PANACEA BIOTEC

HUMBLE BEGINNING... GREAT FUTURE

Panacea Biotec is India's one of the leading health management company. Way back in 1927, the company started of as a pharmacy shop in Sialkot, now in Pakistan. In 1927, the family shifted to Delhi and put up the first pharma plant in Delhi. In 1983, it collaborated with an Italian company called Sclavo, which later on was acquired by Chiron and then by Novartis. The company initially started with its their various products and started marketing them. In 1984, Panacea Drug was set up with a commitment to make novel and innovative medicines affordable to the masses. In 1989, a vaccine manufacturing plant was set up in Delhi under the name of Radicura Pharma.

In 1989, a pharma formulations plant was set up in New Delhi, under the name of Panacea Drug. In 1993, Panacea Drugs and Radicura Pharma were merged to form Panacea Biotec. The company went public in 1995. With the money from IPO, more sales staff were hired and products were introduced.

Between late 90s and early 2000, a collaboration was held with Cuba-based Heber Biotec and a manufacturing plant was set up at Lalru, Punjab for hepatitis vaccine. In 2005, the world's first pentavalent vaccine was developed in collaboration

Dr Rajesh Jain, Joint Managing Director, Panacea Biotech

PHARMACEUTICAL MANUFACTURING SECTOR NEEDS GREATER ASSISTANCE IN TERMS OF AVAILABILITY OF FINANCE, TAX INCENTIVES FOR UPTO 10 YEARS FOR CAPACITY ENHANCEMENT AND SETTING UP R&D UNITS

with Chiron, which was launched in the same year. Also in 2005, the company raised $100 million from the foreign convertible currency bonds to fund expansion and put up more R&D centres.

The team at Panacea Biotec led by Dr Rajesh Jain crafted the 'Vision 2020'. The vision 'To create Panacea Biotec as one of the World's Greatest, Largest and Most Admired Biotechnology Company by 2020.' The vision covered the four perspectives of customer; finance; internal learning, growth, and innovation and internal processes.

Under the vision 2020, the company developed 23 strategic objectives, cascaded with currently 168 strategic initiatives. The three pillars, which lay the foundation of vision 2020, are: 'One Click' (all information is available to anyone with just one click), 'Zero Slip' (deliver whatever you commit without any slips), and 'Zero Defect' (absolutely no defect in the quality to the customer).

MANUFACTURING FACILITIES

The company's manufacturing facilities for vaccines and pharma formulations were situated at Lalru and Baddi. It has state-of-the-art integrated facility for drug substance of vaccines and biosimillars at Lalru and were set up in compliance with international regulatory standards including US FDA, WHO-cGMP and European Union.

PHARMA FORMULATIONS

Facility at Baddi

The facility in Baddi became operational in 2006. It is equipped for conventional tablets, bi-layered tablets, tablet-in-tablet, mini-tablets, complex sustained release coatings and delayed release coatings. The facility has been approved by National Regulatory Authority of India (NRA), US FDA, BfArM Germany and ANVISA Brazil etc. The facility has faced many regulatory audits and successfully received product approvals as under:

- Cleared 3 audits from USFDA,

LAKSH: Drug Discovery Research and Development Centre, Mohali

Global Research and Development Centre (GRAND), Mumbai

◗ Cleared audit from BfArM Germany.
◗ 161 products approval received from 14 countries.

The company has recently set up a Cytotoxic (anti-cancer) formulation facility at Baddi, with two lines dedicated for liquid and lyophilised vials as well as pilot scale up batches. It has filed seven ANDA with US FDA from this facility.

Vaccines formulation facility

The vaccine formulation facility at Baddi is spread across 23 acres. It is WHO pre-qualified for Pentavalent Vaccine Easy FiveTT. It consists of two blocks which started its operations in 2008. The facility consists of production, quality control and quality assurance, warehousing and cold storage facility. It has filling lines for injectable liquid vaccines in pre-filled syringe (PFS), liquid and lyophilised vaccines in vials. The facility has also been approved by Indian NRA.

Vaccine antigens and biosimillars at Lalru

The company has drug substances, vaccine and antigen manufacturing facilities with dedicated blocks for manufacture of recombinant, bacterial and viral vaccine bulk and antigens. It manufactures Recombinant Hepatitis B surface antigen, Haemophilus influenzae type B conjugate bulk (Hib-TT) diphtheria, tetanus toxoids and whole cell pertussis.

Working for 'Make in India'

Panacea Biotec under the leadership of Dr Rajesh Jain lays a strong emphasis on 'Make in

STATE-OF-THE-ART PHARMACEUTICAL MANUFACTURING FACILITY AT BADDI IS USFDA, BFARM, ANVISA CERTIFIED

India'. The company focused on high quality infrastructure, quality management process, skill development, innovation, own R&D and adoption global management practices.

CORE STRENGTHS

Established R&D capabilities

The company has built a strong R&D base over the last decade to support its various business segments and the current research strengths of Panacea Biotec are focused on:

- Drug delivery system design and optimisation
- Discovery and synthesis of new chemical and biological entities
- Design and development of new generation prophylactic and therapeutic vaccines
- Development of humanised and fully human therapeutic monoclonal antibodies.
- The company has several novel vaccines in pipelines few of them includes Japanese Encephalitis, pneumococcal, dengue conjugated tetravalent recombinant vaccine, which the company is intended to launch in next two to three years.

R&D initiative includes:

- Panacea Biotec is the first to develop fully liquid pentavalent vaccine – Easyfive (DTwP-Hep B-Hib)
- First to develop monovalent OPV (Oral Polio Vaccine)
- First to develop Bivalent OPV (Oral Polio Vaccine)
- The company has launched indigenously developed Albumin bound paclitaxel particles formulation – PacliALL for breast cancer

The company has collaborated with leading research institutes, academic universities and commercial corporations.

These efforts are sustained by dedicated R&D centres for biological research, NCE/NBE, NDDS, and difficult-to-develop generics have enabled the company to become one of the leading research institution through its product pipeline such as Nab-Paclitaxel, doxorubicin liposomes, pentavalent vaccine, pneumococcal conjugate vaccine, trasutizumab, recombinant darbepoietin etc. Panacea Biotec's R&D efforts are focused on four major areas of research -

- NCE research: Metabolic disorders, anti-infectives, CNS
- NBE research: Autoimmune diseases, dermatology, metabolic disorders

Pharmaceutical formulation facility, Baddi,
Himachal Pradesh

SAMPANN: Drug delivery research and development centre, Lalru, Punjab

- Drug delivery research: Oral modified release, nanotechnology, depot injections, transdermal systems
- Vaccine research: New generation combination vaccines, new prophylactic vaccines (paediatric and adult)

STRONG BRAND PORTFOLIO

Panacea Biotec's product portfolio includes highly innovative prescription products in important therapeutic areas such as pain management, cardiovascular disease management, organ transplantation, diabetes management, renal disease management, oncology, anti-osteoporosis, anti-tubercular, gastro-intestinal care products and vaccines.

MOTIVATED TEAM

There are around 2,748 people working together to achieve the goal of meeting every healthcare need with a Panacea Biotec brand and service. It has more than 116 scientists, over 571 employees engaged in production and quality control/quality assurance and over 1,289 professionally trained and motivated employees engaged in sales, marketing and logistic activities.

QUALITY ASSURANCE

Quality is at the core of Panacea Biotec's business processes and systems. Its manufacturing facilities for vaccines and pharma formulations comply with various key international regulatory standards like WHO cGMP, USFDA, BfArM Germany, ANVISA Brazil, etc.

INTELLECTUAL PROPERTY

The company has been granted 34 product patents worldwide for different products/ technologies. As at the end of the year under review, the company has filed around 1,516 patent applications worldwide (including 225 Indian and 102 PCT applications) out of which 422 patents have been


UNDER PROCESS

Vaccine formulation facility, Baddi, Himachal Pradesh

granted/accepted for grant including six patents granted in Russia, China, Europe, the US and India during the year under review.

The company has filed over 723 trade mark registration applications out of which 441 have been registered including five applications registered during the year under review.

In addition, the company has also filed 515 International Trade Mark applications out of which 291 have been granted.

Great future ahead

The company's strategy is to develop and launch selective portfolio of difficult to develop generics with high barrier to entry. Following this strategy, the company has already identified some niche products which are currently under different stages of development at its R&D centres, these include:

- Cyclosporine SEDDS capsules
- Anticancer drugs nanoparticles, depot injection, liposomes
- Urology drug depot injection
- Antifungal drug
- Immunosuppressant Modified Release
- Antiemetic Nanoparticle Oral Formulation

The company is also developing 505(b)(2) products for US, these include:

- ESRD Drug Suspension
- Pregabalin Modified Release
- Voriconazole Modified Release
- Mycophenolate Modified Release

Growing in overseas market

The company has laid its future growth strategy with focus on the regulated markets of the US and Europe. The company launched its first product Tacpan (Tacrolimus) in 2011 in Germany and it has now become the second largest generic in Germany. It has also launched Tacrolimus in the US in December 2012.

Over the last few years, the company's R&D centres have completed development of several products and the company has filed 7ANDAs with US FDA since its first product was launched in the US.

The company has also strategically partnered with the Russian Federation government for immunosuppressant's such as Panimun Bioral and Mycept. It will introduce brand Pangraf (Tacrolimus) in the Russian market.

The company is in the final stages of registration and approval in key markets like Egypt, South Africa & Saudi Arabia (GCC).

ACHIEVEMENTS

1984 Incorporated as Panacea Drugs

1989 Production of pharmaceuticals and vaccines commenced

2003 Pre-Qualification of Oral Polio Vaccine (OPV) by WHO

2005 Launch of "EasyFive": 1st fully liquid pentavalent vaccine in the world

2006 Collaboration with Netherlands vaccine Institute (NVI) for introduction of Inactivated Polio Vaccines (IPV)

2008 WHO Pre-Qualification for Pentavalent Vaccine (EasyFive)

2011 Supply of over 45 million doses of Pentavalent Vaccines (EasyFive) to UNICEF, GAVI for supply in over 31 countries

2011 PacliALL – 1st nanoparticle affordable Albumin-based Paclitaxel anti-cancer formulations launched in India which received Biospectrum Product of the Year Award

2012 Collaboration with PT BioFarma, Indonesia

2012 Launch of pharmaceutical formulations in the US market.

2014 Polio eradication: Panacea Biotec has played a key role in polio eradication in India by supplying over 10 billion doses OPVs to Government of India, UNICEF over last 15 years.

2014 Long-term supply contract with WHO for supply of Pentavalent vaccine (Easyfive TT) for the period of 2014-16

2014 Strategic alliance with Apotex, Canada for marketing PBL drugs in North American markets.

2014 Strategic collaboration with Rising Pharmaceuticals. USA, for marketing PBL drugs in US