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**Ramesh Swaminathan, Executive Director, Global CFO, and Head Corporate Affairs, Lupin in an Industry Story**

## **Regulatory scrutiny and pricing pressure is reducing profitability.**

On June 3, global pharma player Lupin announced the launch of Darunavir tablets, to market a generic equivalent of Prezista tablets, a drug used to help control HIV infection, of Janssen Products, LP. Darunavir is estimated to have annual sales of \$308 million in the US, as per the company's release.

Lupin's subsidiary Novel Laboratories Inc, based in Somerset, New Jersey, recently received approval from the United States Food and Drug Administration (USFDA) for its abbreviated new drug application for a generic equivalent of Diastat AcuDialTM Rectal Delivery System of Bausch Health US, LLC.

Lupin is the sixth-largest player in the Indian pharmaceutical market, according to IQVIA. It posted a consolidated net profit of Rs 236 crore for the January-March quarter as against a net loss of Rs 518 crore incurred in the same period last year. Lupin's topline grew 12.1 percent year-on-year to Rs 4,330.3 crore in the fourth quarter.

The company's broad product portfolio in India includes both branded and generic drugs, with a focus on therapeutic areas such as respiratory, cardiovascular, diabetes, and CNS. However, US generics is the largest revenue generator for the company. Ramesh Swaminathan, executive director, global CFO and head of corporate affairs, Lupin speaks to *Forbes India* about the challenges the market is facing and how Lupin is heavily investing in R&D for complex generics, biosimilars, and specialty drugs.

### **Edited excerpts:**

#### **Q. Which are the largest revenue generating markets for Lupin?**

Lupin operates in several markets worldwide, focusing on the United States, India, and Europe. The US market continues to be the largest revenue generator for the company, accounting for approximately 36 percent of its total revenues in Q3 FY2023. Lupin has a strong presence in the US market, with a portfolio of over 200 products, including several complex generics and niche products. The focus in the US is,

however, pivoting to more complex therapies like inhalers, complex injectables and biosimilars.

In addition to the US market, Europe is another key market for Lupin, accounting for approximately 9 percent of its total revenues in FY2021. The company has a presence in several European countries, including Germany, France, and the UK. It has a diverse product portfolio in areas such as biosimilars, respiratory, oncology, and anti-infectives. The global therapy platforms straddling injectables, inhalation and biosimilars are leveraged across several markets, including Europe.

In terms of emerging growth markets, Lupin is focusing on expanding its presence in regions such as Latin America, APAC, Africa, and the Middle East. These markets offer significant growth potential, driven by factors such as rising health care access, increasing demand for affordable drugs, and favourable regulatory environments.

**Q. What are the challenges the industry is facing?**

The pharmaceutical industry has been facing an array of challenges in recent times, such as increased regulatory scrutiny and pricing pressure, leading to reduced profitability. In addition, rising competition from the generic drug industry is putting additional pressure on drug pricing, adding to the complexity. Channel consolidation in the US, has led to sharp headwinds for this industry, causing the market to erode by about 10 percent, over five years. Similarly, a patriotic fervour in several geographies is causing the industry to refresh their strategic priorities.

To stay ahead of the curve, the industry is taking on the challenge of digital transformation and new technology adoption. It's a critical move towards improving efficiency, reducing costs, and meeting new regulatory requirements. But with high costs and a significant cultural shift required, it's easier said than done. Further, inflation in recent times has caused imbalances in the cost structure, which the industry is finding difficult to pass on to channel partners.

**Q. Pricing pressure is a challenge, particularly in the US. How is Lupin dealing with this?**

Lupin is taking a multi-pronged approach to deal with pricing pressure in the US market, including improving operational efficiency, focusing on complex generics and specialty products, and diversifying geographically.

One approach is to improve operational efficiency and reduce costs throughout the value chain. This includes optimising supply chain management, streamlining manufacturing processes, and reducing administrative expenses. By doing so, we are reducing the overall cost structure. We have also rationalised our workforce across factories and R&D centres to align ourselves to market realities.

Lupin is also focusing on developing complex generic drugs that require specialised expertise. These drugs typically face less competition, allowing Lupin to maintain higher prices and margins. Additionally, Lupin has been expanding its pipeline of specialty products, including biosimilars and inhalation products, which have higher barriers to entry and lower competition.

**Q. How are you dealing with the constantly evolving regulations of the US FDA?**

The pharmaceutical industry is highly regulated, and the regulatory environment is constantly evolving, particularly in the US. To stay ahead of the curve, Lupin has a dedicated regulatory affairs team that closely monitors FDA regulations and collaborates with R&D and manufacturing teams to ensure compliance with standards. In addition, Lupin has invested significantly in quality systems and processes to meet current Good Manufacturing Practices (cGMP) and other regulatory requirements.

The company's commitment to compliance and quality, coupled with its focus on innovation and customer needs, has positioned it well to succeed in the highly regulated pharmaceutical industry. Given Covid concerns, FDA had gone slow on their inspection schedules. But this is a thing of the past, and with recent inspections we have got clearance for a few of our facilities and expect a similar response for the others in the days ahead.

**Q. How is the branded generics segment doing for the company, particularly in India and emerging markets?**

Lupin's branded generics segment is performing well, particularly in India and emerging markets like South Africa, the Philippines, and Brazil. In India, the company's focussed approach towards expanding its branded business has helped establish its leadership position in key therapeutic areas like cardiovascular, respiratory, and diabetes.

Similarly, in South Africa, Lupin has built a strong portfolio of branded products, which enabled rapid growth in the region. In the Philippines, Lupin's subsidiary MultiCare is the fifth-largest player in branded generics, with a strong presence in the rheumatology, gastrointestinal, and diabetes segments. Lupin's subsidiary MedQuímica in Brazil ranks as the fifth largest generic pharma company in terms of volume. In Mexico, the subsidiary Laboratories Grin is the second-largest ophthalmic company by units and an important player in the treatment of glaucoma and dry eye.

Lupin's deep understanding of local markets, combined with a customer-centric approach, has enabled the company to leverage its expertise in branded generics to drive growth in emerging markets. With the growing demand for affordable health care and the increasing prevalence of chronic diseases, these markets offer significant growth potential. Lupin's commitment to quality and innovation, along with its strong distribution network, positions it well to achieve sustained growth and success in the branded generics segment.

**Q. Are there new segments that Lupin is expanding into?**

Lupin has been diversifying its portfolio beyond generics and has been investing in R&D to bring innovative products to the market. The company has been focusing on developing and launching complex generics, biosimilars, and specialty drugs, which have higher barriers to entry and offer higher margins. Additionally, Lupin is exploring opportunities in digital health and other innovative technologies to drive growth and enhance its overall value proposition. Lupin also has a robust API business in Cephals and is the world leader in anti-TB drugs.