

Healthcare
Pharmaceuticals
Equity – India

Ranbaxy (RBXY)

Overweight

Target price (INR)	690.00
Share price (INR)	468.85
Potential return (%)	47.7

Performance	1M	3M	12M
Absolute (%)	-7.2	-13.2	0.3
Relative ^A (%)	-5.5	-3.4	-1.4

Index^A BOMBAY SE IDX

RIC RANB.BO
Bloomberg RBXY IN

Market cap (USDm) 4,387
Market cap (INRm) 197,504

Enterprise value (INRm) 199316
Free float (%) 36

Note: (V) = volatile (please see disclosure appendix)

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OW: Mylan asks court to block Ranbaxy's generic Lipitor

- ▶ **Mylan files action alleging FDA failed to make a public decision concerning Ranbaxy's ANDA filing on Lipitor**
- ▶ **Also seeks injunction barring FDA from withholding other generics approvals blocked by Ranbaxy's first-to-file status**
- ▶ **FDA's approach concerning Ranbaxy's generic approval unlikely to be affected. Our model assumes timely approval and launch of generic Lipitor by November 2011. Remain OW**

Mylan sues FDA in attempt to block Ranbaxy's generic approval: Mylan, a competing generic filer in Lipitor, has filed a court action against the US' Food and Drug Administration (FDA) regarding its inability to take a decision on Ranbaxy's ANDA filing which blocks other generics. The complaint requests the court to a) declare the FDA's failure to make a public decision or other determination concerning whether Ranbaxy's generic contains unreliable data or information and thereby clear regulatory status on the ANDA filing; b) enjoin the FDA from approving any ANDA if it contains unreliable data; and c) extinguish any exclusivity grant and approve Mylan's filing should the ANDA be unreliable. In a series of three letters to the FDA and one meeting, Mylan has attempted to get the FDA to deny Ranbaxy's ANDA stating that the available record fails to demonstrate that Ranbaxy will meet statutory criteria for approval.

Ranbaxy's ANDA is a pre-MMA filing and hence retains exclusivity: Ranbaxy's ANDA was submitted to the FDA prior to December 2003 (enactment of Medicare Modernization Act, MMA). This allows Ranbaxy to park exclusivity and block other generic approvals – unless one of the generic players triggers the exclusivity and brings the generic in the market earlier than anticipated. On the contrary, had Ranbaxy filed this ANDA after 2003, it would have lost the exclusivity as per clauses governed by the post MMA statute.

FDA's decision on Ranbaxy's filing unlikely to be affected: Ranbaxy has set the generic Lipitor launch with Pfizer for November this year. We believe that the FDA's course of action concerning approval of Ranbaxy's generic atorvastatin is unlikely to be affected by such litigation. We believe the worst case scenario of the FDA rejecting the ANDA and hence the exclusivity is unlikely given that Ranbaxy has been co-operating with the FDA and is working on remedial measures for all its first-to-file ANDAs. The outcome on Ranbaxy's ANDA will be clearer in the latter half of this year. We value the generic Lipitor opportunity at INR60 per share.

Financials & valuation

Financial statements

Year to	12/2009a	12/2010e	12/2011e	12/2012e
Profit & loss summary (INRm)				
Revenue	75,383	85,670	99,033	111,970
EBITDA	7,109	16,823	26,666	35,043
Depreciation & amortisation	-2,676	-3,257	-3,500	-3,800
Operating profit/EBIT	4,432	13,566	23,166	31,243
Net interest	396	-469	-2,121	-2,312
PBT	10,098	24,915	25,545	34,731
Taxation	-6,991	-5,531	-5,221	-6,999
Net profit	2,965	19,182	20,104	27,483

Cash flow summary (INRm)

Cash flow from operations	-5,247	19,870	16,073	32,592
Capex	-4,205	-2,000	-2,000	-2,000
Cash flow from investment	3,164	-1,818	-1,500	-1,500
Dividends	0	-1,351	-2,218	-3,175
Change in net debt	4,745	-18,634	-13,629	-28,993
FCF pre dividends	-14,721	6,052	9,573	24,792

Balance sheet summary (INRm)

Intangible fixed assets	27,946	27,946	27,946	27,946
Tangible fixed assets	23,189	21,932	20,432	18,632
Current assets	65,493	85,873	106,346	139,239
Cash & others	17,824	32,458	44,087	71,080
Total assets	116,629	135,752	154,725	185,818
Operating liabilities	41,112	44,087	45,180	52,139
Financial liabilities	36,295	32,295	30,295	28,295
Total liabilities	72,662	73,136	73,729	80,189
Net debt	18,471	-162	-13,792	-42,784
Shareholders funds	41,675	60,641	79,022	103,655

Ratio, growth and per share analysis

Year to	12/2009a	12/2010e	12/2011e	12/2012e
Y-o-y % change				
Revenue	3.1	13.6	15.6	13.1
EBITDA	-12.4	136.7	58.5	31.4
Operating profit	-16.2	206.1	70.8	34.9
PBT		146.7	2.5	36.0
HSBC EPS	-73.7	1094.0	97.0	43.1

Ratios (%)

ROE	0.8	8.0	11.5	12.6
ROCE	4.4	23.6	21.9	24.3
EBITDA margin	9.4	19.6	26.9	31.3
Operating profit margin	5.9	15.8	23.4	27.9
Net debt/equity	42.0	-0.3	-17.0	-40.5
CF from operations/net debt				

Per share data (INR)

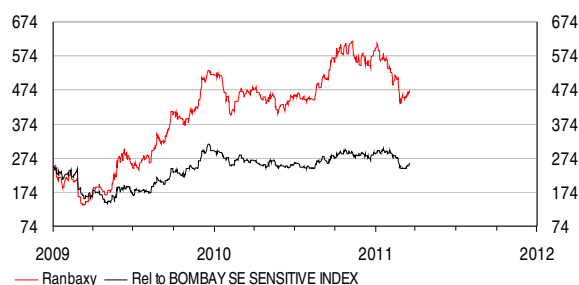
EPS reported (fully diluted)	6.93	44.83	46.98	64.23
HSBC EPS (fully diluted)	0.80	9.57	18.85	26.98
DPS	0.00	2.87	4.71	6.74
Gross CFPS	13.51	52.91	55.68	73.69

Valuation data

Year to	12/2009a	12/2010e	12/2011e	12/2012e
EV/sales	2.9	2.3	1.9	1.4
EV/EBITDA	30.7	11.8	6.9	4.4
P/CF	34.7	8.9	8.4	6.4
PE*	585.0	49.0	24.9	17.4
FCF yield (pre div) (%)	-7.4	3.0	4.8	12.6
Dividend yield (%)	0.0	0.6	1.0	1.4

Note: * = Based on HSBC EPS (fully diluted)

Price relative



Source: HSBC

Note: price at close of 18 Mar 2011

In a not so similar situation (but which involves Ranbaxy), Apotex too had filed a DJ (declaratory judgement) against Eisai in District Court of North Carolina in an effort to “unpark” 180-day exclusivity for generic Aricept, stating that Ranbaxy may not be able to launch the generic product in time. District court had however denied Apotex’s DJ motion, stating that Apotex failed to establish that any delay caused by Ranbaxy’s block is sufficiently real or immediate so as to present the court with a justifiable Article III controversy. We do however acknowledge that the donepezil case is not exactly similar in nature given that in relation to atorvastatin, Mylan has already settled with Pfizer (unlike for donepezil, where Apotex had to trigger the exclusivity by filing a DJ) and is expected to enter along with Teva post exclusivity of Ranbaxy (and Watson AG).

Valuation and risks

We retain our OW rating and haven’t changed our estimates post last quarter results. We remain confident of a positive outcome on Lipitor, which is the next key catalyst for the stock. Our target price of INR690 is based on 22x CY12e EPS of INR27.

Exhibit 1: ANDA filers on Lipitor

	ANDA filer	Sued on	30-month expiry	Status	Remark
1	Ranbaxy	511, '740, '893, '995		FTF, Settled	Launch in Nov-11
2	Teva	995	End 2010	Settled	Launch post expiry of exclusivity
3	Cobalt	995, '971, '104, 156		AG, Settled	Launch with Ranbaxy
4	Mylan	156, '740, '511	Nov-11	Settled	Will likely enter with Teva post Ranbaxy exclusivity
5	Dr Reddy's	156	May-12	Trial scheduled for Dec-11	
6	Apotex	995, '667, '156	May-11		Filed DJ and got covenants on '971 and '104. Will likely enter with Teva post Ranbaxy exclusivity
7	Kudco	156	May-12		Sued on crystalline patent
8	Actavis	156			Sued on crystalline patent

Source: HSBC

Exhibit 2: Patents covering Lipitor

Patent	Type	Expiry date
4681893*PED	composition	24-Mar-10
5273995*PED	composition	28-Jun-11
5686104*PED	formulation	11-May-15
5969156*PED	crystalline	8-Jan-17
6126971*PED	formulation	19-Jul-13
RE40667*PED	claim 9 of '995	28-Jun-11

Source: FDA (in addition there are amorphous patents not listed in OB)

Risks to our call include non approval of generic Lipitor ANDA and subsequent forfeiture of exclusivity. In addition, any other attempt to monetize the Lipitor generic opportunity may substantially reduce the potential benefit from the opportunity.

Exhibit 3: Ranbaxy Para-IV opportunities

Brand	Molecule	Brand (USDm)	Generic launch	Exclusivity	Status	Net profit (USDm)	NPV (INR per share)
Lipitor	atorvastatin	5,100	Nov-11	FTF, with AG	Settled	649	59
Caduet	atorvastatin + amlodipine	500	Nov-11	FTF, with AG	Settled	57	5
Nexium	esomeprazole	2,835	Nov-14	FTF, with Teva?	Settled	215	13
Valcyte	valganciclovir	200	Mar-13	Sole FTF	Settled	82	7
Actos	pioglitazone	3,212	Aug-12	Shared FTF with Mylan, Watson	Settled	98	8
Provigil	modafinil	961	Apr-12	Shared FTF	Settled	22	2
Total		12,808				1,123	94

Source: HSBC, Company

Disclosure appendix

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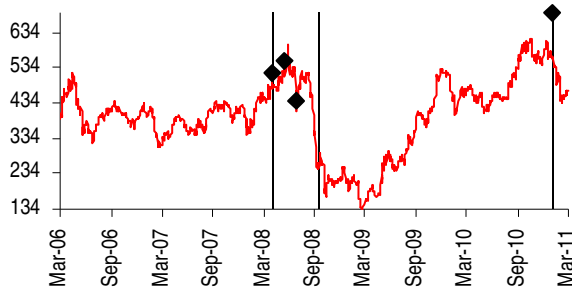
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Share price and rating changes for long-term investment opportunities

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



Source: HSBC

Recommendation & price target history

From	To	Date
Overweight	Neutral	21 April 2008
Neutral	N/A	06 October 2008
N/A	Overweight	20 January 2011
Target Price	Value	Date
Price 1	522.00	21 April 2008
Price 2	555.00	05 June 2008
Price 3	442.00	16 July 2008
Price 4	N/A	06 October 2008
Price 5	690.00	20 January 2011

Source: HSBC

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Company	Ticker	Recent price	Price Date	Disclosure
RANBAXY	RANB.NS	468.85	19-Mar-2011	2, 4, 7

Source: HSBC

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