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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 6TH AGM OF THE COMPANY

Dear Fellow Shareholders

On behalf of the Board of Directors I take pleasure in welcoming all of you to the 6th AGM of your Company.

2010-11 has been a particularly busy year. A lot of exciting work has been done on new technologies and products. Some more products based on SPARC's technologies have reached the Indian market. Also, there is an exciting new tie up with Merck for the Emerging Markets that will make use SPARC's technologies, details of which I will cover later in my speech.

As you probably know, Sun Pharma recently entered into a joint venture with the international pharmaceutical company Merck & Co., Inc, covering emerging markets. This joint venture will over the next 2 or three years, pick a list of innovative and differentiated branded generics, which would be developed, registered, manufactured and marketed by Merck. Some of these branded generics would make use of the innovative drug delivery technologies that are being developed at SPARC. As we've told you earlier, these drug delivery systems are designed to be more effective, patient friendly, and easy to use. We would have more details to share going ahead, as the joint venture shares more information. This, we believe, is a strong validation of the work that is being done at SPARC Ltd.

Performance

The financials for 2010-11 have been published and available with you. This year your company posted a net loss of Rs. 8.5 crores on revenues of Rs. 59.6 crores. The total spend, all of which is on supporting innovative R&D, has increased by 21% 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 and higher level of resource commitments over much longer time durations.

Just as a reminder, given the inherent uncertainties in innovative research, a high comfort level with risk is a pre-requirement for this work. Even as projects continue to make progress to subsequent stages, it may still be a while till they reach market, and sometimes some projects may have to be abandoned if results are not in line with our expectations, or a superior drug reaches market ahead of us. Hence we expect to see continuing losses for some time.

As we create intellectual property through our focus on specific areas and projects at SPARC, 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. International statistics validates this--new drug discovery takes over 10 years of development time before a product reaches market.

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In this meeting, we shall be seeking your approval for raising a further Rs. 200 crores through a rights issue to fund further work at SPARC. This again is in line with the manner in which innovative R&D companies all over the world operate and raise funds to support their pipelines till their products reach market and begin to earn revenues, or till they licence out products or technologies to partners.

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

NDDS Programs

First let me brief you about the novel delivery technologies and associated products that SPARC has developed. I am not explaining in great detail technologies that we have covered in the earlier AGMs.

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 been launched in India. For the US, Phase III clinical trials for spasticity will now begin after intensive user surveys and specific protocol assessment at the USFDA. Baclofen GRS is also being studied in alcohol dependence, and regulatory approval for clinical trials is under way.

Next, is the wrap matrix technology, which can be used to develop once-a-day formulation of high dose and high solubility drugs.

SPARC is currently developing several products using Wrap Matrix technology. Eight products such as the antihypertensive metoprolol and combinations, ropinirole, pramipexole, have been launched in India. For the wrap matrix formulation of Levetiracetam, an anti-epileptic with high solubility, pivotal pharmacokinetic studies have been finished. A skeletal muscle relaxant is in phase I studies. A controlled release formulation of a cardiovascular drug is in pharmacokinetic studies. Several combinations of this cardiovascular drug are under development. An anticancer formulation and two CNS agents are also under development.

Now I'll share with you updates on the nanoparticle technology platform for injections of water insoluble anticancer drugs. This technology offers higher proportion of delivery 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 Pacliltaxel and Docetaxel, which are widely used anticancers.

Paclitaxel Injection Concentrate for Nanodispersion (PICN) formulated using this 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®. Unlike the already marketed product Abraxane, our product does not use albumin and hence is free of immune related concerns.

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In Phase II/III, PICN seems to be well tolerated at a higher dose, with higher objective response rate. A PICN combination therapy study will shortly begin.

Docetaxel Injection Concentrate for Nanodispersion or DICN was found to be safe at 7.5 times the dose of conventional Docetaxel in animal studies. In India, a phase I study in solid tumor patients has been completed, and higher doses could be tolerated compared to plain Docetaxel alone. A phase II study in Non Small Cell Lung Cancer patients is planned as well as a pre- IND meeting with USFDA.

As we've shared earlier, our proprietary depot techynology is an interesting way of administering drugs that need to be given over a long time.

Somatostatin analogue for the treatment of acromegaly and growth hormone dependent cancers is one of the projects under development. A phase III study in acromegaly patients has now been completed and product launched in India. A three-month product, as well as a few CNS agents are under development.

One product that we're excited about is SPARC's proprietary Dry Powder Inhaler (DPI), which is close to market in India, in fact field studies are ongoing with key opinion leaders. As you know, this device is designed to be 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 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.

The initial feedback from the marketing soft launch is positive. For the US, a pre IND meeting has been completed and an IND is now to be filed.

Latanoprost RT is a product used in glaucoma treatment that has been brought to market this year using SPARC Ltd's swollen micelle technology. Surfactants like benzalkonium chloride (BAK) are often used in eye drops to solubilize drugs, however, BAK can damage the eye. Latanoprost BAK-free ophthalmic solution, a non-infringing formulation, is stable at room temperature, lowers risk of eye surface damage, and is safe and effective. For the US, IND has been approved and enrollment for a Phase III study is under way.

Another eyecare product that has found good market response is the glaucoma drug Timolet, Timolol Maleate 0.5%, which uses Gel Free Reservoir technology, or GFR. GFR technology increases the duration of action of drugs, localizes drug action with minimal systemic absorption, and creates a clear and nonirritant formulation.

Combining the advantage of both these technologies, eyedrops that contain latanoprost BAK free and Timolol OD, GFR- based, have been developed. Phase III study is ongoing in India, and filing is likely by 505 b(2) for the US.

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NCE Programs

Now a brief update on the candidates from the drug discovery program, that now includes an exciting new molecule.

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.

The advantages that SUN-1334H showed in early studies were that it was non-sedating, with quick onset of action. Chronic toxicity studies with the oral formulation are ongoing, with cardiac and renal safety studies planned.

Eye drop formulation of SUN-1334H showed excellent anti histamine action in preclinical studies. A Phase I study has been successfully concluded and chronic toxicity studies are ongoing. Phase II studies are ongoing in the US.

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 low oral bioavailability which means it is poorly absorbed, so it is free of systemic side effects. Sun 597 is in different stages of development for different dosage forms. For the nasal form, Phase I has been started, and interim data submitted to the regulatory authority. For the inhalation product toxicity studies are in progress and IND filing is likely this year. Topical formulation is in preclinical studies. Ophthalmic formulation is in preclinical studies and formulation development. I expect to share more about these formulations going ahead.

One of the areas that SPARC has addressed is developing prodrugs for molecules that are poorly absorbed. 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 has been approved in India, and Phase I is likely to begin in FY 12.

The spasticity drug Baclofen is effective but needs to be given several times a day because it is poorly absorbed. SUN-09 is a prodrug of baclofen, which is absorbed much better. In preclinical studies, SUN-09 had shown good efficacy without any additional safety concerns. Phase I of the immediate release tablets have been completed satisfactorily, and Phase I of the slow release formulation is expected to be completed by end of the year.

Now for the new lead that we've been working on, Sun K706 for the treatment of the resistant form of chronic myelogenous leukemia. We have good data points in preclinical studies and look forward to some developmental work, with IND filing likely in 2013.

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Team SPARC

Research is skill intensive and people-dependent, the key resource in innovation is the team. A well-qualified, committed, motivated and excellence oriented team can make all the difference.

At SPARC, we have assembled a 237 person strong, highly skilled team that continually upgrades skills and stays current with the best in the world developments in their areas. This equips them to deal with the challenges of innovation.

Drug discovery and technology and the ownership of intellectual property are as yet new domains for India, and getting the right people remains a crucial task. We will continue to invest in our team, and in building the right environment for innovation, so that we create world class products.

Thank you.