Text of the speech delivered by Mr Dilip Shanghvi, Chairman and Managing Director of the Sun Pharma Advanced Research Company Ltd., at the 3rd Annual general meeting of the company held on Sept 6, 2008 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 3rd 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 are now validating 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 Internationally several molecules have been withdrawn even after being marketed.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 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 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 and internationally acceptable. 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 tighter checks for new product approvals by leading regulatory agencies continues, not only for completely novel devices and therapies such as inhaled insulin, but also for small molecules such as muraglitazar from BMS, vildagliptin from Novartis, and many more. With withdrawals of products like some cox 2 inhibitors and the increased label warning for glitazones, I would expect that this caution on new molecules would continue, particularly for new chemical classes. The FDA is said to have approved in 2007 a total of only 19 new molecular entities 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 for safety and to prove superiority in efficacy in order to get approved.

Performance

The financials for 2007-08 are already with you. This is the first full year for SPARC after it received the innovation business from Sun Pharma. This year your company posted a net loss of Rs. 5 crores on revenues of Rs.38 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. For the first 2 to 3 years, when income will reflect revenues earned out from licensing of IP as opposed to product revenues, we will continue to show a loss. 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 50-60 mill for R&D in the first 3 years. We believe we are more or less on track.

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

In the new molecule area, as you know we're working on therapeutic analogue based programs in allergy / inflammation, as well as modification of poorly absorbed molecules.

SUN 1334 H, 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 used for seasonal and allergic rhinitis, urticaria, etc.

As you know, one of our projects is **SUN 461**, a soft steroid anti-inflammatory for asthma and COPD, which is being developed as an inhalation drug, with similar activity but significantly lower side effects when compared to other marketed steroids.

SUN 44, a prodrug of gabapentin for the treatment of neuropathy and seizures, uses molecular modifications in the structure for better absorption. The preliminary animal studies on this molecule are ongoing and has shown it to be better than existing products in neuropathic pain models.

SUN 09 is a prodrug of a currently marketed drug used as a skeletal muscle relexant for spasm related disorders, with better bioavailability.

Preclinical and acute toxicity studies are completed for the above NCEs. Subacute studies on these molecules are ongoing.

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 2009, and an NDA will be filed for regulated markets by 2011.

In the initial human study we are able to achieve significant steroid sparing effect. We have achieved equivalent efficacy and blood levels at 50% of the dose.

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.

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. Our ANDA filing for Effexor XR which is currently awaiting approval from USFDA, is based on this Wrap matrix technology. We are preparing to file an NDA for a new product in the US using the wrap matrix technologies during this year.

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 slated for 2008. 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 nano particulate technology 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.

Innovation and Team SPARC

As the 174 member strong SPARC 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 innovation, offering our team of scientists the support to do worldclass work. We will continue to invest in our team, in offering opportunities for learning and growth, and in creating lab facilities that are comparable with the best internationally, so that they can deliver world class work.

Thank you.