Sun Pharma Advanced Research Company. **26th February, 2010**

Stock Details

BSE Code	532872
CMP – 24th Feb, 2010	Rs. 84.25/-
Market Capitalisation	Rs. 17,449 mn
Face Value (Re.)	1
Book Value (Rs.)	1.72
52 Wk High (BSE)	Rs. 97.4/-
52 Wk Low (BSE)	Rs. 40.6/-

Company Profile

Sun Pharma Advanced Research Company (SPARC) is a pharma research and drug discovery company. It was formed in 2007 when India's leading specialty Pharma Company. Sun Pharma Industries Ltd., separated out its active projects in drug discovery and innovation into a new company with an objective to bring in the right focus and opportunity for growth for these projects that address international markets. A team of scientists had been working since the year 2000 on these projects which are now at different stages of preclinical and clinical development.

It is the 1st innovative R&D company to be listed in India.

It continues to invest independently in generic research, both for process development for API (Active Pharmaceutical ingredient (API) and formulation development for dosage forms.

About the Projects

Opportunity – Summary....

SPARC NCE Projects...

Product	Therapeutic	Treatment of	Global Market Size	Opportunity
SUN 1334 – H	Anti allergy	Allergic rhitnis/Urtcaria	US$ 5.5 bn	Patents expiring on competing products
SUN 461	Anti – inflammatory	Asthma and COPD	US$ 8 bn	Results comparable to corticosteroids
SUN 44	Neuropathy	Seizure/CNS related disorder	US$ 1.2 bn	Higher blood level Results positive
SUN 09	Muscle relaxant	Muscle Spasticity	US$ 200 mn	No. of patients under treatment – 1.5 mn

SPARC NDDS Projects...

Product	Treatment of	Benefits
DPI	Asthma and COPD	Give visual, audio and tactile feedback
Baclofen GRS	Muscle Spasticity	Ease of switchover from IR (3times/day) to GRS (once a day)
Biodegradable Implants/Injection	Patient Trauma and Pain	No local anesthetic required while delivering drug; injection less painful

About the Projects

NCE Projects/Anti Allergy: SUN 1334 H, is a novel anti allergic molecule that has completed phase II clinical trials in the US. It is used for the therapy of allergic disorders such as seasonal and perennial allergic rhinitis, urticaria, etc.. Preclinical studies have also shown SUN 1334H to have a clean, safety and toxicological profile, including desirable characteristics such as fast onset of action, and lack of sedation. Clinically, this could eventually confer low side effect potential for the molecule, besides good efficacy in patients afflicted with allergies.

In phase I trials in Europe, the molecule was found to be well tolerated, and showed preliminary efficacy as an antihistamine in human volunteers. The profile of SUN 1334 H in studies so far has indicated the possibility of once-a-day dosing.

NCE Projects/Soft Steroid: SUN – S 461 is an anti inflammatory molecule for use in the treatment of asthma/allergic rhinitis and COPD.

Essentially a glucocorticoid receptor agonist, this molecule belongs to the category called soft corticosteroids. In soft corticosteroids, an affinity for the metabolic pathway for deactivation is built within the molecule itself. Clinically, this translates into significantly lower systemic side effects.

Soft corticosteroids are designed based on a retrometabolic approach. These drugs produce the desired pharmacological effect at the site of action, but are inactivated through rapid metabolism once absorbed from the site into the system. Thus there is lesser likelihood of producing steroid associated side effects, unlike in classical corticosteroids.

In pre clinical studies, SUN – S461 has demonstrated suppression of inflammatory response (anti-inflammatory activity) which was comparable to currently marketed steroids with a better side effect profile.

It has completed Phase I Human Studies in 2008 and is in advanced stages of clinical trials.

About the Projects

NCE Projects/Anticonvulsant/Modification of Absorption: Certain drugs when taken by the oral route, are absorbed only from certain segments in the gastrointestinal tract. Since specific transport mechanisms are involved in their uptake, their absorption cannot be increased by just increasing the dose.

SPARC's lead molecule, SUN-G 44, is a prodrug of the currently marketed drug gabapentin, which is used for the treatment of neuropathy and seizures. The molecular modification in SUN-G 44's structure allows for better absorption because of utilization of commonly available transport mechanisms.

In preliminary animal studies, on equivalent dosage, this molecule was found to be far better absorbed and safe, when compared to existing products as well as competing products currently in phase III studies internationally. This profile indicates the possibility of administering a higher dose, formulating this as a once-a-day product, and better safety. This molecule will now enter further stages of preclinical and clinical testing.

The chemical delivery system design used in SUN-G 44 can be extended to develop prodrugs of other molecules having similar limitation of poor oral absorption. It has completed Phase I Human Studies in 2008 and is in advanced stages of clinical trials.

NCE Projects/Muscle Relaxant/Modification of Absorption: SPARC's SUN – B 09, is a prodrug of a currently marketed drug used as a skeletal muscle relaxant.

SPARC expects SUN – B09 to find use in the treatment of spasm related disorders, such as those associated with cerebrovascular injuries, cerebral palsy, multiple sclerosis, spinal lesions and head injury. The molecule's physicochemical and structural features have been modified for better absorption through the gastric tract. SUN-B09 is eventually metabolized with enzymes that are widely present in the body. The molecule can easily be formulated into an injectable and once-a-day dosage form. Preclinical and acute toxicity studies on SUN-B09 are ongoing. In animal models, the lead has shown much better absorption and efficacy, compared to the competing drug. IND Filing was done in 2008 and is in advanced stages of clinical trials.

NDDS projects/Nanoemulsion: Nanotechnology uses biocompatible/biodegradable polymers and lipids to encapsulate the drug within nanometer sized carrier molecules.

Most cancer treatments involve the use of drugs that are toxic, since these reach both normal and cancer cells, and may cause side effects. By improving drug delivery to cancer cells it is possible to minimise side effects.

SPARC process offers over 98% encapsulation of the medication, and in doing so, removes non-encapsulated drug and other undesirable excipients. SPARC process can be used on a commercial scale with high reproducibility across batches. This nanoparticle platform technology is at preclinical development stage, with demonstrated proof of concept. Two cytotoxic products are being developed based on this technology.

About the Projects

NDDS projects/Biodegradable Implant/Injection: Hormone dependent cancers as well as several psychiatric ailments require daily injections for periods spanning several months to years and this is very painful to the patient.

SPARC's depot technology uses long-acting microparticles that offer slow/sustained drug release over a month to several months, which can be given using a conventional injection. The competitor's product involves administration using a thick hypodermic needle. The particle size of SPARC's biodegradable polymer-based product is such that the product can be injected by normal subcutaneous or intramuscular injection.

Conventionally used solvents and diluents are used to formulate the injection, minimizing the likelihood of a reaction. No local anesthetic is required to administer this injection. This technology can be applied to the production of peptides also. A manufacturing friendly, closed and semiautomatic process has been developed to give a kilogram scale, reproducible product.

These are high risk projects and face uncertain timelines.

NDDS projects/Dry Powder Inhalation Technology: Asthma and COPD are treated with dry powder inhalation technology.

SPARC has developed an inhaler that is easy to use with a simple operating sequence: open-inhale-close. This device has been engineered to give visual, audible and tactile feedback of user steps, reassuring the patient that a dose has been delivered. Multiple doses are placed into one device, and each dose is individually separated. The fail-safe dose counter helps keep track of doses. Our device has been developed to comply with the current USFDA and European requirements for inhalers, which we believe, will make it easier for us to register across markets.

Since this device delivers a uniform dose over a range of patient effort, it can be used with confidence by the very young and the very old, as well at times when emergency medications have to be delivered .

SPARC's product can be used to deliver currently marketed combinations of steroids and bronchodilators, as well as NCE steroid molecules.

These are high risk projects and face uncertain timelines.

About the Projects

NDDS projects/Gastro Retentive System for Controlled Release

Some drugs cannot be formulated as controlled release dosage forms because of poor solubility, degradation in the alkaline media, or presence of specific transport mechanism in the small intestine. This leads to the presence of a 'window' or 'narrow zone' of absorption. SPARC Gastro Retentive Innovative Device (GRID) is designed to offer longer retention times in the stomach, of about eight hours, for such drugs.

This innovative system is a dosage form with specialized multiple coatings. On ingestion of the dosage form along with food, it floats instantaneously on the gastric contents. GRID's coatings are activated by gastrointestinal fluid, eventually leading to swelling, to about eight to eleven times its initial volume.

Specific release profiles for drugs can be tailored to achieve combination of immediate and slow release using this innovative dosage form. Retention of the dosage form close to its site of absorption may help in reducing the dose and thus the side effects.

Based on the GRID technology, Baclofen ER has been developed to treat muscle spasticity due to cerebrovascular accidents, cerebral palsy, multiple sclerosis, spinal lesions, head injury, etc. There has been a good switchover from the three times a day immediate release formulation to the GRS formulation with effective symptom control and lower sedation. For India, phase 1, 2 and 3 have been completed and the product is approved. For the US, preparations for the IND filing are ongoing.

These are high risk projects and face uncertain timelines.

NDDS projects/Wrap Matrix Controlled Release Systems

This technology offers gradual and controlled release of medicines. Even the drugs that have high solubility and are given in high doses can be formulated into a once daily dosage form using this system.

Advantages of wrap matrix include constant blood levels, which avoid the peaks and troughs associated with immediate release dosage form, leading to convenient once a day administration. This system can also be formulated to give minimum "food effect" so that medicine can be taken irrespective of the meal pattern.

This technology has been proven, with a formulation of Metoprolol XL developed and launched in India with a once-a-day release profile.

A few ANDAs based on this technology have been filed with the USFDA.

These are high risk projects and face uncertain timelines.

SPARC Future Plan of Action

New Chemical Entities (NCEs):

Allergy – SUN -1334 H:

a) Completed phase II human trials in the USA for season allergic rhitnis
b) Complete studies on cardiovascular safety, metabolism, toxicity etc required for phase III trials
c) Carcinogenicity study initiation

Novel Drug Delivery Systems (NDDS)

Novel device for inhaled drugs

a) Design and validation of device
b) Clinical trials in humans for semi – regulated markets
c) Launch in semi – regulated markets in 2010

Nanoemulsion

To complete technology development for 2 cytotoxic products that are being studied. Phase I for one cytotoxic, the first in human study has been initiated, for the second cytotoxic, first in human study is likely in 2010

Biodegradable injections/implants

a) Clinical trials in humans in India completed
b) Launch in semi regulated markets in 2010
c) Complete pre clinical studies for depot injection of GnRH analogue that is being developed likely to take it for Clinical trials in humans

Industry Overview

Nascent Industry…

Innovative Pharma R&D industry is in the nascent stages. Long standing expertise in chemistry, a large pool of professionals and untreated patients who are ideal for clinical research, have often been cited as factors that are working to India's advantage in pharma R&D.

However, sufficient skills and large enough scientific pool in the area of biological sciences – molecular biology, pharmacology, toxicology, clinical pharmacology are still being learnt on the go as the industry evolves.

Shrinking new developmental pipelines…

Internationally, new developmental pipelines from inhouse R&D have been shrinking due to several factors such as: complexity of therapeutic targets, falling R&D productivity, escalating costs associated with development of new products, greater regulatory hurdles and increasing challenges of managing innovation. Since there are fewer replenishment candidates that can be sourced internally for large blockbusters that go off patent at Big pharma, new molecules are often licensed in and/or acquired from smaller or boutique pharma companies, that have demonstrated either a delivery technology or new biology advantage. This arrangement seems to work well, since smaller companies appear to be adept at innovating, while large pharma companies have the expertise in navigating the regulatory process. Based on the current trend, it appears that 25% to 30% of research is outsourced by Big Pharma.

USFDA approved 21 new molecular entities and 2 biologicals in all of 2008. Strictly new products were estimated at less than 50% of total new approvals. Of these, a large number originated outside the research Laboratories of Big Pharma.

The changes in the patent laws in India, bringing in the same level of intellectual property protection as in the developed nations, have been both the impetus and the reason for invest

Opportunities

Indian companies are addressing 2 areas: analog chemistry for new chemical entities with improved profiles of validated targets and development of novel drug delivery systems for existing/marketed molecules designed to offer a specific advantage.

In recent times, innovative R&D in India has been attracting venture capital funds. This may help Indian pharma to work on innovative projects that typically have very large R&D budgets, which would otherwise be out of their reach. The second advantage here is the expertise that such funds bring to the table.

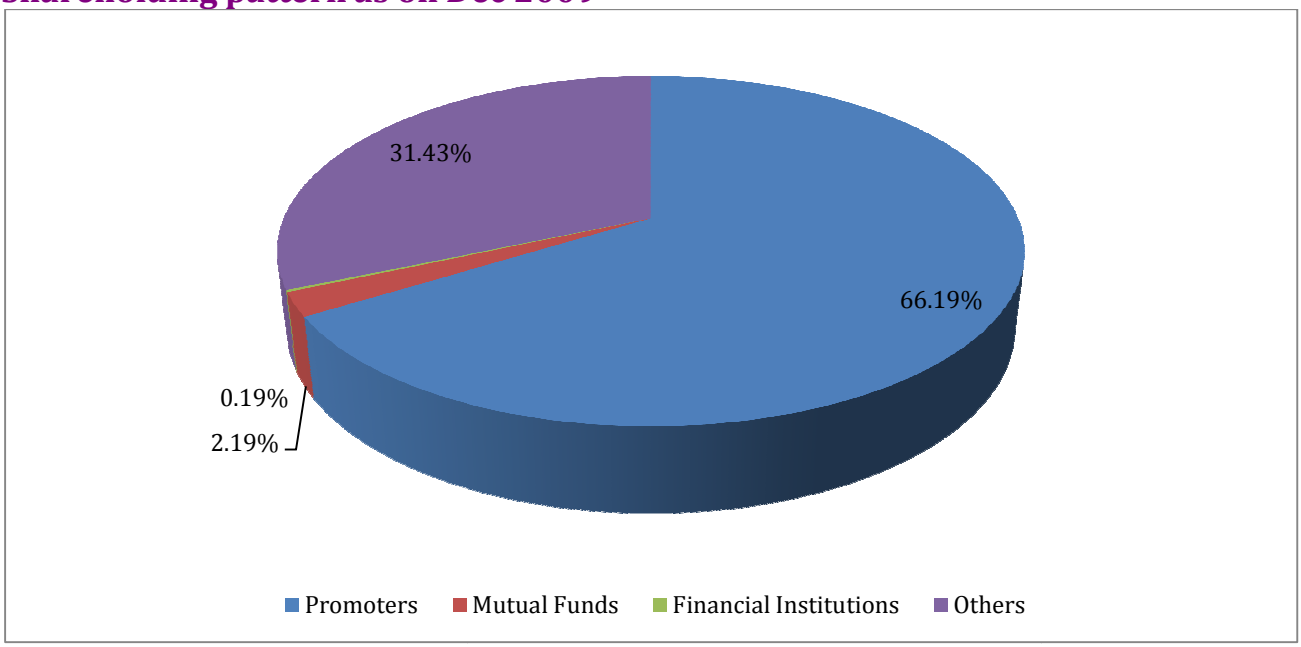
Formulation development capabilities, process chemistry expertise, state-of-the-art tertiary healthcare facilities, skilled work force and cheaper costs are the key factors that are quoted as working in India's favour as an R&D partner of choice. There are estimates that quote the cost of doing R&D in India as a fraction of the cost in an advanced country. Also, India offers an edge in costs over other low cost countries such as China.

Benefits of Research and Development Projects:

SPARC's R&D projects are long term projects, with a higher risk profile compared to generic projects and typically take 8-10 years to reach the market, if at all. NCE's upon commercialization are expected to provide patients with better treatment options or safer side effect profile for the disorders for which these therapies are being developed.

The new drug delivery systems that are being developed are platform technologies that can be used for several different drugs. The eventual commercialization of the products based on these technologies would provide patients with newer dosage forms that are safer, more effective in terms of availability in the body and easier for the patient to take or to administer.

Shareholding pattern as on Dec 2009



Risk & Concerns:

Research is inherently a high risk area; it is likely that an investment may go waste if a project has to be abandoned at a later stage in its development.

A project may need a much higher investment or longer time frame than initially visualized. New tests or trials may require much greater investment than originally envisaged.

A competing technology or product might diminish the potential that we anticipate for NCE or NDDS.

Financials

Income Statement – (Rs. in millions)

Particulars	FY 08	FY 09	9M FY 10
Income from operations	**375**	**351**	**182**
Expenditure			
Materials consumed	69	94	60.5
Personnel cost	133	164	165.6
Operating and other expenses	206	198	168.9
Total Expenditure	**408**	**457**	**395**
EBITDA	**(34)**	**(105)**	**(213)**
Depreciation	13	18	19
EBIT	**(46)**	**(124)**	**(232)**
Finance Charges	0.14	2	1.5
Other Income	1	1	3
Profit before tax & extraordinary items (EI)	**(46)**	**(125)**	**(230.5)**
Less: Tax	(3)	34	(0.10)
Net Profit after Tax	**(49)**	**(91)**	**(230.6)**
Diluted EPS (Rs.)	**(0.25)**	**(0.44)**	**(1.11)**

Consolidated Balance Sheet – (Rs. in millions)

Particulars	FY 08	FY 09
LIABILITIES		
Share Capital	207	207
Reserves and Surplus	340	340
Loan Funds	4	17
Deferred Tax Liability (Net)	34	-
Total	**585**	**564**
ASSETS		
Fixed Assets	379	600
Less: Depreciation	54	72
Net Fixed Assets	**326**	**528**
CWIP	**6**	**44**
Current Assets, Loans & Advances (A)	**283**	**43**
Current Liabilities (B)	**128**	**242**
Net Current Assets: (A) – (B)	**155**	**(199)**
Profit and Loss account (Debit Balance)	**99**	**190**
Total	**585**	**564**

Comments

Success of any of the following molecules can generate blockbuster revenues for the company ~FY12.....

New Chemical Entities – Pipeline

i. Sun – 1334H: An anti – allergic molecule
Current Global Market Size: US$ 5.5 bn (**Opportunity:** Patents expiring on competing products)

Status: Phase II completed

ii. Sun – 461: An anti – inflammatory molecule for use in the treatment of asthma and COPD
Current Global Market size: US$ 8 bn

iii. Sun – 44: A prodrug of gabapentin
Current Global Market size: US$ 1.2 bn (gabapentin is a generic product across most markets)

iv. Sun 09: A prodrug of marketed muscle relaxant
Current Global Market size: US$ 200 mn

We expect that SPARC would receive a milestone payment of US$ 100- 200 mn as the molecules are at advanced stages of clinical trials.

Weighted deduction on R&D raised to 200% from150% in Union Budget 2010 -11 would also benefit SPARC

With due consideration to the above factors, we recommend a **"BUY"** at the current market price with a price target of Rs. 160/- per share for investors with a 2 years horizon.

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