



# *Panacea Biotec*

*Innovation in support of life*



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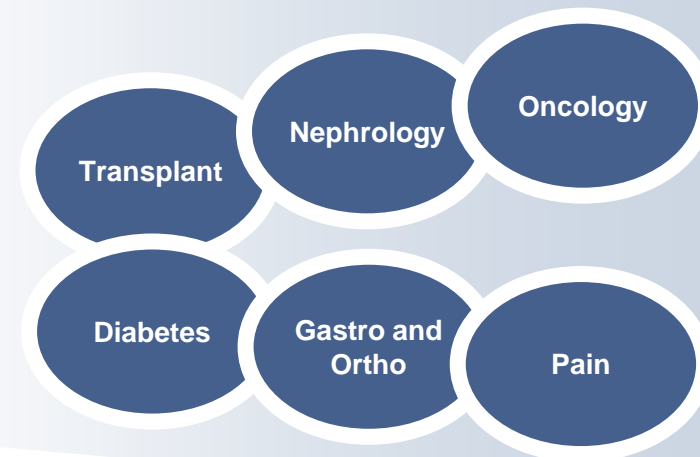
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## Corporate Overview

- **Core Business : Pharmaceuticals, Vaccines**
  - 2nd largest vaccine producer in India
  - Leadership position in key pharmaceutical therapeutic segments like Oncology, Nephrology/Transplant, Diabetes, Gastro-intestinals, Health Supplements
- **Key Business Highlights (Pharma)**
  - Commercialized Tacrolimus in US, Europe & ROW countries
  - Commercialized over 25 branded products including PacliAll - Paclitaxel Nanoparticles (albumin Bound) in Emerging Markets & ROW countries
  - 6 ANDAs filed in US and 17 products (ANDA & 505 (b)2 NDA) in pipeline
  - 4 NCEs in development, 1 best in class molecule in phase-1 under US IND
- **Key Business Highlights (Vaccines)**
  - Developed and launched world's first fully liquid pentavalent vaccine and bivalent oral polio vaccine globally
  - Selected by WHO as partner to develop sIPV in collaboration with RIVM, Netherland

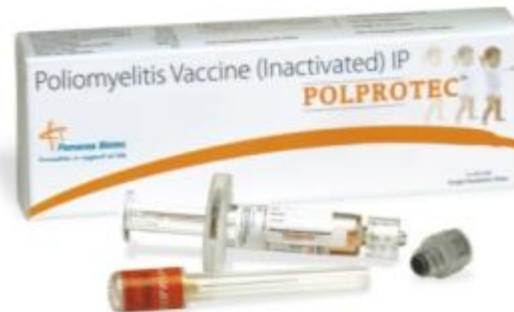
# Pharmaceuticals Business Overview

- Wholly owned subsidiary in Germany & Switzerland
  - Panacea Biotec Germany GmbH- Focus on specialty hospital products – commercialized Tacrolimus as branded generic (Tacpan) & Mycophenolate
  - Panacea Biotec Switzerland – Focus on Global Business Development , in-licensed products for commercialization in Europe, ANZ
- Strategic Collaborations in North America:
  - Apotex – Co-investment and Marketing Partner for Nanoparticle and Liposome Drug Delivery Products
  - 6 ANDAs being reviewed by USFDA
- Presence in over 20 Emerging markets:
  - CIS, LATAM, Africa, Middle East, Asia
  - 50 branded products
- Strong Presence in Indian Market:
  - 7 Strategic Business Units
  - Leading brands in Diabetes, GI Oncology, Nephrology & Organ Transplant segments



## Vaccine Business Overview

- Established presence of over 25 years in vaccines - Leading player in **critical pediatric** vaccines
- Played pivotal role in polio eradication, being the largest supplier of oral polio vaccines to UNICEF and GOI (**supplied over 9 bn doses of oral polio vaccines**)
- Amongst largest suppliers of vaccines to UNICEF, Govt. of India's, National Governments
- Developed and launched **world's first fully liquid pentavalent vaccine** and bivalent oral polio vaccine globally
- Selected amongst first two technology transfer partners for WHO project of Safe & Affordable **sabin IPV (sIPV)** for the developing world in collaboration with RIVM, Netherlands
- **Fully Liquid Hexavalent Vaccine** – Launch Planned – in 2016
- **Pipeline:** Pneumococcal Conjugate Vaccine, Dengue Vaccine





## Innovation Capabilities



### **GRAND : Platform Drug Delivery Systems**

- Focus areas : Nanoparticles, Liposomes, Microparticles, Gastroretentive Systems, Oral films
- **Nanoparticle** paclitaxel introduced in India
- 4 high barrier to entry ANDAs filed in US



### **Sampann : Molecule Specific Drug Delivery Systems, Generics**

- Focus areas : Oral modified release, SMEDDS in softgels, Transdermal, MD tablets, High barrier to entry generics
- 10 Novel Drug Delivery products in India
- 2 Products approved in EU, 1 Product approved in US, 1 FTF ANDA under review in US

### **Onestream : Drug Discovery Novel Biologicals, Biosimilars, Vaccines**

- Target identification to development of pre-clinical candidate
- Biosimilars : Darbepoetin, Trastuzumab,
- Vaccines : Pneumococcal, Dengue, Meningococcal, Japanese Encephalitis



### **Laksh : Drug Discovery Small Molecules**

- Target identification to development of pre-clinical candidate
- Focus areas : Metabolic disorders, Anti-infectives, CNS
- 4 NCEs in development



# Drug Delivery Technologies

## TECHNOLOGY

- Nanoparticle systems:
  - For targeted release and reduced side effect profile
  - For bioavailability enhancement

## PRODUCT

- Paclitaxel Nanoparticles

- Liposome systems:
  - For prolongation of circulation time of therapeutic agents
  - For delivery of vaccines

- Doxorubicin Liposomes

- Microparticle systems:
  - For long acting depot injectables

- Leuprolide Depot
- Octreotide Depot

- Advanced oral drug delivery systems
  - Gastroretentive systems (SPORT platform)
  - Oral films delivery system
  - Inorganic Particle Synthesis and Delivery

- Memantine SPORT
- Tadalafil Film
- Lanthanum Suspension

- Inorganic Sol-Gel topical delivery systems

- Acyclovir Cream



## Manufacturing facilities (Pharma Formulations)



Source: Management

### Location – Baddi, India

- **Start of operations:** April 2006
- **Oncology unit established in 2012**
- **No. of employees:** 425
- **Total built up area-** 70,000 sqm

### Capacity

Production Lines	Annual capacity (mns)
<b>Anticancer (Cytotoxic Products)</b>	
Liquid and lyophilized Injectables	1.2
<b>Other Dosage Forms</b>	
Tablets	3,000
Hard Gelatin Caps	650
Soft Gelatin Caps	150
Ointments & Gels	42
Liquid Orals	24

## Manufacturing facilities (Pharma Formulations)

- State of art cGMP facility with approvals from global regulatory authorities viz. US FDA, EU agencies, ANVISA, TGA and many other agencies
- 161 products approval received from 14 countries
- Maintain high standards of manufacturing by using state of art GMP compliant machines like Sejong for tablet compression, BQS for packaging
- Equipped for: **Bi-layer tablets, Tablet-in-Tablet, Mini-tablets, Complex Sustained release coatings and Delayed release coatings.**
- Oncology injectable facility is equipped for manufacturing **Conventional, Nano particular, Liposomal, Lyophilized products**

### Major Accreditations:

- USFDA
- German Authorities
- Brazil (ANVISA)
- Australia
- Turkey

# Manufacturing facilities (Vaccines)

**Baddi, HP**



**Lalru, Punjab**



Okhla, New Delhi	
Start of operations	1988
Area	50,000 sqft
No. of employees	257
Capacity	820 mn doses p.a. (3 vial filling lines)
Accreditations	Indian NRA WHO GMP*

Baddi, HP	
Start of operations	2002
Area	129,167 sqft
No. of employees	253
Capacity	One bn doses p.a. (2 filling lines for bacterial and viral vaccines)
Accreditations	Indian NRA WHO GMP

Lalru, Punjab	
Start of operations	2007
Area	98,000 sqft
No. of employees	473
Capacity	25 mn doses p.a. (recombinant, bacterial, tetanus and cell culture capabilities)
Accreditations	Indian NRA WHO GMP

**Two vaccine formulation facilities with a combined capacity of 1 billion doses per annum with capabilities in pre-filled syringes and vials**

**Indigenous & fully integrated bulk antigen manufacturing facilities**

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# *Thank you*

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