



September 1, 2022

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 USFDA nod for Drug Product Capabilities”

Thanks & Regards,

For **Strides Pharma Science Limited**,

Manjula Ramamurthy
Company Secretary

Encl. As above

Strides Pharma Science Limited

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Stelis Biopharma's flagship facility receives USFDA nod for Drug Product Capabilities

- ⇒ Receives *Establishment Inspection Report (EIR) from USFDA for Drug Products (DP) at Company's flagship facility in Bengaluru, India.*
- ⇒ *EIR to enable commercial DP supplies for the partner products in the next two quarters.*
- ⇒ *Stelis' flagship facility offers unique DP capabilities across all injectable formats, including cartridges, pen devices, auto-injectors, pre-filled syringes, liquid, and lyophilized vials.*
- ⇒ *The facility also houses Drug Substance (DS) capabilities across the microbial and mammalian platforms on the same premises.*

Bengaluru, India, September 1, 2022: 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), today announced that it received the Establishment Inspection Report (EIR) from U.S. Food and Drug Administration (USFDA or agency) for the Drug Products (DP) facility inspection that was completed at its flagship manufacturing site (Unit 2) at Bengaluru, India.

This outcome for the DP facility comes after the USFDA on-site Pre-Approval Inspection (PAI) at Stelis flagship manufacturing facility for several product submissions by the partners to the agency. The Unit 2 facility has high-end automated DP lines integrated with isolators to convert drug substances (DS) into stable formulations and fill finish within the same facility in all injectable formats, including cartridges, pen devices, auto-injectors, pre-filled syringes, liquid, and lyophilized vials.

Arun Kumar, the Founder, commented on the development, saying, *"I am very pleased with the USFDA nod for DP capabilities at our flagship facility, a second major win after receiving the EU-GMP approval in June 2022. While these two outcomes validate our GMP systems and Global Quality fabric, it fast-tracks our ability to close out on the impending manufacturing services agreements for the pre-commercial revenues. The EIR from USFDA now also paves the way for the commercial services revenue from the site in the next two quarters after our partners receive respective product approvals. We have had an exciting year so far, and we continue to deliver even better financial outcomes as we accelerate and build on the opportunities in the Global CDMO landscape."*

As a fully integrated biologics CDMO, Stelis can offer a complete spectrum of services from its Unit 2 facility. Besides the DP capabilities, 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. While the microbial DS is already commissioned, the mammalian DS capabilities designed on industry-leading Single Use Bioreactor (SUB) systems will be available to partners later this month (September 2022). The integrated capabilities at Unit 2 offer significant operational flexibility, greater efficiency, and varied scope within the same premise. Earlier in June 2022, the facility received European Union Good Manufacturing Practice (EU-GMP) approval.

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, and a large commercial scale with over 48,000L of drug substance across modalities and over 400 million units of 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