

**SPEECH DELIVERED BY MR. DILIP SHANGHVI, CHAIRMAN AND MANAGING DIRECTOR OF SUN PHARMA ADVANCED RESEARCH COMPANY LIMITED AT THE 14th AGM OF THE COMPANY**

Dear Shareholders,

On behalf of the board of directors, I take great pleasure in welcoming you all to the 14th AGM of your Company. The year that passed by, has been special for SPARC, we saw meaningful progress on several of our important priorities.

When we met last time, we had filed New Drug Applications (NDA) for Xelpros™ and Elepsia™ XR in the US. I am happy to report that both NDAs were approved by the USFDA ahead of schedule and this indeed is a proud moment for SPARC. At this point I would like to thank all our employees and shareholders who have been part of our evolution over the years.

Xelpros™ was made commercially available during Q4 of financial year '19 and is gradually gaining prescription share. Our Company received milestone payment on commercialization of Xelpros™ and has been getting royalty on Xelpros™ sales.

We also witnessed Taclantis™ (PICS) moving closer to finish line, we completed the bioequivalence (BE) study versus Abraxane®, Taclantis™ was bioequivalent to Abraxane® on all the parameters evaluated. We filed NDA with USFDA for Taclantis™ based on BE study outcome and USFDA has accepted the NDA for review with a standard review cycle. SPARC expects to commercialize Taclantis™ post approval by USFDA.

Our ophthalmology programs under late stage clinical development also made progress as planned. PDP-716 and SDN-037 pivotal clinical trials are recruiting patients currently. Both the programs are expected to complete registrational studies during FY 20-21 and we intend to file NDA for these programs during FY 20-21 if the data is supportive.

These are noteworthy milestones for our Company as we now have two products approved by USFDA and several programs closer to approval or NDA filing. This provides validation to our hypothesis and creates near term revenue opportunities for SPARC. Completion of these programs will mark conclusion of SPARC's initial set of programs that were focused on improving drug delivery and we would see SPARC's pipeline transitioning to new chemical and biological entities.

Our early stage clinical programs crossed important milestones and will advance to later phases of clinical development this year. SCC-138 program initiated its Phase 2 trial in early Parkinson's disease (PD) patients after completion of its Phase 1

package. SCC-138 is the most advanced c-ABL inhibitor for PD and has the potential to be a disease modifying intervention in multiple neuro-degenerative conditions.

Phase 1 studies of SCO-088 and SCD-044 were completed during the year and SPARC is transitioning these programs to late stage development currently. We successfully completed pilot Human Abuse Liability (HAL) study for SDN-021.

SPARC not only made swift progress to execute clinical stage programs but has also been augmenting its pre-clinical pipeline. Your Company continued its pursuit of collaborations with academic innovators and entered into agreements with several university systems and commercial organizations to strengthen the pipeline. The academic partnerships are aimed at sourcing new assets based on novel biology while the intent of commercial alliances is to reduce the development time. These efforts are targeting newer disease pathways to address unmet medical needs of patients in Oncology, Immunology and Neuro-degeneration.

SPARC has over the years fine-tuned its portfolio prioritization into a robust process to ensure optimal resource allocation to promising assets. Based on FY19 review of potential opportunities and challenges, we have decided to de-prioritize S597 topical, SDD-098 topical and SDE-124.

While SPARC made important progress this year in executing its strategy, capital markets look for visibility and predictability of future financial performance in value determination. We at SPARC, always strive to maximize shareholder value and stay committed to highest standards of transparency and governance. We remain extremely confident of the long term promise of our portfolio and would like to briefly review the macro and micro factors supporting our hypothesis before doing a deep dive into some key programs.

## **GLOBAL R&D MARKET ENVIRONMENT**

Intellectual property protections and pricing power offered to the pharmaceutical industry in larger markets continue to be the most important driver of life sciences innovation globally. While manufacturers continue to enjoy freedom to set drug prices in larger markets like U.S., the reimbursement system is becoming increasingly complex and restrictive in both public and private insurance markets. Within this tightening environment, commercial insurers and healthcare providers have continued to consolidate, building their negotiating power and evolving the tools and mechanisms they practice to influence usage and pricing of therapeutics.

The growth of net price realizations of the pharmaceutical industry have slowed down considerably and price increases on established products have drawn public

wrath, as at least some of these increases were deemed excessive by the public and policy makers. These pressures are reshaping the reimbursement landscape in profound ways with long term implications for pharmaceutical innovation. Drug pricing in large pharmaceutical markets generally and US in particular has taken a sharp turn towards a world in which differentiated outcomes have become table stakes.

On the other hand, continued advances in basic sciences and a growing understanding of disease bio-processes are enabling the development of drugs targeting new disease pathways and molecular targets. The types and mechanisms of drugs under development are therefore changing, along with treatment paradigms. These include shifts from symptomatic therapies to disease-modifying agents that slow or halt disease progression, as well as the emergence of Next-Generation Biotherapeutics, which include cell based therapies, gene therapies and regenerative medicines.

Additional technical advancements have also made biologics easier to develop and manufacture, resulting in a growing percentage of the drug pipeline being created using recombinant DNA technology. Biologics now account for almost a third of new drug approvals.

Regulatory agencies understand the industries potential to make progress against intransigent diseases and enabling faster entry of 'needle moving therapies' through progressive regulatory policies and execution.

The 21st Century Cures Act provides for a number of regulatory changes in the United States by promoting acceptance of more diverse drug development approaches, including: novel designs (e.g., adaptive trials), risk-based monitoring, Real World Data use within clinical trials, use of digital health technologies, electronic records and electronic signatures in clinical trials and biomarkers and precision medicine approaches.

Separately, the European Union Clinical Trials Regulation aims to standardize trial submissions and data reporting in the European Union to create a favorable environment to conduct clinical trials and improve trial efficiency.

Smaller or emerging biotech companies are aggressively leveraging new science and progressive regulatory policies to become the anchor of innovation and sectorial energy. Emerging biopharma companies now contribute a lion's share of new drug approvals and active development pipeline.

The development of innovative medicines has evolved dramatically over the past decade. As advances in science, technology and data find broad applications in drug

discovery and translational development, our reimbursement environment and regulatory thinking are changing rapidly and significantly. Such disruption offers very attractive opportunities for younger and nimbler companies like ours to redefine the game and assume leadership.

## **INDIAN PHARMA and R&D INDUSTRY**

Indian Pharma is navigating a difficult phase. In the recent past, the industry has faced many challenges both in domestic as well as in global market. In the domestic market, industry was impacted by evolving regulatory landscape, pricing control, alternate means of engaging with doctors & patients and a new tax regime. Whereas, in global markets, factors such as increased competition, number of product approvals, decreased value from new product launches, increasing pricing pressures, customer consolidation and protectionism have impacted our industry growth.

As a result, the Indian pharmaceutical companies with significant free cash flows have started to build innovative commercial portfolios through asset acquisitions and increased investments in R&D. Global pharmaceutical companies are also showing interest in establishing operations in India for R&D, manufacturing or distribution through captive operations or collaborations. The Indian pharmaceutical industry is witnessing a transformational change from pure-play generic focus to building specialty portfolios.

However, this transformation requires commitment to disciplined innovation, global mind set and investor appetite for risk.

Disciplined innovation is not just about adhering to tasks and timelines, it is about discipline of making choices and most of the times these are hard choices of pursuing certain paths and not pursuing others.

Having a global mind set is as important if not more compared to disciplined innovation. One has to be malleable to meet expectations of diverse global stakeholders and creative in identifying possible solutions to difficult unmet needs, piecing together components and competencies from around the world. Innovative drugs will drive the growth of the industry and we need to recognize this and work towards solving complex problems with creative and cost effective solutions.

Finally, for creating a successful R&D organization, one has to be patient and persistent. An innovative portfolio has significantly nuanced and dynamic risk profile compared to generic or specialty generic portfolios. One needs to be cognizant of this fact and should have a long term view to be successful in creating an efficient R&D organization and for reaping the rewards of R&D.

SPARC has taken note of the macro changes and has made significant strategic adjustments over the last couple of years.

SPARC consciously transitioned from programs focused on delivery system to NCEs for validated targets and now its pipeline also includes several potentially 'first in class' programs. Rigorous selection and ongoing data driven prioritization of programs are absolutely critical for allocation of resources. Portfolio prioritization exercise is based on validated scientific models and ensures appropriate level of resourcing to high value programs and early closure of less attractive assets.

SPARC has been integrating itself into the global discovery ecosystem with several collaborations. During last year, SPARC entered into agreements with multiple academic centers and commercial organizations like Schrodinger & Hitgen. SPARC over the years have evolved its approach towards strategic collaborations and today has an effective process to execute different types of partnerships. These alliances not just provide access to newer assets but also help to create a global footprint for SPARC.

We remain committed to the SPARC vision. We have visibility to significant value inflection points in the short term. Out-licensing of Taclantis, PDP-716 and SDN-037 are some of the near term cash opportunities for SPARC, followed by its lead NCE program SCO-088 for treatment of CML.

Let me share additional detail on specific programs which are important from a short to medium term value standpoint

### **1. Xelpros™ Eye Drops for Treatment of Glaucoma**

Xelpros™ was the first USFDA NDA approval for SPARC. Our commercialization partner SPIL launched Xelpros™ in the USA and SPARC received milestone payment on USFDA approval and commercialization of Xelpros™.

Xelpros™ is gaining prescriptions steadily post launch and SPARC expects to get higher royalty revenues with Xelpros™ topline growth.

### **2. Elepsia™ XR Once-a-Day Tablet for Treatment of Epilepsy**

Elepsia™ XR was approved by USFDA ahead of its PDUFA date and SPARC received milestone payment upon USFDA approval. SPIL returned the rights of Elepsia™ XR to SPARC as CNS is no longer a focussed therapeutic priority in the US market for SPIL.

Although this is a setback for SPARC, we expect to license Elepsia™ XR to an appropriate partner soon. SPARC is in discussion with potential partners for licensing of Elepsia™ XR for US market.

### **3. Taclantis™ for Treatment of Solid Tumours**

Taclantis™ is a Cremophor® and Albumin free nano particle formulation of Paclitaxel developed using SPARC's proprietary Nanotecton™ Technology. Taclantis™ offers ease of reconstitution & administration, shorter infusion time and potentially reduced risk of allergic reactions compared to both Abraxane® and Cremophor® based formulations.

SPARC's NDA has been accepted by USFDA for review and SPARC has also notified Celgene regarding Para IV filing of Taclantis™. SPARC expects FDA's response to Taclantis™ NDA by Q4 FY19-20.

SPARC has initiated discussions with potential partners for out-licensing of Taclantis™.

### **4. PDP-716 Eye drops for Treatment of Glaucoma**

PDP-716 is once-a-day formulation of Brimonidine developed using SPARC's TearAct™ Technology for treatment of Glaucoma. PDP-716 provides dosing convenience to patients compared to currently marketed product that requires thrice-a-day dosing.

SPARC initiated pivotal Phase III study for PDP-716 in the USA. The study is randomizing patients and if the data is positive SPARC expects to file NDA for PDP-716 during FY 20-21.

SPARC is in discussion with potential partners for licensing of PDP-716.

### **5. SDN-037 Eye drops for Treatment of Ocular Pain and Inflammation**

SPARC is developing a novel long acting (twice-a-day) formulation of an USFDA approved ophthalmic steroid for eye pain and inflammation after cataract surgery. Currently marketed steroidal eye drop requires administration every 4 to 6 hours. Apart from providing dosing convenience, SPARC's formulation is clear compared to marketed formulation which is a milky emulsion causing blurring of vision after administration of the eye drop.

SPARC initiated pivotal Phase III study for SDN-037 in USA. The study is randomizing patients and is expected to be completed during FY 20-21.

SPARC is in discussion with potential partners for licensing of SDN-037.



## **6. SCC–138 for Treatment of Parkinson’s Disease**

Parkinson’s disease is an aging disorder and currently approved drugs only manage the symptoms of the disease. There are no drugs approved which can prevent, slow down or possibly reverse the unfortunate trajectory of this disease.

In pre-clinical studies, SCC–138 has demonstrated significant neuro-protective activity in Parkinson’s disease models. SPARC is developing SCC–138 as a potential disease modifying agent for treatment of Parkinson’s disease.

SPARC continues to enroll patients in Phase 1 dose escalation study of SCC–138 as MTD has not yet been established. In addition, SPARC is recruiting patients with Parkinson’s disease in the Phase 2 proof-of-concept study of SCC–138, which is expected to be completed in about 2 years.

SPARC is also evaluating SCC–138 in other neuro-degenerative disorders.

## **7. SCO–088 for Treatment Resistant Chronic Myeloid Leukemia (CML)**

SCO–088 is highly selective BCR-Abl kinase inhibitor and thus may have lower potential for serious and life threatening side effects as observed with less selective and currently marketed BCR-Abl targeted agents. Patients treated with currently available tyrosine kinase inhibitors respond initially but eventually develop resistance. Today, there are limited treatment choices for patients who have failed 2 or more lines of therapy.

SCO–088 appears to be very well tolerated in a wide spectrum of concentrations, providing a significant safety window for heavily pre-treated CML patients. In the Phase I study haematological response was observed in 60% patients and the responses were durable with 40% patients receiving over 6 months of treatment. SPARC has submitted the part C study design to USFDA and expects to start the study by Q3 FY 19-20.

## **8. SCD–044 for Treatment of Autoimmune Disorders**

SPARC, in collaboration with Bioprojet (a French biotechnology company), is developing highly selective S1P Receptor 1 agonist for autoimmune disorders. The currently available S1P Receptor agonists are less selective and have reported a wide variety of serious side effects.

SPARC completed Phase 1 study of SCD–044 in healthy human volunteers. In Phase 1 study, SCD–044 demonstrated dose dependent exposure. Lymphopenia, a marker for efficacy was assessed in the study and >50% decrease in lymphocytes from baseline at 24 hours was observed in all dose regimens evaluated.

SPARC plans to initiate Phase 2 study of SCD-044 in Q3 FY 19-20.

## **9. SDN-021 for Treatment of Pain**

SPARC has developed a platform technology to address the escalating problem of prescription drug abuse. SPARC's platform technology deters oral multi-pill abuse. Upon ingestion of multiple pills, the technology reduces peak drug levels and slows down their release.

SPARC completed pilot Human Abuse Liability (HAL) study in recreational users. The study demonstrated that the Cmax is blunted when multiple pills of SPARC formulation are ingested versus the reference product. SPARC plans to out-license the program and would develop it further in collaboration with a partner.

Over the last couple of years, SPARC has transitioned to a significant portfolio with multiple assets spread across the development continuum. We recognize the challenges of operating at this level in terms of resources and competencies required. We have been actively investing in building competencies, partnerships and infrastructure to ensure SPARC's competitiveness. SPARC has augmented its competencies in computational chemistry, biomarker development and has initiated a significant internal effort to develop novel biologics.

Your company today is a contemporary development engine which can prosecute an asset from conception to clinic and it gives me immense pleasure to have reached this stage over the last decade.

I would like to thank all our employees, shareholders and partners for their commitment and unconditional trust in building the organization to its current level.

We would continue to aggressively pursue our vision to develop novel drugs for unmet medical needs in the area of Oncology, Ophthalmology, Neuro-degeneration and Autoimmune disorders and remain committed to maintaining high standards of transparency and corporate governance.

On behalf of everyone at SPARC, I thank you all again for your time today and your trust over the years. We look forward to your questions, feedback and suggestions.

Thank you.

Place: Vadodara

Dilip S. Shanghvi

Date: July 29, 2019

Chairman & Managing Director