

# Biotechnology

NOVEMBER  
2011



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- ❖ Advantage India
- ❖ Market overview and trends
- ❖ Growth drivers
- ❖ Success stories: Biocon
- ❖ Opportunities
- ❖ Useful information

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## Advantage India

### Demand potential

- India's billion-plus population base offers a huge market for biotech products and services
- Increasing economic prosperity fuels demand for healthcare services

### Innovation opportunities

- Public funding for product innovation and research in the biotech sector
- Focused R&D activities by private biotech firms

FY17F

Market size:  
USD11.6  
billion

### Advantage India

### Increasing investments

- FDI investment up to 100 per cent is permitted via the automatic route
- A low cost and skilled labour force is attracting outsourced research activity

### Policy support

- The sector has experienced significant growth in government spending since 1985
- Increasing budgetary allocations to the biotech sector

FY11

Market size:  
USD3.6  
billion

Source: Association of Biotechnology Led Enterprises (ABLE),  
Global Industry Analysts report (GIA), Aranca Research  
Notes : 2017F : Forecast for 2017

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## Major milestones in Indian biotechnology industry

1978-1990

- 1978: India's first biotech firm, Biocon, was setup
- 1981: Centre for Cellular and Molecular Biology was setup in Hyderabad
- 1984: Institute for Microbial Technology, Chandigarh was setup
- 1986: Department of Biotechnology (DBT) was formed
- 1987: National Institute of Immunology was setup by DBT
- 1989: Bangalore Genei commenced operations

1990-1999

- 1991: National Centre for Biological Sciences pursues R&D in molecular biology
- 1994: Syngene, India's first Contract Research Organisation(CRO), starts its R&D services
- 1997: Centre for Biological Technology (CBT) was established to focus on bioinformatics and genomics
- 1998: Monsanto Research established an R&D centre for plant genomics
- 1998: DBT approves Mahyco-Monsanto to grow Bt cotton

Post 2000

- 2000: India's first bioinformatics company, Standard Genomics, formed
- 2001: The drug authority implements Good Clinical Practice (GCP) guidelines for clinical trials
- 2002: Genetic Engineering Approval Committee (GEAC) approves Bt cotton for commercial planting
- 2007: National Biotechnology Development Strategy launched
- 2009: National Biotechnology Regulatory Authority Bill 2008 to be introduced in parliament

Source: EXIM bank of India research, Aranca Research  
Notes: R&D- Research and Development

## Key segments in the Indian biotechnology industry

Biotechnology

Bio-pharma

Bio-pharmaceutical products are therapeutic or preventative medicines that are derived from materials naturally present in living organisms, using recombinant DNA (rDNA) technology

Bio-services

Bio-services mainly include clinical research and CRO along with custom manufacturing

Bio-agri

Bio-agriculture is segmented into hybrid seeds, transgenic crops, bio-pesticides and bio-fertilizers

Bio-industrial

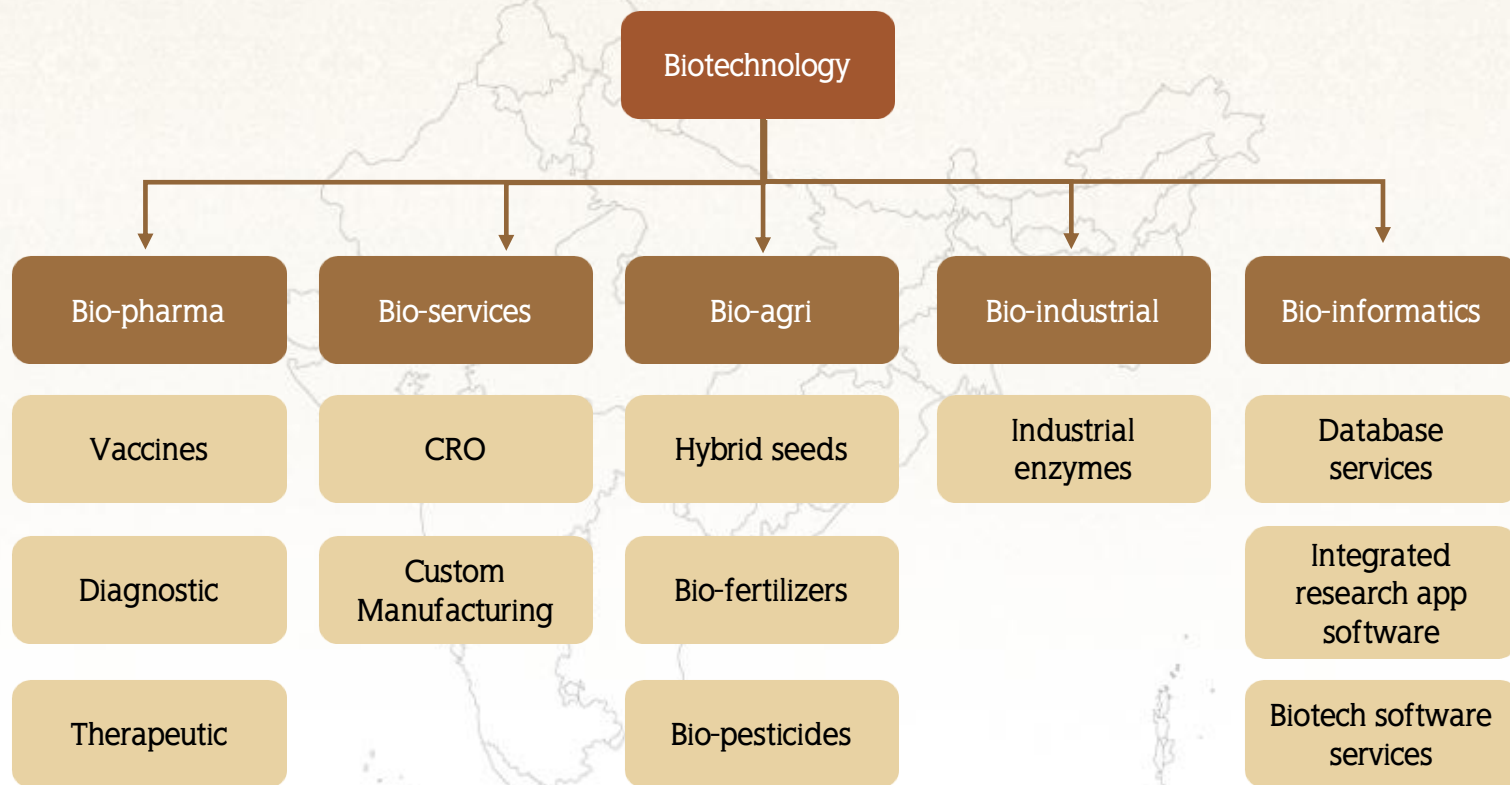
Bio-industrial predominantly comprises enzyme manufacturing and marketing companies

Bio-informatics

Bio-informatics deals with the creation and maintenance of extensive electronic databases on various biological systems; it is the smallest part of the current domestic biotechnology industry

*Source: ABLE-Biospectrum industry survey, June 2011; Aranca Research*

## Major products/services of the Indian biotechnology industry



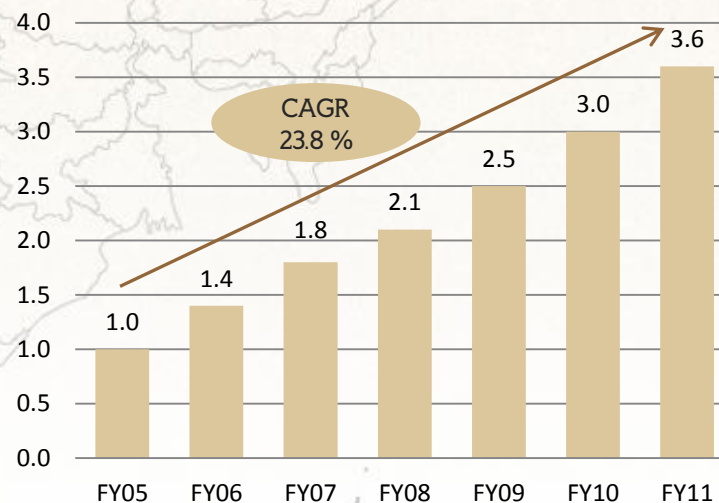
Sources: ABLE-Biospectrum Industry Survey, June 2011;  
Aranca Research

## Robust growth in the biotech industry ... (1/2)

- In FY11, the industry recorded revenues worth USD3.6 billion, registering a y-o-y growth of 20 per cent over FY10
- The industry is expected to grow significantly to USD11.6 billion by 2017, driven by various government initiatives

Source: Global Industry Analysts report (GIA)

Market size over the past few years in USD billion

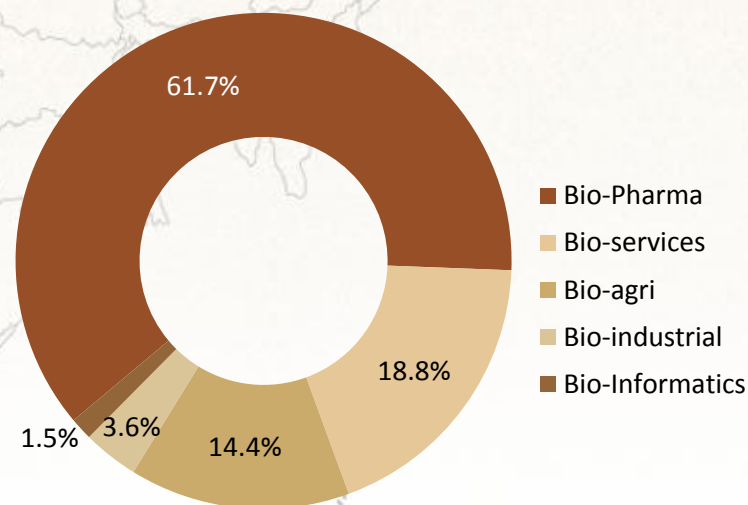


Source: ABLE-Biospectrum industry survey, June 2011, Aranca Research  
Notes: CAGR- Compound Annual Growth Rate

## Robust growth in the biotech industry ... (2/2)

- The bio-pharmaceutical sector accounted for the largest chunk of the biotech industry, with a share of 61.7 per cent in total revenues
- Bio-services and the bio-agri segments followed the bio-pharmaceutical segment with a share of 18.8 per cent and 14.4 per cent respectively, in FY11

Market break-up by revenues (FY11)

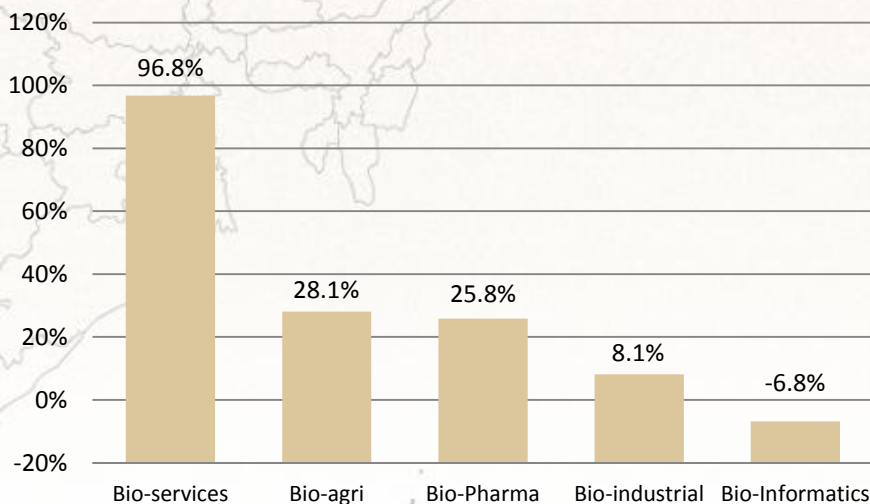


Source: ABLE-Biospectrum industry survey, June 2011, Aranca Research

... driven by both domestic and export markets ... (1/2)

- Domestic bio-services sector record a growth of 96.8 per cent in FY11 followed by bio-agri (28.1 per cent) and bio-pharma (25.8 per cent), respectively

Domestic business growth of biotech industry (FY11)

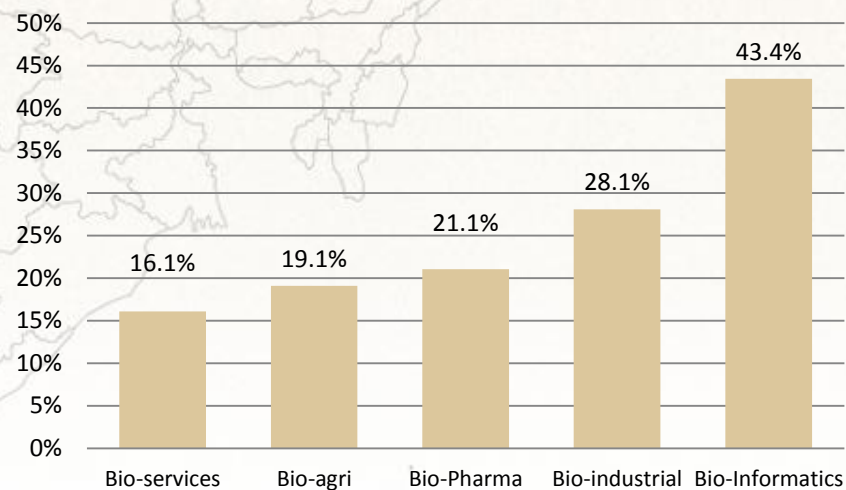


Source: ABLE-Biospectrum industry survey, June 2011, Aranca Research

## ... driven by both domestic and export markets ... (2/2)

- Bio-informatics export revenue recorded a growth of 43.4 per cent in FY11 followed by bio-industrial (28.1 per cent) and bio-pharma (21.1 per cent), respectively

Export business growth of biotech industry (FY11)

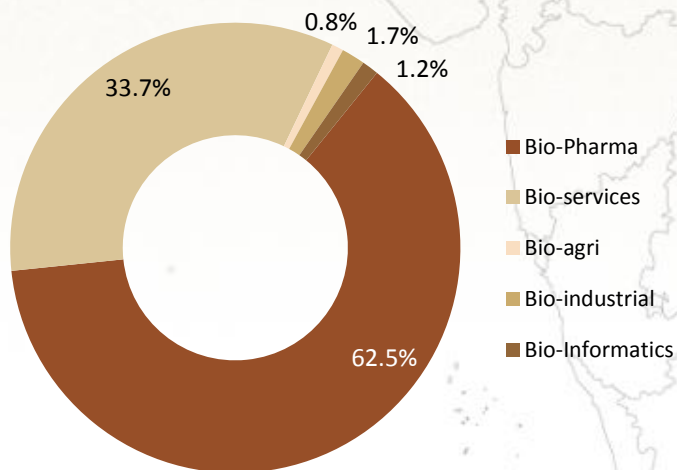


Source: ABLE-Biospectrum industry survey, June 2011, Aranca Research

## Bio-pharma leads the export earning business

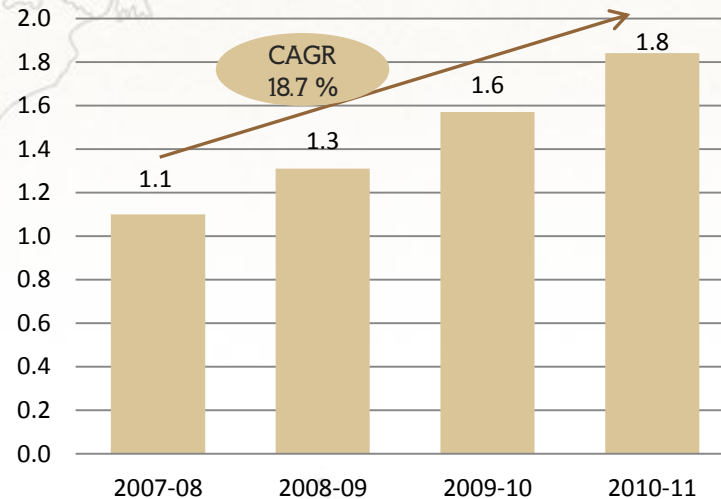
- Revenues from biotech exports were valued at USD1.8 billion in 2010–11, constituting 52 per cent of the biotech industry's revenue
- Export revenue from biotech grew by compound annual rate of 18.7 per cent over 2007-10
- Bio-pharma contributes maximum to export earning followed by bio-services

Export share among major sub sectors (FY11)



Source: ABLE-Biospectrum industry survey, June 2011, Aranca Research

Exports of biotechnology products (FY11): USD billion













Source: ABLE-Biospectrum industry survey, June 2011, Aranca Research

The Indian biotech industry is fairly competitive

Top 20 companies accounted for 52 per cent of industry revenues in FY11

### Top 10 players in the Indian biotech industry

Company	Revenue (USD million) FY11	Company	Revenue (USD million) FY11
Biocon 	309.0	Quintiles 	99.2
Serum Institute of India 	216.9	NovoNordisk 	96.3
Panacea Biotec 	193.4	Rasi seeds 	77.5
Nuziveedu Seeds 	127.1	Mahyco 	76.0
Reliance Life sciences 	102.1	Transasia 	72.9

Source: ABLE-Biospectrum industry survey, June 2011, Aranca Research

## Notable trends in the Indian biotech sector

### Remarkable global positioning

- India is amongst the top 12 biotech destinations in the world
- India ranks second in Asia, after China
- India is the largest producer of recombinant Hepatitis B vaccine in the world

### Pharma companies are focusing on biotech

- Ranbaxy, Cadila Healthcare, Lupin, Wockhardt and Dr Reddy's are among the major Indian pharmaceutical companies that operate in the bio-pharma segment

### Global companies setting up base

- Lonza, the global leader in the production and support of pharmaceutical and biotech products, is planning to set up a manufacturing base in India at an investment of USD150 million in Hyderabad. The investment outlay has been planned over two phases:
  - Phase I (from 2011 to 2013) would include the development of R&D labs for more than 100 resources
  - Phase II (from 2014 to 2015) would include the expansion of manufacturing capabilities and the provision for increasing R&D lab capacity for biologics with 200 additional resources

*Source:* Aranca Research, Indian Law Offices

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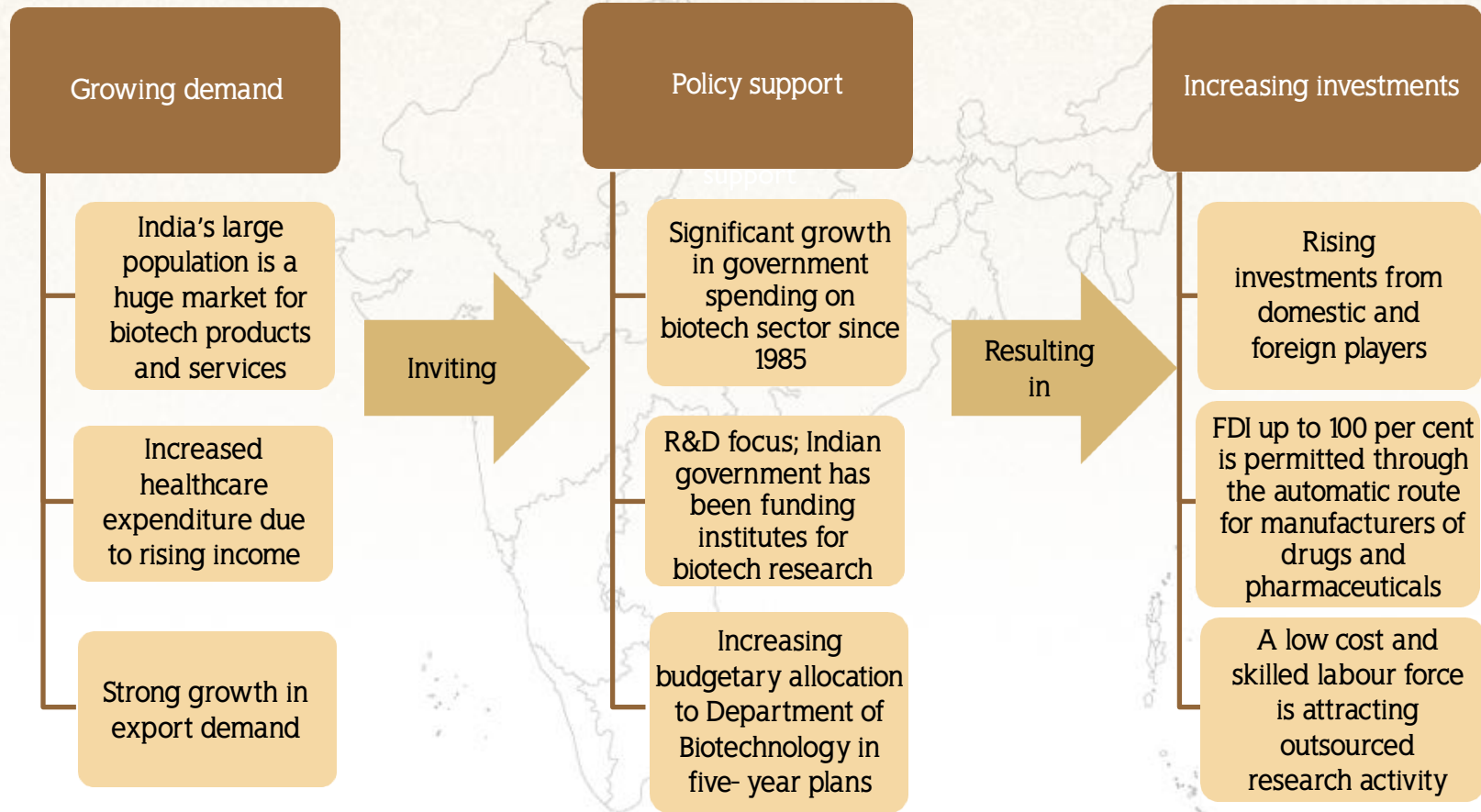
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## Sector benefits from both rising income and population

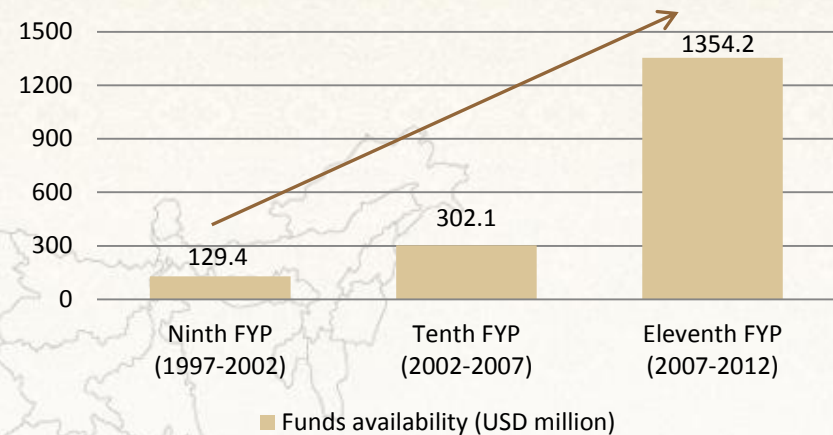


Source: Aranca Research

## Increased healthcare expenditure driving domestic demand

### Exponential growth in government funding

- Healthcare expenditure, as a percentage of GDP, was recorded at 4.2 per cent in 2008, with public and private contributions at 1.4 per cent and 2.8 per cent respectively
- During 2007–10, the percentage of allocated resources utilised by DBT was 94.5 per cent



Source: Mid term appraisal, Eleventh Five Year Plan, National Biotechnology development strategy, DBT, Aranca Research

Notes: FYP – Five Year Plan

### Specialised treatment

- The disease profile that inflicts the Indian population has experienced a gradual shift. The number of lifestyle-related diseases being reported is rising; this has led to demand for various kinds of specialised treatments
- Ailments such as cancer and diabetes have boosted demand for biological products

### Preventive healthcare

- Around 1.2 billion ailments are reported annually, and this number is expected to rise by at a CAGR of 30 per cent to reach 15 billion cases by 2015. Better access to healthcare facilities and rising lifestyle diseases are driving this trend
- Population growth have elevated the vaccine demand for the geriatric and paediatric population

Source: WHO Statistics 2011

## Rising income and incidence of chronic diseases

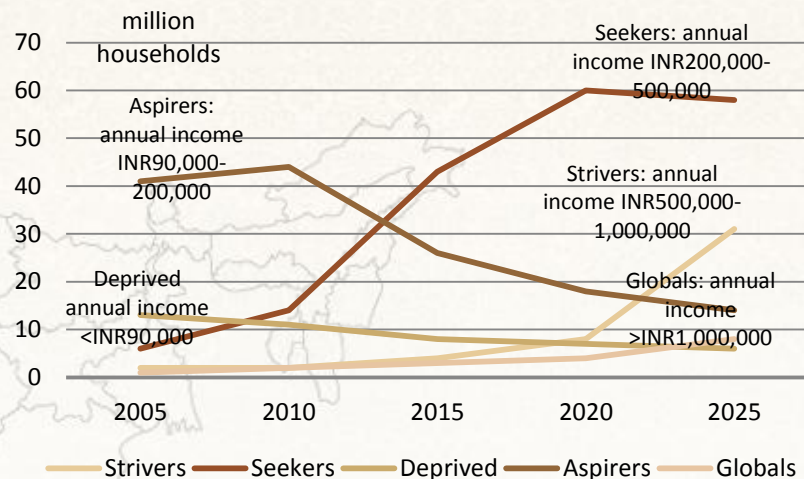
### Rising incomes; growing middle class

- Growing per-capita incomes; rural incomes also rising
- Expanding middle class population; this segment's size is estimated to touch 550 million by 2025 from 50 million in 2010
- Rising per capita income leads to increased spending on medical and healthcare services

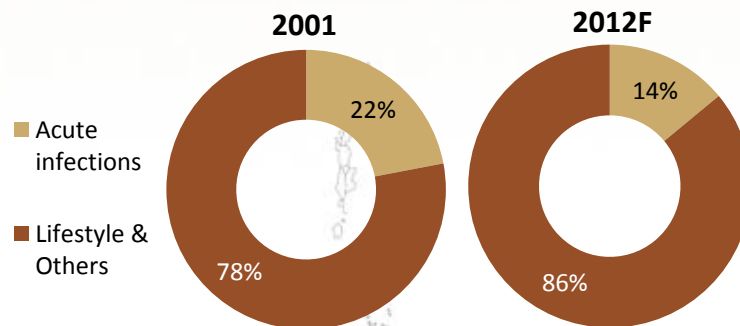
### Higher incidence of chronic diseases

- Lifestyle diseases are set to account for a greater part of the healthcare market
- Lifestyle diseases such as cardiac diseases, cancer and diabetes are treated with the help of biotechnology products, thereby boosting revenues of biotech companies

Notes: Greater distributional efficiencies, increasing demand (especially from rural areas) due to rising disposable incomes have created new markets for products within the country



Source: McKinsey Quarterly, Aranca Research



Source: Fortis Healthcare Limited 2008-09 ANR

## Strong policy support is crucial to the sector's development

### New facilities

- DBT set up 35 facilities during 2002–07 to produce and supply biological products, reagents, culture collections and laboratory animals to scientists, industries and students at nominal costs
- The government launched a biotechnology industry partnership programme for developing new technologies

### National Biotechnology Development Strategy

- DBT designed National Biotechnology Development Strategy (NBDS) to strengthen the industry's human resources and infrastructure while promoting growth and trade
- As part of the NBDS, government has decided to spend 30 per cent of DBT's budget in public private partnerships to promote Research & Development at various stages

### Single-window clearance

- As per NBDS, a proposal has been made to set up National Biotechnology Regulatory Authority (NBRA) to provide a single-window clearance mechanism for all bio-safety clearances of products to create efficiencies and streamline the drug approval process

*Source: "Biotechnology facilities," Department of Biotechnology, Aranca Research*

## Government funding is crucial for the biotech industry

### Venture fund

- The government announced a plan to set up a USD2.2 billion venture fund for supporting drug discovery and research infrastructure development projects
- Government funding is crucial for the biotech industry as they have limited access to other sources of funding

### Infrastructure development

- India's central government and the state governments in collaboration with private players continue to develop new infrastructure facilities , especially through biotechnology parks
- Government is developing three major biotech clusters at Mohali in Punjab, Faridabad in Haryana, Bangalore in Karnataka.

### International collaborations

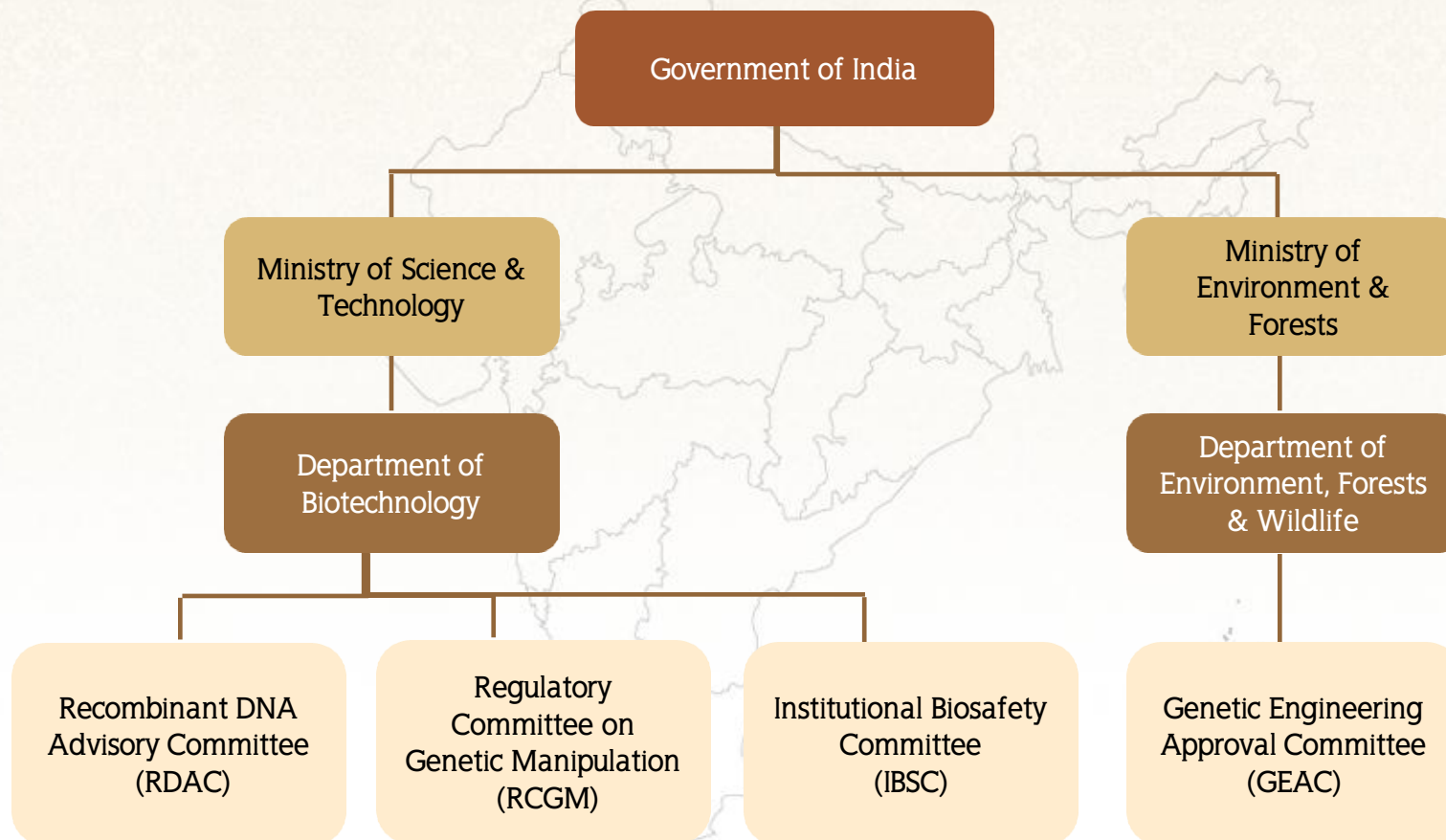
- International collaborations with different countries are directed at enabling the effective transition of knowledge
- India has partnered with countries such as the UK, Russia, Italy, the US and France to enable knowledge transition

### Clinical Establishments Bill

- In a move to standardise procedures, the Indian Parliament passed the Clinical Establishments Bill 2010, which would make registration of clinical trials as well as clinical research organisations mandatory in the country
- The bill also includes standard operating procedures for various trial related tasks

Source: Ernst & Young, Aranca Research

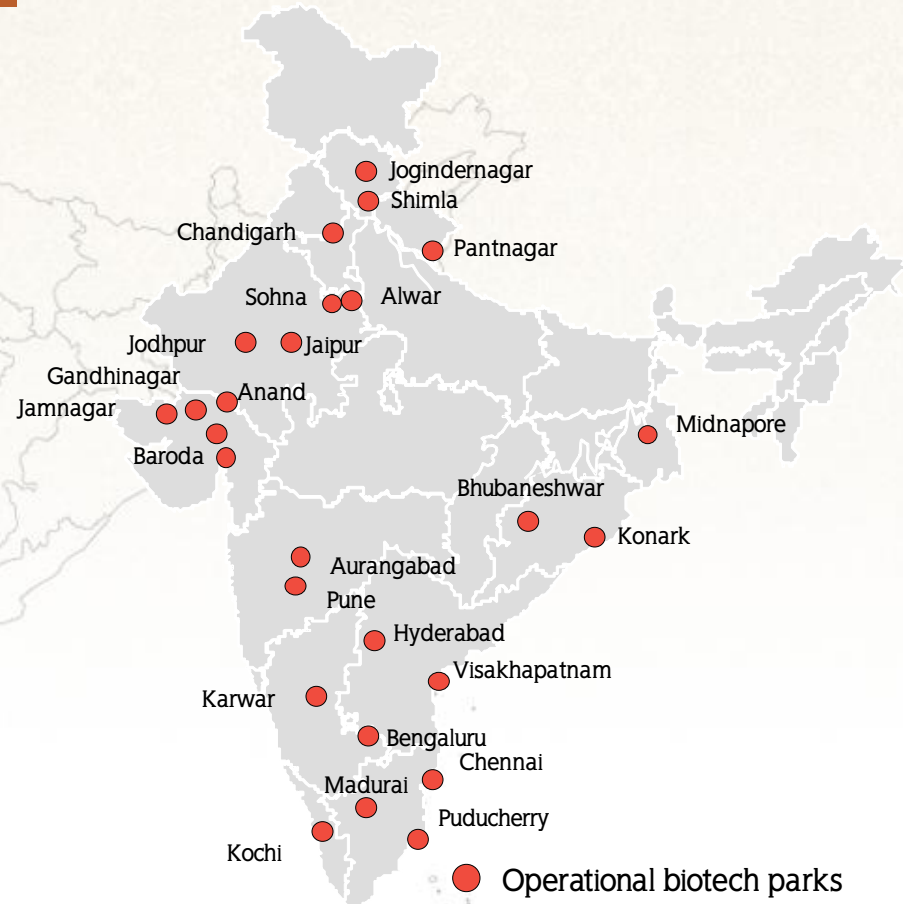
## Regulatory framework of the Indian Biotech Sector



*Source:* Policy and rules," Department of Biotechnology website, Aranca Research

## Solid industry infrastructure would drive growth

- The Eleventh Five Year Plan aims to establish biotechnology parks to involve small and medium enterprises in product development and translational research
- Biotechnology infrastructure is witnessing a shift from traditional clusters to specialised industrial infrastructure such as biotech or science parks
- States such as Andhra Pradesh, Maharashtra, Tamil Nadu and Kerala have been early movers in establishing world-class biotech parks and clusters
- Investors such as TCG Biopharma and Alexandria have significantly contributed to the establishment of biotechnology-related infrastructure in India



Source: Aranca Research, "Mid term appraisal," Eleventh Five Year Plan

## High-end research infrastructure creates scope for innovation

- During FY10, postgraduate biotechnology teaching programmes were launched at eight new universities in addition to the existing 62 universities
- Fellowships rose from 100 to 250 per year for PhD students in addition to 100 postdoctoral and 50 biotechnology overseas associateships
- The Eleventh Plan aims to provide grant-in-aid to the industry for R&D in certain diseases such as malaria and leishmaniasis or kala-azar

### Details of key biotechnology parks in India

Parks	City	Area (in acres)
Shapoorji Pallonji Biotech Park	Hyderabad	300
ICICI Knowledge Park	Hyderabad	200
International Biotech Park	Pune	103
Lucknow Biotech Park	Lucknow	20
Golden Jubilee Biotech Park	Chennai	8
Ticel Bio Park	Chennai	5

### Key research institutes in India

Central Drug Research Institute (CDRI), Lucknow
National Institute of Pharmaceutical Education and Research (NIPER), Mohali
Indian Institute of Chemical Technology (IICT), Hyderabad
Centre for Cellular & Molecular Biology (CCMB), Hyderabad
Indian Institute of Chemical Biology (IICB), Kolkata
Indian Toxicology Research Institute (ITRI), Lucknow
Institute of Genomics and Integrative Biology (IGIB), New Delhi
Institute of Microbial Technology (IMTECH), Chandigarh
National Chemical Laboratory (NCL), Pune
National Centre for Biological Sciences (NCBS), Bengaluru
Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), Bengaluru
Indian Institute of Science (IISc), Bengaluru
National Institute of Immunology (NII), New Delhi

Source: Aranca Research, "Mid term appraisal," Eleventh Five Year Plan

## Strong inflows of foreign investment

- From November 2000 to August 2010, the drugs and pharmaceuticals sector attracted foreign direct investment (FDI) worth USD1.8 billion

M&A scenario — details  
(1 January 2010 – 31 October 2010)

Deal type	No of deals	Deal value (USD million)
Inbound	2	24.3
Outbound	1	4.2
Domestic	1	—

Deal Summary

Deal type	Acquirer	Acquirer's country	Target name	Target country	Completion date
Inbound	Sequoia Capital India Invest	Mauritius	Celon Laboratories Ltd	India	5 October 2010
Inbound	Telematic & Biomedica	Italy	MNE Technologies Pvt Ltd	India	31 March 2010
Outbound	Piramal Healthcare Ltd	India	BioSyntech, Inc	Canada	21 October 2010
Domestic	Anu's Laboratoires Ltd	India	Stilbene Chemicals Ltd	India	16 April 2010

Source: Thomson One Banker, Aranca analysis.

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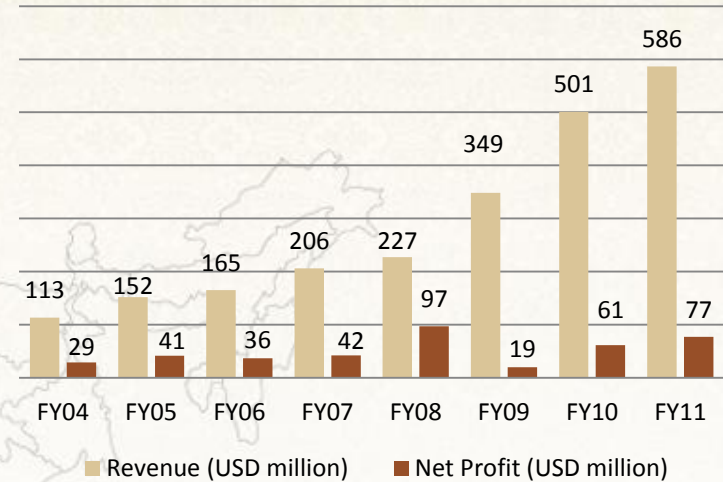
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## Biocon: An early mover to the global biotech market

- Incorporated in 1978 at Bengaluru, India
- IPO offering in 2004 (BSE, NSE India)
- The revenue reported in FY10 was USD501 million and net profit USD61 million
- Among the world's largest producers of statins and immuno – suppressants
- Market cap of USD1.6 billion

Source: Biocon Fact Sheet



### Biocon's position in the Indian market during FY2011

- Ranked 20th in the oral anti-diabetic drugs (OAD) market
- Ranked 3rd in the rh-insulin market
- Ranked 2nd in the glargine market
- Asia's largest insulin producer

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## Huge opportunities for innovation in agriculture/healthcare

### Vaccines

- Vaccines and recombinant therapeutics are the leading sectors driving the biotechnology industry's growth in India, which is expected to reach USD20 billion by 2012
- Newer therapies are anticipated to launch in the next few years, prominent among these are monoclonal antibodies products, stem cell therapies and growth factors
- The country's huge population places it among the world's largest markets for vaccines

### Bioactive therapeutic proteins

- Protein and antibody production and the fabrication of diagnostic protein chips is a promising area for investment
- Stem cell research, cell engineering and cell-based therapeutics is another area, wherein India will cash in its expertise

### Agriculture sector

- India has the potential to become a major producer of transgenic rice and several genetically modified (GM) or engineered vegetables
- Hybrid seeds, including GM seeds, represent new business opportunities in India based on yield improvement

*Source:* India Law Offices, Aranca Research

## Outsourcing opens up further avenues of growth for biotech

### Contract research

- The R&D sector has huge potential; many opportunities have been created with a number of foreign companies investing in this sector
- Indian pharmaceutical companies possess competitive skills in chemical synthesis and process engineering; the companies can leverage these skills to develop new chemical entities

### Clinical trials and outsourcing

- India offers a suitable population for clinical trials because of its diverse gene pools, which cover a large number of diseases
- Cost effectiveness, competition, and increased confidence on capabilities and skill sets have propelled many global pharmaceutical companies to expand their own clinical research investment in the nation

### Bio informatics

- Indian bioinformatics companies can play a significant role in critical areas such as data mining, mapping and DNA sequencing
- There is also opportunity in functional genomics, proteomics and molecule design simulation

### Others

- Some other potential areas of development include medicinal and aromatic plants, animal biotechnology, aquaculture and marine biotechnology, serology, biotechnology, stem cell biology, environmental biotechnology, biofuels, biopesticides, human genetics, genome analysis, and others

*Source:* India Law Offices, Aranca Research

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## Industry Associations

### **Association of Biotechnology Led Enterprises (ABLE)**

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Phone: 91 80 41636853 25633853

E-mail: [info@ableindia.org](mailto:info@ableindia.org)

Website: [www.ableindia.org](http://www.ableindia.org)

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Website: [www.aibaonline.com](http://www.aibaonline.com)

## Glossary

- **Bt:** Bacillus thuringiensis
- **CAGR:** Compound Annual Growth Rate
- **CRO:** Contract Research Organisation
- **DNA:** Deoxyribonucleic acid
- **FYP:** Five Year Plan
- **GCP:** Good Clinical Practice
- **INR:** Indian Rupee
- **NBTB:** National Biotechnology Board
- **OAD:** Oral anti-diabetic drugs
- **R&D:** Research And Development
- **FY:** Indian financial year (April to March)
  - So FY10 implies April 2009 to March 2010
- **USD:** US Dollar
  - Conversion rate used: USD1= INR 48
- Wherever applicable, numbers have been rounded off to the nearest whole number

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