BioSpectrum the business of Bio & Health Sciences

Set to grow ten times

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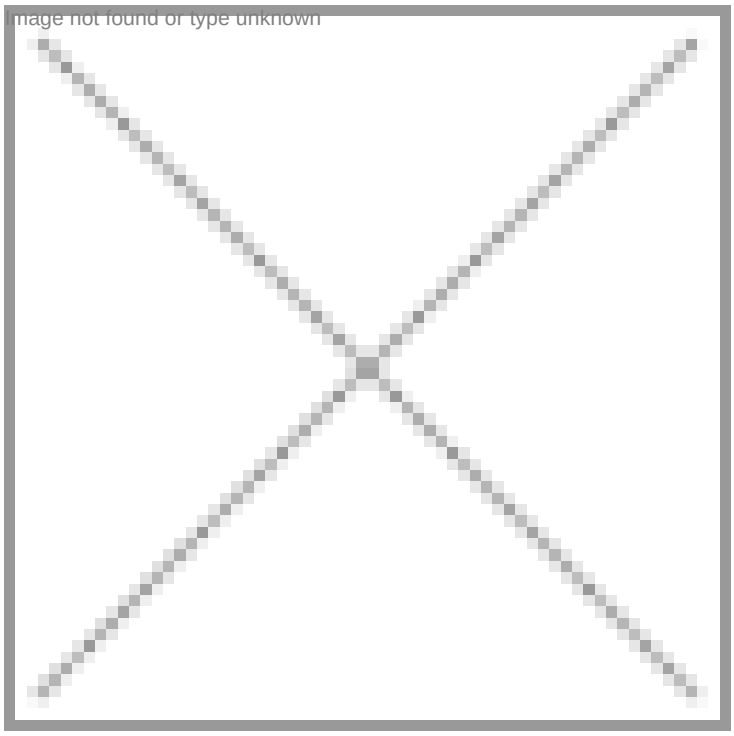

Indian biotechnology sector is currently nascent and accounts for a mere one percent of the global biotechnology market. However, it is poised for an exponential growth over the next five years with an expected global market share of 10 percent. The market for modern biotechnology products and services in India is estimated to be about $150 million (Rs 750 crore) for the year 2002, of which about 40 percent ($60 million) are estimated to be export revenues. The consumption of biotech products in India is estimated to grow 10-fold to $1.5 billion (Rs 7,500 crore) and to $4.5 billion by 2010.

The key markets for Indian biotechnology sector includes industrial biotech (enzymes), vaccines (recombinant Hepatitis B etc.), diagnostics, veterinary products, agri biotech products (genetically modified seeds). The industry comprises mainly of pure biotechnology startups and large established companies in pharmaceuticals, agriculutre, and information technology. Market leaders in this industry are Shantha Biotechnics, Biocon, Bharat Biotech, Wockhardt, Dr Reddy's Laboratories, Serum Institute of India, Zydus Cadila, Aventis Pharma, Rhein Biotech, and Reliance Life Sciences.

Over the last two decades, India has developed an adequate infrastructure and trained manpower in modern as well as classical biotechnology, mainly due to active support of the Department of Biotechnology (DBT). Since its inception, the DBT has made concerted efforts towards capacity building in human resources and infrastructure for research and development. As a result, currently India can boast of about 200 government laboratories and several private research institutions, with state-of-the-art equipment and facilities for modern biotechnology research. These institutions have been quite active in transferring technology to industry for scale-up, validation and commercialization.

The government's budgetary allocation to biotechnology has more than trebled from $ 150 million in 1987-88 to $ 300 million

in 1997-98 and $ 500 million in 2002-03. To promote private sector efforts in biotech research, the national budget of 2002-03 has provided for 150 percent tax deduction for R & D spending on biotechnology.

Indian companies enjoy certain advantages in the area of biotechnology such as low operational costs, low cost technologies, skilled human resource base, large network of research laboratories and abundance of raw materials in the form of plant, animal and human genetic diversity.

Recently, several state governments such as Maharashtra, Andhra Pradesh, and Karnataka have formulate Biotechnology Policies with focus on setting up Biotech Parks, Incubators, Centers of Biotech Excellence and providing fiscal incentives to the investors.

Global Biotech Industry

Based on the industry estimated, there are about 1,457 biotechnology companies in the United States in 2001, representing a growth of 20 percent since 1992. The majority of biotechnology companaies in US (about 76 percent) are either privately owned or are divisions, subsidiaries or joint ventures and only 350 biotech companies (about 24 percent) are publicly traded in the US stock exchanges with estimated market capitalization of $ 331 billion. The size of the US biotech industry has more than trebled since 1992, with revenues increasing from $ 8 billion in 1992 to $ 28 billion in 2001. The number of employees working for biotechnology companies have also increased by almost 100,000 from 79,000 in 1992.

The biotechnology industry in the US is highly concentrated with predominant presence in nine metropolitan areas, which are classified as leading Biotechnology Centers (or Industry Clusters) of US. These biotech centers account for more than three-fifths of all the National Institute of Health spending on research and for slightly less than two-thirds of all biotechnology related patents. Biotechnology commercialization is even more concentrated within these centers; more than three-fourths of all biotech firms with 100 or more employees and those firms founded in the past decade are in one of these nine centers. The same centers account for eight of every nine dollars spent in venture capital for biopharmaceuticlas and for 95 percent of the dollars in research alliances.

The majority of US biotechnology firms are pursuing human healthcare market. The human health care market can be broadly classified into five categories-therapeutics, diagnostics, immunology, drug delivery systems, and vaccines. A study by the Institute for Biotechnology Information (IBI), North Carolina, estimates that about 33 percent of the US biotechnology companies are working in the area of human therapeutics while another 19 percent are pursuing diagnostics as their key activity. In the last two decades (1982 to 2001), the US FDA approved 132 biotechnology drugs for medical usage, developed by biotechnology and pharmaceutical companies.

The US is the leading exporter of agricultural products and has embraced agricultural biotechnology to maintain its leadership in food production. Worldwide, about 271 million hectares (Mha)of land are under cultivation, of which 19.4 percent (53 Mha) consisted of GM crops in 2001, grown by 5.5 million farmers. Between 1996 and 2001, global area of transgenic crops increased more than 30-fold, from 1.7 Mha in 1996 to 53 Mha in 2001. In 2001, four principal countries grew 99 percent of the global transgenic crop area. The US is the world leader in transgenic crops, accounting for over two-thirds of all transgenic crops planted worldwide. Other three major producers of GM crops are Argentina(22 percent), Canada (6 percent) and China (3 percent).

Global Biotech Financing

Biotechnology businesses, just like biopharmaceuticals companies, can operate using a diverse range of business models and early-stage funding mechanisms. A biotech venture can be potentially financed by a wide range of alternative sources such as angel funding (personal savings, friends & family), banks (for capital expenditure and working capital), government grants, university seed funds, general or specialist venture capitalists, investment banks and capital markets.

Notwithstanding the traditional market cycles, the biotechnology sector witnessed a boom in the capital raised throughout the 1990s. The most important market trend was the growth in the size of the funds and the average amount of money available to each fund manager. For instance, whereas a typical biotechnology-specialized fund in the 1980s was measured in the tens of millions of dollars, an equivalent fund today is 10-20 times larger.

The biotechnology sector raised $ 14.7 billion (excluding payments, fees and revenues from corporte partnerships) in 2001, which is substantially more than any other year in the sector's history (with the exception of $ 31.5 billion raised in 2000). However, public offerings, both initial and follow-on, did not play a prominent role as they accounted for a mere 24 percent of all new financing in 2001. In 2000, public offerings, both initial and follow-on, accounted for 59 percent of all money raised. Private investors supplied the rest. Venture capital concerns, institutional investors, corporate funds and the like poured more than $ 11 billion into biotech firms (both private and publicly held) over the course of the year, amounting to 76 percent of the total raised.

The biotech IPO market was quite tepid in 2001, but a handful of companies did manage to come public, all being at lower valuations than those achieved by most companies in 2000.

Ten biotech-related firms completed IPOs in 2001- six in the US, two in Canada, one in Germany and one in Australia, raising a combined $ 434 million.

The emergence of corporate venture capital funds (VCs) is the latest trend in the global biotech industry. With an eye to the future, large pharmaceuticals multinationals have created venture capital arms to invest in startups-and they invest early, long before these startups are even mature enough to sign a partnering deal. Since January 2001, the Novartis Venture Fund and the Novartis BioVenture Fund together have invested in 18 startups; GlaxoSmithKline's affliliates SR Ltd., one, and Euclid SR Partners have put money into 13; Johnson & Johnson Development Corp. has invested in 12; Novo Nordisk's investment arm Nov A/S has contributed funds to nine; and BD Ventures LLC (Becton, Dickinson and Co's venture fund) has invested in four fledgling firms.

This report is an extract from the Executive Summary of the CII-Rabo India Joint report on financing biotech enterprises. The full report, a priced publication is available with both the organizations. The contact persons are Dr Sandhya Tewari (ciico@ciionline.org) or Alok Gupta (alok.gupta@rabobank.com)

Peptimmune gets $41.2 million VC funds

Biopharma drug maker, Peptimmune, Inc. has secured $ 41.2 million in a first round of venture capital financing to accelerate the development of specific targeted immunotherapeutics for the treatment of a broad range of autoimmune disorders.

A company press release said the investment was co-led by New Enterprise and MPM Capital, with additional funding from Prism Venture Partners, Vanguard Ventures, Hunt Ventures LP., and Boston Medical Investors, Inc. Peptimmune, based in Cambridge, holds exclusive worldwide licenses or options to one issued US patent and 32 applications.

Peptimmune has four product candidates in late stage preclinical development and research. Its lead product is an immunotherapeutic specifically targeted to treat pemphigus vulgaris, an autoimmune disorder of the skin, for which Peptimmune anticipates entering Phase I human clinical trials this year. Each of Peptimmune's drug candidates is designed to selectively inhibit harmful immune responses without compromising normal immune function and each product represents a distinct therapeutic approach.

If successful in the initial clinical indication, an opportunity for new therapeutics will arise for diseases, such as multiple sclerosis (MS), rheumatoid arthritis, Type 1 diabetes, myasthenia gravis, and lupus erythematosus. Peptimmune's lead product is an injectible immunotherapeutic designed for pemphigus vulgaris (PV), an autoimmune disease that results in life-threatening blisters of the skin and mucous membranes. PV is a rare disease, which affects several thousand individuals in the United States. PV arises from an inappropriate immune response of the body to desmoglein 3, a protein that holds skin cells together in normal, healthy skin. Peptimmune has identified a specific peptide epitope of desmoglein 3 and has formulated it to induce tolerance in the patient and reduce or eliminate the harmful immune response. Peptimmune expects to file an IND and begin a Phase I clinical study for this drug candidate later this year.

The company has three additional product candidates: Cathespin S inhibitor: a small molecule for the treatment of a variety of autoimmune diseases. The inhibitor suppresses a specific process in autoimmune and allergic diseases. Peptimmune has partnered with Medivir, a Swedish biotechnology company, to develop this drug candidate.

Random Amino Acid Copolymer: a peptide treatment for MS that works by a similar mechanism as Copaxone (R), an approved and marketed MS drug. The new copolymer promises to have superior clinical advantage. Soluble MHC Class II/Ig Fusion Proteins: proteins designed to deactivate disease-specific immune responses by acting as molecular decoys for disease-inducing immune cells.

Peptimmune was established as an independent company by Genzyme Corp. in January 2002. Genzyme provided initial

capitalization for Peptimmune by purchasing $5.5 million in shares of preferred stock and holds a right of first offer to participate in the commercialization of the peptide therapy for pemphigus vulgaris. The new investment in Peptimmune will reduce Genzyme's ownership interest in the company to approximately 10 percent.

IndiGene to invest $10 million in India

The US-based IndiGene Pharmaceuticals, engaged in the development of superior plant based medicines, will be investing $10 million in India to set up a development center at Hyderabad. The center will support product development, supply logistics and manufacturing, from mid-2003.

The release quoting M Vaman Rao, CEO, IndiGene said, "our aim is to rapidly develop and deliver quality prescription and OTC products for the global market and reduce the development risk, cost and time to market. We achieve this goal by scientifically validating and optimizing the therapeutic efficacy of selected plant-derived natural molecular compositions."

" Recent changes in the regulatory policy guidelines in the US Food and Drug Administration now support the commercial development of plant-derived molecular composition medicines, " said Vaman Rao. IndiGene intends to forge partnerships in the areas of product development, manufacturing and distribution with leading pharma companies. " We are not a contract research organization and intend to develop the drugs and then out-license to pharma companies for further development and commercialization," Vaman Rao said.

The release also noted that the company already has a sustainable product development pipeline and is focusing on four therapeutic areas-metabolic disorders, oncology, central nervous system and infections. Within these, it concentrates on Parkinson's disease, HIV, diabetes and hepatitis B. The company has patented a breakthrough rapid drug development process under which multiple molecules can be used for drug development. The release reported that the combined worldwide market for both plant-derived prescription and OTC products of IndiGene is estimated to cross $ 100 billion by 2010.

Biogenus to invest $20 million in Karnataka

Biogenus India Ltd, the Indian arm of US-based biotechnology firm Biogenus Inc, has signed a memorandum of understanding (MoU) with the Karnataka government to set up a marine biotech research station and a bacterial culture and enzymes plant in the state.

The joint venture envisages an investment of around $20 million (Rs 100 crore) in the state. The marine research center would be set up at the Marine Biotech Park in Uttara Kannada district and the manufacturing plant would be in Bangalore.

"Our main focus is on areas like aquatic biotechnology, protein and enzyme biotechnology, bioremediation and aquatic eco-balance systems," KS Reddy, CEO, Biogenus India Ltd, said.

The marine biotech research station would focus on moving shrimp farming via traditional methods to defined farming using technological solutions developed by the company, Reddy said.

Biogenus solution would help in maintaining oxygen levels of shrimps in ponds, controlling algae population, improving disease resistance, feed conversion ratio, prevention from viral diseases, reducing maturity time etc. The manufacturing plant, on the other hand, would focus on manufacturing enzymes and microbial cultures mainly targeted at exports. "We are looking at producing 15,000 tons of enzymes and microbial cultures in the first year of operation," he said.

Looking at the potential opportunities in marine biotechnology, Reddy said, "We see that India offers a big market for fish and shrimp media. Currently, the annual turnover of Indian seafood industry is around $9 billion and is one of the biggest foreign exchange earners for the country. India mainly exports shrimp, finfish, cuttlefish and squid across the world, with shrimps export being the largest. The technology developed by Biogenus will help the shrimp farmers to substantially increase their productivity levels without major mortality risks. "

Biogenus India has signed an MoU with the Andhra Pradesh state government during the CII partnership summit held at Hyderabad early January 2003 to invest around $35 million towards setting up a technology development center and aquamedia plant in the state.

Indian Biotech to get good VC funding

A joint survey report of the Confederation of Indian Industry (CII) and Rabo India on financing biotech enterprises has said that biopharmaceuticals, bioinformatics and biotech services would be investors' main thrust area of investment.

About 60-80 percent of funds indicated their preferences for this cluster. The next preference of the funds is agricultural biotechnology and genomics with 20-40 percent. About 10-20 percent of the investors have preference for medical devices

and contract research.

However, the report says, marine biotechnology and environmental biotechnology are not on the investment radar of the funds, as less than 10 percent of the investors have preference for these areas.

The report has pointed out that the abundance of talented, qualified and cost -competitive human resources are the key features of the Indian biotechnology. Besides, internationally
reputed information technology capabilities that can be applied in bioinformatics and availability of vast gene pool and large patient base, which can be used for drug development are boosting biotech sector in India, the report added.

CII- Rabo India report noted some growth restricting factors that are hindering the progress and growth and investments opportunities in India. The factors include absence of
adequate investments/risk capital, lack of quality entrepreneurs with sound business plans and commercial vision, lack of world class infrastructure facilities, inadequate government support and absence of apt regulatory/policy framework and inability of potential investors to assess intellectual property driven biotechnology business models.

'Effective policy implementation is the key'
With the VC funds looking at growth investments, only a proper policy implementation can bring in more fund to support the biotech industry here, says Alok Gupta, assosiate director of Rabo India Finance.

Speaking to BioSpectrum, Alok Gupta maintained that Rabo India has initiated a move in this direction by working with Maharashtra Industrial Development Corporation (MIDC) for a Biotechnology park at Hinjawadi near Pune.

Public-private partnership is a best way for the growth of biotechnology industry in the country, said Alok Gupta, associate director, Head Life Sciences & Biotechnology, Rabo India Finance Pvt Ltd.

Since the biotechnology is in a nascent stage in the country, he said, venture capital funds are not ready to take risks. At present the funds are looking at growth investments, and proper policy implementation will definitely bring in more funds to support the biotechnology industry in the country. He also observed that state governments should have to come out with more incentive packages instead of making noises.

Besides government funding, big pharma companies have to take initiatives by offering projects to the SMEs on contract basis. Agreeing to the fact that biotechnology companies are struggling for their second round of funding, he pointed out that going in contract projects with overseas firms will definitely bring some relief to these companies.