

PINC Pharma Monthly
 Sector: Pharma
 BSE Sensex: 16,483

MONTHLY R_x

Sector View: Neutral

NEWS ROUNDUP FOR THE MONTH-NOVEMBER

DOMESTIC:

- Pfizer, Ranbaxy sued by 11 California Pharmacies over Lipitor prices
- Ranbaxy gets approval for first antimalarial combination drug developed by an Indian Pharma Company
- DRL seeks denotification of Special Economic Zone at Medak
- Strike at DRL's Srikakulam manufacturing unit has been called off
- Raging Capital and Permian Investment partners oppose Sun Pharma's offer to acquire Taro
- Lupin sued in US for Lumigan patent infringement
- Lupin acquires I'rom Pharma in Japan
- Glenmark receives USD5mn payment from Sanofi-Aventis
- Glenmark enters cosmeceutical segment through a ten-year agreement with Immanence-IDC
- Piramal Healthcare settles patent litigation with Baxter Healthcare
- Piramal Healthcare seeks shareholders' nod for IT, Security and other biz
- Aurobindo, Pfizer reach accord in Lipitor patent case
- TCG ties up with JSW Lifesciences for drug clinical studies
- Hospira received approval for generic Imipenem-Cilastatin, expected to benefit its API supplier, Orchid Chemicals
- Bayer withdraws writ petition against Natco over compulsory licensing of Nexavar

GLOBAL:

- Pfizer aims to keep one third of Lipitor pie
- Teva loses court bid to halt Watson's Seasonique copy
- Teva and P&G launch OTC joint venture called PGT Healthcare
- Mylan pays USD17.5mn to buy rights to develop Pfizer's generic version of Advair
- USFDA warns Mylan over Puerto Rico plant violations
- Watson wins Kentucky drug pricing litigation
- Watson launches authorized generic version of Lipitor in US
- US Court favours GSK in Arzerra patent infringement lawsuit
- Impax sued by Teva's Cephalon over Fentora pain drug patents

INDUSTRY:

- NPPA has issued demand notice of Rs23.6bn for drug overcharging to Indian Pharma companies

Source: Company, Bloomberg, ET, Business Line, Livemint, DNA, Business Standard, WSJ, World Pharma news, Reuters, Businessweek.

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PRICE PERFORMANCE

	1M	3M	12M
BSE Sensex	(5.7)	(1.2)	(17.0)
BSE HC Index	(1.2)	1.2	(9.7)
Apollo Hospitals	15.7	13.8	25.5
Aurobindo	(28.8)	(26.3)	(63.5)
Biocon	(8.2)	(3.5)	(21.1)
Cadila	(6.3)	(16.6)	(8.2)
Cipla	14.2	17.5	(9.7)
Divis Labs	(0.5)	4.4	19.6
Dr Reddy's	(4.0)	3.3	(12.9)
Fortis healthcare	(12.2)	(25.4)	(25.1)
Glaxo	(9.7)	(10.4)	(12.4)
Glenmark	1.7	(3.1)	(12.8)
Ipca	(7.5)	(18.5)	(20.4)
Lupin	(2.1)	3.7	(9.0)
Opto Circuits	(18.6)	(24.4)	(30.0)
Orchid Chemicals	(8.8)	(16.4)	(48.2)
Piramal Healthcare	(0.7)	(1.1)	(19.3)
Ranbaxy	(12.3)	(6.2)	(23.0)
Sterling Biotec	0.9	38.7	(1.4)
Sun Pharma	3.3	6.3	16.5

COVERAGE UNIVERSE VALUATIONS

Company	CMP (Rs)	Mcap (Rs bn)	PE(x)		EV/Sales (x)		EV/EBITDA (x)		Reco.	Tgt price (Rs)
			FY12E	FY13E	FY12E	FY13E	FY12E	FY13E		
Cipla	330	264.9	24.6	21.2	3.8	3.1	17.8	14.6	Reduce	331
Dr Reddy's	1,545	261.5	16.5	15.3	3.2	2.8	21.0	16.7	Sell	1,442
Glenmark	317	85.6	18.8	15.4	2.9	2.5	13.7	11.3	Accumulate	360
GSK Pharma	1,902	161.1	26.5	23.0	6.0	5.1	17.8	14.7	Reduce	1,822
Ipca	254	32.3	11.0	10.9	1.6	1.5	8.3	7.9	Reduce	279
Lupin	466	208.0	21.9	19.4	3.1	2.6	18.0	14.7	Accumulate	513
Ranbaxy	444	186.7	30.5	26.8	2.1	2.0	23.7	14.8	Sell	412
Sun Pharma	521	540.0	26.2	22.8	7.0	5.9	20.4	17.3	Reduce	494

Source: Company, PINC Research

For rating objective and disclaimer, please refer to last page of the report

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KEY NEWS ANALYSIS

Pfizer, Ranbaxy sued by 11 Pharmacies over Lipitor prices

Pfizer and Ranbaxy were sued by 11 California pharmacies over claims that they agreed to hold back generic version of the cholesterol-lowering drug Lipitor in the U.S. and then fixed its price. As per the lawsuit filed in the federal court in San Francisco, due to the agreement with Ranbaxy, Pfizer was able to make USD18bn by extending its time as the exclusive U.S. source of Lipitor. It also claimed that in exchange of this, Pfizer allegedly allowed Ranbaxy to distribute the generic of Lipitor earlier in foreign markets.

PINC Comments: As per Pfizer, the suit has no merit and the company is confident that the Lipitor patent settlement with Ranbaxy is appropriate. In the current context nothing can be inferred as there is no clarity on the facts of the suit until there is a concrete hearing in the court.

Dr Reddy's seeks denotification of Special Economic Zone at Medak

Dr Reddy's Laboratories (DRL) has requested the government to denotify its Special Economic Zone (SEZ) at Medak in Andhra Pradesh. The formulations unit, which was to come up at Medak, will now be moved to Visakhapatnam where the company has another SEZ for manufacturing APIs. As per the company, it has requested for denotification of entire SEZ (Medak) as it would be locating both the SEZs close together (at Visakhapatnam). The Company indicated that having an API unit at one place and formulation unit at another place complicates the whole matter. With regards to the proceedings, the company has given an undertaking to the Commerce Ministry for refunding the duty benefits availed of in the name of SEZ and the Development Commissioner of VSEZ has recommended the proposal. DRL is setting up the formulations SEZ in Vizag for better synergies of management and material flows. In Vizag, it had acquired around 260 acres for the bulk drugs SEZ, which will now house the formulation SEZ as well. The company is expected to invest around USD200mn in both the SEZs. The SEZ land, after denotification, will be used for other expansion plans.

PINC Comments: The above move should help the company synchronize its manufacturing process across the value chain. The vacant Medak land could be used by the company for future expansions.

Raging Capital and Permian Investment partners oppose Sun Pharma's offer to acquire Taro

After the opposition from Grand Slam Asset Management, Raging Capital and Permian Investment Partners followed the league urging Taro's board of directors and all minority shareholders to reject Sun Pharma's proposal and retain independent counsel to obtain an unbiased assessment of fair value. Raging Capital called on the Board to form a special committee composed of members who are truly independent from Sun Pharma and retain independent advisors to explore and evaluate all strategic alternatives to maximize shareholders' value. Permian Investment Partners informed that it intends to fervently protect the value of its investment in Taro on behalf of its limited partners, in accordance with the fiduciary duties and will not part with the shares at a level that does not reflect fair value.

PINC Comments: There are three shareholders now who have opposed Sun Pharma's offer to acquire Taro. They have argued that Sun's offer is at a substantial discount compared to other deals for US generic companies. Thereby, the flowing oppositions would now make it increasingly difficult for Sun Pharma to take full control of Taro at USD24.5/share. The deal was expected to contribute 3.9% to FY13E earnings.

Lupin sued in US for Lumigan patent infringement

Allergan sued Lupin for wanting to sell generic version of Bimatoprost Ophthalmic Solution (0.01%) which it sells in the name of Lumigan. Allergan has filed suit in Texas Eastern District Court after Lupin submitted an ANDA to the USFDA. Allergan believes that by submitting this application, Lupin committed an act of infringement of "the 504 patent", which protects Lumigan till June 13, 2027. Allergan has estimated that Lumigan franchise product net sales would be between USD610-630mn in 2011. Lumigan is the first-line therapy indicated for reduction of elevated intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension.

PINC Comments: Lupin has filed a Paragraph IV certification challenging that patent '504 (expiring in June 2027) is invalid or/and not infringed. Earlier in August 2011, Sandoz had also challenged patent '504. As a result, we expect Sandoz to be the sole FTF holder. However, this in-line with the company's strategy to focus on niche/limited competitive space (OC, Ophthalmic space).

Lupin acquires I'rom Pharma in Japan

Lupin has acquired I'rom Pharma (IP) in Japan. Established in 1947, IP is a specialty injectables company headquartered in Tokyo. For FY11, the company clocked sales of USD70mn (JPY5,361mn). IP has a significant presence in the Diagnosis Procedure Combination (DPC) hospital segments which are fixed-rate payment hospitals and treat acute conditions. DPC hospitals promote the use of generic drugs to cut costs. There are currently over 1,400 DPC hospitals in Japan, covering over 35% of all hospital beds nationwide and have a market size of USD11bn. Thus, generic injectable penetration is slated to grow significantly in future.

PINC Comments: Though Lupin has not provided any details on the acquisition cost, we expect the deal to be valued between 1-1.5x Price/Sales (USD 70-105mn). Lupin is expected to fund the deal through combination of debt and internal accruals. We estimate the acquisition to contribute ~4% to our FY13E sales and to be marginally EPS accretive. The acquisition now strengthens Lupin's position in Japan and provides an entry into injectable space in the region. Japan is a second largest pharmaceutical market with total size of USD96bn and a generic penetration of mere 23% (volume terms). Japan region is now expected to contribute ~16% to Lupin's FY13E sales (Kyowa 12% and IP 4%).

Glenmark receives USD5mn payment from Sanofi-Aventis

Glenmark Pharma (Glenmark) has received USD5mn milestone payment from Sanofi Aventis related to the successful completion of the Phase I clinical study of GRC 15300, a first-in-class TRPV3 inhibitor for treatment of pain. The above payment is part of the deal wherein Glenmark had out-licensed GRC-15300 to Sanofi Aventis and received upfront payment of USD20mn with a potential of total milestone reaching up to USD325mn with royalties on sales.

PINC Comments: The upside from the deal is in line with the expectations and signifies the R&D expertise of the company.

Glenmark enters cosmeceutical segment

Glenmark forays into the cosmeceutical segment in India with the launch of Canadian company Immanence-IDC's anti-ageing product line, through its newly formed division, Glenmark CosmoCare. IDC products are based on strong scientific foundation and Glenmark would offer the advanced cosmeceutical line to a wide network of cosmetologists and dermatologists across the country. Glenmark has entered into a ten-year agreement with Immanence-IDC to distribute the high-end dermatology products in eight countries - India, Brazil, Mexico, South Africa, Egypt, Vietnam, Malaysia and Thailand. It plans to roll out the range in most of these markets by end of FY12. The other financial details are not disclosed.

PINC Comments: The foray of Glenmark into cosmeceuticals will significantly enhance Glenmark's dermatology product offerings and further consolidate its leadership position in the segment. It should be a long term positive for the company.

TENTATIVE ANDA APPROVALS

Company	API	Strengths	Brand	Mkt size (USD mn)
Apotex	Olopatadine Hydrochloride	0.1%, 0.2% base	Patanase	91
Onco Therapies	Oxaliplatin	50,100mg	Eloxatin	1,400
Glenmark	Montelukast Sodium	10mg	Singulair	3,200
Macleod Pharma	Irbesartan	75,150,300mg	Avapro	-
Macleod Pharma	Irbesartan Hydrochlorothiazide	150; 12.5mg , 300; 12.5mg, 300; 25mg	Avalide	-

Source: Company, PINC Research, USFDA

FINAL ANDA APPROVALS

Company	API	Strengths	Brand	Mkt size (USD mn)
Bioniche Pharma	Tranexamic Acid	100mg/ml	Cyklokapron	-
Sun Pharma	Tiagabine Hydrochloride	2,4mg	Gabitril	49
Jubilant Organosys	Risperidone	0.5,1,2,3,4 mg	Risperdal	61
Endo Pharms, Torrent Pharma	Felodipine	2.5,5,10mg	Plendil	97
Aurobindo	Naproxen	250,375,500mg	Aleve	-
Onco Therapies	Carboplatin	50mg/5ml (10mg/ml), 150mg/15ml (10mg/ml) , 450mg/45ml (10mg/ml) , 600mg/60ml (10mg/ml)	Paraplatin	35
Watson Labs	Morphine Sulfate	20,30,50,60,80,100mg	MS Contin	173
Hospira	Cilastatin Sodium; Imipenem	250mg base/vial; 250mg/Vial ,500mg base/vial; 500mg/vial	Primaxin	140
Mylan	Eprosartan Mesylate	400,600mg	Teveten	150
Aurobindo	Lamivudine	150,300mg	Epivir	-
Alembic Pharma	Leflunomide	10,20mg	Arava	-
Apotex	Carbamazepine	100,200,300mg	Equetro	-
Watson Labs	Drospirenone; Ethinyl Estradiol	3mg; 0.02mg	Yaz	173
Princeton Pharma Inc	Risperidone	0.25,0.5,1,2,3,4mg	Risperdal	61
Ranbaxy	Atorvastatin Calcium	10,20,40,80mg	Lipitor	5,400

Source: Company, PINC Research, USFDA

M&A Activities

Acquirer	Target	Deal Size (USD mn)	Rationale
Salix Pharma	Oceana Therapeutics	USD300mn	The acquisition would help Salix expand its product portfolio of innovative products and diversify its base business in the gastroenterology and urology therapeutics.
Invida Pte Ltd	Shalaks Pharmaceuticals	USD25mn	Invida Pte Ltd has acquired dermatology and baby care products in line with its strategy to build up on its specialty product portfolio through in licensing and acquisitions.
Gilead Sciences	Pharmasset Inc	USD11bn	The acquisition in the biotech space will help Gilead change the treatment paradigm and develop oral treatments for Hepatitis-C
Pfizer	Excaliard Pharma	na	The acquisition would compliment Pfizer's innovative product pipeline with differentiated products in the biotech segment
Transgene Biotek	TSS Export	USD5mn	Transgene has sold the recombinant human erythropoietin technology to TSS due to the increased competition led by entry of several players.
UCB	Lectus Therapeutics	na	The transaction involves the acquisition of drug discovery and development programmes targeting ion channels for the treatment of a specific set of CNS indications.

Source: Company, PINC Research

Drug recalls

Product	Recalling firm	Strength	Volume	Reason
Furosemide Injection	Hospira	USP 100 mg (10 mg/ml), 10 ml Ansyr syringe	37,350 vials	Failed pH Specification; 18 month testing interval.

Source: Company, PINC Research, USFDA

Patent Settlements

Generic Company	Innovator	Brand	Mkt Size (USD mn)	Launch date	Comment
Piramal healthcare	Baxter Healthcare	Suprane	-	Jan-14	Piramal has taken a licence under the patent pursuant to which the parties have agreed that Piramal may manufacture its generic Desflurane in the US as of April 24, 2012 solely for sale outside the US. Launch in the US would be in Jan2014.
Aurobindo Pharma	Pfizer	Lipitor	5,400	-	We expect Aurobindo to launch Lipitor with the other generic players, post the 180-days exclusivity period (May 2012)
Kremer Urban Pharmaceuticals	Pfizer	Lipitor	5,400	-	The terms of the agreement are confidential and the agreement itself is subject to review by the U.S. Department of Justice and the Federal Trade Commission. We expect the company to launch Lipitor with the other generic players post the 180-days exclusivity period. (May 2012)
Mylan	Novartis	Vivelle-Dot	240	Dec-2013	Mylan was the first company to have filed a substantially complete ANDA containing a Paragraph IV certification with the USFDA for Estradiol Transdermal System USP.

Source: Company, PINC Research

FTF OPPORTUNITIES

Company	API	Brand	Mkt Size (USD mn)	Comment	Patent Expiry
Mylan	Estradiol	Vivelle-Dot	240	Mylan was the first company to have filed a substantially complete ANDA containing a Paragraph IV certification with the USFDA for Estradiol Transdermal System USP, Twice-Weekly.	Jan-2014

Source: Company, PINC Research

PATENT EXPIRY CALENDAR OVER THE NEXT SIX MONTHS

Brand Name	API	Dosage	Usage	Innovator	US Sales (USD mn)	Patent Expiry	FTF	FTF Launch Date	Other Generic companies
Caduet	Amlodipine/ Atorvastatin	Tablet	High BP& Angina	Pfizer	296	28-Jun-11	Ranbaxy	-	Sandoz, Mylan
Combivir	Lamivudine/ Zidovudine	Tablet	HIV infection	VIIV healthcare	222	15-May-12	Teva	4QCY11	Lupin
Gabitril	Tiagabine HCL	Tablet	Epilepsy	Cephalon	49	30-Sep-11	-	-	Sun Pharma has received tentative approval; Cephalon has filed patent infringement pertaining to 951 patents expiring in June 2017.
Lipitor	Atorvastatin	Tablet	Cholesterol	Pfizer	5,400	28-Jun-11	Ranbaxy	Nov-11	Watson, Mylan, Teva, Apotex, DRL, Kudco, Actavis, Aurobindo
Solodyn	Minocycline	Tablet	Acne	Medicis	368	19-Feb-18	Teva, Mylan, Sandoz, Impax	Nov-11	Ranbaxy, Lupin, Aurobindo

Source: Company, PINC Research

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Rating Objective		
Rating	Large Caps	Mid Caps
	M.Cap > USD1bn	M.Cap <= USD1bn
Return %		
BUY	More than 15	More than 20
Accumulate	5 to 15	10 to 20
Reduce	(-)5 to +5	0 to 10
Sell	Below (-)5	Less than 0



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