



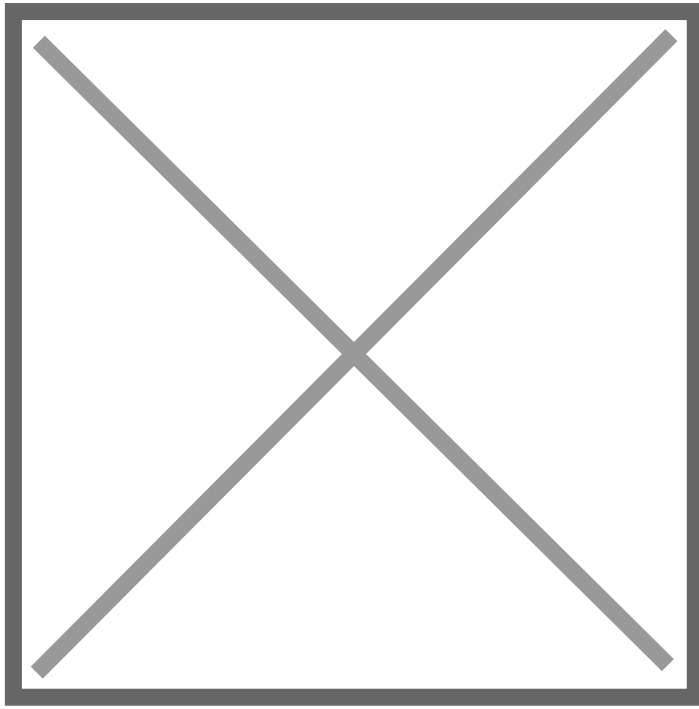
# BioSpect

the business of Bio

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**Will India biotech hit \$10 bn by 2015?**

15 March 2011 | News



## BioSpectrum Explores

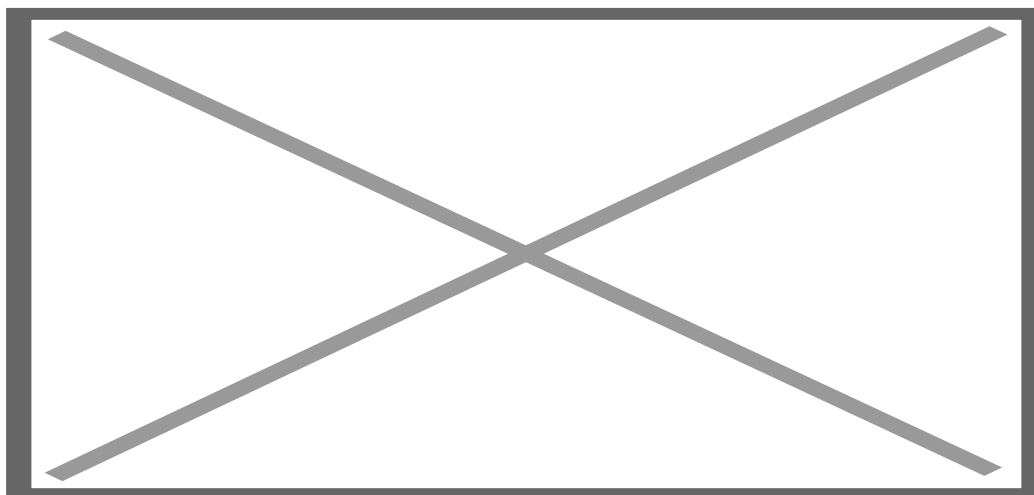
In September 2005, BioSpectrum, in its efforts to promote biotech industry, organized the Biotech CEO Summit. It was the first-of-its-kind platform in India that brought together stakeholders from various domains of biotech industry with a clear agenda of analyzing the ways and means of achieving a target of \$5 billion by the end of 2010.

The then Union Minister of State for Science and Technology and Ocean Development, Mr Kapil Sibal, after inaugurating the summit, said that the initiatives taken by the government at policy level and the ministry's willingness to take the progress forward, would make the dream of achieving the target of '\$5 billion biotech industry by 2010', a reality.

In early 2010, the industry veterans pointed that India's biotech industry will clock \$10 billion mark by 2015. Dr Kiran Mazumdar-Shaw, a prominent person in Indian biotech industry, also pointed out that the industry is predicted to reach \$5 billion by 2011 and will register \$10 billion by 2015. Many big pharma players are already developing strategic alliances and collaborative research programs with Indian partners and this trend is set to continue. And the industry leaders are optimistic about growth in the coming years.

In 2009-10, the biotech industry witnessed a growth of 17 percent as against previous year's growth rate of 18 percent. In 2008-09, the industry witnessed a growth of 20 percent. In 2007-08, the industry clocked a CAGR of over 30 percent for a period of five years. Considering the market potential and opportunities, the biotech industry will see a growth of over 20 percent in the coming years. In 2009-2010, the biopharma sector witnessed a growth of 12 percent, bioagri has grown by 37 percent, bioservices sector has grown by 28 percent, and bioindustrial sector has grown by 18 percent.

In this eighth anniversary issue, BioSpectrum explores the possibility of India achieving the \$10 billion mark in the next four years by analyzing the strengths, weaknesses, opportunities and threats of Indian biopharma and bioservices sector.



(Compiled on the basis of industry inputs)

## BioPharma

### BioPharma: Strengths

*India biopharma sector has a growth-friendly ecosystem. The entrepreneurial spirit, skilled manpower, world-class manufacturing facilities, willingness to take risk, and growing opportunity in the areas of biosimilars and vaccines drive the growth of the sector.*

~India has a good ecosystem with growth prospects. Manufacturing facilities catering to both clinical and commercial space are on a rise. The government policies, especially in Andhra Pradesh and Karnataka, give impetus to biotech R&D. In the US, it is very difficult to penetrate the market. But, in India, we have a good marketing opportunity. With proper clinical research, we can expect more business opportunity. In the next five to 10 years, biotech will bounce back to growth.~

- **Dr DS Brar**, chairman, GVK Biosciences

~In biologics space, India's strength has been in the development of quality and cost-effective vaccines for a number of diseases. It is anticipated that the evolving biotherapeutic segment will increase its share as more quality biosimilar proteins and antibody therapeutics enter the market. Our economic growth and the increasing presence of medical insurance companies in India bring down the costs of the expensive medicines and help in expanding the biopharmaceutical market.~

- **Dr Gopal Dasika**, vice president-biotech, Unichem

~The strength and opportunity that drive the growth of the biopharma industry are skilled manpower, world-class manufacturing facilities with the highest number of FDA-approved manufacturing units outside the US, and cost-effective technology leading to low operational costs. With increasing number of mergers and acquisitions we are truly becoming multinational and making our presence felt globally like never before.~

~Support from government with initiatives like Biotechnology Industry Partnership Program and Biotechnology Industry Research Assistance Program; and agreement with Trade Related Intellectual Property Rights give most needed boost to biopharma sector.~

- **Dr Ajoy Kumar**, CEO, Max Neeman International

~India has a whole line of good leaders but this should be backed by financial investments. Contract Research and Manufacturing Services (CRAMS), by far, has been a great boost for India. In the years to come, biopharma will drive the growth of the industry. Companies such as Advinus Therapeutics and GVK BIO have tremendous strengths in developing new chemical entities.~

- **Mr Sanjeev Saxena**, CEO, Actis Biologics

~Government of India is eager to develop biotech sector and it is the major source of funding for biotech research. India is good at making biogenerics. Pharma companies such as, Dr Reddy's Laboratories, Ranbaxy, Cipla, and Shantha Biotechnics are active players in biogenerics market. Therapeutic monoclonal antibodies (mAbs) constitute a major share of biologics revenue.~

- **Dr Sujay Singh**, CEO, Imgenex

~Entrepreneurial spirit of our people, willingness to take risk, ecosystem involving industrial peers, availability of talented young people, hunger for success and drive for innovation are some of the strengths India has in biopharma sector.

- **Dr Rashmi Barbhuiya**, CEO & MD, Advinus Therapeutics

~Lean cost of IPR generations, increasing government support for small biotech businesses, potential foreign direct investment and clinical trial market maturation will drive the growth forward.

- **Mr Pankaj Sharma**, CEO, LeadInvent

## BioPharma: Opportunities

~Patents for many of the top selling therapeutic mAbs, such as, Herceptin (for the treatment of breast cancer) and Humira (for the treatment of rheumatoid arthritis) will expire in the next five to six years. By 2017, approximately \$38 billion (₹ 171,202 crore) worth of biologic drugs will lose patent protection. This will drive the growth of biotech and pharma companies in India.

- **Dr Sujay Singh**, CEO, Imgenex

~The biosimilar space offers a significant opportunity to Indian biotech industry in the next decade. The global market for biosimilars is estimated to reach \$5-6 billion (₹ 22,500-27,000 crore) in the next 10 years. Indian companies can aim for sizeable share in this market. Even domestic market opportunity for biosimilars is estimated to be \$1 billion (₹ 45,000 crore) by 2020.

- **Mr KV Subramaniam**, president & CEO, Reliance Life Sciences

~If Indian biopharma companies focus on relevant ideas, there are tremendous opportunities. Diabetes is one such area that needs attention and adequate work needs to be undertaken in this area. The research institutes and the private companies must jointly address this problem. The diagnostic tools, preventive tools, and therapeutic tools market need to be strengthened.

- **Dr Jitendra Verma**, MD, Life Care Innovations

~In addition to wide domestic market for bioproducts, India moves ahead in value chain in drug discovery and more opportunities are created as companies out-license their compound pipelines for multi-million dollar deals.

- **Mr Pankaj Sharma**, CEO, LeadInvent

## BioPharma: Weaknesses

~India has advantages in terms of low-cost for manufacturing and product development as compared to developed countries. However, for being a truly-global leader in this space, India needs to focus on strengthening regulatory approval process, maintaining higher standards of biosimilars, developing human competencies and accessing regulated markets.

- **Mr KV Subramaniam**, president & CEO, Reliance Life Sciences

~With few exceptions, India's biotech infrastructure is poor as compared to the US and Europe. India still imports most of the equipments and reagents used in biomedical research. There are no strong collaborations between academia and industries. To support the growth of biotech/ pharma sector, we need to attract best-educated scientists to the industry. Attracted by higher salaries, many of Indian scientists are leaving for the US and Europe. The Department of Biotechnology, Government of India, is spending millions of dollars to foster academia-industry collaboration, which will help to start many new companies and lead to development of indigenous technologies. There is a need for more funding from the venture capital investors. To develop new drugs, even biogenerics, requires major investments.

- **Dr Sujay Singh**, CEO, Imgenex

~Collaborations and partnerships at different stages of product development need to be enhanced both within the country and across the globe. This will lead to optimization of resources, minimize time-to-market, and an overall growth of the bioservices sector. Increased awareness of biotechnology-derived medicines among our medical fraternity is important to propel growth. Government support in the form of policies and regulations that are ethical, rational, and at the same time allowing biotech companies to develop cost-effective, safe and efficacious biotech products is needed.

- **Dr Gopal Dasika**, vice president biotechnology, Unichem Laboratories

~Å?The biggest hurdle faced by biopharma industry is the innovation. We are still waiting for that one home grown global molecule. Other factors that discourage foreign investors are infrastructural constraints and stringent regulatory laws; time consuming application process due to lack of trained regulatory authorities.~Å?~?

- **Dr Ajoy Kumar**, CEO, Max Neeman International

~Å?We still work on a service model rather than an innovation model. We do not have the resource and infrastructure. Huge financial investments are needed to increase our capacity to drive growth. Moreover, for biotech revenues to grow, product sales need to happen at the global level. Our mindset needs to change towards innovation and that trend is gradually picking up in India.~Å?~?

- **Mr Sanjeev Saxena**, CEO, Actis Biologics

~Å?If we analyze the progress made in research before and after bio-revolution, the growth remains the same. No product has so far cleared phase III. Most of the SMEs and big pharmas are giving importance to generics. Academic researchers also failed to come out with any major discoveries so far.~Å?~?

- **Dr Jitendra Verma**, MD, Life Care Innovations

~Å?Poor intellectual property strategies, lack of early stage funding, and non-existent industry-academia collaboration are the limiting factors that hinder the growth of biopharma sector.~Å?~?

- **Mr Pankaj Sharma**, CEO, LeadInvent

~Å?If Indian biotech sector takes an innovation route, we can achieve any expectation in two to three years from now. In India, innovation is happening only in fermentation and insulin space. Out of the US FDA approvals last year, 40 percent of them were biologicals. There is a growing need to take science to the transitional stage.~Å?~?

- **Dr Shreekant Sapatnekar**, medical director & COO, Karmic Lifesciences

~Å?The education system needs to be equipped to generate skilled manpower, especially in the area of biotechnology. Small Indian companies should emphasize to make each other strong by entering into regional and global collaborations in the area of R&D.~Å?~?

- **Dr Rashmi H. Barbhaiya**, CEO & managing director, Advinus Therapeutics

## **BioPharma: Threats**

~Å?We have a lot to achieve in the field of collaborative research. More emphasis needs to be given to R&D, so that we can explore new avenues. One of the major threats to the biotech industry is the patent litigation.~Å?~?

- **Dr DS Brar**, chairman, GVK Biosciences

~Å?Indian biotech/ pharma companies spend much less than their US counterparts in R&D expenses. Biogenerics may bring immediate success to many companies; however, to be successful in the long run companies need to invest more in R&D for the development of innovative drugs. Some of the major players in the global market such as Merck, GSK and Novartis are venturing into biogenerics market. This poses a threat to Indian biopharma companies that are shifting their focus on biogenerics.~Å?~?

- **Dr Sujay Singh**, CEO, Imgenex

~Å?The mergers and acquisitions of major biopharma companies need to be closely analyzed and there has to be an end to it. The unhealthy competition and copycat companies are the biggest threats in the long run.~Å?~?

- **Dr Jitendra Verma**, MD, Lifecare Innovations

~Å?Considering the case of pharmaceutical companies in India, the competition from the regional market is higher. So, we need consolidation of companies to achieve growth in the sector.~Å?~?

- **Dr Krishan Ella**, CMD, Bharat Biotech

~Å?The key issues that affect biopharma sector are the lack of government funding in entrepreneurship, too much focus on basic research, limited number of quality research institutes, and lower priority on premium allocation for scientists, in terms of career and compensation.~Å?~?

- **Dr Ajoy Kumar**, CEO, Max Neeman International

~Å?We do not have a system or policy in place to allow academic institutes to attract best of the talents. Research institutes are unable to match the industry salaries and those institutes are not in a position to enable collaborative research.~Å?~?

## BioServices

### BioServices: Strengths

*Low operational costs, English-speaking people, availability of a large pool of patients, and good healthcare infrastructure drive the growth of the bioservices sector*

"Considering the developments that have happened in the past few years in the global pharmaceutical industry, India is at the threshold of growth. The contract research organizations (CROs) have a lot to look forward to. The pharma companies have lost a lot of talent and therefore they will look to the CROs to fill the gap. So, if you have the proven expertise you will have a lot of business coming your way. The customer wants more (full) services from the same CROs so you need to have a global footprint and be a one-stop shop for them to come to you, and cost and speed have become extremely important, assuming you already have the required expertise and quality. India has already proved itself, in terms of quality, so we are in a great position to attract more work."

— **Mr Apurva Shah**, group managing director, Veeda Clinical Research

"The high quality service sector including clinical trials and contract research is being supported by a solid regulatory framework and a strong network of research and academic institutions, all at a low price."

— **Dr Ajoy Kumar**, CEO, Max Neeman International

"Services is our strength, but, it is not sustainable without intellectual property. Biotech service sector is prone to duplication by other countries (even Bangladesh is beating India in textile/ garment business). Therefore, even if India reach \$10 billion (₹45,000 crore) mark it would be short lived for sure. It is only possible to reach such a milestone by innovating technology/product and maintaining lead on long-term basis. The US (High on IP and natural resources) and Japan (high on IP and low on natural resources) have done it and China (high on IP and natural resources) is heading towards that path. At present, Indian formula (very low IP and high natural resources) does not seem to be a winning one. Our strength is natural resources and high internal consumption and that may be good enough to reach a large figure but may not be sustainable over a long period."

— **Dr Aroop Kumar Dutta**, CEO, Excel Matrix Biological Devices

### BioServices: Opportunities

"For the past couple of years, there has been an increased interest among Indian pharma and CRO companies to invest in infrastructure to support various functional and drug discovery services. This has been fueled by a significant demand on the global pharma industries to outsource such projects. Recent technologies such as Next Generation Sequencing (NGS), non-coding RNA studies and RNA interference are the ones that need extensive discovery support. The other key areas in drug discovery include study of biological pathways, systems biology, biomarkers, validation of targets and thereby, expansion of potential discovery of new drugs. There would be an increase in opportunities in these areas for the Indian bioservices."

"Many experienced scientists are seriously inclined to return to India and contribute to drug discovery efforts. Availability of the right talent pool, financial support and timely inflow of new projects has created an immense opportunity for biopharma and bioservice companies to reach the \$10 billion (₹45,000 crore) mark. With many billion dollar drugs going off patent soon, Indian companies have the opportunity to capture this market."

— **Dr V N Balaji**, director & chief scientific mentor, Jubilant Biosys

"We have opportunities to get into IP-driven knowledge economy. But, so far, we have not tried that in any of the sectors (IT, pharma, biotech, agriculture etc.)"

— **Dr Aroop Kumar Dutta**, CEO, Excel Matrix Biological devices

### BioServices: Weaknesses

"Consistency in quality and timelines are very critical now more than ever before because it affects the cost of development. India needs to really focus on the timelines which is affected very badly by the unpredictable regulatory environment. We have lost a lot of business and reputation due to this in the past and if we are serious of becoming a center for R&D we need to have huge improvement in this area. There are a lot of other countries who have identified clinical research as a growth area

because of the benefits it brings to the country such as upgradation of healthcare and employment to their educated youth. If India loses its momentum then we will be thrown off and it will affect not only the CROs but also the overall R&D in the pharma sector. Our quality has been good so far and we need to maintain that.”

— **Mr Apurva Shah**, group managing director, Veeda Clinical Research

“The number of new products that are reaching the market has stagnated in the last few years, despite large investments in target and lead molecule discovery. Also, concerns related to safety are of prime importance as the attrition of a compound at a late stage of the discovery and development is unpredictable.”

“Strengthening biopharma and bioagri with services that are efficient and services with novel technologies can be an area to ensure low attrition of product development and eventual profitability. The process of receiving approvals from regulatory authorities is still slow in India. This could discourage companies from venturing into newer areas of drug discovery, drug delivery and bioagri. Adherence to stringent quality control is a key requirement in biobusiness. Any lapse could be a serious threat to this business.”

— **Dr V N Balaji**, director & chief scientific mentor, Jubilant Biosys

“In CRO/CRAMS space, a massive inflow of funds is required. Government does give loans, but many small and mid-size companies find it difficult to repay those loans. Moreover, when clinical trials are conducted in India, as a part of global-centric trials, the data is recognized. But if there is a trial which is conducted only in India, the data is usually not recognized.”

— **Mr Sanjeev Saxena**, CEO, Actis Biologics

“Today, India mainly concentrates on biosimilars which I agree is a good opportunity but the future lies in novel biologics. Unfortunately, CROs in India do not have a sound knowledge based on pure biotech but are only looking at biosimilars. The growth of a CRO depends on the growth of the pharmaceuticals industry who have been changing their business models over the recent past.”

— **Dr Arun Bhatt**, president, ClinInvent

“The bioservices sector can also offer significant opportunity to Indian players, given the advantage that India has rich talent pool with technical expertise and comparatively low operational costs. However, services business is difficult to scale-up and there is significant competition from service providers based in other emerging markets like China.”

— **Mr KV Subramaniam**, president, Reliance Life Sciences

“The government has been supportive and have kept themselves in tune with the global trends and demands to improve India's image. The industry has not compromised on ethics and the government has given some fast forward approvals. There has been some aggressive marketing but we still need to gallop. Indian CROs have now realized that they need to demonstrate quality management. To see growth in the CRO industry, Indian companies need to be on the alert. CROs should also gain domain knowledge in biotechnology. A major problem is that the level of understanding of the principal investigators is very low. Lastly, though the regulatory framework has improved over the past five years, it still needs a lot of improvement.”

— **Dr Sapatnekar**, medical director and COO, Karmic Life Sciences

## **BioServices: Threats**

“We need the benefits of doing work to broaden the base of Good Clinical Practice (GCP)-certified investigators and hospitals by having more trainings so that R&D is known to everyone in the right way and shortcuts are not taken. It is the job of every person, company and institution to ensure GCP is followed and studies are done ethically. It is a myth that pharma companies and CROs encourage shortcuts. No good and responsible pharma company or CRO wants this because it eventually stops the work and causes huge losses.”

— **Mr Apurva Shah**, group managing director, Veeda Clinical Research

“Generic competition cannot be considered as our strength any more. Generics is in fact going to be a threat. It sounds strange but it is true. For all generic players it is a pseudo strength only till the me-too competitors kick in. See, what happened to Hepatitis B? How many players are there in the market at present?... (maybe 10 or more and who knows how many are in the fray). None of these manufactures are happy or proud about it anymore. It is because they are competing with each other for local market and none have the edge, strength or IP to compete in the global market.”

— **Dr Aroop Kumar Dutta**, CEO, Excel Matrix Biological Devices

“Post recession, around 90 percent of the outsourcing business went to the top 8 CRO companies in India, the others either shut down or went on to conduct BA/BE studies. The CRO space, globally, has become competitive and today India, no

longer, has the “low cost” advantage because other BRIC nations offer similar cost advantages to companies.”

— **Dr Sapatnekar**, medical director & COO, Karmic Life Sciences

**Narayan Kulkarni, Rahul Koul, Nayantara Som & Suchithra Pillai**