

Industry Flash

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Indian Pharma

Trileptal Exclusivity – Positive for Sun, Glenmark & Jubilant

- **Shared exclusivity in Trileptal** — Roxane, Glenmark and Sun Pharma have received approval from the US FDA to sell their generic versions of Trileptal (oxcarbazepine) in the US market, with shared 180-day exclusivity. From an Indian perspective, besides Sun and Glenmark, we expect Jubilant to be a key beneficiary by virtue of its API supply tie-ups for the product. Glenmark has already launched the product while we expect Sun to launch shortly.
- **Key product for the Indian companies** – Oxcarbazepine would be the first exclusivity launch for both Glenmark and Sun in the US market. We also expect Jubilant to emerge as a key API supplier in this product. It was the first Indian company to file a DMF for oxcarba and has supply tie-ups with five ANDA filers – one of which could be Glenmark (which does not have a DMF filing), in our view.
- **Reasonable upside** — Trileptal, which is indicated as monotherapy or adjunct therapy for treatment of partial seizures, had sales of US\$643m for the year ended June 2007. We believe this represents a reasonable, albeit one-time, upside for the Indian companies despite the shared exclusivity. Besides the financial upside, an exclusive product would help upcoming players such as Glenmark and Caraco (Sun's subsidiary) gain traction with the trade in the US.
- **Impact on financials** — We expect the relative financial upside to be highest for Glenmark owing to its lower base. We expect the 3 generic firms to share the market with an authorized generic during exclusivity. Based on assumptions of 50% price erosion and 20% market share during exclusivity, we expect oxcarbazepine to add 26% (Rs3) and 8% (Rs3.7) respectively to Glenmark's & Sun's EPS in FY08E. For Jubilant, we expect an addition of c6% to FY08E EPS.
- **No material impact on valuations** — While the exclusivity is likely to boost sentiment in the stocks, we believe that there should not be any material impact on valuations. Exclusivity upsides are one-off and with the sharp erosion in market share/profitability after the exclusivity ends, we do not advocate giving a multiple to such earnings upsides. We maintain our ratings on Glenmark (1M), Jubilant (1L) and Sun Pharma (2L).

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

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Trileptal Exclusivity – Positive for Sun, Glenmark & Jubilant

Roxane, Glenmark and Sun Pharma have received approval from the US FDA to sell their generic versions of Trileptal (oxcarbazepine) in the US market, with shared 180-day exclusivity. From an Indian perspective, besides Sun and Glenmark, we expect Jubilant to be a key beneficiary by virtue of its API supply tie-ups for the product. We expect oxcarba to add 26% (Rs3), 8% (Rs3.7) and 6% (Rs1.1), respectively, to Glenmark's, Sun's and Jubilant's EPS in FY08E. While the exclusivity is likely to boost sentiment in the stocks, we believe that there should not be any material impact on valuations. Exclusivity upsides are one-off and with the sharp erosion in market share/profitability after the exclusivity ends, we do not advocate giving a multiple to such earnings upsides. We maintain our ratings on Glenmark (1M), Jubilant (1L) and Sun Pharma (2L).

The Trileptal Opportunity

Figure 1. Upside from formulation exclusivity

(US\$ m)	Glenmark	Sun Pharma
Market Size - annual	643	643
Market Size - 6 months	322	322
Price Erosion	50%	50%
Market Share	20%	20%
Sales	32	32
Net Margin	60%	60%
PAT	19	19
PAT (Rs m)	772	772
Equity (shares mn)	268	209
EPS (Rs)	2.9	3.7
FY08E EPS (base business)	10.9	46.7
% upside	26%	8%

Source: Citi Investment Research

Trileptal is Novartis' brand of oxcarbazepine tablets. Oxcarbazepine is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures. Three generic companies – Roxane, Sun Pharma and Glenmark – have received US FDA approval to market Oxcarbazepine tablets in three strengths – 150 mg, 300 mg and 600 mg – which cumulatively had sales of cUS\$643m for the 12 months ended June 2007. These companies have 180-day exclusivity by virtue of having challenged the patent – we expect them to share the market with an authorized generic during this period.

Oxcarbazepine would be the first exclusivity launch for both Glenmark and Sun in the US market. We believe this represents a reasonable, albeit one-time, upside for the Indian companies despite the shared exclusivity. Besides the financial upside, an exclusive product would help upcoming players such as Glenmark and Caraco (Sun's subsidiary) gain traction with the trade in the US.

Jubilant, on the other hand, is likely to be one of the key API players in this product. It was the first Indian company to file a DMF for this product and has tied up with five ANDA filers to supply the API. In fact, we believe that Jubilant could be the API supplier to Glenmark during the exclusivity period, given that the latter does not have its own DMF filing and was one of the first ANDA filers in the product.

Glenmark has already launched the product while Sun Pharma is likely to launch shortly.

Upside to earnings – Highest for Glenmark

We expect the percentage upside during the exclusivity period to be highest for Glenmark, followed by Sun and Jubilant. However, we believe that it would be much more sustainable for Jubilant after the exclusivity period given that it would start supplying to other customers as well, whereas Sun and Glenmark are likely to see their market share as well as pricing come off due to more competition.

Based on assumptions of 50% price erosion and 20% market share during exclusivity, we expect oxcarbazepine to add 26% (Rs3) and 8% (Rs3.7) respectively to Glenmark's and Sun's EPS in FY08E. For Jubilant, we expect an addition of c6% to FY08E EPS.

Glenmark Pharmaceuticals (GLEN.BO - Rs426.80; 1M)

Company description

Glenmark Pharmaceuticals is a fully integrated research-based pharmaceutical company, with a business model spanning drug discovery research, APIs and formulations in the domestic and international markets. It operates in more than 65 countries, including the regulated markets of the US and Europe, with around 50% of its revenues coming from overseas markets. The company came into the limelight in September 2004 after it licensed out the US market rights of its first new chemical entity (NCE), GRC-3886, to Forest Laboratories.

Valuation

We use sum of the parts to value the stock, valuing the R&D deals and the base business separately. We believe probability-adjusted DCF is appropriate to calculate the option value from Oglemilast and GRC-8200 as it captures the reducing probability of success as the molecules progress on the clinical path. We have used the licensing deal with Forest Laboratories for the US market as a benchmark as well as a 13% discount rate (in-line with Glenmark's WACC) following our adjustment for the higher-risk income streams by probability of success. We arrive at a value of Rs119/share for Oglemilast. We use a similar approach for GRC-8200 and arrive at a value of Rs45/share. We value Glenmark's base business (excluding R&D income) on P/E in view of the healthy growth expected in earnings. Our valuation is based on 20x forward earnings, which is at a premium to the range that we use for other mid-sized pharma companies. We believe Glenmark deserves a premium given its higher value addition in its business and the ability to execute and leverage its assets. Based on 20x mid-FY09E earnings, we value Glenmark's base business at Rs263/share. This takes the total valuation of the company to Rs427/share.

Risks

We rate Glenmark Medium Risk, even though its risk rating according to our quantitative model is Low, as we believe the element of R&D related option value built into the stock warrants a higher risk rating. The main downside risks to our target price and estimates include: (1) Glenmark's efforts to build its own front-end in regulated markets could prove to be a drag on earnings if it is unable to effectively execute its plans; (2) growing competition, rapid price erosion and fragmented market share are risks that are inherent to the generics business; and (3) the failure of Oglemilast or GRC-8200 could lead to the R&D milestone payments getting taken off our estimates. If any of these factors has a greater impact than we expect, the stock could have difficulty achieving our target price.

Sun Pharmaceuticals (SUN.BO - Rs920.20; 2L)

Company description

Sun Pharma is one of the fastest-growing companies in the domestic pharmaceutical market, growing at about 2x the industry rate. The company has followed a strategy of being the first to enter niche, high-growth segments (both organic and through acquisitions). The company has a presence in the CNS, pain management, ophthalmology, cardiovascular and respiratory segments. Sun is facing stiff competition in its traditional strongholds, but has managed to sustain growth and is focusing on new therapeutic areas. The company is looking to export its top formulation products to drive growth, and has set up marketing and distribution infrastructure in various markets. It is also filing for ANDA approvals through its US subsidiary Caraco.

Valuation

Our target price of Rs1,150 is based on a sum-of-the-parts approach. We continue to value Sun's base business using a P/E vs. earnings CAGR approach and ascribe an option value for its patent challenge pipeline. We value Sun's base business at 20x FY09E earnings. With a steadily growing profit line, we believe P/E is the best method to value Sun Pharma. We value frontline pharma stocks at a premium of around 40% to the broad market, due to the intellectual property built into the business models, faster growth as well as the potential to deliver positive earnings surprises. This works out to a multiple of 20x that we use for Sun Pharma as well as its peers such as Dr Reddy's and Cipla. Our estimates do not incorporate the Taro acquisition. However, we believe that it would be dilutive in the short term, i.e. FY08E, before being earnings neutral or mildly accretive in FY09E. As such, we believe that it is relevant to value Sun based on FY09E estimates as the earnings dilution phase is transient, and should not affect fair value. At 20x FY09E earnings, we arrive at a value of Rs1,136 for the base business. We also ascribe an option value of Rs14 to Sun's patent challenge pipeline, using a 15% success rate on the company's patent challenges that are in the public domain.

Risks

We rate Sun Pharma as Low Risk because of its steady growth and visible earnings stream. This is also consistent with our quantitative risk-rating system, which tracks 260-day historical share price volatility. The key risks to our target price are: (1) Price deterioration in any of its key markets; (2) Inability to effectively integrate the Taro acquisition and exploit synergies could keep earnings depressed for longer than we have anticipated; (3) A stronger IPR law in India could lead to a gradual slowdown in growth rates for the Indian market. Upside risks to our target price include a faster-than-expected integration of the Taro acquisition and a win in any patent challenge.

Jubilant Organosys (JUBO.BO - Rs298.00; 1L)

Company description

Jubilant Organosys is the largest specialty chemicals company in India, with a high degree of vertical integration, and global scale and reach in almost all its key products. The company has established itself as a serious player right from fine chemicals to advanced intermediates and APIs. More recently, it has forayed into formulations and regulatory services through acquisitions in Belgium (PSI n.v. and PSI supply) and the US (Trigyn Laboratories). It has set up wholly owned subsidiaries to tap into the high-potential areas of bioinformatics, medicinal chemistry services and clinical services.

Valuation

We use sum-of-the-parts to value Jubilant in view of the diversified nature of its business and earnings streams. We value both businesses using the EV/EBIDTA methodology but apply different target multiples to each business given the difference in their growth and operating parameters. We arrive at a one-year target price of Rs386 (from Rs340 earlier).

We value Jubilant's P&LS business at 15x Sept 2008E EV/EBIDTA and the non-P&LS business at 7x Sept 2008E EV/EBIDTA – rolled forward from June'08E earlier. Our target valuation for the P&LS business is benchmarked to the upper end of Jubilant's past four-year EV/EBIDTA range. We are comfortable using a higher multiple vis-à-vis some of its mid-sized Pharma peers due to strong growth rates and the upside potential when idle FCCB proceeds are deployed in the core business. Industrial chemicals and performance chemicals are mature businesses in which Jubilant has indicated that it does not intend to make any significant incremental investment. However, the company's competitive edge in these areas would ensure that it is able to generate steady profits from these businesses. We therefore value these businesses at 7x Sept 2008E EBIDTA, which is in-line with the multiple that Jubilant used to trade at around four years ago when these businesses contributed almost entirely to the company's revenues and profits.

Risks

We rate Jubilant Low Risk based on our quantitative risk-rating system. The main downside risks to our target price and estimates include: (1) The generics business has become very competitive; (2) Any delay in filing / launch or a litigation loss would affect the timing and quantum of revenues and profits; (3) Inability to integrate and exploit the synergies with its acquired subsidiaries could hurt profitability; and (4) Increases in molasses prices. The main upside risks to our target price include: (1) A significant value accretive acquisition could lead to upside to our estimates; and (2) Pyridine prices could firm up in the medium term.

Appendix A-1

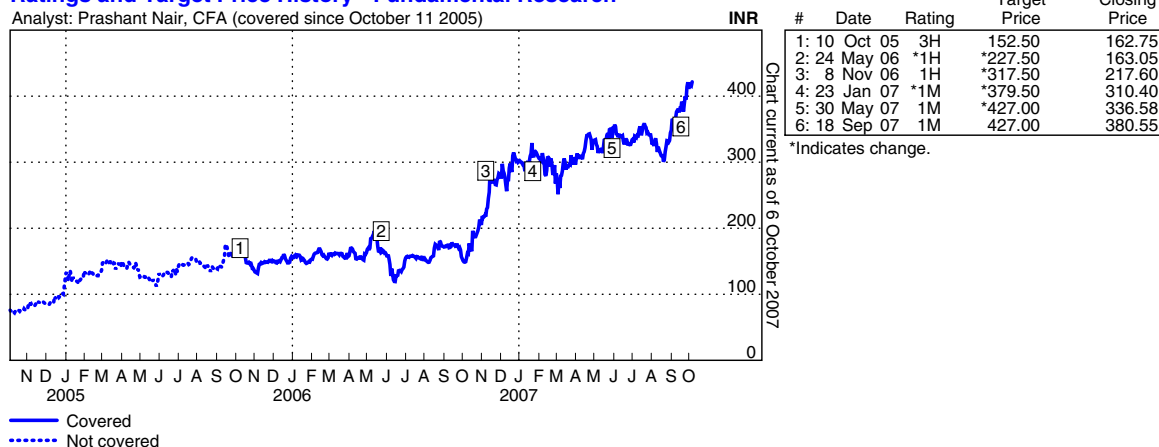
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Analyst: Prashant Nair, CFA (covered since October 11 2005)



Jubilant Organosys (JUBO.BO) Ratings and Target Price History - Fundamental Research

Analyst: Prashant Nair, CFA (covered since October 11 2005)



Sun Pharmaceuticals (SUN.BO)
Ratings and Target Price History - Fundamental Research

Analyst: Prashant Nair, CFA (covered since February 22 2006)



#	Date	Rating	Target Price	Closing Price
1:	25 Oct 04	2L	*408.53	453.10
2:	3 Jan 05	*3L	408.53	555.30
3:	19 Sep 05	3L	*426.29	663.10
4:	7 Jun 06	3L	*617.23	721.40
5:	20 Oct 06	3L	*678.51	912.45
6:	21 May 07	3L	*678.46	1,064.15
7:	30 May 07	*2L	*1,150.00	1,109.20

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