



SPARC/Sec/SE/2023-24/037

August 07, 2023

**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.

*Scrip Symbol: SPARC;*

*Scrip Code: 532872*

Dear Sir/ Madam,

**Sub: Submission of Chairman's Speech delivered at the 18<sup>th</sup> Annual General Meeting of the Company**

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The Chairman's speech delivered at the 18th Annual General Meeting of the Company held today i.e. on August 07, 2023 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 18th ANNUAL GENERAL MEETING OF SUN PHARMA ADVANCED RESEARCH COMPANY LIMITED HELD ON MONDAY, AUGUST 07, 2023**

Dear Shareholders,

On behalf of the board of directors, I once again welcome you all to this 18th AGM of our Company. I look forward to reviewing SPARC's opportunity and portfolio progress with you today. Let me begin by providing an update on the Industry landscape.

The year 2022 was the first full year during which the biopharmaceutical industry showed signs of entering a phase of operational stability in the post-pandemic era. The outlook for global spending on medicines has become clearer as the uncertainties during COVID give way to more predictable challenges.

Even though the global pharmaceutical industry was operating against the backdrop of a possible global recession, the global therapeutics' market is expected to grow at a CAGR of 3-6% through 2027, reaching about \$1.9Tn in total market size. Companies are fast adapting to newer operating models and reorienting their portfolio strategy to sustain growth by investing in acquisitions, divesting non-core assets, expanding R&D spending, and embracing new technologies.

The industry's R&D pipeline continues to grow, with 6,147 programs in active development ranging from Phase 1 through regulatory submission. This is a 49% rise since 2017 and a 2% increase in the previous two years

The global innovative pharmaceutical market remains an attractive opportunity, remaining resilient by responding to rapidly changing drivers of productivity. The Indian pharmaceutical sector is also attempting to transition from a typical generic powerhouse to a prospective IP acquirer and novel drug developer. A key strategic opportunity for India is to position itself as a global innovation hub, eventually making the Country, the preferred destination for R&D and manufacturing outsourcing.

SPARC has made a deliberate and measured response to the shifting external environment that is driving the biopharmaceutical industry's growth trajectory. SPARC has concentrated its emphasis on specific therapeutic categories, namely, cancer and neurodegeneration, which together account for the bulk of pipeline assets and are projected to drive the industry's value growth in the next years.

SPARC continues to grow its skills and adopt new technologies and treatment modalities to produce breakthrough medications in accordance with global trends. Biologics and the ability to generate modular immune-fusions and ADCs have been a prominent area of SPARC's attention in recent years. The technology has found some early success in



preclinical animal models during the assessment of anti-MUC-1 ADC (SBO-154). These newer platforms enable SPARC to expand its operational field beyond small molecules.

The Company also worked with external partners to deploy technology in the drug development process, not just to speed up the process but also to discover appropriate candidates for development.

SPARC will continue to cautiously invest in critical competency areas aligned with the evolving composition of portfolio under development.

Let me now talk about the progress made on SPARC's late stage or clinical programs during FY23.

SPARC was successful in securing NDA approval from USFDA for Sezaby, the only approved formulation of phenobarbital injection for the treatment of neonatal seizures. During the year, SPARC out-licensed US commercialization rights of Sezaby to Sun Pharmaceutical Industries Inc. (Sun). Under the terms of the license agreement, Sun paid SPARC an upfront payment of \$10 Mn. and SPARC will also be eligible to receive payments contingent upon the achievement of regulatory and sales milestones, as well as tiered royalties on sales. Sun initiated the commercialization of Sezaby in the US since January 2023.

SPARC in collaboration with Visiox completed the US NDA submission of PDP-716 in November last year. USFDA issued a Complete Response Letter for the NDA filed for PDP-716 due to inspection findings at a third-party API manufacturing facility. The FDA did not raise any issues with the PDP-176 clinical efficacy or safety and no additional clinical data or trials have been requested. SPARC is committed to work closely with Visiox, the FDA and the third-party manufacturer to resubmit the NDA as quickly as possible. Visiox is evaluating the strategy for the US NDA submission of SDN-037.

The NCE assets under clinical development also made good progress during the year.

The Part B of the SCO-088 study in CML patients was completed. SPARC plans to begin a comparator trial during FY24 to support registration of SCO-088 in the US.

The phase 2 proof-of-concept PROSEEK study of SCC-138 made significant progress in the recruitment of patients. Over 90% of the patients were randomized on the study. SPARC aims to complete the patient recruitment in coming quarters and the top line readout from this study is expected during FY24. The investigator-initiated study in patients with Lewy Body Dementia is also recruiting patients at Georgetown University, Washington D.C.



Vibozilimod, S1PR1 receptor agonist that was previously 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.

Bexirestrant a novel, orally bioavailable, SERD was being developed for the treatment of Hormone Receptor positive, Human Epidermal Growth Factor Receptor 2 negative, metastatic breast cancer. During FY23, SPARC completed a Single Ascending Dose study and a Multiple Ascending Dose study in metastatic breast cancer patients. The Company paused the development of bexirestrant due to changing clinical landscape.

With regards to the cash status, during the year, the warrants issued in 2021 were fully converted and SPARC received ~INR 703 Cr (\$86 Mn). The available cash from conversion of warrants will be sufficient to cover the cost of ongoing clinical studies. The Company also has a line of credit of INR 425 crores (~\$52 Mn) to meet any interim funding requirements.

Let me now provide some direction regarding SPARC's outlook in coming years. The objective for SPARC in the coming year will be to continue to execute well to ensure that the next milestones for the programs under development are achieved as per plan. The other key short-term priority for SPARC is to work with partners to ensure that the supply of approved products is restored. Additionally, SPARC will work with Visiox Pharma for resubmission of NDA of PDP-716.

SPARC is aiming to initiate first-in-human Phase 1 studies for SCD-153 in FY24 and for SBO-154 during FY25. Our collaboration model with academia is expected to add new preclinical programs to SPARC's pipeline.

In the medium term, SPARC will continue to build new competencies that are aligned with the broader portfolio strategy. SPARC is well positioned to leverage the global opportunity and has the potential to be a big catalyst success story for the emerging Indian innovation industry.

I thank you for your commitment and trust in the organization, and I look forward to your continued support as we work to achieve our aim of establishing a company that specializes in providing revolutionary treatment options to patients worldwide.

I want to thank my Board colleagues for their unwavering counsel and support throughout the years. In addition, I'd want to express my appreciation to the SPARC team members who have contributed to the Company's development and progress.

On behalf of the Board, I thank you all for your patient listening.



Disclaimer: Statements in this "Document" 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. The Company undertakes no obligation to update or revise forward looking statements to reflect developments or circumstances that arise or to reflect the occurrence of unanticipated developments/circumstances after the date hereof.

**Sun Pharma Advanced Research Company Ltd.**

17/B, Mahal Industrial Estat, Off Mahakali Caves Road, Andheri (East), Mumbai 400 093, Maharashtra, India.  
Tel.: (91-22) 6645 5645 | Fax.: (91-22) 6645 5685 | CIN: L73100GJ2006PLC047837 | Website: [www.sparc.life](http://www.sparc.life)

**Registered office : Plot no. 5&6/1, Savli GIDC Estate, Manjusar 391775, District: Vadodara, Gujarat, India**