Panacea Biotec

Innovation in support of life
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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, Gasto-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

<table>
<thead>
<tr>
<th>TECHNOLOGY</th>
<th>PRODUCT</th>
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<tbody>
<tr>
<td><strong>Nanoparticle systems:</strong></td>
<td>Paclitaxel Nanoparticles</td>
</tr>
<tr>
<td>– For targeted release and reduced side effect profile</td>
<td></td>
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<tr>
<td>– For bioavailability enhancement</td>
<td></td>
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<tr>
<td><strong>Liposome systems:</strong></td>
<td>Doxorubicin Liposomes</td>
</tr>
<tr>
<td>– For prolongation of circulation time of therapeutic agents</td>
<td></td>
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<tr>
<td>– For delivery of vaccines</td>
<td></td>
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<tr>
<td><strong>Microparticle systems:</strong></td>
<td>Leuprolide Depot, Octreotide Depot</td>
</tr>
<tr>
<td>– For long acting depot injectables</td>
<td></td>
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<tr>
<td><strong>Advanced oral drug delivery systems</strong></td>
<td>Memantine SPORT, Tadalafil Film, Lanthanum Suspension</td>
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<tr>
<td>– Gastroretentive systems (SPORT platform)</td>
<td></td>
</tr>
<tr>
<td>– Oral films delivery system</td>
<td></td>
</tr>
<tr>
<td>– Inorganic Particle Synthesis and Delivery</td>
<td></td>
</tr>
<tr>
<td><strong>Inorganic Sol-Gel topical delivery systems</strong></td>
<td>Acyclovir Cream</td>
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</tbody>
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**Confidential**
Manufacturing facilities (Pharma Formulations)

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

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

Source: Management
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)*

<table>
<thead>
<tr>
<th>Okhla, New Delhi</th>
<th>Baddi, HP</th>
<th>Lalru, Punjab</th>
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<tbody>
<tr>
<td><strong>Start of operations</strong></td>
<td>2002</td>
<td>2007</td>
</tr>
<tr>
<td><strong>Area</strong></td>
<td>50,000 sqft</td>
<td>129,167 sqft</td>
</tr>
<tr>
<td><strong>No. of employees</strong></td>
<td>257</td>
<td>253</td>
</tr>
<tr>
<td><strong>Capacity</strong></td>
<td>820 mn doses p.a. (3 vial filling lines)</td>
<td>One bn doses p.a. (2 filling lines for bacterial and viral vaccines)</td>
</tr>
<tr>
<td><strong>Accreditations</strong></td>
<td>Indian NRA WHO GMP*</td>
<td>Indian NRA WHO GMP</td>
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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

For further Information, please contact:

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