



Company

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Biocon (BION.BO)

Sell: Fresh Hope on Tacrolimus?

Sliver of hope on tacrolimus — The US FDA's move to reject Astellas' citizen's petition on *Prograf* (tacrolimus) & approve Sandoz' generic version was a surprise. Biocon is a key API player in tacrolimus & was not expected to launch in the US before 2012 – earlier approvals for its partners would be positive. However, with Astellas planning to sue the FDA, it could still take some time before the situation becomes clear. Maintain Sell (3H).

- FDA rejects Astellas' CP Astellas had filed a citizen's petition with the US FDA seeking that a) generic companies should be required to conduct more extensive clinical trials to prove bioequivalence; and b) labeling changes that require doctors to be notified when a generic version is about to be provided to a transplant patient. Subsequently, it approved Sandoz' ANDA for the product.
- Biocon could be a leading player Biocon had indicated in an earlier call that it has partnered with 5 ANDA filers for the US – we, however, do not know whether Sandoz is one of them. Although only Sandoz has received approval so far, we believe other players should also get approval if the FDA's decision holds as long as they have cleared the bioequivalence hurdle.
- May be a long haul Astellas plans to approach the court for a preliminary injunction, enjoining the FDA's approval. Also, generic substitution is likely to be slower than in other products given the complexity of immunosuppressants in general & Prograf in particular (narrow therapeutic range).
- Potential upside for Biocon Prograf had US revenues of US\$929m in 12 months through April 2009. Once generic penetration normalizes, we believe Biocon could generate incremental EPS of Rs0.8-1.3 (7-10% of FY11E EPS).

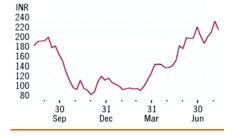
Statistical Abstract							
Year to	Net Profit	Diluted EPS	EPS growth	P/E	P/B	ROE	Yield
31 Mar	(RsM)	(Rs)	(%)	(x)	(x)	(%)	(%)
2007A	2,003	10.01	15.1	22.4	4.2	20.5	0.7
2008A	2,160	10.80	7.9	20.8	3.0	16.9	1.1
2009E	2,109	10.54	-2.4	21.3	2.8	13.7	0.9
2010E	2,312	11.56	9.6	19.4	2.6	14.0	1.0
2011E	2,409	12.04	4.2	18.6	2.4	13.3	1.1

Source: Powered by dataCentral

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

Sell/High Risk	3H
Price (11 Aug 09)	Rs224.50
Target price	Rs140.00
Expected share price return	-37.6%
Expected dividend yield	1.0%
Expected total return	-36.6%
Market Cap	Rs44,900M
	US\$940M

Price Performance (RIC: BION.BO, BB: BIOS IN)



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Equity 🗹

Biocon

Company description

Biocon is an integrated biotechnology company in India that encompasses all three critical stages of drug development - drug discovery, development, and manufacturing and commercialization of biopharmaceuticals and enzymes. With more than 25 years of expertise in fermentation technology, the company has built strong capabilities in high-growth segments like statins, immunosuppressants and anti-diabetes. While statins form the major part of its current business, Biocon is aggressively pursuing the biogenerics opportunity in regulated markets and is also making investments in drug discovery research to build a future pipeline.

Investment strategy

We have a Sell/High Risk rating on Biocon in view of the nascent nature of longer-term growth initiatives. Despite several initiatives being taken by the company to emerge as a biotechnology major, Biocon remains primarily an API player with high exposure to the statins segment. Unlike other Indian companies, Biocon does not have the requisite breadth in its product portfolio to overcome the pressure on statins and delays in biogenerics launches. The setbacks on pravastatin and simvastatin in the US in CYO6 and tacrolimus in CYO8 reflect the high sensitivity of Biocon's earnings to a delayed launch and are an indication of the vulnerability of the company's business model. Overall, we expect a 5% CAGR in net profit for Biocon over FYO9-11E, even after factoring in the full impact of statin sales in the US market and aggressive ramp-up in research services as well as insulin and BioMAb sales. Valuations appear expensive relative to the growth outlook and the vulnerability of earnings in the near to medium term.

Valuation

Our target price of Rs140 for Biocon is based on 12x June 10E earnings, at a 25% discount to our target range for most generic pharma companies in our coverage universe such as Lupin, Glenmark and Cadila. This is due to Biocon's lower earnings CAGR (5% over FY09-11E) and return ratios (c12%). We also believe that the higher vulnerability of Biocon's business model to pricing pressure and delayed product launches /scale-up would continue to keep the stock's multiples on the lower side.

Risks

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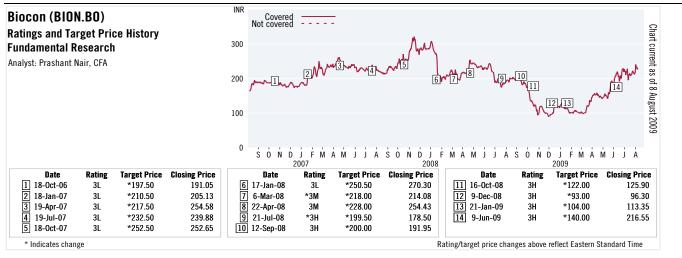
Our risk rating for Biocon is High Risk, factoring in the current volatility in markets. Our quants-based rating system, which tracks 260-day historical share price volatility, suggests Medium Risk. The main upside risks to our target price and estimates include: 1) licensing deals for oral insulin or T1h molecules; 2) progress in biosimilars legislation in the US & / or any approvals from the EU; 3) On Tacrolimus, if its partners are able to litigate and secure early entry into the US, it would be positive for valuations and sentiment.

Appendix A-1

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Hold

38%

45%

Buy

41%

Sell

21%

39%

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