



January 18, 2023

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai – 400 001
Scrip code: 532531

The National Stock Exchange of India Limited
Exchange Plaza, Bandra-Kurla Complex
Bandra (E) Mumbai - 400 051
Scrip code: STAR

Dear Madam/ Sir,

Sub: Press Release

Please find attached Press Release issued by the Company titled:

“Stelis Biopharma’s flagship facility receives EIR from the USFDA on the successful closure of its inspection specific to Drug-Device Combination Products”

Thanks & Regards,
For **Strides Pharma Science Limited**,

Manjula Ramamurthy
Company Secretary

Encl. As above

Strides Pharma Science Limited

CIN: L24230MH1990PLC057062

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Stelis Biopharma's flagship facility receives EIR from the USFDA on the successful closure of its inspection specific to Drug-Device Combination Products

- ⇒ *Establishment Inspection Report (EIR) from USFDA received for the drug-device combination to be commercialized from the Company's flagship facility in Bengaluru, India.*
- ⇒ *The flagship facility, in September 2022, received EIR from USFDA based on on-site Pre-Approval Inspection (PAI), leading to the first US product approval for one of its key customers in December 2022.*
- ⇒ *Stelis continues to onboard new partners for its integrated capabilities offered through three manufacturing facilities.*

Bengaluru, India, January 18, 2023: Stelis Biopharma Limited (Stelis or Company), an emerging biopharmaceutical Contract Development and Manufacturing Organization (CDMO) and the biologics arm of Strides Pharma Science Limited (Strides, BSE: 532531 NSE: STAR), is pleased to announce that it has received Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (USFDA or FDA or Agency) specific to Drug-Device Combination Products to be commercialized at Stelis' flagship facility in Bengaluru, India.

This Abbreviated Quality System Inspection Technique (QSIT) drug preapproval on-site inspection was specifically conducted by the USFDA for the drug-device combination products that are to be manufactured/ commercialized at the site for the partner products by Stelis. Previously, the USFDA issued an EIR to Stelis in September 2022 based on on-site Pre-Approval Inspection (PAI) and, consequently, the first product approval for one of its key customers in December 2022.

Arun Kumar, the Founder, commented on the development, saying, " *We are delighted to have closed our successful inspection within few months by the USFDA covering a larger scope to include Drug-Device combination products where Stelis is emerging as a global leader with significant capacities established and customers onboarded. Several of our customers' key fillings will now progress towards nearer-term approvals leading to an uptick in our CDMO revenues. We remain excited about the strategic progress that the Company has made so far and are confident of delivering better business outcomes.*"

As a fully integrated biologics CDMO, Stelis can offer a complete spectrum of services from its facilities. Besides the DP capabilities in cartridges, pen devices, auto-injectors, pre-filled syringes, liquid, and lyophilized vials, the facility has proven technical expertise and capabilities to manufacture DS across microbial, mammalian, and various other technology platforms with world-class cGMP, regulatory, and quality systems. The Company's integrated capabilities offer significant operational flexibility, greater efficiency, and varied scope within the same premises.

Stelis continues to build its clientele with global partnerships and onboarding of new programs on the drug substance and drug product side. It remains a strong biologics CDMO player given its comprehensive capabilities, high-quality systems, large drug substance (DS) scale across modalities, and significant fill-finish capacity.

About Stelis

Stelis Biopharma Limited (Stelis) is an emerging global biopharmaceutical CDMO with a complete, integrated, end-to-end offering. It is equipped with world-class Process Development (PD) and manufacturing infrastructure for both drug substances (mammalian and microbial-based therapeutic proteins and other emerging modalities) and drug products (lyophilized vials, liquid vials, pre-filled

syringes, cartridges, and devices). Stelis offers a complete spectrum of services, from cell line tech transfer to clinical and commercial manufacturing, with in-house capability to convert drug substances to stable formulations and fill and finish in all formats. Stelis has three state-of-the-art facilities, with ~85,000 square meters of PD and manufacturing space and over 800 highly talented professionals. Its facilities are highly automated to increase accuracy, efficiency, and speed at every process stage. Additional details are available at www.stelis.com.

About Strides

Strides, a global pharmaceutical company headquartered in Bengaluru, India, is listed on the BSE (532531) and National Stock Exchange of India Limited (STAR). The Company mainly operates in the regulated markets and has an "in Africa for Africa" strategy and an institutional business to service donor-funded markets. The Company's global manufacturing sites are located in India (Chennai, Puducherry, and two locations in Bengaluru), Singapore, Italy (Milan), Kenya (Nairobi), and the United States (New York). The Company focuses on "difficult to manufacture" products sold in over 100 countries. Additional information is available at the Company's website at www.strides.com.

For queries related to Stelis, feel free to write to ankit@stelis.com

For questions about Strides, please reach out to Sandeep.baid@strides.com