

**NATIONAL CONFERENCE ON RECENT ADVANCES IN DRUG DISCOVERY
RESEARCH, POONA COLLEGE, PUNE**

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March 16, 2008, Pune

Principal, Dr. Qudratullah, Dr. G.M. Nazeruddin Co-ordinator of the Conference, delegates and participants to the Conference on Recent Advances in Drug Discovery Research, ladies and gentleman,

It is indeed a great pleasure for me to participate in this valedictory function of this National Conference. I do hope the deliberations have been fruitful and productive. The students of this college and also from others, hopefully, must have gained a perspective of the complexities of the drug discovery process.

Discovery research in drugs is at a crossroads today. Several issues confront this segment of industry. Decreasing returns on increasing R&D spend, diminishing new drugs pipeline, increasing share of generics in pharma market, death of the blockbuster model, decreasing number of new drugs gaining regulatory approval, increasing awareness of drug safety, high profile consumer litigation, leading to recall of established drugs, increasing number of drugs going off patent in the period 2006-2010 and poor countries making demands for cheaper drugs and threatening to override patents through "compulsory licensing".

The global drug industry is taking a huge beating. Chief Executives of the three of the biggest pharma companies have been forced out by share holders. Share prices are at historic low. Global pharma companies are shutting down facilities, laying off people and moving R&D and manufacturing to low cost economies.

During this period, India pharma has taken some bold steps. India has exploited its low cost manufacturing and process chemistry skills in bringing generics to markets. It has excelled in API's and is fiercely competing with China in low cost API's. It has honed its skills by forward integration in areas such as pre-clinical and clinical trials, safety and toxicology, novel drug delivery systems, bio-similar and therapeutics derived from natural products. These skills are extremely valuable in closing the chain on drug discovery.

Indian pharma companies have taken some bold steps in drug discovery. It is a risky step, beset with many uncertainties. Yet, it helps companies build people and processes capable of straddling the full discovery chain. They are also forging partnership with global companies to manage the risk of discovery research. Most of our pharma majors

have spun off drug discovery into independent companies, to protect existing share holders from the risk of failure and to explore global partnerships as well as seek funding/capital infusion.

What then is the future of drug discovery research? Generics will drive growth for a few more years, but the competition is stiff and margins are shrinking. Greater innovation in process chemistry will be called for. The pharma industry has poorly managed batch productivity, efficiencies, (process and energy), process optimization, recycling etc. Greater attention is needed by process engineers with an objective to optimize energy and materials efficiency. The cost arbitrage that India enjoys today will not last long. Ultimately we have to compete based on innovation and new ideas.

India's ability to close the drug discovery chain, on its own, will be very challenging. Top ten pharma companies of the world spent US \$ 52 billion in 2006. In contrast all the Indian pharma companies spend on R&D is about one billion dollars! At this intensity of R&D spend, Indian pharma companies are expected to be severely handicapped. Additionally, India's capability in front end biology research is still weak. Basic molecular biology, gene and protein expression, molecular taxonomy of diseases, creation of cell based targets and assays, animal model for diseases are areas where India's skill, is not fully aligned to drug discovery process. There is little effort in India on mechanistic understanding of the origin of diseases.

Apart from this all, Indian challenge to drug discovery is unique and distinctive. We have diseases of poverty and poor public health (malaria, tuberculosis, HIV) as well as diseases of affluence (diabetes, myocardial infarction), diseases of the young as well as diseases of the old. Strategies for drug discovery will have to be different depending on whether you are focused on diseases of poverty or affluence. Increasingly, public institutions and nongovernmental organizations will have to focus on the diseases of poverty, for there is no appropriate business model that will provide incentives for companies to invest in such research. Such R&D must be in public space, devoid of intellectual property related issues, low in cost and high in terms of impact. This requires completely new models of drug discovery – as yet unexplored.

Friends, the challenges are enormous. Yet history tells us that they can be met.