

December 16, 2024

BSE Limited

Department of Corporate Relationship
1st 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, 5th Floor,
C-1, Block G, Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
Scrip Code: CAPLIPOINT.

Dear Sir/Madam,

Sub: Press Release – Grant of USFDA Approval

Attaching herewith a Press Release regarding grant of final approval by the United States Food and Drug Administration (USFDA) for the Abbreviated New Drug Application (ANDA) Difluprednate Ophthalmic Emulsion, 0.05% (Eye drops), a generic therapeutic equivalent version of the Reference Listed Drug (RLD) DUREZOL, from Sandoz Inc, 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 DIFLUPREDNATE OPHTHALMIC EMULSION

Chennai, Dec 16, 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) Difluprednate Ophthalmic Emulsion, 0.05% (Eye drops), a generic therapeutic equivalent version of the Reference Listed Drug (RLD) DUREZOL, from Sandoz Inc.

“We’re pleased to receive a first cycle approval for this complex emulsion product. Few more emulsion and suspension products have been filed or in the pipeline, which should augment Caplin Steriles’ portfolio in the US and emerging markets”, commented Chairman C.C.Paarthipan.

Difluprednate Ophthalmic Emulsion, 0.05% (Eye drops) is a topical corticosteroid that is indicated in the treatment of inflammation and pain associated with ocular surgery, and in the treatment of endogenous anterior uveitis. According to IQVIA™ (IMS Health), Difluprednate Ophthalmic Emulsion, 0.5% had US sales of approximately \$21 million for the 12-month period ending October 2024.

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 7th 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:

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