

SUN PHARMA  
ADVANCED RESEARCH  
COMPANY LTD.  
PLOT NO. C/1, G BLOCK,  
BANDRA KURLA COMPLEX,  
BANDRA (EAST),  
MUMBAI - 400 051.

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**July 31, 2013**

National Stock Exchange of India Ltd,  
Exchange Plaza, 5th Floor,  
Plot No. C/1, G Block,  
Bandra Kurla Complex,  
Bandra (East),  
Mumbai – 400 051.

BSE Limited,  
Market Operations Dept.  
P. J. Towers,  
Dalal Street,  
Mumbai - 400 001.

Dear Sirs,

**Sub: Submission of Text of the Chairman's Speech delivered by Shri Dilip S. Shanghvi, Chairman & Managing Director of the Company at its 8th Annual General Meeting of the Company held at Vadodara.**

With reference to the above, we are pleased to enclose herewith Text of the **Chairman's** Speech delivered by Shri Dilip, Shanghvi, Chairman & Managing Director of the Company, at the 8th Annual General Meeting of the Company held on Tuesday, 30th July, 2013 at Vadodara.

Please note that we have also up-loaded the same on our Website.

This is for your information and record.

Thanking you,

Yours faithfully,  
For Sun Pharma Advanced Research Company Ltd



Meetal S. Sampat  
Company Secretary

Encl: as above

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**SPEECH DELIVERED BY MR. DILIP SHANGHVI, CHAIRMAN AND MANAGING  
DIRECTOR OF SUN PHARMA ADVANCED RESEARCH COMPANY LIMITED AT THE 8TH  
AGM OF THE COMPANY**

Dear Fellow Shareholders

On behalf of the Board of Directors I take pleasure in welcoming all of you to the 8th AGM of your Company.

2012-13 has seen us making further progress in the journey of discovery. Some more technologies and products progressed to their next stage of development. There was immense learning as some of the findings from clinical trials reached us and were analyzed. During the year, SPARC earned milestone and royalty income from a subsidiary of Sun Pharma, related to the approval and commercialization of Liposomal Doxorubicin injection in the US.

SPARC made significant progress in the development of some of the New Drug Delivery Systems (NDDS) projects. Currently, products based on seven NDDS platform technologies are being developed, including oral, injectable, and topical dosage forms. SPARC also made progress in the development of some of the New Chemical Entity (NCE) projects. We currently have a pipeline of 6 NCEs across 10 indications.

**Performance**

The financials for 2012-13 have been published and available with you. This year your company has been able to reduce its net loss to Rs. 22 crores compared to net loss of Rs. 72 crores last year. The revenue for FY12-13 at Rs. 87 crores was significantly higher than the Rs. 29 crores recorded last year. This improvement was mainly driven by the milestone income for Liposomal Doxorubicin. This milestone income is non-recurring in nature.

At SPARC, 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.

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Last year we raised Rs. 198 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.

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

### **NDDS Programs**

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

#### **GRID Technology**

As we have shared previously, Gastro Retentive Innovative Device (GRID) technology 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 three years.

The product is undergoing Phase-III clinical trials in the US for spasticity indication. A Phase-II study is planned in the European Union in FY14 for alcohol de-addiction.

#### **Wrap Matrix Technology**

The next technology, on which we have done extensive work and have products to show for, 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.

NDA's filed with the US FDA using this technology include that for Venlafaxine and Levetiracetam. While we are awaiting US FDA's response on Venlafaxine, we have received a Complete Response Letter from the US FDA for Levetiracetam. A Complete Response Letter is a communication from the FDA to companies that an NDA cannot be approved in its present form. In the Complete Response Letter, the FDA specified that the clinical data submitted by SPARC establishes bioequivalence in the fasted state. However, the FDA has raised certain queries on the pharmacokinetic data in the fed state. SPARC is evaluating the contents of the letter and plans further discussions with the FDA.

Other products currently being developed using the Wrap Matrix technology include, a skeletal muscle relaxant with ultra short half-life and a CNS agent. Both these products are at an early stage of development.

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### **Self Dispersing Nanoparticle Technology**

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 with fewer side effects.

Using this technology, SPARC has developed Paclitaxel Injection Concentrate for Nanodispersion (PICN) for breast cancer and Docetaxel Injection Concentrate for Nanodispersion (DICN) for Non-small cell lung cancer.

PICN is a Cremophor and Albumin free formulation and gives the benefit of an easy one-step dilution and infusion preparation. It does not require any pre-medication with steroids or antihistamines and does not give rise to any significant hypersensitivity reactions in patients. We plan to file this product in the US under the 505(b)(2) route.

DICN also gives similar benefits in terms of usage of non-toxic solvents in the formulation, no pre-medication required, no hypersensitivity risk and avoids limitations of specific bags and in-line filter use. DICN has completed Phase-I trials in India and we have initiated the Phase-Ib trials. For the US market, we plan to file this product with the US FDA through the 505(b)(2) route.

### **Biodegradable Depot Injections & Implants**

SPARC has developed a proprietary Depot Technology with biocompatible and biodegradable micron size polymer particles that contains the drug in its matrix, and offers long term systemic delivery of the drug. The treatment of serious conditions such as prostate cancer, acromegaly, etc. requires long term maintenance of drug levels in the body, over several months or years. Drugs used for these indications are not suitable for oral use and have very short half life when given by parenteral route thus requiring daily or frequent injections, which is cumbersome for the patient.

Octreotide depot Injection (1 Month) has been developed at SPARC with biodegradable depot injection platform. Based on clinical studies undertaken on Acromegaly patients, Octreotide depot injection has been launched in India. Octreotide 3-Month depot Injection is currently under development at SPARC. We plan to file this product with the US FDA through the 505(b)(2) route in FY15.

### **Dry Powder Inhaler**

SPARC's Salmeterol and Fluticasone DPI (Starhaler) is a pre-metered, 60 dose, inhalation activated device for administration of combination of inhaled steroids and bronchodilator drugs useful for asthma and COPD. The device is small, convenient and easy to carry. It is easy to use across paediatric, geriatric, and adult patient populations. The device delivers uniform dose, independent of inspiratory flow rate. The device is also designed to avoid double dosing.

Starhaler was launched in India in FY12 post which it encountered certain functional issues which have now been resolved. The product has been re-launched in select markets in India in 1QFY14. For the US market, we plan to file this product with the US FDA by 4QFY14.

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### **Swollen Micelle Microemulsion (SMM) Technology**

SMM technology is a platform technology for solubilising ophthalmic drugs with limited or no water solubility. This technology does not require the use of quaternary ammonium preservative/surfactants like Benzalkonium Chloride (BAK) which may be damaging to the eyes.

SPARC has developed BAK-free Latanoprost eye drops using SMM Technology. This is a patented formulation of Latanoprost with the same strength and dosing of the market leader Xalatan®. Removal of BAK reduces tearing, burning, itching and hence reduces drainage from the surface of the eye. The NDA filing for this product with the US FDA is planned in FY14. Filings in select emerging markets are also planned in FY14.

### **Gel-free Reservoir Technology**

GFR technology platform consists of a unique polymer that shows synergistic increase in viscosity without the loss of clarity and flow property. Using the GFR technology, SPARC has developed a fixed dose combination of Latanoprost and Timolol into a once-a-day ophthalmic product. This product is being developed combining essential features of both SMM Technology and GFR Technology.

In Phase-III trials in India, SPARC's combination product, besides allowing the convenience of once-a-day dosing, was found to be comparable in efficacy to the concomitant therapy of Xalatan® once daily and Timoptic® twice daily. The safety of the product was also comparable to concomitant therapy. This combination has been approved in India based on the data from the Phase-III trials. SPARC plans an EU scientific advice for this product in FY14.

### **NCE Programs**

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

#### **SUN-597**

SUN-597 is a topical glucocorticoid being developed for allergic rhinitis, inflammation, asthma and other applications. We are currently developing the molecule for administration as a nasal spray, an inhalation product, an ophthalmic product as well as a dermal product.

Phase I studies for assessing the safety of SUN-597 nasal have been completed in India. SUN-597, on direct administration to lungs causes non-significant thymolysis and glycogen deposition.

This implies a high safety index for SUN-597 for undesired side-effects. Our pre-clinical studies indicate that SUN-597 has a wide therapeutic index for local anti-inflammatory efficacy to undesired systemic side effects. The clinical trial application filing for this NCE is planned for FY14.

#### **SUN-L731**

SUN-L731 is being developed as an oral LTD4 antagonist for treatment of Asthma & Allergic Rhinitis. In pre-clinical studies, SUN-L731 was found to have fast onset and long duration of action coupled with good oral bio-availability.

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For asthma indication, SUN-L731 is approximately 10-fold more potent than Montelukast and has 24 hrs duration of action, implying potential for once-a-day dosing. For allergic rhinitis indication, SUN-L731 has better efficacy than Montelukast in animal model for eosinophilia and has demonstrated approximately 70% oral bioavailability.

In terms of development timelines, we plan to initiate the safety pharmacology and toxicity studies for IND filing by 3QFY14 while the IND filing in India is being targeted for FY15.

### **SUN-K706**

SUN-K706 is a novel tyrosine kinase inhibitor (TKI), intended for the treatment of chronic myelogenous leukaemia (CML). While currently available oral drugs like Imatinib (Gleevec®), Nilotinib (Tasigna®) and Dasatinib (Sprycel®) are quite effective chemotherapeutic agents for CML, these drugs are ineffective on the most resistant form of mutation in leukemic cells, viz., the T315I mutation.

SUN-K706 is a selective Bcr-Abl TKI that targets this T315I resistance in CML. In vitro studies have demonstrated that SUN-K706 potently inhibits, besides other major mutant forms, the T315I mutant of the Abl kinase. SUN-K706 has higher anti-tumour activity in tumour xenograft model compared with approved drugs at clinically relevant doses. SUN-K706 also did not show inhibition of any of the major cytochromes and any significant hERG K<sup>+</sup> channel binding affinity.

We plan to file an IND in India for this NCE in FY14.

### **Portfolio Re-assessment and commercial evaluation for certain projects**

We believe that, in the current reimbursement scenario, it will be challenging to get appropriate pricing for products in developed markets without any clear clinical benefit which will justify the commercial returns. With this view we are undertaking a commercial reassessment for our other NCE programs, viz., SUN-1334H (oral & ophthalmic), SUN-09 and SUN-44.

### **Monetization of Liposomal Doxorubicin**

SPARC had contributed its technical and development expertise to a subsidiary company of Sun Pharma for meeting the US FDA's regulatory requirements for generic Doxorubicin Liposomal Injection. SPARC is eligible for certain milestone and royalty payments from this company for the product. It is also eligible for milestone and royalty payments for some of its NDDS products.

### **Outlook**

Being an R&D company, it is imperative for SPARC to strike a reasonable balance between risks and rewards that such a business necessitates. Over the past few years, SPARC has attempted to balance out between medium-term and long-term R&D projects.

Broadly, our New Drug Delivery System (NDDS) projects are directed at potential commercialization in the medium-term while our New Chemical Entity (NCE) projects will potentially get commercialized in the long-term. As we take our NCE and NDDS projects ahead on the research pathway, we're learning about how to manage in a changing regulatory environment, handle the technical demands of innovation, and balance the requirements of projects that have short term, medium term and long term timeframes.

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While we're satisfied with the progress on our projects so far, we recognize that we have quite some distance to go before we reach market, though some NDDS projects are closer to market than they were previously.

#### **Team SPARC**

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

SPARC, has a dedicated team of about 248 employees, of which 206 are highly qualified and experienced scientists comparable to those existing internationally. We believe in our team, will continue to invest in it and building the right environment for innovation.

Thank you.