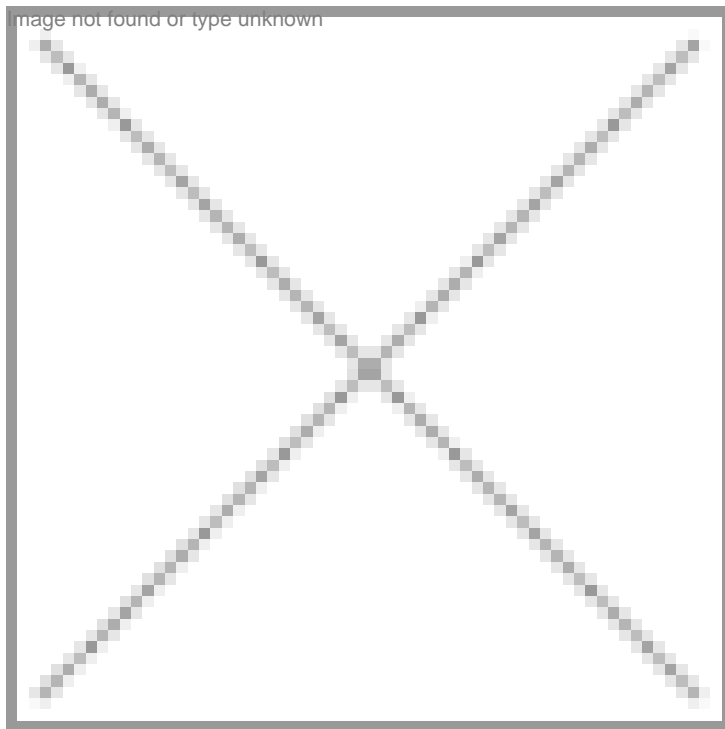


GLOBAL BIOTECH INDUSTRY RECOVERS

11 July 2011 | News



HIGHLIGHTS FROM THE WORLD'S LARGEST BIOTECH GATHERING

Efficient raising of capital to fuel innovation is the challenge before the global biotech industry, according to the 25th anniversary edition of Beyond Borders: the Global Biotechnology Report 2011 of Ernst & Young (E&Y)

The bad days are over for the global biotech industry, which has recovered in revenues and profits following the economic downturn of 2008, with the revenues close to \$100 billion and marginal profitability, said Mr Gautam Jaggi, managing editor of E&Y's Beyond Borders report 2011.

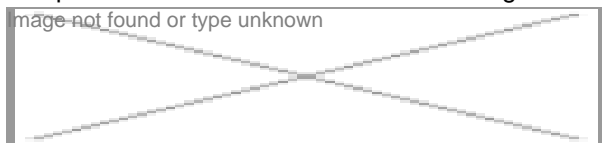
Releasing the report at a crowded Bio International Conference session in Washington DC on June 28, 2011, Mr Jaggi cautioned the biotech industry about the pitfalls ahead. This industry has to make urgent changes in the business model and improve capital utilization efficiency to sustain innovation.

Giving an overview of the sector, Mr Jaggi said the industry, which is primarily measured by the performance of publicly listed biotech companies in North America, Europe and Australia, increased the overall revenues by eight percent over the 2009 numbers. More importantly, the profitability returned with only one percent margin.

The collective R&D spending by the industry has also touched two percent of the revenues as compared to the 13 percent decline in the previous year. The industry managed to raise around \$25 billion in capital, as compared to the figures prevalent during the heydays of the industry.

However, Mr Jaggi said that there are some signs of warning. Companies that raised the capital used majority of it for retiring debt and restructuring balance sheet. And the actual quantum of investments in innovations, which in the long run would hurt the industry, were modeled on creating new products. With the recovery, employment has increased by four percent over 2009. In the previous year, the employee count had declined by four percent.

The number of new drugs approved by the US regulator, FDA (Food and Drugs Administration) in 2010 was only 21 as compared to 26 in 2009. “This is a sign of a cautious regulator not taking too many risks in the post-Vioxx withdrawal



In such a scenario, E&Y prescription for the industry: Do more with less funds through increased research efficiencies and prove or lose it early. This implies that the companies will have to arrive at conclusions to go ahead and stop work on novel compounds earlier than usual.

“The pressures on the biotech business model have now increased to extraordinary levels, even by the standards of an industry that has for long faced funding constraints,” Mr Jaggi wrote in the report along with co-author Mr Glen Giovannetti, the global leader of E&Y life sciences program.

The statistics tell the tale. Biotech industry growth is fueled by venture capital investments for promising start-ups. However, in the US, venture capital (VC) raised has declined by nearly 20 percent in the last two years. And VCs are increasing the share of investments in hot social media ventures at the cost of biotech companies.

Adding to the problems of biotech companies is the trend of funds being disbursed in tranches, Mr Jaggi said. So, biotech companies now do not get all the promised funds upfront but in tranches, tied to milestone payments. This has the potential to further increase pressure on innovative biotech companies to show results more quickly and consistently.

ANTI-CANCER DRUG AVASTIN LIKELY TO BE WITHDRAWN

A panel of experts at the US regulator, Food and Drugs Administration (FDA) has recommended withdrawal of Genentech's blockbuster breast cancer treatment drug, Avastin, on the ground that it is actually harmful to the patients. Health experts of FDA ruled that it does not provide significant cure but, in fact, endangers patients with breast cancer. With annual global sales of \$6.8 billion (INR 30,600 crore), Avastin is the world's largest selling biotech drug.

FDA's decision to withdraw the drug, during late 2010, was challenged by Genentech, which is owned by German drug maker, Roche. The matter went to a six-member advisory committee, which recommended unanimously that the drug be withdrawn. FDA commissioner, Ms Margaret A Hamburg, will take the final call. Usually the FDA heads do not overrule the decisions of expert committees.

Avastin could, however, be used in other treatments. For breast cancer patients, a year's treatment using Avastin costs over \$88,000 (INR 45 lakh). Presently, over 17,500 women in the US are undergoing Avastin treatment. “We are very disappointed by the committee's recommendation,” said Mr Hal Barron, Genentech's chief medical officer, in a media statement. “We remain ready to collaborate with the FDA to find a solution that is in the best interest of patients who need Avastin.” This latest decision is likely to further put pressure on FDA as there has been widespread condemnation that the agency was too risk-averse. Many demonstrators appeared near the agency's office with placards asking FDA to “Save Avastin, Save Women.”

Appearing at a panel discussion at the Bio International conference, FDA commissioner, Ms Hamburg defended the agency's science-based decision. While other panelists and participants too voiced their concern that American citizens were becoming too “risk-averse” and this has an impact on the decisions taken by policy makers. This approach is increasing the cost of conducting clinical trials and other compliance measures and it costs now nearly \$1.5 billion (INR 6,750 crore) to bring a new drug to the market, compared to just \$1 billion (INR 4,500 crore) five years ago, or \$100 million (INR 450 crore) 20 years back, many industry veterans said during the discussions.

INDIA PAVILION ATTRACTS GLOBAL ATTENTION

Dr M K Bhan, secretary, Department of Biotechnology, inaugurated the India pavilion at the BIO exhibition in Washington on June 29. The pavilion, being showcased at the four-day event, was supported by the Confederation of Indian Industries (CII) and the Association of Biotechnology Led Enterprises (ABLE) along with the Department of Biotechnology, Govt of India.

Mr Arun Kumar Singh, deputy chief of the mission, Embassy of India in the US and Dr Rajesh Jain, chairman of CII national committee on biotechnology and joint managing director of Panacea Biotech, were among the many dignitaries present at the inauguration.

Many industries and state governments of India participated in the exhibition that drew a lot of attention from the global biotech players looking for collaborations.

The yearly exhibition was preceded by the CII's 10th Biotech Mission to the US. About 45 Indian delegates participated in the mission led by Dr Bhan and Dr Jain. The delegation visited premier institutions like the National Institutes of Health, University of Maryland and Johns Hopkins University.

DR PAUL OFFIT GETS BIO AWARD

Dr Paul Offit, the co-inventor of the rotavirus vaccine and a leading American scientist, was honored with the Biotech Humanitarian of the year 2011 award by the Biotechnology Industry Organization (BIO) at Washington convention. Mr Jim Greenwood, president of BIO, presented the award to Dr Offit, who is currently the director of the Vaccine Education Center at The Children's Hospital of Philadelphia, US. Dr Offit has spent 25 years to develop RotaTeq, one of the key vaccines against rotavirus infection. RotaTeq has been recommended for use in children to save them from crippling dehydrating diarrhea.

US LAUNCHES BIOTECH PODCAST FOR CHINA

The US has launched a Mandarin version of a radio program on biotechnology. The program's host, Dr Moira Gunn, announced that the weekly biotech segment of Tech Nation will be podcast through the Internet in Mandarin, China. It will be called BioTech Nation China and will be hosted by Dr Xiaohua Yang, a professor of management at the University of San Francisco.

MALAYSIA, A HOT DRAW

Agila Specialities Sdn Bhd, a subsidiary of India's Strides Arcolabs, is set to spend \$40-60 million to set up a manufacturing facility at the biotechnology park in Malaysia. Bio-XCell, the investment arm of Malaysian Biotechnology Corporation, also sealed a strategic partner agreement with MOX-Linde Gases Sdn Bhd to supply industrial gas for use of biotechnology companies located in the park.

TAIWAN COS SIGN DEAL WITH PHARMANET

Taiwan-based pharmaceutical companies will collaborate with a leading western CRO, PharmaNet Development Groups. Non-profit Pharmaceutical Industrial Technology Development Center (PITDC) and Pei Lei Pharmaceutical Company signed mutual cooperation agreements with the CRO on the opening day of the conference. PITDC also signed an agreement with Aihol Biomedical for co-developing some drugs.

26 FIRMS PART OF KIWI SHOW

More than 26 New Zealand companies showcased their capabilities in human health care, animal husbandry, plant and food research, research technologies and more at the convention. The country displayed its 150 years of expertise in genetic improvement of animals and plants, and world-class research institutions led by industry organizations, NZBIO and New Zealand Trade and Enterprise.

QUEENSLAND PUTS IN \$100 MN FOR BIOTECH

The State of Queensland in Australia announced an additional \$100 million grant in the state budget to boost investments in the biotechnology sector and attract researchers. The funds will be used to co-invest with industry, universities and the Commonwealth, said Ms Anna Bligh, premier of the State of Queensland. The Australian delegation at the convention included scientists, researchers and executives from the state of Victoria, which has long been the hotbed for biotech

innovation down under.

- **Narayanan Suresh** in Washington D C