

12.06.2020

BSE Limited
Department of Corporate Relationship
1st Floor, New Trade Ring, Rotunda Building
Phiroze Jeejeebhoy Towers
Dalal Street, Mumbai- 400001
Scrip Code: 524742

By BSE Listing

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.

By NEAPS

Dear Sirs,

SUB: PRESS RELEASE – DISCLOSURE UNDER REGULATION 30 OF SEBI (LISTING OBLIGATIONS AND DISCLOSURE REQUIREMENTS) REGULATIONS, 2015.

Please find the enclosed copy of Press Release being published today.

Thanking You,

Yours Faithfully,
For Caplin Point Laboratories Limited


Company Secretary
Enclosure: As above



PRESS RELEASE

CAPLIN STERILES GETS USFDA APPROVAL FOR PHENYLEPHRINE HYDROCHLORIDE INJECTION USP

Chennai, June 12, 2020: Caplin Point Laboratories Limited (BSE: CAPPL (524742), NSE: CAPLIPOINT) Caplin Steriles Limited, a Subsidiary Company of Caplin Point Laboratories Limited, has been granted final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Phenylephrine Hydrochloride injection USP, 10 mg/mL Single-Dose Vial, 50 mg/5 mL (10mg/mL) Pharmacy Bulk Package, and 100 mg/10 mL (10 mg/mL) Pharmacy Bulk Package, a generic therapeutic equivalent version of (RLD), VAZCULEP Injection, of Avadel Legacy Pharmaceuticals LLC. According to IQVIA™ (IMS Health), Phenylephrine Hydrochloride injection USP had US sales data of approximately \$45 million for the 12-month period ending Mar 2020. Caplin Steriles Limited, has developed and filed 17 ANDAs on its own and with partners, with 9 approvals so far.

Phenylephrine Hydrochloride injection is indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

Mr.C.C.Paarthipan, Chairman of Caplin Point Laboratories Limited commented “We’re confident of growing well in the US, in terms of filings and revenues. We’re expecting some more ANDA approvals in the current FY which should augment our growth trajectory in the US. A few products in our pipeline are under shortage or for emergency usage, and we hope to receive priority review for those.”

The Company is also working on a portfolio of 35 simple and complex Injectable and Ophthalmic products, to be filed 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. Caplin Point Laboratories Limited has state of the art manufacturing facilities that cater to a complete range of finished dosage forms. The Company’s Subsidiary Caplin Steriles Limited caters to the Regulated Markets for Injectable and Ophthalmic products.

Caplin Point Laboratories Limited has been selected on Forbes Asia’s “200 Best Under a Billion” list for three consecutive years (2014, 2015 & 2016), and was recently 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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