

SPARC/Sec/SE/2020-21/027

1<sup>st</sup> October 2020

To

**The 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**

P J Towers,

Dalal street,

Mumbai - 400001

**Subject: Speech delivered by Mr. Dilip Shanghvi, Chairman and Managing Director of the Company at the 15<sup>th</sup> Annual General Meeting of the Company held on 30<sup>th</sup> September 2020**

Dear Sir/ Madam,

Please find enclosed, copy of the Speech delivered by Mr. Dilip Shanghvi, Chairman and Managing Director of the Company at the 15<sup>th</sup> Annual General Meeting of the Company held on 30<sup>th</sup> September, 2020.

We request you to kindly disseminate the same through your web portal.

Thanking you,

Yours faithfully,

For **Sun Pharma Advanced Research Company Ltd.,**

A handwritten signature in black ink, appearing to read "Debashis Dey", with a horizontal line extending to the right.

**Debashis Dey**

Company Secretary

Encls: A/a.

**DISCLAIMER:**

*Statements in the Chairman's Speech describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied.*

## **SPEECH DELIVERED BY MR. DILIP SHANGHVI, CHAIRMAN AND MANAGING DIRECTOR OF SUN PHARMA ADVANCED RESEARCH COMPANY LIMITED AT THE 15th AGM OF THE COMPANY**

### **Introduction**

Dear Shareholders,

On behalf of the board of directors, a very warm welcome to the 15th AGM of our Company. Thank you so much for taking the time to be with us today. Many of you have been attending SPARC AGMs over the past several years and your continued support and engagement are a great source of motivation for all of us at SPARC. I am delighted to be addressing you again as the Chairman of SPARC.

We are meeting virtually today given the extraordinary circumstances due to the COVID-19 pandemic. Never before, in recent history, have we encountered a challenge of this magnitude. I hope you and your family are safe and healthy.

I would like to first express our deepest respect for the country's corona warriors who have relentlessly worked to ensure safety of population at large.

Amidst the COVID-19 pandemic, our main focus has been to maintain continuity of our operations. I wish to take a moment to recognize the commendable work of our team during this difficult time.

Let me discuss the performance of SPARC during the previous year. The financial year '20 was a year of many notable firsts for SPARC. We achieved several milestones for the first time in the history of SPARC. Let me share some of those with you:

- SPARC executed its 1<sup>st</sup> commercial in-licensing agreement, SPARC obtained exclusive global rights of SCD-044 from Bioprojet (France).
- SPARC established first commercial partnership for China region with China Medical System, out-licensing commercial rights of five assets namely Xelpros, Elepsia, Taclantis, PDP-716 and SDN-037.
- During the year, SPARC executed its first NCE out-licensing agreement when we partnered global rights of SCD-044.
- Two of the SPARC's programs were granted orphan drug designation by USFDA i.e. Vodobatinib for CML and Phenobarbital formulation for treatment of neonatal seizures.

While we made progress on most of our programs, we faced a setback for Taclantis due to receipt of Complete Response Letter from USFDA. We are in active

discussions with the FDA on finding a path forward on Taclantis. The other key challenge encountered not just by SPARC but the entire industry was the impact on patient enrollment in the ongoing clinical studies due to lockdowns imposed in most parts of the world. While we did face disruptions initially like the rest of the industry, patient recruitment and clinical studies have resumed and we are working to put them back on schedule.

Before I provide an update on key programs I would like to highlight some of the strategic shifts that we have made over last couple of years.

SPARC's emphasis during the early years was on low risk 505(b)(2) opportunities. While these programs offer advantage to the patients, the industry was witnessing shift towards programs offering significant clinical differentiation and benefit for the patients. Programs offering only patient convenience benefit can no longer attract higher price premiums, and therefore lead to unviable low returns. Furthermore, we have seen challenges even in the NCE space for those who are not the first movers and do not offer significant clinical differentiation. While pockets of opportunities do exist, and these opportunities can still be an area where we play, it is not the place where we want to focus.

Today, SPARC has transitioned to a company with multiple assets, several of which are first-in-class assets. NDDS based programs which were more than 80% of our portfolio five years ago are less than 20% today. And one third of our current programs have the potential to be first-in-class drugs.

We are cognizant of the fact that this shift requires different set of capabilities and competencies. We have been actively investing in building competencies, partnerships and infrastructure to ensure SPARC's competitiveness. Our company today is a contemporary development engine which can prosecute an asset from ideation to full clinical development and it gives me immense pleasure to have reached this stage over the last decade.

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

Let me share details of our clinical stage programs which are important from a short to medium term value standpoint.

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

Rights of Elepsia™ XR were returned back to SPARC last year by SUN FZE and SPARC team has now licensed the US commercialization rights of Elepsia™ XR to Tripoint Therapeutics. Under the terms of the agreement SPARC is eligible to receive royalties on net sales of Elepsia™ XR ranging from 15% to 50%.

The teams of both the organizations are working closely to ensure Elepsia™ XR is made available to the patients in USA as soon as possible.

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

SPARC provided update on the CRL that we received for Taclantis™. We met with the agency subsequently on several occasions since to find an acceptable way forward for the program. While we managed to make progress, USFDA is still considering the options. We expect to receive feedback soon from the agency.

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

PDP-716 is once-a-day formulation of Brimonidine for treatment of Glaucoma.

The patient recruitment in the pivotal Phase III study for PDP-716 is completed and the topline data from the study is expected to be available by Q4 FY21.

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

SDN-037 is a twice daily eye drops of a potent steroid for treating pain and inflammation, post cataract surgery. The pivotal study is completed and the top line data of the study is expected soon.

## **5. Vodobatinib for Treatment of Neurodegenerative Disorders**

SPARC has established PK characteristics in Parkinson's patients through single and multiple dose studies and have found that the drug is generally safe and well tolerated in this patient population. Currently, a Phase 2b proof-of-concept study named PROSEK is enrolling patients.

We have also taken several measures to ramp up the patient recruitment in the PROSEEK study. Some of these include dedicated website for PROSEEK, use of media i.e. both social media and traditional media among other measures.

Vodobatinib is being evaluated in Lewy Body Dementia as well. The study is conducted as an investigator initiated study in collaboration with Georgetown University.

Both these studies are expected to be completed in 2022.

We are also expanding the program to Alzheimer's disease with additional pre-clinical studies.

## **6. Vodobatinib for Treatment Resistant Chronic Myeloid Leukemia (CML)**

Vodobatinib is also under investigation for CML. The Phase 1 study of vodobatinib is completed and data from the study is encouraging. The major cytogenetic response rate in the population that we intend to use for approval, that is, patients failing 3 or more tyrosine kinase inhibitors one of which includes ponatinib, is very substantial at 58%.

Vodobatinib also appears to be safe as no new SAEs were reported since last year. Mild to moderate gastrointestinal and musculoskeletal complaints were the most common safety findings reported in the Phase I study. Pivotal study in patients who are refractory to 3 or more TKIs, including ponatinib is enrolling patients across the world. The topline results of this study are expected in FY23.

## **7. SCD-044 for Treatment of Autoimmune Disorders**

SCD-044 was a collaborative development with a French Biotech, Bioprojet. SPARC licensed Bioprojet's rights to the asset last year. Since then SPARC completed the IND enabling studies.

SPARC out-licensed the global rights of SCD-044 to Sun Pharma, we are particularly proud of this deal as it is the first NCE we have successfully developed and partnered. SPARC received an upfront payment of US\$ 20 million and is also eligible to receive up to US\$ 125 million as milestone payments contingent upon the achievement of clinical, regulatory and sales milestones, in addition to tiered royalties on sales.

Sun Pharma will be responsible for the development, regulatory filings, manufacturing and commercialization of the product globally.

## **8. SCO-120 for Treatment of Breast Cancer**

SCO-120 is an oral selective estrogen receptor degrader (SERD) program for the treatment of patients who stop responding to initial treatments with anti-hormonal agents.

The IND for SCO-120 was filed in January and a dose escalation study is ongoing. We've studied doses up to 100 mg and there have been no significant AEs. We hope to complete the proof-of-concept study in patients by end of next year.

The execution of the clinical trials of these programs was impacted due to COVID-19 as the hospital systems across the world were shut down or repurposed to handle the pandemic resulting in drastic reduction of clinical research activity. Closing or scaling down of manufacturing facilities impacted IP supply and scaled down lab operations have had an 'across the board' impact on pipeline movement. Global airline restrictions negatively impacted the supply chain, and disrupted the normal way of doing business. But, we have responded well and have continued to push forward using new and novel ways of doing business where we can. .

We have taken several steps early on to identify and mitigate risks as much as possible. One of the primary priorities was to protect the patients who are already in trials through a combination of ancillary support and virtualization. We have also managed to maintain high lab productivity. Today we are at, 70% of our resources working from labs at sites and 30% working from home. We have also used this period to scale the clinical trial site infrastructure so that we can scale fast when things normalize later this year or early next year. Especially for our key trials, we have been adding trial sites through virtual site initiation visits and other start up activities. In summary, the COVID challenges were significant and are still evolving, but we are working to put our key priorities back on schedule as soon as possible.

## **Closing Remarks**

We are now at an important inflection point at SPARC and I would like to spend a moment to discuss some of the near term key priorities. With the completion of our ophthalmology programs and pending conclusion of our regulatory discussions on Taclantis, we will increase our focus on NCE opportunities even beyond where we are today.

As a result, we need to continue to invest in the capabilities that will set up SPARC to be an industry leader in innovation. We will be reviewing our team and looking to add expertise on the pre-clinical and clinical development side. We will look to expand our ongoing collaborations with academia and partner with key commercial organizations who can help us to continue our journey.

We hope to bring additional assets into our preclinical ecosystem and advance additional assets into the clinic in the next 18 months. We are expecting important data readouts in 2022 that are expected to be catalysts for generating value for SPARC. The maturing of our clinical portfolio will bring with it our first real opportunity at sustainable financial independence. But, in order to get there, we need to continue to invest. Currently, we are evaluating our options, but we expect there will be another fund raising event over the next 12 months.

On behalf of the Board, I thank you and our valuable shareholders, for the continued encouragement through the years. As always, I will depend on your support as we steer the Company through this challenging journey to build the new SPARC focussed on NCEs and NBEs.

Thank you.

Place:

Dilip S. Shanghvi

Date: September 30, 2020

Chairman & Managing Director