

Company

10 June 2010 | 12 pages

Ranbaxy (RANB.BO)

On the Mend

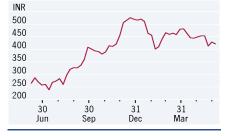
- Focus on Putting Things Right We met the Ranbaxy management recently. While the focus remains on resolving the FDA/DOJ issues, Ranbaxy is also revisiting its strategy on various markets in a bid to improve profitability. We expect this to reflect fully in financials (normalized EBIDTA margins of 16-20%) once the FDA issues are resolved. While it is difficult to predict a timeline, we maintain that the worst is behind us. Maintain Buy.
- FDA Issues Ranbaxy appears confident of some progress in CY10, though it is tough to predict any timeline for resolution. It recently brought in a senior person from Daiichi (Mr. Dale Adkisson) as global quality head. Besides addressing the issues related to Paonta, Dewas & Gloversville (details inside), it is also working on strengthening the internal reporting network between its various sites.
- Revisiting Strategy in Key Markets Besides regaining lost ground in India & US (resolve FDA issues, secure FTFs, focus on profitable products), Ranbaxy has identified South Africa, Romania & CIS (potential US\$100m+ markets) as key growth markets over the medium term. At the same time, it intends to pull down its presence in EU & LatAm, besides focusing on Japan & GCC in the longer term.
- Key Longer-Term Growth Drivers Ranbaxy has identified biosimilars (thru Zenotech), vaccines (thru Biovel) & Japanese generics (thru DS Espha) as key longer-term growth drivers. It is also optimistic on creating some value through its drug discovery efforts (anti-malarial NCE in Ph-3) & synergies with Daiichi.
- Other Takeaways 1) Nexium API supplies to Astra to start by end CY10 from Toansa & formulations in CY11; 2) In discussion with Daiichi for an ideal biz model for China; 3) Expects to launch an improved version of isotretinoin in the US, in the next 2 years, under its deal with Cipher; 4) Aligning drug discovery efforts with Daiichi.

Year to	Net Profit	Diluted EPS	EPS growth	P/E	P/B	ROE	Yield
31 Dec	(RsM)	(Rs)	(%)	(x)	(x)	(%)	(%)
2007A	4,745	11.86	11.7	35.8	6.1	17.6	2.0
2008A	5,878	13.98	17.9	30.3	4.2	16.6	0.0
2009E	910	2.17	-84.5	196.0	3.6	2.0	0.0
2010E	4,025	9.58	342.3	44.3	2.7	6.9	2.0
2011E	9,772	23.25	142.8	18.3	1.6	11.2	2.0

Buy/Medium Risk1MPrice (10 Jun 10)Rs424.35Target priceRs620.00Expected share price return46.1%Expected dividend yield0.0%Expected total return46.1%Market CapRs178,511MUS\$3,797M

Equity 🗹

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



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Fiscal year end 31-Dec	2007	2008	2009E	2010E	2011E
Valuation Ratios					
P/E adjusted (x)	35.8	30.3	196.0	44.3	18.3
EV/EBITDA adjusted (x)	21.3	24.3	40.1	22.3	12.2
P/BV (x)	6.1	4.2	3.6	2.7	1.6
Dividend yield (%)	2.0	0.0	0.0	2.0	2.0
Per Share Data (Rs)					
EPS adjusted	11.86	13.98	2.17	9.58	23.25
EPS reported	19.35	-22.44	19.57	48.94	107.42
BVPS	70.05	102.20	119.18	157.96	257.35
DPS	8.50	0.00	0.00	8.50	8.50
Profit & Loss (RsM)					
Net sales	69,822	70,852	80,017	103,968	144,112
Operating expenses	-62,859	-68,303	-71,309	-80,714	-90,028
EBIT	6,964	2,549	8,708	23,254	54,084
Net interest expense	-1,412	-2,055	-693	-786	-418
Non-operating/exceptionals	4,434	-15,494	3,165	3,080	2,490
Pre-tax profit	9,985	-15,000	11,179	25,547	56,156
Tax	-2,118	5,651	-2,870	-4,970	-10,996
Extraord./Min.Int./Pref.div.	-124	-84	-84	-4	-4
Reported net income	7,744	-9,434	8,225	20,573	45,156
Adjusted earnings	4,745	5,878	910	4,025	9,772
Adjusted EBITDA	10,086	8,363	4,800	8,263	12,740
Growth Rates (%)	10.0		10.0		
Sales	13.9	1.5	12.9	29.9	38.6
EBIT adjusted	1.5	-15.1	-63.2	151.3	81.2
EBITDA adjusted	15.8	-17.1	-42.6	72.2	54.2
EPS adjusted	11.7	17.9	-84.5	342.3	142.8
Cash Flow (RsM)					
Operating cash flow	11,992	-8,318	13,077	29,082	53,600
Depreciation/amortization	2,183	2,452	2,627	2,804	2,849
Net working capital	573	-2,387	1,447	4,914	5,174
Investing cash flow	- 4,364	-5,555	-14,241	-17,375	-31,475
Capital expenditure Acquisitions/disposals	-5,227 639	-5,749 -745	-4,850 -9,569	-3,600 -13,000	-3,563 -27,000
Financing cash flow	- 392	26,885	-6,698	-13,000 - 4,360	-27,000 - 18,741
Borrowings	4,333	-4,698	-6,005	- - ,500 0	-14,750
Dividends paid	-3,642	-2,620	-0,003	-3,573	-3,573
Change in cash	7,236	13,012	-7,862	7,347	3,384
Balance Sheet (RsM)	,	- , -	,	,	-,
Total assets	00 700	101.001	120 007	140 799	172,721
Cash & cash equivalent	92,782 4,379	121,961 23,956	120,097 9,656	140,733 12,021	12,180
Accounts receivable	4,373	23,930	16,048	17,694	12,180
Net fixed assets	45,619	49,607	51,830	52,626	53,339
Total liabilities	64,178	78,323	69,237	73,569	63,770
Accounts payable	8,615	8,303	8,383	9,243	10,255
Total Debt	41,416	43,114	37,109	37,109	22,359
Shareholders' funds	28,604	43,637	50,860	67,164	108,951
Profitability/Solvency Ratios (%)					
EBITDA margin adjusted	14.4	11.8	6.0	7.9	8.8
ROE adjusted	17.6	16.6	2.0	6.9	11.2
ROIC adjusted	7.6	16.9	-1.0	0.7	-1.6
Net debt to equity	129.5	43.9	54.0	37.4	9.3
Total debt to capital	59.1	49.7	42.2	35.6	17.0

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On The Mend

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Key Takeaways from the Visit

FDA Issues – Work In Progress

Ranbaxy continues to work on addressing the issues raised by the FDA / DOJ on its manufacturing facilities. It remains difficult to predict any timeline for resolution, although the management appeared confident that there would be some progress this year.

The company recently brought in Mr. Dale Adkisson (formerly Senior Director, Quality Assurance with Daiichi Sankyo, USA) as its global quality head. Besides working on the immediate issues related to Paonta Sahib, Dewas & Gloversville, the company is also implementing steps to strengthen the internal reporting network and improve information sharing between its various manufacturing sites. This is to make sure that the entire manufacturing chain can take note of relevant regulatory feedback at any facility.

In terms of the individual manufacturing facilities that have fallen foul of the FDA, the current status is as follows:

- Dewas: Ranbaxy believes it has fully implemented the corrective measures at Dewas. It has also sent a detailed report, addressing the cross contamination issues raised by the FDA, to the agency. Ranbaxy awaits an inspection and is confident that the plant should be found compliant this time around. However, there is no clarity on the inspection timeline.
- Gloversville: Ranbaxy has temporarily suspended manufacturing at the facility after it received a warning letter by the FDA. It has taken steps to address the issues and now awaits a reinspection.
- Paonta Sahib: There is some progress in the effort to get this facility functional for the US market again. The independent auditor, appointed in consultation with the FDA, has concluded its review of the facility. Its report will be submitted to the FDA shortly. After discussion with the FDA, the same auditor will conduct validity assessments of the ANDAs filed from the facility. The next step would be to implement the corrective action plan, recommended by the auditors and the FDA. Clearly, it remains a complex issue and timelines are uncertain.
- Other Plants Appear Clear: Its facilities at Ohm Labs (New Jersey), Toansa (end 2009) and Clinical units (2009 & 2010) have been inspected and cleared by the agency without any major observations.

Figure 1. Ranbaxy – Manufacturing & R&D Sites

Formulations

Dewas, India Paonta Sahib, India Mohali, India Goa, India New Jersey, USA Cluj & Bucharest, Romania South Africa Kuala Lampur, Malaysia Cashel, Ireland Lagos, Nigeria

APIs

Toansa, India Mohali, India Dewas, India Malanpur, India Paonta Sahib, India (Fermentation Facility)

Pilot Plants

Formulations Dewas, India Mohali, India Paonta Sahib, India

<u>API</u>

Toansa, India (Synthetic) Paonta Sahib, India (Fermentation)

Source: Company Reports

Figure 2. Ranbaxy - Key Therapy Areas/Products

Top 5 Therapy Areas

Anti Infective Cardiovascular GI Tract Rheumatology CNS

Top 5 Molecules

Valaciclovir Simvastatin Amoxi/clav Ciprofloxacin Amoxicillin

Source: Company Reports

Recalibrating its Market Focus

Besides regaining lost ground in India and the USA, Ranbaxy has identified South Africa, Romania and CIS (Russia & Ukraine) as key growth markets over the medium term. It also intends to pull down on its presence in Europe and Latin America, besides focusing on Japan and the Middle East over the longer term.

India & USA remain key markets

- India: Ranbaxy has launched Project Viraat, in an attempt to regain market leadership (although the No 1 spot looks out of reach post the Abbott Piramal deal). It has added c1,500 people to its field force, increased SBU count (from 16 to 26) and implemented several initiatives to tap rural markets. It expects India revenues to grow at a c15% CAGR over the next 3-5 years. During this period, Ranbaxy aims to consolidate its position in key therapeutic areas (aims to retain leadership in anti infectives, to be in the top 3 in CVS & in the top 5 in CNS). It is also setting up a new channel to cater to the hospitals segment.
- USA: Ranbaxy's long history in the market & its pipeline (including FTFs on several key products) have kept it relevant in this market, despite the setbacks it has faced recently. After the initial sharp decline (post the import alert on Dewas & Paonta Sahib), core sales (excluding exclusivities / settlements) has settled down in the US\$150-200m annualized range.

The New Jersey facilities of Ohm Labs have emerged as the primary sites for this market. Ranbaxy is investing in capacity expansion as well as developing lines beyond oral solids at these sites. Profitability, however, remains subdued on account of the unabsorbed overheads at Paonta & Dewas, high legal and consultancy costs in resolving the FDA/DOJ issues & the relatively higher cost of manufacturing in the USA.

While the company's key focus, besides getting the FDA issues resolved, is on safeguarding the upside from its FTF/settlement pipeline, it is also using this phase as an opportunity to restructure its product basket by focusing on the more profitable products rather than being present in every product. It has also entered into a tie-up with Cipher Pharmaceuticals to work on an improved version of isotretenoin (CIP-Isotretenoin), which is one of the key products it had to stop selling in the US following the import alert. It expects to be ready to launch in the next two years.

Ranbaxy is also confident that it will be able to capture value from each of its unique opportunities either by way of launch or some other route. It has a good track record on this front – launched generic versions of lmitrex (albeit delayed) & Valtrex (c68% market share during exclusivity) through site transfers & monetized Flomax (US\$50m) through a settlement despite not getting an approval to launch.

Nexium Supplies to Astra: Ranbaxy expects to commence API supplies by end of CY10 from Toansa. It has already supplied validation batches to Astra, which are under evaluation. Supply of formulations is slated to start next year.

Romania, CIS & South Africa – Potential US\$100m+ markets

Ranbaxy expects Romania, CIS (Russia & Ukraine) and Africa to be the main markets, besides US and India, to drive growth over the medium term. Besides targeting US\$100m+ revenues from each of these markets (not a big ask, given that they are already reasonably big in these markets), Ranbaxy also plans to look at local manufacturing options to consolidate its position in these markets.

- Romania: Ranbaxy is the largest generic player in Romania, with revenues of US\$80m in CY09. The market has been in a state of flux after EU accession and also got hit by the recession in CY09. Ranbaxy expects a recovery in CY10 (it has already taken some price hikes in 1Q), although some liquidity issues still persist. The company is also considering using Romania as a hub for its EU operations, as it already has a manufacturing set up and clinical unit in the country.
- CIS (Russia & Ukraine): Ranbaxy had revenues of cUS\$85m from Russia & Ukraine, put together, in CY09 it is quite strong in Ukraine but not as much, relative to competition, in Russia. It is now evaluating the best step forward in this market, given the changing regulatory environment. The company is considering various options in Russia getting a local partner, own manufacturing or acquiring a local facility. Its current facility is quite old and it appears to be leading towards setting up/ acquiring a facility, as the new pharma policy might require drugs to be manufactured locally.
- Africa: Ranbaxy believes that the African market could be a key growth driver over the medium term. It is the second largest company in this market (behind GSK), with a presence in 43 out of 46 countries, and aims to further consolidate its position going forward. We believe Ranbaxy's strengths in anti-infectives and ARV drugs should aid its efforts to grow in this region. The company had revenues of US\$125m in CY09 and expects this to touch the cUS\$250m mark over the next three years.

South Africa is the key market in this region, where Ranbaxy has already established a strong presence through the acquisition of Betabs in late 2006. It is setting up a new manufacturing facility in the country and expects to cross the US\$100m revenues mark over the next two to three years (from cUS\$55-60m in CY09).

Other Markets: Ranbaxy is evaluating its business model for the Middle East region. While it is the largest player in Dubai, it presence is limited in the rest of the region. It is now looking at options in Saudi Arabia and whether it needs some local manufacturing base to make progress in this market. It is also in discussion with Daiichi Sankyo to figure out an ideal business model to target the Chinese market.

Limiting its presence in some other markets

Ranbaxy intends to restrict its operations in Latin America and Europe in order to avoid spreading itself too thin and to focus more on the specific markets that, it believes, hold good potential. To this end, it has started outsourcing extensively, closed down some plants and sold off some businesses.

 Latin America: Ranbaxy has limited presence in this region (revenues of US\$71m in CY09) and intends to focus on a few key markets – viz. Venezuela, Brazil & Mexico – going forward. Europe: Ranbaxy has already started scaling down its operations in Europe in order to improve profitability. Several countries in Europe are going through significant regulatory changes – especially on pricing – making it a difficult market to operate in. Ranbaxy plans to use its facilities in Romania and Ireland as manufacturing hubs to cater to this region.

Key Longer-Term Growth Drivers

Ranbaxy has identified biologics / biosimilars (through Zenotech), vaccines (through its recent acquisition of Biovel) & Japanese generics (DS Espha set up by Daiichi) as key growth drivers over the long term. It is also optimistic on creating some value through its drug discovery research efforts and synergies with Daiichi Sankyo.

- Japan generics: Ranbaxy's play in Japan will be through the recently established Daiichi Sankyo Espha. As agreed with Daiichi Sankyo, Ranbaxy will develop, and manufacture the products, which will then be marketed by DS Espha. We expect this to be a significant opportunity over the long term, as Japan is the second largest pharma market in the world and the government is now taking steps to materially increase generic penetration.
- Biosimilars: Ranbaxy expects to target the biosimilars space through Zenotech, in which it has 47% stake. This is, however, also contingent on resolution of the ongoing litigation between Daiichi Sankyo and Zenotech shareholders over terms of the open offer. There could be some progress on this front in this fiscal, following which business initiatives can be taken up in earnest.
- Vaccines: Ranbaxy's efforts in vaccines would be through the recently acquired Biovel Life Sciences. Biovel has received regulatory approvals for Typhoid Vi antigen and Hib conjugate vaccines, in India. The first launch in India is likely in CY11, but there are no current plans to launch in developed markets.
- New Drug Discovery Research: Ranbaxy has an anti-malarial NCE, being developed in collaboration with GSK, in phase 3 trials. If all goes well, this could be launched in India and other developing countries in end CY11/CY12. The project has been largely funded by external grants as such, the risk is lower. While profitability is unlikely to be very high, it could help generate a lot of goodwill for Ranbaxy in some of its key markets. Ranbaxy also has a molecule in Ph I trials for COPD.

Update on key FTFs

Product	Generic Name	Innovator	Sales (US\$ m)	Status	CIRA Comment
Imitrex	Sumatriptan	GSK		Launched in Feb '10	Launched from New Jersey - delayed due to time taken to shift site - lost most of the upside in the process
Valtrex	Valaciclovir	GSK	nm	Launched in Nov '10 – c68% market share during exclusivity	Launched from New Jersey on time despite having to change sites for both API & formulations – positive signal for other FTFs
Flomax	Tamsulosin Hydrochloride	Astellas / Boehringer	nm	No approval yet; Monetized the opportunity by facilitating entry of another generic — received US\$50m	Indicates that P-IV launches are not a given despite the success with Valtrex & Imitrex Ability to monetize the opportunity despite a lack of approval indicates that there are other options available to the company to capitalize on its pipeline
Lipitor - USA	Atorvastatin	Pfizer	7,500	Settled with Pfizer - launch in Nov 2011	Possibly filed from Paonta(given absence of tentative approval till date), hence may require the AIP to be resolved before a launch is possible – there may be other options to monetize
Lipitor (Non US)	Atorvastatin	Pfizer	5,600	Settled with Pfizer - can launch 2-4 months prior to patent expiry across various markets	Ranbaxy has launched the generic versions in Canada and South Africa; Appears to be secure given that there are no regulatory issues in these markets
Caduet	Amlodipine Besylate / Atorvastatin Calcium	Pfizer	400	Settled with Pfizer - launch in Nov 2011	
Nexium	Esomeprazole Magnesium	AstraZeneca	6,300	Settled with Astra - launch in 2014; The settlement also includes a supply agreement for Nexium API & formulations with Astra, until patent expiry	API supplies to begin from end CY10 & formulation launch in CY11 Exclusivity launch only in May 2014 – provides adequate time for resolution of FDA issues
Actos	Pioglitazone Hydrochloride	Takeda	3,400	Settled with Takeda - launch in Aug 2012; Takeda has also settled with other P-IV filers	We believe that Mylan, Watson & Ranbaxy are FTF; Could lead to cRs12/sh upside (assuming 50% price erosion & 25% market share)
Valcyte	Valganciclovir Hydrochloride	Roche	550	A US district court, in Oct '10, has ruled that Ranbaxy's product does not infringe Roche's patent, while upholding the patent itself (expires in 2015); Ranbaxy has a tentative approval but hasn't received a final approval despite the expiry of the 30-month stay & litigation win	Ranbaxy's DMF for the product is filed from Dewas; Final approval may be contingent on the resolution of FDA issues at Dewas/Paonta; This could be longer than a 180 day exclusivity opportunity given that the patent protection extends till 2015 and there are no other known P-IV filers
Aricept	Donepezil Hydrochloride	Eisai	2,100	Teva has final approval; Ranbaxy is one of the 8 generic players with tentative approval; First patent expiry is in Nov 2010	Ranbaxy could get final approval post the Nov 2010 patent expiry along with other generic players – subject to FDA issues

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.

Investment strategy

We rate Ranbaxy Buy/Medium Risk with a target price of Rs620. The timely approval & launch of Valtrex (generic valacyclovir) in the US market with exclusivity and trends in the last two quarters indicate that the worst is behind for Ranbaxy. There has been tangible improvement in emerging markets, which were severe pressure at the beginning of the year and signs that Daiichi sees a key role for Ranbaxy in its future strategy. The impact of the US FDA action on its facilities (Dewas & Paonta Sahib) is also well understood and built into estimates and valuations. With the approval for Valtrex coming through on time, we also have more comfort on Ranbaxy's ability to successfully change sites and get approvals in time for its other FTF opportunities, reinforcing our positive stance on the stock.

Valuation

We have a target price of Rs620 for Ranbaxy, comprising Rs435 for the base generics business and Rs185 for the company's patent challenge pipeline. We use EV/Sales to value the core business as we believe Ranbaxy's current profitability is skewed downwards by the unabsorbed overheads at Paonta Sahib & Dewas as well as the high legal & consultancy charges being incurred towards resolving the FDA issues at these plants. We value the core generics business (excluding exclusivity upsides) at 2.4x Mar 11E recurring sales, which is at a 10% discount to the median of the band in which it has traded over the past 8-9 years. We believe this discount is warranted given the uncertainty in its business following issues with the US FDA. We value the company's patent challenge pipeline using a probability-adjusted NPV approach and applying a discount rate of 15%.

Risks

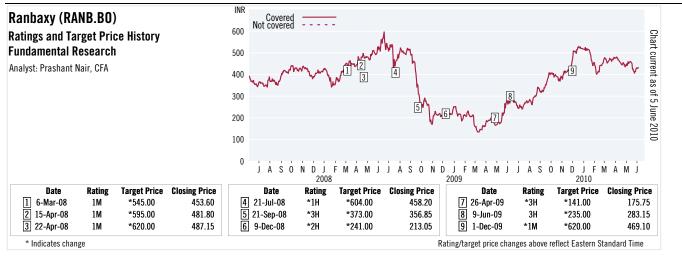
We rate Ranbaxy Medium Risk as opposed to the High Risk rating as suggested by our quant-based rating system, which tracks 260-day historical share price volatility. The recent high volatility in the stock was largely driven by the FDA actions on its facilities at Paonta Sahib & Dewas. We believe that the impact of the FDA action is now well understood and built into estimates and valuations, as such the risk is lower going forward. The key downside risks to our target price include: 1) Slower than expected resolution of the US FDA issues; 2) Setbacks on its already monetized patent challenge pipeline, in form of litigation wins by other generic companies or delay in approvals/launches; 3) Intensifying pricing pressure in the US and European markets.

Appendix A-1

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