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SUN PHARMA
ADVANCED RESEARCH
COMPANY LTD.

Text of the Chairman's Statement delivered by
Dr T Rajamannar, Director & Executive Vice President
of the Sun Pharma Advanced Research Company Ltd., at the 5th Annual general meeting of the Company held on July 24, 2010 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 5th AGM of your Company.

It was three years back, on 18th July 2007 that your Company was listed on the BSE and NSE. In these 3 years, a lot has happened at SPARC.

2009-10 has been a particularly busy year. A lot of exciting work has been done on new technologies and products, which I will outline later. First let me talk of the environment, opportunities and challenges that our business faces.

Environment, Opportunities and Challenges

Despite all the well-meaning efforts by governments, scientific institutes and business organizations, given the past of our country, the research activity in the country as a whole is yet to scale up. While scientific talent pool looks vast in comparison to other countries, the spectrum of research expertise points to critical gaps in availability of trained manpower for several of the research domains. There is hope for tomorrow as the research activity matures at all levels, but that will take time.

Research by its inherent nature is a high-risk venture. Governments and associated agencies usually, and rightly so, channel their energies and funds towards research that has the promise of alleviating the pressing needs of their country's population. Notwithstanding its focus, the multiplier effect of such a research impetus from the Government is quite significant and should not be underestimated. Unlike this, private business organizations usually conduct research looking for solutions with the potential to benefit much beyond national boundaries. As our economy grows apace, and Indian business organizations spread out to establish themselves into key markets around the world, necessity of high quality product development skills will come to the fore. It will be no different for pharma companies, where product development, although for generics, has traditionally received much higher priority compared to several other industries.

In pharma discovery, as you recognize, India is a late entrant and a small player at the moment. I don't want to repeat all that we have said in the past, but mentioning a few key trends that will impact this journey:

- ✓ Drug regulators around the world, and more so in the developed world, which also happen to be the largest pharma markets, are gradually raising the bar for approving new drugs. Applicants are required to demonstrate significant superiority over existing treatments with much lower side effects. As a result, the number of new product approvals has been falling year after year. In such a scenario, companies from India given their limited experience in drug research and development face an uphill task.

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- ✓ This raising of bar by the regulators also impacts the investments required for each product. With limited balance sheet size, Indian companies have limited ability to take full risks of such investments. Risks can be shared via partnerships, which will of course bring in another set of challenges.
- ✓ Empirical evidence suggests that discovery, innovation and creativity flourish better in smaller, entrepreneurial setups. This is a significant opportunity for companies like SPARC.

In face of all of this, we find ourselves well placed. We continue to focus on work that is scientifically novel, internationally acceptable and addresses unmet needs. We have to continue to find ways of cutting the time and effort to reach world scale.

With this in mind we continue to build expertise at SPARC that has a well-qualified scientific team, requisite funding, adequate space and critical equipment to take these projects ahead.

Performance

The financials for 2009-10 are published and available with you. Once again, I will not go through all the details in the annual report. It would suffice to state that this year your company posted a net loss of Rs. 21.6 crores on revenues of Rs. 35 crores. The total spend, all of which is on supporting innovative R&D, has increased by 18% over last year.

At SPARC, as you know, the effort is to develop innovative products and technologies which can be successfully patented and commercialized around the world. Innovation requires a novel approach to scientific problem solving, higher level of resource commitments over much longer time durations. Projects can take years to exhibit proof-of-concept and a few more years to be converted into commercial realities. Several projects may have to be abandoned mid course, for lack of scientific or commercial feasibility. Thus, it would not be an overstatement if I say that the nature of product development effort at SPARC is qualitatively different than the usual product development that you have been used to witnessing in generic pharma companies in India.

You must be wondering about the need for this in an AGM speech. We have seen that some of our fellow shareholders are concerned with continuing losses and absence of dividend. It is to reassure them that with high quality work being done at SPARC, its intellectual property will bear fruits. But as we have said repeatedly, such projects take time to realize. New drug discovery takes over 10 years of continuous effort to qualify for commercial launch. I can only request my fellow shareholders to bestow patience.

Now I'll briefly update about the projects under development. First let me take you through the 7 novel delivery technologies and associated products that SPARC has developed.

As you are aware, **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. This device is designed to keep drug in the stomach for over an eight-hour span, which improves the drug absorption. Such a system offers a combination of instant and sustained drug release profiles. It also improves patient compliance being once a day.

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Baclofen GRS, a once-a-day capsule to treat muscle spasticity, based on **GRID,** has been launched in India. Phase III clinical trials for using this product in spasticity have been initiated in the US. We are planning to conduct a clinical study in one more indication.

Developing controlled release products of high dose and high solubility drugs is a big challenge. Either the resulting pill is very large and hence difficult to swallow or it exhibits a phenomenon called dose dumping. Dose dumping refers to release of the entire drug at the same time as against a controlled release over an extended duration. Another design challenge is to achieve a mix of instant and long-term release together. SPARC has successfully overcome this challenge using its Wrap Matrix technology. Using this technology, a multi-layered matrix-based tablet offers controlled release with once a day dosing, with size of the tablet being reasonable despite large doses.

SPARC is currently developing several products using Wrap Matrix technology, including an anti-epileptic with high solubility and very large dose, an anti-hypertensive, a skeletal muscle relaxant with an ultra short half-life, a CNS agent with very high solubility and an anticancer agent.

Water insoluble anticancer drugs necessitate use of toxic surfactants to solubilise. The drug also reaches healthy tissues in addition to the tumor sites. Nanoparticle technology platform developed by SPARC addresses both these challenges. This technology offers higher proportion of delivery of drug to the cancer cells and lowers the use of excipients. Adding to this, administration of products formulated using this technology obviate the need for pre-medication.

Such nanoparticle formulations of Pacliltaxel and Docetaxel, well-accepted drugs in the cancer treatment, are undergoing clinical development. **Paclitaxel** Injection Concentrate for Nanodispersion (PICN) formulated using this SPARC proprietary technology, has completed Phase I in India and has demonstrated a superior safety profile with a 30% higher concentration in tumor tissues when compared to the marketed drug Abraxane®. Phase I of combination chemotherapy of PICN with carboplatin will be initiated this year in the US. A phase II study for metastatic breast cancer is planned in India. All pre-clinical studies required for Phase I have been completed for **Docetaxel** Injection Concentrate for Nanodispersion (DICN). DICN was found to be safe at 7.5 times the dose of conventional docetaxel. In India, a phase I study in solid tumor patients has been initiated.

Another technology that helps in developing superior products for ailments including cancer is the proprietary Depot Technology. Some chronic treatments require maintenance of drug levels in the body over several months or weeks, which is usually achieved with daily or frequent injections that are extremely painful for the patient. One solution used is depots or reservoirs under the skin from which drug is released over a long period. The current technology of making such depots necessitates a high polymer to drug ratio, requires special needles for injection and specially trained staff. Further, the drug usually needs a few weeks to reach the desired blood levels. As a result, it imposes serious limitations on the use of such depot based products.

SPARC developed **proprietary Depot Technology,** with biocompatible and biodegradable micron size polymer particles that contains the drug in its matrix, offers long term systemic delivery of the drug. Administration is convenient with the use of a conventional needle, absence of patient trauma and pain. Hence, no special training or equipment is needed. In fact, even the injection volume is lower. Such a technology offers rapid onset and prolonged release over months. Peaks and valleys seen with frequent

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daily doses are absent and the product extremely well suited for treating chronic conditions like prostrate cancer.

Goserelin depot 1M injection, for the treatment of hormone dependant tumors like prostate cancer and breast cancer has been developed based on this technology. In India, clinical trials for Goserelin 1M have begun earlier this year. IND filing in the US for Octreotide and Goserelin depot injection 1M is likely in 2011-12.

SPARC has developed a proprietary **Dry Powder Inhaler (DPI)** device compliant to USFDA and European requirements. This premetered, 60 dose, inhalation activated device for the administration of combination of inhaled steroids and bronchodilator drugs 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 children, adults as well as elderly. In clinical trials, drug administered via this DPI achieves the same efficacy as the innovator at 50% of the dose administered.

Phase III of DPI delivering a glucocorticoid and beta agonist combination, has been completed in India. A product based on this novel DPI is likely to be launched in India in 2010-11. Trials in other markets will follow over the next few years.

Surfactants like benzalkonium chloride (BAK) are often used in eye drops to solubilize drugs that are not soluble in water. BAK is toxic for the eye surface. SPARC has developed **Swollen Micelle Microemulsion (SMM)** technology, a BAK-free platform for solubilizing ophthalmic drugs that are insoluble or have limited solubility. This micelle protects the drug from temperature or light fluctuations. Latanoprost BAK-free ophthalmic solution, a non-infringing formulation, is stable at room temperature, lowers risk of eye surface damage, and has demonstrated safety profile and eye comfort in phase III trials in India. The product will be launched soon in India. For US, two Phase III studies are planned to begin in 2010.

Chronic eye ailments like glaucoma typically require short-duration drugs to be instilled several times a day. SPARC has also developed a **Gel Free Reservoir (GFR) technology** that increases the duration of action of drugs, localizes drug action with minimal systemic absorption and creates a clear and non-irritant formulation. GFR Timolol Maleate 0.5% once-a-day eye drop formulation developed at SPARC is found to be equivalent to the brand leader Timolol maleate 0.5% administered twice a day, in a clinical trial. Phase III trials have been completed in India and product launch is likely in 2010-11.

Now a brief update on 4 candidates from the drug discovery program.

SUN-1334H, an antiallergic, selective histamine receptor antagonist, is being developed as oral formulation and eye drops. SUN-1334H is non-sedating, with quick onset of action. It is being studied for use in seasonal allergic rhinitis, perennial allergic rhinitis, chronic idiopathic urticaria and allergic conjunctivitis.

Chronic toxicity studies on SUN 1334H oral are ongoing, with cardiac and renal safety studies planned. Eye drop formulation of SUN-1334H showed excellent inhibition of allergen and histamine induced conjunctivitis in preclinical studies. A Phase I study is expected to begin shortly.

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SUN-597, a topical glucocorticoid is an anti-inflammatory for use in inflammations of the airway, skin, eye and gastrointestinal tract. In preclinical studies, SUN-597 was found to have good potency and selectivity for glucocorticoid receptors; low oral bioavailability and very low liability to systemic side effects. It has a very high therapeutic index compared to currently marketed steroids. Preclinical efficacy and safety pharmacological studies have been completed. Phase I trials for the nasal formulation are planned.

SUN-44, a prodrug of gabapentin for the treatment of neuropathy and seizures, uses molecular modifications in its structure for better absorption. In animal models of epilepsy, SUN-44 shows better efficacy compared to gabapentin. Its profile indicates higher blood availability, feasibility of once-a-day formulation and higher safety. IND has been filed in India, with Phase I to begin in FY 2010-11.

SUN-09 is a prodrug of baclofen, a skeletal muscle relaxant for spasm related disorders. This molecule's physicochemical and structural features have been modified for better absorption throughout the intestine. In preclinical studies, SUN-09 gets rapidly absorbed, and converted to active drug within 2 hours. In animal studies, oral administration of SUN-09 gives dose dependant muscle relaxation and quick onset of action. An IND has been filed for human clinical trials in India, with Phase I to begin.

Team SPARC

The key resource in innovation is our team. If you notice, 40% of our operating expense is employee expenses. A well-qualified, committed, motivated and excellence oriented team can make all the difference.

At SPARC, we have assembled a high skilled and well-balanced team, comparable to the best in the world in their respective specialization. The world-class technology infrastructure, an invigorating workplace environment and most importantly the scientific challenges posed provide a stimulating ecosystem for innovation to the 200 member SPARC team.

Drug discovery and technology development being new domains for India, the challenge has been to source appropriately trained manpower. The scarcity of the right skills requires that we train people once they enter SPARC. 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 products.

Thank you.