitiveness and key capabilities in biotechnology during the event.

### **International Collaborations:**

#### **BIO Chicago 2008**

<p>Exchange of Documents between</p> <ul style="list-style-type: none"> <li>• BiotechCorp</li> <li>• Trusgen, LLP</li> </ul>	<p>Trusgen to set up a biologics manufacturing facility in Malaysia and the company will focus on contract manufacturing of biologics products for pharmaceutical companies. Biologics products are derived from living sources, include vaccines and blood.</p>
<p>Exchange of MoA &amp; MoU between</p> <ul style="list-style-type: none"> <li>• Success Nexus Sdn. Bhd.</li> </ul>	<p>The MoA was for Merloni Progetti to purchase the entire production of second generation biodiesel. The agreement also included the building of the Success Nexus' production plant by Merloni Progetti which is financed by a government export bank of Italy, SACE. The MOU was for</p>



<ul style="list-style-type: none"> <li>• Merloni Progetti, Italy</li> </ul>	<p>Merloni Progetti to enter into a JV with Success Nexus to form new company in Malaysia that looks into biofuel production technology with special focus in the development of technology for feedstock.</p>
<p>Exchange of Documents between</p> <ul style="list-style-type: none"> <li>• Budi Biofuels</li> <li>• PureVision Technology, Inc</li> </ul>	<p>The exchange was to create a technology most suitable and economical for the production of cellulosic bioethanol from empty fruit bunch (EFB). The agreement was a partnership by way of Budi employing PVT's proprietary knowledge and technology to create a biorefining process technology for production of industrial product, ethanol from EFB of oil palm.</p>
<p>Launch the Joint-Venture between</p> <ul style="list-style-type: none"> <li>• ABCAR France</li> <li>• ABCAR Asia</li> </ul>	<p>The other collaboration was a technology licensing agreement between ABCAR Asia and ABCAR for post-harvest processing of agriculture produce such as rice and fruits.</p>

### BIO Atlanta 2009

<p>Exchange of Documents between</p> <ul style="list-style-type: none"> <li>• LARTA</li> <li>• BiotechCorp</li> </ul>	<p>The collaboration agreement was to identify tenancy for incubator programme by sourcing suitable companies to take up tenancy of the Incubator Spaces to be developed by BiotechCorp. LARTA Institute will refer prospects i.e. biotechnology, biotechnology-related and/or agritech-related companies which are interested to commence business in Malaysia or to expand their current business to Malaysia.</p>
<p>Exchange of Collaboration Agreement between</p> <ul style="list-style-type: none"> <li>• BiotechCorp</li> <li>• BBB Management GmBH Campus Berlin-Buch</li> </ul> <p>And</p> <ul style="list-style-type: none"> <li>• BiotechCorp</li> <li>• Belgian Biotechnology Industry Organisation</li> </ul>	<p>Both these exchanges have one thing in common: Promoting Malaysian companies in Germany and Belgium by opening up the channel for collaboration and promoting deal flows. These partnerships will expose the Malaysian companies to a wider audience and accelerate commercialisation.</p>
<p>Exchange of Collaboration Agreement between</p> <ul style="list-style-type: none"> <li>• Centre for Proteomic and Genomic Research (CPGR)</li> <li>• Simugen</li> </ul>	<p>The collaboration is aimed at improving the ability to develop novel, safe drugs fits perfectly into CPGR's vision of creating cutting-edge ex-vivo drug screening workflows that make full use of their genomic &amp; proteomic platforms.</p>

<p>Signing Ceremony between</p> <ul style="list-style-type: none"> <li>• DNA LandMarks</li> <li>• BiotechCorp</li> </ul>	<p>Purpose of the signing was to form a strategic collaboration in marker-assisted breeding technology. The initial focus will be on rice and cucurbit crops – a plant family including squashes and melons – with farm animal species to be added going forward.</p>
<p>Announcement of Sub-Licensing application for nanotechnology platform</p>	<p>BiotechCorp provided a progress update on the nanotechnology platform. BiotechCorp completed its first technology acquisition in nanotechnology and signed a Technology Transfer and License Agreement with Nanobiotix S.A (Nanobiotix) of France on 20 November 2007. This involves the acquisition of a worldwide, exclusive license for the manufacture of nanoparticles and development of related applications such as Drug Delivery Systems and Diagnostics in the non-oncology field. With the completion of said acquisition, interested applicants can apply to BiotechCorp to sublicense the platform acquired to develop applications in non-oncology field.</p>

### BIO Chicago 2010

<p>Global Launch of Malaysian Bio-XCell Sdn. Bhd.</p>	<p>Launch of a conducive biotechnology ecosystem and park build around targeted strategic anchor tenants to accelerate the industry's growth through industrial and healthcare biotechnology which will be based in Nusajaya, Iskandar Malaysia, just 20 minute drive to Singapore.</p>
<p>Launch of Malaysian Biotechnology Country Report 2009 / 2010</p>	<p>The objective of the Country Report was to provide an overview of the biotechnology industry development in Malaysia since 2005 and set out priority actions moving forward into Phase 2 NBP implementation.</p>
<p>Exchange of Documents between</p> <ul style="list-style-type: none"> <li>• Bio-XCell</li> <li>• General Electric International Inc.</li> </ul>	<p>The purpose of the exchange was to explore initiatives of common strategic infrastructure for the ecosystem, particularly for the development of centralised utilities facilities within the park.</p>
<p>Exchange of Documents between</p> <ul style="list-style-type: none"> <li>• Bio-XCell</li> <li>• Glycos Biotechnologies Inc</li> </ul> <p>And</p> <ul style="list-style-type: none"> <li>• Bio-XCell</li> <li>• MGM INGREDIENTS AG</li> </ul>	<p>The purpose of these two exchange were to facilitate discussion and negotiations and the exchange of confidential and sensitive information necessary for the preparation and the execution of the Build to Lease Agreement, Lease Agreement, and Tenancy Agreement and /or other agreements or documents that may be executed between the parties.</p>

<p>Exchange of Documents between:</p> <ul style="list-style-type: none"> <li>• Siogen Biotech</li> <li>• Veeda Clinical Research</li> </ul>	<p>The purpose of the exchange was to collaborate on a drug delivery technology, which will have significant impact on oncology drugs.</p>
<p>Announcement on Stempeutics 1st GMP Certified facility in Malaysia &amp; product launch</p>	<p>BioNexus Status company, Stempeutics, will conduct clinical trials in patients with Ischemic Cerebral Stroke (ICS) after obtaining approvals from the MOH Malaysia. According to WHO, ICS is the leading cause of disability in the world. The clinical trial will study the safety and efficacy of its investigational new drug.</p>
<p>Announcement on Getz Pharma Investments and Establishment in Malaysia</p>	<p>Getz Pharma (Malaysia) is looking to invest over US\$45 million in Malaysia for R&amp;D, production and commercialisation of sterile injectable and other biopharmaceutical products. The company is acquiring 15 acres of land for its facility in Enstek Tech Park, Malaysia.</p>

### **BioInvestor Forum 2009 in Hong Kong and Australia**

This forum focussed on creating awareness of the characteristics and nuances of the Biotechnology industry in Malaysia – to engage the interest of the financial and investment community, to increase their understanding of the industry and to enhance their ability to evaluate Biotechnology companies and projects in Malaysia.

The two locations chosen for its functional benefit in the area of financing and biotechnology and feedback from subject-matter-experts were:

**Hong Kong:** The impact of the financial crisis, while slowing the growth of the Chinese economy, has not had a sharp impact on investors in China, which is focused on the development of its biotechnology sector. Dedicated investors that understand the sector are present here.

**Sydney:** A number of different specialist funds are located in Sydney as several important dedicated investors are located in this city.

As an additional effort to promote the biotech industry in Malaysia, three whitepapers were developed by an Agency (Frost & Sullivan) and it acted as a guideline document when looking at the Malaysian biotechnology industry. The three whitepapers were published for specific content on agriculture, healthcare and industrial biotechnology. Below is a summary of the content of these documents:-

- Overview of each of the Malaysian biotechnology sectors (agriculture, healthcare, industrial);
- Showcase the strong government support for the sector;
- For each sector, it described the natural local strengths of the sector;

- Review of all supporting sector inputs including infrastructure (science parks etc), finance, legal and policy;
- Show growth: Provide a here and now analysis of the sector;
- Showcase select companies and their strengths (products, core IP, revenues etc); and
- Highlight areas of particular focus and describe global opportunity in these focus areas.

#### **2.4.6. Reaching the *Rakyat*: Creating Public Awareness on Biotechnology Initiatives**

Public awareness on biotechnology is essential for the overall success of the implementation of national biotechnology aspiration. With accurate and factual resources available and accessible, public will support the government's efforts and assist in developing biotechnology as a key driver of economic growth.

##### ***BioUsahawan* 2009 & 2010**

*BioUsahawan* was a programme produced with TV3, which features various facets of the biotechnology industry. This outreach programme targeted at the *Rakyat* provided insight into innovation opportunities and potential wealth creations that could be achieved through biotechnology. *BioUsahawan* was used as a consistent platform to showcase consistent top-of-mind awareness on achievements in Malaysian biotechnology by featuring the accomplishment of bio-entrepreneurs, R&D and innovation for the benefit of the *Rakyat* and biotechnology industry.

### **BioIndustry Dialogue and Exhibition 2009 & 2010 in conjunction with “*Karnival Jom Heboh – TV3*”**

To strengthen the positioning of BiotechCorp as a lead agency for biotechnology industry in Malaysia, BiotechCorp participated in “*Karnival Jom Heboh*” organized by TV3 which was held in Sabah, Sarawak, Penang, Johor, Kelantan and Kuala Lumpur. This was an outreach program for BioNexus status and life sciences companies to showcase their innovations and commercialisation activities. The participation was aimed at increasing awareness of biotechnologies at the grass root and encourages the use of biotechnology applications in the daily life of the *Rakyat*. This is part of our effort to emphasize the impact of commercialising life sciences on the general public.

## **2.5. Moving Forward**

There are strengths and opportunities within the Malaysian biotechnology sector. The assessment of the current state of the industry is in line with the goals set out in the Phase 1 NBP. The following are the key strengths and opportunities within the Malaysian biotechnology sector.

### ***Strengths***

- Starting base of 187 BioNexus status companies which are accountable for almost RM1.7 billion investment;
- Success of local firms with five listed BioNexus status firms generating revenues of more than RM2.2 billion;
- One of the 12 mega biodiversity countries in the world;
- Domestic industrial base, such as petrochemicals services and manufacturing;
- Presence of dedicated organisations that support firms in start-up and commercialisation;
- Government recognition of biotechnology as a thrust of technology and innovation as part of the RMK-9, RMK-10, and the NEM;
- Cost-competitive labour industry at the global level, although relatively smaller when compared to that in larger nations like China or India; and
- Cost-effective country in terms of running a business.

### ***Opportunities***

- Malaysia’s existing resource in the petroleum, natural resources (including bio-diversity) and agro-industries could well fulfil the requirement to establish Malaysia as the base for the industrial biotechnology industry;
- Presence of a biotechnology support organisation that has been successful in supporting firms to develop from start-up mode to commercialisation mode;
- Continued Government support that can drive R&D; for instance, encouraging measures are expected to be introduced by the Government through the NEM and RMK-10;
- Malaysia’s manufacturing base can be used as a starting point to be further developed and aligned to global healthcare standards. This will provide potential to develop the Malaysian

healthcare sector in line with global standards to take advantage of the opportunities in the CMO or CRO sector; and

- Ability to utilise a strong agriculture base in IHLs as a platform to increase commercialisation in this sector; streamline and encourage technology transfer to firms in this area through sector-focused incentives.

The key building blocks of Malaysia biotechnology industry is prepared to propel into Phase 2 NBP. Key requirements set forward as precedent conditions would take into account private and government sector financial backing to stimulate more growth.

At present stage, Malaysia with its biodiversity is already attracting foreign investment since opening its doors in the biotechnology industry five years ago. It has drawn interest from private investors and also has listed five BioNexus companies on the stock exchange.

BiotechCorp needs to seize the opportunity of establishing Malaysia as a mega biotechnology hub. BiotechCorp has already initiated its Programmes for Phase 2 NBP so that biotechnology companies can move up from the Small Medium Enterprise (SME)<sup>12</sup> definition. The current biotechnology start-ups and SMEs companies will need to graduate with stronger business fundamentals and sustainable revenue models.

With strong growth potential and supported by evidence and constructive feedback from industry stakeholders, it is essential that BiotechCorp moves ahead with utmost urgency on Phase 2 NBP (Science to Business) through the systematic framework that already has been laid out within Phase 1 NBP.

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<sup>12</sup> Small to Medium SMEs, as per the SME Corp's definition





**Achievements  
of NBP Phase 1  
Capacity Building  
Targets**



### 3.1. Introduction- Measuring the Performance as per the Targets Set

Announced on 31<sup>st</sup> March 2006, the RMK-9 defined and detailed the goals of the Malaysian Government in relation to the biotechnology local sector. More importantly, the Plan had identify & allocated the amount of funding committed to developing the sector. A total of RM2.02 billion was allocated in the RMK-9. This is a near four-fold increase from the RM577 million allocated under the RMK-8. As the Malaysian biotechnology industry was in the early stage of development, almost half of the funding in the RMK-9 was allocated for infrastructure, RM463 million for R&D and RM530 million for biotechnology business development.

In order to have a measured approach towards the development of the Biotechnology industry in Malaysia, the Government has set clear target for each of these indicators over the period of five years, as depicted in table below:

Table 3.1: Phase 1 NBP KPIs	
Indicators	Phase 1 NBP: 2005-2010
Investment by private sector and government	RM6.0 billion
Employment	40,000
Total revenue	RM20.0 billion
Contribution to GDP	2.50 percent

Source: BiotechCorp.

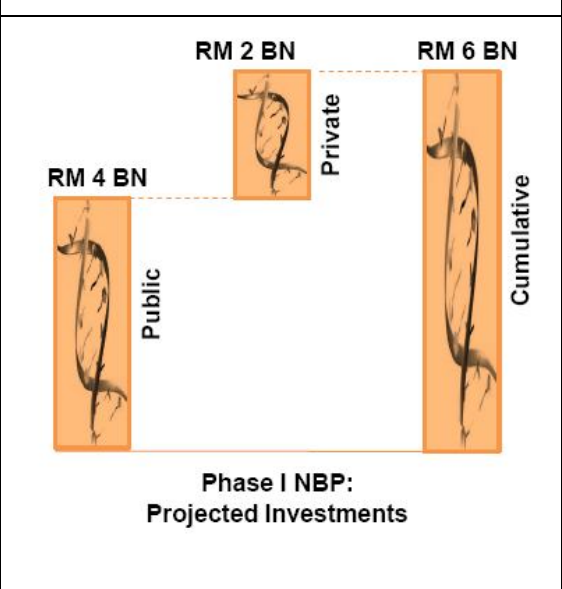
### 3.2. Investment & Funding

An ambitious target of RM6.0 billion worth of investments was set in Phase 1 NBP to develop a critical mass, which will have a long-term impact on the Industry. This was led by the Government with RM4.0 billion worth of investment with the remaining balance taking by private sector.

Eyeing the future prospects of the industry and its potential social benefits, the Government was envisioned to be the primary driver for the investments. Hence, a target investment of RM4.0 billion was planned in Phase 1 NBP, which would be supported by an investment of RM2.0 billion by private investors.

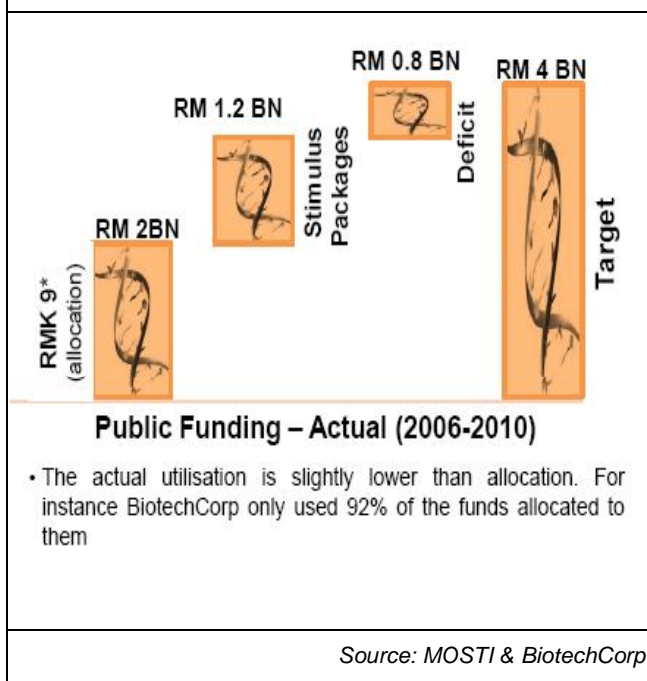
In terms of the actual performance during the RMK-9 period, the government sanctioned RM2.0 billion investments for biotechnology and another RM1.2 billion from MOSTI Science and Technology Funds and Stimulus Packages. Hence, there was an investment gap of RM0.8 billion in terms of investments by the Government.

**Figure 3.1: Target Investment – RMK-9**



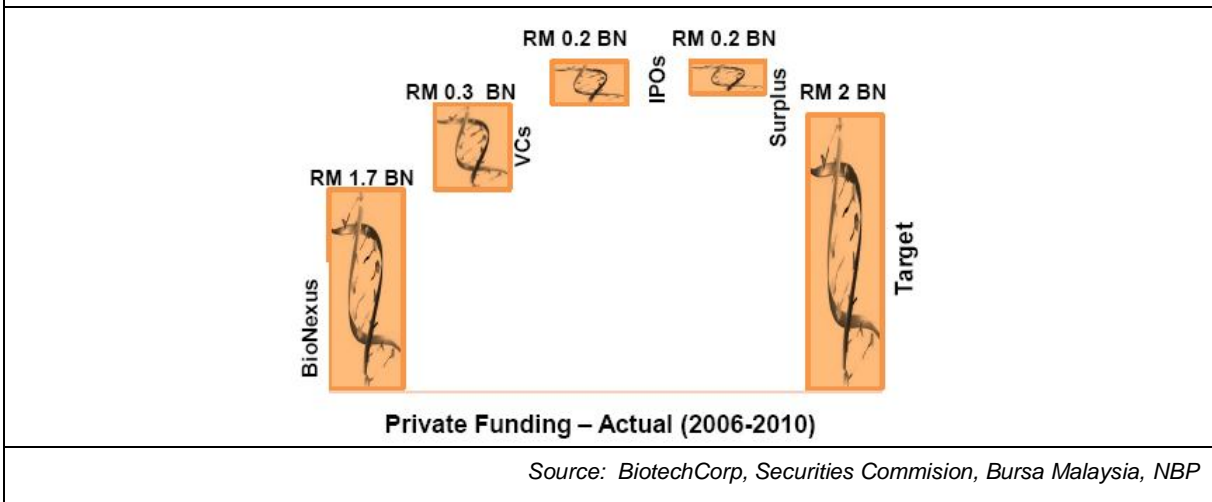
Source: National Biotechnology Policy 2005-2020

**Figure 3.2: Public Funding – Actual Investments (2006-2010)**



The industry also managed to raise private investment of RM2.2 billion. BioNexus status companies funded RM1.7 billion into biotechnology related activities while the balance funds of RM0.3 billion and RM0.2 billion were raised through VCs and Initial Public Offerings (IPOs) respectively.

**Figure 3.3: Private Funding – Actual Investments vs. Targets (2006-2010)**

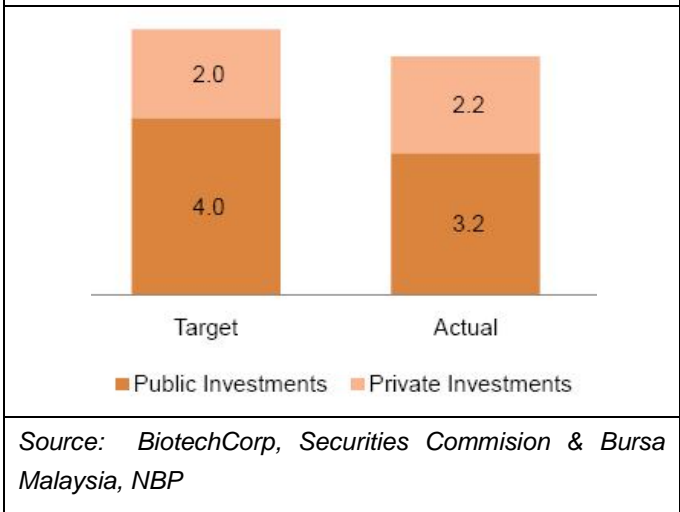


Although there is a gap of RM0.6 billion between actual and targeted investment in the Phase 1 NBP, the ratio of private vis-à-vis public investments in the Malaysian Biotechnology industry remained favourable considering its early stages of evolution. The role of the VCs and IPOs are also likely to significantly increase, as many companies are heading towards commercialisation. Hence, the Government would be able to realise returns in terms of social impact through employment generated, products developed and companies formed.

Engagements with various local and foreign investors such as private VCs,

corporations, financial institution and individuals were conducted to introduce potential biotechnology deal flows. Biotechnology companies and projects looking for funding were also assisted and matched with private investors or funders. Investment into biotechnology companies or projects are made directly into the biotechnology companies and projects, or through a dedicated venture fund established for the biotechnology industry.

**Figure 3.4: Total Funding – Actual Investment (2006-2010)**



Efforts were also initiated to create awareness and interest among the financial and investment community on the business and technical aspects of the biotechnology market. To this end, BiotechCorp had organised two BioFunding Conferences in 2009 and 2010, with the conference in 2010 providing a more global perspective with a majority of the presenters/speakers represented coming from other countries. The BioFunding Conferences attracted a total of 229 participants coming from organisations such as government linked funders, VCs, Financial Institutions, Corporations as well as Corporate Advisors and Consultants.

BioNexus status companies that participated in the conferences also benefited as it provided them with knowledge on how to attract investors & funders to participate in their business as well as providing an avenue for them to network with the investors and funders.

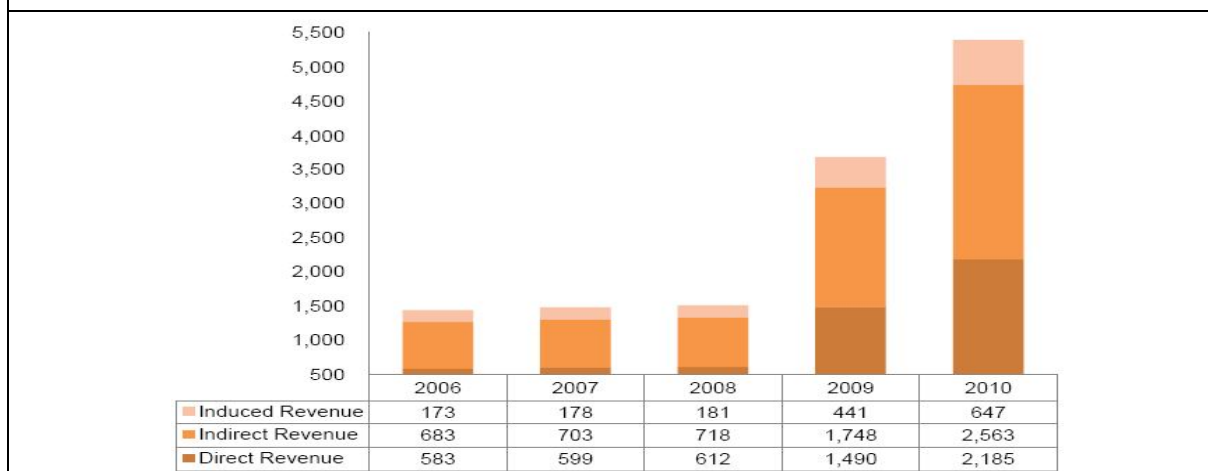
The participation of large institutional investors is important to bring the scope of financial resources needed to finance a robust risk capital industry. To this end, Malaysia should ensure that institutional investors can legally invest in risk capital, encourage them to be involved in the industry, and also facilitate the involvement of banks within the industry (e.g. insurance companies and pension funds) to invest up to a ceiling percent of their reserves in risk capital.

### 3.3. Revenue

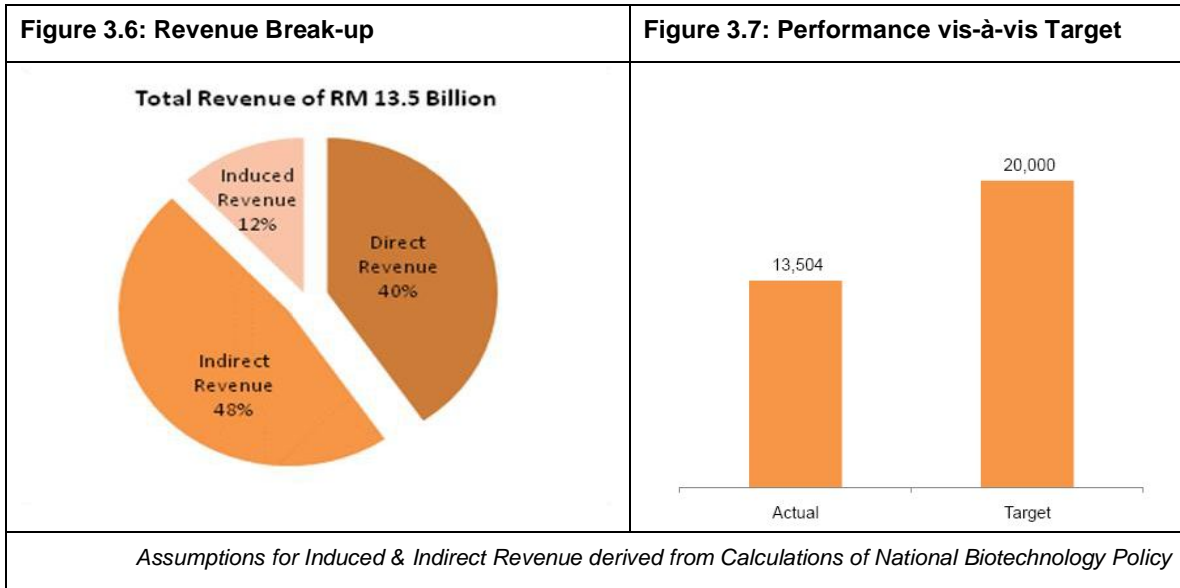
When compared to the target of RM20.0 billion set under the Phase 1 NBP, the actual total revenues generated were RM13.5 billion. The definition of Revenue as per the National Biotechnology Policy is:

$$\text{Biotechnology Revenues} = \text{Direct Revenues} + \text{Indirect Revenues} + \text{Induced Revenue}$$

**Figure 3.5: Revenue Estimates – Biotechnology Sector**



Sources: Bio-Indicator Report – MOSTI; For Revenue Estimates (2006-2009), Frost & Sullivan Projections for 2010 Assumptions for Induced & Indirect Revenue derived from Calculations of NBP

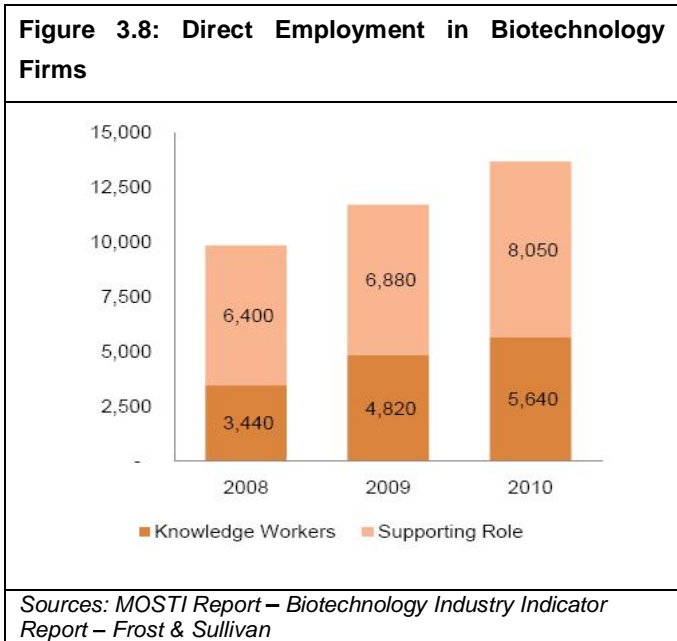


The total revenue generated in 2010 by biotechnology firms was estimated at close to RM2.2 billion. Almost two thirds of the revenue was generated within the domestic market, while the remaining was from international markets.

Considering the global financial crisis in 2009, which affected all sectors in Malaysia, the revenue achieved by biotech sector is considerably high. Since, the NBP vision did not provide for this unforeseen challenge, it can be concluded that the progress of biotechnology industry in terms of revenue is on track. The industry is already witnessing a recovery and is likely to achieve envisioned growth during the period of 2011 to 2015.

### 3.4. Employment Generated

Employment in Malaysian biotechnology firms has changed significantly over the last five years. As at the end 2010, the biotechnology sector in Malaysia employs 13,690 employees with 41.2% (5,640 employees) engaged directly in biotechnology related activities and can be classified as Knowledge workers (K-workers). Of these K-workers, 43 % are employed in firms, and 57 % in RIs/IHLs. The remaining 8,050 employees are involved in supporting roles to the biotechnology industry, which includes, but is not limited to, administrative, management, sales, supply and distribution related activities.

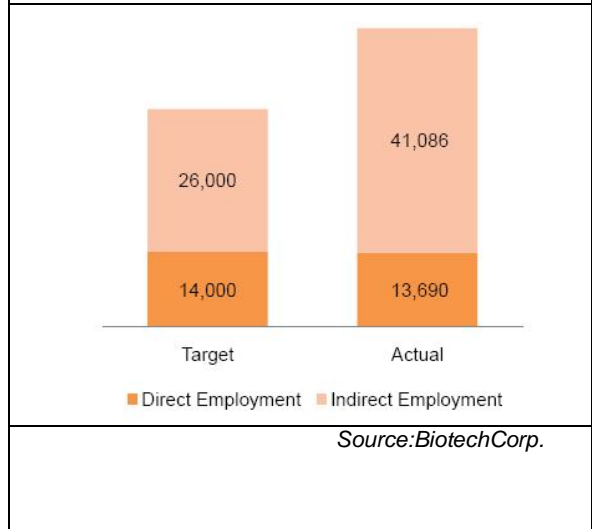


When compared to the targets set in Phase 1 NBP, the industry has been successful in creating employment opportunities. The biotechnology industry has created around 54,776 employment opportunities either directly or indirectly (Source: BiotechCorp). This means that the achievement is 37 percent above the target.

From 2011 to 2015, it is expected that the number of new employments related to biotechnology will reach 80,000; and then 160,000 from 2016 to 2020. In other words, a total of 280,000 new jobs, or almost two percent of the nation’s job market, is targeted to be created from 2005 to 2020 along with the growth of industry and investment on human capital development.

In terms of size of companies, from 2006 to 2010, the number of firms with less than 50 employees was around 90 percent. It is estimated that by 2015, 80 percent of the firms will still have less than 50 employees. While it is expected that a large proportion of biotechnology firms in a country will have a small number of employees due to the specific and emerging nature of the sector, it is important for more established companies to expand into commercialisation with a sales and marketing focus, which will lead to larger sized firms. South Korea for example is a good benchmark, with approximately 40 percent of their firms having more than 50 employees.

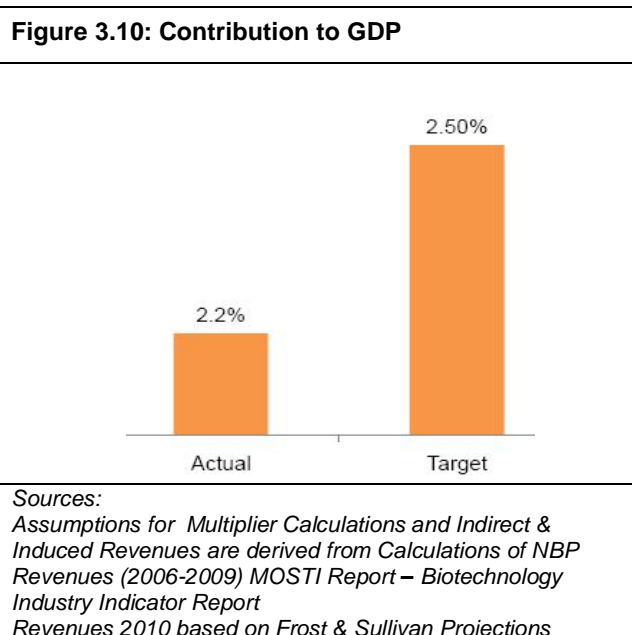
**Figure 3.9: Employment Generated By Biotechnology Industry**



### 3.5. Contribution to GDP

In terms of contribution to GDP, the industry has achieved 2.2 percent contribution to GDP against the target of 2.5 percent. However, the industry is expected to see a significant growth in size and the contribution to GDP is likely to rise significantly, in the forthcoming years.

The significant contribution of the biotechnology industry to Malaysia's economy in the past five years reflects its important role in the country's economic growth. In fact, the present industry growth is a result of successful implementation of Government initiatives through the Programmes.



### 3.6. Other Measurable Indicators

While the KPIs have been clearly defined, the success of Programmes, in the industry can also be measured by other indicators. While the next chapter provides a detailed outlook on targets achieved by individual Programmes, some of the generic indicators are provided in this section.

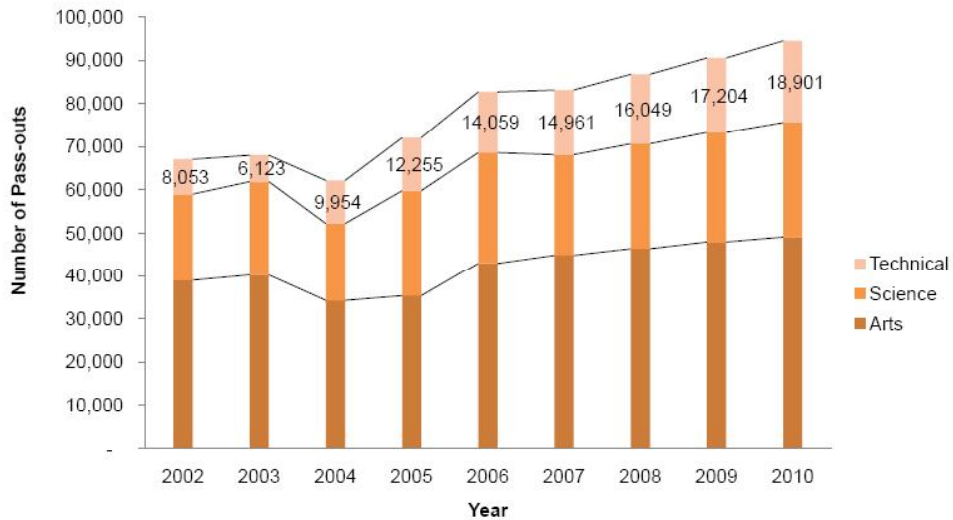
#### a. Human Capital

It is necessary to provide a ready talent pool for firms to employ from, and this shortfall in the available human capital is a limitation to the industry's growth. One of the barriers is a seemingly weak interest in science related fields among students. Therefore, an interest in science related fields especially biotechnology has to be instilled in early schooling years to cultivate a generation of students that are keen to be a part of this industry.

In 2007, only 29 percent of the graduates were awarded science degrees as their first degree. The proportion of science graduates in Malaysia has not increased as opposed to those in the arts in 2006 and 2007 as can be seen in Figure 3.11.



**Figure 3.11: First Degrees Awarded in Malaysia (2002-2010; Number of Graduates)**



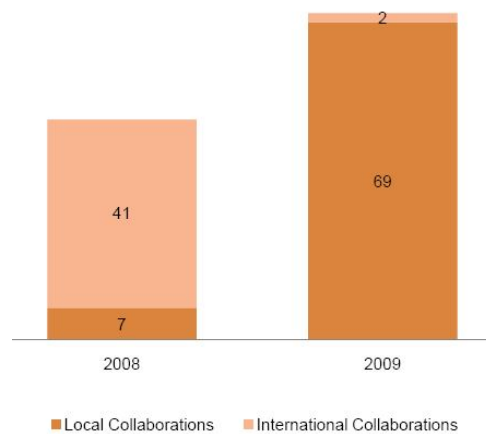
Source: Ministry of Higher Education (MOHE) & Frost & Sullivan Estimates

During the RMK-9, the Biotechnology industry has been the front runner in terms of increasing the number of pass-outs. IHLs have added Biotechnology in their curriculum, and have been fairly successful in creating critical mass of manpower for the industry to leverage. However, the IHLs still face challenges such as providing required hands-on experience to staff; being research focused and commercially driven.

**b. Biotechnology Alliances**

The number of alliances and partnerships in the biotechnology sector in Malaysia increased from 87 agreements in 2008 to 103 agreements in 2009, representing a growth of 18 percent.

**Figure 3.12: Number of Projects Developed with Collaborators by Firms, RIs and IHLs, 2008-2009**



Source: MOSTI Bio-Indicator Report 2010

Figure 3.13 shows that, of the 103 transactions in 2009, 54 were MOUs, 39 were licensing agreements, five were M&As and the remaining five were other transactions, for example partnerships or other commercial arrangements.

There are 103 alliances, 71 percent of which are formed by biotechnology firms. Licensing agreements and MOU are the key forms of alliances; 60 percent of the alliances in RI and IHLs are MOUs. Licensing agreements is one of the fastest growing types of collaborations for biotechnology firms, which is a positive trend.

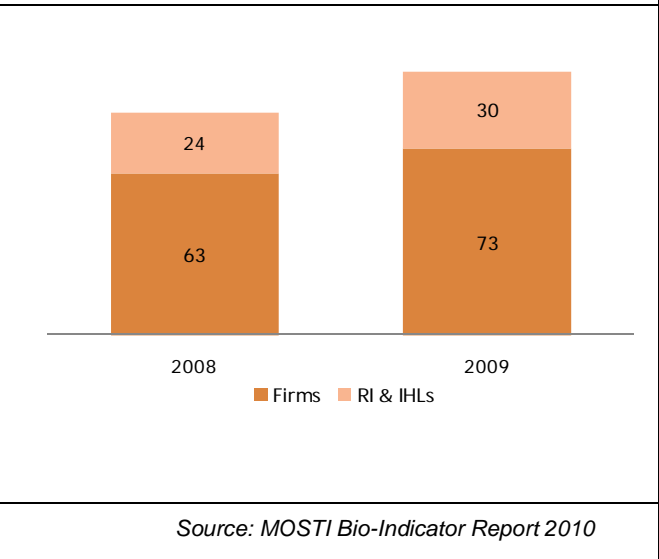
Overall, there are 101 projects in place, of which 32 percent are with international collaborators. Attracting foreign firms to form partnerships with local firms or institutes will be the driver for the growth in the Malaysian biotechnology sector. The focus for the country should be on alliances and partnerships, as well as licensing agreements as these have a higher potential in generating innovative products and processes.

**c. Number of Biotechnology Entities**

There are close to 232 participants including 187 biotechnology firms, 16 RIs and 29 IHLs. Based on historical data and future projections, it is estimated that by 2015, Malaysia will have 400 participants in the biotechnology sector. This growth is expected to come from the increase in the number of private firms, driven by the BioNexus Programme.

The number of BioNexus status companies increased from 92 in 2008 to 187 in 2010, reflecting the success of this Programme. Of these, nine companies or their subsidiaries are listed on Bursa Malaysia and other Exchanges. A list of these companies is provided below:

**Figure 3.13: Number of Alliances by Biotechnology Firms, RIs and IHLs, 2008–2009**



**Figure 3.14: Number of Biotechnology Entities**

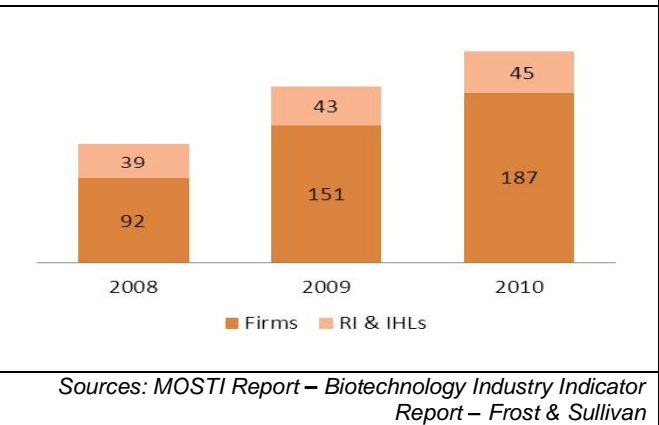


Table 3.2: Listed BioNexus Status Companies/Subsidiaries –(Bursa Malaysia and Other Exchanges <sup>13</sup> )		
Name	Listed	Business Description of BioNexus status companies
<b>Directly Listed</b>		
Stemlife Berhad	ACE	First integrated home-grown cord blood and adult stem cell banking and therapeutics company.
Malaysian Genomics Resource Center Berhad	ACE	MGRC provides genome sequencing and analysis services that are designed to rapidly sequence, analyse and extract meaningful biological information for downstream R&D in large volume.
<b>BioNexus Companies Are Subsidiaries of the Following Listed Entities</b>		
PureCircle Ltd.	AIM	PureCircle Sdn. Bhd.: Research, development, production and commercialisation of Stevia-based sweeteners.
Sunzen Biotech Bhd.	ACE	Sunzen Lifesciences Sdn. Bhd.: Focused on developing in-feed anti-bacterial animal feed supplements and feed additives.
Hovid Bhd. (formerly a.k.a Ho Yan Hor)	Main	Hovid Research Sdn. Bhd.: Clinical research services, preclinical drug development, drug delivery system and related services for pharmaceutical based companies.
INS Bioscience Bhd.	ACE	Hopematic Sdn. Bhd.: Specialising in herbal preparation, health and functional food.
TMC Life Sciences Bhd.	Main	Stemtech International Sdn. Bhd.: Cordblood and adult stem cell banking and stem cell medical therapy.  TMC Biotech Sdn. Bhd.: R&D on treatment tools, techniques and procedures pertaining to human fertility.

<sup>13</sup> The basis for selection of these companies is their substantial contribution to the business of their listed parent companies.

Carotech Bhd.	ACE	Carotech Bio-Vits Sdn. Bhd.: R&D, production and commercialisation of tocotrienol and carotene Supercritical Fluid Chromatography.
Holista CollTech Ltd.	ASX	Holista Biotech Sdn. Bhd.: Delivers first class “healthy-style” natural products, medicine, food, supplements and herbs.
Source: Compiled from respective companies' websites and BiotechCorp		



**Status Update  
of Programme  
Outputs/Outcomes**

#### 4.1. Introduction

Under RMK-9, the Government had allocated RM2.0 billion for biotechnology development from 2006-2010. Of this, 45.9 percent was utilised for physical infrastructure development, with the remaining used for soft infrastructure development including R&D, commercialisation and business development programmes.

BiotechCorp was allocated a sum of approximately RM 265 million by the Government of Malaysia to undertake six Developmental Programmes namely:-

- **Biotechnology Commercialisation Grant;**
- **Biotechnology Entrepreneur Programme;**
- **Biotechnology Entrepreneurship Special Training Programme;**
- **Intellectual Property Research & Management Programme;**
- **Biotechnology Acquisition Programme; and**
- **BioNexus Partners Programme.**

These Programmes are initiated to implement strategies outlined in the three development phases of NBP. Targets are set by the EPU to measure the success of the Programmes implementation, and these targets are ultimately tied to the indicators of NBP.

Despite the achievements of the Programmes, each Programme faced its challenges during execution. BiotechCorp will review the opportunities in the industry and find ways to implement the strategies more effectively to achieve the envisioned growth within the NBP (Phase 2 and Phase 3).

#### 4.1. Biotechnology Commercialisation Grant Programme (BCG)

BiotechCorp with the introduction of BCG has played a major role in spurring growth within the biotechnology sector in Malaysia resulting in increased number of biotechnology companies.

BCG addresses the following areas of concern:

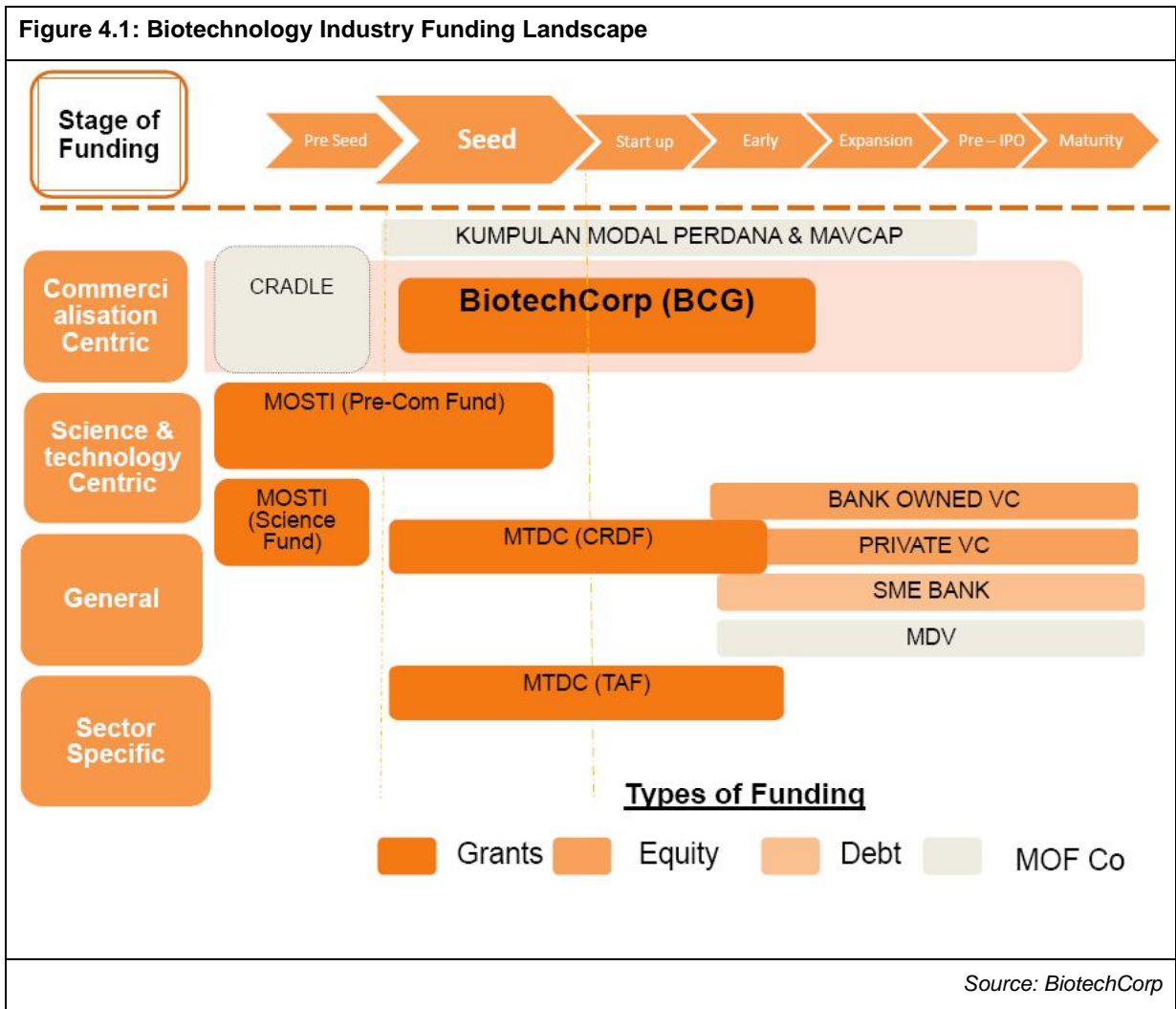
- To provide funding to priority biotechnology areas and to bridge funding gaps between existing public and private sector funding;
- To complement existing public and private sector funds and provide a comprehensive government Grant mechanism, encompassing the entire R&D value chain from pre-seed, seed to development and commercialisation funding;
- To attract and provide incentives to researchers and companies to develop the biotechnology industry; and
- To provide funding and capital for bio-entrepreneurs to commercialise viable products and services.

The Programme's objective is to provide crucial support needed especially by start-ups to mature and grow their businesses locally and globally. The foundation of the Programme has three components:

- Seed Fund;
- R&D Matching Fund; and
- International Business Development (IBD) Matching Fund.

Considering the challenges faced by innovation based companies, the programme focuses on addressing the funding requirements at most crucial stages. Globally, most enterprises struggle to raise the funds at the seed stage. To promote the biotechnology industry's sustainable growth, most Governments across the globe devise funding mechanisms to assist companies at this stage. RMK-9's BCG program is relevant and critical to assist BioNexus status companies in terms of long-term development funding. This is well reflected by the fact that currently 98 percent of the BioNexus status companies are start-up and SMEs companies.





#### 4.1.1. Achievements of the Programme

On average, 24 BioNexus status companies are granted with BCG annually. This is in line with the Government's effort to facilitate the industry with a comprehensive government grant mechanism. Details on the approvals under this programme during RMK-9 are as follows:

Table 4.1: BCG Funding During RMK-9						
Type of Fund	2008		2009		2010	
	Approval		Approval		Approval	
	No. of Projects/ Companies	Amount (RM)	No. of Projects/ Companies	Amount (RM)	No. of Projects/ Companies	Amount (RM)
Seed Fund	16	39,522,290	28	67,750,368	18	38,983,436
R&D Matching Fund	4	3,984,286	1	1,000,000	2	2,000,000
IBD Matching Fund	0	0	3	3,749,904	1	981,000
<b>Total</b>	<b>20</b>	<b>43,506,576</b>	<b>32</b>	<b>72,500,272</b>	<b>21</b>	<b>41,964,436</b>
Average 24 companies per year						
<i>Source: BiotechCorp</i>						

Under the BCG, a cumulative grant of over RM158.0 million was approved. The KPI was achieved by allocating funds to 73 companies over the period.

The Programme has received wide spread support from the biotechnology industry as new bio-entrepreneurs can now have access to funds to facilitate further commercialisation activities.

The initial development of any biotechnology industry cluster will normally require heavy investment on infrastructure lay-out and expertise. The Malaysian biotechnology industry is still at a developing stage. Compared to other biotechnology clusters worldwide, BiotechCorp would need critical mass that will spur more entrepreneurship, innovation and R&D, all of which demand sustainable funding ecosystem.

**Examples of Beneficiaries of BCG Funds and Their Output:**

**DNA Laboratories Sdn. Bhd.**

The company is involved in development and manufacturing of *in-vitro* DNA-based molecular diagnostic kits and provides genetic screening services to detect human chromosomal abnormalities. With the Seed Fund, the Company has commercialised its *in-vitro* molecular diagnostic kits for analysing the most common single gene mutations in Malaysia e.g. Thalassaemia carrier genes and chromosomal abnormalities such as Down Syndrome, Patau Syndrome, Edward Syndrome and Klinifelter Syndrome.

Project Output:

- ChromosomesCheck™ - Detection of chromosomal abnormality (Down, Patau, Edward and Klinifelter Syndromes);and
- ThalaCheck® - Single Gene Mutation Detection (Thalassaemia Carrier).

**Asia Pacific Special Nutrients Sdn. Bhd.**

The company's core activities are in R&D, manufacturing, and sale of diagnostic products for use in veterinary, food, agriculture, and medical/pharmaceutical applications. With the Seed Fund, the Company has successfully commercialised their products as below.

Project Output:

- Rapid H2S Faecal Coliform Test Kits for detection of water contamination;
- Rapid Cystostain;
- Multiplex Polymerase Chain Reaction for detection of Van A/B genes in vancomycin resistant enterococci;
- Rapid assay for detection of nitrofurans, phenicol and mycotoxins;
- Food pathogen Uniplex Polymerase Chain Reaction series for detection of salmonella, listeria and campylobacters; and
- Livestock Diseases Uniplex/Duplex Polymerase Chain Reactive series for detection of avian pneumovirus, porcine circovirus, chicken anaemia virus and *Mycoplasma synovaie*.

**BioFact Life Sdn. Bhd.**

BioFact Life Sdn. Bhd. is one of the pioneer biotechnology companies in the world to cultivate cordyceps in a specially designed clean room environment. BioFact Life is a seed-to-shelf approach company with extensive research and development. They produce, manufacture and market locally and internationally. BioFactLife has successfully embarked on the cultivation of Cordyceps stroma on commercial scale using the biotechnology based solid substrate fermentation method. BioFact Life's products (under the brand name: Timo®) are marketed in both Malaysia and Asia Pacific.

Project Output:

- Cordyceps (brand name Timo®).

**Ar-Raudhah Bio-Tech Farm Sdn. Bhd.**

Ar-Raudhah has successfully produced and commercialised life animal, animal's semen and embryo by employing biotechnology reproduction techniques; Artificial Insemination (AI) and Embryo Transfer (ET) as well as produce and commercialise organic fertiliser derived from animal waste. In addition, the Company has commercialised to provide animal's semen and embryo transfer services.

Project Output:

- Livestock animals (Boer Goats) which are bred using biotechnology Advanced Reproduction Techniques (ART) e.g. Artificial Insemination (AI) and Embryo Transfer (ET).

**Asma Agro (M) Sdn. Bhd.**

Asma Agro has acquired a license to use the fruit tissue culture production from a technology provider. This has enabled Asma Agro to commercialise and export the plantlets produced using the technology beyond Peninsular Malaysia.

Project Output:

- High quality fruit plantlets clone using Tissue Culture Technology (Pineapple, Cavendish Banana, Jati Mas).

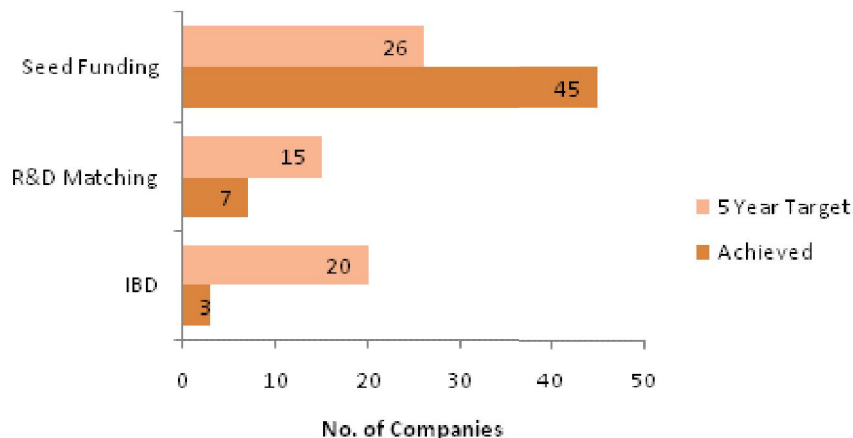
**IBG Manufacturing Sdn. Bhd.**

IBG Manufacturing Sdn. Bhd. has developed and commercialised biopesticides using biofermentation process which involves an initial study on *Metahirizium anisopliae*. It is a bio-based solution to replace the existing usage of chemical based non ethical pesticide.

Project Output:

- Biopesticides against rhino beetle, a major cause of palm defects.

**Figure 4.2: KPIs for BCG**



Source: BiotechCorp

The following are testimonials from recipients of the BCG:

“Under the Seed Fund Programme, we are now able to restructure our traditional herbal company to a biotechnology company without too much risk of losing the existing market. We hope that with this Programme, we will have the knowledge and know-how to implement our other products (in phases) into potential biotechnology products.” – **Aning Biotech Corporation Sdn. Bhd.**

“The funds were used to develop and market a new product, which has been successfully introduced to the market place” – **Holista Biotech Sdn. Bhd.**

“Increased our product export sales. The fund really boosts the production and various strategies could be implemented as the fund was granted.” – **Biotrack Technology (M) Sdn. Bhd.**

“It helped to fund our strategies to develop our products.” - **Borneo Plant Technology Sdn. Bhd.**

“We were able to kick-off our company utilising the seed grant. It enabled us to rent a space for our lab, set-up our lab and hire our critical first staff. We were then in better position to obtain venture funding.”- **Cerca Insights Sdn. Bhd.**

“The provided grant has brought our Company to the next level. Our new service under this grant was successfully launched right after the completion of the grant and we are now monitoring its progress.” - **First Base Laboratories Sdn. Bhd.**

“It helps to develop the strategies to commercialise the products locally and internationally.” - **Orchid Life Sdn. Bhd.**

“The Seed Grant has enabled us to set up our R&D&C centre in Lumut office. Through IBD grant it has helped to promote our biodiesel/glycerol products and biotechnology in Vietnam. This publicity has marketed our biodiesel and mobile plant facility in the ASEAN region. To ensure continuity of commercialization and promoted industry growth, Government need to allocate more funding and resources via BiotechCorp.” - **Success Nexus Sdn. Bhd.**

“We have benefitted from being able to bring in the technology to produce and further developed in Malaysia.” - **Biosafe Microbe Development Centre Sdn. Bhd.**

“Being an entrepreneurial company, we were unable to support sales and marketing activities and plan for international business development in APAC for the commercialisation of MyDENKit™, which was developed under MOSTI grant. Funds and grants from BiotechCorp helped us to support these activities and increase the awareness among the general public, clinical pathologists, hospitals, and medical technicians about the availability of molecular diagnostics and screening kit for dengue fever/dengue virus infection. This is very important because most of the general practitioners and hospital staff were totally unaware of Polymerase Chain Reaction (PCR) based kit for dengue, which is confirmatory test for dengue fever, dengue shock syndrome (DSS) and dengue haemorrhagic fever (DHF). We are very happy that we accomplished all the milestones committed in the grant proposal.”- **Geneflux Biosciences Sdn. Bhd.**

#### 4.1.2. Future Outlook of the Programme

Frost & Sullivan’s assessment shows that there is strong demand for funding by the biotechnology companies. Many companies have indicated that continuity is the key and most important factor in ensuring the growth of their R&D and hence commercialisation. Majority of companies have indicated that the BCG is an excellent effort by the Government and BiotechCorp to help nurture not only young companies at seed level but also companies that are ready to go global. Some have expressed gratitude as they have obtained seed level support in order to grow their R&D and others have been able to increase exports globally.

Many companies have also requested that grant allocations to be increased with current level of costs to cater for the need of growth and overcoming challenges. At this stage, BiotechCorp is on the right direction with disbursement of grants to help provide, the much needed support throughout the value chain.

BiotechCorp is providing opportunities to Malaysian scientists and bio-entrepreneurs to create and explore full potential of bio-business through BCG Programme. Majority of the new start-ups have

taken advantage of this and have experienced growth over the years due to constant nurturing and mentoring from BiotechCorp.

The Programme has played a vital role of building critical mass of biotechnology industry through selective funding of worthy bio-business propositions. It is vital for BiotechCorp to ensure more deserving companies are funded for conducting R&D and grow their business. The layout of the funding platform has definitely provided a boost in the biotechnology industry. Many biotechnology companies commented that there should be continuance of the funding programmes as currently the industry in Malaysia is still at early stage of development.

Biotechnology companies find that the BCG is a great motivating aspect in the biotechnology development in Malaysia. The development of this Programme has received good support from the industry and has benefited many companies. It has attracted many investors to Malaysia to set up operations and work with local expertise. This assimilation is ideal to create and spur innovation and increase the R&D and commercialisation culture in the Malaysian cluster.

#### **4.1.2.1. Scope of Improvement**

- To increase total funding allocation to ensure more deserving BioNexus status companies are funded adequately. This will hopefully translate into successful commercialisation of R&D that will accelerate economic growth;
- To continuously provide value added services in terms of business matching, nurturing and facilitation after BCG funding, especially for start-ups and SMEs; and
- To spur more start-ups and encourage them to understand benefits and rewards within the industry.

#### **4.1.2.2. Changing Role of the Programme in Phase 2 NBP**

- BCG forms a vital element of the value chain that supports the biotechnology ecosystem. The Programme will now need to shift its focus to commercialisation. Bio-innovations that are viable and feasible with market potential need to be identified and commercially exploited;
- To attract overseas companies to invest in Malaysia biotechnology industry through newly set up or existing BioNexus status companies; and
- To provide key market information on Malaysia biotechnology and assist local companies to explore and expand their competitive edge. As the international market could be very saturated or volatile, development of local market will render resiliency for these companies during an economic downturn.

In conclusion, BiotechCorp is in the right direction with disbursement of much needed grants to create critical mass throughout Malaysian Biotechnology industry value chain by enabling companies to lay out their business infrastructure and capability.



## 4.2. Biotechnology Entrepreneur Programme (BEP)

One of the greatest challenges for scientists is converting scientific discoveries and innovations into tangible solutions for consumers. The "Valley of Death" has to be crossed by bio-entrepreneurs who often have limited experience and expertise necessary to convert their ideas into commercial products suitable for public consumption. In addition, VCs are increasingly reluctant to invest in early stage biotechnology companies, presenting another hurdle to researchers hoping to commercialise their innovations. Hence, various programmes such as business incubation and technical expertise transfer are needed to populate, drive and create new bio-business opportunities in Malaysia.

Recognising this challenge, BEP has been outlined under Thrust Five, Human Capital Development of NBP. The objective for the Phase 1 NBP was to promote entrepreneurship in the country, which in turn leads to creation of local biotechnology companies through the BioNexus programme. The BEP had the ultimate objective of capacity building, through development of bio-companies with potential to grow into large biotechnology enterprises.

The overall objectives of the BEP are:

- To provide bio-entrepreneurs with the necessary skill sets and knowledge to commence, fund and manage new biotechnology ventures;
- To encourage the establishment of start-ups and development of SMEs; and
- To enhance competitiveness of entrepreneurs and their enterprises.

The expected outcome from this programme is to create the industry base of bio-entrepreneurs and biotechnology companies that would contribute to industry growth. There were three sub Programmes implemented:

- **International Conferences and Dialogues**

This Programme aims at providing training, encouragement and networking opportunities to aspiring bio-entrepreneurs. The conference lectures were delivered by panels of experienced, international industry experts such as bio-entrepreneurs, researchers, VCs and representatives from regulatory bodies. Topics discussed included business plan development, funding mechanisms, licensing strategies, legal and regulatory issues, industry trends, competitive intelligence and ethical issues.

- **Entrepreneur Development Programme**

The objective of the Programme is to provide focused bio-entrepreneur development through industry workshops and roundtable discussions. Experienced trainers and industry experts were invited to speak at these events. The outcome of the Programme aimed to provide better insights of the biotechnology industry for entrepreneurs to start their businesses.

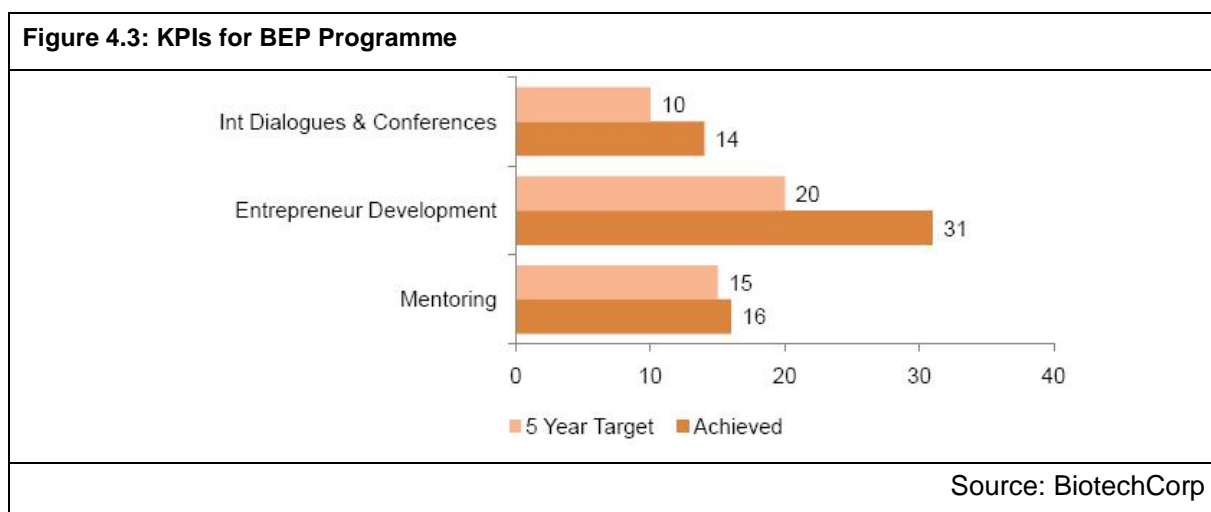
- **Mentoring Programme**

This is a specialised, one-on-one targeted development Programme for bio-entrepreneurs. The mechanism includes the appointment of a panel of recognised mentors to provide biotechnology companies, individuals and newly founded organisations involved in biotechnology activities with operational, financial and marketing advisory services. The mentoring relationship is supported through placements, advisory services, joint collaboration, retreats and networking sessions.

#### 4.2.1. Achievements of the Programme

The BEP is recognised by entrepreneurs in Malaysia as a key entrepreneurship support programme in biotechnology. The talent pool created by BEP enhanced the capabilities of local budding bio-entrepreneurs. The benefits of the Programme will be realised on a long term basis as the trained bio-entrepreneurs will be better equipped to commercialise biotechnology research results.

The BEP programme had achieved its target in line with the objective for Phase 1 NBP. In terms of the initiatives undertaken by the program owners under RMK-9, the Programme was successful; as it achieved the targeted KPI for RMK-9.



#### *International Conferences and Dialogues*

Fourteen International Conferences were held during RMK-9, surpassing its target of 10 events within five years. Various international conferences and dialogues were held, for example:

- Industry Dialogue – Double Helix : Decoding Biotech start-ups and Investment Options in Malaysia at San Francisco, 2008;
- Symposium on Human Capital for Biotechnology, 2008;

- New Academy of Sciences for Developing World (TWAS) Regional Young Scientists Conference on Food, Health & Fuel, 2009;
- BIOCAMP Sabah and Sarawak, 2009;
- Bio-Entrepreneur Conference, 2007-2009. The topics covered within these conferences include technology transfer, funding and entrepreneurship activities at grassroot level; and
- Biotechnology Education Symposium, 2010. The purpose of this symposium is to educate, expose and cultivate the interest in biotechnology to the younger generation at the foundation level, starting from the school.

More than 700 industry participants attended the conferences and dialogues under BEP. Strategic issues and industry challenges were identified and discussed among the biotechnology experts, policy makers, entrepreneurs and investors. These discussions and recommendations were translated into actionable plans to further grow the Malaysia's biotechnology industry. In addition, the programmes had created a healthy flow of information and an interactive think-tank platform through networking at the individual level.

#### *Entrepreneur Development Programme*

Thirty-one Entrepreneur Development Programmes were held during RMK-9, surpassing its target of 20 events within five years. Selected Programmes are highlighted below:

- Biotechnology Entrepreneur Workshop series 2007-2009, with total of 12 workshops conducted;
- BioNexus Clinics series 2009, with total of six clinics conducted;
- Accelerating Commercialisation in biotechnology: Review & Discussion on Formation of Business Entities of Public Sector Institutions, 2009;
- Workshop on the Art of Patent Drafting, 2009, and
- Seminar on Commercialisation of Intellectual Property – Realising the Potential of Your IP.

#### *Mentoring Programme*

Sixteen Mentoring Programmes were held during RMK-9, surpassing its target of 15 events within five years. Selected Programmes are highlighted below:

- Programme with QB3, where four programmes were implemented from 2007 – 2010;
- IGNITE Program in Cambridge, United Kingdom 2008 and 2009 – Fast tracking the development of bio-entrepreneurs from IHLs with direct availability of partners/financiers;
- LARTA – Global Bridge Programme for Technology Commercialisation, 2009 – 2010;
- Executive-in-Residence (EIR) Programme – Renowned biotechnology experts were appointed as mentors providing direct assistance to start-up BioNexus status companies;
- Best Practice Programme for establishment of Science and Research Park by Association of University Research Park (AURP), USA in the year 2009; and
- National Business Incubation Association (NBIA): Malaysian Incubator Management Certificate Programme, 2009.

## High-Impact International Mentoring Programme

### QB3 Malaysia Programme

QB3 was created in 2000 to fuel the California bio-economy. QB3 is a consortium of more than 200 laboratories from the University of California campuses at Berkeley, Santa Cruz, and San Francisco. Armed with world-class researchers, state-of-the-art facilities and entrepreneurial resources, QB3 is a multi-disciplinary institute designed to accelerate discovery and innovation to benefit society at large.



The QB3 Malaysia Programme is a tailor-made Programme that aims to achieve the vision of building a Malaysian biotechnology industry by providing training to Malaysian graduate students and post-doctoral fellows in the life sciences arena. The ultimate objective for these researchers is to return to Malaysia and work as a team at the Malaysian Institute of Pharmaceuticals and Nutraceuticals (iPHARM) to advance the fast expanding local drug industry.

The Programme represents a collaborative effort between the Malaysian Institute of Pharmaceuticals and Nutraceuticals and QB3 and is part of QB3's effort to advance global health care.

The Global Bio-Entrepreneurship Course is a one-week comprehensive course in bio-entrepreneurship tailored to the needs of Malaysia professionals' for biotechnology industries. The course provides a content-rich overview of the life sciences industry, entrepreneurship and venture financing. Leveraging the experience and expertise accumulated at the University of California, San Francisco (UCSF) and QB3, the Global Bio-entrepreneurship Course aims to help new bio-entrepreneurs bring their scientific discoveries from bench to market. More than 80 participants from Malaysia from IHLs/RIs, entrepreneurs and government agencies attended QB3's Global Bio-entrepreneurship Course (GloBE), throughout the period of 2007 to 2010 at the UCSF Mission Bay campus.



### LARTA – Global Bridge Programme

BiotechCorp has enlisted the services of LARTA to design, develop and implement the Malaysian Global Bridge Programme to help advance the market readiness and potential Malaysian bio-entrepreneurs in all segments of biotechnology.

LARTA plays a significant role in improving the transition to Phase 2 NBP: Science to Business. This partnership has vast potential since LARTA's network includes subject matter experts, seasoned entrepreneurs, investors, and Fortune 1000 companies seeking to access innovative

new business opportunities. Since 1993, LARTA has helped the entrepreneurs to raise over US\$ 1.5 billion in capital.

The partnership and collaboration with LARTA had provided BiotechCorp and the potential delegates with access to world-class content and experience to enable the creation and development of global Malaysian biotechnology enterprises.

### **IGNITE Programme**

IGNITE Programme is a joint Programme with Centre for Entrepreneurial Learning (CfEL), Cambridge University. IGNITE is an intensive, one week training Programme for aspiring entrepreneurs and corporate innovators to trial and prepare business ideas for the commercial environment. BiotechCorp has implemented this Programme for two consecutive years. In 2008, 10 seats were offered to researchers, and received 18 applications. There were an increased number of applications in 2009 whereby 15 sponsorships were offered and in return 57 applications were received.

IGNITE Programme has also created a pipeline of bio-entrepreneurs who have commercially viable bio-business ideas. This is supported by constructive feedback from the CfEL panel towards researchers' bio-business plans. The panel agreed that the local researchers have "great concepts" and viable, timely ideas with good potential and strong underlying technology and business viability.

### **The Results:**

From this Entrepreneur Development and Mentoring Programme, 274 new entrepreneurs and researchers were trained. Thirty five Malaysian researchers with global potential bio-business ideas presented value propositions to international VCs and industry experts. As a result, 51 bio-business ventures (commercialisation projects and technology licensing) and nine spin offs were created from these BEP programmes.

The BEP Programmes have laid a strong foundation to prepare Malaysia's biotechnology industry players for Phase 2 NBP. The mentoring programme had imparted valuable experience, learning and advice to those young entrepreneurs and IHLs/RIs researchers to commercialise their innovations.

Some of the success stories which have been showcased in *BioUsahawan* are as follows:

**Success Story 1: GranuLab Sdn. Bhd. – Development of bone graft substitute using calcium phosphate ceramics.**

GranuMaS™ – an osteoconductive granular synthetic bone graft material based on calcium phosphate hydroxyapatite – is an alternative material for the repair of bone defects. It is derived from pure chemicals and Malaysian limestone, manufactured using a patented process. Now, it is used as a bioactive coating on many surgical and dental implants.

GranuMaS™ alleviates concerns over *Halal* and ethical issues. It has gone through extensive biocompatibility and safety evaluation, demonstrated excellent biofunctionality in clinical trials, and been successfully screened by various *in vitro* and *in vivo* tests. Its highly osteoconductive properties promote good callus formation and the subsequent healing of bone defects. Being a synthetic bone graft, GranuMaS™ removes the risks of disease transmission from allograft (bone from a human donor) and xenograft (bone from animal origin) bones.

**Success Story 2: Medical Biotherapy Sdn. Bhd. - Sterilarvae™ Maggot Debridement Therapy (MDT)**

Sterilarvae™ offers a low cost and effective solution to address the main complication for people with diabetes – chronic hyperglycemia. The disease results in neuropathy – which decreases circulation and diminishes a person's sense of pain (thus a small cut or blister on the foot can easily become infected and lead to a need for amputation).

The breeding of sterile larvae (maggots) from the species *Lucilia cuprina* and the commercialisation of its use in Maggot Debridement Therapy (MDT) has helped heal chronic wounds in diabetic patients quickly, and effectively.

Sterilarvae™ has committed its resources to extensive research into the field of biosurgery. Their state-of-the-art pharmaceutical production unit has been designed in-house and provides the best facilities available today for the production of sterile larvae.

**Success Story 3: Neopeutics Sdn. Bhd. - High-throughput Drug-Target Identification Technology**

Neopeutics Sdn. Bhd. is the first commercial enterprise to emerge from QB3's Malaysia Programme. It is a drug discovery company, was founded to transfer expertise and boost the growing Malaysian biotechnology sector. The company is currently based at iPharm's bio-pharma incubation facilities in Penang, Malaysia with a support office in San Francisco, US.

Neopeutics primary services are centred on contract research for private and governmental regulatory agencies and for industry, and include drug-discovery services, data analysis and interpretation, advisory services, value-adding services and quality assurance services. In tandem with their services, the main product offerings include bioinformatics software, a drug screening technology package and potential therapeutic compounds derived from natural resources.

#### 4.2.2. Future Outlook of the Programme

The assessment shows that there is a stronger demand for hand-holding activities by the young biotechnology companies. Many have indicated that continuity is the key factor to provide much needed business mentoring programme. Many companies have indicated the BEP is an excellent effort by Government and BiotechCorp to help nurture early stage companies and SMEs. In addition, the policy makers had indicated that they gain valuable industry insights from BEP, which translates into more adaptive and market-driven policies that creates a more vibrant local biotechnology market.

Currently, BEP acts as a transition programme for the researchers (mainly those with Science and Technology background) to venture into the fundamental aspects of business know-how. However, the IP for the innovation/invention largely belongs to the IHLs/RIs; thus the participants are unable to create their own company unless it is the IHLs/RIs who undertake spin-off, technology licensing, joint-venture and/or collaboration. As such, future Programme can be designed to facilitate the commercialisation process of IHLs/RIs bio-innovations.

The next generation of scientists will transform scientific practice by incorporating more business elements into their research. These new scientists will be both multidisciplinary and business-oriented. Under this future prospect, the business coaching and mentoring is critical to support these new generation scientists into their business ventures.

BEP's role will be more critical in future, with the requirements to assist these young bio-innovators to create lightweight business models that leverage on the open-innovation network.

#### 4.2.3. Changing Role of the Programme in Phase 2 NBP

- Capability development: Continuation to mentor next generation of entrepreneur;
- To provide specific training and mentoring for bio-businesses at different stage of life cycle, with focus on creating biotechnology SMEs;
- To provide exposure to business opportunities with concerted programme to prepare SMEs to compete at both local and international level; and
- Collaboration with Performance Management and Delivery Unit (PEMANDU), Talent Corporation Malaysia Sdn. Bhd. (TalentCorp), *Agensi Inovasi Malaysia* (AIM), Cradle Investment Fund (Cradle) and IHLs/RIs to promote entrepreneurship in biotechnology industry.



### 4.3. Biotechnology Entrepreneurship Special Training (BeST) Programme

At the beginning of RMK-9, availability of the talent pool with relevant expertise has been cited as one of the major constraints of industry growth. Students that graduated from IHLs needed to enhance and accumulate hands on experience of working with high-tech equipment.

Further, the students also have limited knowledge in critical aspects of the product development life cycle, as well as business skills and other soft skills. This has significantly affected the local companies as they were required to train these graduates for a period of around one year before they could be productive. Attrition also enhanced the concern as employers felt that the effort was not reaping the desired benefits.

Hence, BiotechCorp introduced the BeST Programme, which acts as a bridge to enhance the education provided at the IHLs and provide students with additional skill sets to meet industry requirements. The industry participated in defining the course structure which would primarily help them in reducing the time gap between the date of joining and the time when productive utilisation of the employee begins.

BeST is a six month intensive and structured re-tooling Programme for graduates from all disciplines, wishing to enter the biotechnology industry and other related industries in general. Combining classroom-based learning, laboratory work and industry internship, the Programme aims to:

- Equip graduates with essential skills and knowledge for entry-level positions within biotechnology companies or biotechnology-related companies;
- Enhance their knowledge and skills of graduates in biotechnology and life sciences-related fields to match industry requirements; and
- Ensure adequate supply of qualified human capital to cater to the industry demands.

The Programme modules are designed to nurture talent and maximise potential in biotechnology which are also the key aspirations of BeST Programme, with the goal of producing graduates with the high competencies with the right exposure.

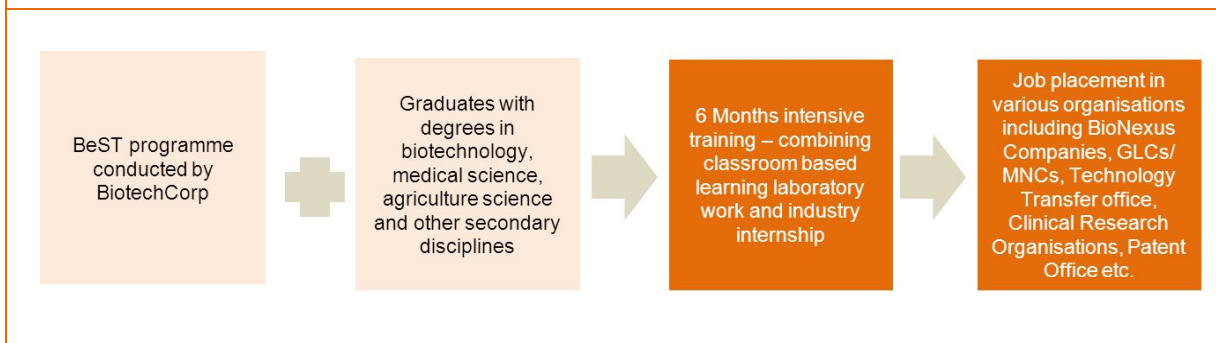
The participants of this Programme are primarily graduates with a degree in biotechnology, life science, agricultural science and other secondary disciplines i.e. business administration, marketing, finance, engineering and law.

This Programme is fully funded by the Government and BiotechCorp and has been conducted nationwide.

*Overall Programme descriptions are:*

<b>Development of work-ready practical skills and knowledge</b>
The Programme curriculum was developed in consultation with leading industry players and academic experts to impart skills and knowledge required for an entry-level career in the biotechnology industry.
<b>Practical industry exposure as part of the Programme</b>
The graduates had undergone an internship placement with biotechnology/biotechnology related companies for a period of three months to gain hands-on industry exposures and experience.
<b>Expertise from industry specialists brought into the classroom/laboratory</b>
The classroom-based and laboratory-work had included facilitation by industry specialists wherever applicable.

**Figure 4.4: BeST Programme Structure**



**4.3.1. Milestone and Key Achievements of the Programme**

In 2007, BiotechCorp implemented the BeST Programme with a special budget allocation from the Ministry of Finance (MOF) with targeted numbers of 200 trainees. Under this program, 270 students were trained, 97 percent secured employment and three percent of the graduates had decided to further their studies. Based on the proven track record of the Programme, BiotechCorp has also secured subsequent funding under the second stimulus package with targeted 500 trainees to be trained throughout the economic corridors. BiotechCorp had an additional budget under RMK-9 to train 150 trainees in 2010. The target milestones achieved are shown in Table 4.2.

Table 4.2: Milestones for BeST programme				
No	Budget	Targeted Numbers to be Trained	Actual	Targeted Percentage of Job Placement (@ 75%)
1	MOF	200	270	150
2	2 <sup>nd</sup> Stimulus Package	500	620	375
3	RMK-9	150	150	113
<b>Total</b>		<b>850</b>	<b>1,040</b>	<b>638</b>

Out of 1,040 students that were trained under the BeST Programme, 650 students secured employment in the industry, the rest decided to start new business ventures or further their studies. Hence, the program had exceeded its target both in terms of students trained and job placements achieved.

As the response for the BeST Programme from the graduates was encouraging, the targets of trainees for each budget are usually exceeded. Apart from providing the biotechnology skills and knowledge, graduates from the BeST Programme are better positioned to take advantage of job opportunities in the related industries, shortened the period of job search/placement and the graduates had better vision about their career pathway in the biotechnology industry.

Through this Programme, BiotechCorp established strong relationship with the Economic Corridors, IHLs/RIs, Government agencies and Ministry departments. BeST had created a spill-over of talents that are much needed for the local economic corridors especially in the biotechnology sector.

As a result, BeST is recognised by the industry players for its significant contribution in developing talents for biotechnology industry. Through this programme, BiotechCorp was awarded as Industry-Lead Body (ILB) by Ministry of Human Resource (MOHR) in 2010.

An ILB is responsible for defining, maintaining and improving national standards of performance for National Occupation Skill Standard (NOSS). They represent their sector of employment, including small and leading-edge employers and must have credibility as employment-led organisations. To date, there are 10 ILBs that have been identified in their respective industry/sector by MOHR including BiotechCorp as shown below.

Organisation/Association	Sector/Industry
National Agricultural Training Centre (NATC)	Agricultural & Agro based
Construction Industry Development Board Malaysia (CIDB)	Building & Construction
Multimedia Development Corporation (MDeC)	Information & Communication Technology
Malaysian biotechnology Corporation (BiotechCorp)	Biotechnology
Malaysian Association of Hotels (MAH)	Malaysian Association of Hotels
Federation of Malaysia Manufacture (FMM)	Machinery & Equipment
Institut Bank-Bank Malaysia (IBBM)	Business Management
Malaysia Palm Oil Board (MPOB)	Oil Palm based
Malaysian Textile Manufacture Association (MTMA)	Textiles & Apparel
Malaysia Oil & Gas Services Council (MOGSC)	Oil & Gas

**Testimonials:**

“...The endorsement letter from BeST, helped me secure an internship placement with a further opportunity to be employed permanently in the company. “ - **Shiela Ho Shuk Kyun**

“BeST is a good Programme for the graduates as it provided us the knowledge as well as the skills needed for the market. The Programme could be improved further to prepare the graduates for more challenging, specialised careers in the biotechnology sector.” – **Mariani Rajagopal**

“BiotechCorp could collaborate with more BioNexus companies, and hence giving more job opportunities to BeST participants when compared to those fresh graduates (who did not attend this programme)” - **Norfarhana Khairul Fahmy**

“Being with BiotechCorp and KRIBB has not only broadened my view, but also exposed me to entrepreneurship opportunities. During my training at KRIBB, I not only worked with the renowned professionals at KRIBB, but also learnt more about Korean culture. We used to visit Korean village every week to understand the local culture. The automatic admission which includes a scholarship in Korean University will significantly improve my career prospects. I foresee myself opening my own company in Marine engineering” – **Qurbanii**

“When I was a graduate, I was unsure about the future career prospects in biotechnology. The experience in KRIBB and BiotechCorp opened up my eyes to the tremendous opportunity presented by the biotech Industry not just in Malaysia but globally. The BeST and KRIBB courses helped me in getting hands-on experience with best-in-class equipment. I foresee myself being a successful entrepreneur of a biotechnology based consulting company” – **Farhzan**

### 4.3.2. Future Outlook of the Programme

BeST Programme is seen as one of the significant successes of the BiotechCorp. The impact of the Programme is both long term as well as sustainable.

BeST Programme has managed to assist graduates in biotechnology and life sciences to prepare themselves for entry level positions. Through the BeST Programme, graduates have managed to sharpen their skills and knowledge on Biotechnology concepts and applications, as well as gain an appreciation of entrepreneurship and business issues in the industry.

The graduates are more confident in communication and business presentations. Skills such as project management and preparation of reports and business proposals have helped them to convince biotechnology companies and related organisations to offer them employment.

The talent pool created by this Programme assists in fast tracking the capability building of young professionals from Malaysia. The future Programmes such as *MyBeST US* Programme, plan to leverage this critical mass of talent pool to benefit the Malaysian biotechnology Industry.

#### **Success Story 1: Collaboration Programme between BiotechCorp and KRIBB**

This collaboration programme was a follow-up initiative from the official visit of the Prime Minister, Dato' Seri Najib Tun Razak to Korea in 2009. It is a collaborative effort of the Malaysian and the Korean Government in giving specific technical knowledge in bioprocess to graduates from Malaysia, who will eventually be absorbed into the biotechnology industry.

KRIBB is a research institution fully funded by the Korean Government entrusted to develop research and development in bioprocess areas for the Korean industry. KRIBB is also an independent body under the Korean Research Counsel for Core Science and Technology and one of the research institutions specialising in biotechnology R&D. The main mandate for KRIBB under Bio-Vision 2020 is to make Korea as one of the top seven countries in biotechnology R&D by 2016. A MoU had been signed on 7<sup>th</sup> July, 2009 between KRIBB and BiotechCorp involving collaborations in the area of biotechnology.

The training programme had been implemented from 4<sup>th</sup> October 2010 to 26<sup>th</sup> November, 2010. Upon the completion of the programme, the participants were required to specialise in bioprocess related areas with commercial or government organisations in Malaysia. They were also allowed to work with IHLs/RIs in Malaysia. The exposure to bioprocesses was provided by KRIBB where it involved R&D experts together with industry practitioners from Korean bioprocess related companies.



Eight graduates, who had completed their training under the BeST Programme, had been selected for the KRIBB Training Programme. They were being trained and exposed in the bioprocess areas under the KRIBB Training Programme to become specialists in bioprocesses that are highly demanded by the industry. Out of the eight graduates, three graduates were selected for admission into prestigious Korean IHLs with scholarships. It is a form of recognition on Malaysian talents for their potential in biotechnology industry.

#### ***Success Story 2: Stem Cells Operational and Professional Excellence (SCOPE) programme***

BioNexus status company Stempeutics Research Malaysia Sdn. Bhd. (Stempeutics) had trained its first batch of 15 Malaysian employees in Bangalore, India, under the Stem Cells Operational & Professional Excellence (SCOPE) programme, supported by BiotechCorp. The Programme was intended to prepare knowledge and skilled workers for Stempeutics stem cell lab at Technology Park Malaysia.

Under this Programme, Stempeutics (a subsidiary of India-based Manipal Education & Medical Group) was established to promote stem cell activities in Malaysia.

The SCOPE programme by Stempeutics was part of talent creation in the field of stem cells with focus on cutting-edge research, therapeutics and therapy in the field of regenerative medicine. It is a significant step with multiple benefits - enhancing FDI of up to RM20 million to Malaysia, a wealth of resource in international research and expertise, expanding access and exposure for Malaysian talent in stem cell research.

While the first batch will undergo stem cell training in Bangalore, future batches will be trained at the Stempeutics facility in Kuala Lumpur. It is expected that this specialised training will help to create good talents in Malaysia in the area of biotechnology, especially future regenerative medicine.

#### **4.3.3. Scope of Improvement**

- To implement more internship and practical experiences with the biotechnology companies;
- To further create awareness about the BeST Programme and develop branding amongst industry players and recruiters on the quality of the Programme graduates;
- To develop a comprehensive prospectus about tentative curriculum, trainers/lecturers plans and activities. This will allow the public and the prospective students to have better perspective on the BeST programme and its benefits;
- Increase collaboration with the industry to develop market-driven curriculum that is up-to-date and offers the overall bio-business perspective in both local and global context;
- Enhance collaboration with other BioNexus status companies and let these companies be well-informed about the BeST Programme. This will give an advantage to the BeST participants' versus those fresh graduates who did not attend, in terms career opportunity exposures; and

- Introduce advanced BeST Programmes that could be tuned towards two distinct syllabuses: Entrepreneur skills development and professional skills development. In both syllabuses, specialised modules for different industry segments i.e. healthcare, industry and agricultural can be introduced.

#### **4.3.4. Changing Role of the Programme in Phase 2 NBP**

- The BeST Programme will evolve from general to specialised training on critical areas. The Programme will be refined to create a talent ecosystem, focusing on the specialised technical skills on (e.g. bioprocess, tissue cultures, analytical lab instrumentation, clinical research, IP management, herbal and natural extraction) that is required by the industry;
- The target group for BeST programme can be extended to high-school leavers, diploma holders and lateral trainings for semi-skilled workers in other industry sectors;
- Engage Malaysian experts overseas to train local potential trainers in the focused areas;
- To offer customised BeST programme for IHLs after their graduation. The IHLs' students will undergo the BeST program before they graduate, with focus on practical skills and internship. Alumni of BeST will be engaged to contribute to future training programmes;
- Create awareness and international branding of the Programme;
- Introduce additional Programmes that could be used by professionals working overseas to interact with the Malaysian biotechnology industry; and
- Propose that part of the Programmes, especially the soft skills and lab skills development to be incorporated into IHL curriculum.



#### **4.4. Intellectual Property Research and Management Programme (IPRM)**

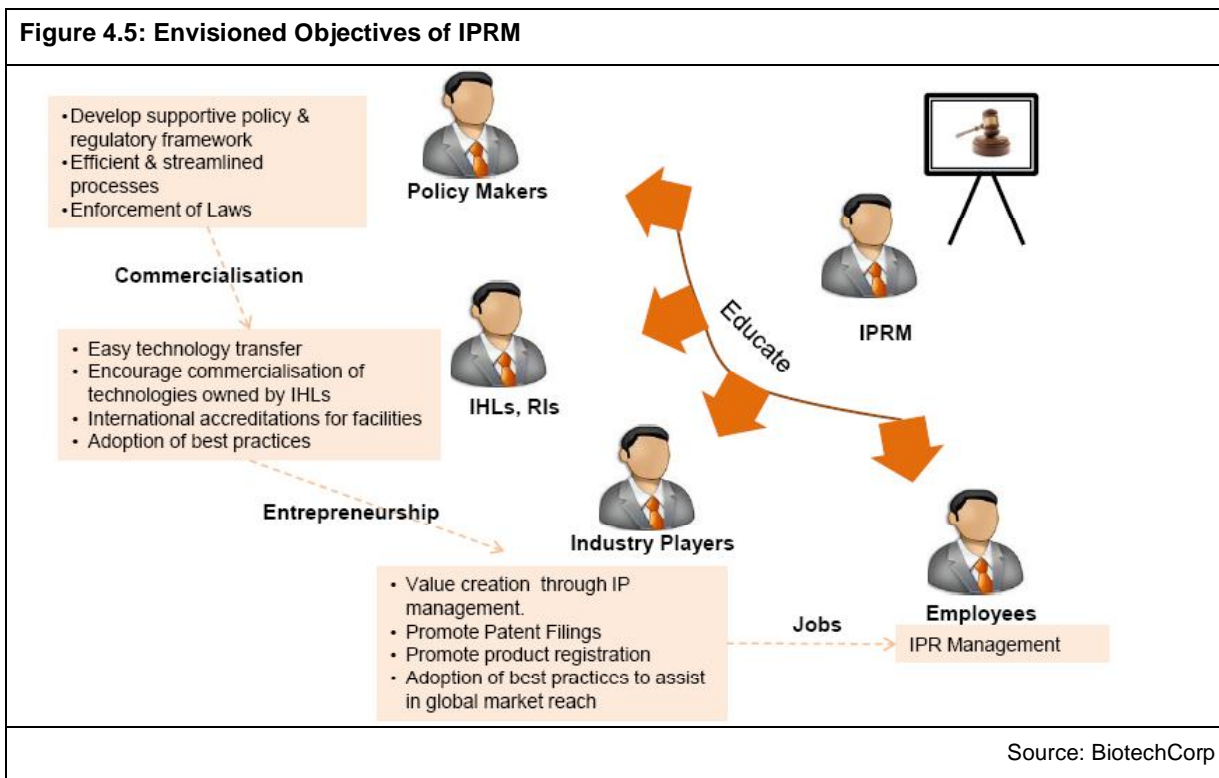
The IPRM programme has its roots from Thrust Seven of the NBP which emphasises the importance of establishing a solid and supportive regulatory framework for the development of biotechnology. It envisages the Government to play a proactive role in shaping the regulatory agenda for the biotechnology industry.

##### **4.4.1. Objectives of the Programme**

Under the IPRM, BiotechCorp has sought to:

- Promote a supportive regulatory framework and environment that takes into consideration the developmental aspirations of the country, encourages innovation and ensuring public safety;
- Contribute towards the development of a strong regulatory framework for IP rights;
- Contribute towards encouraging the creation and filing of biotechnology-related patents with a view on commercialisation;
- Contribute towards a balance between value creation and access to local genetic resources, while not hampering genuine initiatives and cooperation between access providers and access seekers;
- Promote and support initiatives for the attainment of international accreditation and compliance with international standards; and
- Contribute towards the establishment of a strong and enabling regulatory framework for the enhancement of efficacy in relation to product registration.

With this broad based approach, BiotechCorp organised various engagement initiatives such as organising dialogue sessions, workshops, trainings, certification courses and conferences with various industry players and stakeholders, who are in a position to influence the regulatory environment of the country.



#### 4.4.2. Programme Classification

Various activities and programmes were conducted in Phase 1 NBP with the following objectives:

- To strengthen and enhance public awareness;
- To engage with relevant international and local bodies to facilitate the development of a balanced legislative and regulatory framework;
- To advocate the adoption of best practices and the streamlining of processes; and
- To ensure that Malaysia remains competitive in line with its developmental agenda in the area of biotechnology.

IPRM focused on the following four key areas in Phase 1 NBP. These include:

- Intellectual Property
- Pharmaceutical Regulation
- International Accreditation
- Biosafety and Access and Benefit Sharing

### A. Intellectual Property

One of the objectives of the IPRM programme was to formulate a comprehensive and integrated IP management system. Some of the key initiatives conducted during RMK-9 are listed below:

- i) **Law Review** – continuous law review to ensure that the IP protection system in Malaysia is at par with global innovation clusters;
- ii) **IP Management Training** – Various training programmes have been conducted for relevant stakeholders to ensure that the IP management ecosystem is supported. This includes:
  - IP Commercialisation Workshops;
  - Patent Drafting Workshop on Biotechnology;
  - Patent Examiner Training Programme;
  - IP Clinics; and
  - Malaysian Institute of Management (MIM) Certified Professional IP Manager Programme.From 2007 to 2010, 1154 participants benefited from the programmes and training organised under this programme;
- iii) **IP Law Training** – This training was conducted in collaboration with MyIPO specifically for officers involved in the IP Courts which includes judges, prosecution officers and enforcement officers from the Ministry of Domestic Trade, Co-operatives and Consumerism;
- iv) **International Benchmarking Study on IP**– This benchmarking study evaluated Malaysia's competitiveness with regards to the IP framework amongst selected countries (such as UK, US, Australia, Singapore, India etc.);
- v) **International Exchange Programme for Patent Examiners** – This initiative was designed to enhance the skills and expertise and widen the exposure of patent examiners to current technologies and best practices. Eight MyIPO patent examiners attended an exchange programme with the Korean Intellectual Property Office (KIPO) and the European Patent Office (EPO). Further, another eighty patent examiners attended a hands-on patent examination workshop by international experts from KIPO and the United States organised by BiotechCorp in collaboration with MyIPO; and
- vi) **Reducing Patent Files Backlog** - This initiative was designed to increase the patent examination capacity of MyIPO via short term as well as long term measures. Four patent examiners have undergone 'on the job' training placements with IP Australia in 2007. An additional ten contract patent examiners were placed at MyIPO beginning 1<sup>st</sup> July 2010 to boost examination capacity.

### Testimonials

*“BiotechCorp’s cooperation and support through the programme had helped us achieve our objectives and all the programmes ended successfully. The patent examiners have improved their skills in conducting searches, examination and in processing patent applications” - Ms Shamsiah Kamaruddin, Deputy Director General MyIPO*

*“BiotechCorp has shown strong support towards capacity-building by providing relevant and targeted IP programmes under RMK-9. This is a wise move as a clear understanding of IP issues is essential to the growth of the biotechnology sector in Malaysia. The programmes have a strong focus on workshops and practical hands-on learning utilising case studies which helps the participants to absorb the materials taught. The participants have been able to move beyond the legal paradigm to look at the commercial aspects of IP and Intellectual Asset Management. They have gained a more holistic approach incorporating business, legal and technical perspectives. Therefore, it’s not just IP protection that is now the focus but IP value extraction is the core objective.” - Mr. David Oh, CEO, MindVault Sdn. Bhd. (MIM-CPIPM certification)*

## B. Pharmaceutical Regulations

The development of regulations in relation to pharmaceuticals in Malaysia is relatively progressive and remains well-developed under the stewardship of the NPCB under MOH. NPCB will further strengthen the registration activities of vaccines and biotechnology products through the establishment of related policies and guidelines, protocol reviews, GMP inspections, laboratory testing and collaboration with relevant stakeholders. With the objective to enhance the efficacy of product registration, some of the key initiatives carried out during RMK-9 are listed below:

- i) **Introduction of Biosimilars Guidance document** – BiotechCorp played an active part in the workgroup headed by the NPCB in developing the Biosimilars Guidance document. The workgroup consisted of local and multinational pharmaceutical companies and the local biotechnology association. The members worked together to create a set of guidance documents and guidelines which will regulate the registration of biosimilars in Malaysia. As a result, Malaysia is now one of the few countries in Asia Pacific that has outlined regulations for biosimilars registration;
- ii) **Representation in Regional Discussion Forums** – BiotechCorp is involved in the Malaysian working group to provide input on biotechnology related regulatory issues in moving towards the harmonisation of regulations to enhance cooperation amongst ASEAN member states through the ASEAN Consultative Committee for Safety and Quality (ACCSQ) Product Working Group (PWG). The working group covers the following areas:
  - Pharmaceuticals: (ACCSQ- PPWG);
  - Traditional Medicine and Health Supplements: (ACCSQ TMHS-PWG); and
  - Medical Devices: (ACCSQ MDPWG).

iii) **Capacity Building through Workshops and Seminars:** From 2007 to 2010, 693 participants benefited from the programmes and training organised under this programme. Among the programmes conducted were:

- Workshop on Regulatory Requirements for Traditional Medicine and New Chemical Entities (NCE);
- Workshop on Biosimilars;
- Workshop on Product Submission Dossier for US & Europe;
- Workshop on ASEAN Medical Dictionary for Regulatory Activities (MedDRA); and
- Workshop on QC Biosimilars.

#### Testimonials

*“The collaboration between BiotechCorp and NPCB under RMK9 were overall positive and benefited various stakeholders as well as our internal human resource team. BiotechCorp acted as an intermediate party by arranging a few meetings between NPCB and the stakeholders which include both local and international companies and were able to provide funding for capacity building both for the stakeholders and the regulatory authority. The strengths of this partnership program was to improve the understanding of the needs between the industries/stakeholders and the regulatory authority to provide a conducive business environment without compromising the standards and infringing regulatory requirements”. – Dr Kamaruzaman Salleh, Head of Centre for Investigational New Product, NPCB*

### C. International Accreditation

Thrust Seven of NBP had also recognised the importance to adopt and implement international standards such as GMP, GLP and GCP to ensure Malaysia’s competitiveness in relation to other countries with similar biotechnology initiatives. Some of the key initiatives conducted during RMK-9 are listed below:

- i) **GMP** - Malaysia is a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). PIC/S' mission is "to lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products." Malaysia and Singapore are moving towards harmonised GMP inspections as in April 2009, all ten ASEAN member countries signed a Mutual Recognition Arrangement (MRA) to harmonise GMP inspections. Towards this initiative, BiotechCorp conducted workshops such as the “GMP seminar for biotechnology” for various stakeholders.
- ii) **GLP** – In line with the national aspiration to achieve full adherence to the Mutual Acceptance of Data (MAD) System of OECD GLP by 2012, NPCB and Standards Malaysia in collaboration with BiotechCorp are working hard to ensure compliance to the OECD GLP MAD system.

Two GLP Compliance Monitoring Authorities (CMA) have been appointed, namely:

- NPCB as CMA for pharmaceutical products, cosmetic products, veterinary drug and food additives; and
- STANDARDS MALAYSIA as CMA for pesticides, feed additives, industrial chemicals and non-pharmaceutical biotechnology products.

The IPRM programme contributed to the preparation towards full adherence of the OECD GLP MAD system under the GLP Compliance Monitoring Program through the following initiatives:

- **Meetings:** Numerous preparatory meetings were facilitated by BiotechCorp between the CMAs and the test facilities periodically for progressive reports into implementation and compliance with the principles of GLP;
- **Training:** Training sessions for test facilities were organised for committed test facilities such as Melaka BiotechCorp, SIRIM, IMR and IFNM. These trainings were facilitated by both CMAs and also foreign CMA (e.g. NATA, Australia and Norwegian Accreditation); and
- **CMA Inspector Trainings:** Training and attachment programmes for inspectors, done locally and at respective OECD member countries were funded through the IPRM programme.

Concurrently, mutual co-operation between the two CMAs on the implementation of the OECD GLP MAD system were initiated by way of meetings, joint inspections, exchange of views on non-compliance of GLP issues and discussions on issues of mutual interest related to GLP.

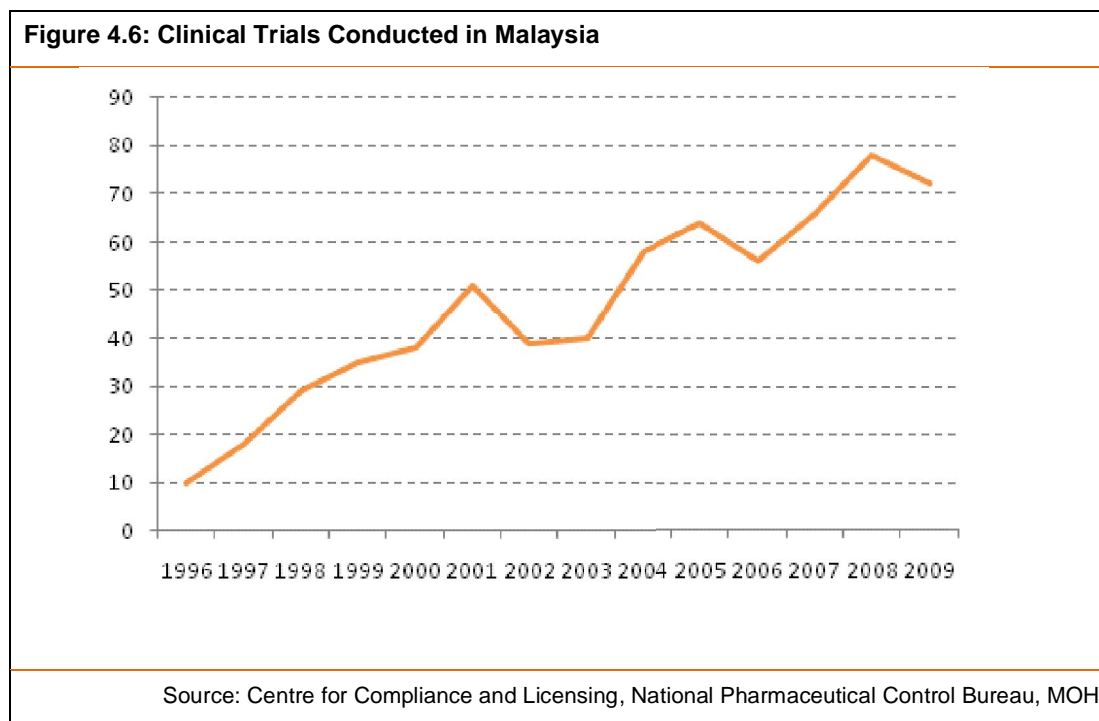
GLP inspections were conducted on nine committed test facilities in which three are found to be ready for testing in compliance to the OECD GLP requirements.

- iii) **GCP** - Malaysia is the ideal clinical research destination in Asia. In addition to its large multi-ethnic population, the nation offers excellent healthcare infrastructure, GCP-trained clinical researchers who are mostly English-literate, strong government support and efficient regulatory processes.

In 2008, more than US\$35 billion was spent on clinical research of investigational treatments, up from US\$18 billion in 2000, an 8.6 percent eight-year annual growth rate. During the period 2004 to 2008, clinical research spending from all sources grew by 9.0 percent each year.<sup>14</sup> As a result of proactive Government initiatives, the clinical research activity in Malaysia is also on the rise, with as many as 200 clinical trials expected to be done in Malaysia in 2014 as compared to 72 in 2009. The number of sites for clinical trials is also expected to rise to close to 1000 in 2014 from 352 in 2009.

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<sup>14</sup> Source: Tufts CSDD and published survey results from PhRMA.



Presently, 11 international and four local Clinical Research Organisations (CROs) are operating in Malaysia. By 2014, these figures are likely to touch 20 and six respectively. In terms of number of patients, 6,390<sup>15</sup> patients opted for clinical trials in 2008. This number is likely to double by 2014.

There are 17 CRC located in all major public hospitals in the country. MOH ensures each trial proposal goes through a rigorous review. The trial itself is strictly monitored and regularly audited. The Centre for Investigational New Product of NPCB plays an important role in issuing Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) in ensuring compliance with GCP. With the objective of promoting Malaysia as a hub for clinical trials, BiotechCorp through the IPRM programme, collaborated with CRC and NPCB on the following initiatives:

- **GCP Investigators Certification** - From the year 2007 to 2010, over 750 GCP investigators were certified by the CRC through collaboration with BiotechCorp.
- **GCP Workshops** – BiotechCorp in collaboration with CRC and MOH conducted a series of workshops for the various stakeholders on topics such as Clinical Research Governance and Ethics, Clinical Project Management, Clinical Trial Management and Clinical Research Bioethics.

<sup>15</sup> **Note** These statistics are based on the number of applications received by National Pharmaceutical Control Bureau for the clinical trial import license for unregistered products. Drug-related clinical trials for registered products which do not require clinical trial import license is not controlled by the Drug Control Authority.



Overall, from 2007 to 2010, 1240 participants benefited from the GMP, GLP and GCP programmes and training organised under this programme.

#### **D. Biosafety**

Malaysia is a signatory of the Cartagena Protocol on Biodiversity (the Protocol), which is the first legally binding international agreement governing trans-boundary movement of living modified organisms (LMOs). The Protocol which came into force on 11<sup>th</sup> 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.

One of the key factors to be considered when coming up with national policy and laws on biosafety is the need to take into account the developmental goals of the nation and interests of industry while ensuring sustainability of biodiversity, natural resources and ensuring public safety. Malaysia needs to ensure that the biosafety policy and laws strike a delicate balance between public protection and also encourage the development of biotechnology in the country.

The Biosafety Act 2007 came into force on 1<sup>st</sup> December, 2009. The Biosafety Regulations 2010 came into operation on 1<sup>st</sup> November, 2010 and this will help support and operationalize the Biosafety Act. 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. Some of the key initiatives conducted during RMK-9 are listed below:

- i) **Law Promulgation** – BiotechCorp was actively involved in advocacy and engagements with various stakeholders during the drafting of the Biosafety Act and Regulations by forwarding views from the industry to ensure that the biosafety framework and processes are business and research friendly.
- ii) **Capacity Building** - BiotechCorp has actively conducted various dialogues, symposiums, meetings and conferences on biosafety. From 2007 to 2010, a total of 931 participants attended the initiatives relating to biosafety.
- iii) **Regulator Training** –The IPRM programme funded training programmes on biosafety for regulators.
- iv) **Benchmarking Studies** - Several benchmarking studies in relation to biosafety were conducted for various stakeholders.

#### **Testimonials**

*“BiotechCorp has helped the Biosafety Department to promote and raise awareness amongst biotechnology companies to comply with biosafety regulatory requirements in accordance with the Biosafety Act 2007.” - Dr Mohamed bin Mohamed Salleh, Director, Research and Evaluation Section, Department of Biosafety.*

*“It is an excellent program and can move forward to achieve their target on capacity building in biotechnology”.- Kayathri Panjavaranam, Science Officer, Department of Biosafety on training titled “Biosafety – An International Short Course in Environmental Aspects of Agricultural Biotechnology” at Michigan State University*

### Access and Benefit Sharing (ABS)

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 Access and Benefit Sharing (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 (PIC) of the Contracting Party providing such resources. Mutually agreed terms 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.

There are currently no domestic ABS laws to date. In view of the developments in the international front for example the progress made at the recent Conference of Parties (COP 10) in Nagoya and the importance of this subject to our country, it is anticipated that the national level laws on ABS is in the pipeline. The primary initiatives carried out under the IPRM programme for ABS are:

- i) **Law Promulgation** – BiotechCorp participated in international meetings organised by the CBD for the purpose of following the development of the International Regime on ABS. Pertinent issues from the vantage point of stakeholder/industry will continue to be highlighted to the Malaysian delegation led by NRE in working toward a conducive environment for biotechnology development in Malaysia; and
- ii) **Regulator Training**- Stakeholders i.e. MOSTI were funded to attend the CBD international meetings for them to have a broad understanding of the pertinent issues as they will be involved in the drafting of the national ABS laws.

#### 4.4.3. Achievements of the Programme

The following section describes some of the success stories achieved by the IPRM through its various initiatives. Each story entails the background of the initiative, the benefits and impact of the project.

##### Success Story 1: MIM Certified Professional Intellectual Property Manager (MIM CPIPM) Programme

IP that is well-managed can be utilised as valuable commercial competitive advantage. For an organisation to survive in today's fiercely competitive environment, it is imperative that it learns how to manage its IP asset portfolio in order to strategically position its business and maximise value generation from its intangible assets.

Trainer	Background of company
The Malaysian Institute of Management (MIM)	Inaugurated as a voluntary society on 29 January 1966, the MIM was incorporated as a company limited by guarantee on 28 March 1975. As the national management organisation, the primary role at MIM is to promote continuous management skills within the Malaysian enterprise, introducing the best in management practices from all corners of the world to our Malaysian companies, and building what we hope are important bridges between the private and public sectors.

BiotechCorp started inviting selected participants to attend the MIM CPIPM Programme run by MIM in 2007. This Programme provides an understanding of IP rights and Intellectual Asset Management (IAM). It is aimed at developing management skills that cover the business, technical and legal fields and has been designed to assist participants to obtain comprehensive and practical knowledge and skills in managing their IP Portfolio. The Programme covers topics like IP Risk Management and Commercialisation of IP.

Over 130 Certified IP Managers were trained through nine batches of this Programme. The participants came from BioNexus companies, IHLs/RIs and Government Agencies. Through the MIM CPIPM Programme, IP departments and committees had been formed in various organisations. Budgets have been raised so that organisations can implement IP strategies to maximise and unlock value from its current and future IP portfolio.

#### Testimonials

*“IPRM was a very good programme and related to my work as the IP Manager for National University of Malaysia/Universiti Kebangsaan Malaysia (UKM). I was very fortunate to participate in the programme. It really helped me to understand better on how to manage IP strategically and gave more confidence to talk about IP with the researchers at the University. UKM benefited from the programmes as the programme facilitated us to table a proposal to UKM on managing its IP strategically and the proposal was accepted. I also managed to train a few more staffs in IP management”.* - **Tengku Nor Kirana, IP Manager/ Assistant Registrar, Centre for Collaborative Innovation UKM**

#### Success Story 2: Full Adherence to OECD GLP MAD System

As earlier mentioned, it is the national objective to achieve full adherence to the Mutually Acceptance of Data (MAD) System of OECD GLP by 2012. The GLP Compliance Monitoring Programme is intended to ascertain whether Test Facilities have implemented requirements as described in documents of OECD Series on Principles of GLP and Compliance Monitoring. Test Facilities requesting for certification of compliance to Principles of GLP, and subsequent inclusion into the CMAs GLP Compliance Programme need to make the relevant application to CMAs. This objective is part of the recommendations under the NBP for the attainment of international accreditation and compliance with international standards.

Compliance Monitoring Authority	Background
National Pharmaceutical Control Bureau (NPCB)	NPCB has been designated as the Malaysian CMA for the non-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs and food additives. For NPCB the decision by the Government of Malaysia is enforced by the issuance of a Directive under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 in June 2009.
STANDARDS MALAYSIA	STANDARDS MALAYSIA has been designated as the CMA for the non-clinical safety testing of test items contained in industrial chemicals, pesticides, feed additives, and biotechnology (non-pharmaceuticals)

The IPRM programme contributed to the preparation towards full adherence of the OECD GLP MAD system under the Compliance Monitoring Program through the following initiatives:

- Numerous preparatory meetings were facilitated by BiotechCorp between the CMAs and the test facilities periodically for progressive reports into implementation and compliance with the Principles of GLP;
- Training sessions for test facilities were organised for committed test facilities like Melaka BiotechCorp, SIRIM, IMR, IFNM and IHL. These trainings were being facilitated by both CMAs and also foreign CMA e.g. NATA (Australia) and Norwegian Accreditation; and
- Training and attachment programmes for CMA inspectors, done locally and at respective OECD member countries were supported by BiotechCorp.

GLP inspections have been conducted on nine committed test facilities in which three are found to be ready for testing in compliance to the OECD GLP requirements.

Malaysia is now at the final phase of preparations for full adherence to the OECD GLP MAD system. During the recent Working Group meeting in Paris on 5<sup>th</sup>-7<sup>th</sup> April 2011 attended by two representatives from the CMAs, it was decided that the Mutual Joint Visit (MJV) shall take place on 14<sup>th</sup>-19<sup>th</sup> November 2011. A team of three OECD inspectors will inspect the readiness of the national CMA inspectors at a test facility decided by the inspectors. Upon the successful completion of the inspection, it is anticipated that Malaysia will gain full adherence to the OECD GLP MAD system.

Being fully adherent to the MAD system will ensure that non-clinical health and environment safety data generated in Malaysia in accordance with OECD GLP Principles will be accepted by OECD member countries for assessment purposes. This way duplicative testing can be avoided thus saving costs, time, resources as well reduce trade barriers.

#### 4.4.4. Impact of the Programme

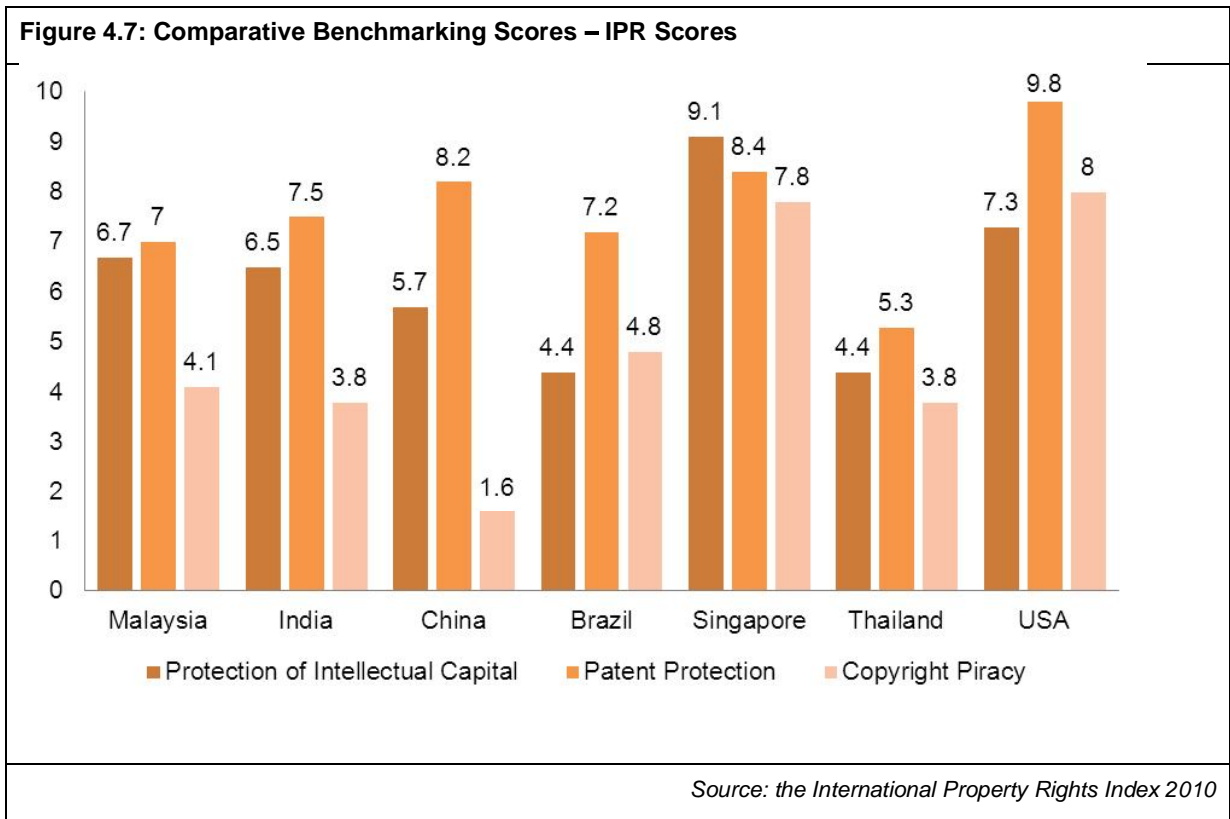
The IPRM programme owners worked closely with regulators and related organisations on various areas including IP, Biosafety, Access and Benefit Sharing, International Accreditation and Pharmaceutical Regulations to fulfil the objectives outlined in the NBP and to bridge the gaps in preparation for Phase 2 NBP. The capacity building initiatives carried out under the IPRM programme served a dual purpose:

- Provided valuable information and knowledge to key stakeholders; and
- A useful advocacy tool whereby key messages and important areas of focus were highlighted to the relevant policy and law makers.

IPRM program has played a role of the supporting agency, which is instrumental in educating the policy makers about the technical and legal implications of the proposed laws and regulations on the Biotech Industry. IPRM has made notable contributions and participated in development of following laws, regulations and directives, since the introduction of the NBP in 2005:

- Accession to the Patent Corporation Treaty on 16<sup>th</sup> August 2006;
- Biosafety Act passed by Parliament on 11<sup>th</sup> July 2007;
- The Biosafety Regulations came into operation on 1<sup>st</sup> November 2010;
- Protection of New Plant Varieties Act 2004 came into force 1<sup>st</sup> January 2007;
- Protection of New Plant Varieties Regulations 2008 came into operation on 20<sup>th</sup> October 2008;
- The Biosimilars Guidance document issued by NPCB (MOH) in August 2008;
- The GCP Inspection Programme issued by the Director of Pharmaceutical Services, MOH in 2010;
- The Data Exclusivity Directive introduced in 2011;
- Malaysian became a Provisional Member of OECD GLP MAD system in 2008; and
- Target for full adherence to OECD GLP MAD system by 2012

According to the Intellectual Property Rights Index 2010, Malaysia has moved up six spots to 31<sup>st</sup> from 37<sup>th</sup> in 2009 for the Protection of IP Rights. According to the World Economic Forum's IMD Global Competitiveness Report 2010-2011, in terms of IP protection, Malaysia has moved four places to 33<sup>rd</sup> from last year's ranking of 37<sup>th</sup>.

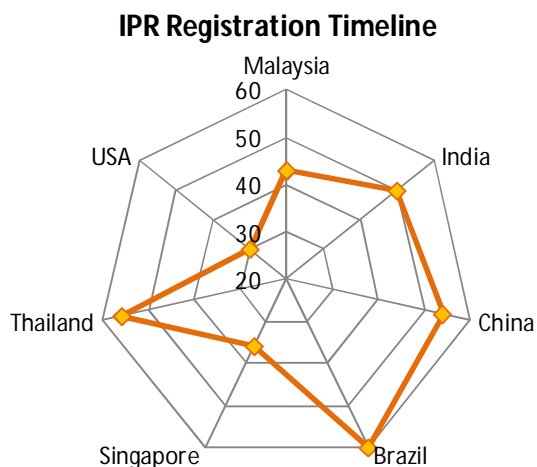


#### 4.4.5. Future Outlook

Moving into Phase 2 NBP, it is important that the regulatory framework remains supportive to encourage commercialisation of biotechnology products. There has to be intensified focus on reducing the regulatory barriers for new entrants. For instance, IPR registration timelines in Malaysia are expected to considerably improve. During the launch of the National IP Day on 26<sup>th</sup> April 2010, the Deputy Prime Minister proudly announced that the IP Office is now putting a new target of 36 months in 2011 and 32 months in 2012<sup>16</sup>.

<sup>16</sup><http://www.pmo.gov.my/tpm/?frontpage/speech/detail/1575>

**Figure 4.8: Comparative Benchmarking IPR Registration Timeline**



Source: Compiled by Frost & Sullivan

While this is just an example, steps need to be taken across all aspects of regulatory policy development. 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 conducive environment for the development of the biotechnology industry and towards supporting Phase 2 NBP – Science to Business:

- Continue constructive engagement with regulatory stakeholders to provide an avenue for discourse and alignment towards national policies;
- Increase awareness of strategic IP management and focus on areas such as securitisation and collateralisation of IP;
- Support NPCB and STANDARDS MALAYSIA (being the CMAs for Malaysia) for Malaysia to achieve full adherence to the OECD GLP MAD system by 2012;
- Assist identified facilities for GLP accreditation in terms of capacity building and training;
- Participate and contribute in the development of pharmaceutical regulations; and
- Provide inputs and feedback, with regard to the development of national biosafety and ABS laws.



#### 4.5. Biotechnology Acquisition Programme (BAP)

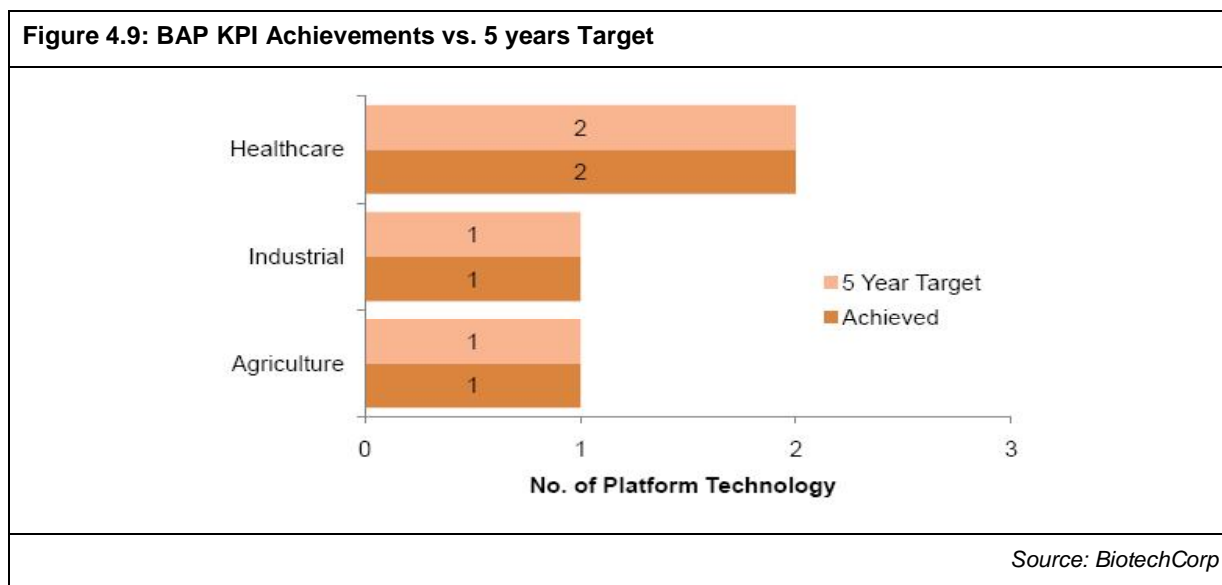
Thrust Four in the NBP, R&D and Technology Acquisition Development states the need to have Centres of Excellence as a mechanism to bring together multidisciplinary research teams in a coordinated effort for research and commercialisation. Therefore, under RMK-9 Programme, BiotechCorp has been entrusted to undertake a BAP which serves the following objectives:

- To facilitate the development of core and priority biotechnology areas and establish an advanced biotechnology industry in Malaysia; and
- To accelerate growth of the biotechnology industry and build the required skills sets and knowledge base through public and private R&D partnerships, domestically and internationally, internal collaborations and smart strategic alliances.

BiotechCorp has successfully acquired four platform technologies under BAP and the respective custodians are:

Table 4.3: BAP Technologies				
Focus Areas		Platform Technology	Custodian	Technology Description
1.	Healthcare	Nanotechnology platform in non-cancer applications	USM	Nanoparticle-based systems that allow design and synthesis of multifunctional inorganic nanoparticles of specified size for various applications e.g. drug delivery system and diagnostics in non-oncology field.
		DotScan™ antibody microarray diagnostic platform technology	UPM and IMR	The technology platform allows the users to customise and design the desired, specific antibodies for biomedical research applications, diagnosis and disease treatment including oncology applications.
2.	Agriculture	Marker Assisted Selection (MAS) in Plant and Animal Breeding	MARDI	Technology platform that utilise DNA markers to select desired genotype for agriculture applications.
3.	Industrial	Supercritical Fluid (SFE)	UPM	Commercial scale technology that produces standardised natural products extracts of high purity, quality and consistency through extraction and fractionation of nutraceuticals and bioactive compounds from natural sources using CO <sub>2</sub> technology.

All the four platform technologies acquired had undergone a rigorous process involving internal and external due diligence conducted by BiotechCorp and Consultants which include the technical, legal, intellectual property and financial due diligence. For the Phase 1 NBP, the KPI is to acquire two Healthcare platform technologies, one Agriculture platform technology and one Industrial platform technology.



#### 4.4.1 Benefits and Impact of BAP

Following table summarises the importance of BAP in national biotechnology development based on BiotechCorp’s perspectives and how the benefits will be translated to the beneficiaries of the Programmes in the NBP.

Benefits of the Technologies Platform Acquired by BAP
<p><b>1. Create a knowledge-based industry</b></p> <p>The technology acquired is in line with the Government and IHLs/RIs policies on utilising natural and local human resources for building a knowledge-based economy.</p> <ul style="list-style-type: none"> <li>• MARDI – Custodian of MAS platform technology</li> <li>• USM – Custodian of Nanotechnology Platform</li> <li>• UPM – Custodian of SFE technology</li> <li>• UPM and IMR – Custodians of DotScan™ Antibody Microarray technology</li> </ul>

**Benefits of the Technologies Platform Acquired by BAP**

**2. Increase in number of knowledge workers, improve skill sets and knowledge of Malaysian human capital**

Learn know-how of the technology to bridge gaps in research.

Training provided to all the custodians of the four platform technologies i.e. USM team enables the team to perform research on nanoparticles for biomedical application, MARDI on development of new applications through MAS, UPM on extraction of high value products from SFE at pilot manufacturing scale and IMR/UPM on potential new diagnostics and therapeutics applications from antibody microarray.

**3. Strengthen R&D capabilities**

The acquisition of the technology provides an access to ready developed technology in other country to expedite Malaysia's R&D capabilities. It also leads to development of centre of excellence that provides services and R&D collaborations locally and internationally.

- A centre of excellence in high through-put marker discovery and validations (CMDV) is being established in MARDI for services and R&D collaborations in this area.
- Establishment of NanoBRI@INFORMM to provide expertise to interested parties in the form of technology transfer on nanotechnology.
- Contract manufacturing facilities for SFE will be set up in UPM to further develop value-added products especially from Malaysian nutraceuticals.
- Technology transfer on antibody microarray to IMR and UPM will enhance the R&D capabilities and human capital development in this area.

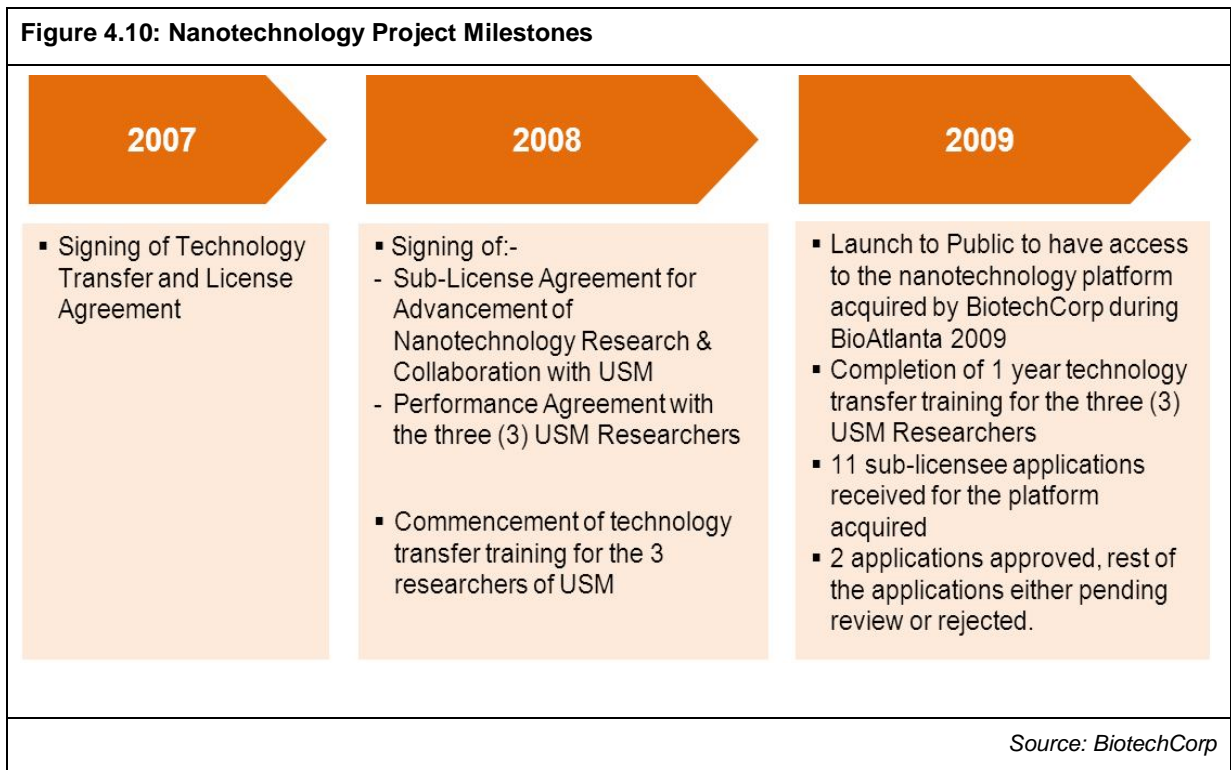
**4. Application of technology creates new growth opportunities to the industry**

It is expected that the acquisition of the technology will improve industry performance in a shorter time frame, create new business opportunities through various applications, thus driving the overall growth of the industry.

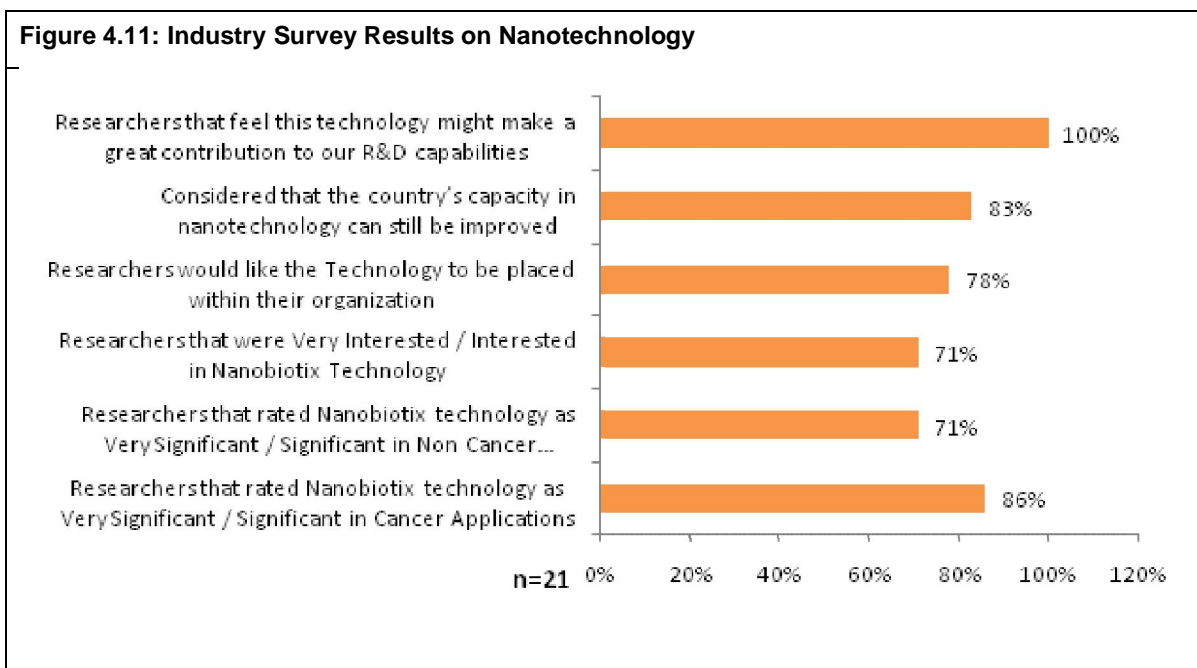
- MAS: Potential new varieties for rice, watermelon and goat with desirable economical traits can be produced much faster than the conventional approach.
- Nanotechnology: Main applications are focused healthcare nanotechnology especially in diagnostic and drug delivery. Other potential applications include tissue engineering, nanofiltrations, nanobatteries with supercapacitors, quantum computers, etc.
- SFE technology: Extraction of high valued flavour/fragrances, food ingredients, nutraceuticals, active pharmaceutical, cosmeceutical ingredients and specialty industrial chemicals. Other potential applications include material treatment and pollution abatement.
- DotScan™ Antibody Microarray: Development of Immunoassay reagents and therapeutic monoclonal antibodies.

#### 4.5.1. Nanotechnology Project Milestones

BiotechCorp acquired the exclusive worldwide license in non-cancer applications from Nanobiotix S.A (Nanobiotix) in 2007 to allow the design and synthesis of multifunctional inorganic nanoparticles of specified size for various applications, such as drug delivery system and diagnostics in non-oncology field.



To build a consensus before purchasing of the technology, BiotechCorp concluded a detailed industry wide survey to understand the demand patterns for the technology.



The technical due diligence findings suggest that projects of Nanobiotix are a new approach to cancer therapy and the novelty rests in the intracellular activation of a therapeutic agent by physical means in combination with the preferred uptake of the agent by cancer cells, based on physical principles.

As the main Licensor to the nanotechnology platform acquired, BiotechCorp can sub-license the platform technology acquired to any potential sub-licensee(s) interested to utilise the said platform technology to develop non-cancer applications.

#### *Collaboration with Local Nanotechnology Research Institutions/ Organisations*

USM has been selected as a custodian in 2008 for the nanotechnology platform acquired and three researchers from USM were sent for one year training with Nanobiotix. As part of the Sub License Agreement for Advancement of Nanotechnology Research & Collaboration between BiotechCorp and USM, USM has completed its nanotechnology laboratory facilities, Nanobiotechnology Research and Innovation (NanoBRI) Institute for Research in Molecular Medicine (INFORMM), which comprises:

- Nanostructure synthesis laboratory;
- Characterization laboratory;
- Pre-biological laboratory;
- Cell culture facilities; and
- Imaging laboratory.

In addition to the above, USM is also currently developing the following application/project:

- First project: Utilises Nanosilica-based platform to develop new silica based particles as carrier for in drug delivery system (DDS) application for therapeutic applications. Tuberculosis has been chosen as the disease to be treated in the drug delivery system proof-of-concept;
- Second project: To produce gold colloidal conjugated antibodies for diagnostic applications; and
- BiotechCorp has also appointed a commercial sub-licensee i.e. Cerebro Sciences Sdn. Bhd. to develop neuron specific delivery of gonadotropin-releasing hormone (GnRH) in small interfering RNA (siRNA) for drug delivery.

*Potential clients (which can also be sub-licensees) and applications*

The next milestone for BiotechCorp is to appoint sub-licensee(s) and generate products/applications for commercialisation. The target is to develop a minimum of 8 projects/applications of a substantial commercial value between the years 2008–2012.

Nanobiotix has identified 23 applications, which can be developed by potential sub-licensee(s) in the field of healthcare, environmental and agriculture as well as food and cosmetic industries using the platform technology:

Table 4.4: Applications that can be Potentially Developed		
Healthcare	Environmental and Agriculture	Food and Cosmetics
Microbial destruction	Water/Air treatment	Packaging additives to prolong food conservation
Drug delivery systems	Improvement of materials' biodegradability	Flavour nanoencapsulation
Cardiovascular therapeutics	Biofilm prevention	Solar protection
Ophthalmology therapeutic	High-efficacy fertilisers	Age spots, sun spots and wrinkle removals
Antiviral agents	Biodefense ( <i>bioagents detection</i> )	
Bone replacement		
Aseptic surgery		
Implants biocompatibility enhancers		
Improvement of micro material physical properties		
Ultrasensitive biopsy		
<i>In vitro / in vivo</i> diagnosis, imaging and biology agents		

### *Market Potential and Future Outlook of Healthcare Nanotechnology<sup>17</sup>*

The global healthcare nanotechnology market size was estimated at US\$ 10.92 billion in 2009. It is forecasted that the global healthcare nanotechnology market will grow at a CAGR of 21.5 percent reaching the size of US\$29.93 billion by the year 2014. North America was the largest market for healthcare nanotechnology applications in 2008 with revenues of US\$3.7 billion, and is expected to increase with the introduction of new products in regenerative medicine and coatings and implants. Europe is the second largest market for healthcare nanotechnology with France, Germany and UK contributing to its market share.

With the exception of drug delivery platforms, nanotechnology research is still in its early development stage and it may be at least five years or more before the new generation of Malaysian nano-products and nano-devices become commercially available. Despite the market excitement and availability of this nanotechnology platform, many challenges remain. These include regulation, competition, patenting, ethical, legal, public perception, safety and toxicity and commercial viability, among others.

However, the field of nanotechnology is rapidly evolving and opportunities exist to integrate it within many aspects of R&D, including overcoming research bottlenecks; product repositioning; the development of new imaging agents and Point of Care diagnostics; and the emergence of personalised medicine. The new era of Malaysian nanotechnology has arrived. The only question that remains is how quickly and widely the Malaysian biotechnology industry will embrace this technology within its R&D process.

#### **4.5.2. DotScan™ Technology Project Milestones**

BiotechCorp signed the patent and technology license agreement with Medsaic Pty Ltd in 2009 to license its technology platform DotScan™ antibody microarray. Antibody microarrays are measurement devices used in biomedical research applications to determine the presence of or the amount of proteins in biological samples such as blood and serum. The greatest demand for antibody microarray is likely to be in basic research where scientists looking at biological systems at the molecular level need to identify large groups of interactions simultaneously. The other potential applications include biomarker discovery, disease diagnosis, characterisation of signalling and protein pathways, drug target discovery, drug response profiling and patient stratification.

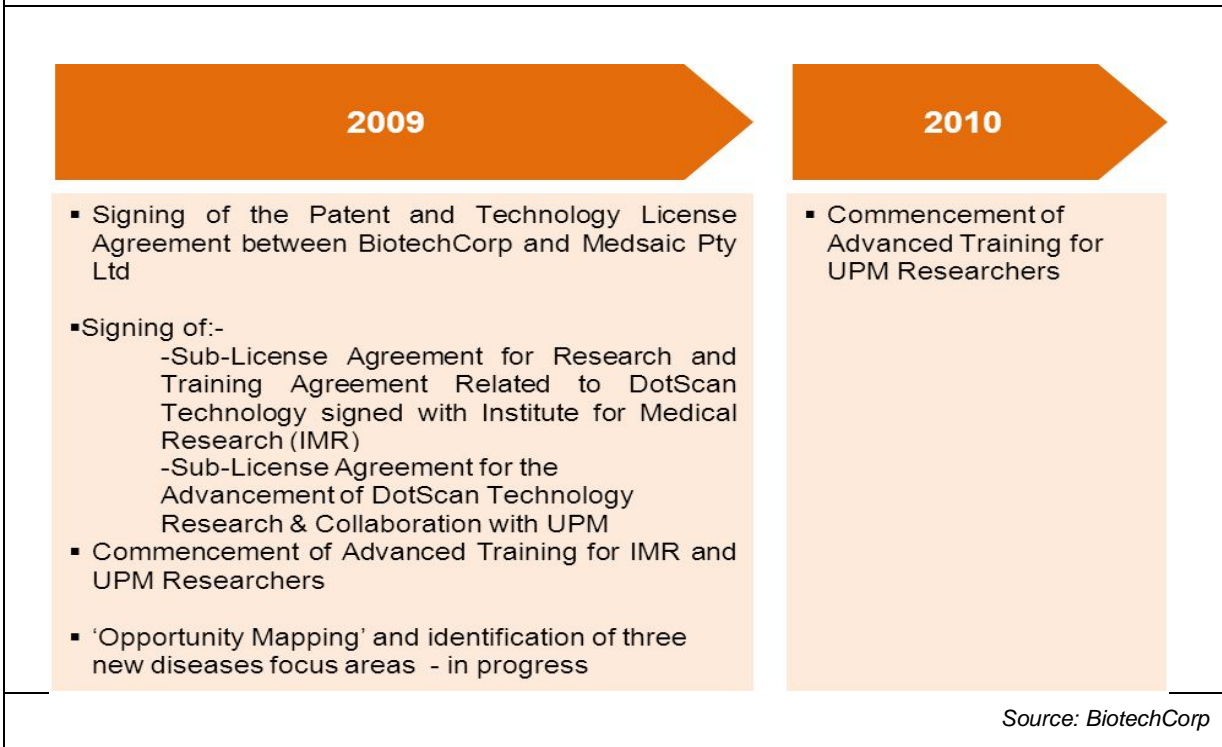
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<sup>17</sup>References:

- D123 – Applications of Nanotechnology in Healthcare. Frost & Sullivan, 2008.
- Nanotechnology in Healthcare. Market outlook for applications, tools and materials and 40 company profiles. Business Insights, 2010.
- Nanotechnology: Revolutionizing R&D to develop smarter therapeutics. Business Insights, 2007.

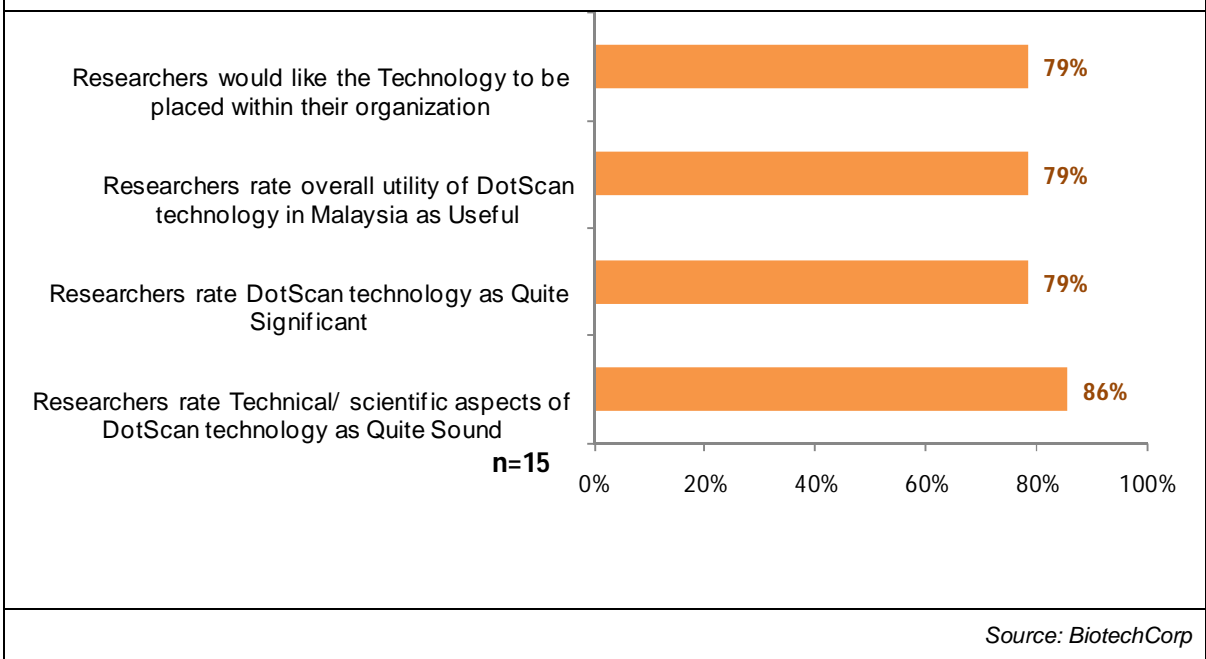


**Figure 4.12: DotScan™ Project Milestones**



To build a consensus before purchasing of the technology, BiotechCorp concluded a detailed industry wide survey to understand the demand patterns for the technology.

**Figure 4.13: Industry Survey Results on DotScan™**



Based on technical due diligence conducted, the findings of the study amongst others are:

- Medsaic's DotScan™ technology is fundamentally robust and offers many unique benefits both for research and clinical markets;
- The value proposition of the technology lies in the combination of a particular disease-specific biochip and its associated disease-specific software, in being able to diagnose the particular disease the software it is designed for;
- Other potential applications of Medsaic's technology, includes biomarker discovery, disease diagnosis, characterisation of signalling and protein pathways, drug target discovery, drug response profiling, patient stratification and predicting disease recurrence (prognosis); and
- The application of antibody microarray methods to cancer research has been most promising, as shown in studies on proteins in sera, cell culture and resected tissue samples.

#### *Collaboration with Local Research Institutions/Organisations*

As the acquisition and technology of DotScan™ was completed recently, the platform technology is yet to be sub-licensed except to the custodians i.e. IMR and UPM to undertake technology transfer and develop applications/projects. In addition, two IMR and two UPM researchers have completed the training in 2010.

BiotechCorp is actively looking for companies who are interested to commercialise the developed applications in the diagnosis of lymphoma and leukaemia as well as collaborators in the development of the diagnostic tools. The success of this technology will depend on the number of commercialised diagnostic tools developed resulting from the use of DotScan™ and the royalty from the commercial sale of the related products.

#### *Market Outlook for Antibody Microarray<sup>18</sup>*

The shift in research approach from genomics to proteomics, the attempt to catalogue every protein and characterise their functions had highlighted the importance of antibodies in research activities supply, biotechnology and pharmaceutical markets. Modelled after the multiplexed methods of genomics, proteomic investigations involve simultaneous measurement of many proteins in experimental samples. Multiplexed measurement is logical for biological discovery with proteins because it constitutively functions within networks, pathways, complexes and families.

Antibodies represent the vast majority of immunoassay reagents, which is the largest of nine segments - DNA synthesis & sequencing, polymerase chain reaction, protein synthesis and

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<sup>18</sup>Sources:

- Biocompare Surveys and Report, Global Industry Analysts, Frost & Sullivan
- Multiplexed Protein Measurement: Technologies and Applications of Protein and Antibody Arrays. Nature Reviews Drug Discovery, 5:310-321, 2006.
- Frost & Sullivan, "Antibody Technology Developments", September 30, 2005
- Global Industry Analysts, "Reagents and Supplies in Biotechnology", August 1, 2006
- 2007 Antibody Report: Current trends and future outlook. Biocompare Surveys and Report, 2007.

sequencing, electrophoresis, bio/chemiluminescence, chromatography, flow cytometry, cell and tissue – of biotechnology reagents in the world. In 2006, immunoassay reagents brought in an estimated US\$8.87 billion. With a CAGR of 7.55 percent, revenues should reach US\$12.03 billion by 2010. The Asia-Pacific region leads the world with a growth rate of 8.33 percent followed by the United States, Japan, Europe, Latin America and Canada, respectively. Revenues in the Asia-Pacific region should reach US\$1.8 billion by 2010. At that point, the U.S. will continue to lead as the top consumer, bringing in revenues of US\$4.3 billion, followed by Europe, Japan, Canada and Latin America, respectively.

The cream of the antibody industry is therapeutic monoclonal antibodies (mAbs). About 18 mAbs have now been approved by the U.S. Food & Drug Administration. Five of these – Synagis(palivizumab) by MedImmune, Herceptin (trastuzumab) and Rituxan (rituximab) by Genentech and ReoPro (abciximab) by Centocor already have annual revenues of more than US\$3 billion apiece, spurring biotechnology companies, and increasingly big pharma, to bring numerous mAb candidates through the pipeline, into human trials and onto the market.

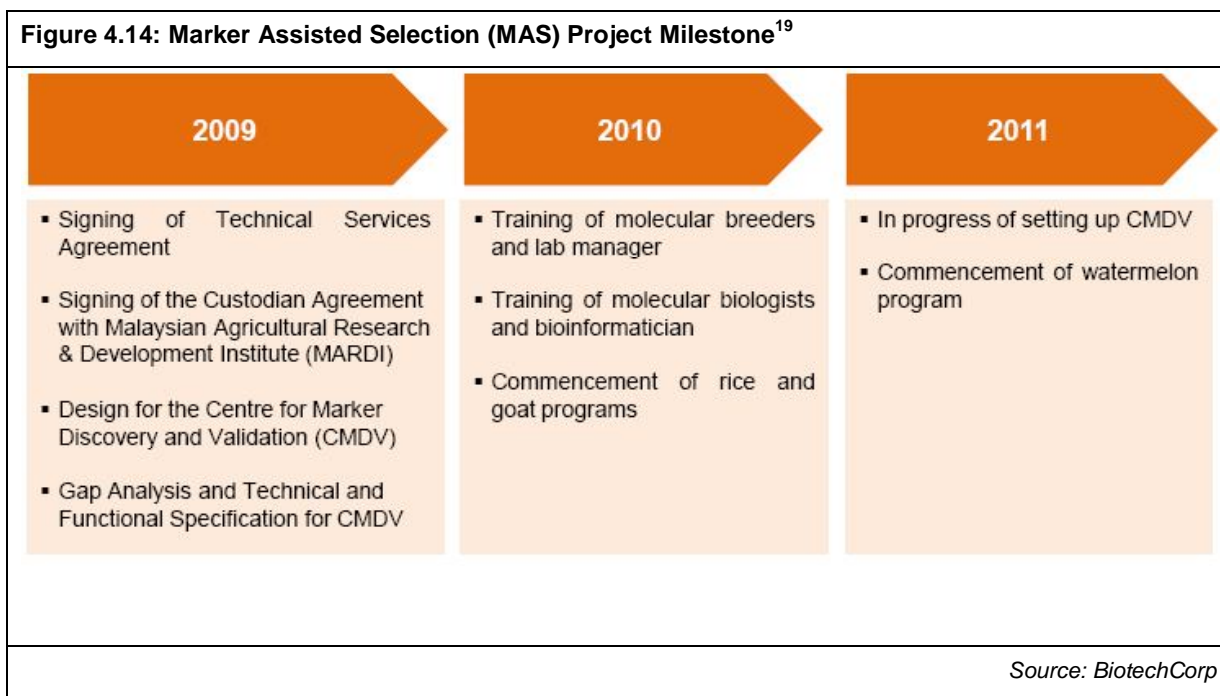
#### **4.5.3. Marker Assisted Selection (MAS) Project Milestones**

In its efforts to stimulate Malaysia's agriculture biotechnology sector, BiotechCorp executed a strategic collaboration with DNA Landmarks Inc, from Canada for the licensing of a marker discovery and validation technology.

The MAS 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. The training provided by DNA Landmarks to custodian will:

- Develop capabilities in high throughput genotyping of Malaysian agriculture crops and livestock;
- Discover and validate genetic markers on these crops and livestock; and
- Transfer of knowledge, skills and animal breeding in Malaysia.

The MAS 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.



The MAS technology provides:

- An accelerated method for identifying the best breed of plants and animal for use in commercial farming programmes;
- Jumpstart the agriculture industry by providing information on best traits and/or breeds, thus saving years of conventional selection and breeding; and
- Stimulate the growth of the agriculture industry by ensuring the availability of superior traits and breeds at a faster rate.

Through the acquisition of the MAS platform technology, the agricultural industry will be able to cultivate and produce high-quality, value-added agricultural products for local and international markets. It will also greatly assist the seed industry in Malaysia in the validation of quality seed materials.

<sup>19</sup>Theoretical and Applied Genetics, vol. 107(5), pg. 922-930.Philosophical Transaction of The Royal Society Biological Sciences vol. 363, pg. 557-572.

- Trends in Biotechnology, vol 21, pg 59-63.
- Current Opinion in Plant Biology vol 5, pg 94-100.
- Plant Physiology vol 130, pg 103-105.
- Nucleic Acid Research vol 31, pg 183-186
- Marker Assisted Selection: Current status and future perspectives in crops, livestock, forestry and fish. Food and Agriculture Organisation of United Nation, 2007.

### *Collaboration with Local Research Institutions/Organisations*

MARDI was chosen as the custodian of this technology because of their extensive experience in the field of molecular markers and agriculture genomics. As a significant part of this technology acquisition, a Centre of Molecular Marker Discovery and Validation (CMDV) would be set up at Biotechnology Research Centre, MARDI. The purpose of CMDV is to generate technology platforms for discovery and validation of molecular markers, molecular breeding in livestock and crops as well as DNA fingerprints. This CMDV will be part of the National Key Economic Areas (NKEA) initiatives towards the development of the seed industry in Malaysia, where it is responsible to bring in GNI for the agricultural sector.

To date, the centre has just completed its building and technical training for technicians operating the centre. Tenders have also been awarded to facilitate the purchase of equipment for CMDV. Although CMDV is yet to be fully operated; the following BioNexus status companies have shown great interest in using the centre to assist their breeding programme:

- Green World Genetics Sdn. Bhd.;
- IOI Palm Biotechnology Sdn. Bhd.; and
- Asiatic Centre for Genome Technology Sdn. Bhd.

### *Future Outlook for MAS Adoption in Asia Pacific Region<sup>17</sup>*

The extent to which DNA marker technology has already spread to agriculture institutes coupled with the enormous amount of data from previous genome mapping and marker studies should lead to the greater adoption of MAS. Many such institutes in APAC e.g. Thailand Agriculture Research Agency and Indian Agriculture Research Institute possess the essential equipment and expertise required for marker genotyping, coupled with dedicated research funding.

Integrated agriculture research approach combining MAS, genome mapping and simultaneous variety development had produced encouraging results. Moving forward, genome mapping and marker development should always be conceived together in a holistic manner.

Increased use of genetic transformation technology will allow MAS to be used directly to select progeny that possess transgenes via target gene selection. Specific genotypes often with superior agronomic characteristics are routinely used for transformation. Therefore, MAS can be used to track the transgenes during elite line development.

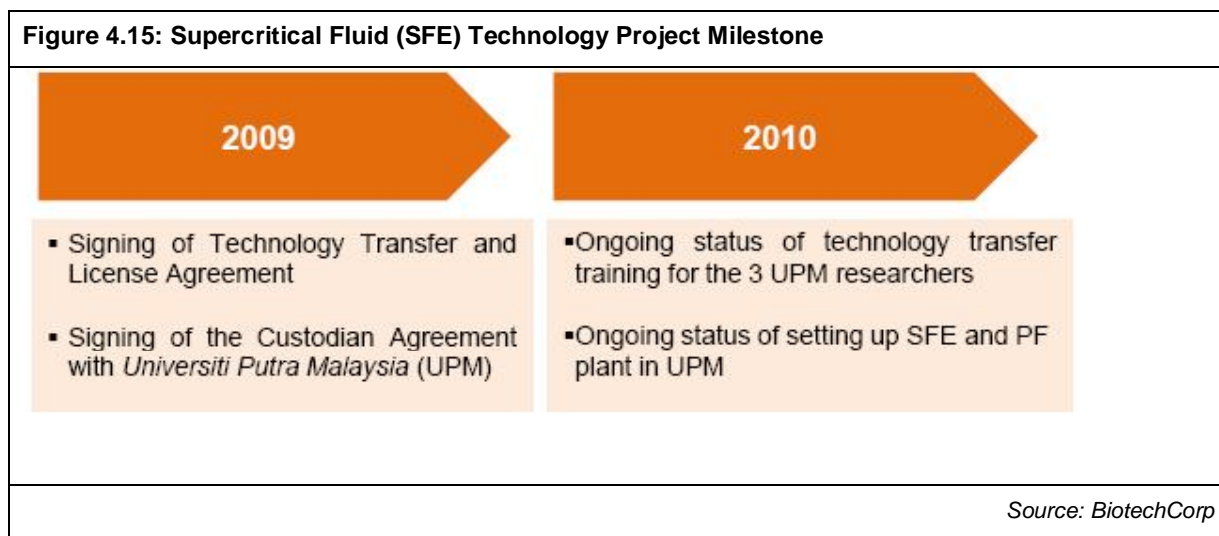
Many new high-throughput methods for DNA extraction and especially new high-throughput marker genotyping platforms have been developed, using SNP (Single Nucleotide Polymorphism, DNA sequence variation when a single nucleotide in the genome differs among the same organism species) markers. Due to their widespread abundance and potentially high levels of polymorphism, and the development of SNP genotyping platforms will have positive impact on MAS adoption in the future.

The availability of large numbers of publicly available markers and the parallel development of user-friendly bioinformatics databases for marker and genome mapping will encourage more widespread use of MAS. In cereals, two of the most extensive and useful databases are 'Gramene' and 'GrainGenes'. The development of these databases to keep pace with the continually growing amount of data generated will be critical for the efficient use of markers in the future.

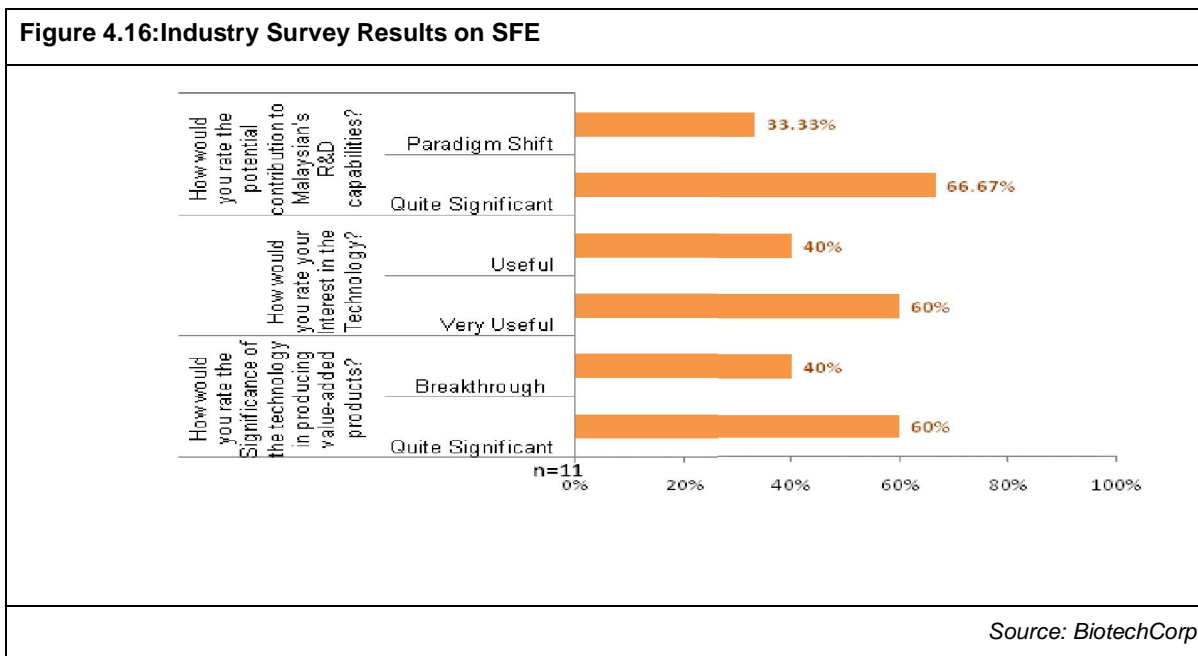
#### 4.5.4. Supercritical Fluid (SFE) Technology Project Milestones

The Supercritical Fluid Extraction (SFE) and Particle Formation applications were licensed from FeyeCon Development & Implementation B.V., Netherlands in June 2009. SFE produces standardised natural products extracts of high purity, quality and consistency through extraction and fractionation of nutraceuticals and bioactive compounds from natural sources using CO<sub>2</sub> technology. This new way of conducting extraction overcomes inherent limitations in conventional fluid extraction and distillation. Through the acquisition of the SFE platform technology, the local natural product industry will be able to:

- Possess the capability and capacity to produce high value herbal, food and industrial extracts; and
- Produce particles with a defined shape, uniform size and controlled morphology that are particularly suitable as active ingredients in pharmaceuticals.



The platform technology will enable Malaysia's local natural product industry to produce high value-added products and enable the country to become a leader in global natural products. To build a consensus before purchasing of the technology, BiotechCorp concluded a detailed industry wide survey to understand the demand patterns for the technology



*Collaboration with Local Research Institutions/Organisations*

Custodian agreement between BiotechCorp and UPM has been signed in June 2009. There are 33 recipes and operating procedures included in the technology transfer agreement.

Table 4.5: Transfer of 33 Established Recipes and Operating Procedures	
<ul style="list-style-type: none"> <li>• Ajowain Seed Oil</li> <li>• Ambrette Seed Oil</li> <li>• Amaranth</li> <li>• Black Pepper Oleoresin</li> <li>• Black Pepper Oil</li> <li>• Cardamom Oil</li> <li>• Nutmeg Oil</li> <li>• Cardamom Oleoresin</li> <li>• Celery Oleoresin</li> <li>• Celery Oil</li> <li>• Cumin Black Oil</li> <li>• Cumin Black Oleoresin</li> <li>• Cumin Oil</li> <li>• Vetiver</li> <li>• Turmeric Oil</li> <li>• Thyme Leaf Extract</li> </ul>	<ul style="list-style-type: none"> <li>• Vanilla 12% Vanillin</li> <li>• Ginger Oleoresin</li> <li>• Indian Holy Basil (Tulsi) Oil</li> <li>• Ginger Oil</li> <li>• Neem Seed Oil and Leaf Extract</li> <li>• Nutmeg Oleoresin</li> <li>• Coriander Extract</li> <li>• Cinnamon (Cassia) Extract</li> <li>• Pomegranate Seed Oil</li> <li>• Sea Buckthorn Seed</li> <li>• Cumin Oleoresin</li> <li>• Fenugreek Oleoresin</li> <li>• Coffee Oil</li> <li>• Clove Oil</li> <li>• Vanilla 26% Vanillin</li> <li>• Spilanthis Acmella</li> </ul>



A contract manufacturing facility at UPM, named the Supercritical Fluid Centre (SFC) will be set up for the commercial production of SFE products.

*Potential Clients (which can also be sub-licensees) and Applications*

The SFE is currently undergoing Site Acceptance Test (SAT), therefore, the technology has yet to be utilised. Nevertheless, four companies have expressed interests in using the services provided by SFC:

- Amway (Malaysia) Sdn. Bhd.;
- CNI Holdings Bhd.;
- Yakin Biolab Sdn. Bhd.; and
- Avenue Biotechnology Sdn. Bhd.

*Market Outlook on Super Critical Fluid Extraction Technology<sup>20</sup>*

At the present time, it is clear that the most important markets are related to *natural product processing* for “classical” applications in food and nutraceutical/pharmaceutical/cosmetic industries. For these areas, SFE is known to lead to higher prices than organic solvent extraction that is presently widely used, explaining that the CO<sub>2</sub>-extracts market is still limited and restricted to some niches.

**Regulatory Issues:** In a growing number of countries, most organic solvents are banned for food products extraction or authorised with extremely low residual concentrations; similarly, pesticide removal from natural products is of growing interest, as it is already operated on ginseng.

**Quality Consideration:** SFE is being developed for the preparation of high-value products such as food supplements and nutraceuticals, for which the “natural” character of the preparation mode has a high marketing value.

**Innovative Products:** “New” food ingredients that are not at all comparable with those obtained from classical solvent extraction or distillation can be manufactured, but they need acceptance by the users that their manufacture is often long and sometimes costly. The pharmaceutical industry is paying great attention to drug delivery systems that are opening new therapeutic routes for many major drugs related to widespread diseases (asthma, diabetes, cancer, etc.).

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<sup>20</sup> Sources:

- Supercritical fluid extraction: Recent advances and applications. *Journal of Chromatography A*, 1217 (2010), 2495-2511
- Supercritical Fluid Applications: Industrial Developments and Economic Issues. *Industrial Engineering Chemistry Research* 39 (2000), 4531-4535.
- Multiple unit processing using sub- and supercritical fluids. *The Journal of Supercritical Fluids* 47 (2009) 598-610.

**Innovative Processes:** Innovation is required for solving many environmental problems, like Volatile Organic Compounds (VOC) emission reduction, and supercritical processes are often considered as a “radical” solution that permits one to eliminate organic solvents, and particularly chlorinated solvents, such as those for painting, metal degreasing, or textile cleaning or dyeing. On the other hand, “green” chemistry will drastically develop in the next decade, using supercritical fluid (mainly carbon dioxide and water) as reaction media and/or separation agents.

Table 4.6: SFE - Fields of Application	
Field	Applications <sup>21</sup>
Flavours/Fragrances	Extraction of essential oils and fragrance compounds of higher organoleptic quality, generally closer to natural stuff. The absence of any organic solvent residue is very favourable for consumers.
Food Ingredients	Extraction of colorants (natural colorants, orange colour from the pot marigold flower, carotenoids from palm oil, shellfish, or carrots, etc.), antioxidant preservatives (deodorisation of rosemary extract), texture agents (lecithin purification), and low-fat products (egg-yolk powder).
Nutraceuticals	Processing of medicinal plants or SFE of oils, constitute, an increasing market to substitute extracts obtained with organic solvents and to propose new high-quality products; some raw materials are treated for elimination of pesticides (ginseng) or for deodorisation/purification (fish oil)
Pharmaceutical/cosmetic active principles	Extraction of active molecules from natural products, and SFE for elimination of residual solvents (synthetic drugs), of monomers (polymeric patches or implants and cosmetic lacquers), or of other toxic pollutants. However, the more promising applications seem to be the manufacture of new drug delivery systems based on particle design: nano- or microparticles for improving the bioavailability of poorly soluble molecules, microspheres or microcapsules for sustained-release drugs, microparticles for inhalation, etc.
Chemical industries	Separation and purification of specialty chemicals using SFE, Supercritical Fluid Fractionation(SFF), or chromatographic processes and possibly soon for synthesis in these media, with the requirement of moving to a “green” chemistry

<sup>21</sup>Source:

- Frost & Sullivan,
- Industrial & Chemical Engineering Chemistry Research, vol 39, pg 4531-4535
- Journal of Chromatography A, vol 1217, pg 2495-2511

Table 4.6: SFE - Fields of Application	
Field	Applications <sup>21</sup>
Material treatment	Polymer purification and expansion, porous material (polymer, wood, paper, etc.) impregnation, particle design especially for paint manufacture and delivery systems (pesticides, preservatives, drugs, etc.), aerogel drying for high-performance insulation materials, coatings and surface treatment, ceramics binder removal, and carbon fibre/carbon alloys preparation, etc. Surface treatment is also receiving great attention in order to avoid organic solvents: metal degreasing and dry cleaning (for which hundreds of machines are planned to be marketed in the next years), textile dyeing, coating applications, etc.
Pollution abatement	Pollutant extraction or concentration by SFE (industrial wastes, soil remediation, polluted waters, etc.). However, very innovative technologies are yet to be developed to reach “acceptable” costs, even if this technology permits one to recycle valuable products at the difference with most other processes.

#### 4.5.5. Achievements of the Programme

Apart from achieving the KPI set for BAP, the success of the Programme can also be defined by number of present and future sub-licensee(s), applications and commercialised products (number of licenses comes with the obligation to develop and commercialise the approved applications).

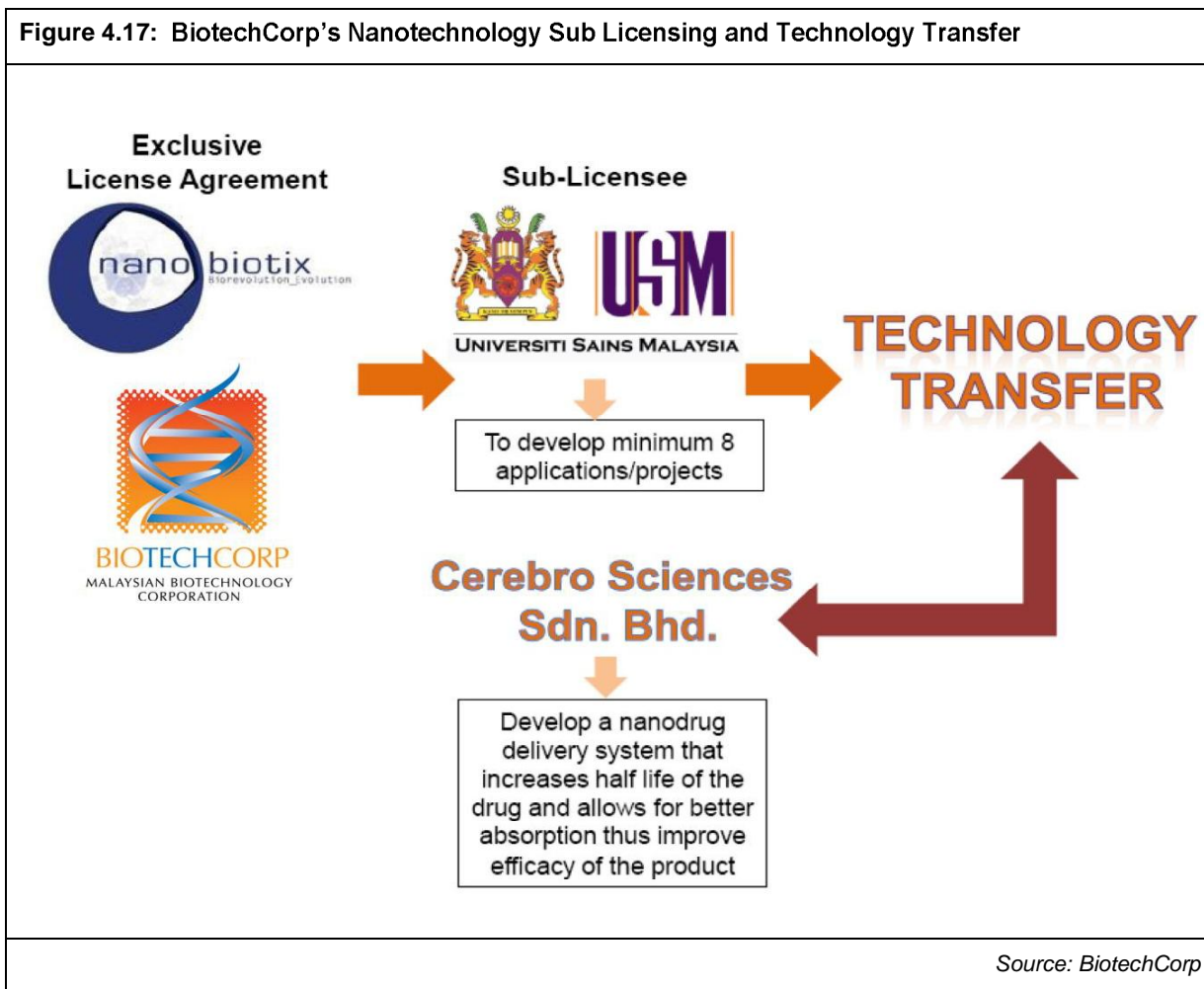
#### Success Story 1: First Commercial Sub-licensee for Nanotechnology Platform

Cerebro Sciences Sdn. Bhd. served as the first commercial sub-licensee appointed for this nanotechnology platform. Cerebro Sciences Sdn. Bhd. will use the nanotechnology platform to develop a nano-drug delivery system that increases half-life of the drug and allows for better absorption, which will benefit the commercialisation of the product. The project objectives are to:-

- Use potent GnRH compounds as pharmacological tools to overcome infertility and mood disorders; and
- To develop a biostable delivery system using nanoparticles that will overcome the blood-brain barrier to target GnRH compounds to GnRH positive neurons.

USM will work closely with Cerebro Sciences Sdn. Bhd. to provide the necessary support for the development of the proposed nanomedicine application that has significant commercial value.

**Figure 4.17: BiotechCorp’s Nanotechnology Sub Licensing and Technology Transfer**



Source: BiotechCorp

#### 4.5.6. Future Outlook of the Programme

BAP program has achieved its targets in RMK-9, by acquiring four technology platforms in accordance with the industry requirements and in adherence to ISO certified technology acquisition process. These four technologies have the potential of providing a niche to Malaysian biotechnology industry to jumpstart the R&D and commercialisation activities. The program provides the following to the industry:

- Access to technical know-how, manufacturing techniques and other commercially privileged information proprietary that helps to build the required skill sets and knowledge base of custodians, strengthening the IHLs/RIs research and innovation capabilities;
- Sublicensing of this technology generates revenue for BiotechCorp and both stakeholders when products are commercialised; and
- Accelerated growth of biotechnology industry through public and private R&D partnerships.

In Phase 2 NBP, BAP intends to consolidate its position and focus on post technology acquisition programmes which will be conducted by Technology Management Office (TMO).

Based on stakeholder's assessment, BAP is important as it facilitates the development of biotechnology through acquisition of technology that focuses on identified key areas. BAP has provided a platform for local research institutes to build the required skills sets and knowledge base through public and private R&D partnerships, develop the local industry as well as its related service and support industry, thus providing greater job opportunities for the nation.

#### 4.5.6.2. Stakeholders Perspective on Success of the Programme

Since the first phase for BAP focuses on acquiring potential technology, the custodians of the technology are the direct beneficiaries of the Programme. Interviews with some of the custodians reveal the importance of the Programme as well as scope of improvement.

##### **Testimonials**

Nanobiotechnology Research and Innovation Institute for Research in Molecular Medicine (INFORMM), USM cited the benefits that the team received from the BAP *“Technical know-how to synthesise nanoparticles and their characterisation. Ways to bridge material science to biomedical field are to be further explored that could lead to products commercialisation...”*

MARDI commented that the overall BAP is *“Very good effort especially in terms of the technology acquired for MAS. With this technology and setting up of the CMDV lab, it is a huge step forward to enhance crop and livestock breeding that leads to potential value-added innovations commercialisation in Malaysia.”*

In addition, BAP provides opportunity to access technology already developed outside Malaysia to boost the development of certain industries. In her feedback *“As of now MARDI has gained significantly by being the direct beneficiary of the MAS technology. Other technologies under BAP have not been utilised yet by MARDI such as SFE that is also relevant to the R&D activities of MARDI.”*

#### 4.5.6.3. Scope of Improvement

In Phase 2 NBP, the role of the BAP program would shift from Technology Acquisition (successfully concluded in RMK-9) to Technology Management. This would require both structural and implementation changes to the program.

- **Need to Focus in Increasing the Number of Applicants for the Uptake of the Platform Technologies:**

Although the acquisition of technology was done recently, it has not attracted substantial number of applicants for the uptake due to limited awareness among the scientific community. Therefore, in Phase 2 NBP, it is important to increase the awareness,

promotional and commercialisation Programmes to bring the technology platforms forward. For example, BiotechCorp and USM can work together and organise seminars/road shows that highlight benefits of the technologies and services to increase uptake of applicants at a national level. Another example is to run a business development Programme involving Nanobiotix S.A. that seeks for opportunities to collaborate with international entities.

- **Strong Government Support on the Nanomedicine:**

Support from the government on the nanomedicine development by employing this technology is needed. This can be developed as a focus area under the umbrella of National Nanotechnology Institute, MOSTI to centralise available resources that will achieve better efficiency in development of new nanomedicine applications.

- **Rapid Utilisation to Avoid Potential Technology Turning Obsolete:**

The cost of obtaining a single platform technology, as well as equipment to operate the technology is high. There is a possibility that the technology acquired will be out-dated if not utilised as desired. Therefore, it is crucial for the BAP to focus on post technology acquisition development Programmes in the upcoming phase to increase the utilisation of the technologies.

- **Provide Funding Support:**

One of the main priorities in Phase 2 NBP is to develop competitive and resilient SMEs that are equipped with strong technical and innovation capacity. However, limited funding for small start-ups and public research institutes to in-license the acquired technologies is the barrier for further commercialisation activities. It will be useful if some schemes can be provided to these companies to support this.

Some of the local researchers/institutions opined that there are limited funds for purchasing equipment, conducting further research and training as well as paying for human resources. In addition, the local researchers also require technical support in terms of technology development or using the acquired technology to suit certain applications. Therefore, it is anticipated that BiotechCorp can continue to support and assist these researchers and institutions.

Malaysia has acquired licenses of four huge potential technologies, and investments must be made to help the local companies and researchers to utilise these technologies.

#### 4.5.6.4. Changing Role of the Programme in Phase 2 NBP

- Accelerates growth of the biotechnology industry and builds the required skills sets and knowledge base through public and private R&D partnerships, domestically and internationally through internal collaborations and smart strategic alliances;
- Continue its efforts on business development post technology acquisition to ensure the success of commercialisation of the technologies;
- Target to create more spin-off companies through collaborations with the industry;
- Intensify smart collaboration with centre of excellence and industry players;
- Facilitate training, technical and financial supports as well as provide guidance for the industry to realise the commercial potential of their products and services; and
- Set up biotechnology incubators in key areas of biotechnology: agriculture, healthcare and industrial. Incubators can be set up at or near custodians' location to tap on the existing facilities and expertise.

In conclusion, the technology platforms acquired by BiotechCorp are commercially viable and closely related to Malaysia biotechnology industry. It is crucial that there is a continuation in the BAP as the four technologies acquired must be commercialised to capitalise their business potentials in Phase 2 NBP, achieved via the post technology acquisition development programme e.g. business development, joint venture R&D and contract research activities to encourage industry players to utilise these technologies.



#### 4.6. BioNexus Partners Programme (BNP)

As one of the most successful Programmes under the BiotechCorp, BNP has been able to provide access to infrastructure to facilitate R&D&C in Malaysia. BiotechCorp is driving the biotechnology sector in the country and laboratories under the Programme are seen as the catalyst for unlocking the potential of the biodiversity that Malaysia possesses.

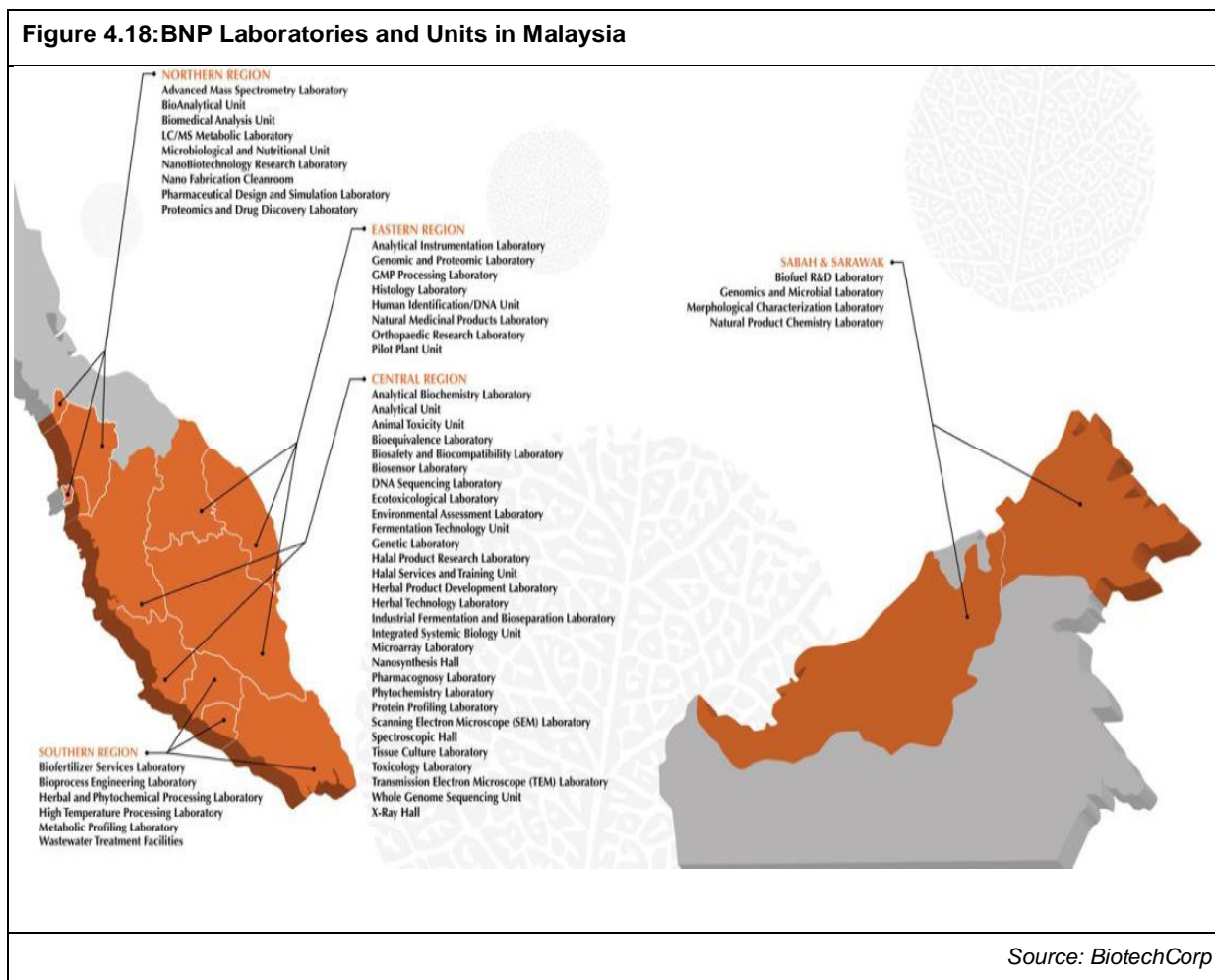
Some of the BioNexus status companies have already translated their success in research and are now in the process of commercialisation of technology. Chapter two highlights the successfully listed entities during the RMK-9 period.

To date, BNP includes 56 laboratories and units from 13 IHLs, three research institutes and two Government-Linked Companies (GLCs). BiotechCorp’s partners include:

<ul style="list-style-type: none"> <li>• <i>Universiti Malaya,</i></li> <li>• <i>Universiti Putra Malaysia,</i></li> <li>• <i>Universiti Sains Malaysia (USM),</i></li> <li>• <i>Universiti Teknologi Malaysia (UTM),</i></li> <li>• <i>Universiti Kebangsaan Malaysia (UKM),</i></li> <li>• <i>Universiti Malaysia Perlis (UniMAP),</i></li> <li>• <i>Universiti Sains Islam Malaysia (USIM),</i></li> <li>• <i>Universiti Malaysia Pahang (UMP),</i></li> <li>• <i>Universiti Malaysia Terengganu (UMT),</i></li> <li>• <i>Universiti Malaysia Sabah (UMS),</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Universiti Malaysia Sarawak (UNIMAS),</i></li> <li>• <i>Universiti Teknologi MARA (UiTM),</i></li> <li>• <i>International Islamic University of Malaysia (IIUM)</i></li> <li>• <i>Malaysian Agricultural Research and Development Institute (MARDI),</i></li> <li>• <i>SIRIM Berhad,</i></li> <li>• <i>Forest Research Institute Malaysia (FRIM), TPM Biotech Sdn. Bhd.</i></li> <li>• <i>Kedah BioResources Sdn. Bhd.</i></li> </ul>
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This section of the report provides a brief overview of the Programmes.

Figure 4.18:BNP Laboratories and Units in Malaysia



### Background

In line with the BioNexus Bill of Guarantees No. 8, “Access to shared laboratories and other related facilities”, BiotechCorp initiated a Programme called BioNexus Partners (BNP). BNP is aimed at supporting the needs of Malaysia’s biotechnology related life sciences industry for high end research facilities, infrastructure and capabilities. The objectives of the Programme are to:

- Provide a mechanism for laboratories and/or units from IHLs/RIs, Technology Parks, Incubators and GLCs to collaborate with the industry;
- Support and develop relevant laboratories and facilities through targeted financial incentives;
- Maximise the visibility and utilisation of key services/equipment facilities within laboratories and/or units; and
- Provide an avenue for human resource development through industry-BNP partnering.

BNP laboratories and units are given incentives designed to support their services/equipment/facilities. In return, these laboratories and units are required to provide

BioNexus status companies and other relevant commercial entities access to the services/equipment/facilities that they offer.

Financial incentives
Infrastructure maintenance grant such as Service Maintenance Contract (SMC), ad hoc repairs/equipment spare parts/equipment accessories
Infrastructure development grant such as training of staff, salary for contract staff and accreditation/certification

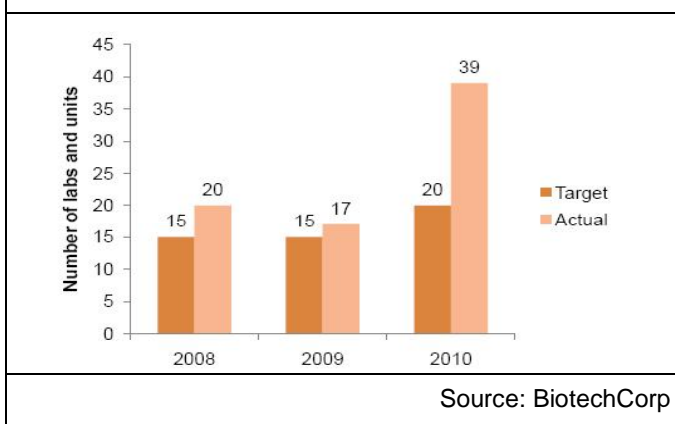
Non-Financial Incentives
Access to BiotechCorp's One Stop Centre (OSC) facilitation and advisory services
Access to BiotechCorp's Resource Centre (RC), Triple Helix portal and other BiotechCorp's online facilities
Eligibility to be involved in Programmes that may be developed for the BioNexus status companies such as BioNexus networking sessions, internships, entrepreneur development and other human capital development programmes

One focus of the Programme is to assist laboratories in getting International Organisation of Standardisation (ISO), GLP, GMP and Hazard Analysis and Critical Points (HACCP) international accreditations. This will assist Malaysian research being accepted on an international scale. It would also act as a catalyst for international technology transfer agreements. BNP has completed the first stage of identifying and measuring the capabilities of all the labs in Malaysia and is presently working on the process of assisting these labs in getting necessary accreditations. Nevertheless, in Phase 1 NBP, BNP has managed to exceed the target set for the Programme.

**2008: Target number of BNP laboratories and units was 15**

Twenty laboratories and units owned by IHLs/RIs and research institutes had been opened up for access to BioNexus status companies and the biotechnology industry. These BNP laboratories/ units have been 100 percent utilised.

**Figure 4.19: Target vs. Actual Number of BNP Labs and Units**



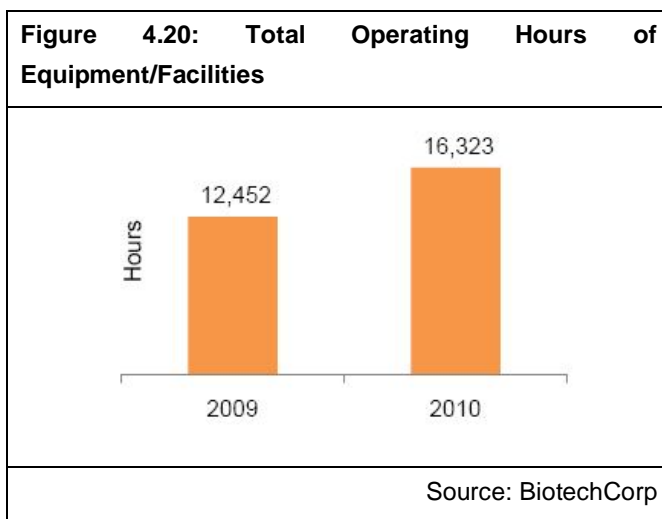
**2009: Target number of BNP laboratories and/or units was 15**

As of October 12, 2009, 17 laboratories and units had been accorded the BNP status for Phase 2 NBP and which are now opened for access to BioNexus status companies and the biotechnology industry.

**2010: Target number of BNP laboratories and/or units was 20**

In 2010, a total of 39 laboratories and units were accorded the BNP status.

In addition to this KPI, BiotechCorp also requested the first 20 laboratories/units to submit details on equipment/ facilities used by the industry, total operating hours per equipment and equipment log reports. The purpose of the request is to study the capacity utilisation of life sciences equipment/facilities offered by these BNP laboratories/units to the industry, as an evaluation of BNP’s progress. The results of the study show that:-



- Total capacity utilisation for the 20 BNP laboratories/units in 2009 was 12,452 hours;
- Total capacity utilisation for the 20 BNP laboratories/units in 2010 was 16,323 hours; and
- Therefore, the total capacity utilisation of the 20 BNP laboratories/ units has increased by 31 percent in 2010.

This study is the first study conducted internally to assess capacity utilisation of BNP laboratories and units. BiotechCorp intends to carry out this study on a regular basis to monitor the growth/trend of different equipment and facilities used by the industry. It is expected that the total capacity utilisation will increase on a year-on-year basis.

**4.6.1. Achievements of the Programme**

The following section describes some of the success stories achieved by the BNP Programme through collaboration between public-private sectors. Each story entails the background of the collaboration, type of research or process undertaken by the BNP laboratories or units, the benefits and impact of the collaboration to the industry.

### Success Story 1: Bio-Organic and Biochemical Fertilisers

All Cosmos Industries Sdn. Bhd. (ACI) in collaboration with UTM Bioprocess Engineering Laboratory - IBD, UTM is currently providing ACI with cell banking facilities, microbial cultivation and analysis equipment to facilitate in the development of a novel industrial platform for the high cell density cultivation of N-Fixing bacteria. This collaboration had successfully led to high cell mass production of *Azotobacter vinelandii* (Nitrogen fixing bacterium that is capable to convert stable nitrogen gas into ammonia, which could be further converted into ammonium or nitrate, a nitrogen source accessible for plant) for biofertiliser applications and optimisation of *Rhizobium trifolii* (a species of highly effective nitrogen fixing bacteria) high cell mass production in semi-industrial scale. These researches had improved the cell mass yield by more than 200 percent through optimising the chemical compositions of the cultivation medium, reduced the wasting of glucose residue and decrease the usage of peptone significantly.

ACI is a 100 percent subsidiary of All Cosmos Bio-Tech (ACBT) which is a Malaysia-based investment holding company established by Taiwanese investors. ACI is a leading manufacturer and marketer of Bio-Organic and bio-chemical fertilisers. The products help in propagating healthy and natural plant growth through soil-structured enhancement processes.

ACBT has set up a RM7 million exclusive research centre at its plant in Johor to tap into this high growth market. This research centre was set up in collaboration with UTM and will spearhead research into other types of effective microorganisms and variants for application into the food and health sectors. To date, the company had invested RM250 million for three plants in Johor (Malaysia), Ho Chi Minh (Vietnam) and Medan (Indonesia) with a combined annual production capacity of 300,000 tonnes of bio-organic fertilisers, making it one of the biggest bio-fertiliser producers in Asia.

Effective Microorganisms (EM) is capable of positively influencing decomposing organic matter such that it reverts into a life promoting process. It is used to maintained sustainable practices such as farming and sustainable living and to support human health and hygiene. Microbes are the oldest form of life on earth. Nitrogen fixing microbes fix nitrogen from the air. Certain microbes breakdown phosphate and potassium to break down organic matters and thus, making them available to be absorbed by plant roots.

The usage of inorganic N fertilizers is often linked with hazards such as nitrate leaching, ammonia volatilisation, water pollution and greenhouse gas emissions. Hence, there is a need to develop an alternative means to supplement plants with a sustainable nitrogen source. N-fixing bacteria are able to convert stable atmospheric Nitrogen into ammonia, an N source which is readily absorbed by plants. Therefore, there is a need to develop a novel platform for high cell density cultivations of various N-fixing bacteria.

Table 4.7: Global Fertiliser Market Outlook <sup>22</sup>			
	Nitrogen	Phosphate	Potassium
2010 Revenues (US\$ Mn)	33,750	26,130	8,130
CAGR (2010-15)	6.8 percent	14.7 percent	11.4 percent
Major Product Classes (CAGR 2010-15)	Ammonium Nitrate (12.1 percent)	Citric Acid (16.1 percent)	Potassium Chloride (11.8 percent)

### Success Story 2: Biomaterial for Repair of Bone Defects

A common misconception about Halal products is that it is only related to food. However, Muslim consumers are now increasingly aware that some biomaterials for medical applications contain ingredients derived from animal origins and are thus concerned about the Halal status of these products.

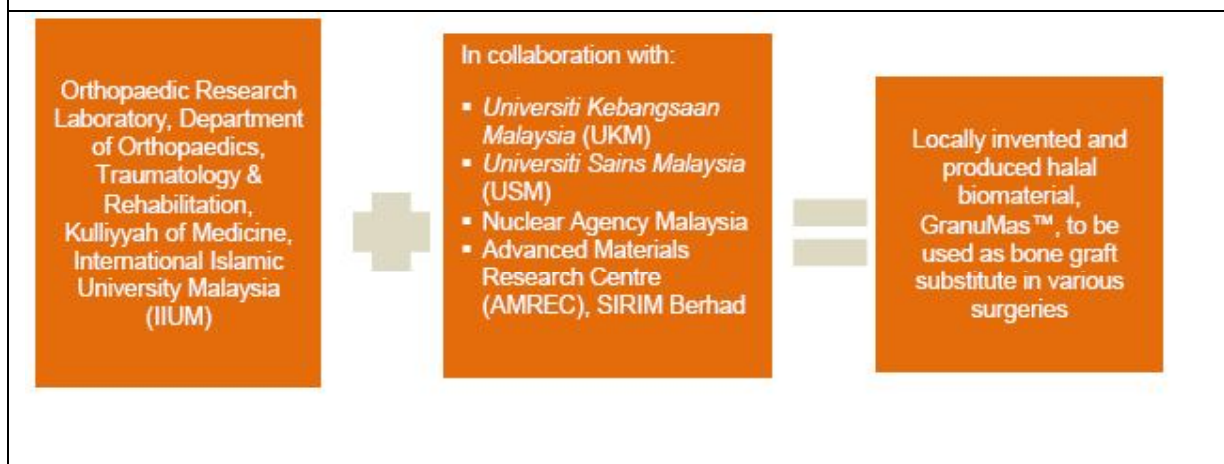
Eyeing this potential global opportunity, Orthopaedic Research Laboratory, Department of Orthopaedics, Traumatology & Rehabilitation, Kulliyah of Medicine, IIUM, was established during their top down project during RMK-8. Their project on “*Biomaterials for Medical Applications – Development of Bone Graft Substitutes Based on Calcium Phosphate Ceramics*” was conducted with research collaborators from:

- Nuclear Agency Malaysia;
- Advanced Materials Research Centre (AMREC), SIRIM Berhad;
- USM; and
- UKM.

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<sup>22</sup>Sources:

- International Fertilizer Industry Association, 2009.
- Current World Fertilizer Trends and Outlook to 2011/12. Food and Agriculture Organization of United Nations. Rome, 2008.

**Figure 4.21: Collaboration between a BNP Lab and Local Institutions**

The research was a success with the product called GranuMaS™. GranuMaS™ is an osteoconductive granular synthetic bone graft material based on calcium phosphate hydroxyapatite. It is an excellent alternative material for the repair of bone defects due to the hydroxyapatite that is currently being used as a bioactive coating on many surgical and dental implants.

GranuMaS™ uses a patented process to derive pure commercial chemicals from Malaysian limestone and has fulfilled all of the criteria required under the ASTM F1185-88 (1993) Standard for Composition of Hydroxyapatite (HA) for Surgical Implants.

GranuMaS™ has gone through extensive biocompatibility and safety evaluation and has also demonstrated excellent biofunctionality in clinical trials and successfully screened through various *in vitro* and *in vivo* tests. Its highly osteoconductive properties promotes good callus formation and the subsequent healing of bone defects. Being a synthetic bone graft, GranuMaS™ alleviates the concerns over transmission of disease from allograft (bone from other human donor) and xenograft (bone from animal origin) bones. GranuMaS™ also alleviates the concerns over halal and ethical issues<sup>23</sup>.

#### *Outcome of the Collaboration*

- Prior to GranuMaS™, synthetic bone used in most local hospitals was imported. It is also exorbitantly priced costing about RM1500/ cm<sup>2</sup> - whereas the surgical needs for it is usually more than just a cubic cm. The development of GranuMaS™ helps to reduce the overall costs of import and dependence on foreign medical products.

<sup>23</sup> [www.sirim.my/f\\_corp/SIRIMLinkpercent20Septpercent2007percent20upload.pdf](http://www.sirim.my/f_corp/SIRIMLinkpercent20Septpercent2007percent20upload.pdf)



- The collaboration of local institutions on this research has brought up the level of expertise and development of new technology in the biotechnology sector, enabling the country to be more self-reliant in providing quality healthcare services in future.
- Since its first clinical applications in August 2004, about 100 dental and 35 orthopaedic patients have benefited from the product.
- Through the Technical Licensing Agreement with SIRIM Berhad, GranuLab (a BioNexus company) has been granted the sole licensing to commercialise GranuMaSTM for 10 years with 10 years renewal option. GranuLab is also eligible for a Government Grant of RM4.0 million from Malaysian Technology Development Corporation (MTDC) to finance the setting up of a production centre for GranuMaS™ and medical grade laboratory for further research.
- The future plan is to market and export GranuMaS™ to other countries like Indonesia and Germany. GranuLab predicts 70 percent to 80 percent of its future production is for the export market.

*Key Milestones achieved by GranuMaS™*

- GranuMaS™ has won many awards both domestically and internationally, such as the Prime Minister’s Award for Malaysian Innovation 2007, ISESCO Science Award 2006, Gold Medal – Salon International Des Inventions Geneva (2005), Silver Medal – Expo Science, Technology and Innovation (2004), SIRIM Best Innovation Award 2004 – Category – Product: GranuMaSTM, and SIRIM Best Innovation Award 2004 – Category – Technology<sup>24</sup>.
- GranuMaSTM is aggressively being promoted in the local market especially to hospitals for use in surgeries requiring bone grafting applications. More than 25 local hospitals and private clinics are currently using GranuMaS™<sup>25</sup>.

*Market Potential*

While the overall Biomaterial market incorporates ceramics, metals, polymers, and composites, one of the biggest opportunities is within Biomaterials medical products. These are classified into orthopaedic, cardiovascular,

Biomaterials Medical products 2009	US\$25.50 billion
Biomaterial Device Market Size 2010	US\$115.4 billion
Biomaterial Device Market Size 2014	US\$252.7 billion

<sup>24</sup> [www.sindora.com.my](http://www.sindora.com.my)

<sup>25</sup> <http://www.mosti.gov.my>

<sup>26</sup> Source: Markets&Markets- Global Biomaterial Market (2009-2014) – Published in Sept 2009

gastrointestinal, wound care, urology, plastic surgery, and others. Reconstructive surgery and orthobiologics are the dominant segments in orthopaedic biomaterials market.

#### 4.6.2. Future Outlook of the Programme

This Programme has had the maximum impact on capacity building of Malaysian biotechnology Industry. Several research initiatives undertaken in BNP labs are now in early stages of commercialisation. The Programme needs to be continued and in fact, to be expanded to ensure continued growth of the sector. Based on stakeholder’s assessment, the BNP Programme has given great support to Malaysian laboratories and units to create business opportunities and value propositions within the industry.

The following table compares the benefits offered by BNP Programme versus benefits received from respective stakeholders – the findings show the positive outcomes of BNP Programme implementation as intended by the Government in Phase 1 NBP.

Benefits for BNP laboratories and units:

<b>Table 4.9</b>	
<b>BNP’s perspectives</b>	<b>BNP laboratories/units’ perspectives</b>
Maximise the visibility and utilisation of key facilities/equipment/services within IHLs/RIs, technology parks, incubators and GLCs.	<ul style="list-style-type: none"> <li>• The Programme provides a link between the IHLs/RIs and companies (PPP).</li> <li>• The marketing effort increases the visibility, thus utility of the laboratories and units</li> </ul>
Reduce downtime of cutting-edge facilities/equipment by supporting their service maintenance contracts and costs for the spare parts/equipment accessories.	<ul style="list-style-type: none"> <li>• Support the development of laboratories and facilities through financial assistance</li> </ul>
Increase the capability of laboratories and units in R&D activities by gaining and maintaining recognised accreditation and certification (e.g. ISO, GMP, and GLP).	<ul style="list-style-type: none"> <li>• Provides training to improve knowledge and skill sets.</li> </ul>
Provide an avenue for human resource development through industry-BNP partnering.	<ul style="list-style-type: none"> <li>• Helps to create more job opportunities as well as business values.</li> <li>• Through the collaboration between public-private partnerships, level of expertise and capabilities are raised.</li> </ul>

Benefits for companies:

Table 4.10	
BNP's perspectives	Company's perspectives
The multiple business matching services and commercialisable projects with BNP laboratories and units thus creating win-win partnering opportunities.	<ul style="list-style-type: none"> <li>• Provides a link between the IHLs/research institutes and companies: PPP and creates business opportunities.</li> <li>• Knowledge sharing through private and public partnerships.</li> </ul>
Favourable rates for using facilities/equipment/services within IHLs, RIs, technology parks, incubators and GLCs.	<ul style="list-style-type: none"> <li>• Reasonable fee for accredited services.</li> </ul>
Reduce or avoid expenditure in the development of new facilities/equipment if they are available within the BNP laboratories and units.	<ul style="list-style-type: none"> <li>• Able to access local laboratories that have tests that meet company needs.</li> <li>• Some of the testing equipment/ facilities/ services have accreditation to meet international requirements.</li> </ul>

#### 4.6.2.1. Stakeholders Perspective on Success of the Programme

The stakeholders of BNP Programme are the awarded laboratories and units, as well as the companies which use their services. Interviews with some of the stakeholders reveal the importance of the Programme as well as scope of improvement for better fulfilment of the industry's needs.

##### Quotations on Benefits Achieved

###### Testimonials

*"BNP is an excellent Programme as it provides a chance for laboratories/units in IHLs to explore some projects related to industry. It has enabled our team to carry out at least six to eight projects with a couple of local generic manufacturers, and these companies will no doubt have the confidence to engage us in more projects in future as they gain confidence in our expertise and capability."* - **Prof. Datin Dr Zahurin from the Bioequivalence Laboratory, University of Malaya**

*“We understand the underlying reasons on why BiotechCorp work with us. In return, upon receiving assistance and becoming a member of BNP, we are now in a better position to take challenges for contract research and into the possibility of commercialisation.”- Associate Prof. Dr Abdul Hamid Ahmad, Natural Product Chemistry Laboratory, Universiti Malaysia Sabah.*

*“Good marketing by BiotechCorp to highlight the publicly funded laboratories through BNP recognition. This has sparked awareness among biotechnology companies on the existence of those labs, which are readily accessible. We have managed to utilise some of the allocated grants in sending our staff for technical training. The grants have also been capitalised to purchase accessories deemed crucial for some of our services. Through this recognition, BioNexus status companies are more aware of services offered by our labs.”- Encik Mohd Helme Mohd Helan, the Head of Biosafety and Biocompatibility Laboratory, SIRIM*

*“BNP is good and supportive.....Nanocen has almost all the equipment needed by Granulab, and some of the tests in Makmal Bioserasi UKM are recently accredited.....the laboratories are near to Granulab, about 20-30 km away. The company has gained new knowledge, easy and direct communications, share opinions and knowledge with (the BNP laboratories/ units) experts.”- GranuLab Sdn. Bhd.*

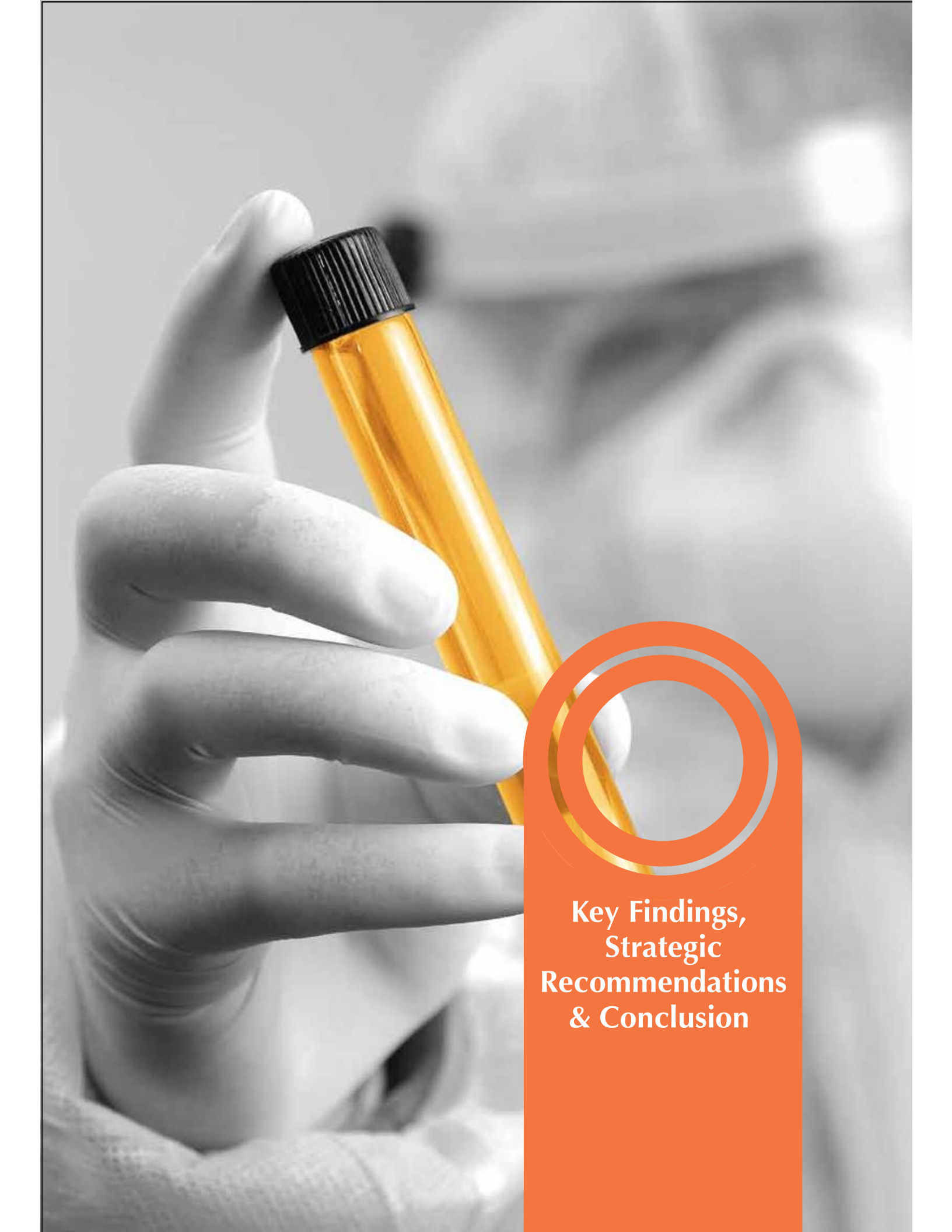
*“The Bioprocess Engineering Laboratory was able to provide us with a platform to further improve our existing products and also to develop new products. The key strength of the Programme is that it provides a research platform at minimal cost, able to facilitate development of new technology, assist in pre-commercialisation stage of new products.”- All Cosmos Industries Sdn. Bhd.*

#### 4.6.2.2. Scope of Improvement

- Increase international and domestic collaborations as the biotechnology industry is a niche market;
- Aggressive marketing/advertising to promote the services/equipment/facilities available in the BNP laboratories and units. The country has many advanced testing instruments at local IHLs/RIs but some of them are not fully utilised; and
- The BNP laboratories should be customer centric, playing the role of supporting the commercial success of biotechnology companies. The equipment in BNP laboratories should meet requirements for commercial production, cost efficient with high quality output.

#### 4.6.2.3. Changing Role of the Programme in Phase 2 NBP

- Focus on increasing the number of accredited facilities to meet international standards (for examples, US pharmacopeias, EU pharmacopeias, ISO standards, ASTM etc.). Address all concerns of less accurate/reliable results delivered by non-accredited equipment. Therefore, it is important that accreditation is done first to attract demands.
- Focus on increasing the utilisation rates of the existing laboratories through better laboratory management. Considering the fact industry is gradually moving up the value chain, the preparedness of industry players to use high-end devices is also increasing. Hence, target utilisation rates should also increase year on year.
- Government needs to increase grants for maintenance of equipment and training of staff that can operate these high-end devices.
- The Programme links BioNexus status companies to major public IHLs/RIs to promote greater collaborations and access to technology infrastructure and facilities.
- By providing maintenance focused incentives, BNP laboratories and units are able to conduct more in-depth research to create awareness of Malaysian research breakthroughs, and hence promote innovation.
- Lower the barrier of entry for entrepreneurs for high quality research.
- Enhance the accessibility of equipment for entrepreneurs at minimum costs.
- Assistance in pilot scale production of biotechnology products for market trial and technical and economic feasibility studies.



**Key Findings,  
Strategic  
Recommendations  
& Conclusion**

### 5.1 Introduction

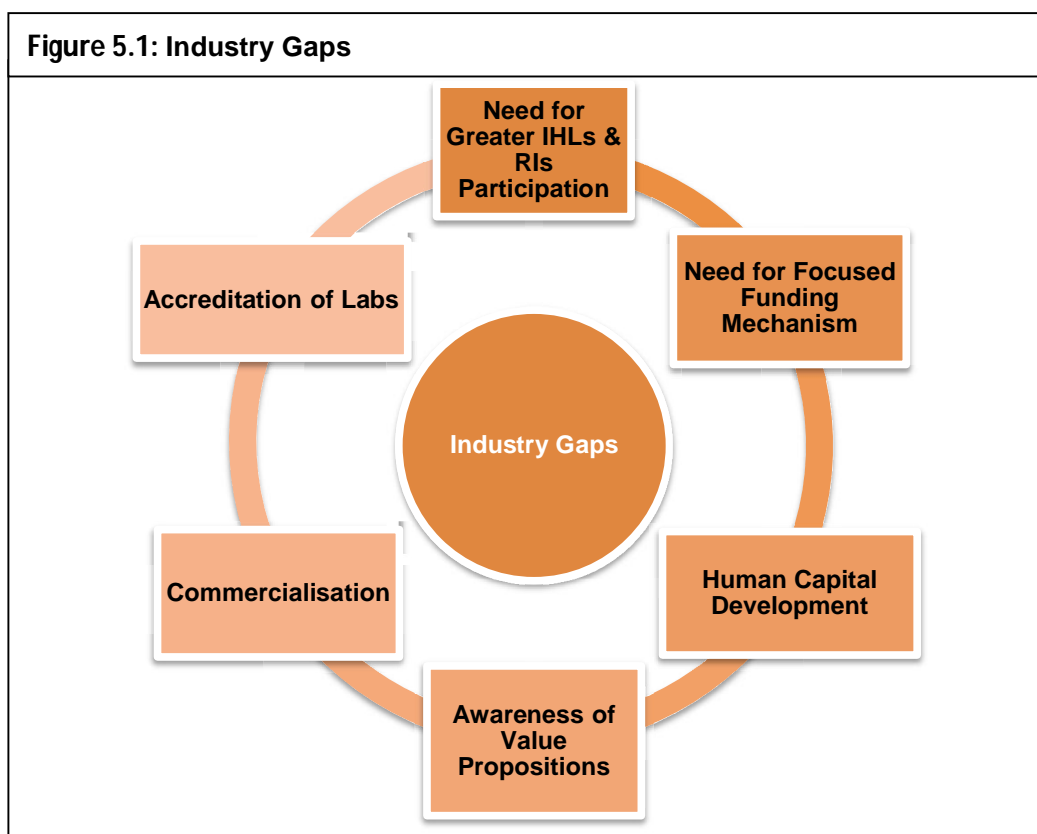
Frost & Sullivan conducted a survey with representative samples comprising stakeholders and beneficiaries to develop an understanding on industry perspective on Government initiatives undertaken during RMK-9 and their potential impact on the industry. Programmes undertaken by the Government and BiotechCorp are praiseworthy and widely accepted by local and international industry players.

The Government support has been identified as one of the primary growth drivers for the industry in the last few years and is seen as an important catalyst. Industry experts have provided suggestions on some of the vital steps that need to be taken in order to continue with the growth. Hence, this chapter has been broken down into two sub-segments:

- Industry Gaps; and
- Improvement Opportunities and Recommendations on Way Forward

### 5.2. Industry Gaps

While the Biotechnology industry Programmes have been widely successful, there is potential for improvement. Based on the stakeholders’ assessment, the following **Figure 5.1** depicts the six major industry gaps that need to be addressed by BiotechCorp in the Phase 2 NBP.





## 1. Need for Greater Participation of IHLs/RIs

While Malaysian IHLs/RIs are actively developing intellectual property assets, the industry participants expect a greater role for IHLs /RIs in the commercialisation of technologies. Industry believes that IHLs/RIs need to enhance capabilities and willingness to engage private players in developing technologies.

## 2. Limitation of Funding

The industry stakeholders appreciate the funds provided by BiotechCorp in Phase 1 NBP, however, there are a few challenges that the stakeholders face in relation to the funds disbursed by BiotechCorp:

### *i) Limited Funds for Small Start-ups and Public Research Institutes*

There is a need to increase funding for small start-ups and IHLs/RIs to in-license the acquired technologies, as limited funding had created a barrier for the growth of SMEs within the industry.

### *ii) Funding Requirements for Expansion*

The industry needs continuous financial support from the Government, due to the nature of biotechnology that has longer gestation periods, high upfront capital investment and extensive regulatory requirements.

Current funding is perceived to be insufficient, particularly if compared to funding provided by developed Asian countries such as South Korea. Instead of focusing to grow their business, many BioNexus status companies have to dedicate significant amount of time and resources on fund-raising activities. Some stakeholders also opined that they need capital funds especially after setting-up production facility to cope with the initial build-up of inventory and sales.

Other than the private sector, the local IHLs/RIs also commented that there are limited funds for upgrade and upscale of their scientific research activities. The limitation on sufficient funding restricts the progress of the research industry, thus slowing the progress of innovation and commercialisation.

### *iii) Narrow Criteria for Grant Utilisation*

The scopes of grant utilisation are too narrow in nature. The industry participants believe that in the initial stages of growth companies find it difficult to ask for funds for a specific purpose. Hence, there is a need to expand the scope for utilisation of funds.

### *iv) Limited Venture Capital for Biotechnology and Life-Sciences*

In 2010, Malaysia was ranked second globally (ranked fourth in 2009), in terms of VC availability<sup>27</sup>. Total committed funds at the end of 2010 amounted to RM5.96 billion, an 11 percent increase from 2009. Total capital investment witnessed 31 percent growth (from RM2.6 billion in 2009 to RM3.39 billion in 2009), with 84 companies benefiting from this investment exercise. While the Government

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<sup>27</sup> Source: IMD World Competitiveness Yearbook, 2010

plays a vital role in venture capital funds (51.4 percent or RM3.06 billion of total committed funds in 2010), the private sector contribution continues to be minimal. Banks, insurance companies and pension funds contributed about 7.6 percent in the total committed funds in 2010.

It is observed that there is a significant funding gap especially in seed and start-up funding, where total investment for these two stages contributed to only 5.2 percent in 2010. Overall investment in life sciences remained unchanged at 24.8 percent in 2010 from 25.2 percent in 2009.

<b>Table 5.1: Venture Capital Investment in 2010</b>			
<b>Business Stage</b>	<b>Investment details</b>		
	<b>Total investment (RM '000)</b>	<b>Percent of total investment</b>	<b>No. of investee companies</b>
Seed	10,662	2	9
Start-up	12,740	3	8
Early-stage	122,066	27	24
Expansion/growth	175,643	39	25
Bridge/mezzanine/pre-IPO	132,122	29	18
<b>Total</b>	<b>453,233</b>	<b>100</b>	<b>84</b>
Source: Securities Commission			

Biotechnology players in Malaysia continue to face difficulty in obtaining VC funds. This might be due to several factors:

- Large information asymmetries between the entrepreneurs and VCs. It is difficult for outside VCs to ascertain the quality and potential value of the technology innovation without detailed know-how;
- Different mindset of innovators and VCs. Often, the innovators overlooked the challenges in selling their innovations and had limited understanding of their innovation valuation. The terms offered by VCs are often misunderstood by entrepreneurs as stringent. On the other hand, VCs would like to introduce corporate governance mechanisms to maximise potential and minimise risks of investment;
- VCs are often reluctant to put their money into biotechnology companies due to perceived risk profile, complexity of the biotechnology industry and opportunities in other industries (ICT and mineral resources);
- VCs need to have well-trained managers for biotechnology sector, who understand the unique dynamics of the biotechnology business and investments; and
- Lack of exit avenues for biotechnology investors in Malaysia, in terms of IPOs, M&As and trade sales.

Traditionally, most biotechnology innovation potential starves financially because VCs prefer to wait until a biotechnology start-up is closer to clinical test phase or have partially commercialised their innovations in the market. As such, a multiple-pronged approach and financial resources are necessary.

### **3. Human Capital Development**

Although Malaysia has implemented Programmes for human capital development for Phase 1 NBP, there is still a gap in the number of competent and skilful workers. Without sufficient number of skilled workers, it is difficult for the industry to be innovative, competitive and cost efficient. There is significant demand for experienced patent examiners, IP managers as well as regulators to create conducive business environment for biotechnology.

Furthermore, it is opined that the local IHLs/RIs can be more proactive to commercialise their innovations.

### **4. Need to Increase Public Awareness on Value Propositions of BiotechCorp Programmes**

The awareness level of various Programmes can be further enhanced. BiotechCorp needs to increase the awareness among the research community on the commercialisation opportunities under Phase 2 NBP Programmes.

### **5. Need for Funding Support on Technologies Acquired**

Industry participants believe that while the platform technologies acquired by BiotechCorp are based on market demand, there is a need to provide funding support for follow up and sub-licensees to ensure optimal utilisation of these technologies.

### **6. Limited Number of Accredited Laboratories and Facilities**

Another industry gap is the improvement of number of accredited equipment labs and facilities that meet international standards in order to establish credibility of Malaysian biotechnology industry.

### 5.3. Improvements Opportunities /Recommendations and Way Forward

BiotechCorp has excelled under the RMK-9 Programme, providing opportunities and platforms to various biotechnology companies in Malaysia. The Malaysian biotechnology cluster is starting to show strong prominence with over five local companies catapulted to global platform. Under the strategic recommendation chapter, a new host of opportunities have arisen from BiotechCorp’s initiative in the past five years.

Targets for Phase 2 NBP are stipulated as follow:

	Phase 1 NBP (2005 – 2010) Capacity Building		Phase 2 NBP (2011-2015) Science to Business	Phase 3 (2016-2020) Global Business
	Target	Actual	Target	Actual
<b>Investment</b>	RM6.0 b	RM5.4b	RM9.0 b	RM15.0 b
<b>Employment</b>	40,000	54,776	80,000	160,000
<b>Total Revenue</b>	RM20.0 b	RM13.5b	RM50.0 b	RM100 b
<b>GDP Contribution</b>	2.5 percent	2.2 percent	4.0 percent	5.0 percent

Frost & Sullivan has mapped important opportunities and improvements that will further propel the growth of biotechnology Industry in Malaysia as follows:-

#### Strategies to Attract FDI and Encourage DDI into Malaysia Biotechnology Industry:

##### 1. Market Guided Funding Mechanism to Encourage Growth of a Venture Economy<sup>28</sup>

In 2010, Malaysia was ranked second globally (ranked 4<sup>th</sup> in year 2009) in venture capital availability<sup>29</sup>. Total committed funds at the end of 2010 amounted to RM5.96 billion, an 11 percent increase from year 2009. Total capital investment witnessed an encouraging rise of 31 percent growth (from RM2.6 billion in 2009 to RM3.39 billion in 2009), with 84 companies benefiting from this investment exercise. While Government plays a vital role in venture capital funds (51.4 percent or RM3.06 billion of total committed fund in 2010), the private sector contribution continues to be minimal. Banks, insurance companies and pension funds contributed about 7.6 percent of the total committed fund in 2010. The top three players as of 31<sup>st</sup>December, 2010 were Malaysia Venture Capital Management Bhd., Kumpulan Modal Perdana Sdn. Bhd., and Malaysia Life Science Capital Fund Ltd<sup>30</sup>.

<sup>28</sup> Reference: Avishai Friedmand, 2007. Dissertation for Masters in Business (MBus), University of Auckland.

<sup>29</sup>Source: IMD World Competitiveness Yearbook, 2010

<sup>30</sup>Source: Securities Commission Annual Report 2010

Numerous academic studies have highlighted the role of entrepreneurship and venture financing in stimulating innovations. These findings suggest that entrepreneurs and small firms play a key role in observing where new technologies can meet customers' needs, and rapidly introducing products. A single dollar of venture capital generates as much innovation as three dollars of traditional corporate research and development. Consider these two case studies as critical guideposts for successful encouragement of venture economy:

#### *Case Study 1: Taiwan*

Taiwan is a good example of a targeted tax policy in terms of both promoting venture capital and calibrating it to a particular sector. The latter reflects a policy determination of foregoing revenues in favour of developing the high technology industry. Taiwan's 1999 repeal of its tax incentives can also be seen as a model to follow in the sense that tax incentives need not be permanent.

From 1983 until 2000, Taiwan offered a 20 percent tax credit on investments made by investors in strategic, high technology industries. The tax credit was applied gradually over the lifetime of the investment after a mandatory two-year moratorium period. Individuals and corporations could claim the tax credit only for shares held in first-time venture capital investment enterprises.

When combined with other government actions promoting venture capital development, including government funding, the tax credit was clearly successful. By the end of 1999, there were 153 venture capital funds in existence in Taiwan managing a total of US\$3.4 billion in capital. According to the Taiwan Venture Capital Organisation, the tax credit encouraged many investors to participate in the venture capital industry. The government ended the tax credit at the end of 1999, apparently believing that this incentive was no longer needed at the mature stage of the industry's development. In response, or perhaps due to other market conditions, there has been a slowdown in funding for venture capital.

However, Taiwanese VCs often highlight the gaps in Taiwan biotechnology industry, including the need of large domestic market to support, new product development and branded products with large margins to sustain long-term R&D efforts. Combined with the Original Equipment Manufacturers/ Original Design Manufacturers business model, these factors prohibit effective connections with end customers and their needs, further hindering product innovations. VCs also believe the valuation system of the island's capital markets, which limits IPO returns through a high fixed starting valuation fetters product innovation, although this has been partially mitigated with the introduction of the GreTai Security Market.

#### *Case Study 2: New Zealand Venture Investment Fund (NZVIF)*

Limited activity in the local market, the government sought to accelerate the growth of the New Zealand venture capital market through co-investment with private investors and related market development activities in 1999. The government adopted a so-called fund-of-funds approach, whereby it made investments in private venture capital fund managers. Project's designers deliberately asked for no special rights. The fund managers were given responsibility for making and managing investments without government interference. NZVIF leaders participated in investor governance decisions on the same terms as private investors, with the same voting rights.

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The funds were geared towards investors in early-stage companies, and every dollar had to be matched with two dollars from the private sector. NZVIF's decision to invest in a fund is made following completion of an extensive selection and due diligence process, undertaken by the fund manager. A monitoring and reporting framework is agreed with each NZVIF seed fund manager. This enables NZVIF to collect the economic and financial data it needs for the required regular reports on the performance of each fund and the impact of the Programme. This also enables NZVIF to monitor each fund to ensure it is compliant with its investment agreement and investor governance requirements. Once fund agreements are finalised, investment activity commences. While the Programme is still young, its success to date has been very promising.

From these two case studies, it is observed that:

- *Entrepreneurial activity does not exist in isolation*

Encouraging entrepreneurial activities will require the existence of favourable ecosystem and access to variety area of expertise. In many cases government officials hand out money without thinking about barriers other than money those entrepreneurs face. It is critical to take a broad view and address not just the availability of capital but also other components of conducive ecosystem in which entrepreneurs could operate; and

- *Bottom-up approach funding mechanism: Market demand as a guide*

One of the case studies used matching funds to determine where public subsidies should go. In using the market for guidance, policymakers should keep in mind that these initiatives should not compete with independent venture funds or finance substandard firms that cannot raise private capital. Matching funds will need to be focused on the niche area (e.g. light weight bio-innovation, nutraceutical and agriculture technology) that leverage on core strength of the Malaysian biotechnology industry.

Some of the suggestions to promote venture economy in Malaysian context include:

- To restructure Government-owned venture fund, the goal of which would be to bring foreign VC investment expertise and network of contacts to Malaysia. The fund could be provided in the form of matching funds to investors, with option to buy back the government stake within the first three to five years for the initial value plus a preset interest rate of roughly four to six percent based on prevailing financial conditions. The fund needs to measure success on the basis of milestones achieved by the company. Hence, subsequent funds could be provided on completion of each stage of research. This will act as an effective de-risking funding mechanism for both public and private sectors;
- Government to provide more pre-commercialisation funding for both public and private sectors, with specific goals to develop certain strategic technologies that will be investor ready and have direct national interests;

- Create a healthy flow of information within the biotechnology industry. The well-connected VC (and general investors) community and biotechnology industry is one of the key factors for long term success. Forum, conference, business meetings and exhibitions are organised to create a dialogue platform among two parties; and
- Encourage joint-venture between IHLs/RIs and VC firms. Since, a large value of intellectual assets belong to IHLs/RIs, it would be beneficial for VCs to engage IHLs/RIs in commercialisation of these assets for the benefit of the society. On the other hand, the IHLs/RIs can benefit from the VC's business perspectives, corporate management skills, business knowledge transfer and is relieved partially from the burden and risk of commercialisation.

## **2. Increase Seed Funding From Government Sector<sup>31</sup>**

There has to be more Seed fund allocation provided to the biotechnology sector. Governments around the world such as in Korea and Taiwan have realised the sheer potential of this blue ocean zone. They have committed billions of dollars to spur up their biotechnology industry. The success stories have already started in countries like Korea, which has only over 20 years of experience but has managed to bag dozens of discoveries. Malaysia has strong potential to emulate these success stories.

### **Strategies to Create Value-Added and Quality Employment:**

#### **3. Building Global Reputation of IHLs and RIs**

BiotechCorp has to develop a stronger brand name globally. It has to increase biotechnology activity by conducting many more global events featuring the Malaysian biotechnology industry and its high quality of research and commercialisation opportunities. Further, the awareness needs to be created amongst all stakeholders about the value created by each Programme. For instance, reputation of the BeST Programme needs to be created amongst global recruitment agencies to ensure better placements.

The role of Malaysia's IHLs/RIs in nurturing talent has always been recognised by respective stakeholders. In the current period of economic transformation, increasing prominence has been given to their role in stimulating economic growth through industry-driven research, technology commercialisation, high-tech spin-offs, attraction of foreign talent, and injection of entrepreneurial mind-set among its graduates.

Many of the local private enterprises that had developed in the earlier Industrialisation phases still tend to be laggards, rather than leaders, in engaging in R&D and innovation activities. Consequently, compared to their more technologically mature counterparts in the advanced

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<sup>31</sup> Reference: Khairiah Salwa Mokhtar et. al., 2010. *Economia Seria Management* Vol 13, Nr 1/2010. Current Biotechnology Outlook in Malaysia.



economies, local industries in Malaysia often have less experience, and lower capability, to commercialise knowledge generated from local IHLs/RIs<sup>32</sup>.

#### *Dedicated Fund for Biotechnology Technology Transfer Office*

Re-Organisation of the technology licensing office is necessary to make it more “inventor and investor friendly,” with less emphasis on maximising licensing revenue, and greater focus on getting greater deployment of Malaysian technology to the marketplace, whether through licensing to existing firms or spinning off new firms. New Programmes are needed to provide assistance to Malaysia-based professors, researches and students to commercialise their inventions and knowledge that include:

- Provision of incubator facilities on campus and in the biotechnology clusters;
- Establishment of a seed fund that provides very early stage seed funding to Malaysia IHLs spin-off companies; and
- A dedicated biotechnology start-up fund can be also established to provide smaller seed funding to new ventures started by students and researchers.

#### *Introduction of Technopreneurship Elements into Biotechnology-Related Courses*

Conventional solution of concentrating on technical specialisation during the undergraduate training and leaving the injection of business skills and entrepreneurial acumen to a later stage (e.g., through an MBA education) may not be optimal for the increasingly dynamic labour market of a global, knowledge-based economy. Several new approaches can be considered to introduce the elements of technopreneurship among the students and academicians:

- Apprenticeship in a foreign or local based high-tech start-up or growth in enterprises will expose the students to the tactical aspects of entrepreneurship and business culture. The Programme does not expect the students to be able to start their own ventures right after graduation, but rather, to infuse in them an entrepreneurial mindset that will orient their future research toward commercialisable innovation, as well as influence their future career choices toward more entrepreneurial and innovative settings;
- A technopreneurship minor Programme can be introduced that can be taken by any undergraduate student. At the graduate level, elective courses in new venture creation can be introduced, targeted at Master’s and Ph.D. students interested in commercialising their inventions;
- Raising awareness and interest in bio-entrepreneurship among students and faculty, through activities such as business plan competitions, development of student entrepreneurship society on campus, and conducting regular “techno-venture forums” that bring prominent entrepreneurs and venture professionals to campus to speak; and

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<sup>32</sup> Reference:Poh-Kam Wong et.al., 2007. World Development vol 35 (6), pg 941 – 958. Towards an “Entrepreneurial University” model to support knowledge-based economy development: The case of National University of Singapore.

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- Technology transfer officers will need to build a network of entrepreneurs, VCs, and angel investors to provide IHLs spin-offs with mentoring by practitioners and access to external venture funding.

#### *Increase Funding for IHLs/RIs Laboratories*

There has to be an increase in funding for IHLs/RIs to conduct more market-driven R&D. The focus would be to further enhance labs to have the right infrastructure and expertise to make it more effective. With the increased funding, more initiatives could be drawn up to motivate and encourage greater participation within this industry that hopefully leads to more commercially viable products.

Financial support is also needed to expand and upgrade the physical infrastructure supporting the industry in order to enable integrated service and equipment in biotechnology development across the segment. This can be implemented by attracting international service companies to establish new facilities and/or collaborate with Malaysia's laboratories in upgrading existing facilities. The public sector can support infrastructure needs such as laboratories for providing GLP analytical, bio-analytical and histopathology services, physical and technical facilities for conducting GLP pharmacology tests and for supporting and developing GMP formulation capabilities, GLP Toxicology *in-vitro* and *in-vivo* tests, as well as GMP chemical synthesis and biopharmaceutical development facilities.

#### **4. Tapping into Global Biotechnology Experts**

BiotechCorp also could tap the top brains from around the world to form a network of experts in niche biotechnology areas. This network could be made up of Malaysians living abroad and/or foreign overseas experts. There could be an initiative to tap the minds and expertise of the experts through programmes introduced by BiotechCorp. Local biotechnology companies would then get connected directly through these link-up programmes to get mentoring or specific expertise which were previously not available.

## Strategies to Increase Total Revenue within Malaysian Biotechnology Industry:

### 5. Create Opportunities for Innovation through Local Government Procurement<sup>33</sup>

Procurement is the process of acquiring goods, works and services by government or public sector Organisations, both from third parties and from in-house providers. Besides trying to deliver value for money, public procurement also aims to further social inclusion, sustainability, regeneration, employment generation and support for small businesses. The aspiration to harness public procurement in support of innovation has recently gained recognition and momentum by the global governments. Situation that leads to local innovation due to public procurement:

- In some cases, governments have actively searched for innovative procurement solutions to pressing problems, which have led to product innovations;
- Strategic commissioning of adapted services, particularly where procurement has not been involved traditionally and where markets are underdeveloped;
- Strategic partnerships with private and not-for-profit Organisations can also lead to innovations; and
- Procurement for large, complex services is a key source of technological innovations requiring greater capabilities in terms of contract design, contract management and risk management

Public procurement has a profound influence on innovation. Engaging suppliers early, managing their expectations and increasing the transparency and accessibility of the process are more likely to lead to innovations. This is apparent in South Korea, where the government gives priority to local innovations especially in healthcare, information communication technology and biotechnology that spurs the innovation activities within these industries. The adoption of local innovations will give confidence to the foreign potential buyers as it is an 'informal certification' on the quality of these innovations by local governments. Examples of these potential local innovations are:

- Local based medical diagnostic kits, which offer both advantages in terms of pricing and turnaround time;
- Local meat production, to reduce reliance of import from other countries;
- Local bio-fertilisers and bio-pesticide technologies that will promote sustainable agriculture;
- Local nutraceuticals as post-treatment regime especially in the case of cancer and cardiovascular disease treatment; and
- Local super generics (bio-generics) drugs.

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<sup>33</sup> Reference:

- Elvira Uyerra, 2010. Manchester Institute of Innovation Research. Opportunities for innovation through government procurement
  - Khairiah Salwa Mokhtar et. al., 2010. *Economia Seria Management* Vol 13, Nr 1/2010. Current Biotechnology Outlook in Malaysia.
-

## Strategies to Increase Contribution to GDP through Biotechnology Industry:

### 6. Positioning Malaysia as Global Tropical Biotechnology Hub

BiotechCorp needs to continue to promote Malaysian cluster globally. There has to be more advertising campaigns, seminars, workshops and think tanks positioned to attract more foreign investments and biotechnology companies from around the world. Malaysia can be positioned as a biotechnology destination for tropical bio-innovation (e.g. tropical diseases, feedstocks, bio-diversity) with good infrastructure, policy and funding mechanisms coupled with strong research and commercialisation opportunities.

### 7. Conduct Industry-led Technology Foresight Exercises

A long-term industry-led scientific and technological forecast is needed and should be integrated into the unified system of long term strategic management of the Malaysian economy. It should include the maximum possible applications of the selection methods to implement biotechnology development priorities, in both applied and fundamental research.

The best example is the national foresight in Japan. Once in five years, along-term national science and technology forecast is developed in Japan. The forecast horizon is 30 years, covering more than 15 industries with more than 4,000 experts' participation in the last forecast. Results of surveys conducted in the foresight framework were used:

- To collect data for R&D planning, in particular, a survey of long-term technology trends and identification of important emerging technologies;
- To monitor the state of the art in science and technology, including the level of science and technology activity in Japan in comparison with other countries;
- To identify fields where the need for international cooperation is felt; and
- To isolate factors impeding technological development

The results were used by Japan's Council on Science and Technology to formulate future government science and technology policy. Information was also supplied to other ministries and to industry. These forecasts are some of the most important elements of the decision making on Japan's science and technology policy and are actively used by all ministries and agencies.

### 8. Launching Innovation-Focused Missions

Applying biotechnology to development involves operational activities that are implemented at working levels (e.g., community, farm and enterprise level). An approach that focuses on specific local problems could serve as an organising framework that rally specific knowledge and other resources. This approach will require clear identification on the issues to be addressed, outline the options available for solving the problem and identify a choice of delivery mechanisms.

This can be achieved through a cohesive policy or strategy that focuses on biotechnology missions which serve as a basis for rallying both local and international resources. For example, the establishment of Lake Victoria Basin Commission by East African countries had effectively served as a coordinating mechanism for the management of the resources of Lake Victoria. Such a commission, if properly located in an IHL/RI, could serve as an important organ for leveraging international and local resources. This could be extended to combat certain specific diseases

through development of new products. Through this approach, it would differ from the conventional methods of seeking national R&D budget without specifying the challenges that such funding must be met. Several innovation-focused missions that can be considered in Malaysia:

- Biomass management – focus on research and technology development that could convert waste to wealth using biomass in Malaysia (e.g. palm oil and rubber);
- Maliau Basin Commission in Sabah. Maliau Basin, the Lost World of Sabah is considered the oldest rainforest ecosystem that is available in Malaysia today. The sustainable management of this resource is critical, to protect and explore the million years of biological evolution products for the benefit of society;
- Rice Revolution in Malaysia. In view of rising food price and national food securities, sustainable and lower-turnaround time for harvesting with better quality rice is urgently needed; and
- Malaysia has the potential to be a Centre of Excellence in management of tropical diseases. Global warming, bacterial and viral resistance to current treatment regime and urbanisation in tropical developing countries pose a serious economic and social threat. With Malaysian specialised knowledge and experience in tropical diseases, Malaysia is well positioned to be a regional or global centre of reference in this area.

## **9. Review of the Strategies in National Biotechnology Policy**

Government's attitudes toward promoting national innovation capacity play a key role in determining differences. For example:

- Taiwanese government adopts a more active top-down approach that makes use of substantial government research funding and resources to develop target industries;
- Irish government takes a bottom-up approach that focuses on creating an innovation environment and encouraging firm-level research and development. Substantial inward foreign direct investment into Ireland over the past three decades has created the potential for substantial learning by locally owned enterprises; and
- During late 1990's and early 2000, Europe's regulatory framework had become more stringent due to negative public perception on biotechnology. Restrictive regulation and political hostility had deterred research; innovation and investment—witness the reduction of research releases in the EU since 1997.

Strong Taiwanese innovation performance may be due to the high priority of bio-innovation systems, coupled with policies that support research funding and government targeting. The weaker levels of innovation seen in Ireland can be linked to inadequate IHLs systems and the lack of a clear innovation focus. However, Ireland obtains resources to benefit its economic development from regional economic integration organisations such as the EU; it improves its economic and industrial performance by participating in member state markets. The previous negligence towards biotechnology has been largely lost in Europe at present, but the current Commission strategy is in active progress to correct this.

In Malaysia’s context, we have seen different patterns on biotechnology projects realised in 2009, cutting across biotechnology segments:

<b>Table 5.2: Biotechnology Projects Realised in 2009</b>				
<b>Segment</b>	<b>FDI</b>	<b>DDI</b>	<b>FDI &amp; DDI</b>	<b>Total</b>
Agriculture	2	34	0	36
Healthcare	17	12	0	29
Industrial	0	14	3	17
<b>Total</b>	<b>19</b>	<b>60</b>	<b>3</b>	<b>82</b>
<i>Source: BiotechCorp Annual Report 2009</i>				

Based on these investment trends, perhaps Malaysia should review its biotechnology policy with specific and customised approaches for each biotechnology segments.

It is important that innovation and industry performance to be used as a feedback to direct the current and future policies, that is worthwhile to evaluate from time to time. For small economies like Malaysia, bio-innovation can be important for all concerned, and successful bio-innovation policies should be tailored to our specific needs, culture and structures. This will set new requirements for the knowledge base and instruments of policy-making.

## Conclusion

This study assesses the achievements of BiotechCorp's Programmes during the RMK-9 period (2006 – 2010). Based on the study, the analysis and industry players feedback have been overall positive and encouraging. BiotechCorp had played an active role for the well-being of biotechnology industry in Malaysia by providing the crucial interface and institutional connectivity. Despite the global financial crisis in 2009, Malaysia's biotechnology industry had emerged with stronger fundamentals, ready for Phase 2 NBP, Science to Business.

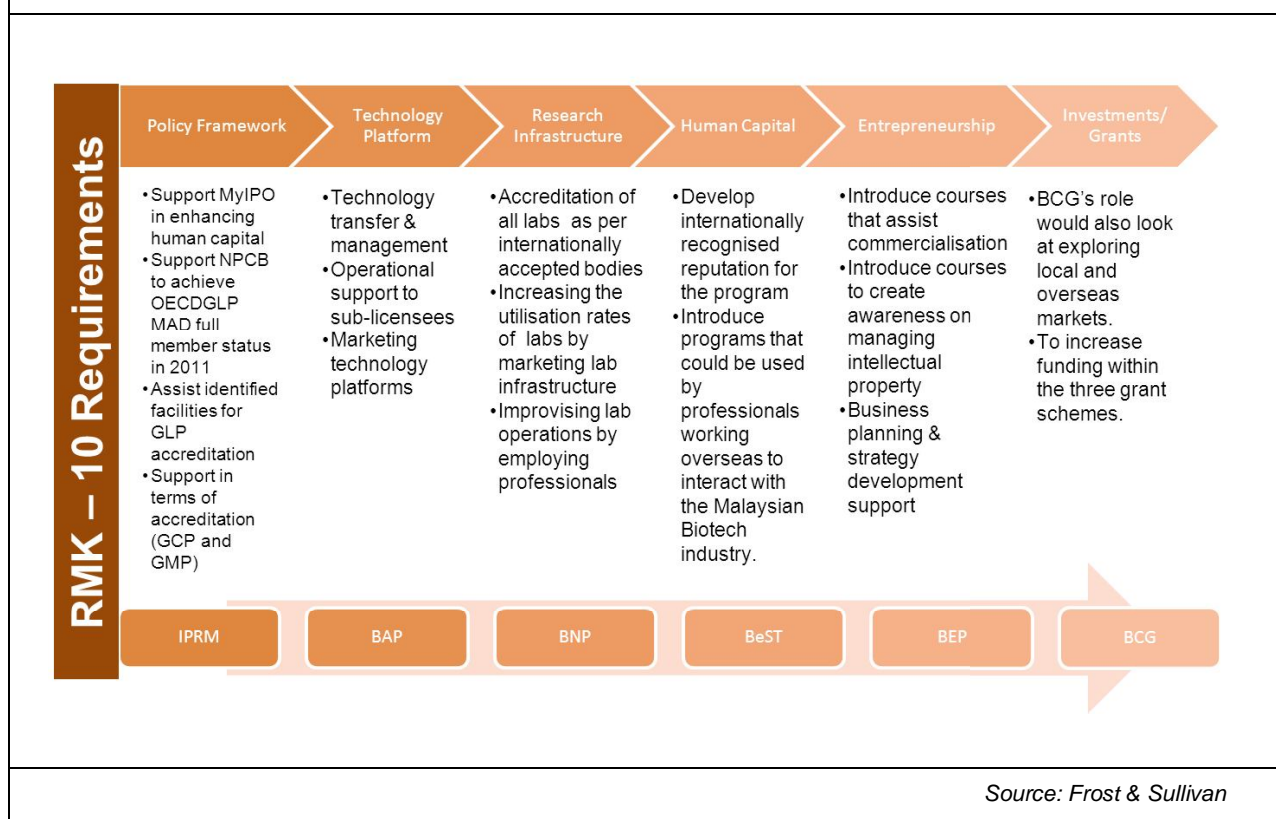
Phase 1 NBP was well-linked to Government's economic goals and had adequately supported by specific Programmes initiated by BiotechCorp . While the critical elements of vibrant biotechnology ecosystem are present in Malaysia, continuous public sector support is needed to strengthen these building blocks in Phase 2 NBP:

- Due to its inherent nature, the biotechnology industry takes longer to mature and requires more funding relative to other industries;
- Continuous investment from both public and private sector is essential to create the critical mass leveraging on the BioNexus status companies;
- The funding gap to create the critical mass needs to be addressed to build a strong and sustainable industry base;
- While the fundamental talent pools are present in Malaysia, specialised skills are required in Phase 2 of NBP across the value chain of the biotechnology industry; and
- Most of the BioNexus status companies are in the start-up and growing stage, as such the priority will be gearing these companies to move up the value chain via targeted collaborative programmes. This will require further nurturing activities while building momentum on revenue generation from these companies.

Recognising these industry gaps, continuance of the Six Programmes (under BiotechCorp) is essential for the Malaysian Biotechnology industry to continue to grow at its current rate. The roles of the Programmes need to be revised, enhanced and re-strategised to be more market-oriented to address the commercialisation needs of Phase 2 NBP.



**Figure 5.2: Requirement of Biotechnology Sector in Phase 2 NBP (During RMK-10)**



The target during Phase 2 NBP had increased significantly:

Indicators	Phase 1 NBP Target	Phase 1 NBP Achievement	Phase 2 Target 2011 – 2015	Target Increment (Phase 1 vs. Phase 2)
<b>New Investment:</b>	<b>RM 6.0 b</b>	<b>RM 5.4 b</b>	<b>RM 9.0 b</b>	<b>+ 50%</b>
<b>Public</b>	RM 4.0 b	RM 3.2 b	RM 4.0b	+0%
<b>Private</b>	RM 2.0 b	RM 2.2 b	RM 5.0b	+ 150%
<b>Employment</b>	<b>40,000</b>	<b>54,776</b>	<b>80,000</b>	<b>+ 100%</b>
<b>Direct</b>	14,000	13,690	28,000	+100%
<b>Indirect/Induced</b>	26,000	41,086	52,000	+100%
<b>Revenue (End of Phase)</b>	<b>RM 20 b</b>	<b>RM 13.5 b</b>	<b>RM 50 b</b>	<b>+ 150%</b>
<b>Direct</b>	RM 9b	RM 6.5 b	RM 22 b	+ 144%
<b>Indirect/Induced</b>	RM 11b	RM 7.0b	RM 28 b	+154%
<b>GDP contribution</b>	<b>2.5%</b>	<b>2.2%</b>	<b>4.0%</b>	<b>NA</b>

The role of private sector is expected to be more significant in Phase 2 NBP. Private investment and total revenue is targeted to increase by 150 percent. This will require more public-private partnerships, where the role of the public sector will be more towards facilitation, proactive steps to reduce the risks and create a sustainable ecosystem through market-driven approach.

Looking at the performance of BiotechCorp, within the last five years, biotechnology industry has managed to register 2.2 percent contribution towards the GDP, attracted RM5.4 billion worth of investments from (private and public sector), achieved a total of RM13.5 billion in revenue and created 54,776 jobs in the background of global financial crisis. .

Through the initiatives from the Government and BiotechCorp, the biotechnology industry sector has witnessed significant growth compared to pre-NBP era. An enabling environment for biotechnology industry has been built, where Malaysia's society at large can start to receive positive impacts from these efforts. New innovations and technologies were adopted, new specialised and high value jobs were created, public and private collaboration creating value added to local IP and products that attracted investments-all create impacts on Malaysia's economy. With effective execution strategies from the Government and BiotechCorp, the biotechnology sector has shown its potential to drive Malaysia towards a high-income and knowledge-based economy by year 2020 as per national aspirations in the NEM.

### Formula Sheet

For the purpose of deriving numbers and aligning them to the forecasts as per National Biotechnology Policy 2006, Frost & Sullivan has used a few formulas. These have been detailed in this section.

#### Revenue Calculation:

The revenue estimates are based on the recent report published by MOSTI, which provides direct revenues for Biotechnology industry for the period 2006 -2009. Frost and Sullivan estimated the revenues for 2010, based on revenue growth seen by a representative sample of companies.

The indirect and induced revenue were then derived using following multipliers:

- Indirect Revenue to Direct Revenue; and
- Induced Revenue to Direct Revenue.

These multipliers are in line with the assumptions made in the NBP.

#### GDP Contribution:

The GDP contribution includes two basic components:

- Revenue Contributions; and
- Contributions through other factors such as tax from employees, investments infused into the society, opportunities to other sectors such as real-estate, finance, IHLs etc.

Since, there is no accurate method for calculation; we have used the same multiplier as the ones used in the NBP. The multiplier for direct revenues to other contributions is derived based on following assumptions:

- The target cumulative income for Phase 1 NBP is RM 20 billion;
- The estimated GDP as per NBP for 2010: RM 753 billion; and
- Assumed expected growth in Biotechnology revenue is 15 percent

#### Employment Projections:

The direct employment estimates are based on the recent report published by MOSTI, which provides direct revenues for Biotechnology industry for the period 2006 -2010. This includes both employees working as knowledge workers and those employed in other job profiles within the Biotechnology companies.

For estimating the indirect employment we have used the same multiplier as the ones used in the NBP.



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## **Abbreviations**

## Abbreviations

Abbreviation	Full Form
ABS	Access Benefit Sharing
ACBT	All Cosmos Bio-Tech Sdn. Bhd.
ACCSQ	ASEAN Consultative Committee for Safety and Quality
ACE	Access Certainty Efficient Market, Kuala Lumpur Stock Exchange
ACI	All Cosmos Industries Sdn. Bhd.
AI	Artificial Insemination
AIM	Agensi Inovasi Malaysia
AIM (LSE)	Alternative Investment Market, London Stock Exchange
AMREC	Advanced Materials Research Centre
ART	Advanced/Assisted Reproduction Techniques
ASEAN	Association of South East Asia Nations
ASTM	American Society for Testing and Materials
ASX	Australian Stock Exchange
AURP	Association of University Research Parks
BAP	Biotechnology Acquisition Programme
BCG	Biotechnology Commercialisation Grant
BEP	Biotechnology Entrepreneur Programme
BeST	Biotechnology Entrepreneurship Special Training Programme
BIC	Biotechnology Implementation Council
BIO	Biotechnology Industry Organisation
Biocon	Biocon Ltd
BiotechCorp	Malaysian Biotechnology Corporation Sdn. Bhd.
BNP	BioNexus Partners Programme
CAGR	Compounded Annual Growth Rate
CAP	Commercialisation Assistance Programme
CBD	Convention on Biological Diversity
CfEL	Centre for Entrepreneurial Learning
CMA	Compliance Monitoring Authority

CMDV	Centre of Molecular Discovery and Validation
CMO	Clinical Manufacturing Outsourcing
COP10	Conference of Parties
CPGR	Centre for Proteomic and Genomic Research
CPIPM	Certified Professional Intellectual Property Manager
Cradle	Cradle Fund Sdn. Bhd.
CRC	Clinical Research Centre
CRO	Clinical Research Organisation
CS	Cerebral stroke
CTIL	Clinical Trial Import License
CTX	Clinical Trial Exemption
DDS	Drug Delivery System
DHA	Docosahexaenoic Acid
DLM	DNA Landmarks Inc.
EFA	Eicosapentaeoic Acid
EFB	Empty Fruit Bunch
EIR	Executive-in-Residence
EM	Effective Microorganisms
ENT	Ear, Nose and Throat
EPO	European Patent Office
EPU	Economic Planning Unit or Unit Perancang Ekonomi
ET	Embryo Transfer
EU	European Union
FDI	Foreign Direct Investment
FRIM	Forest Research Institute Malaysia
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GLCs	Government Linked Companies
GloBE	Global Bio-entrepreneurship Course
GLP	Good Laboratory Practice

GlycosBio	Glycos Biotechnologies Inc.
GMP	Good Manufacturing Practice
GnRH	Gonadotropin-releasing hormone
HA	Hydroxyapatite
HACCP	Hazard Analysis and Critical Points
HSP	Hsinchu Science Park, Taiwan
IAP	International Advisory Panel
IBD	International Business Development
ICT	Information Communication Technology
IFNM	Institut Farmaseutikal dan Nutraseutikal Malaysia
IHLs	Institutes of Higher Learning
IHLs/RIs	Institute of Higher Learning/Research Institutes
IIUM	International Islamic University Malaysia
ILB	Industry-Lead Body
IMD	International Institute for Management Development
IMR	Institute of Medical Research
INFORMM	Nanobiotechnology Research and Innovation Institute for Research in Molecular Medicine
IP	Intellectual Property
IPO	Initial Public Offering
IPRM	Intellectual Property Research Management Programme
ISO	International Organization of Standardization
IVD	In vitro Diagnostic
KIPO	Korean Intellectual Property Office
KPI	Key Performance Indicators
KRIBB	Korea Research Institute of Biotechnology and BioScience
LARTA	Larta Institute
LMO	Living Modified Organism
mAbs	Monoclonal Antibodies
MAD	Mutual Acceptance of Data

MARDI	Malaysian Agriculture Research Development Institute
MAS	Marker Assisted Selection
MAT	Mutually Agreed Terms
MDPWG	Medical Device Product Working Group
MDT	Maggot Debridement Therapy
METEX	Metabolic Explorer SA
MGI	Malaysia Genome Institute
MGRC	Malaysian Genomics Resource Centre Berhad
MIM	Malaysian Institute of Management
MIT	Massachusetts Institute of Technology
MJV	Mutual Joint Visit
MLM	Multi-Level Marketing
MOA	Memorandum of Agreement
MoC	Memorandum of Collaboration
MoF	Ministry of Finance
MOH	Ministry of Health
MOHR	Ministry of Human Resources
MOSTI	Ministry of Science, Technology and Innovation
MoU	Memorandum of Understanding
MRA	Mutual Recognition Arrangement
MTDC	Malaysian Technology Development Corporation
MyIPO	Intellectual Property Corporation of Malaysia
NATA	National Association of Testing Authorities, Australia
NBIA	National Business Incubation Association
NBP	National Biotechnology Policy
NEM	New Economic Model
Novartis	Novartis Pharma AG
NOSS	National Occupational Skill Standard
NPCB	National Pharmaceutical Control Bureau
NRE	Ministry of Natural Resources and Environment

OECD	Organisation for Economic Cooperation and Development
PDO	Propanediol
PEMANDU	Performance Management and Delivery Unit
PIC	Prior Informed Consent
PIC/S	Pharmaceutical Inspection Co-operation Scheme
POC	Proof of Concept
PPP	Public Private Partnership
PPWG	Pharmaceutical Product Working Group
PWG	Product Working Group
QB3	California Institute for Quantitative Biosciences (QB3)
R&D	Research and Development
RIs	Research Institutes
RMK-10	Tenth Malaysia Plan or Rancangan Malaysia Ke-10
RMK-8	Eighth Malaysia Plan or Rancangan Malaysia Ke-8
RMK-9	Ninth Malaysia Plan or Rancangan Malaysia Ke-9
RTO	Reverse Take Over
SAT	Site Acceptance Test
SBC	Sarawak Biodiversity Council
SCOPE	Stem Cells Operational and Professional Excellence
SFE	Supercritical Fluid Extraction
SFF	Supercritical Fluid Fractionation
SIRIM	Standards and Industrial Research Institute of Malaysia
siRNA	Small Interfering Ribonucleic Acid
TalentCorp	Talent Corporation Malaysia
TLO	Technology Licensing Office
TMHS-PWG	Traditional Medicine and Health Supplements Product Working Group
TPM	Technology Park Malaysia
TTO	Technology Transfer Office
TWAS	New Academy of Science for Developing World
UCSF	University of California, San Francisco

UiTM	Universiti Teknologi MARA
UM	Universiti Malaya
UMP	Universiti Malaysia Pahang
UMS	Universiti Malaysia Sabah
UMT	Universiti Malaysia Terengganu
UniMAP	Universiti Malaysia Perlis
UNIMAS	Universiti Malaysia Sarawak
UPEN Kelantan	Unit Perancang Ekonomi Kelantan
UPM	Universiti Putra Malaysia
US	United States of America
USIM	Universiti Sains Islam Malaysia
USM	Universiti Sains Malaysia
UTM	Universiti Teknologi Malaysia
VC/VCs	Venture capital/venture capitalists





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