

## BioPharma Analysis

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The BioPharma industry has registered 44 percent growth on account of high growth in statin sales by Biocon. Biocon registered almost 118 percent growth in this business. The largest biopharma company was Serum Institute of India, with total sales of Rs 555 crore. The biopharmaceuticals consist of the diagnostics, vaccines, and recombinant therapeutic proteins. The biotech regulator Genetic Engineering Approval Committee (GEAC), has granted marketing licenses for many recombinant therapeutic proteins and vaccines. These include human insulin, Hepatitis B vaccines, streptokinase, erythropoietin, human growth hormone, human interleukin, granulocyte colony stimulating factor (and granulocyte macrophage colony stimulating factor (G-CSF), alpha and gamma interferon, blood factor VIII, follicle stimulating hormone, tissue plasminogen activator. Of these hepatitis B, erythropoietin, r-DNA human insulin, G-CSF are produced in India. The rest are imported and sold in the local market.

### Vaccines

In vaccines segment, the key players include Bharat Biotech, Biological E, Cadila Healthcare, Cadila Pharmaceuticals, GlaxoSmithKline Pharmaceuticals, Haffkine Bio Pharmaceuticals, Hindustan Antibiotics, Intas Pharmaceuticals, Panacea Biotech, Serum Institute of India, Shantha Biotechnics, Wockhardt, and Wyeth. While Indian Immunologicals is the largest foot and mouth vaccine manufacturer in the world, Venkateshwara Hatcheries is a leading poultry vaccine and diagnostic manufacturer. Others like Hester Pharmaceuticals, Indovax and Agrivet Farm Care, a division of GlaxoSmithKline Pharmaceuticals are some other manufacturers of poultry vaccines in India.

Serum Institute of India is working on combination vaccines (hepatitis B + DPT (diphtheria, pertussis and tetanus), which is expected to launch during the year. It will be the second company after GlaxoSmithKline to launch combination vaccine in the world. Even other companies Shantha Biotechnics and Panacea Biotec are also working on combination vaccines. Indian Immunologicals will launch the r-DNA rabies vaccine, which was developed in collaboration with IISc.

Most of the India biopharmaceutical companies import procedures in bulk and resell it in the local market. Companies like Serum Institute and Haffkine Bio-Pharmaceuticals export their produce to the developing countries at subsidized prices under UNICEF/ WHO programs. These companies are selling DPT, DT, Tetanus Toxoid, BCG, oral polio, measles, mumps, rubella, hepatitis B vaccine, rabies (tissue culture based), typhoid (injectable) vaccines. In 2003-04 the vaccines business registered 28.15 percent growth and accounted for 47.17 percent of the market share.

The next biggest segment was therapeutics, with total sales of Rs 415 crore. This segment accounted for 16.7 percent of the total biopharma market share and grew by over 23 percent. Eli Lilly, Bharat Biotech International, Cadila Healthcare, Cadila Pharmaceuticals, Emcure Pharmaceuticals, Intas Pharmaceuticals, M J Pharmaceuticals, Nicholas Piramal, Novo Nordisk, Roche Scientific Company, Serum Institute of India, Shantha Biotechnics, Shreya Life Sciences, and Wockhardt are some of the big names in this segment. Biocon is likely to launch its human insulin in India this year.

Several companies are investing about 5-7 percent of their total revenue on R&D programs to develop cures for diseases such as tuberculosis, HIV, malaria, cholera, dengue, cancer, typhoid, and heart diseases. Intas Pharmaceuticals has developed Granulocyte macrophage colony stimulating factor (G-CSF) and launching it under the brand name Neukine in August.

## Diagnostics

In the diagnostics segment only a handful of companies manufacture diagnostic kits. These include Accurex Biomedicals, Beacon Diagnostics, Bhat Biotech, Bio-systems Diagnostics J Mitra & Co, Monozyme India, Span Diagnostics Ltd, Transasia Biomedicals, Tulip Group and XCyton Diagnostics. The Department of Biotechnology (DBT) has facilitated the transfer of many technologies for diagnostic kits to the industry developed at the CSIR labs.

| Top BioPharma Companies  |                       |                       |          |
|--------------------------|-----------------------|-----------------------|----------|
| Company                  | 2002-03<br>(Rs Crore) | 2003-04<br>(Rs Crore) | % growth |
| Serum Institute of India |                       | 555                   |          |
| Biocon Ltd               | 200                   | 435.37                | 117.69   |
| Panacea Biotec           | 169.23                | 149.53                | -11.64   |
| Nicholas Piramal         | 70.64                 | 130                   | 84.03    |
| Novo Nordisk             |                       | 110                   |          |
| Venkateshwara Hatcheries |                       | 88                    |          |
| Wockhardt Ltd            | 74                    | 84                    | 13.51    |

|                                |         |         |        |
|--------------------------------|---------|---------|--------|
| GlaxoSmithKline                |         | 80      |        |
| Bharat Serums                  | 58      | 79.68   | 37.38  |
| Eli Lilly                      | 46.05   | 67.46   | 46.49  |
| Krebs Biochem                  | 64.26   | 56.88   | -11.48 |
| Indian Immunologicals          | 46.13   | 56.7    | 22.91  |
| Cadila Healthcare              |         | 55      |        |
| Biological E                   | 17.06   | 38.48   | 125.56 |
| Shantha Biotechnics            | 24.29   | 36.5    | 50.27  |
| Span Diagnostics               | 26.77   | 35.62   | 33.06  |
| Bharat Biotech                 | 19.98   | 31      | 55.16  |
| Indian Herbs Research & Supply | 17.85   | 23.95   | 34.17  |
| Haffkine Bio-Pharma            | 71.31   | 29.9    | -58.07 |
| Themis Medicare                | 10.1    | 11      | 8.91   |
| Total TOP20 BioPharma          | 915.67  | 2154.07 | 135.25 |
| Total Others*                  | 805     | 326.03  | -59.5  |
| Total BioPharma Segment        | 1720.67 | 2480.1  | 44.14  |

*Note: \*Others in 2002-03 include the sale of some of this year's Top 20 companies, the figures for which were not available during the year.*

These diagnostic companies are selling kits mainly in the areas of pregnancy, ovulation, estimation of T3, T4 & TSH, HIV infection, HBV infection, HCV infection, rheumatoid diseases and disorders, cancer (cervix, colon, prostate, lungs, mouth etc.), kidney function tests and liver function tests.

The total diagnostic market in 2003-04 stood at Rs 260 crore and accounts for 10 percent of the total market share of the biopharma sector. This sector grew by about 46 percent.

The others primarily have been the statins business. This business was in excess of Rs 500 crore. In the last fiscal indigenously developed recombinant streptokinase was announced by Shantha and Bharat Biotech. But these products may be available this fiscal commercially. Besides these products, we may see the launch of Biocon's insulin and Intas' Neukine, a granulocyte colony-stimulating factor G-CSF, Indian Immunologicals r-DNA rabies vaccines. The market is also upbeat about the possibility of a new national biotech policy and also some changes in the regulations. The industry is hopeful and the total biopharma segment is forecast to grow by about 35-40 percent in FY 2005.