

**06<sup>th</sup> January, 2025**

**BSE Limited**

Department of Corporate Relationship  
1<sup>st</sup> Floor, New Trade Ring, Rotunda Building  
Phiroze Jeejeebhoy Towers  
Dalal Street, Mumbai- 400001  
*Scrip Code: 524742*

**National Stock Exchange of India Ltd.,**

Department of Corporate Services  
Exchange Plaza, 5<sup>th</sup> Floor,  
C-1, Block G, Bandra Kurla Complex,  
Bandra (E), Mumbai – 400 051  
*Scrip Code: CAPLIPOINT.*

Dear Sir/Madam,

**Sub: Press Release – Receipt of Establishment Inspection Report**

Attaching herewith a Press Release regarding receipt of Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (FDA) with Zero 483 observations for the unannounced inspection conducted at Caplin Steriles' injectable and ophthalmic manufacturing facility located at Gummidipoondi between August 05<sup>th</sup> and 09<sup>th</sup>, 2024.

Kindly take the same on your records.

Sincerely Yours

**For Caplin Point Laboratories Limited**

**Venkatram G**  
**General Counsel & Company Secretary**  
**Membership No A23989**

## **CAPLIN POINT RECEIVES ESTABLISHMENT INSPECTION REPORT (EIR) FROM FDA WITH ZERO 483 OBSERVATIONS**

**Chennai, January 06, 2025:** Caplin Point Laboratories Ltd. (“Caplin Point” or the “Company”) (BSE: 524742 | NSE: CAPLIPOINT), announced today that it has received the Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (FDA) for the recent inspection conducted at Caplin Steriles’ injectable and ophthalmic manufacturing facility located at Gummidipoondi. The unannounced USFDA inspection was conducted between August 5<sup>th</sup> and 9<sup>th</sup>, 2024 and was concluded with Zero 483 observations, reflecting the company’s commitment to maintaining the highest standards of quality and compliance.

This press release follows the intimation made to the Stock Exchanges on August 9<sup>th</sup>, 2024 immediately upon completion of the inspection about its outcome. The inspection, which is a routine part of the FDA’s regulatory oversight, evaluates compliance with Good Manufacturing Practices and other regulatory requirements.

### **About Caplin Steriles Limited**

Caplin Steriles Limited, a Subsidiary of Caplin Point Laboratories Limited, is a fast growing sterile product manufacturing company that is approved by several regulatory agencies such as US FDA, EU-GMP, ANVISA and INVIMA. Caplin Steriles Limited, has developed and filed 45 ANDAs in USA on its own and with partners, with 31 approvals so far. The Company is also working on a portfolio of 40+ simple and complex Injectable and Ophthalmic products, that it intends to file over the next 4 years. The company also has multiple products filed with several approvals in non-US markets such as Mexico, Australia, Canada, South Africa etc

### **About Caplin Point Laboratories Limited:**

Caplin Point Laboratories Limited is a fast-growing pharmaceutical company with a unique business model catering predominantly to emerging markets of Latin America and Africa. The Company has state of the art manufacturing facilities that cater to a complete range of finished dosage forms. Caplin Point is one of the few companies to show consistent high-quality growth in cashflows, Profitability and Revenues over the last 15 years.

Caplin Point has appeared on **Forbes “Asia’s 200 Best Under a Billion”** list for an unprecedented 7<sup>th</sup> time in the last 10 years, and was awarded “The Emerging Company of 2018” and “Business Excellence Award for 2019” by Economic Times.

**CAUTIONARY STATEMENT:**

*This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Caplin Point Laboratories Ltd and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the related industries, increasing competition in and the conditions of the related industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Caplin Point Laboratories Ltd, nor our directors, or any of our subsidiaries/associates assume any obligation to update any forward-looking statement contained in this release.*

**For details, please contact:**

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| <b>Investor Relations at Caplin</b><br>Mr G Venkatram (General Counsel & Company Secretary)<br>Tel: +91 44 24968000<br><a href="mailto:investor@caplinpoint.net">investor@caplinpoint.net</a><br><br><b>Churchgate Partners</b><br>Anvita Raghuram / Rajiv Pandya<br>+91 22 6169 5988<br><a href="mailto:caplinpoint@churchgatepartners.com">caplinpoint@churchgatepartners.com</a> | <b>Registered Office</b><br>Caplin Point Laboratories Limited<br>3 <sup>rd</sup> Floor, Ashvich Tower, No.<br>3, Developed Plots Industrial<br>Estate, Perungudi,<br>Chennai – 600 096, Tamil<br>Nadu, INDIA.<br>Tel: +91 44 2496 8000<br>CIN: L24231TN1990PLC019053<br>ISIN: INE475E01026<br>NSE Code: CAPLIPOINT<br>BSE CODE: 524742<br>Website: <a href="http://www.caplinpoint.net">www.caplinpoint.net</a> |
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