PINC Pharma Monthly
Sector: Pharma
BSE Sensex: 15,455

MONTHLY Rx

Sector View: Neutral

PHARMA MONTHLY UPDATE

NEWS ROUNDUP FOR THE MONTH - DECEMBER

DOMESTIC:

- Ranbaxy launches generic version of Lipitor with a profit sharing deal with Teva
- Ranbaxy launches authorized generic version of Caduet
- Ranbaxy signs consent decree with the USFDA
- Ranbaxy Labs' consent decree could engulf multiple facilities
- Dr Reddy's shifts drug discovery focus away from heart diseases
- Dr Reddy's offers VRS to Mexico arm employees
- Dr Reddy's splits its marketing division, Acura to resurrect its ailing domestic business
- Dr Reddy's plans Lipitor generic launch in June
- Dr Reddy's launches pain treatment cream 'Supamove' in India
- Lupin's generic Fortamet launch is prohibited due to grant of Preliminary injunction
- Lupin eyes USD300mn revenues from Japan in the next 2 years
- Lupin to replicate Japan model for expansion in various markets
- Lupin receives final approval for Tricor
- Glenmark to initiate filing for Crofelemer as Salix submits NDA
- Glenmark gets DCGI nod for phase III trials of Crofelemer in India
- Sun Pharma's Dilip Shanghvi buys 3.5% stake in Natco Pharma
- IsZo Capital Management LP, minority shareholder of Taro rejects Sun Pharma's Taro acquisition proposal
- Cadila acquires Biochem Pharmaceuticals
- Orchid Chemicals gets USD1.5mn milestone payment from Merck
- Orchid Chemicals to raise USD100mn ECBs to redeem its outstanding FCCBs
- Clinigene, subsidiary of Biocon enters into collaborative clinical research services agreement with Pacific Biomarkers
- Opto Circuits US arm supplies cardiac devices to Australian soccer clubs

GLOBAL:

- Teva failed to win US clearance for the first OTC emergency contraceptive
- WHO approves Mylan generic HIV drugs for use in developing world
- Mylan wins ruling, overturning generic Doryx antibiotic ban
- Amgen plans to team up with Watson on generics
- GSK to sell non core OTC brands in US and Canada to Prestige Brands Holdings for USD660mn

INDUSTRY:

- 500 drug companies told to pay Rs40bn penalty for over charging

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

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PRICE PERFORMANCE

	1M	3M	12M
BSE Sensex	(4.1)	(6.1)	(24.2)
BSE HC Index	(3.1)	0.05	(12.4)
Apollo Hospitals	(7.3)	8.7	20.4
Aurobindo	(6.5)	(31.4)	(67.3)
Biocon	(14.1)	(18.9)	(34.4)
Cadila	(0.2)	(7.2)	(8.9)
Cipla	(2.5)	13.7	(13.3)
Divis Labs	3.8	5.6	20.1
Dr Reddy's	0.03	6.4	(6.4)
Fortis healthcare	(25.9)	(33.1)	(41.7)
Glaxo	1.5	(7.0)	(16.3)
Glenmark	(6.8)	(9.1)	(16.8)
Ipca	10.2	10.4	(16.1)
Lupin	(5.6)	(5.6)	(5.7)
Opto Circuits	(1.1)	(9.8)	(23.6)
Orchid Chemicals	(17.3)	(20.0)	(56.6)
Piramal Healthcare	3.7	5.8	(17.6)
Ranbaxy	(6.8)	(21.2)	(31.4)
Sterling Biotec	(2.5)	13.4	(9.7)
Sun Pharma	(5.3)	7.6	3.2

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	320	256.6	23.8	20.5	3.6	3.0	17.3	14.2	Reduce	331
Dr Reddy's	1,589	268.9	17.0	15.7	3.3	2.9	21.6	17.2	Sell	1,442
Glenmark	291	78.5	17.3	14.1	2.7	2.3	12.8	10.5	Buy	345
GSK Pharma	1,937	164.0	27.0	23.4	6.1	5.2	18.2	15.1	Sell	1,822
Ipca	281	35.7	12.2	12.0	1.8	1.6	9.1	8.7	Sell	279
Lupin	447	199.5	21.0	18.6	3.0	2.5	17.2	14.1	Accumulate	513
Ranbaxy	405	170.4	27.4	24.1	1.9	1.8	21.3	13.3	Reduce	355
Sun Pharma	497	514.5	25.0	21.8	6.6	5.6	19.4	16.4	Reduce	494

Source: Company, PINC Research

KEY NEWS ANALYSIS

Ranbaxy launches generic version of Lipitor with a profit sharing deal with Teva

Ranbaxy announced the launch of generic Lipitor (10, 20, 40 and 80mg tablets) from Ohm Labs. It also announced an agreement with Teva under which it would share a portion of the profits earned during the exclusivity period.

PINC Comments: Post the intense competition and profit sharing agreement with Teva, we expect generic Lipitor to contribute USD486mn (at 30% market share) to the revenues and NPV of Rs25/share during the exclusivity period. Although the terms of the agreement with Teva are not disclosed, it seems to be more of the nature of an insurance cover. We estimate Teva to share at-least 15-20% (USD72-97mn) of the profits earned from generic Lipitor during the exclusivity period. As per Bloomberg, for the week ended Dec 16, Ranbaxy has been able to increase its market share to 21% as compared to 11% in the previous week. The market share of Pfizer has decreased to 46% (48%) followed by Watson at 33% (41%).

Ranbaxy launches authorized generic version of Caduet

Ranbaxy announced the launch of authorized generic (AG) version of Caduet (Amlodipine Besylate and Atorvastatin Calcium tablets) in the US which is used for treatment of hypertension. Caduet had US sales of USD339mn as per IMS data. Ranbaxy would make available the entire range of Caduet.

PINC Comments: As Ranbaxy didn't receive the approval in the stipulated time, it had to forfeit its exclusivity, wherein Mylan grabbed the opportunity with a Day-1 launch of Caduet. Since Ranbaxy is now an AG, which would entail revenue sharing with Pfizer, we estimate generic Caduet to contribute USD23mn in sales and USD4mn in profit over the next 12 months.

Ranbaxy signs a consent decree with the USFDA

Ranbaxy has signed a consent decree with the USFDA committing to strengthen its procedures and policies as well as to comply with cGMP. The company has also indicated that it intends to make a provision of USD500mn with regards to investigation by the U.S. DOJ. The company has adequate resources to fund the penalty and does not plan to raise any debt for the same.

PINC Comments: The consent decree is an important step towards the long awaited USFDA and DOJ issue resolution, and a sentimental positive for the stock. We are estimating launches of products from the Indian facilities from H2CY12. Further, Ranbaxy does not expect any additional penalty over and above USD500mn. However, the amount is higher than estimated (USD250mn) and would negate the expected cash flow of USD450mn from the FTF opportunities in CY12.

Ranbaxy Labs' consent decree could engulf multiple facilities

The consent decree entered by Ranbaxy with USFDA may involve more than just the two Indian facilities at Paonta Sahib and Dewas which have been on high alert over the past few years. The high cost of the consent decree may prove to be an exhaustive experience for Ranbaxy and entail more than just the amount of the penalty fee. Ranbaxy has made a provision of USD500mn with regards to investigation by US DOJ. Although the fine print of the consent decree is not available, Ranbaxy's agreement could encompass four US facilities and three facilities outside of the US (which could include Paonta Sahib and Dewas) and mandate the creation of a chief data reliability officer and data integrity expert, alongside deputing additional data quality auditors, if lawyers quoted in a US health policy publication are to be believed.

PINC Comment: While we still wait for the fine print on the consent decree which is likely to be out in next few weeks, inclusion of other facilities in the consent decree in addition to Dewas and Paonta Sahib facilities would be a negative surprise.

Dr Reddy's offers VRS to Mexico arm employees

Dr Reddy's Laboratories (DRL) has announced a voluntary retirement scheme (VRS) for employees of its Mexico subsidiary as one of its cost-cutting measures, trimming the over- staffing of the company. The company has taken such measures in the past as well. Last year, it reduced its workforce in Germany from 200 to around 80. Following that, the company announced VRS scheme for its Indian workforce, which comprised of nearly 14,000 employees and allotted Rs136mn towards the total programme that was completed in Sept 2011. The latest is the announcement for the Mexico subsidiary which reported strength of 340 people at the time of the acquisition.

PINC Comments: The move has been in the right direction by the company to reduce the burden of overstaffed business and is expected to be beneficiary in the long run.

Lupin's generic Fortamet launch is prohibited due to grant of Preliminary injunction

The District court of Delaware has granted Shionogi Pharma's (Sciele Pharma) motion for preliminary injunction on generic Fortamet thereby prohibiting Lupin from further selling the product in the US till the outcome of the case. However, the court denied the motion of Shionogi Pharma for recall of Lupin's already distributed generic Fortamet during the two weeks of at-risk launch in October 2011. The court also ordered Shionogi Pharma to deposit a security bond of USD15mn for losses likely to be suffered by Lupin in next one year, pending the outcome of the case. Earlier, on Sept 30, 2011, Lupin had launched the generic Fortamet at-risk triggering its 180-days exclusivity. However, on October 12, 2011 Shionogi Pharma filed a preliminary injunction in the court to prohibit Lupin from further selling of the product. The court on October 17th, 2011 issued an order enforcing standstill agreement whereby Lupin agreed not to sell any generic Fortamet in US until the next court hearing concerning the preliminary injunction.

PINC Comments: Lupin has already lost one month of exclusivity on account of the standstill agreement and is likely to lose the remaining exclusivity on back of the injunction. Further, Watson and Mylan are also expected to launch the product in CY2012. However, during the two weeks of at-risk launch in October 2011, Lupin was able to fill the channels for couple of months there by partially monetizing the opportunity. As a result, we don't expect Lupin to be substantially impacted by the grant of preliminary injunction. Further, the denial of recall and security bond of USD15mn by Shionogi Pharma is a bit positive, if the outcome is in Lupin's favour.

Lupin receives final approval for Tricor

Lupin has received the USFDA final approval for generic Tricor (fenofibrate, strength-48,145mg). Among the various other generic filers namely Teva, Biovail, Impax, Ranbaxy and Wockhardt; Lupin is the only company that has received the final USFDA approval.

PINC Comments: Teva in its CY12 guidance concall has announced that it does not intend to launch generic Tricor in CY12, which would forfeit its 180-days exclusivity. This would be positive for Lupin as it would result into early launch (July 2012) and limited competition opportunity. As per IMS data, generic Tricor is estimated to have USD1.3bn in sales, we expect Lupin to garner at least 20% market share which would result in revenue of USD31mn. Early launch is likely to result in an additional revenues of USD8-10mn for Lupin in FY13.

Lupin to replicate Japan model for expansion in various markets

Lupin plans to replicate its Japanese business model of expansion through acquisitions in the markets like Latin America, Europe and Canada as it looks to strengthen overseas business by FY13. Maintaining its growth trajectory in the Japanese markets (eyeing USD300mn in next two years backed by the recent acquisition of Irom Pharma), the company has declared markets like Brazil, Argentina and Europe to be on its priority. Currently, in Brazil the firm has a tie up with state- run Farmanguinhos for marketing of its products, while in Argentina it has arrangements with third parties to distribute WHO-approved TB drugs. In terms of markets of interest, the company is evaluating entries into certain markets in Latin America.

PINC Comments To expand its foot-print in the global market, Lupin has prudently adopted the inorganic growth route. In line with this, the company made small acquisitions across geographies prominent among these being the acquisition of Kyowa in the growing Japanese market. We believe that Lupin's strategy to acquire relatively smaller companies to get a foothold in new geographies is paying off.

Glenmark to initiate filing for Crofelemer as Salix submits NDA

With regards to Crofelemer, Napo Pharma (Napo) has terminated the collaboration agreement with Glenmark entered in July 2005 pertaining to development and commercialization of Crofelemer in emerging countries (140 countries). Napo has alleged that Glenmark has breached the terms of the agreement. Further, Napo has also terminated agreement with Salix Pharma (Salix) to commercially develop Crofelemer in US, Europe, Japan, Canada and Mexico. Glenmark has stated that Napo does not have any right to terminate the agreement and requested the arbitration panel to issue an interim order directing Napo to comply with the collaboration agreement. The second leap of development involves the fact that Salix has submitted the NDA to the USFDA.

PINC Comments: Although the termination of contract with Napo was a negative for the company, the submission of the NDA by Salix has brought Glenmark back on track to start with its filings for the drug to be launched in 140 countries. The company remains affirm on launching the drug in the next 15-18 months.

Zydus Cadila acquires Biochem Pharmaceuticals

Zydus Cadila (CDH) has acquired 100% stake in Biochem, a Mumbai-based mid-sized drug company. Biochem has a strong presence in manufacturing and marketing of antibiotics. It has presence in therapeutic areas of antibiotics, cardiovascular, anti-diabetic and oncological segments with the top five brands of the company together contributing 40% of the company's sales. Three of Biochem's brands fall in the top 300 pharma brands of India, stated a CDH's release. India, as one of the fastest growing drug market, lures more local players to strengthen presence through domestic acquisitions.

PINC Comments: We expect following rationale for the acquisition 1) Immediate boost to the domestic top-line as Biochem acquisition is expected to contribute ~14% to the domestic formulation revenues 2) Biochem is estimated to have OPM of 17-18% which would be marginally below CDH's OPM. 3) Minimal overlap across portfolio. 4) CDH would be able to increase the penetration of the top brands of Biochem across India through its strong field force.

TENTATIVE ANDA APPROVALS

Company	API	Strengths	Brand	Mkt size (USD mn)
Teva	Atorvastatin Calcium	10,20,40,80mg base	Lipitor	5,400
Lupin	Duloxetine Hydrochloride	20,30,60mg	Cymbalta	3,500
Akorn Inc	Dexmedetomidine Hydrochloride	100mcg (base) /ml	Precedex	-
Mutual Pharm	Ibandronate Sodium	150mg	Boniva	-
Matrix Labs	Candesartan Cilexetil	4,8,16,32mg	Atacand	216

Source: USFDA, Company, PINC Research

FINAL ANDA APPROVALS

Company	API	Strengths	Brand	Mkt size (USD mn)
Breckenridge Pharm	Methscopolamine Bromide	2.5,5mg	Pamine	7
Apotex	Trospium Chloride	20mg	Sanctura	25
Apotex	Metformin Hydrochloride	500,850mg, 1gm	Fortamet	83
Sun Pharma	Tramadol Hydrochloride	100,200,300mg	Ultram	125
Lupin	Duloxetine Hydrochloride	20,30,60mg	Cymbalta	3,500
Onco Therapies	Cytarabine	20mg/ml	Cytosar-U	12
Mylan	Metoprolol Succinate	25, 50, 100, 200mg base tartarate	Toprol Xl	1,180
Mylan	Levetiracetam	500,750mg	Keppra	163
Hospira	Ampicillin Sodium; Sulbactam Sodium	1gm; 500mg, 2gm; 1gm ,10gm; 5gm base/vial	Unasyn	50
Acs Dobfar	Cilastatin Sodium; Imipenem	250, 500mg/Vial	Primaxin	140
Onco Therapies	Fludarabine Phosphate	50, 25 mg/ml	Fludara	15
Perrigo R and D	Desloratadine	5mg	Clarinex	212
Novast Labs	Norethindrone; Ethinyl Estradiol	0.5; 0.035mg , 0.75; 0.035mg,1; 0.035mg ,0.035; 0.4mg ,0.035; 1mg	Femcon Fe	35
Novartis	Letrozole	2.5mg	Femara	556
Watson	Ursodiol	250,500mg	Urso 250	60
Sandoz	Voriconazole	50,200mg	Vfend	189
Ranbaxy	Acetaminophen	650mg	Tylenol	-
Amneal Pharms	Felbamate	600mg/5ml	Felbatol	17.6
Aurobindo Pharma	Amoxicillin; Clavulanate Potassium	200,28.5 , 400; 57 ,600; 42.9mg base/5ml	Augmentin	-
Caraco	Dexmedetomidine Hydrochloride	100mcg	Precedex	-
Lupin	Fenofibrate	48,145mg	Tricor	1,300

Source: USFDA, Company, PINC Research

M&A Activities

Acquirer	Target	Deal Size	Rationale
Vivimed Labs	Uquifa	USD55mn	The acquisition of the API and intermediate player is expected to boost Vivimed's growth in the geographies of Europe and America as well as compliment its product mix.
Momenta	Virdante Pharma	Upfront: USD4.5mn	The agreement is to buy the Sialic switch assets of Virdante Pharma, including intellectual property and cell lines, relating to the sialylation of intravenous immunoglobulin (IVIG) and other proteins Momenta may make additional contingent milestone payments, which, if all development and regulatory milestones are achieved, will total USD51.5mn.
Astrazeneca	Guangdong BeiKang Pharmaceutical	Undisclosed	The deal would give Astrazeneca the opportunity to grow in the emerging markets, bringing generic products into China. It would get access to a portfolio of injectable medicines used to treat infections, which will be sold in China under the AstraZeneca brand.
Valeant Pharma	Dermik (Dermatology business of Sanofi)	USD422.5mn	The scope of the transaction includes Dermik assets, which consist of an aesthetic and therapeutic business in the US and Canada, as well as an aesthetic business around the world.
Cadila Healthcare	Biochem Pharma	Undisclosed	The acquisition is expected to be an immediate boost to the domestic top-line as Biochem acquisition is expected to contribute ~14% to the domestic formulation revenues. Also with minimal overlap across the portfolio, CDH would be able to increase the penetration of the top brands of Biochem across India through its strong field force.

Source: Company, PINC Research

Drug recalls

Product	Recalling firm	Manufacturer	Strength	Volume	Reason
Panadol	Glaxo	Glaxo	-	602,578 units	cGMP Deviations; some of the analytical process validation activities did not contain primary data.
Etodolac	Gsms, Camarillo	Taro	Etodolac:200,300,400,500mg, ER: 400,500,600mg Capsule: 200,300mg	10,185 bottles	Labeling: Incorrect or Missing Package Insert: Certain lots of Etodolac Immediate Release tablets were packaged with Etodolac Extended Release inserts.
Hydroxyzine Pamoate Capsules	Watson	Patheon Pharma	50mg	288 bottles	cGMP Deviations: Some capsules were found to have an additional cap over one-half of the capsule body
Fluoxetine Capsules	Teva	Pliva Krakow S.A	10mg, 1000-Count Capsules Per Bottle	1,199 bottles	cGMP Deviations: Firm's laboratory investigation was not performed in accordance with strict adherence to the "FDA Guidance for Industry Investigating Out-of-Specification Test Results for Pharmaceutical Production."
Tetracycline Hydrochloride	Teva	Barr Labs	500mg	2,572 boxes and bottles	cGMP Deviations: Product is being recalled due to an Out-of-Specification for particle size.
Metformin Hydrochloride Tabs	Aurolife Pharma	Aurobindo Pharma	1000mg	21,624 bottles	Labeling: Label Mix-up: Some bottles of Metformin Tablets 1000 mg were mislabeled as 500 count instead of 100 count.

Source: Company, PINC Research

Patent Settlements

Generic Company	Innovator	Brand	Mkt Size (USD mn)	Launch date	Comment
Lupin	Genzyme	Renagel/Renvela	171/295	*Sept 2014	Genzyme had also sued Sandoz; Watson and Endo pharma for the same product, outcome of the same is awaited. The launch date has not been indicated.
Sun Pharma	Sanofi and BMS	Plavix	6,000	*May, 2012	As per the settlement, Sun has been stopped from making or selling its proposed generic except as permissible under the parties' deal. Sun has entered into a licence agreement with Sanofi-BMS. This could be in form of an authorised generic that Sun could make in case of Plavix as other generic drug makers are also expected to enter the market from day one.

*Source: Company, PINC Research; Note: *Patent expiry*

FTF OPPORTUNITIES

Company	API	Brand	Mkt Size	Comment
Mylan	Norethindrone and Ethinyl Estradiol	Generess Fe	USD4.5mn	Mylan believes that this application submitted is the first substantially complete ANDA containing a Paragraph IV certification and expects it to qualify for 180 days of marketing exclusivity upon final approval.

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	225	17-Mar-12	Teva, DRL shared exclusivity	Mar-12	-
Avapro	Irbesartan	Tablet	High blood pressure	Sanofi Aventis	38	30-Mar-12	-	-	Alembic, Zydus Pharm, Mylan, Lupin, Macleod Pharm
Boniva	Ibandronate Sodium	Injection	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	Jul-12	-
Lexapro	Escitalopram	Tablet	Depression	Forest	2,259	14-Mar-12	Teva, DRL, 10+ shared exclusivity	Mar-12	Sun Pharma
Seroquel	Quetiapine	Tablet	Schizophrenia	Astrazeneca	357	26-Mar-12	Teva	Mar-12	Biovail, Accord, Handa Pharma
Geodon	Ziprasidone	Injection	Schizophrenia	Pfizer	864	2-Mar-12	DRL, Lupin, Sandoz	Mar-12	-
Stalevo	Carbidopa; Entacapone; Levodopa	Tablet	Parkinson's disease	Orion	139	19-Oct-13	Sun Pharma, Wockhardt	Apr-12	-
Plavix	Clopidogrel	Tablet	Prevent blood clots	Sanofi Aventis	5,020	17-May-12	Apotex: had to halt due to injunction	Jul-12	Cobalt, Ivax, Mylan, Roxane, Sandoz, Sun, Teva, DRL, Torrent

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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