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Business of Future

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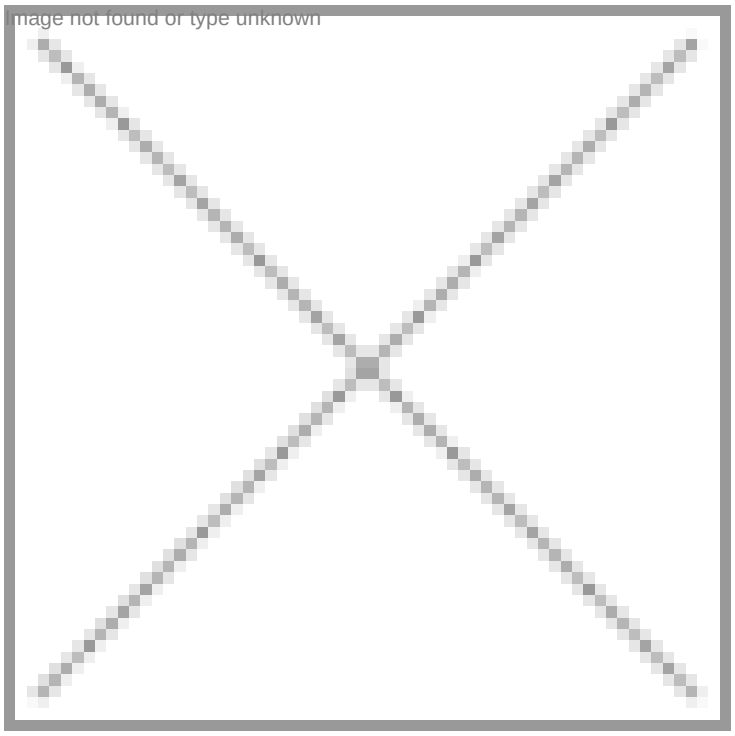

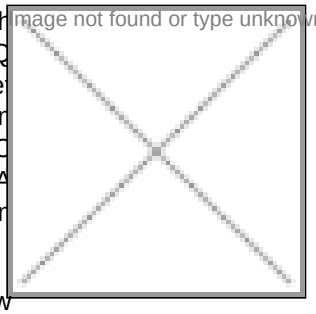

The global biotechnology industry has much to celebrate in 2003, a year that symbolizes the 50th anniversary of DNA discovery. The biotech sector saw a major recoveryâ€"the NASDAQ biotechnology index surged 46 percent after a 67 percent plunge in the previous year. The market capitalization of the US listed biotech companies grew to $200 billion in June 2003 from $93 billion in 1998, representing a growth of 120 percent. The biotech sector accounted for 15 percent of VC investments in 2003 wherein 66 biotech companies raised $640 million from VC investors. M&A activity was prolific, where mega deals struck between biotech and pharma companies valued in excess of $1 billion.

Against this backdrop, the Indian biotech sector witnessed a notable growth in terms of new companies registered, larger product pipelines, increased patent filings and several product launches. Another milestone in the Indian biotech sector was ABLE - The Association of Biotechnology Led Enterprises, an organization that serves to be the collective face of the Indian biotech industry to provide a common platform for interaction and representation between industry, academia and the government.

It is important, however, to highlight the fact that investment in the sector continues to remain inadequate, venture funding is scarce, infrastructure is expensive and regulatory regimes are deficient. Despite this difficult environment, entrepreneurs are bravely setting up new ventures in the country. What this reflects is an intrinsic belief in biotechnology being the business of the future.

The year saw the launch of Shantha Biotechnic's interferon, Shanferon and Wockhardt's recombinant human insulin, Wosulin. Proagro's GM Mustard, however, did not receive the regulator GEAC's nod and Bt cotton continues to remain the sole Genetically Modified (GM) crop in the Indian market. x-Cyton launched a new diagnostic for hepatitis C, Hep-Chex C and the development of a dengue diagnostic based on an in-licensed DNA-based technology from ICGB. Other products in the development and approval pipeline include Biocon's recombinant human insulin Insugen, Bharat Biotech's Streptokinase and Shantha's GCSF. Strand Genomics launched Acuris, an ADME prediction software for drug discovery and Avesthagen announced a new gene expression platform for a variety of crops.

On the innovation front, there remains a cautious skepticism about the protection of Intellectual Property Rights (IPR). International investors and VCs continue to voice their concern and Indian industry finds it difficult to allay these fears. 2005 seems to be the red-letter day for the Indian industry when foreign investment in R&D is expected to be made in a "no holds barred" manner! Today, several biotechnology companies have managed to cross these IP hurdles and are now successfully working with international partners on the basis of confidentiality and non-disclosure agreements, which spell out terms of sharing potential intellectual property that is likely to emanate from such partnerships.

Bangalore's biocluster stands out in terms of innovation, where companies like Strand Genomics have developed and licensed a number of proprietary software tools for data mining and drug discovery. Gangagen Technologies are actively developing a range of proprietary phage-based products which will soon go into clinical development. Metahelix, an agri-biotech company, has already demonstrated its proprietary skills in gene expression systems in a variety of crops and has bagged a research contract from New Zealand's Fontera Group. Biocon, the country's premier biotechnology company, has filed 100 patents to date and is currently developing a mammalian cell culture technology for the production of an anti-egf monoclonal antibody for oncology. x-Cyton, a diagnostics biotech company, has embarked on an ambitious program to develop a number of novel diagnostics based on DNA-based detection kits including dengue. This is in addition to its existing portfolio of diagnostic kits for HIV, hepatitis C and neurocysticercosis. Avesthagen, another innovative agri-biotech company has recently announced a unique platform for gene expression. Clinigene, a division of Biocon, has embarked on a longitudinal research program to investigate type II diabetes in pursuit of novel biomarkers and has jointly filed a number of patents with Strand Genomics for diabetic nephropathy. It is this intense innovation activity that makes the Bangalore biocluster special.

The custom research sector has made rapid strides both in terms of R&D and clinical development services. The most significant development was the joint venture between Siro Clinpharma and Covance. This sector is forecast to attain a size of $1 billion by 2008. However, Schedule Y continues to be the main hurdle and ABLE expects to lobby strongly for permitting phase I clinical trials, which are currently permitted only for new drugs developed in India.

2003 also saw significant interest being generated by the IT sector where both Wipro and Infosys have set up divisions in life sciences.

Another important milestone in 2003 was the creation of a biotechnology fund by APIDC, which has already invested $1 million in three new biotech companies started by NRI bio-entrepreneurs. This initiative is expected to catalyze the formation of several other biotech focused funds.

The BioSpectrum-ABLE Biotech Index will now generate reliable national data with respect to the biotech sector, which will allow a systematic tracking of the various divisions that constitute the biotechnology sector. In addition, ABLE have commissioned Frost&Sullivan to initiate international bench-marking studies, which will enable the Indian biotech sector to be profiled in a manner that is better deserving of its existing skills and performance.

In conclusion, I believe that Indian biotechnology is rapidly attaining critical mass in terms of skills and capabilities. Investments in innovation are incremental and are helping the sector to develop a robust pipeline of high value products and technologies. The next five years are critical to the Indian biotech sector in terms of government policies with respect to IPR, regulatory reforms and fiscal support. A strong IPR regime coupled with conducive regulatory reforms that enable faster product approvals will go a long away in shaping the Indian biotech industry into a global player.

(The author is the president of ABLE and chairman, Biocon Group, Bangalore)