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SUN PHARMA
ADVANCED RESEARCH
COMPANY LTD.

Text of the speech delivered by Mr Dilip Shanghvi, Chairman and Managing Director of the Sun Pharma Advanced Research Company Ltd., at the 4th Annual general meeting of the company held on Sept 11, 2009 in Vadodara

Dear Fellow Shareholders / Ladies and Gentlemen:

On behalf of the Board of Directors I take pleasure in welcoming all of you to the 4th AGM of your company.

I would like to share the key highlights:

- Our first lead new drug being developed, an antiallergic, has now finished phase 2 clinical trial in the US. We continue to validate this data. We had previously shared information about other three new molecule projects and four delivery system platforms from our pipeline so far.
- We continue to build the expertise at SPARC that has a well qualified scientific team, requisite funding, adequate space and critical equipments to take these projects ahead.

Environment and challenges

The environment for research, particularly for Indian companies making investments in research, continues to be demanding.

Research in itself is quite a challenge. A particular approach may or may not work after years of hard work and investment, or a competitor following a different approach may reach the market earlier. The risk of project failure at all stages is quite high. Internationally several molecules have been withdrawn even after being marketed.

As you probably know, we have yet to see a new molecule from an Indian company reach the international market. SPARC, like several other Indian companies, is approaching innovation at this scale and level for the first time. So to some extent there is the need for being doubly sure, or even

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time required to do additional work that a more experienced company may have been able to predict .I do not see any shortcut - new areas, expertise or ways of working have to be mastered, so that we can do work that is scientifically novel, internationally acceptable and addresses the concerns of unmet human heathcare needs. We need to be realistic and place this in perspective. These are the initial years, and we are trying to compress the learning that has perhaps taken other countries several decades.

The trend of increased regulatory requirements, significantly longer approval times and stringent checks for new product approvals by leading regulatory agencies continues. The FDA is said to have approved a total of only 24 new molecular entities in 2008 that represent a significant advancement in medicine.

With the changing economic scenario globally, a reduction in healthcare costs will remain a priority in most developed nations. New molecules that offer advancements over products that are already marketed thus have a higher hurdle to cross both in terms of better safety and superiority in efficacy in order to get approved.

Performance

The financials for 2008-09 are already with you. This year we posted a net loss of Rs. 9.14 crores on revenues of Rs. 35 crores. As we continue to focus on creating intellectual property, taking projects through different phases of research and bringing them closer to market, our R&D spend will accelerate even as intellectual property assets are built. This phenomenon of "burn rate of cash" while projects are in development, is a common factor of drug discovery companies globally.

We had shared overall guidance of spending USD 65-70 mill for R&D in the first 3 years. We believe that we are more or less on track.

Now I'll briefly update about the projects under development.

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In the new molecule area, as you already know, we're working on therapeutic analogue based programs in allergy / inflammation, as well as modification of poorly absorbed molecules. Our project SUN 1334H has completed Phase II of clinical trials, while three more leads are at preclinical stages.

SUN 1334H, a selective histamine receptor antagonist, has now completed Phase II clinical trials in the US, and we are in the process of analyzing data. This is an antiallergic molecule for use in seasonal allergic rhinitis, urticaria, etc. As we have shared earlier, in preclinical studies, SUN 1334H was found to have high specificity for H_1 receptors, and this indicates a low side effect profile. SUN 1334H was found to have a clean profile with a fast onset of action. Previously, Phase I trials in Europe had indicated that the molecule was well tolerated..Initiated certain critical human safety studies and nonclinical chronic toxicological (carcinogenicity) studies.

As you know, one of our projects is an anti-inflammatory molecule SUN 461, which is a soft steroid for asthma and COPD. It is being developed as an inhalation drug, As a part of this program, a new candidate has been identified which offers enhanced in vivo efficacy similar to that of marketed products in the inflammatory and disease models evaluated and with a significant lower side effect profile.

SUN 44, a prodrug of gabapentin for the treatment of neuropathy and seizures, uses molecular modifications in the structure for better absorption and efficacy in neuropathic pain model.
SUN 09 is a prodrug of a currently marketed drug used as a skeletal muscle relexant for spasm related disorders, with better bioavailability.

INDs wil be filed in Q3 and Q4 after completing the ongoing toxicity and safety evaluations.

The second category of products I'll discuss is delivery system based products.

We continue to work on our novel DPI for asthma and COPD. Our DPI delivers a uniform dose over a range of patient effort and can be used both with existing steroid and bronchodilator combinations, as well as NCE steroid molecules. A product based on this novel DPI is likely to be launched in semi-regulated markets by 2010, and an IND will be filed for regulated markets by 2009.

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Our Gastro Retentive Innovative Device (GRID) for controlled release is designed to retain and release a drug over an eight hour span, ideal for an once-a-day system.
Baclofen GRS, a once-a-day formulation for treatment of muscle spasticity, has been developed and approved for India, with a prospective IND filing for the US, as we had shared.

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Our Wrap matrix system for controlled release is a multi-layered matrix based tablet designed to offer a controlled release of high dose and high solubility products. Metoprolol XL with a once-a-day advantage, is doing fairly well in India. We have also launched Bupropion ER Once a day product which is also based on wrap Matrix Technology Our ANDA filing for Effexor XR which is currently awaiting approval from USFDA, is based on this Wrap matrix technology.

Our Depot Technology uses long-acting injectable microparticles for slow/sustained drug release over a month to several months using biocompatible and biodegradable polymers. A GnRH analogue is in preclinial trials, with clinical studies now to follow. Clinical studies were completed for a somatostatin analogue, and the product is likely to be launched in the near future.

We have active projects in nanoemulsion based products that offer higher drug localization to the cancer cells and improved safety. They are based on an unique encapsulation process that offer more than 98% encapsulation of bioactive substance. We continue to work on two cytotoxic products that are being developed with this technology, one of these being paclitaxel.

SPARC'S proprietary Nanotechnology platform uses biocompatible polymers and lipids to encapsulate the drug within nanometer sized carrier molecules. Nanoparticle compositions using this platform technology are capable of delivering higher payload without increased adverse event profile. Other benefits include ease of use and no premedication requirement, shorter infusion times and improved toxicological and safety profile allows better patient treatment compliance.

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Developmental product has also demonstrated high activity against human cancer xenografts both, in-vitro and in-vivo in nude mice. Our technology has completed preclinical development and set for clinical trials.

Innovation and Team SPARC

As the over-200 member strong SPARC team moves along its path of bringing novel drugs and delivery systems to global markets, our topmost priority is to create a work environment that is challenging and fosters creativity and innovation; besides cereating infrastructure to do world class research. We will continue to invest in our team, in offering opportunities for learning and growth, and in creating facilities that are comparable to the best internationally, so that they can deliver world class work.

Thank you.