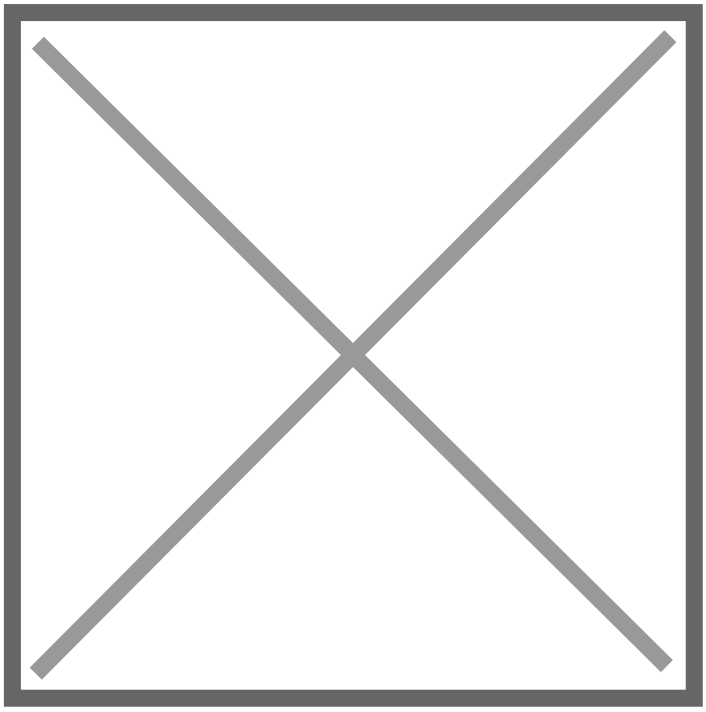
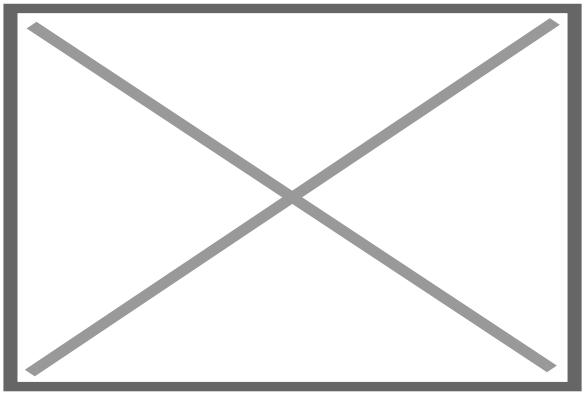
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Indian biotechs line up for Malaysia

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Even as India is emerging a hot destination in Asia for doing contact research and manufacturing, clinical research, and discovery services, Indian companies are heading to Malaysia in large numbers. They are going to be Asian neighbors for biomanufacturing, drug discovery, stem cell R&D, molecular diagnostics, aquaculture companies like Biocon, Dr Reddy's Labs, Avesthagen, Actis Biologics - are looking at expanding their operations to Malaysia, lured by its attractive offers and advantages of setting up a base there.

Bangalore-based Biocon, India's leading biotechnology company, on October 27, 2010, announced Strategic Foreign Direct Investment of $160 million in Malaysia with the Malaysian biotechnology corporation, BiotechCorp. The investment will be made towards establishing a biomanufacturing and R&D facility in Bio-XCell, a custom-built biotech park and ecosystem in Iskandar Malaysia.

In October 2010, India's premier biotechnology company Biocon announced a strategic foreign direct investment (SFDI) of $160 million in Malaysia with the Malaysian Biotechnology Corporation (BiotechCorp). The investment is for setting up a biomanufacturing and R&D facility in Bio-XCell, a custom-built biotechnology park and ecosystem in Iskandar, Malaysia.

Ã¢â?¬Å?Biocon's strategic investment in Malaysia will propel our industry to the next level. It will be a catalyst in our commercialisation efforts, as we enter phase 2 of our National Biotechnology Policy Ã¢â?¬â?? the Science to Business Phase,Ã¢â?¬? said Dato' Iskandar Mizal Mahmood, chairman, Malaysian Bio-XCell& CEO, BiotechCorp.

Ã¢â?¬Å?This will be the first high-end biosimilar and biopharmaceutical manufacturing and R&D facility in Malaysia. In compliance with US FDA cGMP standards, it will raise the bar for quality and excellence in the sector and market. Biocon will stimulate growth for the sector and provide commercial opportunities for Malaysian biotechnology's SMEs. We can expect an increased presence of Biocon-affiliated global giants, growing the sector to new heights,Ã¢â?¬? Dato' Iskandar said.

In this backdrop, customized incentives for large investments, access to ASEAN markets through Free Trade Agreements, no restrictions on equity, adoption to ICH & FDA guidelines for manufacturing activities, industry-friendly regulations, and many other factors are drawing Indian companies to invest in Malaysia.

Exchanging the business intent documents to this effect, in the presence of Indian Prime Minister Dr Manmohan Singh and his Malaysian counterpart, Mohd Najib Tun Abdul Razak, Kiran Mazumdar-Shaw, chairman & managing director, Biocon said, Ã¢â?¬Å?Malaysia is a compelling global destination for biotechnology, backed with world-class infrastructure and attractive

tax incentives. Investing in Malaysia provides us with an international location with strategic geographical proximity to India. Biocon is pleased to be an early mover in this emerging opportunity, as we dovetail our research and biomanufacturing operations with those in Malaysia, to gain a global competitive advantage.Ã¢â?¬?

The Biocon project would focus on R&D and production of high-end biosimilars ,besides other biopharmaceutical products. The investment is the largest for Malaysian biotechnology sector, so far. In the first phase, Biocon proposes to invest about 720 crore ($161 million) in the facility, which is slated to be operational by 2014.

Ã¢â?¬Å?Malaysia is a compelling global destinationÃ¢â?¬?

-Kiran Mazumdar-Shaw, CMD, Biocon

Early movers

In a span of four years, India has become the fourth largest investor in biotechnology space in Malaysia, with five companies having established operations there - Stempeutics Research, Aurigene Discovery Technologies, Suvarna Rekha Marines, Geneflux Biosciences and Vivia Bio Tech.

While Avesthagen is working with Inno Biologics, a leading local contract manufacturing company.Â Suvarna Rekha Marines, an aquaculture biotechnology company based in Visakhapatnam (Andhra Pradesh) is an early mover in setting up operations in Malaysia. Since 2006, the company has been involved in aquaculture biotechnology R&D, and the commercial cultivation of the fresh water prawn Macrobrachium rosenbergii, also known as the Giant Malaysian Freshwater Prawn; and locally known as 'Udang Galah' in Malaysia.

Bangalore-based Geneflux Biosciences, a technology-driven molecular diagnostics company, has been involved in product-oriented research, development and manufacturing of molecular diagnostic kits in Malaysia. Since 2007, it has invested about 9 crore ($2 million) on infrastructure, international business development and marketing expansion strategies. Ã¢â?¬Å?We have a state-of-the-art molecular diagnostic laboratory in Malaysia, supported by a small team of Bioinformaticians in India Ã¢â?¬? said Dr Prashanth Bagali, director & senior vice president (Science & Technology) & COO, Geneflux (India & Malaysia). Ã¢â?¬Å?The company has ISO9001:2008 certification, and is being audited for IEC/ISO 17025:2005 accreditation. Recently, we enrolled into Ã¢â?¬Å?CAP A Quality Assurance Programs Private LimitedÃ¢â?¬?, Australia; and have participated in inter laboratory quality assurance scheme, conducted by Institute of Medical research (IMR), Malaysia,Ã¢â?¬? he added.

Geneflux that received Ã¢â?¬Å?2010 Asia Pacific Frost & Sullivan Niche Company of the Year Award in Molecular DiagnosticsÃ¢â?¬? has a niche benefit and competitive edge for being both manufacturer and service provider of molecular diagnostics kits. It has developed six PCR-based products, namely MyDENKit (dengue virus detection and serotyping), MuraFlu (Methicillin resistance staphylococcus aureus identification), FluFinder (H1N1 virus identification), MyCMV (Cytomegalovirus detection), Chikungunya virus detection kit and Meliokit (Melioidosis caused by Burkholderia pseudomaleii detection), that are being marketed in Malaysia and abroad. It also provides qualitative and quantitative diagnostic services for hepatitis B, hepatitis C, HSV 1 and 2 (human simplex virus), VZV, HIV and other infectious diseases caused by virus and bacteria.

Incentives for biotechnology companies

A company that is into biotechnology activity and has been approved with BioNexus Status by the Malaysian Biotechnology Corporation is eligible for the following incentives:

? An exemption from tax on 100% statutory income for 10 years of assessment, from the first year the company derived statutory income from the new business, or for five years of assessment from the first year the company derived statutory income from the existing business and expansion project;

? An exemption of 100% statutory income, derived from a new business or an expansion project that is equivalent to an allowance of 100% of qualifying capital expenditure incurred for five years;

? A BioNexus Status company is entitled to a concessionary tax rate of 20% on statutory income from qualifying activities for five years;

? Pioneer status (exemption of the statutory income from qualifying activities for a period of five years);

? Tax exemption on dividends distributed by a BioNexus status company; Exemption of import duty and sales tax on raw materials/components and machinery and equipment;

? Double deduction on expenditure incurred for R&D; and for the

Ã¢â?¬Å?We will increase sales in ASEAN countriesÃ¢â?¬?

-Dr Prashanth Bagali, director, senior VP - science & technology & COO, Geneflux India and Malaysia

Q Has Geneflux received any support from Malaysian government agency?

Geneflux, in association with a Malaysian university, launched the world's first PCR-based commercial kit, MyDENKit (acronym for Malaysian Dengue Kit) during BioMalaysia 2008 conference.

Geneflux was awarded the Ã¢â?¬Å?BioNexus StatusÃ¢â?¬? by the Malaysia Biotechnology Corporation. In 2008, MOSTI (Ministry of Science, Technology and Innovation) recognized our Ã¢â?¬Å?passion for scienceÃ¢â?¬? and granted 1.2 crore (MYR815,000) for the pre-commercial development of MyDENKit, and clinical trials at eight international research centers across dengue epidemic regions. In 2009, MOSTI recognized our contribution and awarded a Ã¢â?¬Å?Certificate of AchievementÃ¢â?¬? for the successful completion of dengue project.

In 2009, we received the second round of funding of 3.1 crore (MYR2.5 million) from Malaysian Biotechnology Corporation (BiotechCorp) that boosted our strength and we became champions in molecular diagnostics production and services. Recently, we received the Ã¢â?¬Å?2010 Asia Pacific Frost & Sullivan Niche Company of the Year Award in Molecular DiagnosticsÃ¢â?¬Ï.

Q What are your future plans for the Malaysian operations?

We will invest in international business development to increase sales within Ã¢â?¬Å?Free Trade ZoneÃ¢â?¬? of ASEAN countries.

We will collaborate with American and European companies for the development of kits and transfer of technology, to reduce time to market for diagnostic kits.

We offer diagnostic services on 30 different tests, and will increase the number of tests to 50 diseases (or microbes) by the end of year 2011. We are looking for partners in ASEAN countries, for collaboration and Malaysia in 2010. Aurigene works

B nipal Education & Medical Group, opened the first-of-its-kind stem cell research facility in Malaysia, citing the ease in getting early approvals. Since its inception in 2008, Stempeutics has been working together with leading medical institutions in Malaysia, to drive long-term research activities to further strengthen its leadership position in the area of stem cell research.

As a result of collaborative efforts, Stempeutics Research announced in May 2010 that it has received clearance from Medical Research and Ethics Committee, Ministry of Health, Malaysia, for conducting human clinical trials in patients with ischemic cerebral stroke (CS), using investigational new drug (IND)-based on Mesenchymal Stem Cells, derived from donated bone marrow.

Stempeutics became the first international company in Malaysia to get the BioNexus status by BiotechCorp. Also it has received National Pharmaceutical Control Bureau (NPCB) certification for its manufacturing facility for conforming to the requirement of current good manufacturing practices (cGMP), in accordance with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guides and its relevant annexes for Isolation, Processing and Storage of Mesenchymal Stem Cells. Stempeutics is the first stem cell company in Malaysia to have obtained this conformance certification.

Another Bangalore-based Aurigene Discovery Technologies, a 100 percent subsidiary of Dr Reddy's Laboratories too, opened operations in Malaysia in 2008. Aurigene works exclusively with partners on a project for different stages of drug discovery called Hit Generation, Lead Generation, Lead Optimization and Pre-Clinical development. Aurigene has a unique hybrid model, where it is able to run a profitable operation on the strength of its risk-sharing early partnership deals, and therefore, has a sustainable business model with the potential to generate long-term value.

In March 2010, Avesthagen, a leading systems biology biotechnology company from Bangalore commenced manufacture of two of its biosimilars at Inno Biologics, a leading contract manufacturing company in Malaysia. Ã¢â?¬Å?We are currently carrying out cGMP manufacturing of our first biosimilar product, AVDESP for clinical trials at Inno Biologics facility. The second biosimilar, AVENT will also be produced for clinical quantities in Inno Biologics,Ã¢â?¬? says Dr Villoo Morawala Patell, founder, chairperson & managing director, Avesthagen.

Indian companies in Malaysia

Company	Areas	Started in
Stempeutics Research	Stem cell research	2008
Aurigene Discovery Technologies	Drug discovery research and services	2008
Suvarna Rekha Marines	Aquaculture biotechnology	2006
Geneflux Biosciences	Molecular diagnostics	2007
Vivio Bio Tech	Animal testing lab	2010
Avesthagen	Biomanufacturing	2010
Biocon	Biomanufacturing and R&D	

"Malaysian facility offers improved manufacturing efficiency"

—Dr Villoo Morawala Patell, founder and CMD, Avesthagen

Q What are the driving factors for Avesthagen to invest in Malaysia?

Avesthagen has been fortunate to work with a contract manufacturing organization (CMO) in Malaysia that has a manufacturing capability of mammalian cell-based biologicals, in conformation with FDA and European c-GMP guidelines The Malaysian facility offers improved manufacturing efficiency The willingness of the Malaysian facility to be flexible and adapt to Avesthagen's needs, has been very helpful. Manufacturing in Malaysia has offered a very important advantage, it is compliant with The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and US Food & Drug Administration (FDA) guidelines, for all manufacturing activities.

Q Any support Avesthagen has received from the Malaysian government?

The facility being used by Avesthagen, Inno Biologics, is a government facility. Besides that, there is indeed significant support from the government to obtain clearances and other licensing support.

Q What are your future plans for the Malaysian operations?

Avesthagen will initially focus on completion of clinical batches of the first two molecules. With the support extended by Inno Biologics and the Malaysian government, the relationship with Malaysia is sure to be

that of long lasting mutual benefit.

Avesthagen has built a robust pipeline of eight biosimilars — of which four are in an advanced stage of development. The first product for anaemia, AVDESP has already completed preclinicals, and is ready for cGMP manufacturing for conducting clinical trials in India. The second biosimilar for auto-immune disorders, AVENT, will also be produced at the Inno Biologics facility. Inno Biologics has been contracted to produce clinical grade material of Avesthagen's biosimilars, which will be used for human trials.

Vivo Bio Tech, a biotechnology company from Hyderabad, plans to set up a biotechnology laboratory in Malacca, a state in southern Malaysia, that will test medications for cancer and diabetes. Trial medicines will be tested on dogs, primates and other animals. The company says it plans to import beagles from Holland and capture primates from the local area. The facility is a ₹630 crore ($141 million) joint-venture (JV) between Vivo Biotech, state government-owned Melaka Biotech Holdings and a local company, Vanguard Creative Technologies. Despite stiff resistance from animal rights groups, Malaysia has no laws overseeing the testing on animals, the Malacca State Chief Minister Mr Mohamad Ali Rustam is proud to have the lab in his state.

Mumbai-based Actis Biologics, a biotech venture technology company focusing on life sciences sector, plans to set up a biotech park called Biocity in Melaka, for which it has been allotted 270 acres of land. Biocity would provide buildings and other facilities for biotech companies. It is talking to a few real estate developers and investors to partner with the Biocity, which is at present on hold, due to real estate issues, and after effects of economic slowdown. Actis is planing to set up the first phase of Biocity, at an investment of ₹4500 crore ($1 billion), to house about 25 units in a 270-acre area. In the second phase, involving an investment of another ₹6700 crore ($1.5 billion), it plans to house 40-50 units. The Malaysian government had earlier assured to provide 500 acres adjacent to the first phase.

Eyeing lucrative market

Malaysia is positioning itself as a cost-competitive country and a regional hub for global biotechnology companies. It is drawing Indian companies — with tax incentives such as 10-year tax holiday, duty exemptions, customized incentives for large investments, access to Association of Southeast Asian Nations (ASEAN) markets through Free Trade Agreements, and no restrictions on equity.

Regulations in Malaysia are flexible and guidelines are evolving. This provides a scope for early movers. The regulatory approvals for stem cell research takes about seven months in Malaysia as against 18 months in India. Besides, Malaysia's membership of ASEAN and Organization of Islamic Conference (OIC) provides scope of marketing products in the member states of these associations.

Malaysian Biotechnology Corporation (BiotechCorp), the lead development agency for the biotechnology industry has been showcasing initiatives mooted by the government, and incentive schemes offered to companies, in different countries including India. By participating in leading bio exhibitions like Bangalore India Bio and road shows in Chennai and Hyderabad, BiotechCorp has succeeded in drawing the attention of Indian companies. While some companies have already made investments, others including India's leading biotech company, Biocon announced strategic foreign direct investment (FDI) in Malaysia.

He further added "Malaysia hopes the Biocon investment will stimulate growth for the sector, and provide commercial opportunities for Malaysian biotechnology's small and medium enterprises (SMEs).

Narayan Kulkarni in Bangalore