



April 02, 2020

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai – 400 001

The National Stock Exchange of India Limited
Exchange Plaza, Bandra-Kurla Complex
Bandra (E) Mumbai - 400 051

Scrip code: 532531

Scrip code: STAR

Dear Madam/ Sir,

Subject: Press Release

Please find attached Press Release issued by the Company titled:

**“Strides provides updates as USFDA requests all manufacturers to
withdraw Ranitidine products from the US Market”**

Thanking you,

Yours faithfully,
For **Strides Pharma Science Limited**

A handwritten signature in blue ink that reads 'Manjula R.'.

Manjula Ramamurthy
Company Secretary



Encl. As above

Strides Pharma Science Limited
(Formerly Strides Shasun Limited)
CIN: L24230MH1990PLC057062

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Strides provides updates as USFDA requests all manufacturers to withdraw Ranitidine products from the US Market

Bangalore, April 02, 2020 - Strides Pharma Science Limited (Strides or the Company) today informed that US Food and Drug Administration (USFDA or the Agency) on April 1, 2020, has published a statement¹ and issued letters to all manufacturers of Ranitidine across dosage forms requesting withdrawal of all prescription (Rx) and over-the-counter (OTC) ranitidine drugs from the market immediately. This latest step is based on their ongoing investigation of the N-Nitrosodimethylamine (NDMA) impurity in ranitidine medications. The USFDA's statement, though, points out, *"we didn't observe unacceptable levels of NDMA in many of the samples that we tested"*, but results indicate that NDMA levels may increase over time or when exposed to high temperatures.

Background

Ranitidine is an Rx and OTC drug used as an H₂ (histamine-2) receptor blocker, which decreases the amount of acid created by the stomach. **Strides has approval for Rx and OTC Ranitidine tablets for the US market, and it currently commercializes only the Rx product in the US.**

In September 2019, following a citizen petition filed in the US by an online pharmacy, the USFDA learned that some ranitidine medications contain NDMA at low levels and FDA issued a statement alerting patients of NDMA found in samples of Ranitidine. The agency, then, did not announce any intention to recall the product and requested all Ranitidine manufacturers to conduct laboratory testing to examine levels of NDMA in Ranitidine, recommending the use of an LC-HRMS testing protocol. Consequently, Strides submitted the requested data to the USFDA and until test results were available, **Strides voluntarily suspended the sales of ranitidine Rx tablets in September 2019.**

In November 2019, USFDA announced the Laboratory testing and analysis² of Ranitidine and advised the acceptable NDMA limits. In the summary of test results provided by USFDA, **Strides' Ranitidine Tablets were found to be within the acceptable limits for NDMA of 96 nanograms (ng) per day or 0.32 parts per million (ppm)** which was also considered reasonably safe by most of the regulators for human ingestion based on lifetime exposure. **Subsequently, Strides announced the relaunch of Ranitidine tablets in the US market. The Company also tested the NDMA content for all its commercial batches and its product met and continues to meet the FDA recommended NDMA specification limit of NMT 0.32 ppm within the labelled expiration date.**

Near Term View on Ranitidine

Based on the letter issued to all manufacturers of Ranitidine, the USFDA has requested to withdraw all Rx and OTC Ranitidine drugs from the market immediately. As a result, Strides has ceased further distribution of the product. Besides, Strides will work with the agency regarding the request to withdraw the product from the market immediately.

Strides also intends to work on generating the required additional data which is requested by the agency to consider allowing Ranitidine product back on the US market. The Company anticipates this activity would

¹ <https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market>

² <https://www.fda.gov/news-events/press-announcements/statement-new-testing-results-including-low-levels-impurities-ranitidine-drugs>

take a significant period and shall continue to provide updates. Ranitidine is one of the top 5 products for Strides in the US market, and at this point of time, the Company is estimating the full impact on the revenues due to the USFDA requested withdrawal of Ranitidine

US Business Outlook

In FY20, Strides has reported a strong performance in the US with 9M FY20 revenues of ~US\$ 180 million against the outlook of US\$220-US\$240 million for FY20 (US\$150 million in FY19). The growth during the year was driven by market share gains for a base portfolio, including products relaunched through our frontend and introduction of new products.

Despite the discontinuation of Ranitidine, Strides remains confident of its US Business and continues to maintain a positive growth outlook for FY21. As of date, the Company has 123 cumulative ANDA filings with USFDA of which 85 ANDAs have been approved already, and only 35+ products are commercialized in the US. The Company also has a pipeline of 38 products pending approval with the USFDA. The future growth in the US will primarily be driven through improved market shares and healthy order book for our commercialized products, and a robust pipeline of new launches in the market.

About Strides

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is a global pharmaceutical company headquartered in Bangalore, India. The Company mainly operates in the regulated markets and has an “in Africa for Africa” strategy along with an institutional business to service donor-funded markets. The Company’s global manufacturing sites are located in India- Bangalore (two locations), Pondicherry, and Chennai, Singapore, Italy- Milan, Kenya- Nairobi and United States-Florida. The Company focusses on “difficult to manufacture” products that are sold in over 100 countries. Additional information is available at the Company’s website at www.strides.com

For further information, please contact:

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