

#### **Caplin Point Laboratories Limited**

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E-mail: info@caplinpoint.net / Website: www.caplinpoint.net

CIN: L24231TN1990PLC019053

January 8, 2024

#### **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,

## <u>Sub: Press Release - Disclosure under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015</u>

Attaching herewith a Press Release regarding grant of final approval from the United States Food and Drug Administration (USFDA) for the Abbreviated New Drug Application (ANDA) Ofloxacin Otic Solution 0.3%, to our Subsidiary Caplin Steriles Limited. 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 OFLOXACIN OTIC SOLUTION

Chennai, January 08, 2024: 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) Ofloxacin Otic Solution 0.3%, a generic therapeutic equivalent version of (RLD), FLOXIN Otic Solution of Daiichi Pharmaceuticals Inc.

Ofloxacin Otic Solution 0.3% is used as anti-infective (antibacterial) for otic (ear) use. According to IQVIA<sup>TM</sup> (IMS Health), Ofloxacin Otic Solution 0.3% had US sales of approximately \$36 million for the 12-month period ending June 2023.

#### **About Caplin Steriles Limited**

Caplin Steriles Limited, a Subsidiary of Caplin Point Laboratories Limited, is a niche sterile product manufacturing company that is approved by several regulatory agencies such as US FDA, EU-GMP and ANVISA. Caplin Steriles Limited, has developed and filed 37 ANDAs in USA on its own and with partners, with 25 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.

#### **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 6<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

#### **Press Release**



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:

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**NSE Code: CAPLIPOINT** 

BSE CODE: 524742

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