BIOTECHNOLOGY

November 2010
Contents

- Advantage India
- Market overview
- Industry infrastructure
- Investments
- Policy and regulatory framework
- Opportunities
- Industry associations
Advantage India

- India is one of the preferred destinations in custom research outsourcing (CRO) and custom manufacturing outsourcing (CMO).
- The clinical trials market has witnessed 31 per cent growth during 2004-2008.
- CMO has recorded around 43 per cent growth, at thrice the global market rate.

- India offers a significant cost advantage over the US and is recognised globally for its low-cost fermentation technology and generic biologics.
- Manufacturing costs in India are approximately 35 to 40 per cent of those in the US, supported by low installation, manpower and manufacturing costs.

- India possesses the second-largest English-speaking population in the world.
- In 2009, 15,000 scientists were engaged in the biotechnology sector.
- As of 2009, every year, 3 million graduates, 0.7 million postgraduates and 1,500 PhDs are added to India’s talent pool.
- It is equally supported by education infrastructure of more than 200 research institutes.

In 2009, India had more than 120 US Food and Drug Administration (FDA)-approved plants and around 84 UK Medicines and Healthcare products Regulatory Agency (MHRA)-approved plants, with capabilities to manufacture products of exceptional quality.

- The industry is constantly engaged in upgrading technology to enhance the quality of products.
- India is expected to be one of the top five innovative hubs with contributions of around 50 per cent of drugs discovered worldwide from India.

Contents

- Advantage India
- Market overview
- Industry infrastructure
- Investments
- Policy and regulatory framework
- Opportunities
- Industry associations
Market overview

• In 2009–2010, the industry recorded revenues worth US$ 3 billion, registering y-o-y growth of 12.36 per cent (in US$ terms) over 2008–09.

• The industry is expected to witness robust growth and reach US$ 15 billion by 2015, driven by various government initiatives.

Sources: ABLE-Biospectrum industry survey, June 2010; Ernst & Young analysis
This segment accounts for majority of the biotech industry’s revenues. It contributed 62 per cent to total revenues in 2009–2010.

In 2009–2010, bio-services was the second-largest contributor to the industry, constituting 18.7 per cent of total revenues. This segment contributed 33 per cent of exports.

This segment generated around US$ 410 million revenues in 2009–2010, accounting for 13.7 per cent of total revenues.

The bio-industrial segment contributed approximately 4 per cent to total revenues in 2009–2010.

The bio-informatics industry is at a nascent stage, contributing 1-2 per cent of total revenues in 2009–2010.

Sources: ABLE-Biospectrum industry survey, June 2010; Ernst & Young analysis
Exports

- Revenues from biotech exports have been valued at US$1.57 billion in 2009–2010, constituting 52 per cent of the biotech industry’s revenues.

Sources: ABLE-Biospectrum industry survey, June 2010; Ernst & Young analysis
Domestic demand

• The disease profile that inflicts the Indian population has experienced a gradual shift. The number of lifestyle-related diseases being reported is rising, which has led to the demand for various kinds of specialised treatment. Ailments such as cancer and diabetes have heightened the demand for biologic products.

• Around 1.15 billion new cases of ailments are reported annually. The reported number of ailments is expected to rise by a compound annual growth rate (CAGR) of 30 per cent to reach 15 billion cases by 2015. A growing population, increasing affordability, easier access to healthcare facilities and a shift toward lifestyle diseases are driving this trend. Demographic changes have led to an increase in the demand for vaccines, both for geriatricians and pediatrics population.

Source: Ernst & Young research
Growth drivers — increased healthcare expenditure and funding for the biotechnology sector

- Healthcare expenditure, as a percentage of GDP, was recorded at 1.09 per cent for 2009–2010, with the growth being driven primarily by the rise in private expenditure.

- During 2007–2010, the percentage utilisation of allocated resources by the Department of Biotechnology (DBT) is 94.49 per cent as compared to science and technology sector average of 90.56 per cent.

**Growth drivers — government support**

<table>
<thead>
<tr>
<th>New facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The Department of Biotechnology (DBT) set up 35 facilities between 2002 and 2007 to produce and supply biologicals, reagents, culture collections and laboratory animals to scientists, industries and students at nominal costs. To fill the viability gap in developing new technologies, the Government of India (GoI) started a biotechnology industry partnership programme for funding support.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>• According to the National Biotechnology Development Strategy (NBDS), there is a positive inclination to set up a centralised national biotechnology regulatory authority to provide a single-window clearance mechanism for all bio-safety clearances for products.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>International collaborations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Various international collaborations with different countries are in the pipeline, directed at enabling the effective transition of knowledge. A re-entry fellowship grant has been initiated with the UK-based Wellcome Trust. India has also partnered with countries such as the UK, Russia, Italy, the US and France to enable knowledge transition.</td>
</tr>
</tbody>
</table>

Growth drivers — rising incidence of chronic diseases

- Lifestyle diseases are set to assume a greater share of the healthcare market.
- Lifestyle diseases such as cardiac diseases, cancer and diabetes require biotechnology products for treatment, thereby increasing the revenues of biotech companies.

Changing disease profile

Key trends — pharma companies are focusing on biotech

- Ranbaxy, Cadila Healthcare, Lupin, Wockhardt and Dr Reddy’s are among the major Indian pharmaceutical companies that have entered the bio-pharma segment.

Source: Ernst & Young research

Global companies setting up base

- Lonza is planning to set up a manufacturing base in India at an investment of US$ 150 million in Hyderabad. The investment outlay has been planned over two phases:
  
  - Phase I (from 2011 to 2013) will include the development of R&D labs for more than 100 resources.
  
  - Phase II (from 2014 to 2015) will include the expansion of manufacturing capabilities and the provision for increasing R&D lab capacity for biologics with 200 additional resources.
Key players

- The leading 20 companies (in terms of revenues) accounted for 52 per cent of industry revenues in 2009–2010.

- Biocon and Serum Institute of India are the two leading players in the industry.

- MNCs such as Novo Nordisk and Novozymes feature among the leading 15 biotech companies.

- Of the top 10 companies, 5 generated revenues close to or greater than US$ 100 million in 2009–2010.

<table>
<thead>
<tr>
<th>Leading 10 companies (2009–2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company</strong></td>
</tr>
<tr>
<td>Biocon</td>
</tr>
<tr>
<td>Serum Institute of India</td>
</tr>
<tr>
<td>Panacea Biotec</td>
</tr>
<tr>
<td>Nuziveedu Seeds</td>
</tr>
<tr>
<td>Reliance Life sciences</td>
</tr>
<tr>
<td>Quintiles</td>
</tr>
<tr>
<td>Rasi seeds</td>
</tr>
<tr>
<td>NovoNordisk</td>
</tr>
<tr>
<td>Shantha Biotech</td>
</tr>
<tr>
<td>Mahyco</td>
</tr>
</tbody>
</table>

Sources: ABLE-Biospectrum industry survey, June 2010; Ernst & Young analysis
Contents

- Advantage India
- Market overview
- Industry infrastructure
- Investments
- Policy and regulatory framework
- Opportunities
- Industry associations
Industry infrastructure … (1/2)

- 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 and Alexandria have significantly contributed in establishing biotechnology-related infrastructure in the country.

Source: Ernst & Young research, "Mid term appraisal," Eleventh Five Year Plan
Industry infrastructure … (2/2)

- Around 27 operational parks are operational 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>

Source: Ernst & Young research
Enabling research infrastructure

- In 2009–2010, postgraduate teaching programs in biotechnology were launched at 8 new universities in addition to existing 62 universities.

- Fellowships increased from 100 to 250 per year for PhD students in addition to 100 postdoctoral and 50 biotechnology overseas associate ships.

- The Eleventh Plan aims to provide grant-in-aid to industry for R&D in certain diseases such as malaria and kala-azar.

Sources: Ernst & Young research, "Mid term appraisal," Eleventh Five Year Plan
Contents

- Advantage India
- Market overview
- Industry infrastructure
- Investments
- Policy and regulatory framework
- Opportunities
- Industry associations
Investments… (1/2)

• Four deals were completed in 2010.

• In June 2010, Piramal Healthcare Ltd acquired Canadian biotechnology company Biosyntech, Inc for US$ 4.196 million.

<table>
<thead>
<tr>
<th>M&amp;A scenario — details</th>
<th>Cumulative FDI inflow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Period: January 1, 2010 to October 31, 2010</td>
<td>Period: November 2000 to August 2010</td>
</tr>
<tr>
<td>Deal type</td>
<td>No of deals</td>
</tr>
<tr>
<td>Inbound</td>
<td>2</td>
</tr>
<tr>
<td>Outbound</td>
<td>1</td>
</tr>
<tr>
<td>Domestic</td>
<td>1</td>
</tr>
</tbody>
</table>

Sources: Thomson One Banker, accessed 15 November 2010; Ernst & Young analysis.
## Investments… (2/2)

<table>
<thead>
<tr>
<th>Deal type</th>
<th>Acquirer</th>
<th>Acquirer’s country</th>
<th>Target name</th>
<th>Target country</th>
<th>Completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inbound</td>
<td>Sequoia Capital India Invest</td>
<td>Mauritius</td>
<td>Celon Laboratories Ltd</td>
<td>India</td>
<td>October 5, 2010</td>
</tr>
<tr>
<td>Inbound</td>
<td>Telematic &amp; Biomedica</td>
<td>Italy</td>
<td>MNE Technologies Pvt Ltd</td>
<td>India</td>
<td>March 31, 2010</td>
</tr>
<tr>
<td>Outbound</td>
<td>Piramal Healthcare Ltd</td>
<td>India</td>
<td>BioSyntech, Inc</td>
<td>Canada</td>
<td>June 21, 2010</td>
</tr>
<tr>
<td>Domestic</td>
<td>Anu’s Laboratories Ltd</td>
<td>India</td>
<td>Stilbene Chemicals Ltd</td>
<td>India</td>
<td>April 16, 2010</td>
</tr>
</tbody>
</table>

*Source: Thomson One Banker, accessed 15 November 2010.*
Contents

- Advantage India
- Market overview
- Industry infrastructure
- Investments
- Policy and regulatory framework
- Opportunities
- Industry associations
Policy and regulatory framework… (1/2)

• The National Biotechnology Development Strategy (NBDS), approved in 2007, was aimed at strengthening the industry’s human resources and infrastructure while promoting growth and trade. To further support the NBDS, the GoI allocated US$ 375 million for biotech R&D in 2009, which constitutes around 30 per cent of the total budget allocation for this sector.

• The authority to approve biotech products rests with various agencies such as the Review Committee on Genetic Manipulation (RCGM), the Genetic Engineering Approval Committee (GEAC) and the Drugs Controller General of India (DCGI). The NBDS has proposed the establishment of an independent and autonomous statutory body, the National Biotechnology Regulatory Authority (NBRA), to provide a consistent mechanism for regulatory approvals.

• In July 2008, India’s DBT drafted a new legislation, the National Biotechnology Regulatory Act, to establish and empower the NBRA.

• In the Eleventh Plan, the approval process for legal framework “The Protection and Utilisation of Public Funded Intellectual Property Bill, 2008” was initiated. The bill aims to promote innovation and patenting between innovators and institutions on a profit-sharing basis.

Policy and regulatory framework… (2/2)

Contents

- Advantage India
- Market overview
- Industry infrastructure
- Investments
- Policy and regulatory framework
- Opportunities
- Industry associations
Opportunities — product segments … (1/3)

**Vaccines**
- According to the Eleventh Plan, India is well-poised to become the world’s vaccine manufacturing hub with vaccines for various therapy areas at various stages of clinical trial.
- Development of vaccines for a wide array of diseases are in various stages of approval. Phase –iii clinical trials for rotaviral vaccine have been initiated and vaccines for diseases such as rabies, typhoid, leprosy, anthrax, cholera, malaria and Japanese encephalitis are in various stages of trials. India is well positioned to launch about four vaccines a year beginning 2012.
- Vaccine for H1N1 has been developed under government’s programme for development of indigenous products.

**Oncology**
- In India, the oncology market in 2008 was valued at around US$ 225 million and is expected to reach US$ 850 million by 2012, growing at a CAGR of nearly 30 per cent.
- Companies such as Dabur, Biocon, Dr Reddy’s, Intas, Roche, Cipla and Sun Pharmaceuticals have a significant market presence in the Indian oncology market.
- In addition, current size for cancer diagnostics and treatment equipment is close to US$ 270 million in 2009, which form the largest segment in medical devices segment and is an opportunity for segment related diversification.

**Insulin**
- Novo Nordisk, Eli Lilly, Biocon and Shantha Biotech are the leading players in this segment, while Ranbaxy, Sun Pharma and Glenmark are among the new players.
- Companies are targeting the development of drugs with non-invasive insulin delivery technology.

Opportunities — product segments … (2/3)

**Stem cell research**

- Stem cell research is an emerging opportunity area. India is the second country after the US to allow human clinical trials for drugs using stem cell research. Stem cell research centres at AIIMS and CMC Vellore have been launched.
- A new treatment for heart attack is under development at the research centre of India’s biggest stem cell banking company, LifeCell, in collaboration with US-based device manufacturer for stem cell harvesting, Harvest Technologies. In addition, stem cell finds application in the treatment of Parkinson’s disease, Alzheimer’s disease and diabetes.

**Nanotechnology**

- The GoI supports nanotechnology through its Vision Group initiative. The GoI plans to build three national institutes for nano-science by investing US$ 250 million in infrastructure programmes.
- Nanotechnology has the potential to revolutionise the Indian agriculture scenario and transform the entire food industry. Several Indian firms and research institutes are also working on developing drug delivery products using nanotechnology.

Opportunities — biosimilars … (3/3)

- The increasing use of biologics in disease areas such as cancer and auto-immune and orphan diseases, in addition to healthcare cost containment, has driven the growth of biosimilars.

- Companies in this space include Reliance Biopharma, Shantha Biotech, Panacea Biotec, Wockhardt, Dr Reddy’s, Biocon, Intas Biopharmaceuticals and Avesthagen.

Future opportunity in biosimilars (US$ billion)

<table>
<thead>
<tr>
<th>Patents expired before 2010</th>
<th>Patents expiring 2010-2015</th>
<th>Patents expiring 2016-2020</th>
<th>Biosimilar opportunity-2008 brand value</th>
<th>Biosimilar opportunity-2015 brand value</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.0</td>
<td>39.0</td>
<td>76.0</td>
<td>23.0</td>
<td>115.0</td>
</tr>
</tbody>
</table>

Sources: “Teva investor presentation,” Teva Pharm website, [www.tevapharm.com](http://www.tevapharm.com), accessed 28 January 2010; Ernst & Young research.
Contents

- Advantage India
- Market overview
- Industry infrastructure
- Investments
- Policy and regulatory framework
- Opportunities
- Industry associations
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Note

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