PINC Pharma Monthly
Sector: Pharma
BSE Sensex: 17,584

MONTHLY Rx

Sector View: Neutral

PHARMA MONTHLY UPDATE

NEWS ROUNDUP FOR THE MONTH-FEBRUARY

DOMESTIC:

- Wyeth claims USD960mn from Sun Pharma in the Protonix case
- USFDA allows Sun Pharma for temporary importation of Doxil
- Ranbaxy's Une says generic Lipitor sales to stay strong in 2012
- Lupin enters into settlement with Santarus and Depomed over generic Glumetza
- Lupin plans USD20mn facility in Pune
- Glenmark completes Phase-I trials for pain and respiratory disorders molecule (GRC 17536) in Europe
- SPARC opts for rights issue to conduct clinical trials in US
- Aurobindo sued on Prandin
- Piramal Healthcare to acquire further 5.5% stake in Vodafone India for Rs30bn
- Orchid Chemicals redeems FCCBs worth USD167.6mn
- Opto to partner German firm to supply AEDs to aircraft makers
- Aanjaneya Lifecare acquires Hyderabad-based firm Apex Drugs and Intermediates for Rs2.5bn
- Pfizer hives-off animal health biz to subsidiary for Rs4.4bn
- Shasun Pharma to sell 11.93% stake to US firm OrbiMed for Rs500mn
- Sanofi signs deal with Emcure Pharmaceuticals to sell rabies vaccine
- Jubilant Biosys inks drug discovery pact with Mnemosyne Pharma

GLOBAL:

- WellPoint to drop branded Lipitor from its formulary
- Daiichi Sankyo in buyout talks with 3 mid-sized firms in India
- Mylan acquires two dermatological products from Valeant
- Merck firms up plan for emerging markets
- Apotex pays Bristol, Sanofi damages over Plavix drug
- Mylan to launch generic Copaxone in H2CY13
- Watson files ANDA for Beyaz

INDUSTRY:

- DoP to give final shape to the National Pharmaceuticals Pricing Policy within three to four weeks
- First US rules for generic biotechnology drugs set out in draft proposal

Source: Company, Bloomberg, ET, Business Line, Livemint, DNA, Business Standard, WSJ, World Pharma news, Pharmabiz

02 March 2012

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PRICE PERFORMANCE

	1M	3M	12M
BSE Sensex	1.6	6.7	(4.7)
BSE HC Index	0.1	5.23	7.7
Apollo Hospitals	(4.1)	(4.9)	25.7
Aurobindo	(5.0)	20.5	(38.8)
Biocon	3.5	(13.9)	(16.4)
Cadila	8.5	0.8	(4.6)
Cipla	(9.7)	(4.5)	3.0
Divis Labs	(6.2)	(2.0)	22.7
Dr Reddy's	(0.5)	7.9	5.4
Fortis healthcare	2.2	(4.4)	(26.9)
Glaxo	7.6	9.9	(5.0)
Glenmark	4.4	(1.7)	8.0
Ipca	7.7	34.9	25.0
Lupin	0.9	3.7	21.9
Opto Circuits	11.6	33.4	7.8
Orchid Chemicals	6.4	15.5	(31.2)
Piramal Healthcare	6.3	23.6	(2.0)
Ranbaxy	(4.4)	(4.0)	(5.9)
Sterling Biotec	7.2	33.7	52.4
Sun Pharma	0.1	5.3	23.3

COVERAGE UNIVERSE VALUATIONS

Company	CMP	Mcap	PE(x)		EV/Sales (x)		EV/EBITDA (x)		Reco.	Tgt price
	(Rs)	(Rs bn)	FY12E	FY13E	FY12E	FY13E	FY12E	FY13E		(Rs)
Cipla	315	253.3	20.5	18.2	3.2	2.8	14.9	12.8	Reduce	338
Cadila	711	145.7	17.0	13.4	2.7	2.3	12.5	10.1	Accumulate	751
Dr Reddy's	1,667	282.0	16.9	16.2	3.0	2.6	17.8	15.3	Sell	1,519
Glenmark	310	83.6	15.6	12.3	2.3	1.9	11.0	8.9	Accumulate	343
GSK Pharma	2,082	176.3	25.2	22.2	5.7	4.9	16.7	14.1	Sell	1,880
Ipca	343	43.7	12.3	11.2	1.8	1.6	8.8	8.0	Accumulate	334
Lupin	482	215.2	19.6	16.3	2.6	2.2	14.0	11.4	Buy	541
Ranbaxy	425	178.8	26.8	19.1	2.0	1.7	14.9	10.9	Sell	337
Sun Pharma	549	568.4	23.0	18.3	5.8	4.7	16.8	13.2	Reduce	534

Source: Company, PINC Research

KEY NEWS ANALYSIS

Wyeth claims USD960mn from Sun Pharma in the Protonix case

Sun Pharma announced that in the on-going patent litigation on generic Protonix in the US district court of New Jersey, Wyeth (Pfizer) has submitted expert reports claiming damages to the tune of USD960mn (Rs42/share) from Sun Pharma. Wyeth has claimed USD2.1bn from Teva and USD960mn from Sun Pharma for the at-risk launch of generic Protonix. Thus, Wyeth in totality is claiming USD3bn for the launch.

PINC Comments: Our assessment would be that the claims from Wyeth are on the higher side on back of 1) Protonix was USD2bn brand for Wyeth before the launch of generic. 2) Wyeth generated revenues of USD806mn (including AG contribution) from Protonix in CY2008 post the at-risk launch by Teva and Sun. 3) Sun Pharma launched the drug post the launch by Teva and AG. 4) Sun Pharma could have made profits to the tune of USD240-280mn from the launch. We expect that the claims could be in the range of USD300-500mn (Rs13-22/share), if Sun Pharma is unable to get a favourable judgment on the patent litigation. Sun Pharma has a strong balance sheet (cash of USD1bn) and the generic Protonix trial could be a long time driven process.

USFDA allows Sun Pharma for temporary importation of Doxil

The USFDA has allowed Lipodox (manufactured by Sun Pharma) to be imported into the US as an alternative to Doxil. This is a temporary arrangement done by the USFDA to curb the shortage of the drug after Ben Venue Laboratories, which manufactures Doxil for J&J, shut down a manufacturing plant in Ohio in November to address manufacturing problems with some products. The alternative Lipodox has the same active ingredient as for Doxil. Doxil is used in multiple treatment regimens, including treatment of ovarian cancer after failure of platinum-based chemotherapy. Although J&J is in continuous talks with the USFDA to pursue all options to return Doxil to the market, Ben Venue doesn't expect to resume manufacturing until late 2012. This translates into an opportunity for Sun Pharma's Lipodox as it is the only alternative product to overcome the shortage for marketing in the US. Sun has initiated the importation of both strengths of the single-vial injectable product – 20mg/10ml and 50mg/25ml.

PINC Comments: We view this as positive development for Sun Pharma. The annual sales of the product are estimated to be ~USD250mn. This could be 6-9months opportunity for Sun Pharma. We expect sales to be in the range of USD113-169mn and profit to the tune of USD 71-106mn (one-time EPS impact of Rs3.1-4.6).

Ranbaxy's Une says generic Lipitor sales to stay strong in 2012

In a recent conference call with the Chairman of Ranbaxy, Tsutomu Une, the key highlights included comments on the outlook of Lipitor, that it expects Ranbaxy to maintain the market share of generic Lipitor more than 40% in the US going forward as well. The key to the ramp up in the market share is attributed to the strong relationships with its business partners. Secondly on the Consent decree, he indicated that it was a five year project and that Ranbaxy has entered into a contract with Arun Sawhney to be the chief executive officer for the next five years, as of Jan1, 2012 to command and complete the project. He also emphasized on the fact that Ranbaxy is hiring outside consultants to improve the manufacturing practices and setting up an independent committee to check manufacturing data before filing future products for marketing approval to the regulators.

PINC Comments: With regards to generic Lipitor, Ranbaxy has been able to increase its market share WoW above our estimated level of 30% but we expect that to come at a price discount. The price erosion is now in range of 60-70%. On the other hand, Consent decree would also be a costly (impacting base margins) and time consuming process for the company.

Lupin enters into settlement with Santarus and Depomed over generic Glumetza

Santarus and Depomed have settled a patent dispute with Lupin allowing it to launch generic version of the diabetes drug Glumetza. Lupin could start selling the generic drug from February 1, 2016, or earlier under certain circumstances. Lupin had filed a paragraph IV certification with the USFDA to market generic versions of Glumetza (500mg and 1000mg tablets) prior to the expiration of the asserted patents. Depomed commenced the lawsuit within the requisite 45 day time period, resulting in an USFDA stay on the approval of Lupin's proposed products for 30 months which was expected to expire in May 2012. Lupin currently holds a tentative approval for the drug and believes to be the first applicant to file an ANDA, qualifying for 180-days marketing exclusivity. The drug is estimated to have annual US sales of USD71mn as per IMS data. In June 2011, Sun Pharma was also sued by Santarus and Depomed with 30-month stay expiring in Nov 2013.

PINC Comments: Although a small product, we expect Glumetza to contribute revenues of USD12mn and Net Profit of USD8.5mn during the exclusivity period.

Glenmark completes phase-I trials for pain, respiratory disorders molecule in Europe

Glenmark has completed Phase-I trials in Europe of its New Chemical Entity (NCE) used for pain and respiratory disorders (GRC 17536). Glenmark plans to initiate Phase-II trials for GRC 17536 in March 2012 and has completed regulatory submissions with drug regulators in the UK and Germany. The potential market size for asthma drug is about USD30bn globally, while it is about USD10bn for osteoarthritis and neuropathic pain drug.

PINC Comments: With GRC 17536 moving into next stage of clinical studies, the expertise of the company in the TRPA1 discovery programme is further boosted and Glenmark is strongly moving towards optimizing on the global demand for both the drugs under reference.

DoP to give final shape to the National Pharmaceuticals Pricing Policy within three to four weeks

The Department of Pharmaceuticals (DoP) has decided to give a final shape to the National Pharmaceuticals Pricing Policy (NPPP), 2011 within three to four weeks. According to sources, the DoP gave an assurance to the Supreme Court which heard the issue of the government's failure to bring down the prices of essential medicines on February 9. DoP has committed to the Supreme Court that it will submit the final draft policy to the Group of Ministers (GoM) on the Pharma policy led by Union Minister Sharad Pawar within three to four weeks. Post the evaluation, the department would incorporate the appropriate suggestions and give the final outline to the policy and submit the same to the GoM. However, the next hearing on the issue will be held on March 13.

PINC Comments: We view the NPPP-2011 to be prima facie negative for the sector as domestic formulation segment being a branded generic segment having higher margins would now face increased price regulation. Based on our back of the envelope calculation, we expect FY13E sales and earnings estimates for our coverage universe to be impacted by mid single digits. We expect GSK Pharma to be most negatively impacted by the development.

TENTATIVE ANDA APPROVALS

Company	API	Strengths	Brand	Mkt size (USD mn)
Matrix Labs	Atorvastatin Calcium	10,20,40,80mg	Lipitor	5,400
Mylan Labs	Minocycline Hydrochloride	65,115mg	Solodyn	100-150
DRL	Ropinirole	2,4,6,8,12mg	Requip Xl	250
Torrent Pharma	Moxifloxacin Hydrochloride	400mg	Avelox	200
Anchen Pharms	Tramadol Hydrochloride	100,200,300mg	Ultram ER	125
Apotex	Moxifloxacin Hydrochloride	0.5%	Vigamox/Moxeza	-
Watson	Tranexamic Acid	650mg	Lysteda	-
Teva	Finasteride	1mg	Proscar/Propecia	291
Cipla	Efavirenz; Emtricitabine; Tenofovir Disoproxil Fumarate	200,300,600mg	Atripla	3,000
Torrent Pharma	Olanzapine	2.5,5,7.5,10,15,20mg	Zyprexa	3,200

Source: USFDA, Company, PINC Research

FINAL ANDA APPROVALS

Company	API	Strengths	Brand	Mkt size (USD mn)
Apotex	Tizanidine Hydrochloride	2,4,6mg	Zanaflex	11.1
Sandoz	Cisatracurium Besylate	2mg base/ml ,10mg base/ml	Nimbex	-
Actavis Totowa	Carboplatin	50mg/5ml (10mg/ml) , 150mg/15ml (10mg/ml) , 450mg/45ml (10mg/ml) , 600mg/60ml (10mg/ml)	Paraplatin	35
Sun Pharma	Fexofenadine Hydrochloride	30,60,180mg	Allegra	-
Wockhardt	Fexofenadine Hydrochloride	30,60,180mg	Allegra	-
Mylan	Doxycycline Hyclate	150mg	Doryx	264
Mylan	Desloratadine	5mg	Clarinex	212
Onco Therapies	Doxorubicin Hydrochloride	2mg/ml	Doxil	250
Sun Pharma	Doxorubicin Hydrochloride	2mg/ml	Doxil	250
Macleods Pharms	Pantoprazole Sodium	20, 40mg base	Protonix	180-200
Alembic	Losartan Potassium; Hydrochlorothiazide	50mg; 12.5mg , 100mg; 12.5mg , 100mg; 25mg	Hyzaar	100-120
Sun Pharma	Olanzapine ODT	5,10,15,20mg	Zyprexa Zydis	360

Source: USFDA, Company, PINC Research

M&A Activities

Acquirer	Target	Deal Size	Rationale
Roche	Illumina	USD5.7bn	Through Illumina, Roche would expand its diagnostic products portfolio, potentially allowing the company to better target its medicines to individual patients.
Orbimed	Shasun Pharma	Rs500mn	Shasun would sell 11.93% stake at Rs76 per share. Proceeds from the issue would be used to part finance the ongoing capital expenditure plans of the company for FY13, which includes building a new manufacturing facility in Vizag.
Pfizer	Alacer Corp	Undisclosed	Through this acquisition, the Emergen-C family of products will be a part of Pfizer's portfolio.

Source: Company, PINC Research

Drug recalls

Product	Recalling firm	Manufacturer	Strength	Volume	Reason
Xanax	Pfizer	Pfizer	0.5mg	36,129 bottles	Failed USP Dissolution Test Requirements: Stability testing yielded an out-of-specification result for assay at the 36 month stability testing timepoint
Norgestrel and Ethinyl Estradiol tablets	Pfizer	Pfizer	0.3mg Norgestrel with 0.03mg Ethinyl Estradiol	171,928 Packages	Contraceptive tablets out of sequence: some blister packs may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence.
Motrin IB, Ibuprofen Tablets	McNeil Consumer Healthcare	Dr. Reddy's Laboratories Louisiana LLC	200 mg	11,990,160 bottles	Failed USP Dissolution Test Requirements: McNeil is recalling these products because testing of product sample showed that some caplets may not dissolve as quickly as intended when nearing their expiration date.
Norgestimate and Ethinyl Estradiol Tablets	Glenmark	Glenmark	0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg.	7 Lots	The recall is being implemented because of a packaging error, where select blisters were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date visible only on the outer pouch.
Azelastine Hydrochloride Ophthalmic Solution	Sun Pharma	Sun Pharma	0.05% 6ml	155,363 bottles	Impurities/Degradation Products: The total impurities results were out of specification (OOS) during the analysis of 18 month controlled stability sample.

Source: Company, PINC Research

Patent Settlements

Generic Company	Innovator	Brand	Mkt Size (USD mn)	Launch date	Comment
Watson	Jannsen Pharma	Ortho tricyclen Lo	-	Dec-2015	As part of the settlement, the parties have entered into a supply agreement whereby Janssen will manufacture and supply Watson with an authorized generic version of Ortho-Tricyclen Lo. Watson will have the right to market and distribute the authorized generic (AG) from December 31, 2015, or earlier under certain circumstances. Other details of the settlement were not disclosed.
Lupin	Santarus and Depomed	Glumetza	71	Feb-2016	Lupin has a tentative approval for the drug and believes to be the first to file an ANDA for the generic version qualifying for 180 days marketing exclusivity.

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
Avandia	Rosiglitazone	Tablet	Type II diabetes	SB Pharmco	95	17-Mar-12	Teva, DRL shared exclusivity	Mar-12	-
Avapro	Irbesartan	Tablet	High blood pressure	Sanofi Aventis	38	30-Mar-12	-	-	Alembic, Zydus Pharma, Mylan, Lupin, Macleod Pharm
Actos	Pioglitazone HCl	Tablet	Type 2 diabetes	Takeda	3,400	1-Aug-12	Ranbaxy, Mylan, Watson, Teva (AG)	Aug-12	Sandoz, Aurobindo, DRL, DRL, Wockhardt, Torrent, Synthon, Alphapharm, Cadila
Boniva	Ibandronate Sodium	Injectible	Osteoporosis	Roche	47	30-Mar-12	Teva, DRL shared exclusivity	Sep-12	Sun Pharma, Mutual Pharm
Clarinex & Clarinex D	Desloratadine & Desloratadine/ Pseudoephedrine	Tablet	Seasonal allergies	Schering	177/132	1-Dec-18	DRL, Orchid , Lupin, Sun Pharma, Glenmark, Sandoz, Ranbaxy, Mylan	Jul-12	-
Diovan	Valsartan	Tablet	High blood pressure	Novartis	1,585	21-Sep-12	Ranbaxy	Sep-12	-
Diovan HCT	Valsartan and Hydro chlorothiazide	Tablet	High blood pressure	Novartis	1,431	21-Sep-12	Mylan Sandoz (AG)	Sep-12	
Detrol	Tolterodine	Capsules	Overactive bladder	Pharmacia & Upjohn	46	25-Sep-12	-	Sep-12	Teva, Mylan, Impax, Sandoz
Geodon	Ziprasidone	Injectible	Schizophrenia	Pfizer	1,027	2-Mar-12	DRL, Lupin, Sandoz	Mar-12/ Sept-12	-
Lexapro	Escitalopram	Tablet	Depression	Forest	2,315	14-Mar-12	Teva, DRL, 10+ shared exclusivity	Mar-12	Sun Pharma
Provigil	Modafanil	Tablet	Psycho-stimulant	Cephalon	1,059	29-May 24	Ranbaxy, Teva, Mylan, Par	Q2CY12	Barr, Carlsbad-development partner: Watson, Caraco, Apotex, Hikma, Sandoz, Orchid
Plavix	Clopidogrel	Tablet	Prevent blood clots	Sanofi Aventis	6,666	17-May-12	Apotex: had to halt due to injunction	May-12	Cobalt, Ivax, Mylan, Roxane, Sandoz, Sun, Teva, DRL, Torrent
Revatio	Sildenafil	Tablet	Pulmonary arterial hypertension	Pfizer	178	27-Mar-12	-	-	Teva, Apotex, Mylan, Actavis, Amneal
Seroquel	Quetiapine	Tablet	Schizophrenia	Astrazeneca	4,866	26-Mar-12	Teva	Mar-12	Biovail, Accord, Handa Pharma
Singulair	Montelukast	Tablet	Asthma, allergy	Merck	3,219	3-Aug-12	Teva	Feb-12	Torrent, Endo Pharma, Glenmark, Mylan
Stalevo	Carbidopa; Entacapone; Levodopa	Tablet	Parkinson's disease	Orion	139	19-Oct-13	Sun Pharma, Wockhardt	Apr-12	-
Tricor	Fenofibrate	Tablet	Cholesterol lowering agent	Abbott	1,300	9-Jan-18	Teva lost its FTF as it did not get the tentative approval	Jun-12	Illinois, Lupin, Impax, Wockhardt, Biovail, Ranbaxy
Xopenex	Levalbuterol	Liquid	Asthma, COPD	Sunovion	415	25-Mar-13	Watson	Aug-12	Teva and its subsidiary Barr

Source: Company, PINC Research

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

PINC bright thinking

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