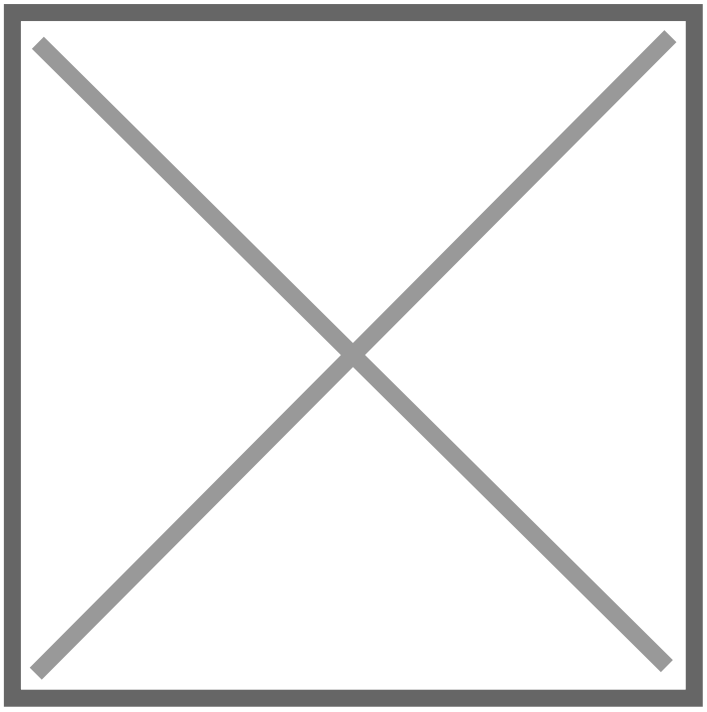
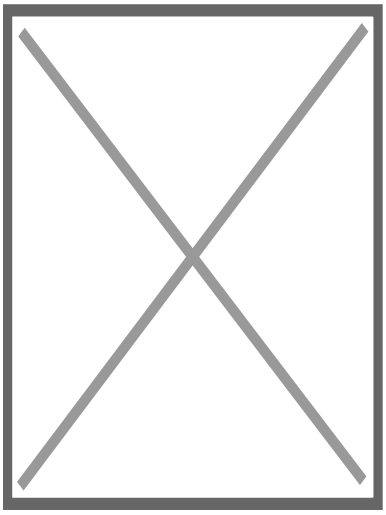


Biotech losing steam?

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Things are not going too well for the biotechnology industry which is dependent on cutting edge innovation to develop new, more effective cures than the chemistry-based pharma sector, against several unconquered diseases. The product pipeline from the biotech industry seems to be shrinking if one considers the approval status biotech products by the US government regulatory, the Food and Drugs Administration (FDA). The US is the world's largest pharma market and hence the FDA approvals are watched with avid interest around the world.

Particularly, the last two years, 2006 and 2007, have been very bad for the biotech industry with just 10 and 11 biopharma products approved by the FDA. According to a comprehensive study done by Dr Ronald A Rader, president of Maryland-based Biotechnology Information Institute, the situation will become alarming for the biotech industry if the FDA approval trend continues. From an average annual approval rate of 16.6 products, with a peak of 23 in 1997, it has been a downhill for the industry in recent years.

Many analysts blame the FDA for its over-cautious approach as a result of recent spate of drug withdrawals from the market. Dr Rader, however, indicates that this may not be the case. Almost every product which did not get the FDA approval had some issues related to safety or efficacy. Majority of the products which got the FDA approval in 2007 were in the me-too

categories. Few of them were original, innovative products. Three most hyped segments-recombinant proteins, monoclonal antibodies (mAbs) and indications against cancer-did not get any approvals from the FDA. In the last 10 years, these three segments were the most talked about parts of biotech and over 350 products were under development in these areas from the year 2000. Over half the products under development are treatments against cancer. Not one mAb or recombinant protein got approved in 2007 in the US. One promising drug, from Roche, Mircera, a pegylated recombinant erythropoietin (PEG-EPO) which got approved in 2007 may not reach the market soon due to issues related to patent infringement.

A lot of drugs are obviously failing during the Phase III stage. This implies that the developers did not fully understand the strengths of the product or the regulators are asking too many questions for which the scientific community has no answers now. Nearly 25 products which had sought FDA approval in 2007 are still pending with the FDA. An equal number of products from biotech companies are likely to seek FDA approval in 2008. The approval trends of FDA will be watched closely this year and in 2009. Whether the biotech industry will continue to be a trendsetter or face economic decline will depend on the FDA approval trends in 2008 and 2009. Every one in the industry is keeping his/her finger crossed.

While the established biotech companies are struggling to increase their product pipeline, a lot of action is taking place on the ground in Asia. Singapore is becoming a big hub for the life sciences industry. India is making every effort to ensure that the country becomes a major destination for contract research and manufacturing services (CRAMS). The national budget for 2008-09 has slashed excise duty on manufactured pharma products by half to 8 percent and decreased the federal value added tax by another 2 percent. The immediate beneficiaries will be the foreign companies who have manufacturing plants for pharma and biologicals in various parts of the country. Many biotech companies who have manufacturing units in Bangalore, Hyderabad, Pune and Mumbai will also benefits. Most Indian pharma companies have shifted their manufacturing plans to tax-free states of Himachal, Uttaranchal and Jammu and Kashmir in recent years. Such units can eventually hope to attract more orders outsourced from pharma companies due to the competitive rates.

Industry leaders will be gathering in Bangalore for the 8th edition of the Bangalore Bio event and hopefully will get some time to discuss the future growth strategy for the domestic industry.

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