

Companies to Watch Out for in 2006

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The biotech industry in India like elsewhere in the world is characterized by small and medium size companies. However, the difference ends there. The Indian start-ups are confronted with the inadequate availability of venture capital or seed capital. They are struck for want of an atmosphere, which has led to spin out of companies from R&D institutes. The industry is nascent and regulatory mechanisms are on the path of being streamlined.

Despite all these, India is a very attractive destination for the availability of low-priced human capital and skilled labor. It's a mature market, feel several of the leading global chief executives. They see India as a place from where a next Amgen will emerge.

Reason: Indian companies have adopted to the challenging environments and learnt to develop business models that start bringing in revenues from the first year of operation itself. Indian biotech companies have focused on services, R&D, and product development as a way out to sustain and grow. Companies here have already set their sight as global companies with local presence. They are using the Indo-global corridor, more specifically the Indo-US corridor as the progression path. Also the Indian pharma industry is quite mature and provides a conducive feeder environment.

In the ensuing pages, we present to you the companies we feel will hit the news headlines. We have deliberately not listed big and well-established companies like Biocon, Bharat Biotech, Lotus Labs, Serum Institute of India, Shantha Biotech, and Vimta Labs. All these today are the flag bearers of India's biotech march and they will certainly be doing well. We have

focused on the companies that will make a difference in the next level of India's biotech march. Interestingly, most of them have a services offering and product development path. And some of them will be big global companies. Read on.

ABL Biotechnologies Ltd

Incorporated as a private limited company in 1992, ABL Biotechnologies Ltd exported its first consignment of Frozen Sea Food to Spain and Japan in 1993. During the same year, it diversified its operations into infrastructure support services for aquaculture by supplying aquaculture equipment and inputs to numerous aqua farms. It entered into long-term agreements with several international companies of repute and became public limited company in 1994. Since then the company has diversified its activities into high technology aquaculture and biotechnology research.

ABL has set up a research and development facility at Vishakapatnam, one of its kind and the only such facility in the private sector in India to be accorded accreditation and recognition by the Department of Scientific and Industrial Research (DSIR). The Microbial Metabolites Laboratory at Chennai works on evaluating new sources of biochemicals from marine organisms. ABL's present focus includes work on pharmaceuticals like anti-bacterials and anti-virals, enzymes, bio-molecular materials, bio-monitors and diagnostics, bio-pesticides, bioremediation and aquaculture. According to KO Isaac, MD, ABL Biotechnologies, 6 marine microbe products are ready for production and two products, Docosahexaenoic Acid (DHA) and phycocyanin production will start in 2006.

Address: ABL Biotechnologies Ltd
No.55, Third East Street,
Kamaraj Nagar, Tiruvanmiyur,
Chennai - 600 041.
Tel.: +91 44 52020501/ 52020502.
Fax: +91 44 52020957.
Website: www.ablbiotechnologies.com

ClinInvent Research Pvt Ltd

ClinInvent Research is a full-fledged Contract Research Organization (CRO), which provides comprehensive services for complete clinical trial management. Within a short existence of over 20 months, it has established business relationships with leading pharmaceutical companies. The company has a tie-up with MDS Pharma and is its preferred CRO for India.

ClinInvent has set up facilities to provide end-to-end capabilities in clinical trials management. Recently it has implemented Oracle Clinical software for data management.

The company has completed trials in the tropical diseases segment, for a new diagnostic test for malaria. It has commenced phase III clinical trials on a respiratory product for an Indian company, but for international submission and is in the process of conducting Phase III trials on an ophthalmology product for a subsidiary of a multinational company. Similarly trials are to commence on a cardiology product, an oncology drug and an anti-fungal product. It has 50 researchers working at different areas like quality assurance, regulatory affairs, clinical data management and statistics, clinical trial supplies management and pharmacovigilance. "We have significant opportunities of participation in global clinical trials. We are a young CRO, which is making steady and solid progress by gaining the confidence of global clients," said Dr Arun Bhatt, president, ClinInvent Research.

Address: A-302, Everest Chambers, Next to Star TV office,
Marol Naka, Andheri-Kurla Road,
Andheri (E), Mumbai - 400059
Tel.: +91-22-28511860, 28595101
Fax: +91-22-28515482
Website: www.clininvent.com

Dabur Research Foundation

Dabur Research Foundation (DRF) is active in the area of developing and screening New Chemical Entities (NCEs), novel drug delivery systems and generic molecules.

It has also initiated work in developing biotechnology-based products. The foundation is at present involved in the development of biotherapeutics especially cancer vaccines and is also active in the areas of genomics, proteomics and molecular diagnostics.

Dabur Research Foundation is developing both therapeutic and prophylactic vaccines, which will target adenocarcinomas and squamous cell carcinomas. According to Dr Rama Mukherjee, president (R&D), Dabur Research Foundation, the main objective of the approach is to provide a disease-free state after the primary therapy and protect high-risk individuals with genetic predisposition and also protect individuals with evidence of pre-neoplastic lesions.

One of the major products in the pipeline is a multivalent synthetic vaccine, which targets antigens over expressed in tumor cells. The vaccine is expected to bring about a cytotoxic T lymphocyte and natural killer cell response and leads to tumor regression. The biomolecule is in preclinical stage of development and is expected to go into the clinical trials by the end of 2008.

Address: Dabur Research Foundation
22, Site IV, Sahibabad, Ghaziabad-201010
Tel.: +91-120-2778501-25
Fax: +91-120-2777303
Website: www.dabur.com

GangaGen Biotechnologies

GangaGen Biotechnologies is a biotechnology company focused on the development of bacteriophage-based products for prevention and treatment of bacterial infections, which has received two US patents for its proprietary bacteriophage technologies "Lysin-Deficient Bacteriophages with Reduced Immunogenicity" and "Incapacitated Whole-Cell Immunogenic Compositions." It has presence in India, the US and Canada.

According to Dr Janaki Ramachandran, president, GangaGen Biotechnologies, the company's scientists knocked out the phage gene that codes for the Lysin enzyme responsible for breaking down the bacterial wall and produced a Lysin-deficient bacteriophage that kills the bacterial host, undergoes one cycle of replication but remains inside the dead bacterium. "Lysin-deficient bacteriophage retain their specificity, kill the pathogenic bacterial host rapidly, but do not cause lysis (breakdown of the bacterial cell wall) and are not released into the patient or the environment. Lysin-deficient phages also permit linear dosing like antibiotics," he said.

The second patent is a logical sequel to the first patent. It enables the development of highly effective vaccine to protect against any bacterial infection in man or animals. GangaGen Biotechnologies Pvt Ltd (GBPL) is developing proprietary phage products to treat infections caused by staphylococcus bacteria, including nasal, urinary tract, and pseudomonas aeruginosa infection in burns and wounds. Founded by Dr J Ramachandran in 2000 with an investment of \$5 million, GangaGen plans to mobilize another \$5 million.

Address: # 5 AC, 705 II Block, Hennur Road, Banaswadi Layout,
Bangalore - 560 043
Tel.: +91-80-25448138/25448146
Fax: +91-80-25447996
Website: www.gangagen.com

GVK Biosciences Pvt Ltd

Hyderabad-based CRO, GVK Biosciences, which started in 2002, has expanded its activities in the last three years and today offers services and collaborative research basis to bio-pharma companies globally in areas including medicinal chemistry, process chemistry, biology, informatics, clinical research, bioanalytical and bioavailability (BA/BE) services and knowledge process outsourcing. The BA/BE division received accreditation by ANVISA, the Brazilian Regulatory and Health Authority.

GVK BIO was selected as the "Best Indian CRO for 2005" in the Drug Discovery Services category, by Proximare, one of the management consulting firms that develops and implements growth strategies for pharmaceutical, biotech and related industries. DS Brar, chairman, GVK BIO said, "It is a big step forward in a short time" for the company. Davinder Singh Brar,

left Ranbaxy Laboratories in 2004 and turned a pharma venture capitalist, and has made a substantial investment in the Sanjay Reddy-promoted GVK BIO and is heading the company as chairman.

GVK BIO has staff strength of 800 employees, of which 85 percent are scientists and currently has around 100,000 sq.ft. of laboratory space and will be investing Rs 60 crore by middle of 2006 to enhance its operations, including research and development, human resources and IT.

Recently it announced the acquisition of the Dai-ichi facility at Nacharam, Hyderabad. In this joint venture, GVK BIO and associates will hold 80 percent equity and would operate under the name of Inogen Laboratories Pvt Ltd (Inogen Labs). Inogen would be engaged in the business of APIs, process chemistry, custom synthesis of NCEs and custom manufacture for chemical entities. It also offers biotechnology and pharma patent drafting and patent search outsourcing services in association with TMPSearchers, a patent search and drafting firm. This is the first time in India a patent search and drafting firm and a major contract research service provider have joined hands to offer patent search, patent drafting and allied services jointly bringing both legal and domain specific expertise available to clients around the world.

Address: GVK Biosciences Pvt Ltd

210, 6-3-1192

Kundanbagh, Begumpet

Hyderabad - 500016, India

Tel.: +91 40 5551 9990

Fax: +91 40 5562 6885

Website: www.gvkbio.com