Company Flash

26 February 2009 | 6 pages

Ranbaxy (RANB.BO)

Hold: Another Bolt from the FDA

- **More FDA trouble** — The USFDA has invoked its Application Integrity Policy (AIP) on Ranbaxy's plant in Paonta Sahib and suspended review of all filings that are based on clinical trial data from this plant. The incremental hit on estimates may be limited (Paonta was already subject to an import alert) but it belies any expectations of a quick resolution to the issue.
- **Getting worse** — The US FDA announced that it has evidence that Ranbaxy's Paonta plant falsified data and test results in approved and pending ANDAs. It has therefore stopped all substantive scientific review of any new or pending ANDAs that contain data generated by the Paonta facility while it investigates the matter further.
- **Impact** — We see three key incremental risks: a) this may affect products filed from its US facilities that were based on clinical data generated at Paonta; b) what does this do to Ranbaxy's image/market share in the US? Will key customers be worried that the issue could spread to other plants and look for alternate suppliers?; c) falsification of data and test results is a serious charge and could involve penalties on final settlement (difficult to quantify).
- **What about settlements?** — Barring Valtrex (already excluded from our estimates), Ranbaxy's large settlement opportunities appear safe to us. The DMFs for *Nexium*, *Flomax*, *Caduet* & *Lipitor* appear to have been filed from Toansa and the company has stated that it has filed ANDAs from multiple sites. Even if some of these use clinical data generated at Paonta, there is adequate time to switch sites in our view. The FDA also mentions in its letter that it may review and act on applications that are in public interest.

Hold/High Risk	**2H**
Price (25 Feb 09)	Rs207.25
Target price	Rs241.00
Expected share price return	16.3%
Expected dividend yield	1.4%
Expected total return	**17.7%**
Market Cap	Rs87,122M
	US$1,747M

Price Performance (RIC: RANB.BO, BB: RBXY IN)

Statistical Abstract

Year to 31 Dec	Net Profit (RsM)	Diluted EPS (Rs)	EPS growth (%)	P/E (x)	P/B (x)	ROE (%)	Yield (%)
2006A	4,243	10.61	43.9	19.5	3.2	16.9	4.1
2007A	5,126	12.81	20.7	16.2	3.0	19.0	4.1
2008E	1,777	4.16	-67.5	49.9	1.3	3.7	1.4
2009E	4,046	9.47	127.8	21.9	1.2	5.8	2.7
2010E	5,679	13.29	40.4	15.6	1.0	7.2	4.1

Source: Powered by dataCentral

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See Appendix A-1 for Analyst Certification and important disclosures.

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Ranbaxy

Company description

Ranbaxy is a leading Indian pharmaceutical company with a strong export business complementing its domestic business. It has a vision of becoming a leading generics pharmaceutical company in the global market and, in the long term, a research-led pharmaceutical company. The company already has a presence in several countries, and has developed a complex business model, perhaps the first of its kind in a developing country. Over the past few years, Ranbaxy has grown rapidly and established itself firmly as a leading generics company globally. While the core pharmaceutical business is growing, it has also invested in R&D. The company also has a strong chemicals and animal healthcare business in India.

Investment strategy

We rate Ranbaxy Hold/High Risk with a target price of Rs241. We believe that the US FDA's move to block imports and new approvals from Ranbaxy's Paonta and Dewas facilities could significantly hit the US business and overall profitability. However, post the sharp decline in the stock on the back of the aforesaid event, valuations appear to build in most foreseeable negatives. While there are still some uncertain issues, which prevent us from being more constructive on the stock at this point, we believe the risk-reward equation appears more balanced at this point.

Valuation

We value Ranbaxy shares using the P/E vs. earnings CAGR methodology to value its core business, as we do in the case of most stocks in the Indian pharmaceutical sector. We also add an additional value for the company's impressive patent challenge pipeline. We value the core generics business (excluding exclusivity upsides) at 11x 12-month forward earnings, at a 20% discount to frontline pharma companies in order to factor in the added uncertainty in its business following issues with the US FDA. At 11x Dec09E recurring EPS, we arrive at a value of Rs104/share for the base generics business. We value the company's patent challenge pipeline at Rs137/share using a probability-adjusted NPV approach and applying a discount rate of 20%. We have not included some of the nearer-term opportunities (Imitrex, Valtrex) in our valuation to account for any delay due to US FDA action. Cumulatively, we arrive at a fair value of Rs241/share.

Risks

We rate Ranbaxy High Risk. The High Risk rating is to account for the added risk to the US operations following the stand-off with the US FDA. Our quants-based rating system, which tracks 260-day historical share price volatility, suggests Medium Risk. The key downside risks to our call include: a) Price cuts in Romania (c8% and c20% of sales & EBIDTA); b) Early triggering of its exclusivity in Nexium, impairing its deal with Astra: each year knocks cRs8/sh off NPV; c) Spillover of FDA issues to other plants. The key upside risks to our call include: 1) Earlier than expected resolution of the US FDA issues; 2) Lower than expected impact on US sales and profitability due to the ban on products from two facilities; 3) Any fresh settlement / patent challenge win in the US could boost sentiment for the stock.

Appendix A-1

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Ranbaxy (RANB.BO)

Ratings and Target Price History
Fundamental Research

Analyst: Prashant Nair, CFA
Covered since February 22 2006

	Date	Rating	Target Price	Closing Price
1	19-Jul-06	*1M	*402.00	325.90
2	6-Oct-06	1M	*505.00	422.35
3	6-Mar-08	1M	*545.00	453.60
4	15-Apr-08	1M	*595.00	481.80
5	22-Apr-08	1M	*620.00	487.15
6	21-Jul-08	*1H	*604.00	458.20
7	21-Sep-08	*3H	*373.00	356.85
8	9-Dec-08	*2H	*241.00	213.05

* Indicates change

Rating/target price changes above reflect Eastern Standard Time

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