

**April 23, 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 USFDA Approval**

Attaching herewith a Press Release regarding receipt of final approval by our Subsidiary Caplin Steriles Limited from the United States Food and Drug Administration (USFDA) for the Abbreviated New Drug Application (ANDA) Phytonadione Injectable Emulsion USP, 10 mg/mL, Single Dose Vial, a generic therapeutic equivalent version of the Reference Listed Drug (RLD) VITAMIN K1 Injection, from Hospira Inc. Request you to take the same on record.

Thanking You,

Sincerely Yours

**For Caplin Point Laboratories Limited**

**Venkatram G**

**General Counsel & Company Secretary**

**Membership No. A23989**

**Encl: A/a**

## **CAPLIN STERILES GETS USFDA APPROVAL FOR PHYTONADIONE INJECTABLE EMULSION**

**Chennai, April 23, 2025:** Caplin Steriles Limited (Caplin), a Subsidiary Company of Caplin Point Laboratories Limited (BSE: CAPPL (524742), NSE: CAPLIPOINT), has been granted final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Phytonadione Injectable Emulsion USP, 10 mg/mL, Single Dose Vial, a generic therapeutic equivalent version of the Reference Listed Drug (RLD) VITAMIN K1 Injection, from Hospira Inc.

Phytonadione Injectable Emulsion possesses the same type and degree of activity as does naturally-occurring vitamin K and is indicated for coagulation disorders which are due to faulty formation of factors II, VII, IX and X when caused by vitamin K deficiency or interference with vitamin K activity. According to IQVIA™ (IMS Health), Phytonadione Injectable Emulsion had US sales of approximately \$18.5 million for the 12-month period ending February 2025.

### **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 47 ANDAs in USA on its own and with partners, with 35 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 contains certain forward-looking statements. Any forward-looking statement applies only on the date of this press release. By their nature, forward-looking statements are subject to a number of known and unknown risks and uncertainties that may or may not occur in the future and as a result of which the actual results and performance may differ substantially from the expected future results or performance expressed or implied in*

*the forward-looking statements. No warranties or representations are made as to the accuracy, achievement or reasonableness of such statements, estimates or projections, and Caplin Point has no obligation to update any such information or to correct any inaccuracies herein or omission here from which may become apparent.*

**For details, please contact:**

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