Overview: Malaysian Healthcare Biotechnology
The Malaysian Healthcare Biotechnology Sector

A Frost & Sullivan Whitepaper
2009
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Introduction

The healthcare biotechnology industry is undoubtedly a strategic investment opportunity, both from an economic as well as a social stand-point. Thanks to cutting-edge research, biotechnology companies have contributed a portfolio of products to diverse industries ranging from human and animal health to protection of the environment and in the food-processing industries. Globally, there are about 4,000 small- and medium-scale enterprises belonging to the biotechnology fraternity, and they are involved in continuous research. Biotechnology has created more than 200 new therapies and vaccines, including products to treat cancer, diabetes, HIV/AIDS and autoimmune disorders. As traditional pharmaceutical industry pipelines dry up, the industry has started looking towards biotechnology to fill this gap.

While the market capital of the top 5 US pharma companies has fallen approximately 20% in the last 5 years, the biotech market capital has seen an 18% gain over the same period.

Despite a general perception and a consensus on the positive outlook for the healthcare biotechnology industry, some of the constraints that plague the progress of the biotechnology industry are highly undervalued stocks of these biotech companies, insufficient funding, inexperienced management and a sound conceptualization of the business model. Investments in biotechnology are considered risky, and investors are increasingly reluctant to invest in biotechnology companies. The number of IPOs within the biotechnology industry has declined as well, reflecting investors’ concern on the average length of time taken to achieve a return on investment.

In the Asian region, other than Japan and Australia, countries like China, India, Korea and Singapore are emerging as key destinations for the healthcare biotechnology industry. Following is Malaysia and Taiwan who are relatively newer entrants into this field. The healthcare market in Asia is a key emerging market that is emerging as key destinations for the healthcare biotechnology industry. Following is Malaysia and Taiwan who are relatively newer entrants into this field. The healthcare market in Asia is a key emerging market that is expected to grow at approximately 8-10% in 2009. The total healthcare market revenue in Asia Pacific was estimated at US$240 billion in 2008, of which pharmaceuticals is two thirds of the market.

Healthcare biotechnology is still a young industry in Malaysia and is a challenging area requiring high technology levels, but with much potential for growth. The Malaysian Government has given strong support and commitment to Biotechnology through financial support for Research and Development (R&D), infrastructure and Human Resource Development (HRD). Other than the commercial incentives, Malaysia also has favourable conditions in terms of infrastructure, logistics and technology from their technology transfer programs.
Goals and Strategies for the Sector

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 2020. The country has a rich biodiversity and cost-competitive skilled labour markets, as well as good transportation networks, ICT infrastructure and strong capabilities in R&D. These combined characteristics make Malaysia an attractive potential destination for foreign biotechnology companies and investors interested in the healthcare biotechnology sector.

The Malaysian Biotechnology Policy

The Malaysian Government has identified the biotechnology sector as one of the key strategic sectors that will support the growth of the Malaysian economy. It is anticipated that growth in the sector will be supported by leveraging on the strength of the country’s diverse natural resources and cost effective human capital talent pool. The Government has identified the need to create a strong supporting framework to facilitate the long term growth of the sector. In 2005 the Malaysian government enacted the Malaysia Biotechnology Policy to achieve this goal. The policy detailed nine focus areas deemed critical to creation of a sustained biotechnology sector, one of which is to support the growth of the industrial biotechnology sector.

The Malaysian Biotechnology Policy detailed a series of aggressive development goals. The biotechnology industry is expected to contribute approximately 2.5 % of national GDP by 2010, 4.0% by 2015 and 5.0% by 2020. Furthermore, it is estimated that the industry will create 280,000 new jobs – both directly and indirectly – by 2020.

The Nine Thrusts of the National Biotechnology Policy

<table>
<thead>
<tr>
<th>Thrust</th>
<th>Description</th>
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<tbody>
<tr>
<td>1. Agricultural Biotechnology</td>
<td>Transform and enhance the value creation of the agricultural sector through biotechnology.</td>
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<tr>
<td>2. Healthcare Biotechnology</td>
<td>Capitalise on the country’s biodiversity for commercialising the discoveries of health related natural products and bio-generic drugs.</td>
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<tr>
<td>3. Industrial Biotechnology</td>
<td>Leverage on the country’s strong manufacturing sector to increase opportunities for bio-processing and bio-manufacturing.</td>
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<tr>
<td>4. Research &amp; Development, Technology Acquisition</td>
<td>Establish centres of biotechnology excellence, through research &amp; development, as well as technology acquisition.</td>
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<td>5. Human Capital Development</td>
<td>Build the nation’s human capital through education, training and research activities, with the aim of producing knowledge generation capabilities.</td>
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<tr>
<td>6. Financial Infrastructure</td>
<td>Provide the right financial support via competitive lab to market funding and incentives to encourage committed participation from academia and the private sector, including Government-linked companies.</td>
</tr>
<tr>
<td>7. Legal &amp; Regulatory Framework</td>
<td>Strengthen the legal and regulatory framework by reviewing ownership of intellectual properties and regulations relating to biotechnology processes and business.</td>
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<tr>
<td>8. Strategic Development</td>
<td>Build international recognition for Malaysian biotechnology and find a niche in the global technology value chain.</td>
</tr>
<tr>
<td>9. Government Support &amp; Commitment</td>
<td>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 Malaysian Biotechnology Corporation Sdn Bhd (BiotechCorp).</td>
</tr>
</tbody>
</table>

Source: BiotechCorp, 2008
The policies describe an over-reaching series of goals, and the development plans for the Healthcare sector are embedded within these policies. This landmark policy encompasses nine thrusts which underline the direction and measure offered by Malaysian Government towards developing biotechnology for wealth creation and national well-being.

**Thrust two** of The Biotechnology Policy highlights the need to capitalize on the strength of biodiversity to commercialize discovery in health-related natural products and bio-generic drugs.

**Thrust three** emphasizes the need to leverage Malaysia strong manufacturing sector by increasing opportunities in bio-processing and bio-manufacturing.

These two thrusts reflect one of the main principles behind the National Biotechnology Policy – which is to leverage the country’s existing capabilities and to move them up the value chain.

**Thrust four** meanwhile is to establish biotechnology centres of excellence in the country. Two examples which have a strong healthcare biotechnology focus are the Center of Excellence for Genomics & Molecular Biology in Universiti Kebangsaan Malaysia and the Centre of Excellence for Pharmaceuticals & Nutraceuticals in collaboration with Universiti Sains Malaysia (USM).

**Thrust six** of The National Biotechnology Policy is to apply competitive lab to market funding and incentives to encourage committed participation from academia and private sector, including government-linked companies.

### The 9th Malaysia Plan

The 9th Malaysia Plan announced on the 31st March 2006 further defined and detailed the goals of the Malaysian government in relation to the biotechnology sector. Importantly the Plan reviewed the amount of funding support committed to developing the sector in Malaysia (as described below). It is anticipated that the healthcare biotechnology sector will benefit from all of these investments, including the funding support directed to healthcare projects which, in part, will focus on technology acquisition/transfer and healthcare biotechnology infrastructure.

<table>
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<tr>
<th>Biotechnology Sector Spending</th>
<th>9th Malaysia Plan Allocation (US$, M)</th>
<th>Allocation (RM)</th>
</tr>
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<tbody>
<tr>
<td>R&amp;D Development</td>
<td>$129.9</td>
<td>$463.0</td>
</tr>
<tr>
<td>Biotechnology R&amp;D</td>
<td>$101.9</td>
<td>$363.0</td>
</tr>
<tr>
<td>Biotechnology Commercialization Fund</td>
<td>$28.1</td>
<td>$100.0</td>
</tr>
<tr>
<td>Biotechnology Acquisition Programme</td>
<td>$28.1</td>
<td>$100.0</td>
</tr>
<tr>
<td>Biotechnology Business Development</td>
<td>$148.7</td>
<td>$529.8</td>
</tr>
<tr>
<td>Technology and IP Management</td>
<td>$28.1</td>
<td>$100.0</td>
</tr>
<tr>
<td>Entrepreneurship Development</td>
<td>$14.0</td>
<td>$50.0</td>
</tr>
<tr>
<td>Agro-Biotechnology Projects</td>
<td>$22.4</td>
<td>$79.8</td>
</tr>
<tr>
<td>Institutional Support and Equity</td>
<td>$84.2</td>
<td>$300.0</td>
</tr>
<tr>
<td>Biotechnology Infrastructure</td>
<td>$260.6</td>
<td>$928.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$567.3</strong></td>
<td><strong>$2,021.3</strong></td>
</tr>
</tbody>
</table>

Source: 9th Malaysia Plan, Economic Planning Unit
These policies have seen results with local achievements in healthcare biotechnology with a significant increase in terms of revenue capitalisation and number of companies for 2008, as well as local and local-international collaborations. This indicates the ongoing healthy progress of the Malaysian biotech industry. Examples of collaborations, investments significant projects approved are shown below. (Sources: MIDA, BiotechCorp, Frost & Sullivan)

<table>
<thead>
<tr>
<th>Collaboration</th>
<th>Focus Area</th>
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<tbody>
<tr>
<td>University Malaya (UM) and Universiti Kebangsaan Malaysia (UKM)</td>
<td>Molecular Biology</td>
</tr>
<tr>
<td>Medical Biotechnology Cooperative Centre Universiti Malaysia Sarawak (UNIMAS) and Institute of Medical Research (IMR)</td>
<td>Medical Biotechnology</td>
</tr>
<tr>
<td>Malaysia-MIT Biotechnology Partnership Program</td>
<td>Medicinal plants</td>
</tr>
<tr>
<td>BiotechCorp-California Institute for Quantitative Biomedical Research (QB3)</td>
<td>Biomedical research, human capital and bio-entrepreneurship development</td>
</tr>
</tbody>
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<tr>
<th>Company</th>
<th>Research/Investment Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA Laboratories</td>
<td>Developed molecular diagnostic kit named ThalaCheck® for Single Gene Disorder Detection such as Thalasemia Carrier Detection to be launched at BioMalaysia 2009</td>
</tr>
<tr>
<td>WaferGen Biosystems, Inc. (OTCBB: WGBS)</td>
<td>Developer of state-of-the-art gene expression, genotyping, cell biology and stem cell research systems. Announced the formal opening of its state-of-the-art subsidiary, WaferGen Biosystems (M) Sdn Bhd in Kulim Hi-Tech Park, Kedah, Malaysia. This new organization will oversee R &amp; D activities related to the SmartChip™ Real-Time PCR System</td>
</tr>
<tr>
<td>Stempeutics Research Malaysia Sdn Bhd</td>
<td>Focusing on the research and development of regenerative medicine using human stem cell technology, with a proposed investment of approximately USD 1.63 million</td>
</tr>
<tr>
<td>Profound Vaccine Sdn Bhd</td>
<td>Involved in the production and commercialization of a spray-based intranasal vaccine against Pneumonia Pasteurellosis disease in sheep and goats, with an investment of USD 0.7 million</td>
</tr>
<tr>
<td>Innobiologics</td>
<td>The first contract manufacturing organisation (CMO) for biopharmaceutical production in Malaysia. Provides biopharmaceutical manufacturing facilities and services in compliance with global regulatory guidelines and standards. Services cover all stages of the production of mammalian cell-based therapeutic proteins and monoclonal antibodies, from DNA recombination work and bioprocess development to cGMP manufacturing</td>
</tr>
<tr>
<td>Simugen</td>
<td>Entered an agreement with Centre for Proteomic and Genomic Research (CPGR) to develop novel biomarker assays for the prediction of toxicity of existing and novel drug.</td>
</tr>
<tr>
<td>Siogen Biotech Sdn. Bhd</td>
<td>Develop breakthrough allergy therapies allowing patients to tolerate their allergies and the company is aiming to package crude allergens into their platform propriety. Intellectual Property has been transferred from Germany to the Malaysian entity, Siogen Biotech Sdn. Bhd, was awarded as the &quot;Most Innovative Start-up&quot; in Asia Pacific during The 2009 BioSingapore Asia Pacific Biotechnology Awards.</td>
</tr>
</tbody>
</table>
The Malaysian healthcare (pharmaceuticals and medical devices) industry was estimated at USD 1.7 billion in 2008, of which pharmaceuticals was valued at approximately 1.1 million with Compound Annual Growth Rate of 10.5% from 2009-2012. One of the key business drivers is the overwhelming need for effective therapies, diagnostics and medical devices. The pressure to address these and other prevalent diseases is mounting due in no small measure to the increasing influence of developing nations’ government influences as well as that of NGOs, whilst personalised medicine promises to catalyse a major transition in healthcare; factoring in greater understanding of disease on a “systems” level.

With the uniqueness of Malaysia for its biodiversity, Malaysia shows a good progress in herbal industry. It is estimated that the herbal industry in Malaysia would have a market size of approximately RM5.2 (USD 1.6) billion in 2007 and this is expected to double by 2012. The market is expected to reach RM11.7 (USD 3.6) billion in 2012 with annual growth rate between 15-20% per year growing at a CAGR of 17.3% (2007-2012) (Frost & Sullivan 2007).

Malaysia is emerging to make contributions to the biotech industry in Asia. With strong publicity to attract more investment as well as aggressive promotion and support by the Government, Malaysia is heading towards being an integral part of global drug development organizations, clinical trials and contract manufacturing.

In Malaysia, the Government is moving aggressively to make the transition from being a traditional manufacturer of small molecules to developing innovative pipelines through home-grown research or technology transfer. Examples of such initiatives are realisation of projects by Siogen among others.

Siogen, a company based in Germany, owns a drug delivery platform technology, dedicated to detecting and preventing allergies. The company has a registered subsidiary company in Malaysia i.e. Siogen Biotech Sdn Bhd, to develop breakthrough allergy therapies allowing patients to tolerate their allergies and the company is aiming to package crude allergens into their platform propriety. Intellectual Property has been transferred from Germany to the Malaysian entity. Siogen Biotech Sdn. Bhd was awarded as the "Most Innovative Start-up" in Asia Pacific during the 2009 BioSingapore Asia Pacific Biotechnology Awards. It is a great achievement to be proud of, only after 9 months of operation (the company was set up in May 2008).

Hovid Berhad is another example of Malaysia’s healthcare biotechnology success story. Starting out as a single product company in 1945, Hovid today has 12 global patents and a presence in 40 countries worldwide. The company set up another unit, Carotech Bhd. which commenced production in 1995 and has since successfully carved a niche and become a leading supplier of phytonutrients throughout the world, with the US, Europe, Japan and Australia making up the main markets. In January 2008, Hovid bought a controlling stake in Biodeal Pharmaceuticals. For the financial year ended June 30 last year, the company recorded RM214.7 million revenue and RM15.3 million net profit.

Alpha Biologics, with investments funded by Springhill Bioventures Sdn. Bhd. is concentrating on the production of pre-commercial scale pre-clinical trial drugs (completed in June 2007 and now employs around 25 staff). Another healthcare biotechnology company, Innobiologics will specialize in pre-clinical (SPF) animal testing.
Malaysia is one of the key countries challenging other regional players in biotechnology. It has ambitious plans to become the region’s biotech hub and is focusing on developing unique competitive edge over other countries in the region. The key strengths of Malaysia include its sound infrastructure, solid history in medical device and diagnostics manufacturing, well regulated pharmaceutical industry and availability of GMP certified manufacturing facilities. It is also a key centre for clinical trials and has long been a part of global clinical trials. Healthcare biotechnology is one of the key areas of focus of the National Biotechnology Policy, and advances in contract manufacturing, CRO, medical devices and diagnostics and drug discovery are among the key areas that will drive the growth of the healthcare biotechnology industry in Malaysia.

National science and technology plans and policies were formulated to promote R&D in biotechnology and to make the environment conducive for private sector to invest in R&D. Institutes and centres of excellence were established as part of the effort to build the technology and knowledge infrastructure. Incentive schemes providing matching funds to support company R&D, as well as attractive manpower training schemes were made available to locally registered companies. This concerted effort has jump-started biotechnology in Singapore.

India has an emerging biotechnology industry that is aided by a large highly-educated community of scientists and researchers. The country’s biotechnology industry also boasts of strong government support and a growing infrastructure base. India is a leader in the Contract Research industry, and market revenues could reach as high as US$ 250 million by 2009.

Biotechnology in Thailand is a natural outgrowth of the strong base in agriculture and food products, and the sector is as diverse as its natural resources. The establishment of the National Center for Genetic Engineering and Biotechnology, and the development of National Biotechnology Policy Framework (2004-2009), provides a clear direction for biotech development in Thailand that is well on its way towards realization. The Thai biotech sector can be divided into 3 main areas of focus: Agricultural Biotech, Medical Biotech, and Food Biotech.

The biotechnology industry in Hong Kong is an emerging sector with steady growth. The development of biotechnology evolves gradually to the present shape as led by a matrix of factors including the territory’s research and technology prowess, market forces and source of capitals. In 2007, it is estimated that Hong Kong has approximately 250-300 biotech-related companies, comprising of mainly healthcare-related companies with business on pharmaceuticals, medicinal or healthcare products of traditional Chinese medicine origin, and medical devices and diagnostics.

Source: Frost & Sullivan
Healthcare Biotechnology
Focus Areas

The financial crisis has created profitability pressures that are driving multinational companies to find ways to operate more cost effectively. The outsourcing of operations to Asia is one way to achieve these efficiencies.

Healthcare Biotechnology Drivers – Shaping the future use in Asia

1. **Research and Development:** By 2009 R&D outsourcing is anticipated to be worth $7.2 billion (Source: Biospectrum). Services utilized include drug discovery, screening and lead product optimization.

2. **Clinical Trials:** Use of CROs with an Asian presence to reduce clinical trial costs and to ensure Asian populations are represented in clinical studies.

3. **CMO:** Outsourcing of manufacturing to Asia is still focused on the production of APIs. However, Asian centers are developing expertise in biologics manufacturing. Additionally, Taiwan, Malaysia, China and Singapore will play an increasing role in medical device manufacturing.

The healthcare biotechnology sector is broad and for the purposes of this white paper, we will focus on the key areas which Malaysia is able to leverage on its natural strengths and capabilities to develop an internationally competitive position in the market.

**Focus Sector Overview: CMO**

According to a Malaysian Industrial Development Authority (MIDA) report entitled Investment Opportunities in the Manufacturing and Services Sector in Malaysia 2007, the local industry currently produces about 25-30% of the domestic demand and exports to Asia-Pacific Rim countries, the Middle East, Africa and Latin America (total exports of US$130 million in 2005). Moreover, with Malaysia joining the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation/Scheme (PICS) and the large number of GMP production plants, the country’s pharmaceutical exports are poised to grow in the coming years and will include increasing potential exports to the European Union. The countries’ strong GMP compliance also puts it in good stead to capitalise on the CMO market.

It is expected that the next generation biopharmaceutical molecules with lower manufacturing productivity than current small molecules will drive future growth of the CMO market. This is as outsourcing is encouraged as it is more efficient and cost effective. The strengthening of mid-size biopharmaceutical companies, which serve as the engine for a rapidly growing biopharmaceutical pipeline, is further a strong signal for future potential that exists in outsourcing manufacturing.
Opportunities for Malaysia

**Strategic Thrust:** Biotech policy identified contract manufacturing organization as a strategic thrust for Malaysia to become a global centre for biotech shared services outsourcing

**Industry Foundation:** CMOs will provide the necessary foundation and infrastructure to develop Malaysia’s life science industry further from its current reliable GMP base

**Industry Growth:** Global biopharmaceuticals market is poised to grow from US$64.5 million at a Compound Annual Growth Rate (CAGR) of 11.6% between 2007 to 2014

Malaysia also has excellent infrastructure and GMP compliant facilities, cost competitiveness

Local and foreign players:

- **Pharmaniaga:** Contract manufacturing of >200 types of products (including for US multinationals)
- **CCM Duopharma:** Contracts to supply drugs to the Health Ministry worth over RM 30 million per annum
- **Hovid Berhad:** Hovid today has 12 global patents and a presence in 40 countries worldwide. Carotech Berhad, a subsidiary of Hovid Berhad, is involved in the extraction of phytonutrients and biodiesel from crude palm oil.

Focus Sector Overview: CROs

Clinical research organisations (CROs) provide substantial global capacity to drug developers and have become a critical contributor to both preclinical and clinical trial activity. Growth in CRO revenue is increasingly from biotechnology companies as opposed to the traditional pharmaceutical companies.

Biotechnology companies currently account for more than half of all molecules in development, but lack a strong development infrastructure compared to their pharmaceutical counterparts. This is one of the most compelling reasons driving research outsourcing to CROs. Additionally, cost pressures pose a constant challenge to both pharmaceuticals and biotechnology companies, and outsourcing to CROs enables them to convert fixed costs related to building and maintaining facilities into variable costs.

CRO revenues are growing rapidly in line with R&D spending, signifying an increasing shift towards outsourced services. The future outlook for CROs remains healthy, driven by robust demand for services across tiers and strong requests for proposal (RFP) from pharmaceuticals and biotechnology companies.

The global contract research market is estimated by Frost & Sullivan at USD 15 billion in 2007. Asia contributed USD 1.3 billion in 2006 and this contribution is estimated to reach USD 2 billion by 2010 (a CAGR of 14%). Asia has 14% of the total number of registered study sites globally (up from 6% in 2006), and the top 10 emerging trial countries in Asia are Australia, China, India, South Korea, Taiwan, Hong Kong, Malaysia, Thailand and Singapore.

Clinical trials are offered by most big hospitals: both private and government, as well as universities and research institutions. Additionally, there are also CROs from Taiwan, the US and Singapore (Quintiles, Gleneagles CRC, APEX International Clinical Services, Protech Pharmaservices) that have expanded their services to Malaysia.
Focus Sector Overview: Biopharmaceuticals/Biogenerics (biosimilars)

The potential entry and expansion of biosimilars is expected to have major implications on the biopharmaceutical industry with increased competition expanded access to affordable healthcare alternatives and driving increased efficiency from greater competition. The impact of biosimilars on the biopharmaceutical industry is expected to be similar if not greater than the impact of generics on the pharmaceutical industry. Currently biopharmaceuticals are considerably more expensive than conventional medications. However with the projected approval of biosimilars lower cost options could be available creating competition.

Opportunities for Malaysia

**Strategic Thrust:** Biotech policy identified contract research as a strategic thrust for Malaysia - future outlook remains strong in Asia for clinical trials

**Industry Growth:** Global CRO market is estimated to grow by 14%, with Asia contributing USD 2 billion by 2010. Large number of multinational CROs with established businesses in Malaysia.

**Local expertise:** Malaysia has a long history in participating in multi-centre clinical trials for most of the top multi-national pharmaceutical companies.

Opportunities for conducting trials lie in the areas of heart diseases, diabetes, and renal impairment since there is a large patient pool existing in these areas and Malaysia also has the experience, knowledge, and infrastructure for the same. There is also demand in the area of tropical and infectious diseases.

There is also great potential for conducting trials for herbal medicine.

**Key Factors likely to Impact Biosimilar Uptake**

- **Cost-containment**
- **High Prices**
- **High usage of biologicals**
- **Increasing acceptance of generics**
- **Governments encourage generic uptake**
- **Concerns about long term data and safety**
- **Robust cost-effectiveness data will be required**
- **Relatively lower uptake of biologicals**
- **Negative opinions of patients about generics**
- **Regulatory guidelines**

Source: Frost & Sullivan
A large number of first generation biopharmaceutical products are nearing maturity and major biopharmaceutical companies are likely to move these out to CMOs and focus on next-generation drugs which could offer higher revenues and margins. Contract manufacturing of biopharmaceuticals has moved beyond being a function of “available capacity” and “cost” to being a strategic option offering flexibility, quicker time to market and lower scale up costs. Biopharmaceutical manufacturing capacity (CMO + captive) supply is expected to remain higher than the demand up to 2012, although this gap is expected to narrow through this period.

Opportunities for Malaysia

**Strategic Thrust:** Focus on bio-generic, vaccines – strong future growth areas. Malaysia’s position as an international ‘halal’ hub provides market reach to Muslim communities in countries like the Middle East and Indonesia. Current strong local pharmaceutical manufacturing sector with ongoing research in biogenerics

**Vaccines:** Malaysia holds a bigger & better potential for growth in paediatric section due to strong demand of HALAL certified vaccines in OIC countries. The HALAL paediatric vaccines are expected to grow more than 10% by 2010

**Biosimilars/biogenerics:** Asia may be the fastest-growing market for bio-generic/biosimilars by 2013. Sales of these products in Southeast Asia alone may expand to $3.1 billion by 2013 from “hardly anything” now

Local and foreign players:

**Innobiologics:** CMO, first biopharmaceutical API manufacturer in Malaysia

**Alpha biologics:** Independent biomanufacturing organisation offering FDA/EMEA cGMP compliant services, specializing in monoclonal antibodies and recombinant proteins

**Vivo Bio Tech Ltd:** Formed a joint venture company Vivo Bio Tech (M) Sdn Bhd with two local partners - Melaka Biotech Holdings Sdn Bhd and Vanguard Creative Technologies Sdn Bhd. Specialized in Research, development and commercialization of biopharmaceutical products.
Focus Sector Overview: Medical Devices and Diagnostics

Malaysia enjoys a strong regional position in the medical devices sector; it supplies approximately 80% of the world market for catheters, and 70% for rubber gloves. The medical devices sector is expanding its manufacturing value chain by moving from basic processes and conventional assembly to product and process R&D, design and prototyping, distribution and logistics. In 2007, Malaysia’s medical devices industry registered over RM 5 billion (US$1.5 billion) in revenue, according to the Association of Malaysian Medical Industries (AMMI) with a year-on-year growth of 8% forecast over the next few years. According to AMMI, there were 179 medical device companies in Malaysia, the bulk in rubber-based medical supplies and consumables. More than 4,000 foreign medical device companies have done contract manufacturing or operations in Malaysia.

A critical component of this whole biotechnology "ecosystem" is technological advancement; including both single use and increasingly more important platform technologies, in particular advanced diagnostics. Advances in technology play an important role in healthcare globally and certainly in Malaysia as it will prove important in developing both the academic and industry R&D. Following on from this, The BiotechCorp is in the process of acquiring exclusive worldwide license rights for the design and manufacture of nanoparticles from a biotechnology company based in Europe. Additionally, they are also exploring other potential technology acquisition opportunities in the field of antibody microarray and immunomodulators. Also in line with this endeavour, Malaysia is moving to boost and protect intellectual property rights with plans for a US$1.4 billion fund which reportedly includes the potential establishment of an IP court system.

**Opportunities for Malaysia**

**Expertise:** Traditional strength in the medical devices sector. > US$1.5 million in revenue in Malaysia in 2007

**Economic Corridor:** Northern Corridor Economic Region is developing the first medical devices and diagnostic incubators in 2009

**Foreign participation:** Large number of foreign companies with device manufacturing facilities like B Braun, Ansell and Johnson & Johnson. St Jude setting up RM 108 million Asia-Pacific regional plant in Malaysia operation by 2011. Malaysia will benefit from the transfer of technology.

Focus Sector Overview: Therapeutics

Biologicals are therapeutics that are derived from living organisms. The utilization of biomarkers in clinical environment has seen an increasing trend, following the high specificity and high sensitivity demonstrated. The discovery of more biomarkers, springing from different research laboratories, will lead to greater market penetration and adoption. The race in this market focuses on a few key aspects: lower production cost, higher specificity and sensitivity, and broader applications.

Stem cell therapy currently at present focuses on regenerative medicine-the method of growing a large number of stem cells in culture, and transplanting them to the patient to restore the original organ function. Yet another application area is tissue engineering, which is an emerging market with the increasing importance of reconstructive and aesthetic surgery. Potential applications include:

- Pancreatic islet regeneration for diabetes
- Autologous stem cell therapy for various cardiovascular diseases
- Tissue engineered skin substitutes for burns and wound healing
- Biocompatible blood substitutes for blood transfusion
- Tissue engineered cartilage and chondrocyte therapy for bone and joint diseases
- Nerve regeneration technologies for neurodegenerative disorders
- Hepatocyte transplantation for various liver diseases
**Opportunities for Malaysia**

**High growth rate areas of focus:** Stem cells, tropical medicine, infectious diseases. Stem cells is forecast to have one of the fastest growth rates (CAGR of 23% from 2006-2010. Source: Frost & Sullivan)

**Strategic alliances:** Increase in strategic alliances encourages the sharing of technology, further accelerates the research output. Increasing collaboration between R&D institutes, biotechnology, Pharma companies and IVD companies

Promotion of Malaysia as the next biotechnology hub in South East Asia

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**Focus Sector Overview: Drug Discovery & Drug Delivery**

Drug discovery and delivery involves methods for identifying new therapeutic molecules with specific biologic activities. High-throughput techniques include combinatorial chemistry, genomics, and proteomics analysis as the starting point.

While highly specialized drug discovery still is dominated by USA & European Pharma & Biotech companies who are well equipped with innovative technology platforms like genomics, broad based screenings etc., the Global Outsourcing for Drug discovery and R&D is shifting towards Asian countries. With a limited validated target for blockbuster medicine, companies are trying to save on the time by outsourcing functions of a process making it a lucrative market for new entrants who can focus on a niche area.
Key trends in drug discovery and delivery are:

- Cost pressures encourage research and development (R&D) outsourcing
- Strong growth of R&D expenditure by pharmaceutical and biotechnology companies spurs market expansion
- Ageing population and shift from acute to chronic products drives demand for outsourcing to hasten up the drug discovery process.
- Limited development infrastructure for biotechnology, specialty pharmaceutical encourages demand for outsourcing
- Robust biotechnology funding drives outsourcing volumes
- Toxicology capacity addition by outsourcers encourages outsourcing market expansion
- Increasing competition and commoditization of CRO services curtails margins
- Increasingly stringent regulatory standards pose an ongoing quality challenge for CROs

Frost & Sullivan forecasts the global drug discovery market has the potential to grow at a CAGR or 14% up to 2010 to achieve market revenues of approximately US$30 billion. The following shows areas of opportunity for the Malaysian healthcare biotechnology industry in drug discovery and development.

Priority of Areas of Drug Discovery Contract Research

1. Broad-based Screening & Chemistry as it needs little Technology & research specialization
2. Basic Research & Clinical development for Specific Therapeutic segments e.g. Oncology Inflammation
3. Development of In house proprietary technology Platforms for specific segments of diseases domain diagnostics & Therapeutics
4. Clinical Trial Data management, Bioavailability & profiling of Trial candidates for Clinical development phases 1-3
5. Outsourcing Research & development of Naturally derived drug candidates exploiting the Biodiversity of Malaysia

Segments of Research outsourcing

- ONCOLOGY
- AUTOIMMUNE
- Central Nervous System

Segments of Services

- Broad based Screening
- Chemistry Screening
- Infectious & Air Borne Respiratory Disease
- Cardio-Vascular Diseases
- Data management & Biometrics
- Basic research for Chemistry, Biology, Screening, Protein Synthesis & Lead optimization
- Preclinical Research activities
- Clinical Trial Services Phase Iib - IIIa
- Proprietary Technology development
- Out-licensing the R & D activities of drug discovery
- Development of Diagnostics & Therapeutics in specialized disease segment

Source: Frost & Sullivan, 2009
Key Success Factors

Supported by a market-oriented economy and pro-business Government policies, Malaysia offers investors a dynamic and vibrant business environment. A politically stable country with a well-developed infrastructure and productive workforce, Malaysia also provides attractive incentives for investors in the biotechnology sector.

<table>
<thead>
<tr>
<th>Investing in Malaysia</th>
</tr>
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</table>
| **Supportive Government Policies in a Dynamic Business Environment** | • Pro-business policies  
• Responsive Government  
• Liberal investment policies  
• Attractive tax and other incentives  
• Liberal exchange control regime  
• Intellectual property protection |
| **Well developed Infrastructure** | • Network of well-maintained highways and railways  
• Well-equipped seaports and airports  
• High quality telecommunications network and services  
• Fully developed industrial parks, including free industrial zones, technology parks and Multimedia Super Corridor (MSC)  
• Advanced MSC Malaysia Cybercities and Cybercentres |
| **Vibrant Business Economy, Excellent Quality of Life** | • Market oriented economy, moving towards technological advancement  
• Well-developed financial and banking sector, including the Labuan International Financial Exchange  
• Wide use of English, especially in business Legal and accounting practice based on the British system  
• Large local business community with a long history in international business links  
• Large foreign business community in all business sectors & extensive trade links |
| **Economic Strength** | • Natural resources - oil, gas, tin, timber, palm oil, rubber  
• GDP growth - 4.6%  
• Gross national savings - 37.9% of GNI  
• Debt service ratio - 2.7%  
• Unemployment rate - 3.7%  
• Inflation (CPI) - 5.4%  
• Export of manufactured goods 2008 - 70.0% of total exports |
| **Human Resources: An Educated Workforce** | • Young, educated and productive workforce  
• Multilingual workforce, speaking two or three languages, including English  
• Comprehensive system of vocational, industrial and advanced skills training.  
• Harmonious industrial relations with minimal trade disputes |

Infrastructure in Malaysia is designed to serve the business community; it is one of the best in Asia. Telecommunications network served by digital and fibre optic technology, five international airports (all with air-cargo facilities), well-maintained highways and seven international seaports make Malaysia an ideal springboard to the Asia-Pacific market. There are also specialised parks that have been developed to cater to the needs of specific industries, as well as 5 economic corridors to stimulate economic growth.

Malaysia is steadfast in providing for the modern day requirements of investor companies based in the country, and is one of the most technologically developed countries amongst industrialising nations in the ASEAN region. It also offers and excellent quality of life, a safe and comfortable living environment. Other advantages are excellent and affordable housing, modern amenities, good healthcare and medical facilities, and excellent international schools.

Malaysia has used its natural resources to its advantage in developing high technology industries and creating jobs. Multinational corporations from more than 40 countries have invested in over 5,000 companies in Malaysia’s manufacturing and related services sectors. Malaysia today is one of the world’s top locations for offshore manufacturing & service-based operations. Many foreign companies have continued to show their confidence in the country’s potential through expansions and diversifications in high technology projects.

One of Malaysia’s greatest assets is her human resources. The workforce here is young, educated and productive, proving to be one of the best in the region. The Government’s emphasis on human resource development ensures the continuous supply of manpower to meet the needs of the expanding biotechnology sector.

Biodiversity – Healthcare/ Therapeutics

Malaysia is among the world’s top 12 hotspots in the field of biodiversity. Located within the tropical belt, it is richly endowed with a profusion of diverse flora which potentially may have immersed benefits to the future generations. Recent scientifically accepted ethno-botanical studies suggest that at least 20% of the estimated 12,000 higher plant species may possess either medicinal or therapeutic properties. With Malaysia’s richly abundant natural tropical rainforest, the opportunity exists to identify, catalogue and study the vast number of indigenous flora at our own doorsteps, uncovering their hidden secrets. The screening, analysis and processing of native flora has already been successfully carried out on Tongkat Ali (Eurycoma Lingifolia), Misai Kucing (Orthosiphon Staminues) and Kacip Fatimah (Labisia Pumila) for health and well-being purposes.

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<tr>
<th>Scientific name</th>
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</tr>
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<tr>
<td>Andrographis paniculata</td>
<td>Hempedu Bumi</td>
<td>Analgesic, antimalarial, anti-inflammatory, antineoplastic, antiulcerogenic, antibacterial, febrifuge, antiplatelet, antidiarrhoeal and antithrombotic properties, also possess protective activity against various liver disorders.</td>
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<td>Centella asiatica</td>
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Source: Frost & Sullivan, Various (2009)
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Designated Economic Corridors

Biotechnology is expected to drive the economic corridors in further developing the healthcare sector. Malaysia has launched 5 Regional Economic Growth Corridors; i.e.: the Northern Corridor Economic Region (NCER), East Coast Economic Region (ECER), Sarawak Corridor of Renewable Energy (SCORE) and Sabah Development Corridor (SDC) and Iskandar Malaysia. The corridors aim to encourage companies seeking a new growth opportunities in the area of healthcare biotechnology and its implementation.

Source: BiotechCorp, RMK, Frost & Sullivan (2009)
BioNexus

BioNexus Malaysia is essentially a network of centres of excellence throughout the country comprising companies and institutions that specialize in specific biotech subsectors. Three centres of excellence comprise BioNexus:

- The Centre of Excellence for Agro-biotechnology;
- The Centre of Excellence for Genomic & Molecular Biology;
- The Centre of Excellence for Pharmaceuticals & Nutraceuticals.

These three institutes are part of the BioNexus initiative whose goal is to coordinate and strengthen existing universities, laboratories, and research institutes. Through BiotechCorp, the Malaysian Government grants the “BioNexus Status” to eligible international and local biotech companies that qualify for fiscal incentives, grants and guarantees administered by BiotechCorp. (www.biotechcorp.com.my)

In order to achieve BioNexus status, the companies must be able to meet the following criteria:

- Establish a separate legal entity for the BioNexus qualifying business and activities
- Be a provider of a product or services based on life sciences, or substantially using life sciences processes in production or agriculture (mere blending, repacking, mixing, distributing or trading of biotechnology products shall not qualify)
- Possesses research capability and conducts research in thrust areas
- Employs a significant percentage of knowledge workers in its total workforce
- Complies with environmental and ethical laws and guidelines

Total investment from 42 companies with BioNexus status between 2005-2007 amounted to US$ 246 million. The Malaysia Government had allocated USD 3 billion to enhance and strengthen the biotechnology sector. The number of BioNexus companies increased to 97 by end of 2008 with approved investment of USD 360 million, and revenue growth by BioNexus companies grew at an annual rate of 187%. In 2008, 36 out of the 97 companies are highly focused on healthcare biotechnology.

Government Incentives

Malaysia provides competitive financial incentives under existing packages that are applicable to companies in the biotechnology sector. In line with its goal to build a biotechnology sector across the entire value chain the incentives offered support biotechnology ventures at all stages of development. These include:

1. **Incentive for the holding company**: Tax deductions for holding companies that fulfils certain conditions and investment in approved subsidiary biotechnology entities;

2. **Tax exemption**: Approved biotechnology companies will be eligible for Pioneer Status, which entitles them to a 100% income tax exemption for a period of up to 10 years. Specific biotechnology product are import duty and sales tax exempt;

3. **Investment Tax Allowance**: 100% of qualifying investments over a period of 5 years can be set off against profits;

4. **Tax Exempt Dividends**: Dividends issued by biotechnology companies to shareholders will be treated as tax exempt income;

5. **200% deduction on qualifying expenditure on R&D**: which may expenses related to pre-clinical and clinical testing, except for companies carrying out these activities for revenue generation.
Human Capital

Malaysia’s current National Education Policy emphasizes on science and technology in the country’s 37 institutions of higher learning. To date, there are 13 universities offering biotechnology programs and 12 universities offering chemical engineering programs with about 3000 undergraduates studying biotechnology annually. The number is predicted to increase due to high interest among Malaysians to pursue careers in the biotech field. Approximately 23,000 research personnel and more than 5,000 R&D scientists and skilled workforce are expected to be available by 2013.

The continued emphasis on creating and training a strong pool of talent for the biotechnology industry will ensure a stable supply of well trained workforce to meet staffing needs. Thus in thrust five of The National Biotech Policy focusing on building the nation’s human capital in biotechnology via education and training. There is no doubt, biotechnology is built from the power of research and human intellect. The Malaysian Government therefore aims to enhance Malaysian’s knowledge generation capabilities by nurturing research activities and by building a strong human capital base. At the same time, the Malaysia Government firmly believes in giving balanced attention to the entire biotechnology value chain, from R&D to commercialization to the market, and is planning for training and development to ensure that resources to support biotech ventures at all stages of development are available.

The Clinical Research Centre (CRC), has an extensive network of collaborations and welcomes global partnerships for the advancement of clinical research within the country and region. CRC is working closely with the Association of Clinical Research Professionals (ACRP) in human capacity building.

Malaysia’s first brain gain program was introduced in 1995. The program was known as Returning Scientist Program. In 2006, the Government of Malaysia approved the Brain Gain Malaysia Program. Brain Gain Malaysia is the third programme, launched in 2006 as a Ninth Malaysia Plan initiative. It is based on the recommendations of a study commissioned by MOSTI, ‘Strengthening Human Capital: Accelerating Brain Gain for Science and Technology’. Brain Gain Malaysia programme has two Key Performance Index (KPI) – to achieve 1,000 networking scientists and 100 collaborations in priority areas by 2010. The programme focuses on outcome of the collaborations that will benefit the country such as new scientific discoveries, generating new patents and knowledge-based jobs, and wealth creation through commercialization of R&D outputs.

As in June 2009, 677 scientists have registered with the programme as networking scientists while 62 collaborations have been forged between researchers, scientists and engineers (RSEs) abroad with local institutions of higher learning, research institutes, industries, and non-governmental organizations. These institutions and 1,665 members of the public have benefited from knowledge, skills, and technology transfers, and international linkages forged. So far, the programme has generated 30 knowledge-based jobs, filled 5 patents and generated RM19.0 million direct domestic investments.

Intellectual Property Right Protection

Malaysia has a strong intellectual property right (IPR) regime and ranks high among East Asian countries in IPR protection. Malaysia is a member of World Intellectual Property Organisation (WIPO) and signatory to the Paris Convention, the Berne Convention and the Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) under the World Trade Organisation (WTO). Malaysia provides adequate protection to both local and foreign investors. Malaysia’s intellectual property laws are in conformance with international standards and has been reviewed by the TRIPS Council periodically. Malaysia also has acceded to the Patent Cooperation Treaty (PCT) with effect from 16 August 2006. Prior to that, in 2002, Malaysia has been accepted as the member of Pharmaceutical Inspection Co-operation Scheme (PICS). Being a member of PICS, Malaysia has greatly improved its facilities to meet the international standard requirements, and tremendously drive local pharmaceutical industry.
Thrust seven of the National Policy highlighted the need to improve the country’s innovation system by reviewing the legal and regulatory framework. Part of this effort involves making regulatory changes to give researchers a share in the ownership of the intellectual property and in the monetary rewards derived from their work.

To date, the total number of patent and utility applications from 1989 up to May 2008 is 536,566. Out of this figure, 322,709 had been granted. The number of foreign applications encountered for 93% of the total applications (Intellectual Property Corporation of Malaysia).

**Funding**

The commitment and the importance of the role of the Malaysian government in financing the biotechnology sector can be seen by the factor that the public sector remains the largest source of funding for biotechnology projects and companies in Malaysia. Currently a total of RM4.7 billion, allocated across 17 different funds, is available to be invested in biotechnology companies. As of Dec 2008 only RM1.6 billion of this amount has been allocated to existing investments. The amount of funding available strongly contrasts to the limited funding available to biotechnology companies in other parts of the world, where investments in the sector have dropped sharply in line with the deterioration in the global credit markets.

Venture capital funds are active in Malaysia. By the end of 2008, it was estimated that RM394 million of private venture funding was available to biotechnology companies.
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### Available funding sources for healthcare biotechnology

<table>
<thead>
<tr>
<th>Type of Fund</th>
<th>Details</th>
<th>Source</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seed Fund</td>
<td>To fund seed or start-up costs in setting up biotech companies and to assist towards the development and commercialization of biotechnology projects and R&amp;D findings of priority and core areas.</td>
<td>BiotechCorp</td>
<td>Up to RM2.5 million per company</td>
</tr>
<tr>
<td>Research &amp; Development Matching Fund</td>
<td>To provide matching fund for R&amp;D projects which can develop new or improved products and/or processes and/or technologies and lead to further development and commercialization within Malaysia's Biotechnology Focus Areas.</td>
<td>BiotechCorp</td>
<td>Maximum of RM1.0 million per project</td>
</tr>
<tr>
<td>International Business Development Matching Fund</td>
<td>To promote the expansion of BioNexus Status Companies into the global market.</td>
<td>BiotechCorp</td>
<td>Maximum of RM1.25 million per project</td>
</tr>
<tr>
<td>Type A : Pre-commercialization</td>
<td>Pre-commercialization activities comprise development of pilot plant/up-scaling of laboratory prototype or development of commercial ready prototype/pre-clinical or clinical trials/field trials for demonstration and testing purposes and not for commercial production purposes.</td>
<td>MOSTI</td>
<td>Up to RM 5 million</td>
</tr>
<tr>
<td>Type B : IP Acquisition (Laboratory Scale)</td>
<td>Type B comprises acquisition of IP (academic/laboratory scale prototype) from overseas or local sources and must be further developed to pre-commercialization stage (Type A).</td>
<td>MOSTI</td>
<td>Up to RM 2 million</td>
</tr>
<tr>
<td>INNOFUND - Enterprise Innovative Fund</td>
<td>To assist individuals / sole-proprietors, micro and small businesses/ enterprises to develop new or improve existing products, process or services with elements of innovation for commercialization.</td>
<td>MOSTI</td>
<td>Up to RM250,000</td>
</tr>
<tr>
<td>INNOFUND - Community Innovative Fund</td>
<td>To assist community groups to convert knowledge/idea into products / processes / services that improves the quality of life of communities.</td>
<td>MOSTI</td>
<td>Up to RM500,000</td>
</tr>
<tr>
<td>CRDF 1</td>
<td>Feasibility Study on public sector R&amp;D results for university/research institution's commercialization office.</td>
<td>MTDC</td>
<td>N/A – on case basis</td>
</tr>
<tr>
<td>CRDF 2</td>
<td>Commercialization of Public Sector R&amp;D Results via University/Research Institution’s Spin-Off Company.</td>
<td>MTDC</td>
<td>Up to RM 500,000</td>
</tr>
<tr>
<td>CRDF 3</td>
<td>Commercialization of Public Sector R&amp;D Results via Start-up Company</td>
<td>MTDC</td>
<td>Up to RM 500,000</td>
</tr>
<tr>
<td>CRDF 4</td>
<td>Commercial Production of Any Locally Generated R&amp;D Results by SME</td>
<td>MTDC</td>
<td>Up to RM 4 million</td>
</tr>
<tr>
<td>Technology Acquisition Fund (TAF)</td>
<td>Technology Acquisition Fund (TAF) provides partial grant to further promote efforts by the private sector to enhance their technology level and production processes.</td>
<td>MTDC</td>
<td>Up to RM 2 million</td>
</tr>
<tr>
<td>Science and Technology Research Grant</td>
<td>To help in research activities</td>
<td>Malaysia Toray Science Foundation (MTSF)</td>
<td>Up to RM 300,000</td>
</tr>
</tbody>
</table>

Source: Frost & Sullivan, Various (2009)
Towards the second half of the year the outlook for the healthcare biotechnology sector is expected to improve. While credit conditions remain challenging, market conditions for companies in the capital market are starting to improve. To date the IPO market in the US for biotechnology companies has been subdued, with a single US biotech IPO being registered in 2009. In contrast activity in the secondary capital markets and private capital markets has improved significantly. In the last 12 months biotechnology companies have raised US$5.9 billion, which is slightly more than the US$5.8 billion raised by companies in 2008-2007. While private sources of capital, such as private equity, venture capital, PIPEs and other alternative financing make up the bulk of capital inflows the public markets have become more accessible to biotechnology companies since the beginning of the year. In May 2009 alone biotechnology companies raised US$1.1 billion through public offerings.

Healthcare is not an ideal free market commodity and traditionally does not follow the behaviour of other commodities whether in expansion or recession. The reasons behind are partly due to nature of healthcare market forces, political and regulatory measures.

Demand for healthcare services is ever so increasing due to population growth and recently being compounded by factors such as: ageing population, increased affluence, change in diseases patterns that shift towards lifestyle and chronic conditions (cancer, cardiovascular, diabetes, rheumatology etc). Politically, healthcare is regarded, with varied degree, as a state’s obligation towards its citizens hence public spending still remains high contributor to its growth. With the Malaysian Stock Exchange evaluating its listing criteria for biotechnology companies, this would be an area to watch in the region in the coming months to see how the local index performs as compared to the global sector.

The openness of the Malaysian government to attract companies with its incentives and financial support through the BioNexus program has served as an attractive pull for companies to enter the Malaysian healthcare biotechnology market. The financial support is in place and Malaysia also will be focusing on developing the highly skilled capabilities and services needed in healthcare biotechnology research in the 6 core commercial areas. The development of the key focus areas and human capital will help to further prepare the Malaysian healthcare biotechnology sector for this highly specialised area, and the Malaysian Biotechnology Corporation is emerging as a valuable asset to drive healthcare biotechnology forward.
Malaysian Biotechnology Corporation (BiotechCorp) is a central contact point for biotechnology and life science companies in Malaysia. BiotechCorp is the industry’s one-stop-centre providing support, facilitation and advisory services.

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