HSBC Global Research

Healthcare
Pharmaceuticals
Equity – India

Ranbaxy

N: Consent decree dampens expectations

- **Resolution of manufacturing issues at Paonta Sahib and Dewas facilities takes shape under consent decree**
- **USD500mn provisioning in regard to investigation by Department of Justice (DoJ)**
- **Recovery likely to be a long-drawn-out process. Maintain Neutral with target price cut to INR454 from INR500**

Consent Decree with the FDA: Ranbaxy announced that it has entered into a consent decree with FDA resolution of affected facilities – Paonta Sahib and Dewas. Although the terms and conditions of the decree will be publicly available soon, we believe resolution is likely a long process. Additionally, Ranbaxy has made provision of USD500mn in connection with investigation by the US DoJ which is in excess of USD300-400mn expected (though actual fine may be lower).

Resolution timeline unpredictable: As per previous consent decrees entered by other companies with the FDA, the resolution process can take any time between five and eight years. Watson vacated consent decree put in 1998 against its Steris Lab facility in 2004. KV Pharma too announced approval of first discontinued product (Potassium Chloride) in Sep-10 after entering consent decree in Mar-09 (and closing its Ethex corp. facility). Among other Indian generics, Sun Pharma's subsidiary Caraco entered a consent decree with FDA in 2009 and it is still working towards remediation process having received no product approval during this time.

Slower ramp up of generic Lipitor adds to concern: In the second week of launch, Ranbaxy managed to grab c14% of total prescription market versus Watson's (authorized generics) share of 45%. We have assumed net profit of cUSD200mn from generic Lipitor assuming 40% market share for Ranbaxy with c65% price erosion. Meanwhile, the company is satisfied with the initial performance and expects ramp-up in additional weeks. Additionally, the company expects to ramp up its base business through new US FDA approved facility at Mohali. While Mohali can be a replacement site for large part of products for Paonta, the site transfer will take significant amount of time and recovery will be a slow process. Ranbaxy has started Nexium formulation supply to AstraZeneca from Mohali facility in Nov-11. Cash position is cUSD360mn for the company.

We reiterate Neutral with a revised TP of INR454: We value the stock at 20x (10% premium to 5-yr sector average) Sep-13 EPS of INR 20 and INR53 for para-IV opportunities. We maintain Neutral given lack of clear near-term drivers and built in impact of cash outgo in relation to fine payment. Upside in base business and overall margin improvement can be a positive surprise. Inability to scale up gLipitor and slower domestic recovery is a negative risk in our view.

Neutral

Target price (INR)	**454.00**
Share price (INR)	**406.95**
Forecast dividend yield (%)	**0.9**
Potential return (%)	**12.4**

Note: Potential return equals the percentage difference between the current share price and the target price, plus the forecast dividend yield

Performance	**1M**	**3M**	**12M**
Absolute (%)	-9.2	-17.1	-27.2
Relative^ (%)	-7.5	-9.0	-5.4

Index^	BOMBAY SE IDX
RIC	RANB.BO
Bloomberg	RBXY IN
Market cap (USDm)	3,144
Market cap (INRm)	166,306
Enterprise value (INRm)	181712
Free float (%)	36

Note: (V) = volatile (please see disclosure appendix), Potential return and performance as of 21 December 2011 closing price

21 December 2011

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Financials & valuation

Financial statements

Year to	12/2010a	12/2011e	12/2012e	12/2013e
Profit & loss summary (INRm)				
Revenue	85,494	102,642	107,671	114,084
EBITDA	15,351	25,239	25,395	26,437
Depreciation & amortisation	-5,533	-3,059	-3,500	-3,800
Operating profit/EBIT	9,818	22,180	21,895	22,637
Net interest	972	-644	-650	-500
PBT	16,896	19,639	24,445	25,137
HSBC PBT	16,896	19,639	24,445	25,137
Taxation	-5,849	-5,053	-5,867	-6,033
Net profit	10,862	14,420	18,428	18,919
HSBC net profit	2,834	6,127	8,201	8,692
Cash flow summary (INRm)				
Cash flow from operations	10,248	3,557	16,246	27,808
Capex	-3,694	-4,000	-3,500	-3,000
Cash flow from investment	-331	-467	-3,464	-2,500
Dividends	-982	-1,685	-2,255	-2,390
Change in net debt	-12,752	8,981	-13,068	-25,636
FCF equity	448	1,454	9,546	21,808
Balance sheet summary (INRm)				
Intangible fixed assets	27,946	27,946	27,946	27,946
Tangible fixed assets	21,350	22,292	22,292	21,492
Current assets	91,916	72,068	94,535	113,382
Cash & others	37,629	13,606	24,674	48,310
Total assets	141,213	122,306	144,773	162,820
Operating liabilities	41,398	31,485	37,052	37,166
Gross debt	43,348	28,306	26,306	24,306
Net debt	5,719	14,700	1,632	-24,004
Shareholders funds	55,981	61,963	79,827	98,260
Invested capital	62,186	77,215	83,047	77,344

Ratio, growth and per share analysis

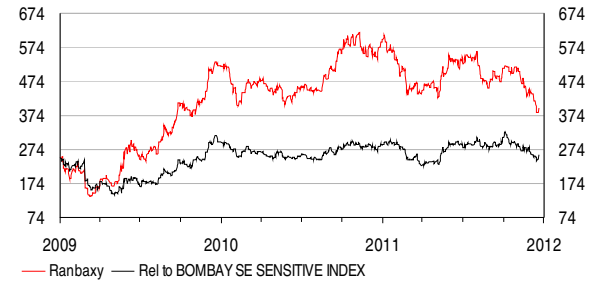
Year to	12/2010a	12/2011e	12/2012e	12/2013e
Y-o-y % change				
Revenue	13.4	20.1	4.9	6.0
EBITDA	115.9	64.4	0.6	4.1
Operating profit	121.5	125.9	-1.3	3.4
PBT	67.3	16.2	24.5	2.8
HSBC EPS	726.4	116.2	33.8	6.0
Ratios (%)				
Revenue/IC (x)	1.4	1.5	1.3	1.4
ROIC	10.2	23.9	21.0	21.7
ROE	5.8	10.4	11.6	9.8
ROA	8.1	11.4	14.3	12.7
EBITDA margin	18.0	24.6	23.6	23.2
Operating profit margin	11.5	21.6	20.3	19.8
EBITDA/net interest (x)		39.2	39.1	52.9
Net debt/equity	10.1	23.5	2.0	-24.4
Net debt/EBITDA (x)	0.4	0.6	0.1	-0.9
CF from operations/net debt	179.2	24.2	995.3	
Per share data (INR)				
EPS reported (fully diluted)	25.38	33.70	43.07	44.21
HSBC EPS (fully diluted)	6.62	14.32	19.16	20.31
DPS	1.97	3.58	4.79	5.08
Book value	130.83	144.81	186.56	229.63

Valuation data

Year to	12/2010a	12/2011e	12/2012e	12/2013e
EV/sales	2.0	1.8	1.6	1.2
EV/EBITDA	11.3	7.2	6.6	5.4
EV/IC	2.8	2.4	2.0	1.8
PE*	61.5	26.4	20.0	17.9
P/Book value	3.0	2.7	2.1	1.7
FCF yield (%)	0.3	0.9	5.7	13.1
Dividend yield (%)	0.5	0.9	1.2	1.3

Note: * = Based on HSBC EPS (fully diluted), PE based on Dec 21, 2011 closing price

Price relative



Source: HSBC

Note: price at close of 20 Dec 2011

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FDA consent decree: a snapshot

What is a Consent Decree? A consent decree is a legal agreement that is reached between an affected company and the regulatory authority (in this case FDA). It is a negotiated agreement between parties which details the actions pledged by the affected company for remedial process, including system and facility improvements and to avoid FDA litigation. A consent decree commits the company to perform corrective actions in a timely manner which is verified by an independent third party.

Why Consent Decree is imposed? FDA adopts the consent decree approach after the company has received repeated FDA warning letters or 483s concerning current good manufacturing practices (cGMP) deficiencies and these repeated deficiencies have not been corrected.

What will affected company do upon entering a consent decree? Once the consent decree is issued, the affected company may be required to assign testing and certain QA responsibilities (such as certification of investigation, approval of validation protocols and annual audits) to a qualified third party. The third party plays a major role in the consent decree and post consent decree periods as the FDA relies on third party report to assess company's remedial steps.

What are consequences of not fulfilling consent decree terms? In addition to paying fines, the company may be forced to delay new product launches and pay additional fines for not completing corrective actions on an agreed upon timeline.

Consent decree entered in last 10 years

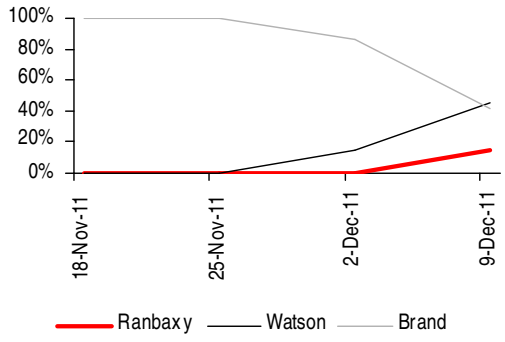
Date	Company	Facility	FDA Issue	Remarks
21-Dec-11	Ranbaxy	Paonta Sahib, Dewas	Deviations from current Good Manufacturing Practice; falsifying data and test results of drugs at the facility	Ranbaxy made a provision of USD500mn for penalty which is far higher than previous expected range of USD300-400mn and it can be major drag on company's profitability
May-10	Genzyme	Allston, Mass.(US)	Manufacturing quality violations	Genzyme signed an FDA consent decree for repeated manufacturing deficits, and has agreed to pay a $175 million federal fine and operate under agency supervision for expected 7 or 8 years. The fine paid is about 41.4% of the company's net profit in CY 2009
Sep-09	Caraco(Sun Pharma)	Detroit, Michigan(US)	Violations of cGMP standards	Caraco had earlier guided for 1-2 product approvals under consent decree per year but later withdrew that in process.
Mar-09	KV Pharma	St. Louis, MO(US)	Violations of cGMP standards	KV closed Ethex Corp facility; announced first approval of discontinued product(Potassium chloride) in Sep-10
Apr-05	GSK	Cidra, Puerto Rico	cGMP violations	The facility was closed in 2007
May-02	Watson	Corona, CA(US)	Violation of cGMP standards.	Since no product was suspended, there was minimal impact to the company's revenue.
May-02	Schering-Plough (Merck)	New Jersey and Puerto Rico facilities	Violation of manufacturing standards.	Schering paid a fine of USD500mn to the FDA. As a result of Consent decree, Schering Plough lowered its 2002 earning estimates to single digits frrom low double digits. Production was suspended for 73 of the 125 drugs impacted by the decree.
Oct-00	Wyeth (Pfizer)	Marietta, Pennsylvania, and Pearl River, New York	Failure to comply with Good Manufacturing Practice	Apart from USD30mn fine, Wyeth has to pay an additional USD 15,000 per day for each day past the deadline (capped at USD5mn). In 2001, Wyeth paid over US267mn in fines as a result of the decree (the fine, product discontinuation, and others). It closed its facility
Nov-99	Abbott	Lake County, Illinois (US)	Quality control issue with the diagnostics devices manufactured at this facility	Abbott paid fine of USD100mn to the FDA. Abbott also assumed one time charge of $168 million apart from the fine paid to the FDA to cover costs associated with meeting FDA requirements. This one-time prompted the company to adjust its previous quarter earnings down to $0.30 from $0.38.

Note: cGMP= current good manufacturing practice
Source: Company data

Generic Lipitor in the second week of launch

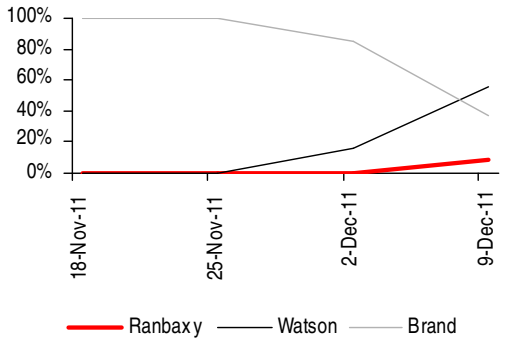
- Generic Lipitor garnered 59% market share of total Lipitor prescription for week ending Dec9, 2011. Ranbaxy's market share was 14% against 45% market share for Watson
- Ranbaxy's market share improved in mail order and long term care channels while Watson led the retail channel prescription (which accounts for c79% of total prescription).

Overall weekly Lipitor prescription market share trend



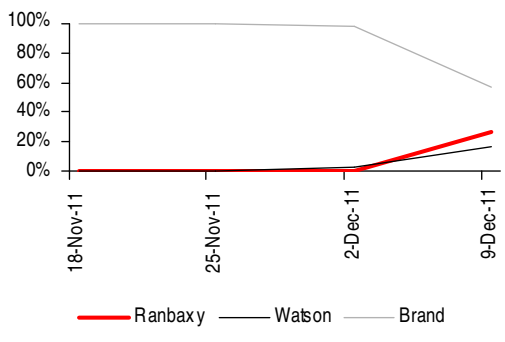
Source: IMS Health

Retail Channel weekly prescription market share trend



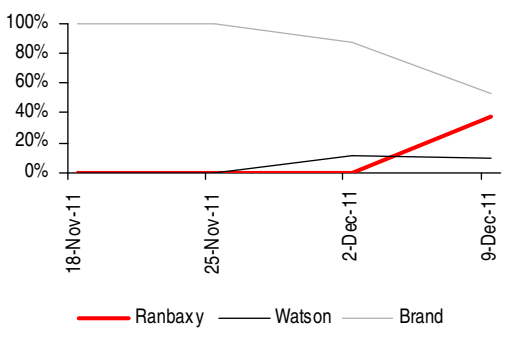
Source: IMS Health

Long term care Channel weekly prescription market share trend



Source: IMS Health

Mail Order Channel weekly prescription market share trend



Source: IMS Health

Ranbaxy generic launch timeline

Molecule	Brand	Indication	Sales (USD mn)	Who is FTF?	Timeline
Levofloxacin	Levaquin	Quinolone Anti-Infective	1,312	Multiple	Launched
Atorvastatin	Lipitor	High Cholesterol	5,329	Ranbaxy	Launched
Atorvastatin, amlodipine	Caduet	High Cholesterol And High BP	800	Ranbaxy	Launched
Minocycline	Solodyn	Acne	370	Impax, Teva, Sandoz, Mylan, Ranbaxy	Launch expected
Alfuzosin	Uroxatral	Benign Prostatic Hyperplasia	200	Multiple	FY12
Irbesartan/hctz	Avalide/Avapro	Hypertension & CHF		Teva/ Ranbaxy?	Mar-12
Modafinil	Provigil	Narcolepsy	961	Ranbaxy, Teva, Mylan	Apr-12
Desloratadine	Clarinex	Anti-Histamine	249	Multiple	Jul-12
Pioglitazone	Actos	Type-2 Diabetes	3,212	Ranbaxy, Mylan, Watson	Aug-12
Valsartan	Diovan	Hypertension & CHF	2,520	Ranbaxy	Sep-12
Fenofibrate	TriCor	High Cholesterol	1,578	Teva	Oct-12
Valganciclovir	Valcyte	Cytomegalovirus Infections	400	Ranbaxy	Mar-13
Oxycodone	Oxycontin	Moderate To Severe Pain	3,150	Ranbaxy, Teva, Endo	Apr-13
Pioglitazone + metformin	Actoplus met	Type-2 Diabetes	478	Mylan	Jun-13
Rivastigmine	Exelon soln	Alzheimer'S Disease	<5	Ranbaxy?	Feb-14
Esomeprazole	Nexium	GERD	2,695	Ranbaxy	May-14
Memantine	Namenda	Alzheimer'S Disease	600	Multiple	Jan-15
Fenofibrate	Antara	Hypercholesterolemia	60	Dr Reddys	Unknown
Total			22,542		

Source: Company data, HSBC

Valuation and risks

We value Ranbaxy's base business at 20x (maintaining 10% premium to the sector average) Sep-13 EPS of INR20 (reduced from INR22.2) and add para-IV value of INR53 to arrive at our 12-month target price of INR454. We are reducing our Sep-13 earning estimates as we have built in impact of cash outgo in relation to fine payment which would reduce other income Our PE multiple is in line with other large caps (at 10% premium to the sector average) to account for its large upcoming exclusive generic opportunities in the US including modafinil, esomeprazole, pioglitazone, and valsartan.

Under our research model, for stocks without a volatility indicator, the Neutral band is 5 percentage points above and below the hurdle rate for Indian stocks of 11.0%. Our new TP of INR454 provides a potential return of 12.4% including dividend yield, which is within the Neutral band of our model, therefore we rate the stock Neutral. Potential return equals the percentage difference between the current share price and the target price, including the forecast dividend yield when indicated.

Risk: The key upside risk is sooner than expected recovery in base business and potential savings of costs resulting in higher margin in base business. The downside risk is inability in gaining market share and a higher than assumed price erosion of generic Lipitor.

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Disclosure appendix

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Share price and rating changes for long-term investment opportunities

Ranbaxy (RANB.BO) Share Price performance INR Vs HSBC rating history

Source: HSBC

Recommendation & price target history

From	To	Date
N/A	Overweight	20 January 2011
Overweight	Neutral	01 December 2011
Target Price	**Value**	**Date**
Price 1	690.00	20 January 2011
Price 2	565.00	10 May 2011
Price 3	500.00	01 December 2011

Source: HSBC

HSBC & Analyst disclosures

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Company	Ticker	Recent price	Price Date	Disclosure
RANBAXY	RANB.NS	394.55	20-Dec-2011	2, 7

Source: HSBC

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