

India

Neutral (no change)**Highlighted Companies****Lupin Ltd****ADD, TP Rs2329, Rs2172 close**

Best visibility on growth, product launches & profitability.

Zydus Lifesciences**ADD, TP Rs1330, Rs1054 close**

A play on the US generics market.

Summary Valuation Metrics

| | Mar24-A | Mar25-F | Mar26-F |
|-----------------------|---------|---------|---------|
| P/E (x) | | | |
| Lupin Ltd | 64.82 | 33.27 | 27.62 |
| Zydus Lifesciences | 27.82 | 22.87 | 20.71 |
| P/BV (x) | | | |
| Lupin Ltd | 6.91 | 5.84 | 4.92 |
| Zydus Lifesciences | 5.38 | 4.49 | 3.79 |
| Dividend Yield | | | |
| Lupin Ltd | 0.35% | 0.39% | 0.39% |
| Zydus Lifesciences | 0.66% | 0.66% | 0.66% |

Pharmaceuticals

Mirabegron setback for Zydus and Lupin

- The US court of appeals has overturned the US district court's ruling favouring generics. The case is remanded to the district court, representing a setback.
- Potential outcome varies from allowing to sell at-risk to the damages limited to profit. We do not foresee any immediate risks to our earnings estimates.
- Cut our target P/E for Zydus to 26x, with a lower TP of Rs1,330. Maintain earnings estimates & TP for Lupin. Retain our ADD rating on Zydus and Lupin.

Latest update on Mirabegron litigation

The US court of appeals for the federal circuit has overturned the US district court's ruling favouring generics in the invalidation of the '780 patent relating to gMyrbetriq/Mirabegron. The case has been remanded to the district court for further adjudication, representing a setback for Zydus Lifesciences (Zydus) and Lupin, both of whom launched the product following an earlier favourable ruling. With the matter remaining sub-judice, it will proceed through the district court and potentially into further appeals. Astellas Pharma's request to assign the case to a different judge has been denied, which means it will return to the same judge who previously ruled in favour of generics.

Potential outcomes

We foresee several potential outcomes:

- The district court's ruling and any subsequent appeals could take 6-12 months or longer, allowing Zydus and Lupin to continue selling the product at-risk. This situation may deter subsequent generic entrants such as Alkem Laboratories and Aurobindo Pharma from launching the product after the 180-day marketing exclusivity period ends in Nov 2024, pending the litigation outcome.
- If the generics case fails in both the district court and the US court of appeals for the federal circuit, they may be liable for damages, likely limited to profits earned from the at-risk launch, which followed an earlier favourable ruling. This process could extend over a longer timeframe.
- Should the innovator secure an injunction while awaiting the ruling, Zydus and Lupin may be prohibited from selling additional quantities. In anticipation of this possibility, we expect both these companies to increase their inventory level to mitigate immediate losses.

Financial impact

Despite the ongoing litigation, we do not foresee any immediate risks to our earnings estimates. We currently project revenue of US\$135m/US\$35m for Zydus, and US\$70m/US\$10m for Lupin in FY25F/26F, respectively, from Mirabegron. Given the litigation's nature and the absence of an immediate outcome, we believe the risk to our FY25F/26F earnings remains low.

Maintain ADD rating on Zydus and Lupin

We have cut our target multiple for Zydus to 26x (from 28x), reflecting increased competition in gAsacol HD and this development in Mirabegron, revising our target price for Zydus to Rs1,330 (from Rs1,434 earlier). We maintain our earnings estimates and target price for Lupin. We also maintain our ADD rating on Zydus and Lupin.

Research Analyst(s)

**Praful BOHRA**

T (91) 22 4161 1552

E praful.bohra@incredresearch.com

Yogesh SONI

T (91) 8850099267

E yogesh.soni@incredresearch.com

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Recommendation Framework

Stock Ratings

Definition:

- Add** The stock's total return is expected to exceed 10% over the next 12 months.
- Hold** The stock's total return is expected to be between 0% and positive 10% over the next 12 months.
- Reduce** The stock's total return is expected to fall below 0% or more over the next 12 months.

The total expected return of a stock is defined as the sum of the: (i) percentage difference between the target price and the current price and (ii) the forward net dividend yields of the stock. Stock price targets have an investment horizon of 12 months.

Sector Ratings

Definition:

- Overweight** An Overweight rating means stocks in the sector have, on a market cap-weighted basis, a positive absolute recommendation.
- Neutral** A Neutral rating means stocks in the sector have, on a market cap-weighted basis, a neutral absolute recommendation.
- Underweight** An Underweight rating means stocks in the sector have, on a market cap-weighted basis, a negative absolute recommendation.

Country Ratings

Definition:

- Overweight** An Overweight rating means investors should be positioned with an above-market weight in this country relative to benchmark.
- Neutral** A Neutral rating means investors should be positioned with a neutral weight in this country relative to benchmark.
- Underweight** An Underweight rating means investors should be positioned with a below-market weight in this country relative to benchmark.