



**SPEECH DELIVERED BY MR. DILIP SHANGHVI, CHAIRMAN OF SUN PHARMA  
ADVANCED RESEARCH COMPANY LIMITED AT THE 16th AGM OF THE  
COMPANY**

Dear Shareholders,

On behalf of the board of directors, I welcome you all to the 16th AGM of our Company. I thank you all for taking the time for attending the AGM today. Similar to last time, this meeting is hosted virtually due to the COVID-19 related restrictions. I sincerely hope you and your family are safe and healthy in these difficult times.

I would like to begin by taking a moment to recognize the tremendous global effort in responding to this unprecedented challenge. Although, we have not fully recovered from the pandemic, the availability of vaccines may allow gradual restoration of normalcy.

The global Pharma industry faced significant operational disruption as a result of lockdowns imposed by governments across the world. The major impact was due to stoppage of manufacturing activity, supply chain disruptions and slow patient recruitment in ongoing clinical trials.

The industry responded with great resilience and ensured that the operations are not impacted for long. This is evident by that fact that the year 2020 saw second highest number of drug approvals in the last two decades. While the emphasis was on COVID-19 vaccines and therapeutics, the US FDA kept up its intense pace of new drug approvals in 2020 and approved 53 new products.

Your Company was also impacted by the interruptions caused by the pandemic. During lockdowns, the lab operations were affected, the patient recruitment in ongoing trials was slowed down. However, SPARC, quickly adapted to the changing environment and took measures to ensure smooth functioning of our labs and offices once the lockdown measures were eased.

Our industry's fundamentals remain strong and exciting. We saw continued acceleration of scientific innovation, entrepreneurial activity and robust funding across geographies in the biopharma sector. This trajectory, driven by deeper understanding of disease processes in major therapeutic areas and resolution of drug development challenges related to several promising new modalities like RNA therapeutics, gene and cell therapies, Antibody Drug Conjugates, etc. promises significant improvements in the standards of care in many 'difficult to treat' diseases.

A macro trend offering important backdrop to this transformation is the accelerated digitization of the broader healthcare space which is expected to shape the future of our industry. While digitization is changing commercial models and healthcare



delivery in significant ways, its impact on research and development is deep and far reaching. Application of novel gene editing technologies, high resolution microscopy, and artificial intelligence is revolutionizing target discovery, asset development and translation.

New types of clinical trial designs and execution collaborations are reshaping later stages of drug development. Novel strategies and technologies, including real world evidence, platform trials, virtualization of clinical testing, and advanced analytics can help organizations succeed in the new regulatory environment, compress timelines, and offer new clinical and commercial insights.

In a nut shell, the research-based pharmaceutical industry is entering into an exciting new era in therapeutics development. Changing the old models of drug development to take advantage of a new wave of scientific breakthroughs will be the way forward for the industry to sustain its growth curve.

SPARC has taken significant steps to take note of the forces reshaping our industry to be competitive in the emerging New Health landscape. As a result our portfolio is emerging as a balanced, multi-modal mix of novel and validated biology with several first in class opportunities.

Let me now move on to reviewing the performance of SPARC during the previous year.

The year 2020-2021 started with lot of uncertainty due to COVID-19, however, SPARC was quick to adopt a hybrid model. Several steps were taken to ensure that two most important aspects of our business i.e. the lab operations and patient recruitment in ongoing clinical studies were not compromised.

Let me share updates of the assets under clinical development stage, starting with the NDDS programs.

SPARC out-licensed the US commercialization rights of Elepsia™ XR to Tripoint Therapeutics and the product is now commercialized by the Tripoint team.

The pivotal study of both of our ophthalmology assets i.e. once-a-day formulation of Brimonidine and twice-a-day Difluprednate formulation read out positively, providing validation to the underlying proprietary technology used for developing these programs. SPARC is in process of filing NDAs of both the assets and also in discussion with potential partners for out-licensing the commercialization rights.



During the year, SPARC consulted and agreed with USFDA for the path forward for NDA filing of its novel formulation of phenobarbital. We are working towards completing the studies necessary to support the filing.

While all the late-stage pipeline assets had positive outcomes, the feedback on Taclantis™ from USFDA under Formal Dispute Resolution (FDR) process was not in favour of SPARC. USFDA acknowledged the data generated from the BE study; however, it maintained that SPARC should conduct a Phase 3 study in metastatic breast cancer patients in order to obtain regulatory approval for Taclantis™.

SPARC believes that conducting a new Phase 3 study would make the program commercially unviable, hence, SPARC has deprioritized the development of Taclantis™ for the US market.

Our clinical NCE assets also made progress and one of the key milestone achieved during the year was out-licensing the global rights of SCD-044 to Sun Pharmaceutical Industries Limited. The transaction is of importance as this was the first NCE licensed by SPARC since inception.

The pivotal study of SCO-088 in Chronic Myelogenous Leukemia, PROSEK study in early stage Parkinson's disease & the Lewy Body Dementia PoC study for SCC-138 and Phase 1 study of SCO-120 continue to actively recruit patients. The recruitment rate was impacted due to COVID-19 associated lockdown imposed in most parts of the world last year.

After the lockdown measures were eased the recruitment rate has picked up for the ongoing studies. Over 30% of the planned patients are randomized under PROSEK study and the patient enrolment is expected to be completed in 2022. Similarly for SCO-088, remedial steps have been taken to increase the patient recruitment on the pivotal study and SPARC expects to complete the study by FY24.

Single Ascending Dose (SAD) portion in healthy volunteers of SCO-120 was completed in the previous year. Currently, the study is enrolling healthy volunteers in the Multiple Ascending Dose (MAD) portion of the study.

We are looking forward to accelerating patient accrual in these important trials this year as healthcare systems slowly move towards a new post-Covid normal.

## **Outlook and Closing Remarks**

Let me briefly touch upon SPARC's continued portfolio evolution and near term objectives. SPARC has completed its pipeline transition from a 505(b)(2) focused R&D portfolio to a significantly more innovative and balanced mix of NCEs and NBEs.



During this evolution, SPARC validated its operating model with several successful market authorizations and commercial partnerships in multiple geographies. In the near term, we will remain focused on achieving clinical milestones for our important NCE assets while advancing additional high value assets to clinical testing. Successful read outs from these studies will establish human proof-of-concept and can generate important value inflection points for SPARC.

As you know, your Company recently completed a fund raise of ~\$150 mn by way of fresh equity issuance to meet the expenses over the next 2-3 years. As we continue our transition towards developing novel treatment modalities, we need to build our capabilities to successfully prosecute more complex and innovative programs. Costs associated with development of such novel treatments will also be higher compared to our historical costs. To meet the cash requirements for funding the development of our future programs, we will continue to evaluate our options to raise additional capital.

Finally before we close, I would like to reaffirm our commitment to maintaining highest standards of corporate governance, compliance and sustainability practices. We have come a long way in a business with long gestation periods and high failure risk. We couldn't have reached here without your backing at every step of the way. We look forward to your continued support as we pursue our vision to build a purposeful institution developing truly innovative therapeutics to move the standards of care for patients across the world.

Let me also thank our employees who have ensured business continuity despite the multiple disruptions resulting from the COVID-19 pandemic and our Board of Directors for their guidance and support in these uncertain times.

On behalf of the Board, I thank you all for joining today.

Thank you.

Place: Mumbai

Dilip S. Shanghvi

Date: September 29, 2021

Chairman

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