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Except for the historical information contained herein, statements in this presentation and the subsequent discussions, which include words or phrases such as “will”, “aim”, “will likely result”, “would”, “believe”, “may”, “expect”, “will continue”, “anticipate”, “estimate”, “intend”, “plan”, “contemplate”, “seek to”, “future”, “objective”, “goal”, “likely”, “project”, “should”, “potential”, “will pursue” and similar expressions or variations of such expressions may constitute "forward-looking statements". These forward-looking statements involve a number of risks, uncertainties and other factors that could cause actual results to differ materially from those suggested by the forward-looking statements. These risks and uncertainties include, but are not limited to our ability to successfully implement our strategy, our growth and expansion plans, obtain regulatory approvals, our provisioning policies, technological changes, investment and business income, cash flow projections, our exposure to market risks as well as other risks. Sun Pharma Advanced Research Company Limited does not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date thereof.
About us

- In 2007, Sun Pharmaceutical Industries Ltd, spun off its innovative business into an independent, listed company, viz; Sun Pharma Advanced Research Company Ltd. (SPARC)
- SPARC is focussing on new drug discovery and novel drug delivery systems based programs.
- 2 state of the art research facilities.
  - 160 labs spread over 120,000 sq ft floor space.
- Scientific manpower 237
SPARC – Innovating, with measured risk.

- A disciplined and systematic innovation process
- Focus on niche indications with predictable and sustainable market
- Develop products/technologies which solve unresolved problems and add meaningful value
- Early confirmation of the proof of concept
- Balanced resource allocation to projects of short and long gestation period
SPARC – Innovating, with measured risk.

Key approaches to research at SPARC

NDDS
Approach

- Improve patient compliance
- Enhance safety
- Reduced regulatory hurdles
- Expand product indications

NCE
Approach

- Work on validated targets and biology
- Address limitations of current products
- Improve therapeutic index and product PK characteristics
Technology Platforms

Oral

- Gastro Retentive Innovative Device (GRID)
- Wrap Matrix System

Injectables

- Nano particulate formulations
- Biodegradable Depot Injections.

Topical

- Dry Powder Inhaler (DPI)
- Extended Release (ER) Microspheres for Topical Applications
- GFR Technology for Once a Day Ophthalmic formulations
- SMM Technology for Ophthalmic Formulations
NDDS – DPI Platform
Salmeterol and Fluticasone DPI Market Opportunity

- 300 million Asthma patients worldwide (WHO).
- Asthma market in developed countries (US, Europe and Japan) was valued at $21 billion in 2008.*
- Inhalation drugs contribute 70% of this market.
- Total market of inhaled beta agonists and corticosteroids in the developed markets was valued at $15.2 billion in 2008.*
- DPIs containing long-acting beta agonists and inhaled corticosteroids constitute largest drug class with sales of US$ 8.3 billion* and market share of 54%.

*Source: IMS
Salmeterol and Fluticasone DPI: Market Opportunity

- Salmeterol and Fluticasone DPI is the most successful DPI globally with annual sales of $7.7 B. in 2009.

Source: IMS
Dry Powder Inhaler (STARHALER™)

SPARC’s DPI is a pre-metered, 60 dose, inhalation activated device for administration of combination of inhaled steroids and bronchodilator drugs

- Uniform dose delivery independent of inspiratory flow rate
- Consistently delivers higher amount of drug to lungs
- Eliminates double dosing and dose wastage
- Provides visual, audible and tactile feedback upon dose administration
- Glow-in-the-dark feature for easy night-time use
- Feature for assisting visually impaired, as reminder to refill device, when 8 doses remain
- Small and convenient for easy to carry.
- Compliant to the stringent USFDA and European requirements.
STARHALER™ – Designed by Best-in-Class Global Development Partners
3 simple user steps: ready when required, no preparation required

Device works irrespective of orientation of device: no dose spillage

Easy to use by pediatric, adult, and geriatric patients
Product performance: >100% higher drug delivery to lungs*

* Based on In-Vitro Studies
Product performance: Significantly reduced Oro-pharyngeal deposition*

*Based on In-Vitro Studies
**Device Resistance**

Starhaler device is a medium-resistance device that can be used effectively by all patient population.

**Resistance (cm H2O^{0.5} min./L)**

- **Inhalator (BI)**
- **Twisthaler (Schering P)**
- **Turbuhaler (AZ)**
- **Starhaler (SPARC)**
- **Diskus (GSK)**
- **Novolizer (Viatris-Meda)**
- **Aerolizer (Novartis)**
Consistent drug delivery at varying flow rates: data for fluticasone*

* Based on In-Vitro Studies
Consistent drug delivery at varying flow rates: data for salmeterol*

* Based on In-Vitro Studies
Equivalent clinical efficacy at “half the dose” of Seretide Accuhaler®

Randomized, Comparative, Active Controlled, Multi-Center Study in Asthma Patients in India

- Comparing
  - SPARC DPI containing Salmeterol 25mcg / Fluticasone 250mcg (TEST) &
  - Seretide Accuhaler® –(Salmeterol 50mcg / Fluticasone 500mcg ) (REFERENCE)
- Treatment duration = 4 weeks, N = 113

Study Outcome

- Equivalent efficacy to Seretide Accuhaler® on all primary and secondary end points

- SPARC’s DPI demonstrated statistically and clinically significant improvement vs. no treatment baseline in all efficacy parameters studied

- Efficacy of SPARC’s DPI in improving lung function demonstrated by:
  - Reduction in use of rescue medication
  - Day and night time asthma symptoms
  - Global impression of change rated by subjects and investigators
Equivalent clinical efficacy at “half the dose” of Seretide Accuhaler®

Average Morning PEFR by Treatment Group by Treatment Week (n = 107)

FEV1 from baseline to week 4 (n = 107)

* p < 0.0001 for change from baseline

- **TEST** = SPARC’s DPI containing Fluticasone 250mcg/Salmeterol 25mcg
- **REF** = GSK’s SERETIDE ACCUHALER® Fluticasone 500mcg/Salmeterol 50mcg
Future development plan

US -505(b)(2) route.
- Pre IND meeting completed.
- IND filing in FY12

India
- Product is launched in India
DPI Platform : Summary

- Efficient drug delivery
- Easy to use
- Optimized device design
- Meets all requirements
- Developed for ICS/LABA combination
- Can be used for other drug combinations in asthma & COPD
- Other products on same platform to follow
- Can be used for other drug delivery through lung

Salmeterol and Fluticasone DPI is registered and launched by Sun Pharma in Q3 FY12.
NDDS – Nano-particulate Injection Platform
Taxane– Market Opportunity

- Taxanes - Most successful drug class for solid tumors.
- Established standard of care for advanced cancers of breast, lung, ovary, prostate, cervix, esophagus and stomach, urinary tract & bladder and head & neck region.
- Both paclitaxel and docetaxel became “blockbuster” anticancer drugs because of their significantly higher response rates and survival advantages in wide range of solid tumors.
- Limitations of Paclitaxel
  - Very high incidence and severity of toxicities especially hypersensitivity reactions, neutropenia and peripheral neuropathies.
  - High incidence of hypersensitivity reactions due to use of Cremophor®.

In USA, an estimated 115,000 patients are treated with paclitaxel per year.
Taxane – Market Opportunity

• ABRAXANE®, is the first marketed “Cremophor® free” formulation of Paclitaxel, now approved in 39 countries.

• ABRAXANE offers the advantages of no requirement of premedication, shorter 30 minutes infusion time, reduced toxicities and ability to give higher paclitaxel dose compared to conventional formulation

• ABRAXANE® commands significantly higher price compared to generic Paclitaxel. (Approx 35 times of the current generic paclitaxel price in USA and at about 2 times the price of TAXOL® in year 2000 before generics entry)

• ABRAXANE® achieved a sales of $317 million (MAT Sep’09) at an estimated 15% patient share (~16000 patients) from generic paclitaxel (~115,000 patients)

Paclitaxel Injection Concentrate for Nanodispersion (PICN) with its demonstrated advantages against ABRXANE, has the potential to command 15 to 20% of the patient share of Paclitaxel

ABRAXANE® is marketed by Celgene corp, USA
Nano particulate Formulations

The Technology

- Novel self-dispersing nano-particle technology platform for “difficult to formulate”, insoluble” anticancer drugs

Composite Nanoparticles
Anticancer Drug + Polymer + Lipid

Nanometer sized particles
i.e. 1/1000th of a human hair thickness

Key Advantages

- Uses very safe excipient with no added toxicities
- Drug molecule remains the same; not covalently bound or altered.
- Low excipient to drug ratio.

- Delivers higher dose without increased adverse event profile.
- Eliminates the need of pre-medication, special infusion bags/bottles, and in-line filters
Paclitaxel Injection Concentrate for Nanodispersion (PICN)

Novel formulation of Paclitaxel using SPARC’s proprietary nano particle platform technology

- Achieves 30% higher drug concentration in tumor tissues compared to conventional paclitaxel
- Shorter infusion time (30 min)
- Unlike ABRAXANE®, quick and easy “one step” dilution and infusion preparation
- Significantly higher MTD dose in Phase I study suggesting of improved safety profile

PICN as How Supplied

PICN after Reconstitution

Electron microscope image of nano particle
Safety established at high doses in Phase I clinical trial

**Study** enrolled 36 patients with metastatic breast cancer and who have progressed to at least one combination chemotherapy.

**Key Findings**

**Safety Data Analysis**

- 28 patients exposed to PICN.
- Dose limiting toxicity was observed at 325mg/m²
- NO pre-medication with high dose corticosteroids, antihistamines or anti-emetics.
- NO hypersensitivity reactions in in ANY patients
- Less neuropathy

**Toxicity comparable to ABRAXANE®***

<table>
<thead>
<tr>
<th></th>
<th>PICN 260mg/m² n= 9, (%)</th>
<th>ABRAXANE®† 260mg/m² n=229, (%)</th>
<th>TAXOL®† 175mg/m² n=225, (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia &lt;2.0 x 10⁹/L</td>
<td>7 (78)</td>
<td>183 (80)</td>
<td>185 (82)</td>
</tr>
<tr>
<td>Neuropathy Any Symptoms</td>
<td>1 (11)</td>
<td>163 (71)</td>
<td>124 (56)</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>23 (10)</td>
<td>7 (2)</td>
</tr>
</tbody>
</table>

*This comparison with large historical data of Abraxane ® and Taxol is for the purpose of interpreting  PICN data. PICN safety remains to be established in large, randomized clinical trial

† ABRAXANE PI
Demonstrated comparable efficacy to ABRAXANE® in ongoing phase II clinical study...

- Phase II study is ongoing with 260 mg/m² and 295 mg/m² PICN dose comparing with 260mg/m² Abraxane® in metastatic breast cancer

**Phase II study at a glance**

- Targeted patient enrollment completed (n = 180)
- Comparable efficacy to Abraxane
- Significantly lower grade III/IV neutropenia and peripheral neuropathies compared to ABRAXANE®

**Interim Efficacy Data Analysis of 140 patients**

<table>
<thead>
<tr>
<th></th>
<th>ABRAXANE®</th>
<th>PICN</th>
<th>PICN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>260mg/m²</td>
<td>260mg/m²</td>
<td>295mg/m²</td>
</tr>
<tr>
<td>n</td>
<td>n=43, (%)</td>
<td>n=51, (%)</td>
<td>n=46, (%)</td>
</tr>
</tbody>
</table>

Objective response rate (ORR): 19 (49%) for ABRAXANE®, 19 (42%) for PICN 260mg/m², and 16 (46%) for PICN 295mg/m².

We looked at early efficacy data with following understanding:

1. Data includes CT scan reports as available in Aug 2011 for Cycle 2, Cycle 4 or Cycle 6.
2. The study is ongoing.
**Significantly lower Grade 3/4 AEs at equivalent doses compared to ABRAXANE® in ongoing phase II study**

<table>
<thead>
<tr>
<th>MedDRA System Organ Class/ PT</th>
<th>ABRAXANE® (N = 43) n (%)</th>
<th>PICN 260 (N = 51) n (%)</th>
<th>PICN 295 (N = 46) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Blood and lymphatic system disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutropenia</td>
<td>10 (23)</td>
<td>6 (12)</td>
<td>13 (28)</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>7 (16)</td>
<td>5 (10)</td>
<td>5 (11)</td>
</tr>
<tr>
<td>Anaemia</td>
<td>2 (5)</td>
<td>1 (2)</td>
<td>5 (11)</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>3 (7)</td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral sensory neuropathy</td>
<td>7 (16)</td>
<td>4 (8)</td>
<td>9 (20)</td>
</tr>
</tbody>
</table>
Future development plan

**US -505(b)(2) route**

- IND filing with USFDA completed
- Initiated Phase I study of a combination chemotherapy of PICN with Carboplatin.

**India**

- A phase II/III study in metastatic breast cancer was initiated in FY11. The study has completed enrollment of targeted 180 patients.
NDDS ORAL Products – Wrap Matrix Platform
Challenges in CR products with high solubility, high dose drugs

- High solubility and high dose challenges
  - High excipient to drug ratio – bigger dosage form
  - Initial dose dumping or a long lag time
  - Difficult to achieve
    - Zero order release
    - Combination of release patterns like IR+SR, IR+SR+IR
  - Release control from dosage form
  - Significant variance in PK between fed & fasted dosing
Wrap Matrix System

The Technology

• Novel oral controlled drug delivery system based on pre-defined, precise and selective surface exposure

Key Advantages

• Once-a-day dosing
• Ability to handle products with larger daily dose
• Suitable for drugs with very high solubility
• No residual drug in dosage form on evacuation
• Minimal food effect
• Difficult to reproduce bioequivalence using any other formulation technology
  • Low risk of generics
Levetiracetam - An Antiepileptic with high water solubility and very large dose

- Levetiracetam requires very high daily dose up to 3500mg, making it necessary for patients to take multiple tablets 2 to 3 times a day.
- Levetiracetam ER tablets (Keppra XR) were launched but they provide only 500mg and 750mg per tablet hence patients still require to take multiple tablets.
- New Levetiracetam ER Tablets are being developed using Wrap Matrix system with higher strengths of 1000mg/1500mg using SPARC’s proprietary Wrap Matrix system.
- High Drug/Excipients ratio makes it possible to formulate a smaller tablet.

Current Status

- Development of 1500 mg and 1000 mg once a day product completed.
- Bioequivalent product to Keppra XR 2 X 750 mg
- Completed Pivotal Pharmacokinetic studies
- Plan to file in US as 505(b)(2) in Q3 FY12
Levetiracetam ER 1000mg, 1500mg: Market Opportunity

- Levetiracetam is one of the most successful anti-epileptic agent worldwide.
- Peak sales of Levetiracetam in the developed markets before the patent expiry reached ~ US$ 2 B in 2008.
- 88% of Rx are for daily doses above >1000 mg requiring multiple tablets dosing per day.
- Kepra XR 500mg, 750mg rapidly growing in US inspite of generics launch suggests the need of long acting products.

Levetiracetam US Prescription data (2007)*

Keppra XR Sales Trend in USA*

- MAT/9/09
- MAT/9/10

Corporate Presentation
Other Products with Wrap Matrix Technology

A Cardiovascular agent - high dose and high solubility
A skeletal muscle relaxant with ultra short half-life
An Anticancer Agent combination with beneficial agent
CNS Agent with very high solubility

ANDAs

- ANDA product - Venlafaxine ER tablets approved in US & Europe
- Additional products based on Wrap matrix technology filed as ANDA (by Sun Pharma)
Other NDDS Platforms
Other NDDS Platforms

**Biodegradable Depot Injections & Implants (INJECTABLE)**
A technology platform of biocompatible and biodegradable micron-sized polymer particles that contains drug molecule in its matrix for long-term systemic delivery of drugs
- Octreotide Depot Inj 1 Month is developed and marketed in India.

**Swollen Micelle Microemulsion (SMM) Technology (OPHTHALMIC)**
“swollen micelles, micro emulsion” is a platform for solubilizing ophthalmic drugs with limited water solubility or completely insoluble ophthalmic drugs.
- Latanoprost “BAK Free” Ophthalmic Solution is marketed in India and undergoing phase III clinical study in USA.

**Gel Free Reservoir (GFR) Technology (OPHTHALMIC)**
Gel Free Reservoir technology platform consist of a unique polymer ratio that show synergistic increase in viscosity without the loss of clarity and flow property.
- Timolol OD Ophthalmic solution is marketed in India

**Gastro Retentive Innovative Device (ORAL)**
Designed for drugs with narrow absorption window; drug is retained in the stomach for longer time (~about 8 hours), thereby providing once a day dosing advantage.
- Baclofen GRS capsules are marketed in India; ongoing SPA with USFDA for Phase III study in US
NCE Programs
## NCE Programs

<table>
<thead>
<tr>
<th>Program</th>
<th>Description</th>
<th>Status</th>
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<tbody>
<tr>
<td><strong>SUN 1334H Anti Allergic</strong>&lt;br&gt;Selective H1 Receptor Antagonist&lt;br&gt;Oral Tablets and Ophthalmic Solution&lt;br&gt;Completed Phase II for Oral Tablets; Ongoing Phase II for Ophthalmic solution in</td>
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<tr>
<td><strong>SUN597 – Soft Steroid</strong>&lt;br&gt;Topically Active Glucocorticoid Receptor Agonist&lt;br&gt;Inhalational (Asthma), Nasal (Allergy), Ophthalmic (Anti-inflammatory) and Skin (Dermatitis, Psoriasis) Applications&lt;br&gt;Nasal formulation in Phase I; Other formulations are at Preclinical stage</td>
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<tr>
<td><strong>SUN 09 – Prodrug of a marketed muscle relaxant</strong>&lt;br&gt;Developed for spasticity with once a day dosing and improved safety profile&lt;br&gt;Ongoing Phase I clinical studies in India</td>
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<tr>
<td><strong>SUN 44 – Prodrug of Gabapentin</strong>&lt;br&gt;Developed for Epilepsy/Peripheral Neuropathies&lt;br&gt;Completed Preclinical studies; Phase I to start in FY12 in India</td>
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<tr>
<td><strong>SUN K706 – Bcr-Abl Tyrosine Kinase Inhibitor</strong>&lt;br&gt;Developed for TKI resistant Chronic Myeloid Leukemia; Active in T315I mutation&lt;br&gt;Ongoing formulation optimization and preclinical studies</td>
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