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EXECUTIVE SUMMARY

**BIOTECHNOLOGY**

The biotech industry is expected to experience significant growth amid favourable business conditions.

Increasing government expenditure is likely to augment growth.

Growing pharmaceuticals market is estimated to aid growth of the biotech industry.

By FY25F, India's biotech industry is estimated to increase to USD100 billion from USD7 billion in FY15.

In its 12th Five-Year Plan, the government aims to spend USD3.7 billion on biotechnology compared to USD1.1 billion in the 11th Five-Year Plan.

India's pharmaceuticals market is expected to grow to USD35.9 billion by 2016F and USD45 billion in 2020 from USD18 billion in 2012.

**EXECUTIVE SUMMARY**

**AUGUST 2015**

For updated information, please visit [www.ibef.org](http://www.ibef.org)
Robust demand
- India’s billion-plus population base offers a huge market for biotech products and services
- Increasing economic prosperity and health consciousness would continue to fuel demand for healthcare services
- Better accessibility to healthcare services further accelerates the demand

Innovation opportunities
- Public funding is being offered for product innovation and research in the biotech sector
- The private sector has been aggressively pursuing focused R&D
- Public-Private partnerships will improve the market with innovative research and development

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
- Launch of Biotechnology Industry Partnership Programme (BIPP) is boosting industry participation

Policy support
- The sector has experienced significant growth in government spending since 1985
- Budgetary allocations to the biotech sector have increased
- Biotechnology Industry Research Assistance Council has been set up
- National Rural Healthcare Mission has been launched to boost healthcare spending

Source: Government of India, Ministry of Health, Planning Commission, ABLE, TechSci Research
Note: E - Estimate

FY13
Market Value: USD4.3 billion

FY17E
Market Value: USD11.6 billion
BIOTECHNOLOGY

MARKET OVERVIEW & TRENDS

AUGUST 2015
BIOTECHNOLOGY

MAJOR MILESTONES IN INDIAN BIOTECHNOLOGY INDUSTRY

1978–90

- 1978: India’s first biotech firm, Biocon, was setup
- 1981: Centre for Cellular and Molecular Biology 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

1990–99

- 1991: National Centre for Biological Sciences pursued R&D in molecular biology
- 1994: Syngene, India’s first Contract Research Organisation (CRO), started 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 approved Mahyco-Monsanto to grow Bt cotton

Post 2000

- 2007: National Biotechnology Development Strategy launched
- 2009: Launch of Biotechnology Industry Partnership Programme
- 2009: National Biotechnology Regulatory Authority Bill 2008 introduced in the parliament
- 2011: Government approved setting up the Biotechnology Industry Research Assistance Council (BIRAC)
- 2012: India ranked 12th in the world in biotech and 3rd largest in Asia-Pacific, after Japan and Korea
- 2013: India became the biggest producer of Hepatitis B vaccine recombinant

Source: EXIM bank of India research, makeinindia, CII, TechSci Research
Note: R&D - Research and Development

For updated information, please visit www.ibef.org

AUGUST 2015
**KEY SEGMENTS IN THE INDIAN BIOTECHNOLOGY INDUSTRY**

- **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-fertilisers.

- **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 currently the smallest part of the domestic biotechnology industry.

*Source: ABLE - Biospectrum Industry Survey, June 2013; TechSci Research*
MAJOR PRODUCTS/SERVICES OF THE INDIAN BIOTECHNOLOGY INDUSTRY

Source: ABLE - Biospectrum Industry Survey, June 2013; TechSci Research
Maintaining the momentum of the previous years, the Indian biotech industry grew 16.28 per cent in FY14; the total industry size was USD5 billion at the end of the financial year and is estimated to be USD7 billion by 2015.

Fast-paced growth is likely to continue; the industry is expected to increased in size to USD11.6 billion by 2017, driven by a range of factors such as growing demand, intensive R&D activities and strong government initiatives.

Fast-developing clinical capabilities with the country becoming a popular destination for clinical trials, contract research and manufacturing activities.

**Market size (USD billion)**

<table>
<thead>
<tr>
<th>FY05</th>
<th>FY06</th>
<th>FY07</th>
<th>FY08</th>
<th>FY09</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
<th>FY14</th>
<th>FY15E</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>1.5</td>
<td>1.9</td>
<td>2.6</td>
<td>2.6</td>
<td>3.0</td>
<td>3.8</td>
<td>4.3</td>
<td>4.3</td>
<td>5.0</td>
<td>7.0</td>
</tr>
</tbody>
</table>

CAGR: 20.33%

**Source:** ABLE - Biospectrum Industry Survey, June 2013, Makeinindia, TechSci Research, Global Industry Analysts Report (GIA)

**Notes:** CAGR - Compound Annual Growth Rate
The bio-pharmaceutical segment accounted for the largest share of the biotech industry, with 62.0 per cent of total revenues in FY14. Revenue from bio-pharma exports reached USD2.2 billion in 2013, accounting for 51 per cent of total revenues of the biotech industry.

In FY14, the bio-services and bio-agri segments accounted for 18.0 per cent and 15.0 per cent of the biotech industry, respectively.

The bio-pharmaceutical segment grew at the fastest rate (17.7 per cent in FY13), followed by bio-services (15.5 per cent) and bio-industrial (10.9 per cent).

Source: ASSOCHAM, Makeinindia, TechSci Research
Remarkable global positioning

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

Pharma companies focusing on biotech

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

Global companies setting up base

- Lonza, a global leader in 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

Biosimilars and molecular diagnostic remain strongholds

- Growth in the sector is anticipated to come from the country's strong position in biosimilars and molecular diagnostics as well as personalised medicine (where export and domestic trends look promising)

Growth in Genetically Modified crops

- In 2013, India had overtaken Canada to emerge as the fourth largest country to grow biotech or Genetically Modified (GM) crops. The global acreages under GM crops increased to 175.2 million hectares in 2013, about five million hectares more than the previous year

Source: Ministry of External Affairs, TechSci Research, Indian Law Offices

For updated information, please visit www.ibef.org
### STRATEGIES ADOPTED

**Strategic collaborations with niche players**
- Indian biotech firms are partnering with niche players to broaden their product portfolio and strengthen global reach.
- Strand Life Sciences recently collaborated with US-based El Camino Hospital to establish a genomics and pharmacogenomics centre in San Francisco, while Hyderabad-based GVK Biosciences entered into an agreement with the US FDA for drug repositioning.

**Mergers & Acquisitions**
- Companies in the industry are exploring new avenues in life sciences to strengthen and upgrade the products and services portfolio through strategic mergers and acquisitions.

**Stepped up investment in personalised medicine**
- Pharma companies, including Avesthagen, TCG Life Sciences, Advinus Therapeutics and Jubilant Biosys have stepped up investments in personalised medicine. The idea is to eliminate the unpredictable nature of drug development through personalised medicine. For instance, Xcode Life Sciences uses InDNA technology to provide personalised solutions for lifestyle-related diseases, such as coronary, diabetes and obesity, using saliva samples. Action Biotech provides genetic tests to predict response from chemotherapy drugs. Geneombio Technologies offer gene-based prediction to assess genetic susceptibility towards major lifestyle diseases.

**Ramping up service offerings**
- Companies are evolving their product mix to reflect growing repertoire in Biologics, Branded Formulations and Research Services.
- In August 2013, Biocon launched Alzumab, a first-in-class anti-CD6 antibody for the treatment of psoriasis in India.

*Source: Ministry of External Affairs, RBI*
BIOTECHNOLOGY

GROWTH DRIVERS

AUGUST 2015
BIOTECHNOLOGY

SECTOR BENEFITS FROM RISING INCOME AND POPULATION

Growing demand
- India's large population, a huge market for biotech products and services
- Higher healthcare expenditure and an increase in Bio-agri products
- Strong growth in export demand and a rise in medical tourism

Policy support
- Significant growth in government spending on biotech sector since 1985
- R&D focus; Indian government has been funding institutes for biotech research
- Increase in budgetary allocations to the Biotech and Healthcare sectors in five-year plans

Increasing investments
- Rising investments from domestic and foreign players
- 100 per cent FDI permitted through automatic route for manufacturers of drugs and pharmaceuticals
- Low cost and skilled labour force attracting outsourced research activity

Source: Makeinindia, TechSci Research
Exponential growth in government funding

- Government spending on healthcare, as a percentage of GDP, for the 12th Five-Year Plan is around 2.5 per cent, and to at least 3 per cent of GDP by 2022.
- Government expenditure on healthcare as a percentage of total expenditure on healthcare in the country was 31 per cent in 2013.
- During the 11th Five-Year Plan, the Department of Biotechnology utilized 94.49 per cent of the allocated resources.

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 led to a higher demand for biological products.

Preventive healthcare

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

Source: WHO Statistics 2012, Note: FYP – Five Year Plan
Source: Planning Commission, MHRD, National Biotechnology Development Strategy, DBT, TechSci Research
RISING INCOME AND INCIDENCE OF CHRONIC LIFESTYLE DISEASES

Rising income; growing middle class

- Per capita income and rural income are increasing
- The number of middle class households (earning between USD4,413.1 and USD22,065.3 per annum) is estimated to increase more than fourfold to 148 million by 2030 from 32 million in 2010
- Rising per capita income leads to increased spending on medical and healthcare services

Higher incidence of chronic lifestyle 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 and increasing demand (especially from rural areas) due to rising disposable incomes have created new markets for products within the country, F - Forecast

### STRONG POLICY SUPPORT CRUCIAL TO THE SECTOR’S DEVELOPMENT

| Programmes for SC/ST and Rural Population | • Training and demonstration programs in various biotechnology based activities were undertaken to empower the population resulting in socioeconomic upliftment |
| Biotechnology Based Programs for Women | • Program on application of biotechnology for women was done to provide employment, skill development, awareness generation, health improvement, and socio-economic upliftment of the women population |
| National Biotechnology Development Strategy | • DBT designed the 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 decided to spend 30 per cent of DBT’s budget in public private partnerships to promote R&D at various stages  
• As per NBDS, a proposal has been made to set up the National Biotechnology Regulatory Authority (NBRA) to provide a single-window clearance mechanism for all bio-safety products to create efficiencies and streamline the drug approval process |
| Single-window clearance | • BIRAC has been established to promote research and innovation capabilities in India’s biotech industry  
• Under BIRAC, the government will provide funding to biotech companies for technology and product development |
| Biotechnology Industry Research Assistance Council | • The Policy aims to encourage new companies to operate in Tamil Nadu, thereby increasing the Research & Development and manufacturing activities in the sector |

Source: “Biotechnology facilities,” Department of Biotechnology, TechSci Research  
Note: BIRAC - Biotechnology Industry Research Assistance Council
The overall strategy of 12th Five-Year Plan is to accelerate the pace of research, innovation and development. The main objective is to advance biotechnology as strategic area by taking India’s strengths in foundational sciences to globally competitive levels. In addition, emphasis is on expanding the application of biotechnologies for overall growth of bio- economy within the framework of inclusive development.

The 12th Five-Year Plan aims to accelerate the pace of research, innovation and development to improve biotechnology in India.

The government plans to strengthen regulatory science and infrastructure, which involves setting up the Biotechnology Regulatory Authority of India (BRAI) and a central agency for regulatory testing and certification of laboratories.

The plan also entails expanding and commissioning new bioclusters at Faridabad, Mohali Kalyani and Hyderabad.

It aims to encourage and increase the pool of research scholars and scientists by three-fivefold in biological and interdisciplinary space across levels (PhD, PDFs, young faculty).

12th Five-Year Plan expenditure (USD billion)

<table>
<thead>
<tr>
<th></th>
<th>11th Five Year Plan</th>
<th>12th Five Year Plan</th>
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<tbody>
<tr>
<td></td>
<td>1.1</td>
<td>3.7</td>
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</table>

12th Five-Year Plan fund allocation (USD billion)

- Medical biotech: 26%
- Agri biotech: 21%
- Basic bio & emerging areas: 17%
- Biodiversity, bioresources & Environment: 14%
- Capacity building: 22%

Source: Deptt. of Science and Technology, Planning Commission, TechSci Research
### GOVERNMENT FUNDING CRUCIAL FOR THE BIOTECH INDUSTRY

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Funding Agency</td>
<td>The DST has consistently enabled transformational changes through appropriate responses and non-participative roles. DST accordingly played the role of an extra mural research funding agency wherein competitive grants for research was provided to investigators based on technical merit.</td>
</tr>
<tr>
<td>Venture fund</td>
<td>The government announced a plan to set up a USD2.2 billion venture fund to support drug discovery and research infrastructure development projects. Government funding is crucial for the biotech industry due to limited access to other sources of funding.</td>
</tr>
<tr>
<td>Infrastructure development</td>
<td>India’s central government and state governments, in collaboration with private players, continue to develop new infrastructure facilities, especially at biotechnology parks. The government is developing three major biotech clusters at Mohali in Punjab, Faridabad in Haryana, and Bengaluru in Karnataka. It plans to set up an agri-biotech cluster in Pune (Maharashtra) and Kolkata (West Bengal).</td>
</tr>
<tr>
<td>International collaborations</td>
<td>India has partnered with countries such as the UK, Russia, Italy, the US and France to enable knowledge transition.</td>
</tr>
<tr>
<td>Clinical Establishments Bill</td>
<td>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.</td>
</tr>
</tbody>
</table>

Source: Ernst & Young, Times of India, TechSci Research
### CENTRE AND STATE GOVERNMENT INITIATIVES PROVIDE BIG BOOST TO BIOTECH INDUSTRY

#### Increasing government support

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
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<tbody>
<tr>
<td>100 per cent foreign equity investment is possible in manufacturing of all drugs except recombinant DNA products and cell targeted therapies</td>
<td></td>
</tr>
<tr>
<td>Single window processing mechanism for all biotech projects involving FDI</td>
<td></td>
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<tr>
<td>Depreciation allowance on plant and machinery raised to 40 per cent from 25 per cent</td>
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</tr>
<tr>
<td>Customs duty exemption on goods imported in certain cases for R&amp;D</td>
<td></td>
</tr>
<tr>
<td>Customs &amp; excise duty exemption to recognised Scientific &amp; Industrial Research Organisations (SIRO)</td>
<td></td>
</tr>
<tr>
<td>150 per cent weighted tax deduction on R&amp;D expenditure</td>
<td></td>
</tr>
<tr>
<td>Three years excise duty waiver on patented products</td>
<td></td>
</tr>
<tr>
<td>100 per cent rebate on own R&amp;D expenditure</td>
<td></td>
</tr>
<tr>
<td>125 per cent rebate if research is contracted in public funded R&amp;D institutions</td>
<td></td>
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<tr>
<td>Joint R&amp;D projects provided special fiscal benefits</td>
<td></td>
</tr>
<tr>
<td>Set up a venture capital fund to support small and medium enterprises</td>
<td></td>
</tr>
<tr>
<td>Promote innovations through BIPP, SBIRI, BIRAC and Biotech parks</td>
<td></td>
</tr>
</tbody>
</table>

#### Favourable IP climate

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indian Copyright Act, 1957</td>
<td></td>
</tr>
<tr>
<td>The Patent Act, 1970</td>
<td></td>
</tr>
<tr>
<td>Indian Patents and Design Act, 1972</td>
<td></td>
</tr>
<tr>
<td>The Trademarks Act, 1999</td>
<td></td>
</tr>
<tr>
<td>Biotechnology Patent Facilitating Cell (BPFC)</td>
<td></td>
</tr>
<tr>
<td>Foundation of Biotechnology Awareness and Education (FBAE)</td>
<td></td>
</tr>
<tr>
<td>National Research Development Corporation (NRDC)</td>
<td></td>
</tr>
<tr>
<td>National Guidelines for Stem Cell Research (2013)</td>
<td></td>
</tr>
<tr>
<td>Tamil Nadu Biotechnology Policy 2014</td>
<td></td>
</tr>
</tbody>
</table>

*Source: Ernst & Young, TechSci Research*

REGULATORY FRAMEWORK OF THE INDIAN BIOTECH SECTOR

Government of India

Ministry of Science & Technology

Department of Biotechnology

Ministry of Environment & Forests

Department of Environment, Forests & Wildlife

Recombinant DNA Advisory Committee (RDAC)

Regulatory Committee on Genetic Manipulation (RCGM)

Institutional Biosafety Committee (IBSC)

Genetic Engineering Approval Committee (GEAC)

Source: Policy and rules, Department of Biotechnology website, TechSci Research
The 12th Five Year Plan aims to set up 3–5 bio-clusters with technology incubators, technology parks, innovation centres and entrepreneurship development units.

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 Bio-pharma and Alexandria have significantly contributed to the establishment of biotechnology-related infrastructure in India.

Source: Planning Commission, TechSci Research, "Mid-term appraisal", Eleventh Five Year Plan

For updated information, please visit www.ibef.org
The flow of job and income generation in biotechnology, through involvement of public and private initiatives with proper utilisation of available resources, is explained in the following diagram:
During the 11th Five-Year Plan, the government started six new institutions in different fields of biotechnology across India.

Fellowships rose from 100 to 250 per year for PhD students, in addition to 100 postdoctoral and 50 biotechnology overseas associateships.

Government provided 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

<table>
<thead>
<tr>
<th>Parks</th>
<th>City</th>
<th>Area (in acres)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shapoorji Pallonji Biotech Park</td>
<td>Hyderabad</td>
<td>300</td>
</tr>
<tr>
<td>ICICI Knowledge Park</td>
<td>Hyderabad</td>
<td>200</td>
</tr>
<tr>
<td>International Biotech Park</td>
<td>Pune</td>
<td>103</td>
</tr>
<tr>
<td>Lucknow Biotech Park</td>
<td>Lucknow</td>
<td>20</td>
</tr>
<tr>
<td>Golden Jubilee Biotech Park</td>
<td>Chennai</td>
<td>8</td>
</tr>
<tr>
<td>Ticel Bio Park</td>
<td>Chennai</td>
<td>5</td>
</tr>
</tbody>
</table>

### 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: TechSci Research, "Mid-term appraisal", Eleventh Five Year Plan*
### STRONG INFLOW OF FOREIGN INVESTMENT

<table>
<thead>
<tr>
<th>Date announced</th>
<th>Acquirer name</th>
<th>Target name</th>
<th>Value of deal (USD million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec 2014</td>
<td>Leaders Group Asia Ltd</td>
<td>Dr Datsons Labs Ltd</td>
<td>-</td>
</tr>
<tr>
<td>Oct 2014</td>
<td>B Braun Singapore Pte Ltd</td>
<td>Ahlcon Parenterals (India) Ltd</td>
<td>7.89</td>
</tr>
<tr>
<td>May 2014</td>
<td>Cancer Genetics Inc</td>
<td>Bioserve Biotechnologies</td>
<td>1.9</td>
</tr>
<tr>
<td>May 2014</td>
<td>Anglo Gulf Ltd</td>
<td>SciGen BioPharma Pvt Ltd</td>
<td>7.00</td>
</tr>
<tr>
<td>Jan 2014</td>
<td>Lotus Pharmaceutical Co Ltd</td>
<td>Alvogen Pharma India Pvt Ltd</td>
<td>10.00</td>
</tr>
<tr>
<td>Oct 2013</td>
<td>Innovation Software Exports</td>
<td>Agrata Biotech Ltd</td>
<td>-</td>
</tr>
<tr>
<td>May 2013</td>
<td>Bio Harvest Pte Ltd</td>
<td>Camson Bio Technologies Ltd</td>
<td>51.06</td>
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<tr>
<td>Dec 2012</td>
<td>Malabar Trading Co Ltd</td>
<td>SPL Biotech Pvt Ltd</td>
<td>-</td>
</tr>
<tr>
<td>Oct 2012</td>
<td>GE Equity International</td>
<td>Syngene International Ltd</td>
<td>302.13</td>
</tr>
<tr>
<td>Jun 2012</td>
<td>Nandan Cleantec PLC</td>
<td>Xtraa Cleancities Infra</td>
<td>-</td>
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<tr>
<td>Mar 2012</td>
<td>Origio A/S</td>
<td>Trivector Scientific Pvt Ltd</td>
<td>8.61</td>
</tr>
<tr>
<td>Aug 2011</td>
<td>DMV-Fonterra Excipients GmbH</td>
<td>Brahmar Cellulose Products</td>
<td>-</td>
</tr>
<tr>
<td>Aug 2011</td>
<td>Arvind Remedies Ltd</td>
<td>Undisclosed Pharmaceutical Co</td>
<td>-</td>
</tr>
</tbody>
</table>
**Vaccines**
- Vaccines and recombinant therapeutics are the sectors driving the biotechnology industry’s growth in India
- Newer therapies are anticipated to be launched in the next few years; prominent among these are monoclonal antibodies products, stem cell therapies and growth factors
- The country’s huge population places makes it among the world’s largest markets for vaccines

**Bioactive therapeutic proteins**
- Protein and antibody production and fabrication of diagnostic protein chips are promising areas for investment
- Stem cell research, cell engineering and cell-based therapeutics are other areas, where India can cash 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

**Intellectual Property**
- Using the patent system as a mechanism to control drug pricing forestalls making the difficult decisions about necessary investment in the healthcare system, but does not deal with the underlying issues.

*Source: India Law Offices, TechSci Research*
For updated information, please visit www.ibef.org

For updated information, please visit www.ibef.org

BIOTECHNOLOGY

HUGE OPPORTUNITIES FOR INNOVATION IN AGRICULTURE/HEALTHCARE

Bio services Sector

- Beyond biotherapeutics, the bioservices sector represents an area of significant promise for India because of its skilled labor force, attractive costs, and access to major markets in Asia.
- India’s bioservices sector includes global contract research organisations, such as Quintiles, as well as Indian companies including GVK Bio, Jubilant Biosys, and Advinus.

Bio Pharmaceutical Industry

- As the cost of bringing new molecules from discovery to market continues to rise, the global biopharmaceutical industry is seeking ways to improve efficiency.

Manufacturing

- Manufacturing is also an area where India is leveraging its cost-competitiveness.
- India has the opportunity to replicate in biologics the same type of success it has had with small molecule drugs.

Bioinformatics

- The convergence of the life sciences with information technology is creating a particular opportunity for India.
- The country has well-established strengths in the information technology area, and with the advent of low-cost, whole genome sequencing and the growing role of molecular diagnostics in both precision and preventive medicine, there is a proliferation of data creating demand for bioinformatic analysis.

Source: India Law Offices, TechSci Research
OUTSOURCING OPENS UP FURTHER AVENUES FOR GROWTH OF 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**
- 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 increase their clinical research investment in the nation

**International collaboration**
- Memorandum of Understanding (MOU) have been signed with Denmark and Finland and joint call for proposals have been issued
- Joint projects have also been funded with the Biotechnology and Biological Sciences Research Council (BBSRC), UK
- New agreements on vision research with National Institutes of Health (NIH), USA and an amendment to the agreement with Contraceptive Research and Development Programme (CONRAD)

**Others**
- Other potential areas of development include medicinal and aromatic plants, animal biotechnology, aquaculture and marine biotechnology, seric biotechnology, stem cell biology, environmental biotechnology, biofuels, biopesticides, human genetics, and genome analysis

*Source: India Law Offices, Deptt. of Biotechnology, TechSci Research*
India was the first country in the world to establish a Biotechnology Information System (BTIS) network in 1987. This facilitated development of bioinformatics that has provided support to the biotechnology sector.

Bioinformatics research is poised to become one of the fastest emerging markets in India.

Bioinformatics is estimated to rise at a CAGR of 34.92 per cent to USD2.7 billion during FY12–25.

India currently has close to 10 per cent of the global professional and skilled bioinformaticians.

With 10 per cent of the global professional and skilled bioinformaticians, 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, proteonics and molecule design simulation.

Source: Deptt. of Biotechnology, Marketresearch, ABLE, TechSci Research
Note: E - Estimates
BIOTECHNOLOGY

BIOCON: AN EARLY MOVER IN THE GLOBAL BIOTECH MARKET

BIOCON: AN EARLY MOVER IN THE GLOBAL BIOTECH MARKET

Revenue and net profit (USD million)

- Market cap of USD1.1 billion
- Revenue in FY14 stood at USD486.6 million (up 18 per cent YoY), while net profit totaled USD68.6 million
- Initiated trials for IN-105 (oral insulin program) in the US
- Tied-up with Quark Pharmaceuticals to develop novel siRNA-based therapeutics
- Partnered with Advaxis to develop a novel cancer immunotherapy

Biocon’s position in the Indian market during FY13–14

- Among the world’s largest producers of statins and immunosuppressants
- IPO offering in 2004 (BSE, NSE India)
- Incorporated in 1978 at Bengaluru, India
- 2011: Launched INSUPen®, a convenient and affordable reusable insulin delivery device

Revenue and net profit (USD million)

<table>
<thead>
<tr>
<th>FY09</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
<th>FY14</th>
</tr>
</thead>
<tbody>
<tr>
<td>260</td>
<td>315</td>
<td>408</td>
<td>448</td>
<td>467.3</td>
<td>486.6</td>
</tr>
<tr>
<td>50.9</td>
<td>56.9</td>
<td>74.6</td>
<td>70.6</td>
<td>93.7</td>
<td>68.6</td>
</tr>
</tbody>
</table>

Source: Biocon Fact Sheet

For updated information, please visit www.ibef.org
Serum Institute of India: Gaining Global Ground

- **Company sells products in 140 countries worldwide**
- **Over FY11–13, consolidated revenue increased at a CAGR of 38.3 per cent**
- **Focus on R&D**
  - **1967**: Started operations with manufacturing of Tetanus Antitoxin, followed by Tetanus Toxoid
  - **1994–2000**: Commenced export of vaccines to UN agencies; export crosses over a 100 countries
  - **2005–12**: Focused on gaining R&D edge, global market reach and wide product portfolio
- **Posted revenue of USD437.1 million in FY13**
- **Strong presence in Bio Pharma space**
- **Recognised as India’s number one bio-tech company for two consecutive years**
- **Serum Institute recognised as the world’s largest producer of vaccines for Measles and DTP**
- **One out of every two children in the world vaccinated by Serum Institute’s vaccine**
- **Launched the world’s only adsorbed liquid HDC Rabies vaccine**
- **Launched India’s first MMR Vaccine Tresivac**
- **1967**
  - **1994–2000**
  - **2005–12**

*Source: Company website, ABLE, TechSci Research*

For updated information, please visit [www.ibef.org](http://www.ibef.org)

*August 2015*
PANACEA BIOTECH: FOCUS ON INNOVATION AND R&D

- Established plant for vaccine production at New Delhi under the name Radicura Pharma (1988)
- Forayed into Healthcare Delivery; entered into a collaboration to set up 220-bed multi-super specialty hospital and a R&D centre in Delhi (2005–14)
- Selected by WHO for developing the sabin based injectable polio vaccine
- Approval for development & commercialisation of Anthrax vaccine
- Started drug delivery R&D centre at Lalru
- Licensing agreement with National Institute of Health, US, for hair growth hormone 2004
- Started new state-of-the-art Oncology centre at Baddi
- Strategic alliance with Kremers Urban for entry into generics
- More than 1,510 patent applications filed globally; of this, 415 have been granted
- Presence in more than 35 countries worldwide
- Posted revenue of USD84.8 million in FY14
- In FY10–11, revenues grew 32 per cent to USD203.7 million

Source: Company website, TechSci Research

For updated information, please visit www.ibef.org
USEFUL INFORMATION
Association of Biotechnology Led Enterprises (ABLE)
# 123/C, 16th Main Road, 5th Cross, 4th Block
Near Sony World Showroom/Headstart School
Koramangala, Bengaluru – 560034
Phone: 91 80 41636853 25633853
E-mail: info@ableindia.org
Website: www.ableindia.org

All India Biotech Association (AIBA)
"VIPPS Center" 2. Local Shopping Centre Block EFGH, Masjid Moth,
Greater Kailash-II, New Delhi-110048
Tel: 91 11 29211487 (Direct), 29220546/547
Fax: 91 11 29223089, 29229166
Email: unmalik@aibaonline.com
Website: 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 AUGUST)
  - So FY10 implies April 2009 to AUGUST 2010
- **USD**: US Dollar

Wherever applicable, numbers have been rounded off to the nearest whole number.
### Exchange rates (Fiscal Year)

<table>
<thead>
<tr>
<th>Year</th>
<th>INR equivalent of one USD</th>
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<tbody>
<tr>
<td>2004–05</td>
<td>44.81</td>
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<tr>
<td>2005–06</td>
<td>44.14</td>
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<td>2006–07</td>
<td>45.14</td>
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<tr>
<td>2007–08</td>
<td>40.27</td>
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<tr>
<td>2008–09</td>
<td>46.14</td>
</tr>
<tr>
<td>2009–10</td>
<td>47.42</td>
</tr>
<tr>
<td>2010–11</td>
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<td>2011–12</td>
<td>46.88</td>
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<td>2012–13</td>
<td>54.31</td>
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<tr>
<td>2013–14</td>
<td>60.28</td>
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<tr>
<td>2014-15(Expected)</td>
<td>60.28</td>
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</tbody>
</table>

### Exchange rates (Calendar Year)

<table>
<thead>
<tr>
<th>Year</th>
<th>INR equivalent of one USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>43.98</td>
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<tr>
<td>2006</td>
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<tr>
<td>2007</td>
<td>41.34</td>
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<tr>
<td>2008</td>
<td>43.62</td>
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<tr>
<td>2009</td>
<td>48.42</td>
</tr>
<tr>
<td>2010</td>
<td>45.72</td>
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<tr>
<td>2011</td>
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<tr>
<td>2012</td>
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<td>2013</td>
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<tr>
<td>2014</td>
<td>61.03</td>
</tr>
<tr>
<td>2015(Expected)</td>
<td>61.03</td>
</tr>
</tbody>
</table>

Average for the year
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