



## **Biotech in India - A perspective**

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**To BIO Academy NRW “Asian Biotech Hotspots”**

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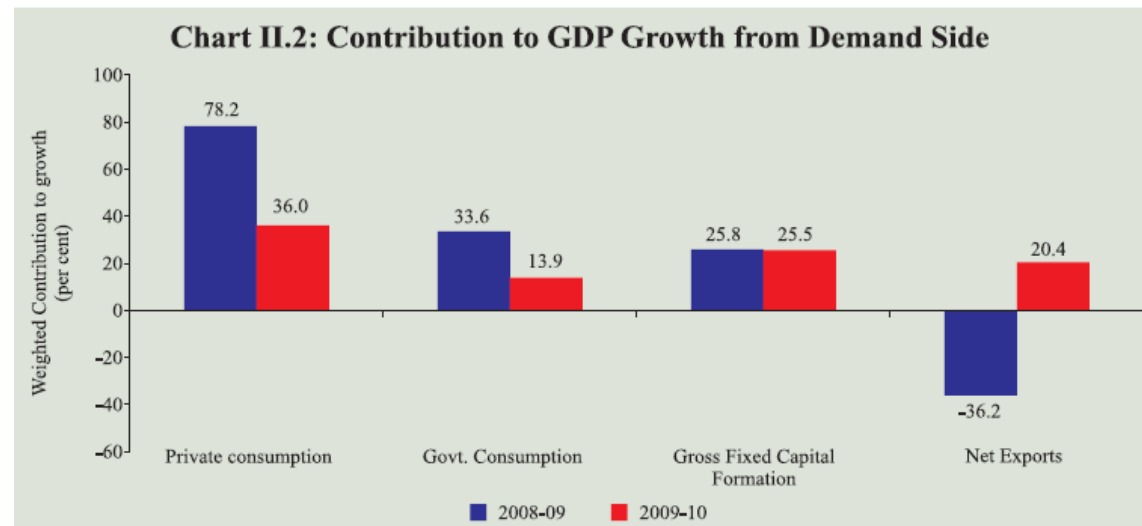
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## Indian Economy

# India - Land of paradoxes

- India unprecedented levels of economic expansion
- One of the first and fastest economies to recover from recent global economic crisis
- Driven by domestic consumption despite continuing high levels of poverty
- Services and industry were the primary growth drivers with no significant increase in job creation
- One of the most “expensive” capital markets with P/E multiples of 20+

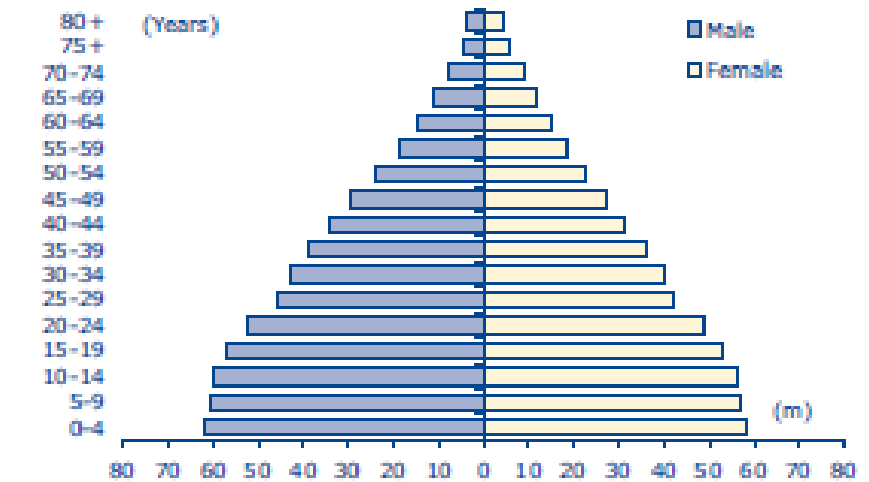


Source: Macroeconomic and Monetary Developments in 2009-10, Reserve Bank of India

# India's diversity

- India, the world's largest democracy, follows the federal parliamentary system with elected governments in States. 28 States and 7 Union Territories
- India has 36 cities with population of more than one million (150 in China). These cities are evenly distributed across the length and breadth of the country
- Hindu 80.5 per cent, Muslim 13.4 per cent, Christian 2.3 per cent, Sikh 1.9 per cent, other 1.8 per cent, unspecified 0.1 per cent (2001 census)
- There are 22 official languages and more than 500 different tribes residing in India
- In India, 50% of the population is under 25 years of age and the country's labor force should grow 1.7-1.84% annually up to 2015
- Distribution of family income – Gini Index: 36.8 (in 2004). India ranks 79 in the world on this scale

59% of population below 30 years of age



Source: World Bank

Note: Gini index measures the degree of inequality in the distribution of family income in a country. The higher the index, the more inequality in income distribution  
Source: Unlocking India's Treasures, CLSA Asia-Pacific Markets, March 2008; CIA (www.cia.gov)

# Indian ingenuity drives growth

- Widespread disparities in the Indian demographics
  - Urban – Rural
  - Rich – Poor
  - Literate – Illiterate
  - Employed – Unemployed
  - Traditional – Modern
  - Variety of religious, regional, language and ethnic backgrounds
- Domestic challenges
  - High poverty and illiteracy levels
  - Inadequate infrastructure
  - High level of corruption and absence of good governance
  - Underdeveloped capital markets



- Indian businesses have to deal with disparities, inadequate infrastructure, corruption, poor governance and an emerging financial order
- Appropriately tailored range of products and services
  - Low cost vaccines as well as high end research on stem cells
  - Luxury products as well as low cost granularly retail (e.g. cigarettes sold in single units) services

# Increasing awareness and maturity adding to growth



- An aware citizenry is increasing pressure on leadership to fulfill economic aspirations
- There are new enactments across different areas
- There is greater investment in reducing the urban-rural divide, employment generation, job mobility and development of the skill base
- Competitive pressures are bringing about greater innovation
- Political leadership is increasingly recognizing economic development as key to reelection
- The government's direction is to sort out underlying issues in the country. Technology is playing a key role in these efforts

# Putting India on a brisk growth path

- India's GDP is set to quadruple over the next ten years and India is likely to be a Euro 3.4 trillion economy by the year 2020
- Per capita Income to triple: from present level of Euro 763 to Euro 2,410
- Annual incremental savings to go up 3.8 times: present Euro 317 billion to Euro 1,200 billion
- Domestic consumption expenditure set to triple: from Euro 500 billion to Euro 1,883 billion
- Infrastructure investment set to triple: from Euro 350 billion in XI plan to about Euro 1,033 billion
- Massive growth expected over several sectors
  - Life insurance sector: 4.7 times growth
  - Domestic Pharma & Healthcare: Six times growth

Note: Exchange rate used in the whole presentation: 1 Euro = 60 INR and USD 1 = 45 INR  
Source: India 2020, Seeing Beyond – Edelweiss Capital, March 2010

## **Biotech Strategy**

## Responsible use of life sciences and biotech to promote broad-based balanced growth of the society

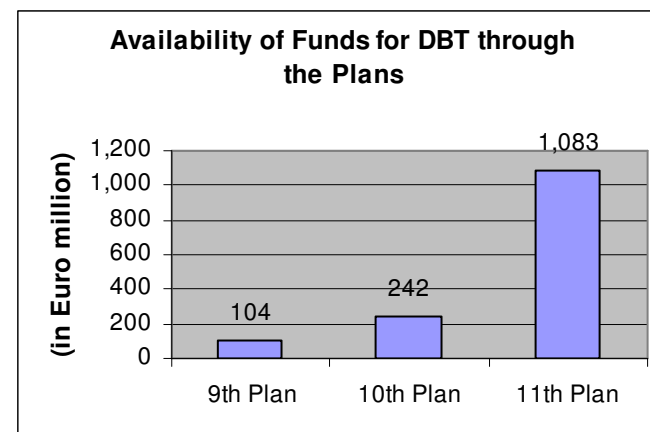
- Biotech is a **sunrise sector**; needs focused attention
- Enhance current **manufacturing** and **services** capabilities
- Lay a strong foundation for **discovery** and **innovation**
- Utilize **novel technology platforms** to benefit agriculture, animal productivity, human health, environmental security and sustainable industrial growth
- **Integrate** by connecting different disciplines and sectors to enhance synergy
- Create **infrastructure** around R&D, creation of investment capital, technology transfer, absorption and diffusion, IPR, regulatory issues, building public confidence, and tailor made human capital

## Regulatory framework

- A National Biotechnology Regulatory Authority (NBRA) - an independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes
- Responsible to regulate the research, manufacture, importation and use of genetically engineered organisms and products derived thereof

## Micro-infrastructure

- 30 percent of Department of Biotechnology's (DBT's) Budget to be spent on public-private partnership programs to promote innovation, pre-proof-of-concept research, accelerated technology and product development in biotechnologies related to agriculture, human health, animal productivity, biomanufacturing and environment
- Biotechnology Industry Partnership Programme (BIPP) to generate Intellectual Property Rights (IPR) in advanced technology areas such as agriculture, health, environment, bioenergy and biomanufacturing
- Expansion of the existing Small Business Innovation Research Industry (SBIRI) scheme to promote innovation in SMEs
- Biotechnology Industry Research Assistance Council (BIRAC) to act as an interface between academic and private sector, particularly SMEs and startups; nurture and catalyze R&D and innovation in biotechnology in the private sector and promote public-private partnerships



## Human Capital

- Star College status to life sciences and biotechnology colleges to achieve a unique and world class brand
- Revamping of existing university departments to combine both education and research, and address key research areas
- Attract young people in the industry, new initiatives such as expansion of doctoral and post doctoral programs, novel industry-oriented programs, fellowships at college level, regional training centers
- Encourage DBT's autonomous institutes to develop efficient and powerful R&D networks and partnership programs
- UNESCO Regional Center for Science, Education and Innovation in Biotech at Faridabad, Haryana, as part of a Health Science and Technology Cluster
- Innovative re-entry packages in terms of fellowships and R&D support to attract scientists to return to Indian laboratories
- Establish Centers of Excellence (CoEs) to support multi-disciplinary research efforts
- Build capacity in technology transfer and IPR to translate scientific leads into useful products

## Infrastructure for innovation

- Cluster development to promote synergy, innovation and accelerated technology and product development
- Promotion of infrastructure facilities/support systems such as GMP scale facilities, DNA and stem cell banking facilities, repositories of biologicals, etc.
- New institutions to be set up in critical areas such as translational research, stem cell engineering, agri-food biotech, animal and marine biotech, etc.

## Legislation

- New legislation around protection of IP, DNA profiling, stem cell research, etc.

## **Societal Needs**

- Emphasis on translational initiatives to promote mass use technologies in the areas of designer crops through genomics, novel foods, animal health and productivity, new generation vaccines, biodrugs, bioimplants, green manufacturing and other areas relevant to societal needs

## **Global Collaborations**

- International partnerships for joint IP generation, harmonization of regulatory processes, smooth trans-boundary movement of biological materials, and to access global markets

## **Integration**

- A high-powered Inter-ministerial Committee under the chairmanship of secretary, DBT, to effectively coordinate the development of the sector by addressing cross cutting issues

- Agricultural Biotechnology
- Bioresource Development and Utilization
- Medical Biotechnology
- Stem Cells
- Bioengineering & Devices
- Human genetics and Genome Analysis
- Environmental Biotechnology
- Nano-Sciences and Nano-Technology
- Energy Bio-Sciences

# The NBDS builds on India's comparative advantages



- Well defined biotech strategy and supporting programs by the Government
- Low cost operations
  - Cost of clinical trials 50 percent lower in phase I and 60 percent lower in phase II compared to global markets
  - R&D costs in India significantly lower
  - Cost effective manufacturing capabilities
- Numerous top-notch life science education and research institutes
  - However, the gap between industry and academia needs to be bridged
  - The Government recognizes this gap and there are initiatives to re-engineer the institutes
- Favorable IP climate
  - Adherence to the TRIPS agreement with regard to the Patent Protection Act implemented in 2005 has increased the confidence of innovator companies in India
- Presence of a well-defined and vibrant drugs and pharmaceutical industry
  - Significant growth potential in healthcare and pharma due to low penetration level and low per capita expenditure on drugs and healthcare
- Rich Biodiversity: India's human gene pools offer an exciting opportunity for genomics

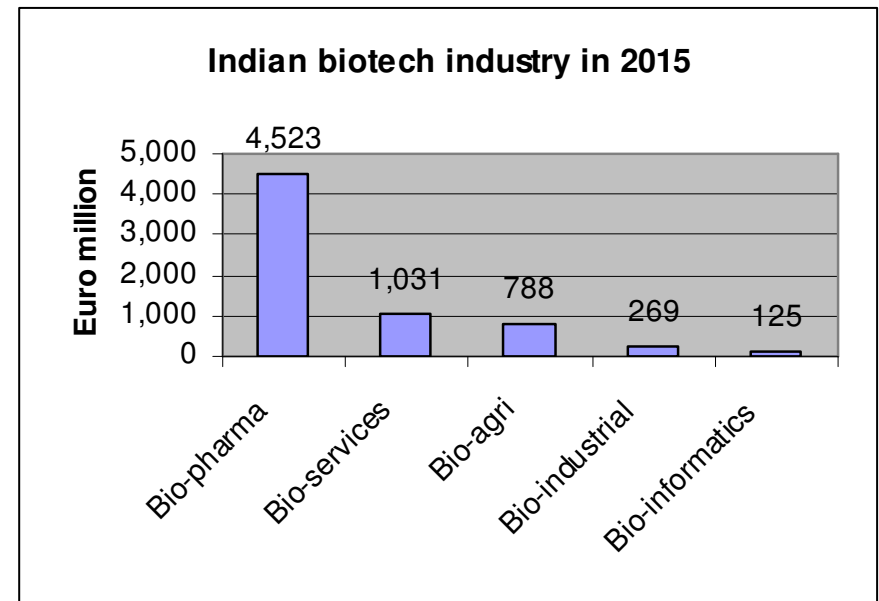
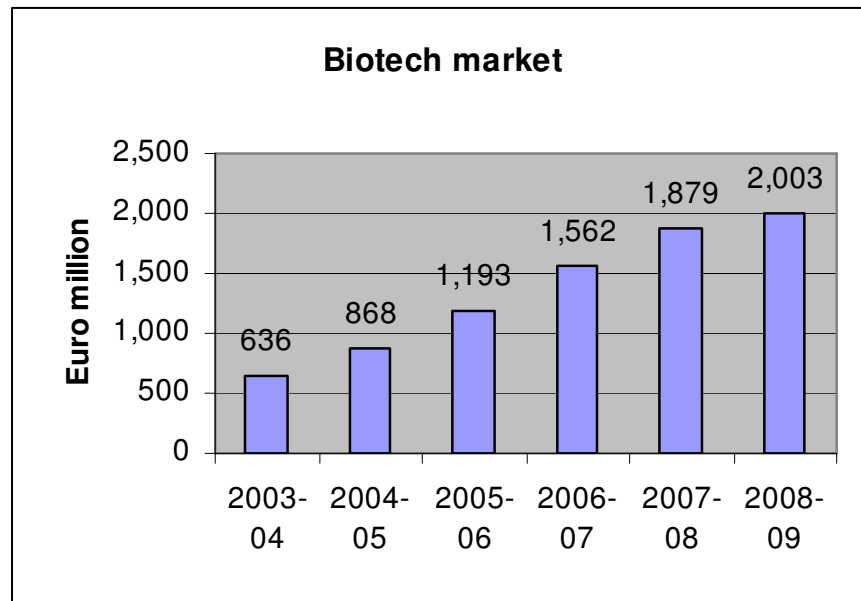
# Creating more opportunities..

- Vaccines
  - Estimated to reach Euro 15 billion market in 2012
  - Newer therapies – monoclonal antibodies products, stem cell therapies, etc.
- Bioactive Therapeutic Proteins
  - Production of proteins and antibodies and fabrication of diagnostic protein chips would be a promising area for investment
  - Stem cell research, cell engineering and cell based therapeutics
- Agriculture Sector
  - Hybrid seeds, including genetically modified seeds represent new business opportunities in India based on yield improvement
  - Development of a production base in biopesticides and biofertilisers
- Contract Research
  - Indian pharma companies possess competitive skills in chemical synthesis and process engineering, which they can leverage to develop new chemical entities, and with the application of bioinformatics tools, tap into the high-potential biogenerics segment.
- Clinical Trials and Outsourcing
  - India offers a suitable population for clinical trials because of its diverse gene pools covering a large number of diseases
- Bioinformatics
  - Data mining, mapping and DNA sequencing, besides functional genomics, proteomics and molecule design simulation in the Euro 1.5 billion world market for bioinformatics services

**Biotech Market**

# Market size and growth

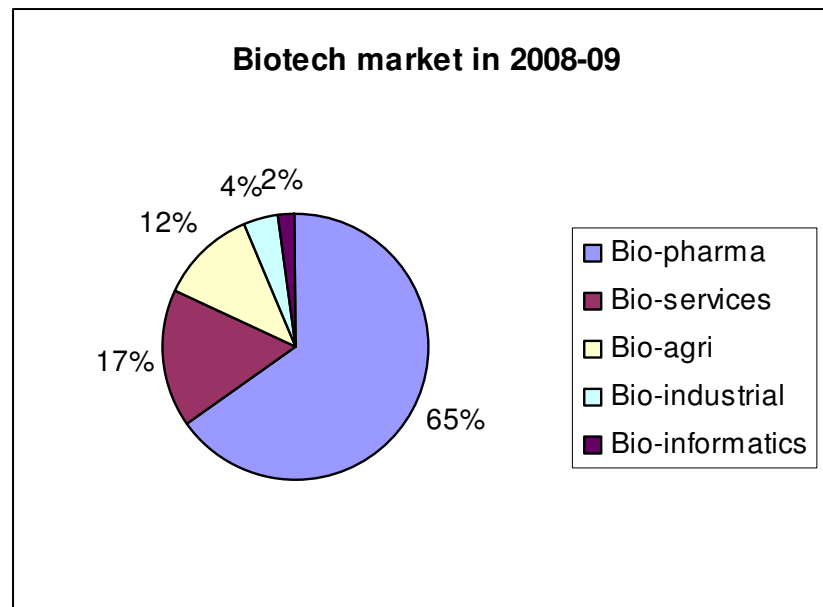
- The biotechnology industry in India earned revenues of Euro 2 billion in 2008-09, growing at 18 percent over the previous fiscal and 26 percent CAGR since 2003-04
- The Indian market is expected to touch Euro 3.75 billion by 2010 and Euro 18.75 billion by 2015, representing a CAGR of 45 percent
- India is among top 12 biotech markets globally, and ranks third in the Asia-Pacific region, after Japan and Korea
- India holds 2 per cent share of the global market
- India has joined an elite group of six countries which have successfully decoded the human genome indigenously



Source: Biospectrum Industry Survey, Jun 2009

# Market composition

- Exports accounted for nearly 60 per cent of the total business in 2008-09 and went up by almost 25 per cent. The domestic business registered a growth of 10 per cent in the same period
- In 2008-09, the biopharma sector accounted for a 65 per cent share of the total pie with revenues of Euro 1.3 billion
- The global clinical research outsourcing market is projected to touch Euro 17 billion by 2011 and India is expected to garner at least 15 per cent of this market
- The stem cell research is estimated to be growing at a compound annual growth of 15 per cent to cross Euro 338 million in 2010-11
- India's main bio-clusters are located in Bangalore, Hyderabad, Pune-Mumbai and Ahmedabad-Vadodara



Source: Biotechnology, September 2009, India Brand Equity Foundation, [www.ibef.org](http://www.ibef.org)

# Market segments

## Biopharma

- Top five players accounted for 40 percent of the biopharma market
- Serum Institute is the leading company with revenues of Euro 184 million in 2008-09
- Vaccine is the biggest segment in biopharma, followed by diagnostics and therapeutics
  - India is one of the largest producers of traditional vaccines
  - Human insulin is the largest contributor to the therapeutics market. Plasma proteins and Monoclonal Antibodies (mAbs) are emerging categories

## Bioservices

- Second largest contributor to the biotech industry
- Accounted for 27 percent of the exports in 2008-09
- More than 70 companies are involved in bioservices in India
- Syngene is the leading company with revenues of Euro 37 million in 2008-09

## Bioagri

- Top three companies – Rasi Seeds, Nuziveedu Seeds and Mahyco – accounted for 63 percent of the segment revenues in 2008-09
- Driven primarily by Bt cotton seeds
- About 38 GM crop products are being developed by both the public and private sector
- Biodiesel, biopesticides and biofertilizers are emerging areas

## Bioinformatics

- Over 75 percent of the segment revenue comes from exports
- Areas of opportunity include integrated research application services, database services and discovery software, and software requirements of the biotech industry
- Players include Strand Life Sciences, Ocimum Biosolutions, Molecular Connections etc.

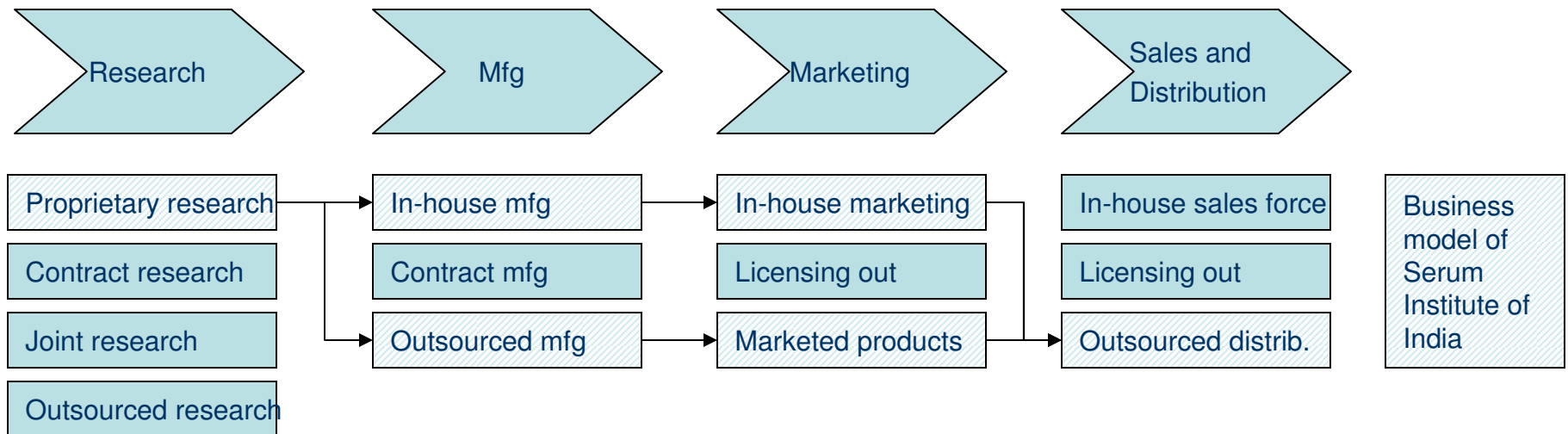
## Bioindustrials

- About 15 companies in India are involved in the enzymes business
- Top three bioindustrial companies accounted for 74 percent of the segment revenues in 2008-09
- New areas of application – food processing, animal nutrition, dairy, marine etc.

# Top companies by turnover in biotech

## Top biotech companies in India

Rank	Company	Revenue 2008-09 (in INR million)	Revenue 2008-09 (in Euro million)	Location	Sub-segment
1	Serum Institute of India	11,140	184	Mumbai	Biopharma
2	Biocon	9,120	151	Bangalore	Biopharma
3	Panacea Biotec	5,970	99	Delhi	Biopharma
4	Rasi Seeds	3,760	62	Attur, TN	Bioagri
5	Nuziveedu Seeds	3,640	60	Hyderabad	Bioagri
6	NovoNordisk	3,300	55	Bangalore	Biopharma
7	Siro Clinpharm	2,800	46	Mumbai	Bioservices
8	Novozymes South Asia	2,500	41	Bangalore	Bioindustrial
9	Shantha Biotech	2,470	41	Hyderabad	Biopharma
10	Jubilant	2,420	40	Noida	Biopharma, Bioservices and Bioagri
11	Bharat Biotech	2,340	39	Hyderabad	Biopharma
12	Indian Immunologicals	2,310	38	Hyderabad	Biopharma
13	Syngene International	2,250	37	Bangalore	Bioservices
14	Mahyco	2,110	35	Jalna	Bioagri
15	Eli Lilly	1,640	27	Gurgaon	Biopharma
16	Bharat Serums	1,400	23	Mumbai	Biopharma
17	Ocimum Biosolutions	1,130	19	Hyderabad	Bioinformatics



# Autonomous and public institutes - a rich source of opportunities

Institution	Type of Institution	Area of focus
National Center for Biological Sciences	Autonomous	Biochemistry, bioinformatics and genetics
Jawaharlal Nehru Institute for Advanced Scientific Research	Autonomous	Molecular and chemical biology and genetics
National Institute of Immunology	Autonomous	Immunology
Institute of Genomics & Integrative Biology	Autonomous	Genomics, genome informatics and proteomics
International Centre for Genetic Engineering and Biotechnology	Autonomous	Molecular biology and biotechnology
Centre for Cellular & Molecular Biology	Autonomous	Bioinformatics and genetics
Centre for DNA Fingerprinting & Diagnostics	Autonomous	Computational biology and bioinformatics
Central Drug Research Institute	Autonomous	Drug discovery and regulatory studies
Bharat Immunologicals and Biologicals Corporation Limited, Bulandshahar	Public	Immunology and biologicals
Indian Vaccines Corporation limited, Gurgaon	Public	Vaccines

# Current trends in the biotech industry

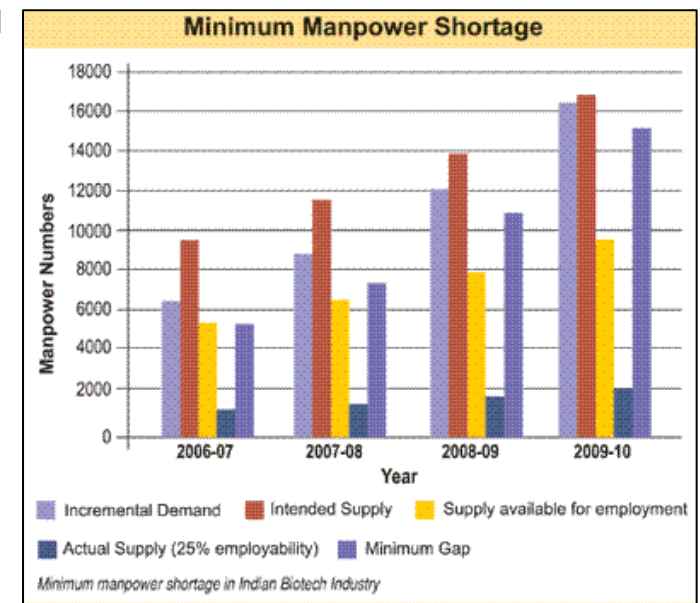


- More focus on strengthening confidentiality and IP protection
  - Patent applications can be submitted in four locations in India
- The industry is witnessing convergence between pharmaceutical and biotech companies
  - Sanofi's vaccine's division, Sanofi-Pasteur, paid Euro 550 million (INR 36 billion) for Shantha Biotech
  - Syngene has entered into a research partnership with international pharma player Bristol-Myers Squibb
- Foreign companies are increasingly making direct investments into Indian biotech
  - Avesthagen raised money from Europe's Groupe Danone, Groupe Limagrain, bioMerieux
  - Shantha Biotechnics received funds from its major French partner Merieux Alliance
  - Amgen has established a wholly owned subsidiary in Mumbai
- Indian companies are expanding facilities and capabilities to global standards
  - Biocon plans to set up a new plant worth Euro 87 million in Andhra Pradesh
  - Reliance Life Sciences (RLS) plans to invest Euro 164 million into four new facilities for clinical and generic products
- Emerging areas are stem cells and nanotechnology
  - DBT is setting up Centre for Stem Cell Research which has been approved by the Indian Council of Medical Research (ICMR) to conduct India's first ever multi-centric clinical trials with stem cells
  - Dabur Pharma developed the country's first indigenously developed nanotech-based chemotherapy agent
- There is interest from financial institutions in the biotech sector
  - Orbimed, the world's largest healthcare-dedicated investment firm with approximately Euro 3.8 billion in assets under management, invested an undisclosed sum in Bharat Serums in April 2010
  - OrbiMed also invested in Bangalore-based clinical research organisation Ecron Acunova, in December 2009

Source: Biotechnology, September 2009, India Brand Equity Foundation, [www.ibef.org](http://www.ibef.org)

# Current issues faced by the industry

- Lack of skilled people in the industry
  - 15,000 students graduated from 400 biotechnology colleges in 2009. However, the average employability of these graduating students is only 22-25 percent
  - Lack of practical knowledge and hands-on experience at educational institutions
  - On an average, more than 40% of the students prefer to study abroad for higher degrees and specialization
- Limited access to vital technologies
  - Scientists have inadequate access to high-end platform technologies
  - They have difficulties accessing information and participating in knowledge network
  - Indian universities are not well-equipped with proper research infrastructure
- Underdeveloped innovation ecosystem
  - Innovative solutions developed in research labs are not rapidly applied
  - Goals of research institutes should be aligned with the industry
  - Incubators and innovation centers should be set up to help entrepreneurs develop their projects
- Shortage of seed funding
  - Time and capital intensive industry
  - India has many late stage funds but there is a gap in startup funding
- Entrepreneurship
  - The number of entrepreneurs in the biotech sector remains small
  - Lack of funding mainly at early stages is a major hurdle
- Regulatory inefficiencies



Source: Biospectrum, Mar 2010, [www.biospectrumindia.ciol.com](http://www.biospectrumindia.ciol.com)

# Biologics companies

- Company 'A'
  - Fully integrated Biologics manufacturing company with a strong R&D team and Lab
  - Market leaders in the first generation biologic products like erythropoetins and filgrastim
  - Moving in to mAbs (biosimilars) – process development, contract manufacturing and marketing
  - Possible Structure: Strategic alliance
- Company 'B'
  - Company with an established name in the contract manufacturing of pharmaceutical formulations.
  - With elite domestic and international client base
  - Starting the contract manufacturing in Biologics for clinical trials batch with the help of a well known European biologics manufacturer
  - Separate facility for mammalian and bacterial cell lines
  - Possible Structure: Strategic Alliance

# Stem cell therapy company

Halcyon 

- The company, till January '10, has done approx. 350 infusions for stem cell therapy
- They are the leaders in the CNS related disorders and have done record number of Cerebral Palsy patients
- The company currently has tied up with 12 hospitals giving them access to 3150 beds, based on the success rates with the patients till now the company has established a level of credibility for itself with the physicians
- The company is in the process of tying up with a renowned Italian cord blood bank
- The company is entering in to the cosmeceuticals market for which they are in the process of acquiring a product based technology for the skin cell regeneration
- This will be the first company in India to develop a therapy for Mascular Dystrophy for which they have already enrolled 35 patients and the treatment has already begun over two patients
- Possible structure: Strategic alliance with divestment of stake

Source: SBI Capital Markets Ltd.

# Companies developing NCEs

- Company 'A'
  - A drug discovery and innovation company managed by well experienced and skilled people with a vast experience in Innovation
  - Focuses on targeting well characterized pharmacological pathways and then rationally design the drug to find better medicines in chronic disease areas
  - The company has internal expertise & integrated resources from drug design to Phase IIA/POC clinical development
  - Possible structure: Strategic alliance in R&D
- Company 'B'
  - A full service formulation Research and Development service company
  - Focuses on reducing the cost of process and product development
  - The company designs and develop effective and innovative formulation solutions and provide complete regulatory and technical support in order to bring pharmaceutical products to the global market place faster and in a cost effective manner
  - Possible Structure: Strategic Alliance in Process/Product development

# Companies in CRAM business



- Company A
  - An integrated Pharmaceutical and Life Sciences Solution Provider offering products & services to its customers across the globe
  - The Pharma and Life Sciences business is the major building block of the Company consisting of CRAMS, Pharmaceutical Products, Life Sciences Chemicals , Nutritional Ingredients and Healthcare. Besides, they are also in agri-products
  - The Company's strategic focus is to innovate, collaborate and accelerate the process of delivering products to the market for its customers
  - Possible Structure: Contract Research and Manufacturing, Process Development
- Company B
  - Research based Formulations and APIs manufacturing company
  - Can carry out difficult chemistries and work on the niche and complex molecules
  - Involved in Formulations and Process research, Advanced and Novel Drug Delivery Systems
  - Have developed a biotechnology center as well
  - Possible Structure: Strategic alliance in Contract Manufacturing and Research and Development

Source: SBI Capital Markets Ltd.

# Vaccine companies

- Company 'A'
  - Involved in research, manufacturing and marketing of branded pharmaceutical formulations, vaccines and natural products
  - The company supply vaccines to the WHO and the UNICEF
  - The focus areas for research are in NCE (New Chemical Entities), NBEs (New Biological Entities), Novel Drug Delivery System (NDDS) based pharmaceutical formulations, Novel peptides & human monoclonal antibodies and Vaccine development
  - Possible Structure: Strategic Alliance
- Company 'B'
  - One of the largest vaccine manufacturers of India.
  - They have widespread global reach
  - They supply vaccines to the organizations like WHO, UNICEF, PAHO
  - Huge manufacturing capacities compliant to WHO cGMP
  - Possible Structure: Strategic Alliance

## Regulatory Framework and Other Infrastructure

- Stem cell research worldwide often is a hot-button triggering furious protests, whereas in India perhaps a Hindu-influenced worldview pervades scientific progress and everyday discourse
- Hindu mythology and religion is full of life forms with superior strengths that combine human and animals
  - Ganesha, elephant head and a human torso - a God of good beginnings
  - Narasimha, half man and half lion - a God created to destroy humanly indestructible evil
- The Indian Council of Medical Research's (ICMR) "Ethical guidelines for biomedical research on human participants" requires research using human beings to be for
  - The PURPOSE of increasing knowledge about human condition in relation to its social and natural environment
  - Is CONDUCTED under conditions that no person or persons become mere means for the betterment of others and that human beings who are subject to any medical research or scientific experimentation are dealt with in a manner conducive to and consistent with their dignity and well being
  - Such research be subjected to a regime of EVALUATION at all stages of the proposal i.e., research design and experimentation, declaration of results and use of the results thereof

# Key enactments, regulations and guidelines



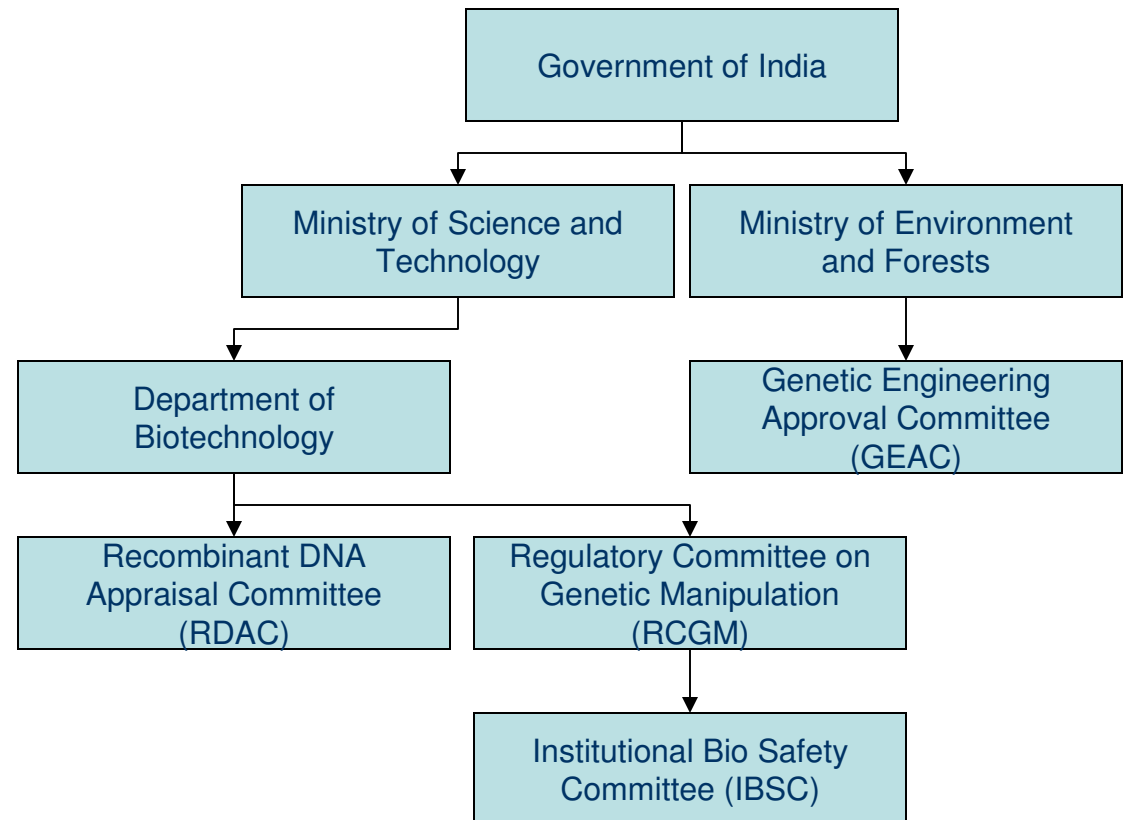
- DBT Guidelines cover the entire spectrum of activities relating to genetic modification
  - This includes research involving genetically modified organisms, genetic transformations of green plants, rDNA technology in vaccine development, and large-scale production and deliberate/accidental release into the environment of organisms, plants, animals and products derived from rDNA technology
- Guidelines for Research in Transgenic Plants & Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts
  - Adds to the regulatory architecture by calling for toxicity and allergenicity data for ruminants, such as goats and cows, from consumption of transgenic plants
- Guidelines for Generating Preclinical and Clinical Data for rDNA Therapeutics
  - The guidelines specifically are on safety, purity, potency and effectiveness of the product
- Rules for the manufacture, use, import, export and storage of hazardous micro organisms, genetically engineered organisms or cells; notified by Ministry of Environment & Forests under Environment and Protection Act
  - Applicable to any substances, products and food stuffs, etc. of which genetically engineering organisms, micro-organisms or cells hereof form part
- The Bio-Medical Waste (Management and Handling) Rules
  - The concerned Biotechnology company or person involved in research work to take all the necessary steps to ensure that the Biotechnology waste is handled without any adverse effects to human health and the environment.

# Proposed new regulations

- The Protection and Utilization of Public Funded Intellectual Property Bill, 2008
  - Innovations in universities, academic and research institutions have not been reaching the industry because of lack of appropriate legal framework in these organizations for commercialization and procedural complexities in technology transfer and absorption
  - To provide a uniform legal framework for protection and utilization of the IP generated out of public funded R&D
  - The bill would streamline the industry-academia link, by granting the title in such inventions produced via public funding to the organizations that have undertaken it, with a particular entitlement (of 30% of the revenue that accrues from working the patent) to the researcher involved in the development of the patent
- DNA Profiling Bill
  - To regulate the use of DNA profiles for lawful purposes
  - Establish standards for laboratories, staff qualifications, training, proficiency testing, collection of body substances, custody trail from collection to reporting and a Data Bank with policies of use and access to information, its retention and deletion
- The proposed Biotech Regulatory Authority of India (BRAI) bill is being discussed in the parliament. However, there are concerns about the following issues:
  - Only a three-member regulator
  - No participation of state governments, stakeholders (farmers & consumers groups) or public interest groups
  - The Central government is allowed to give directions to the regulatory authority, allowing it to interfere with matters that are scientific and technical in nature
  - No clear provision for revocation of approval to prevent harm to public or environment

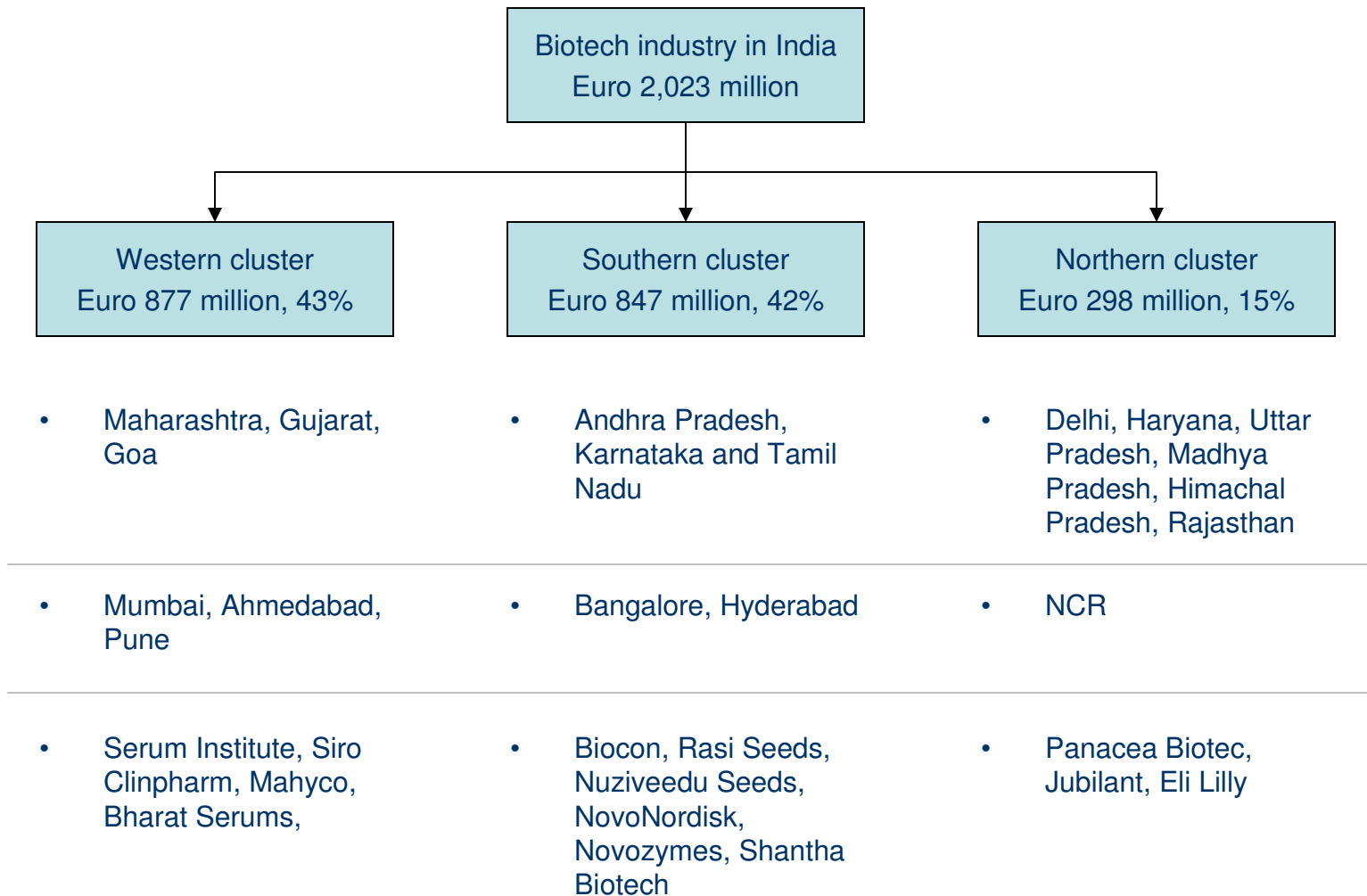
# Current regulatory structure

- Every institution in India engaged in research involving genetic engineering and production of genetically engineered products to constitute an IBSC
- Following an approval from IBSC, RCGM monitors the safety aspects of ongoing projects involving genetic engineering
- Once RCGM have reviewed field trials, it is brought to GEAC. GEAC authorizes large-scale production and commercial use (including import) of transgenic material post field trials
- In addition to the bodies under central government, there are state level bodies as well
  - State Biotechnology Coordination Committee (SBCC)
  - District Level Coordination Committee (DLCC)
- BRAI is supposed to replace GEAC



- Biotechnology Industry Research Assistance Council (BIRAC): As an interim measure, a pilot biotechnology industry R&D assistance program, has been approved by the government which would facilitate and promote industrial research through technology transfer and IP management, technology acquisition and technology forecasting
- DBT announced a jointly-funded Biomedical Research Career Program with Wellcome Trust UK to fund cutting-edge biomedical research in India in September 2008. The £80m scheme, jointly funded by DBT and the Wellcome Trust over five years, aims to strengthen the research base of Indian biomedical science by providing fellowship programs to support researchers from newly-qualified postdocs through to senior researchers
- The Government approved launching of Biotechnology Industry Partnership Program (BIPP) - An Advanced Technology Scheme (ATS), envisaged as a government partnership program with industries for support on cost sharing basis for high risk discovery and innovation, accelerated technology development specially for futuristic areas

# Biotech clusters of India



## Objectives

- To facilitate product advancement and innovation through the development of a biotechnology industrial cluster
- To produce biotechnologists and entrepreneurs who have a strong foundation in research and innovation

## Functional parks

- Biotechnology Incubation Centre at Shapoorji Pallonji Park by the Indian Institute of Chemical Technology, Hyderabad
  - Investment of Euro 115 million. Has 33 companies
- Biotechnology Park, Lucknow
  - Healthcare, Agriculture, Environment, Industry application and Energy
  - Marker-based screening tools, clinical research and other service providers, Agri-biotech products, Liposomal products etc.
- Golden Jubilee Biotechnology Park for Women, Chennai, Tamil Nadu
  - Production units include herbal cosmetics, biofertilizers & biopesticides, spice-powders fortified with herbs & greens and essential oil etc
- TIDCO Centre for Life Sciences (TICEL) Bio Park, Chennai, Tamil Nadu
  - In technical collaboration with Cornell University, USA
  - Pharma R&D, Medical Biotechnology, Ophthalmology R&D and Bioinformatics

## Parks under planning stage

- Biotechnology Park, Mohali
- Business Incubation Centre at University of Agricultural Sciences, Bangalore
- Biotechnology Park, Guwahati
- Nano Biosym Technology Park, Himachal Pradesh
- Marine Biotech Park at Ahmedabad
- Biotechnology Park, Kerala
- Biotechnology Park, Karnataka
- Biotechnology Park, Orissa

## Objectives

- To enable area-based research and capturing leads of R&D for translation into usable products

## Clusters

- Health Biotech Science Cluster, Faridabad (NCR)
  - Create core technology resources using an innovative and efficient management structure allowing effective cluster-wide access to technologies such as containment facilities for biohazardous work, engineered laboratory animal resources, high-end imaging, large data-sets on proteomics, genomics and metabolomics; large bio-library and high throughput screening resources
- Agri-food Biotechnology Cluster, Mohali, Punjab
  - To promote translational research in the area of Agri-Food processing
  - Constituents include National Agri-Food Biotechnology Institute (NABI), Bio-Processing Unit (BPU) and Agri-Food Biotech Park & Incubator
- Bangalore Biotech Cluster, Bangalore
  - Developed around National Centre for Biological Sciences (NCBS)
  - An Institute for Stem Cell Biology and Regenerative Medicine-the Stem Cell Institute (SCI) is being established by DBT
  - NCBS and SCI are creating the Centre for Cellular and Molecular Platforms to provide core resources

## Foreign Investment – Financing and Taxation

- The government recently released a consolidated Circular on the FDI policy and an annual review document - these documents serve as valuable reckoners on the FDI policy of the Government
- 100% FDI is permitted under the automatic route in the biotech sector, including in cases that involve the use of recombinant technology
- The Government has recently removed the limits for payments of royalties and brand/trademark license fees
- The Biotech sector enjoys preferential treatment while setting up Special Economic Zones – the minimum land size is only 25 acres
- The introduction of Limited Liability Partnerships (LLPs) provide a tax effective option to carry on business in India – the guidelines on foreign investment in LLPs are awaited

- Fiscal incentives
  - The government is committed to the introduction of Goods and Services Tax (GST) from April 1, 2011 – this will eliminate inconsistencies in classification of activities and streamline credits of taxes paid
  - The introduction of the new Direct Tax Code (“DTC”) is expected from April 1, 2011 – the rate of corporate tax will be reduced to 25%, which will be amongst the lowest in the world
  - India has a very wide network of Tax Treaties and the rate of withholding on royalties and fees for services under the domestic law is itself a low 10% - this facilitates in-licensing kind of arrangements with minimal tax implications
  - Contract Research currently enjoys a 100% income-tax holiday under the SEZ scheme – it is widely expected that this will continue under the DTC as well
  - Single window processing mechanism for all mega-biotech projects involving FDI of Euro 16.5 million or more
  
- Changes in Budget 2010-11
  - Reiterating its commitment to R&D, the recent Union Budget has increased the weighted deduction from 150% to 200% on expenditure incurred on in-house R&D facilities
  - Excise duty on bulk drugs to rise from 8% to 10%
  - MAT hiked from 15% to 18%
  - Concessional basic duty of five percent, countervailing duty (CVD) of four percent and zero special additional duty on medical equipment
  - Service tax exemption on testing and certification of seeds
  - Tax incentives for the business of setting up and operating “Cold Chain” infrastructure, which is an integral part in the logistics for vaccines and many biotech products

# Investment structuring - tax considerations

- Tax considerations in Mauritius
  - The fund will be liable to tax in Mauritius on its taxable income at the rate of 15 percent
  - In computing the taxable income, credit is allowed for taxes that the fund's income has suffered in other jurisdictions, including underlying taxes where the fund owns at least 5 percent of the shares of a Portfolio Company's equity
  - A deemed credit computed at 80 percent of the applicable Mauritius tax is granted, where actual foreign tax credits are lower than 80 percent of the applicable Mauritius tax
  - Capital gains realized by the fund, distributions (including redemption) by the fund to investors are not liable to tax in Mauritius under the Mauritius income tax regulations
- Tax considerations in India
  - Dividends received by the fund from an Indian portfolio company would be exempt from tax in India. However, Indian portfolio companies would be required to pay Dividend Distribution Tax
  - Interest received by the fund would be taxed at a rate depending on the denomination and convertibility of the debt
  - Profits from sale of realized investments can be treated as business income or capital gains depending on whether the fund is regarded as an investor or trader in securities
  - Taxes on capital gains depend on the duration for which the corresponding investment was held prior to its sale, and the manner in which the sale is effected

- Domestic financing
  - Government grants/loans
  - Banks
  - Angel, venture capital and private equity investors
  - Capital markets
  - Strategic investors
  
- Foreign financing
  - Angel, venture capital and private equity investors
  - Strategic investors

## Case Studies

## Background

- Founded in 1966 with the aim of manufacturing life-saving immuno-biologicals
- The world's largest producer of Measles and DTP group of vaccines
- Products used in 140 countries across the globe
- Manufacturing and sale (including export) of bacterial, viral and combination vaccines; and anti-cancer, anti-sera, hormonal products
- Marketing of hormonal and other pharma products
- Key proposition is to manufacture life-saving biologicals at affordable prices and in abundance

## Infrastructure

- Conform to WHO current Good Manufacturing Practice (cGMP) requirements
- State of the art EDP system, which controls and provides instant information on every aspect of Production and Quality Control
- 64 FDA approved Production experts and 45 FDA approved Testing experts

## Financials

- Grew from Euro 84 million in 2004-05 to Euro 186 million in 2008-09 at a CAGR of 22%
- EBITDA and PAT margin of 43 and 35 percent respectively

## Deals

- Acquired shares worth Euro 1.2 million in Orchid Chemicals and Pharmaceuticals, in Sep 2009
- Acquired one million shares of US based pharma and contract manufacturing company, Akorn Inc, for Euro 2.67 million in Sep 2006
- Picked up 12 percent stake in UK based biopharma company, Lipoxen, for Euro 2.95 million in Aug 2006

## Initiatives

- Serum Bio Pharma Park, India's first biotech Special Economic Zone (SEZ)
  - Sector-specific SEZ meant for biotechnology and pharmaceutical products
  - Various tax benefits such as income tax, import duty on capital goods etc. have encouraged a lot of foreign companies to partner with Serum Institute of India

## Background

- Founded in 1978 as an enzyme-manufacturing company and turned into a fully integrated biopharmaceutical enterprise over time
- Businesses in
  - Custom research (Syngene) - from target identification and validation to small molecule and library synthesis
  - Clinical development (Clinigene) - specializes in Phase I-IV clinical trials and studies
  - Biopharmaceuticals (Biocon) - commercialization of Insulin, Immuno-ssuppressants and a range of Biogenerics
- Focusing on unmet medical needs in cancer, diabetes and inflammatory diseases

## Infrastructure

- Biocon-Bristol Myers Squibb Research Center
- Laboratory Animal Research Center
- Chemical and Biological Pilot Plant Facility – cGMP compliant

## Financials

- Grew from Euro 110 million in 2004-05 to Euro 152 million in 2008-09 at a CAGR of 8%
- EBITDA and PAT margin of 20 and 14 percent respectively
- Trading at P/E of 30, as against industry P/E of 27

## Deals

- Biocon entered into a definitive agreement to buy the bulk pharmaceutical business of the Hindujas-owned IDL Specialty Chemicals Ltd, Hyderabad in Oct 2009
- Biocon acquired 70 per cent stake in Germany-based pharmaceutical distribution company AxiCorp for Euro 29 million in Feb 2008. Axicorp is a marketing and distribution company addressing the generics market in the European Union with a heavy focus on Germany

## Initiatives

- Euro 150 million Special Economic Zone (SEZ), Biocon Park – Asia-Pacific's largest integrated biotech hub

## Your local contact – Raj Kaul, RK Associates, Dusseldorf, NRW

Halcyon

Raj Kaul, founder of RK Associates, Dusseldorf started with Bayer Crop Science, India in 1983 as Executive Director Ag Business. In 1989 he moved to Bayer AG to head the global M&A activities for Crop Science. During this period he executed approximately 200 transactions including Joint Ventures, Licensing, Research Agreements, Acquisitions and Divestments etc in the areas of Ag Chem, Biotech, Seeds, Animal Health etc.

Raj was a member of the board of Bayer India up to 2008. He was a member of the Investment Committee of Burrill & Co's Biotech VC Fund, during which the IC evaluated approximately 350 proposals and approved 35 investments totaling USD 110 million in early stage situations. He was on the panel of advisors to the Expert Committee for Development of Research established by the Ministry of Agriculture, Peoples Republic of China. He was an Advisor to SDS Biotech, Japan, a company focused in Ag business.

He currently sits on the board of several companies including PI Industries Limited, an Agri Input and Contract Research company in India. He continues to be an advisor to Bayer Crop Science, and in this role is extensively involved in some of Bayer's Indian forays amongst other things.

RK Associates provides Business Advisory and M&A services in his areas of expertise, Ag Chem, Biotech and Seeds. To date RK Associates under the Patronage of Dr Jochen Wulff, former Chariman Bayer Crop Science has completed 4 assignments with Indian and global players. RK Associates works closely with Halcyon and also has technical experts to assist on specific subjects.

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**Thank You**

<http://www.halcyongrp.com>

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