



SPARC/Sec/SE/2022-23/052

September 22, 2022

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.

Ref: Scrip Code: NSE: SPARC; BSE: 532872

Dear Sir/ Madam,

Sub: Submission of Chairman's Speech delivered at the 17th Annual General Meeting of the Company

The Chairman's speech delivered at the 17th Annual General Meeting of the Company held today i.e. on September 22, 2022 is enclosed herewith.

This is for your information and dissemination.

Thanking you,

Yours faithfully,

For **Sun Pharma Advanced Research Company Limited**

Dinesh Lahoti
Company Secretary and Compliance Officer
ICSI Membership No. A22471

Encl: As above

SPEECH DELIVERED BY MR. DILIP SHANGHVI, CHAIRMAN AT THE 17th ANNUAL GENERAL MEETING OF SUN PHARMA ADVANCED RESEARCH COMPANY LIMITED HELD ON THURSDAY, SEPTEMBER 22, 2022

Dear Shareholders,

Let me begin by providing an update on the Industry landscape. The biopharmaceutical industry is resetting itself and has done a remarkable job of adapting, re-focusing and overcoming many operational and organisational challenges in the post COVID-19 era.

The innovation cycle in the sector is accelerating as the stakeholders increase their efforts to speed up the delivery of scientific breakthroughs to patients. The median time from first patent filing to launch in the U.S. has fallen to its lowest level in the past two years; 21 drugs were launched within five years into their patent terms.

Industry experts believe that the worldwide sales of prescription drugs, which are projected to increase at a CAGR of 6.4% from 2021 to 2026, are further proof that the commercial picture for pharmaceutical business is still strong. The predicted rise is based on the robust pipeline of drugs currently in development and the rate at which new drugs are being approved.

The increase in number of assets under evaluation has also resulted in higher number of drugs being approved globally. The new drug approvals have seen an upward trend in recent times, specifically during 2021, US FDA approved 58 novel drugs, the highest number for the last three years, and well above the 10-year average of 48 novel drugs. Similar growth trend was observed for drugs approved by EMA, 54 novel drugs were approved by the EMA in 2021 which represents a 35% increase compared to 39 drugs approved in 2020.

The conducive development environment has led to an increase in investment from the past 2 years, especially in the year 2021. At a CAGR of 4.2% from 2020 to 2026, the global Research & Development (R&D) expenditure is anticipated to reach USD 254 billion. While large biopharma businesses are anticipated to account for the majority of this rise in R&D spending, smaller players with cutting-edge science are anticipated to have access to funding to support their R&D.

The biotech sector recently experienced valuation pressures as a result of being a part of a larger market downturn, pricing issues, and rerating of early stage development risk. This is despite the fact that the industry made rapid progress with understanding disease pathways and potential interventions. Even for businesses with late-stage clinical assets that can attract funding, valuations are likely to remain under pressure in the near- to medium-term. In the last months of 2021 and the first two quarters of 2022, the US Biotech index showed signs of continuing bearish sentiment.

During the previous year, industry continued to witness the impact of COVID-19 albeit to a lesser degree which led to increase in initiation of clinical trials. SPARC also had an upswing in patient recruitment in its ongoing clinical studies. SPARC offices were also functional and most team members returned to working from office paving way for face-to-face interactions and increased collaborations between teams.

In summary, despite a challenging financial market climate, the biopharmaceutical industry made considerable progress in advancing drug discovery and development. It is anticipated that advances in scientific knowledge and the creation of novel therapies would not only give patients new treatment options but also reverse the current market sentiment.

SPARC has adopted new technologies and modalities along the developmental value chain as a measured response to the changing environment. SPARC has developed expertise in bioinformatics, machine learning, and computational drug discovery during the past few years. In the discovery stage, the Company has built robust capabilities in biologics with the ability to create modular platforms of immunofusions and antibody drug conjugates.

Let me now provide you with an update on the key programs and the progress made during FY22.

SPARC out-licensed the global commercialization rights (excluding Greater China and India) of PDP-716 and SDN-037 to Visiox pharma, an ophthalmology focussed company. The transaction was of significance to us as SPARC is entitled to receive 10% equity in Visiox Pharma apart from the royalty and milestone payments. SPARC & Visiox collaborated and completed the pre-NDA meeting with US FDA for both PDP-716 and SDN-037. Both the organizations are now working closely to prepare the NDA for filing.

SPARC filed the NDA for benzyl alcohol free formulation of phenobarbital injection for the treatment of neonatal seizures. The Company expects response from US FDA to the NDA in Q3 FY23. In addition to filing the NDA, the Company is in talks with potential partners for licensing the commercialization rights of phenobarbital injection.

The ophthalmology programs, viz. PDP-716 and SDN-037, and the phenobarbital injection formulation are the only 505(b)(2) assets currently in active development at SPARC. The pipeline transition to NCEs and NBEs will be completed once these programs have been fully prosecuted.

The NCE assets under clinical development started to see an uptick in the patient recruitment which was hampered due to COVID-19 related challenges in the last couple of years.

The pivotal study of SCO-088 in Chronic Myelogenous Leukaemia continues to recruit patients. The recruitment has been challenging over the years not just because of COVID-19 related impact but also due to limited number of patients that are eligible for treatment once they fail ponatinib. SPARC has taken several measures to ramp up the recruitment of patients and expects data readout in FY24.

The phase 2 proof-of-concept PROSEK study of SCC-138 is progressing well and post the easing of the COVID-19 related restrictions the study is recruiting patients at a higher rate. Around 70% of the planned patients are randomized and the patient enrolment is expected to be completed in FY23. The top line results are expected to be available in FY24.

The single centre phase 2 study of SCC-138 for treatment of lewy body dementia is also recruiting patients and the data read out is expected around the same time as the PROSEK study.

Vibozilimod, S1PR1 receptor agonist that was licensed to Sun Pharmaceutical Industries Limited by SPARC is continuing to recruit patients in the ongoing phase 2 studies for treatment of psoriasis and atopic dermatitis.

SPARC completed the multiple ascending dose study and the food effect study in healthy volunteers for its oral SERD, SCO-120. The phase 1 study in HR +ve, HER 2-ve metastatic breast cancer patients has been initiated.

During FY22, SPARC in-licensed antibodies from Biomodifying against a unique oncology target. The licensed antibodies help to bolster the biologics pipeline of SPARC and also strengthens it's resolve to develop novel immunofusions and antibody drug conjugates.

During FY22, SPARC raised USD 148 million to complete the ongoing clinical studies. SPARC received INR 409 Cr (~USD 54 million) being 25% payable on application as well as upon conversion of few warrants; balance INR 703 Cr (~USD 94 million) is expected to be received by December 2022 upon the conversion of remaining warrants by warrant holders.

Outlook and Closing Remarks

Let me now summarize SPARC's strategic intent and future outlook. SPARC has transitioned into a company with focus on discovery & research of novel drugs prioritized in three therapeutic areas, namely oncology, neurology and immunology. Our focus on selected therapeutic areas is determined by a rigorous evaluation of the unmet patient needs and the business possibilities.

In oncology, de novo or acquired treatment resistance is a major challenge with the existing drugs apart from the issues pertaining to quality of life of patients. With SPARC's focus on targeted agents and biologics like ADCs for treatment of cancers, there may be a possibility to target the drivers of resistance and being selective it can also provide better quality of life.

Similarly, neurodegenerative disorders like Parkinson's disease and Alzheimer's disease have limited treatment options with no approved therapy that can delay or halt neurodegeneration. The pre-clinical data generated for SPARC's SCC-138 suggests that SCC-138 could potentially delay the progression of Parkinson's disease. SCC-138 is leading the class and if approved can potentially be the first c-Abl inhibitor approved for treatment of Parkinson's disease.

The key objective for SPARC in the near term is to ensure completion of the ongoing clinical trials to deliver the next set of catalysts and to work with our partners for successful commercialization of the partnered assets. SPARC's initial set of NCEs under clinical evaluation are poised for important read outs in next 12 – 18 months. The read outs are important inflection points for SPARC as the outcomes would drive the future strategy of SPARC.

As the clinical programs mature, SPARC is planning to initiate first-in-human studies for two additional assets and in parallel continue to build the pre-clinical pipeline. SPARC's pipeline build-up is primarily driven by our partnerships and collaborations with emerging biotech companies and academic institutes globally.

An important area of focus at SPARC includes development of novel biologics. The Company has built robust capabilities in biologics and will continue to invest in other critical competency areas to fully leverage the competitive advantages of its operating model.

In order to advance our pre-clinical assets and to augment our R&D pipeline, we had obtained shareholders' approval at the last AGM to raise an additional sum up to INR 1,800 crores, which was valid for one year. The said fund raise could not be concluded due to adverse market conditions. Hence, the Company seeks a fresh approval by way of an enabling resolution to raise a sum up to INR 1,800 Cr (~USD 225 million) to meet its growth plans.

Lastly, before I conclude my speech, we would like to reiterate our promise to maintain highest standards of corporate governance, compliance and sustainability practices. I thank you for your commitment and trust in the organization and look forward to your continuing support as we work to realise our goal of creating a Company that specialises in offering cutting-edge treatment alternatives to patients all around the world.

I express my gratitude to my colleagues on the Board for their constant guidance and support over the years. Additionally, I want to convey my gratitude to the SPARC team members who have contributed to the Company's development and growth.

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

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