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SUN PHARMA
ADVANCED RESEARCH
COMPANY LTD.

SPEECH DELIVERED BY MR DILIP SHANGHVI, CHAIRMAN AND MANAGING DIRECTOR OF SUN PHARMA ADVANCED RESEARCH COMPANY LIMITED AT THE 7TH AGM OF THE COMPANY

Dear Fellow Shareholders
On behalf of the Board of Directors I take pleasure in welcoming all of you to the 7th AGM of your Company.

2011-12 has been a decent year. Some more technologies and products progressed to their next stage of development. A few products based on SPARC's technologies reached the Indian market. There was immense learning as some of the findings from clinical trials reached us and were analyzed.

Last year I shared with you briefly about Sun Pharma's joint venture with Merck for the Emerging Markets. As you know, this joint venture can make use of SPARC's technologies under license to Sun Pharma, for certain markets. Over the last year, the first set of branded generics for development have been defined by the jv, and development work has started.

Performance
The financials for 2011-12 have been published and available with you. This year your company posted a net loss of Rs. 72 crores on revenues of Rs. 30 crores. The total spend increased by 50% over last year.

At SPARC, as you know, our focus is on novel technologies for drug development and new molecules for the world markets, which is a high risk business. Innovation requires large investments over uncertain timeframes, a novel approach to scientific problem solving and higher level of resource commitments over much longer time durations. At the same time, the outcome is uncertain and sometimes some projects may have to be abandoned if results are not in line with our expectations, or a competitive molecule is ahead in the race to market.

Hence we expect to see continuing losses for some time.

In the longer term, as we create intellectual property and build value we are confident that our work will bear fruits. But as we have said repeatedly, such projects take time to realize, and have an element of uncertainty.

Last year we had taken your approval for raising a further Rs. 200 crores through a rights issue to fund further work at SPARC. Funds would be required to support pipelines till products reach market and begin to earn revenues, or till we licence out products or technologies to partners. We're awaiting go ahead from the regulator SEBI to file the letter of offer with the stock exchanges.

Now I'll briefly take you through the projects under development.

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NDDS Programs

First I'd like to update you about the novel delivery technologies that SPARC has developed.

As we have shared previously, Gastro Retentive Innovative Device (GRID) developed by SPARC is a once-a-day system for drugs that are otherwise absorbed only in stomach or the small intestine.

Baclofen GRS, a once-a-day capsule to treat muscle spasticity, based on GRID, has now been selling in India for over two years.

For the US, Specific Protocol Assessment has been cleared at the USFDA, and patient enrolment for Phase III clinical trials for spasticity are expected to begin in Q2, FY13 (corrected). This study will be followed by an open-label extension study for evaluating the safety and tolerability of Baclofen GRS on long-term administration. A duration of action clinical study to evaluate once-daily efficacy of Baclofen GRS capsules at end-of-dosing interval will be conducted concurrently with the phase 3 efficacy study.

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Baclofen GRS is also being studied in alcohol dependence. Regulatory approval for phase 3 clinical trial in India has been received, and the clinical trial is ongoing. A phase 2 trial in US/ Europe is planned, to evaluate the effective dose in treatment of alcohol dependence

The next technology on which we have done extensive work and have products to show for it, is the wrap matrix technology, which can be used to make convenient once-a-day formulations of high dose and high solubility drugs.

SPARC has developed several products demonstrating this technology. Eight products such as the antihypertensive metoprolol and combinations, ropinirole, pramipexole, etc are doing well in India. As you know, Venlafaxine ER (An antidepressant) has been approved by EMEA and USFDA for the licensee.

The wrap matrix formulation of Levetiracetam, an anti-epileptic with high solubility is filed as a 505 b(2) in the US in the first quarter of Fiscal 2013 (corrected). Pharmacokinetics studies are completed.

A skeletal muscle relaxant with ultra short half life is in clinical studies. Phase 1 study has been completed in India.

As I had shared previously, a controlled release formulation of a cardiovascular drug is in pharmacokinetics studies (corrected). Several combinations of this cardiovascular drug with various drugs that have complementary mechanisms of action are under development.

For an anticancer combination with a beneficial agent, Phase I is planned.

For one CNS agent in a new indication, proof of concept studies planned.

For another CNS agent with very high solubility, pharmacokinetic studies are ongoing.

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Now I'll move ahead to the nanoparticle technology platform for injections of water insoluble anticancer drugs. This technology enables us to create a product that offers delivery of a higher proportion of drug to cancer cells, uses lesser excipients, and allows a higher dose to be delivered without limiting side effects.

As we've shared previously, we're working on Nanoparticle formulations of the anticancers Pacliltaxel and Docetaxel.

Paclitaxel Injection Concentrate for Nanodispersion (PICN) developed using this proprietary technology is under investigation.

For India, the phase II/III comparative study in metastatic breast cancer demonstrated efficacy in both PICN and Abraxane® arms, however, the pre-defined criteria for therapeutic equivalence were not met based on investigator assessment. Imaging data is now being sent to an independent reviewer for assessment. Further development of PICN in 3-weekly regimen in metastatic breast cancer will be evaluated based on the outcome of the independent review

For the US, IND filing under 505(b) (2) route has been completed, and phase 1 study of combination chemotherapy of PICN with Carboplatin initiated in 3rd quarter of Fiscal 2012. Globally, treatment regimen for metastatic breast cancer is moving from a 3-weekly to weekly paclitaxel administration which is considered more effective and better tolerated. Therefore, we are evaluating development of PICN in a weekly regimen for MBC at the same time. We are also evaluating the possibility of developing PICN in other indications.

Docetaxel Injection Concentrate for Nanodispersion or DICN using the same therapy platform, has completed Phase I in solid tumor patients,and a phase 1b study in NSCLC patients is initiated in the 2nd quarter of Fiscal 2013.

The team was privileged to present a poster on the outcome of the Phase I study at The American Society if Clinical Oncology or ASCO as its more commonly called.

For US, the product is to be filed under 505(b) (2)

Depot technology using micron sized polymer particles is a simple way of administering drugs that otherwise need to be given repeatedly over a long time. A Phase III study for Octreotide 1 month depot in acromegaly has been completed and the product launched in India. IND filing for the US is planned in Fiscal 2013. A three-month product, as well as a few CNS agents are under development.

We're watching with much interest SPARC's proprietary Dry Powder Inhaler (DPI), which was launched in India in the third quarter of fiscal 2012. This device is user friendly, and compliant to USFDA and European requirements. This premetered, 60 dose, inhalation activated device delivers a uniform dose over a range of patient effort and is easy to operate. In addition, the DPI is designed to eliminate double dosing or dose wastages and can be easily used by all age groups including the very young and very old.

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For the US, we are taking the 505 b2 route. We have recently completed pre-IND meeting with USFDA to understand regulatory path for approval. An IND is likely to be filed in fiscal 2013.

Latanoprost RT is an anti glaucoma product that had reached market last year. This is based on SPARC's swollen micelle technology. This eyedrop formulation has been developed free of surfactants like BAK which may damage the eye. For the US, Latanoprost BAK free is being filed under 505(b) (2) route and the IND has been approved by USFDA. FDA requires one Phase 3 study for approval. Patient enrollment for Phase 3 was completed in the third quarter of Fiscal 2012. SPARC's BAK-free Latanoprost eye drops could meet the non-inferiority criteria of 1.5 mm Hg at all time-points. The IOP lowering efficacy was similar to the comparator Xalatan®; however, the second non-inferiority criteria of 1 mm Hg could be met at 4 time points instead of the required 7 time-points. We are planning to have pre-NDA meeting with FDA to discuss the results in FY 2013(corrected).

Another eyecare product that has been marketed to good response is the glaucoma drug Timolet, Timolol Maleate 0.5%, which uses Gel Free Reservoir technology, or GFR.

A combination product that has the advantages of both these technologies, Latanoprost BAK-free and Timolol GFR- based, has been developed. The Phase 3 efficacy and safety study of this product was ongoing in India. The study is completed and the data is under analysis.

NCE Programs

I'll now update you about progress in our drug discovery program.

As you know, our lead molecule, SUN-1334H is an antiallergic for use in seasonal allergic rhinitis, perennial allergic rhinitis, chronic idiopathic urticaria and allergic conjunctivitis. Sun 1334 H is being developed for oral use as well as topical use, as eyedrops and nasal drops.

For the Oral form, chronic toxicity studies are ongoing; pilot cardiac safety studies are ongoing and expected to be completed by 3rd quarter of Fiscal 2013; renal safety study in human volunteers is planned.

For the Ophthalmic formulation, Phase 2 study to assess efficacy of 1334H ophthalmic formulation in allergic conjunctivitis in Conjunctival Allergen Challenge model has been completed in the USA. 1334H was shown to be safe and well tolerated. Highest dose, 0.45% 1334H showed clinically effective prevention of ocular itching with onset of action at the 15-minute, however the study did not meet pre-defined efficacy criteria for development of newer ophthalmic antihistamines.

The next molecule I'll discuss is SUN-597, a topical glucocorticoid, which finds use in inflammation of the airway, skin, eye and gastrointestinal tract. This molecule offers the advantage of steroidal anti-inflammatory action and minimal systemic side effects.

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For the nasal form, Phase 1 clinical trials were completed in the 3rd quarter of Fiscal 2012. The drug was safe on repeated dosing to healthy subjects. Phase 2 study in patients with seasonal allergic rhinitis is ongoing in Germany and is expected to be completed in the 4th quarter of Fiscal 2013.

For the Inhalation form, preclinical toxicity study is ongoing and expected to be completed by 2nd quarter of Fiscal 2013, IND filing in India is targeted by 4th quarter of Fiscal 2013.

Topical cream is also under development. Preclinical studies are ongoing, formulation optimization to be completed by 4th quarter of Fiscal 2013 and IND filing in India is targeted by 4th quarter of Fiscal 2013.

For the Ophthalmic formulation, preclinical studies for the selection of appropriate strength and formulation are ongoing. Formulation development is expected to be completed by the 3rd quarter of Fiscal 2013. IND filing in India is likely by 1st quarter of Fiscal 2014.

I will have more to share about these formulations as they proceed through various stages of clinical development.

One of the approaches that SPARC has pursued is the development of prodrugs for poorly-absorbed molecules.

SUN-44 is a prodrug of gabapentin for the treatment of neuropathy and seizures. In animal models of epilepsy, SUN-44 showed better efficacy compared to gabapentin. Its profile indicates higher blood availability, feasibility of once-a-day formulation and higher safety. IND is approved in India and phase 1 is planned in Fiscal 2013.

The spasticity drug Baclofen is the standard treatment for spasticity but is poorly absorbed. SUN-09 is a prodrug of Baclofen, which is absorbed much better. Phase I of the IR tablet has been completed. Phase I of the slow release formulation has been completed in Q1 2013 and the results are undergoing analysis.

Team SPARC

Research calls for technical skills of a high caliber and people who are inspired and enthusiastic about the work they do.

At SPARC, we have a 249 person strong, motivated team that does world class work.

We believe in our team, will continue to invest in it and building the right environment for innovation.

Thank you.