

## Monthly: November 2011 – US market review **US IMS review for November 2011 and expected catalysts**

December 21, 2011

### **Ranbaxy**

For Nov 2011, US Rx was up 1.4% y-y. Ranbaxy garnered 14% and 1.6% market share in Lipitor and Caduet, respectively, for the week ended 9 Dec. The launch of Caduet AG and Lipitor in partnership with Teva limits downside to the stock, in our view. However, we remain cautious on the back of expectations from a revival of base business being built into the stock. Investors should watch out for market share gains on Lipitor/Caduet.

### **Sun Pharma + Taro**

Prescriptions rose 1.8% y-y. For Nov 2011, Sun had a 20.4% share in generic Uroxatral (USD200mn) and Taro had a 6.3% market share in generic Aldara (USD350mn) for the week ended 9 Dec. Femara (USD650mn) market share is 2.5%.

### **Dr Reddy's**

Dr Reddy's (DRRD) US TRx grew 19% y-y. Prograf market share grew to 19% and Prevacid market share is 22.4%. Amongst recent launches, DRRD had 34.5% and 10.5% market share in generic Levaquin (USD1.5bn) and generic Arixtra (USD340mn), respectively. For the week ended 9 Dec 2011, Teva and DRRD garnered 43.6% and 32.4% market share for Zyprexa and Zyprexa ODT, respectively. Key near-term product opportunities: Geodon, Seroquel, Prevacid OTC, Lipitor.

### **Lupin**

Overall, Rx recorded 11.5% y-y growth; Suprax TRx fell -6% y-y while Antara was flat y-y. LPC's market share in generic Levaquin (USD1.5bn) declined to 13.3% from 40.5% in Aug 2011. LPC launched generic Fortamet (USD70mn) and garnered 60% market share; an injunction has halted LPC from selling Fortamet until the lawsuit is adjudged. However, LPC was not asked to recall inventory filled in the channel.

### **Zydus Cadila**

CDH's US prescription grew 34% y-y. Hospira shared that it has been able to maintain ~50% market share and ~50-55% price discount in generic Taxotere (USD1.2bn).

### **Glenmark**

Overall prescriptions grew 17% y-y. Traction in older products and recent launches like Ondansetron, omeprazole and Mupirocin fuelled growth. GNP launched generic Malarone (USD66mn) with exclusivity and gained 78% market share for the week ended 9 Dec. We believe GNP is the sole filer for the product and exclusivity could last more than 180 days.

### **Anchor themes**

The US opportunity appears to be the most dominant growth theme for Indian generic pharmaceutical companies. Indian generics hold ~20% market share in generic volumes in the US. ~One-third of the pending ANDA applications with the USFDA are filed by Indian companies.

### **Nomura vs consensus**

We expect revenues from the US market to outperform expectations.

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See Appendix A-1 for analyst certification, important disclosures and the status of non-US analysts.

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## Watch out for...

- Ranbaxy's FDA-DoJ resolution and TRx trends of generic Lipitor (USD7.8bn) –**  
 For the week ended 9 Dec 2011, Ranbaxy had a 14% share in Lipitor (USD7.8bn), compared to Watson's 45%. We note that the prescription trends for Aricept, and most recently Zyprexa, suggest that market shares during the exclusivity period are largely established by the second/third week. Thus, based on the current trend, it appears that Ranbaxy's market share can stabilise at 20-25%, in our view. We note that this is below our current estimate of a 45% market share for Ranbaxy during the exclusivity period. Given Ranbaxy's launch of Lipitor in partnership with Teva, investors' focus should now shift to the FDA-DoJ resolution and potential penalty, in our view. We believe current Street estimates account for a revival in the base business post resolution and a potential penalty of USD200-500mn. On generic Lipitor, we believe, the upside for Ranbaxy should be limited given higher competitive intensity and sharing of upside with Teva. We now believe Ranbaxy is likely to gain less than our expected USD560mn during exclusivity, perhaps USD250-350mn.
- Dr Reddy's Arixtra (USD340mn) traction and competition –** DRRD launched generic Arixtra in July 2011. Apotex is AG. So far IMS data suggest DRRD has gained 10.5% market share (week ended 9 Dec). We believe that the slow ramp-up is disappointing. The IMS data suggest there is no improvement m-m. As per the company, the ramp-up should be visible in Jan-Jun 2012 as yield improves, more retail customers are acquired and hospitals are serviced.
- Dr Reddy's Seroquel (USD4.4bn) launch in March 2012 and an undisclosed product –** Dr Reddy's has classified Seroquel (USD4.4bn) as a limited competition opportunity given difficulty in bioequivalence studies (recruitment of schizophrenic patients). The product is losing patent protection in March 2012. Dr Reddy's has tentative approval for only 25mg (USD544mn). Given that Seroquel is a large product, limited competition can present material upside. Additional approvals and competitive landscape are something to watch for over the next three months. Industry channel checks suggest that Par is an authorised generic, and there are ~4 ANDA filings so far. DRRD also has an undisclosed product opportunity slated for FY12. Ramp-up in olanzapine market share could also be an important catalyst, in our view. Teva currently has 43.6% market share (9 Dec).
- Glenmark's Malarone (USD 70mn) ramp-up and Cutivate (USD50mn) launch –** GNP launched Malarone in Sep 2011 and has garnered a 78% market share (week ended 9 Dec). Glenmark is first to file (FTF) and has 180-day exclusivity. There are no subsequent ANDA filers yet as per our knowledge and no authorised generic. We expect Glenmark's exclusivity to stretch well beyond 180 days. Regarding Cutivate, Glenmark had settled for a launch in Mar 2012 under license of the innovator in exchange of royalties. Glenmark is FTF on the product. We believe the product is a limited competition opportunity as Perrigo is the only subsequent filer of which we are aware. Perrigo is expected to launch in Sep 2012 as GNP's exclusivity expires.
- Lupin's OCs approvals and Geodon –** LPC received two OCs approvals for Nor QD (USD52mn) and LoSeasonique (USD27mn). We believe the unfolding of the OC pipeline is a positive for Lupin due to limited competition in the space. We believe LPC is shared FTF on Geodon (USD1bn) along with DRRD and Sandoz and the earliest possible launch is in Mar 2012 (which may be delayed by six months in case Pfizer is granted pediatric exclusivity). As per the agreement with Warner Chilcott, Lupin is the authorised generic for Asacol 400mg (USD700mn) and will launch on another generic entry. However, uncertainty remains on generic launch and is not built into estimates.
- Sun Pharma's Prandin (USD200mn) launch, Aldara (USD350mn) and Cardizem CD (USD100mn) market share ramp-up –** Prandin approval and launch remain a distinct possibility in the near term. The product was initially filed from Caraco, but Sun has undertaken site transfer. Sun has received a favourable patent invalidity judgment, in the District court and the innovator has appealed the invalidity judgment. Post exclusivity, other filers such as Mylan, Paddock and others are likely to enter the space. Sun's market share ramp-up in Cardizem CD would be a positive, in our view. However, Taro's 6.3% market share in Aldara is below expectation and we would watch out for any ramp-up in the space as it is a limited competition opportunity.

For the week ended 9 Dec 2011, Ranbaxy had a 14% share in Lipitor (USD7.8bn) compared to Watson's 45%.

DRRD only has a 10.5% market share in generic Arixtra, which is disappointing, in our view. Management expects a ramp-up in Jan-Jun 2012 as supply constraints ease.

DRRD expects Seroquel (USD4.4bn) to be a limited competition opportunity.

GNP has garnered a 78% market share in Malarone and is slated to launch Cutivate in Mar 2012 with exclusivity. PRGO is the only other Para IV filer for Cutivate of which we are aware.

LPC's Asacol AG launch may come as a positive surprise in case it materialises. The unfolding of the OC pipeline is a positive, in our view.

While Sun has been unable to successfully challenge the change in use code, it has succeeded in invalidating the patent.

# US generic market — overview

## Snapshot of the US generic market

**Fig. 1: Prescriptions in the US generic market**

| TRx in '000        | Dec-10         | Jan-11         | Feb-11         | Mar-11         | Apr-11         | May-11         | Jun-11         | Jul-11         | Aug-11         | Sep-11         | Oct-11         | Nov-11         |
|--------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| TEVA PHARM USA     | 49,004         | 47,541         | 44,642         | 46,981         | 40,884         | 41,322         | 39,013         | 36,239         | 38,493         | 37,413         | 37,887         | 38,699         |
| MYLAN LABS, INC.   | 32,125         | 31,784         | 29,383         | 32,958         | 30,258         | 31,090         | 30,359         | 29,214         | 30,629         | 28,951         | 29,295         | 29,272         |
| WATSON PHARMA      | 18,011         | 17,814         | 17,263         | 18,815         | 17,157         | 18,221         | 18,683         | 17,801         | 18,924         | 17,941         | 17,907         | 18,079         |
| NOVARTIS           | 18,495         | 18,167         | 17,207         | 19,141         | 16,934         | 16,822         | 15,960         | 14,532         | 15,502         | 15,146         | 15,141         | 15,351         |
| LUPIN PHARMA       | 12,449         | 12,647         | 11,747         | 13,667         | 12,544         | 12,891         | 12,857         | 12,645         | 13,465         | 12,885         | 13,014         | 13,106         |
| ENDO PHARM INC.    | 11,548         | 11,781         | 11,330         | 12,695         | 11,703         | 11,990         | 11,888         | 11,327         | 12,615         | 12,380         | 12,471         | 12,685         |
| AMNEAL INC         | 9,230          | 9,289          | 8,683          | 9,994          | 9,134          | 9,499          | 9,856          | 9,195          | 9,824          | 9,652          | 9,720          | 9,647          |
| PFIZER             | 9,654          | 9,507          | 8,943          | 9,760          | 8,762          | 8,743          | 8,248          | 7,318          | 7,730          | 7,549          | 7,684          | 7,903          |
| ZYDUS PHARM        | 5,074          | 5,266          | 5,053          | 5,801          | 5,453          | 5,721          | 5,720          | 5,680          | 6,584          | 6,367          | 6,362          | 6,508          |
| COVIDIEN           | 6,406          | 6,328          | 5,905          | 6,484          | 6,091          | 6,196          | 5,980          | 5,969          | 6,601          | 6,356          | 6,412          | 6,492          |
| DR REDDY INC       | 5,681          | 5,752          | 5,507          | 6,533          | 6,003          | 6,018          | 6,222          | 6,169          | 6,497          | 6,125          | 6,226          | 6,335          |
| ACTAVIS US         | 5,484          | 5,456          | 5,161          | 5,887          | 5,459          | 5,719          | 5,908          | 5,648          | 6,037          | 5,608          | 5,593          | 5,651          |
| SUN PHARMACEUTICAL | 5,365          | 5,376          | 4,840          | 5,663          | 5,103          | 5,144          | 5,322          | 5,120          | 5,560          | 5,100          | 5,151          | 5,258          |
| BOEHRINGER INGEL   | 4,650          | 4,495          | 4,149          | 5,207          | 5,320          | 5,769          | 5,869          | 5,586          | 5,930          | 5,354          | 5,099          | 5,159          |
| WEST WARD          | 4,001          | 4,034          | 3,758          | 4,306          | 4,213          | 4,606          | 4,562          | 4,257          | 4,450          | 4,569          | 4,773          | 4,988          |
| AUROBINDO PHARM    | 2,946          | 3,033          | 2,944          | 3,543          | 3,326          | 3,508          | 3,510          | 3,539          | 4,253          | 4,584          | 4,744          | 4,829          |
| CAMBER PHARM       | 1,621          | 1,845          | 1,784          | 2,219          | 2,470          | 3,096          | 3,283          | 3,603          | 3,848          | 3,784          | 3,931          | 4,020          |
| RANBAXY LABS LIMIT | 4,187          | 4,242          | 3,956          | 4,486          | 4,105          | 3,992          | 3,766          | 3,577          | 3,948          | 3,799          | 3,884          | 3,944          |
| GLENMARK PHARMA    | 2,713          | 2,796          | 2,720          | 3,223          | 2,964          | 3,140          | 3,170          | 3,050          | 3,325          | 3,042          | 2,982          | 3,039          |
| LANNETT            | 3,162          | 3,088          | 2,836          | 3,225          | 3,023          | 3,149          | 3,148          | 2,958          | 3,117          | 2,959          | 2,970          | 2,980          |
| NORTHSTAR RX       | 2,200          | 2,274          | 2,170          | 2,534          | 2,423          | 2,591          | 2,735          | 2,585          | 2,847          | 2,771          | 2,894          | 2,719          |
| PAR PHARM          | 2,795          | 2,942          | 2,743          | 3,086          | 2,756          | 2,821          | 2,798          | 2,613          | 2,756          | 2,641          | 2,691          | 2,716          |
| TORRENT PHARM      | 1,703          | 1,716          | 1,608          | 1,860          | 1,548          | 1,537          | 1,784          | 2,008          | 2,250          | 2,209          | 2,290          | 2,389          |
| PERRIGO INC        | 2,125          | 2,172          | 2,133          | 2,409          | 2,214          | 2,264          | 2,376          | 2,192          | 2,455          | 2,373          | 2,374          | 2,276          |
| HI-TECH PHARMA INC | 1,625          | 1,598          | 1,597          | 1,780          | 1,585          | 1,677          | 1,590          | 1,387          | 1,682          | 1,985          | 2,112          | 2,177          |
| CADISTA INC        | 2,141          | 2,176          | 2,070          | 2,381          | 1,961          | 1,711          | 1,657          | 1,693          | 1,816          | 1,833          | 1,893          | 1,948          |
| UCB INC            | 1,520          | 1,540          | 1,473          | 1,645          | 1,514          | 1,568          | 1,574          | 1,480          | 1,577          | 1,512          | 1,739          | 1,782          |
| NESTLE S.A.        | 1,170          | 1,153          | 1,114          | 1,346          | 1,339          | 1,394          | 1,446          | 1,436          | 1,459          | 1,303          | 1,279          | 1,332          |
| NYCOMED US INC     | 1,497          | 1,425          | 1,285          | 1,439          | 1,281          | 1,287          | 1,278          | 1,138          | 1,199          | 1,085          | 1,073          | 1,064          |
| APOTEX CORP        | 1,193          | 1,270          | 1,227          | 1,469          | 1,407          | 1,424          | 1,236          | 1,084          | 1,090          | 929            | 937            | 1,020          |
| <b>TOTAL</b>       | <b>247,017</b> | <b>246,873</b> | <b>233,132</b> | <b>261,053</b> | <b>238,105</b> | <b>245,178</b> | <b>242,221</b> | <b>230,915</b> | <b>248,108</b> | <b>238,823</b> | <b>242,178</b> | <b>246,062</b> |

Source: IMS, Nomura research

In November 2011, generic prescriptions recorded 4% y-y growth. Zydus Cadila, Dr Reddy's and Glenmark grew strongly in the month, with TRx growth at 34%, 19% and 16% y-y, respectively.

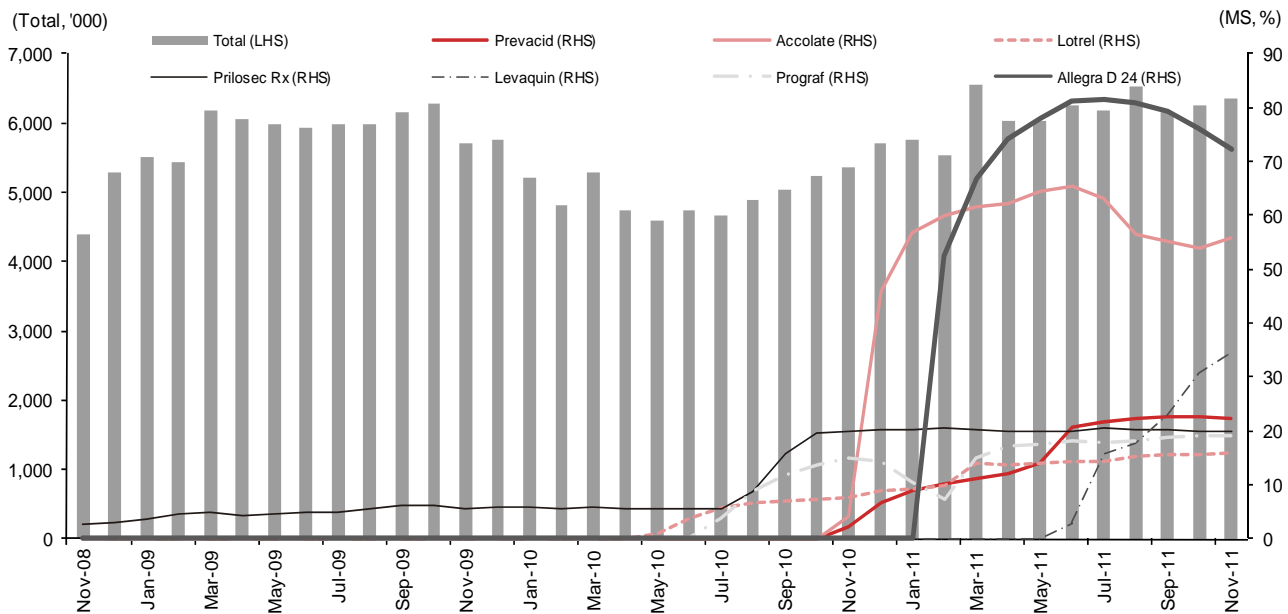
India generic companies accounted for 19.8% market share in November 2011, compared with 16.7% in the same period in 2010. We now consolidate Taro with Sun's TRx to calculate growth and market shares.

# US prescriptions – by company

## Dr Reddy's Lab (DRRD IN, Buy)

### US prescriptions

Fig. 2: Dr Reddy's Lab US prescriptions — past 36 months



Source: IMS, Nomura research

DRRD's US prescriptions were up +19% y-y in Nov 2011.

DRRD has been able to garner a 10.5% market share in generic Arixtra (USD340mn), while the Apotex (AG) has 67.6% market share for the week ended 9 Dec. This is a negative surprise as we were expecting a market share of 30-40% for DRRD. Management expects market share gains as production yields improve in Jan-Jun 2012.

Management expects market share in Arixtra to improve as supply constraints ease going forward.

DRRD's partner Teva garnered 4a 3.6% market share in generic Zyprexa (USD3bn) for the week ended 9 Dec. DRRD is FTF on 20mg and has outlicensed to Teva who is FTF on all other strengths. In Zyprexa ODT, DRRD has garnered a 32.4% market share.

DRRD's partner, Teva, has a 43.6% market share in generic Zyprexa (USD3bn) and DRRD has a 32.4% market share in Zyprexa ODT.

Generic Lotrel prescriptions contributed to the y-y improvement in prescriptions. DRRD's market share for Lotrel in Oct 2011 was 16.1% vs. 7.7% in Nov 2010.

Nov 2011 data indicate stabilisation of Prograf market share for Dr Reddy's at 19.0%. DRRD's market share had slipped to 7.3% for February 2011. The innovator still had 39.9% market share (as of Nov 2011). As per DRRD's annual report, Tacrolimus contributed ~USD39mn to revenues for FY11.

DRRD has gained market share in Accolate from 4% in November 2010 to 56.0% in Nov 2011. The authorised generic Par Pharma increased its share from 0.6% to 36.2% over the same period. For Nov 2011, DRRD's market share in Prevacid was at 22.4%, compared with only 2.1% in Nov 2010.

Consistent gain in Prevacid market share.

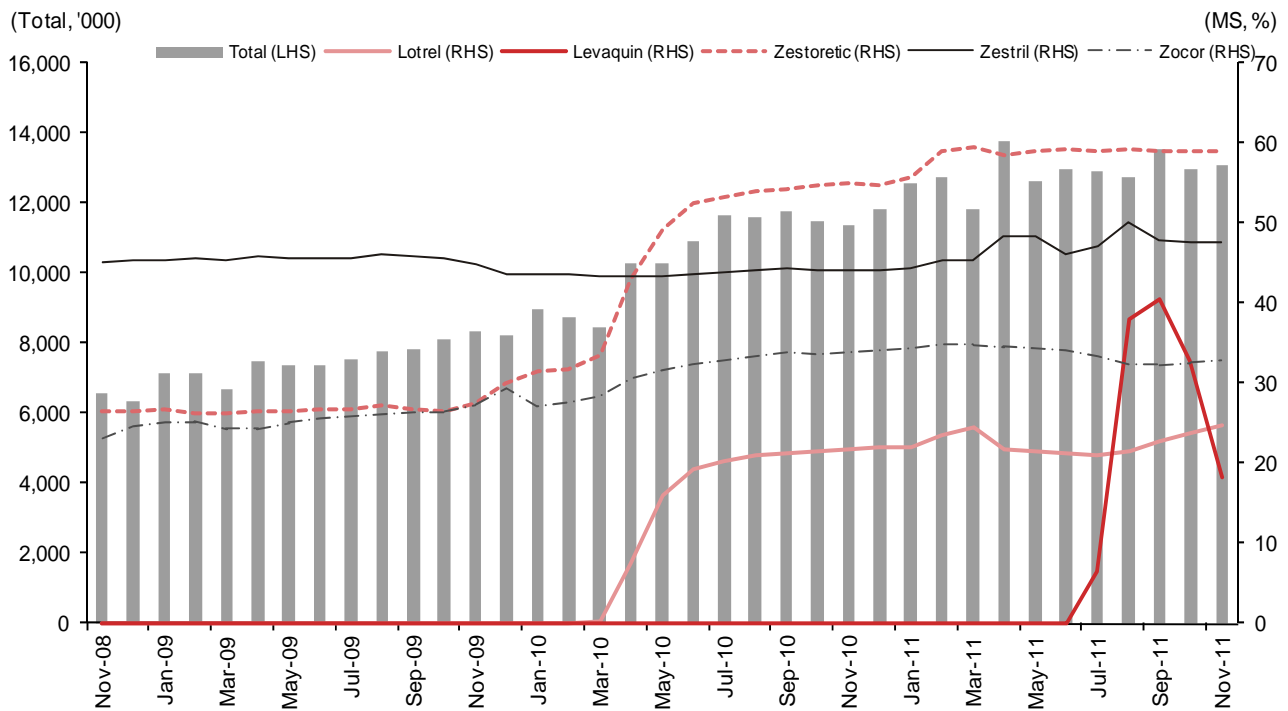
DRRD has gained 22.1% market share in generic Aricept (USD2.5bn). We note that while Ranbaxy has been able to hold on to a 31.8% market share in Aricept, the AG from Pfizer is losing market share to the new entrants. DRRD has also gained a 34.5% market share in generic Levaquin (USD1.5bn).

Other new launches from Dr Reddy's include Effexor XR (post 180-day launch, USD1.5bn) and Femara (multiple generics launch, USD650mn) where it has garnered 0.5% and 2.7% market share, respectively.

# Lupin (LPC IN, Buy)

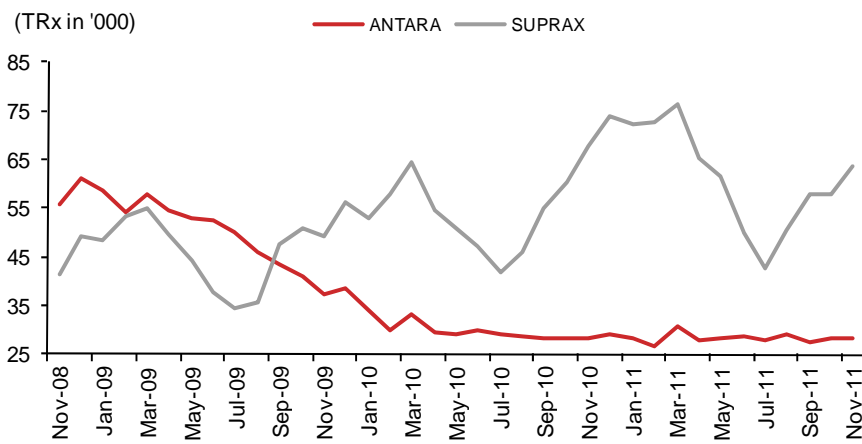
## US prescriptions

**Fig. 3: Lupin US prescriptions — past 36 months**



Source: IMS, Nomura research

**Fig. 4: Lupin brand sales**



Source: IMS, Nomura research

Lupin recorded prescription growth of 11.5% y-y in Nov 2011. Suprax recorded -6% y-y growth with tabs recording growth of 3.2% y-y. Antara prescriptions were flat y-y and m-m. We note that Suprax sales grew 43% in 2QFY12. New contracts for Antara, sales force realignment and increased Suprax sales through more profitable channels should drive growth in the near-term, as per management.

For generic Ultram ER, Lupin garnered 15.6% market share (week ended 9 Dec). LPC's market share in Levaquin (USD 1.5bn) declined to 13.3% in Nov 2011. Over the past 12 weeks, Simvastatin volumes have been marginally declining y-y. We expect the decline in TRx volume to accelerate on expiry of the 180-day exclusivity in atorvastatin. Although an injunction has halted Lupin from selling Fortamet (USD70mn) any further, the inventory in the pipeline was not asked to be recalled. Lupin has garnered ~60% share.

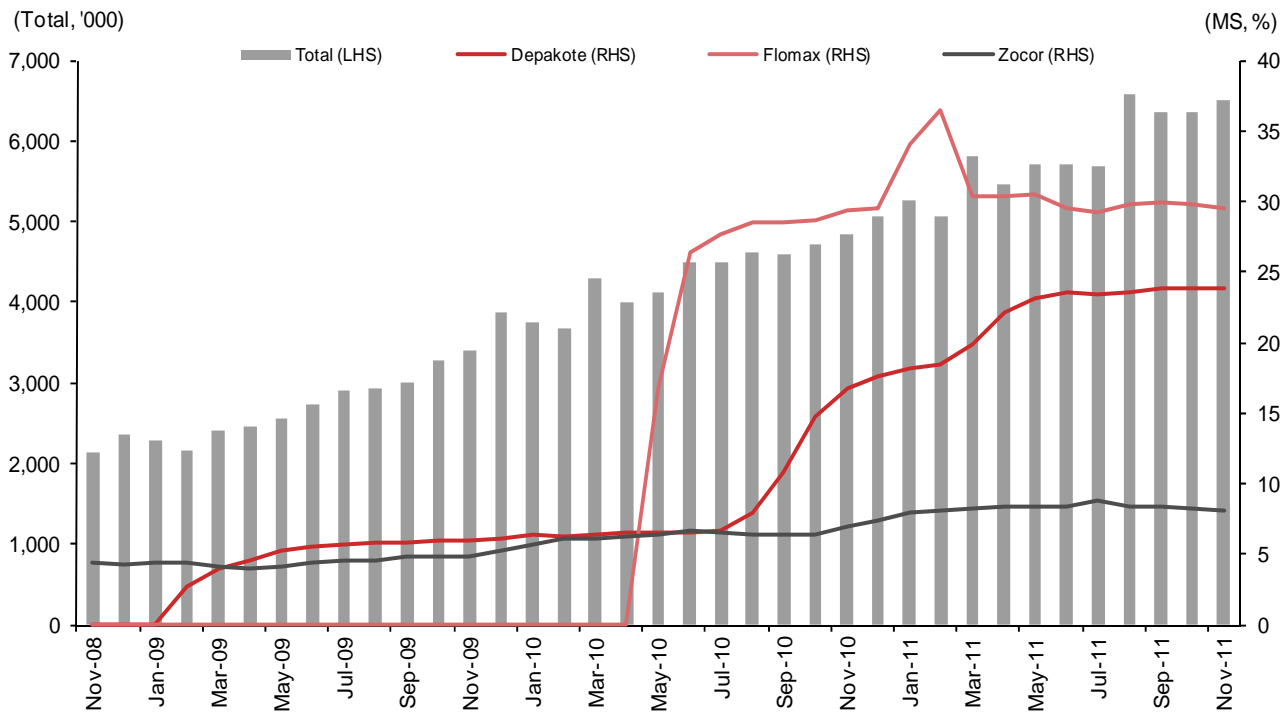
Suprax Rx declined 6% y-y. Antara TRx has thus far failed to record a ramp-up, adversely impacted by results of the ACCORD study.

Although an injunction has halted Lupin from selling Fortamet any further, the inventory in the channel was not recalled.

# Cadila Healthcare (CDH IN, Buy)

## US prescriptions

Fig. 5: Cadila US prescriptions — past 36 months



Source: IMS, Nomura research

Cadila recorded strong prescription growth of 34% y-y, primarily aided by gain in market share of old products such as simvastatin, metformin hcl, among others, and some new launches such as tramadol, tamsulosin, anastrozole, Effexor XR, etc. Cadila’s market share in generic Depakote has grown to 23.8% as of Nov 2011 and that for generic Flomax has stabilised at 29.6%. Cadila has garnered 4% market share in Effexor XR. We believe a warning letter for the Moraiya facility is a headwind that can potentially delay new approvals, as per management.

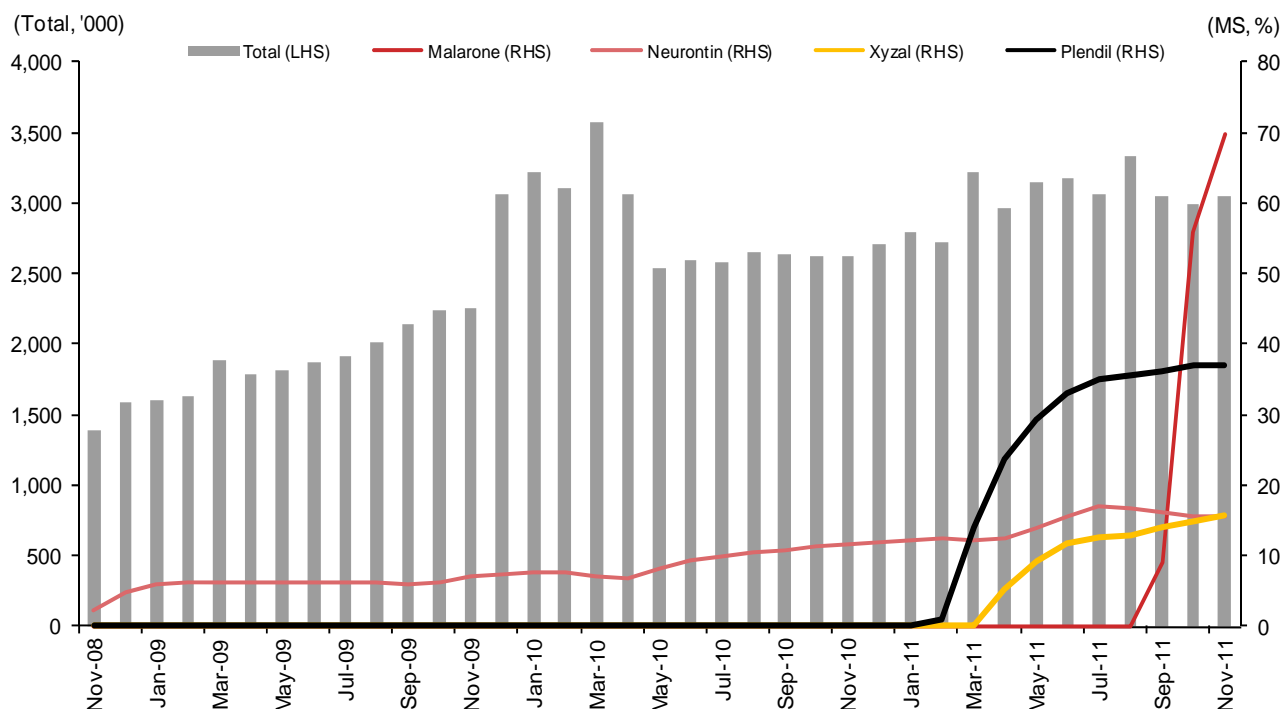
Cadila’s partner Hospira launched generic Taxotere in 4QFY11. The product is being manufactured at a 50:50 JV between Hospira and Cadila under a profit-sharing agreement. We factor in Taxotere to make an EPS contribution of 9.5% and 5% to FY12F and FY13F earnings, respectively. For 3QCY11, Hospira reported USD9.3mn with respect to income from affiliates, compared with USD11.7mn and USD17.2mn in 2Q and 1Q 2011, respectively. Hospira mentioned during the conference call that they should be able to maintain ~50% market share in docetaxel with pricing at 50-55% pricing discount. We believe the price discount may increase and market share may erode going forward due to increased competition from Sandoz (single vial), Sun Pharma and Accord (both double vial) on the product.

Hospira shared that it has been able to maintain 50% market share and 50-55% price discount in the docetaxel space.

# Glenmark (GNP IN, Buy)

## US prescriptions

Fig. 6: Glenmark US prescriptions — past 36 months



Source: IMS, Nomura research

Overall prescriptions grew strongly at 17% y-y. Growth was driven by an increase in TRx of some older launches like gabapentin, mometasone, ropinirole etc. IMS data suggest a strong ~24% m-m growth in OC prescriptions. We believe the ramp-up in OC TRx is a positive.

Discontinuation of Nitroglycerine from all unapproved manufacturers by the FDA due to potential harmful effects on patients and a fall in amlodipine prescriptions put pressure on the y-y growth. Prescriptions for Nitroglycerine declined 94% y-y in Nov 2011.

Post a federal jury verdict that rejected Glenmark's challenge to validity of the '244 patent covering Tarka and awarded compensation of USD16mn (on account of lost sales and profits till December 2010) to the innovator, Glenmark has stopped selling the generic version. The district court verdict announced on 30 Sept granted the innovator a permanent injunction and granted supplemental damages on account of loss of sales due to Glenmark's generic sales from January 2011 to date. We believe Glenmark will appeal against the decision in higher court. In our view, additional sales were mostly on account of the liquidation of channel inventory and loss of sales could be less than USD16mn. However, the secondary prescription audit reports that Glenmark captured 55.4% market share in the product in Nov 2011 vs. 75.0% in May 2011.

Glenmark garnered a 15.8% market share in generic Xyzal (USD230mn) in Nov 2011. Perrigo is the FTF on the product and launched with 180-day exclusivity in Dec 2010. Sanofi also has an AG on the market. Both GNP and DRRD do not have allergy on their approved label and thus are able to launch during Perrigo's exclusivity period. Teva also launched the generic version in Sep 2011 without allergy as an indication. Perrigo has lost market share to Teva in Oct 2011 as GNP and DRRD remained steady.

Glenmark launched generic Malarone (USD66mn) in Sept 2011. Glenmark has 180-day exclusivity and had settled all litigations with the innovator. We believe Glenmark is the only filer for Malarone so far and thus believe that the exclusivity may last more than 180 days. As of week ended 9 Dec, GNP had a 78% market share in the space.

Nitroglycerine has been withdrawn by all unapproved manufacturers following an FDA warning letter.

We believe the supplemental damages for Tarka would be a fraction of the previously granted USD16mn rather than a multiple of it

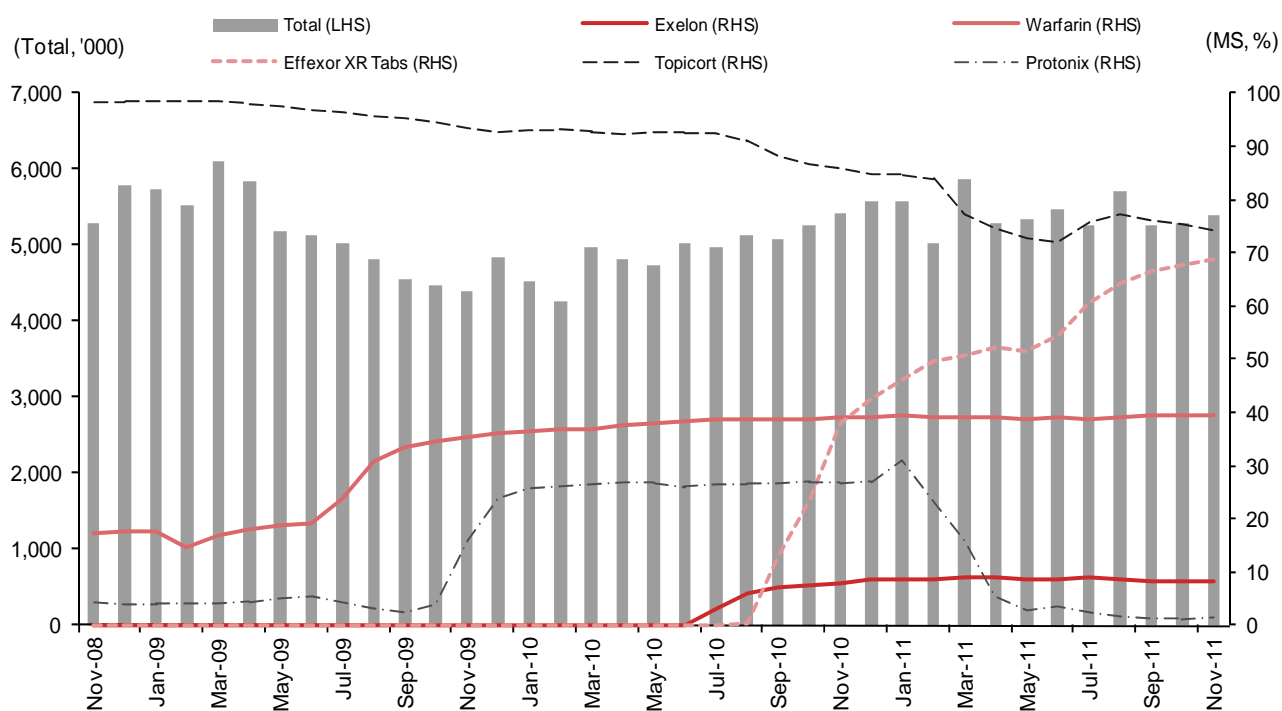
GNP has launched generic Malarone and has been able to garner a 78% market share. The exclusivity may last more than 180 days as there is no other filer of which we are aware.



# Sun Pharma (SUNP IN, Neutral)

## US prescriptions

Fig. 7: Sun Pharma US prescriptions — past 36 months



Source: IMS, Nomura research

Total prescriptions for Sun Pharma, including Caraco and Taro, were +1.8% y-y and flat m-m. We note that post the entry of other generic players for Protonix in Jan 2011, the market share for Sun declined to 1.6% in Nov 2011 from 31.2% in January 2011.

Sun's generic Effexor XR tablets captured a 3.1% market share (69% TRx of Tabs) for Nov 2011. Additional competition entered the market in June 2011, post Teva's 180-day exclusivity on the capsule formulation, and we expect market shares and pricing to decline going forward.

Sun launched generic Femara (USD650mn) in June 2011. However, Sun was able to garner a 2.5% market share in Nov 2011.

Amongst other new launches, Sun has managed to garner a 20.4% market share in generic Uroxatral (USD200mn) for Nov 2011, whereas Torrent pharma was able to capture a 28.4% share over the same period. We note that the product has limited competition as of now with only four generic players on the market.

Taro launched generic Aldara (USD350mn) in Jul 2011. There are currently only four generics on the market including Taro; however, for the week ended 9 Dec, it was able to garner only a 6.3% market share.

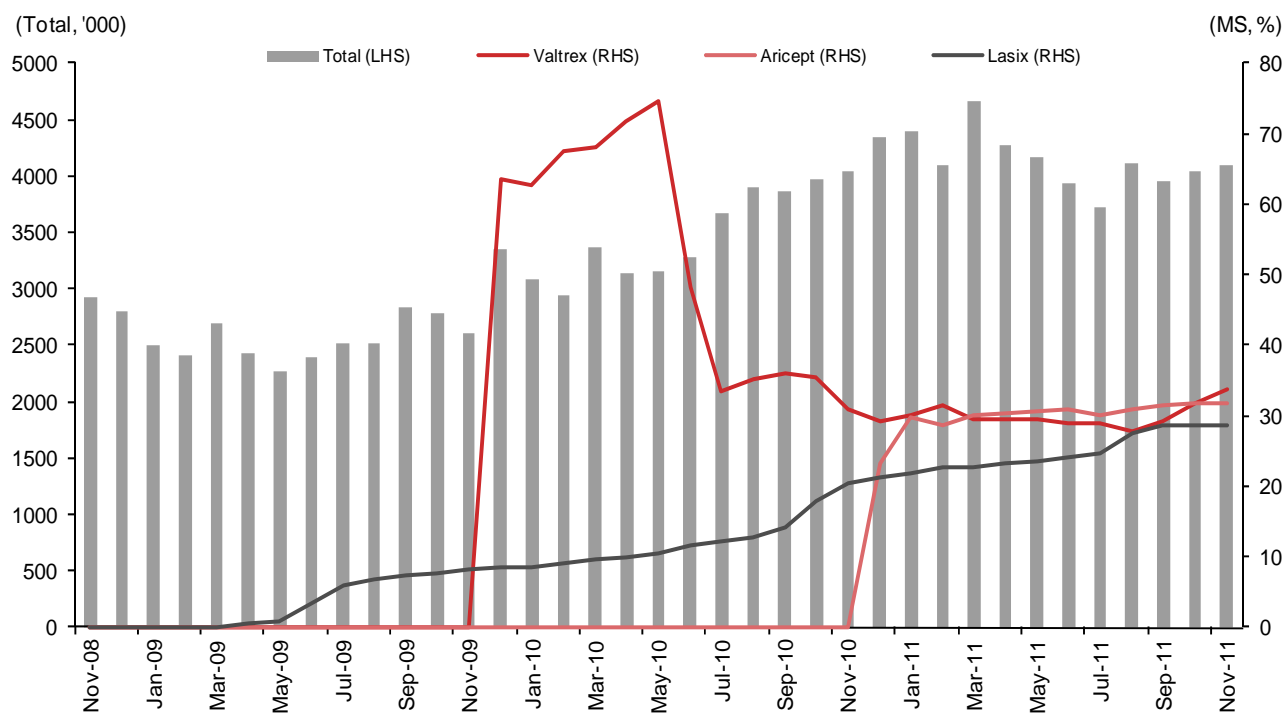
SUNP has garnered a 20.4% market share in Uroxatral, while Torrent has gained a 28.4% share over the same period.

Taro has garnered a 6.3% market share in Aldara. We believe the ramp-up is slow.

# Ranbaxy (RBXY IN, Reduce)

## US prescriptions

Fig. 8: Ranbaxy US prescriptions — past 36 months



Source: IMS, Nomura research

In Nov 2011, prescriptions for Ranbaxy improved +1.4% y-y and +1.5% m-m.

For the week ended 9 Dec, Ranbaxy had a 14% share in Lipitor (USD7.8bn), compared to Watson's 45%. We note that the prescription trends for Ariccept, and most recently Zyprexa, suggest that market shares during the exclusivity period are largely established by the second/third week. Thus, based on the current trend, it appears that Ranbaxy's market share can stabilise at 20-25%, in our view. We note that this is below our current estimate of 45% market share for Ranbaxy during the exclusivity period. We believe the upside for Ranbaxy should be limited given higher competitive intensity and sharing of upside with Teva. We now believe Ranbaxy is likely to gain less than our expected USD560mn during exclusivity, perhaps USD250-350mn. Data indicate that Ranbaxy captured a 1.6% market share in generic Caduet (USD 400mn) for the week ended 9 Dec, whereas Mylan garnered a 10.4% share.

The y-y growth in prescriptions was led by Donepezil and Furosemide. In Nov 2011, y-y growth in TRx for Furosemide was 32% (current market share: 28.8%).

Ranbaxy has been able to hold on to a 31.8% market share in Ariccept, even as multiple generics entered the market in June 2011. Pfizer's AG (Greenstone) lost sizeable market share to new generic entrants like DRRD and has 7.5% share (Nov 2011) vs. 61.4% in May 2011.

Following additional competition post the 180-day exclusivity, Valtrex prescriptions market share marginally improved to 33.7% in Nov 2011, compared to 30.9% in Nov 2010.

For the week ended 9 Dec, Ranbaxy had a 14% share in Lipitor (USD7.8bn), compared to Watson's 45%; Caduet TRx share at only 1.6%.

Ranbaxy has been able to sustain a 31.8% market share in Ariccept even as multiple generics entered in June 2011. Pfizer's AG (Greenstone) lost significant share to new entrants.

# Litigation Updates

## Warner Chilcott sues Lupin over generic oral contraceptive Generess FE (USD4mn)

**12 December 2011:** Bloomberg reports that Lupin has been sued by Warner Chilcott over an ANDA filed by Lupin with Para IV certification on Generess FE (USD4mn). Generess FE is an oral contraceptive product with a chewable tablet formulation. The product is covered by 2 OB listed patents that expire in Jul 2014 and Apr 2019.

**Nomura comment:** We remind investors that Mylan is FTF on the product and has been sued by Warner Chilcott on the Apr 2019 patent. Mylan and Lupin's 30-month stays would expire by May 2014. We believe that Mylan could launch on the expiry of the Jul 2014 patent and Lupin could launch post the expiry of Mylan's 180 day exclusivity. The product is another addition to Lupin's robust OC portfolio. Unfolding of Lupin's OC portfolio is a positive, in our view.

Lupin is a subsequent filer for Generess FE and its 30-month stay expires in May 2014.

# Key Drug approvals

**Fig. 9: Key drug approvals in the past month**

| Company    | Brand name | Active ingredient    | (USDmn) | Date       |
|------------|------------|----------------------|---------|------------|
| Apotex     | Sanctura   | Trospium Chloride    | 4       | 12/06/2011 |
| Apotex     | Glucophage | Metformin Hcl        | 16      | 12/07/2011 |
| Sun Pharma | Ultram ER  | Tramadol Hcl         | 125     | 12/07/2011 |
| Actavis    | Ritalin LA | Methylphenidate Hcl  | 80      | 12/13/2011 |
| Mylan      | Toprol XL  | Metoprolol Succinate | 200     | 12/15/2011 |

Source: USFDA, Nomura research, IMS

Apotex got the third final approval to be granted for generic Sanctura (USD4mn). Glenmark and Paddock received final approvals and launched the product in Aug and Dec 2010, respectively. The product had MAT brand sales of USD29mn before genericization. Glenmark had a market share of 51% in generic Sanctura for Nov 2011. With additional competition, we would expect market share to be under pressure going forward.

Sun Pharma announced final approval for generic Ultram ER (USD125mn). We note that there are three generic players on the market including JNJ AG, Lupin and Par Pharma. Lupin currently has 15.6% market share in the space. We would expect Sun Pharma to launch imminently.

## Key Tentative drug approvals

**Fig. 10: Key tentative ANDA approvals in the past month**

| Company | Brand Name | Active Ingredient        | MAT Sales (USDmn) | Approval date |
|---------|------------|--------------------------|-------------------|---------------|
| Lupin   | Cymbalta   | Duloxetine Hcl           | 3000              | 12/08/2011    |
| Teva    | Reyataz    | Atazanavir Sulfate       | 865               | 12/08/2011    |
| Akorn   | Precedex   | Dexmedetomidine Hcl      | 93                | 12/12/2011    |
| Mutual  | Boniva     | Ibandronate Sodium 150mg | 540               | 12/13/2011    |

Source: USFDA, Nomura research, IMS

FTF Mutual obtained the sixth tentative approval to be granted for generic Boniva (USD540mn). We remind investors that there are multiple FTFs including DRRD. The filers have been sued on the patents expiring in Mar 2012, Oct 2019 and May 2023. We expect generics to be launched on expiry of the '814 patent' in March 2012. However, since there are multiple FTFs we do not see the product as a major contributor to DRRD's earnings.

Lupin announced that it has received the ninth tentative approval to be granted for generic Cymbalta (USD3bn). Lupin will share exclusivity with multiple (~8) other day one filers. Thus, upside during exclusivity is limited. Launch is expected post expiry of the product patent in Jun 2013, in our view.

Lupin will share exclusivity with multiple (~8) other day one filers in Cymbalta (USD 3bn).

FTF Teva received the second tentative approval for generic Reyataz (USD865mn). Teva had previously settled with the innovator for a launch in 2017. Mylan had obtained tentative approval for the generic version through PEPFAR. Teva is sole FTF and will launch with 180-day exclusivity in 2017, in our view.

Akorn obtained the second tentative approval to be granted for generic Precedex (USD93mn). Sandoz is FTF on the product and received tentative approval in March 2011. The product is covered by two OB-listed patents that expire in Jul 2013 and Mar 2019. The final approvals are expected on expiry of the 30-month stays as litigation is still ongoing. SUNP had filed a subsequent paragraph IV on the product. We expect Sandoz to launch on the expiry of the Jul 2013 patent with 180-day exclusivity and subsequent filers like Akorn and SUNP to launch post exclusivity in Jan 2014. The product may be a limited competition opportunity, in our view.

## Paragraph IV filings

**Fig. 11: Para IV filings in the past month**

| Brand name  | Drug name              | Dosage form | Strength                              | MAT Sales (USD mn) | Date of submission      |
|-------------|------------------------|-------------|---------------------------------------|--------------------|-------------------------|
| Focalin XR  | Dexmethylphenidate Hcl | XR capsules | 25 and 35mg                           | 1                  | 09/30/2011 & 09/29/2011 |
| Carac       | Fluorouracil           | Cream       | 0.5%                                  | 42                 | 07/29/2011              |
| Fusilev     | Levoleucovorin calcium | Injection   | 10 mg/mL, 17.5 mL vial and 25 mL vial | 71                 | 10/26/2011              |
| Dilaudid-HP | Hydromorphone Hcl      | Injection   | 10 mg/mL                              | 2                  | 11/04/2011              |

Source: USFDA, Nomura research, IMS

At least one Para IV ANDA was filed with Sanofi's Carac (USD42mn) as the reference-listed drug. The product is covered with one OB-listed patent that expires in Jun 2021. We are not aware of any lawsuits yet. There are multiple DMFs (drug master file) filed for the API by various manufacturers.

At least one Para IV ANDA was filed with Fusilev (USD71mn) as the reference-listed drug. The product is covered with one OB-listed patent that expires in Dec 2019. We are not aware of any lawsuits yet. There is only one DMF on the product as of 3QCY11 filed by GMT Fine Chemicals.

# Trading Multiples and Recommendations

**Fig. 12: Valuation Multiples**

| Current trading multiples - Actual |          |                |                        |                     |       |       |       |           |       |       |          |       |       |
|------------------------------------|----------|----------------|------------------------|---------------------|-------|-------|-------|-----------|-------|-------|----------|-------|-------|
| Company                            | Ticker   | Recommendation | Market Cap<br>(INR mn) | CMP<br>(INR/share)* | P/E   |       |       | EV/EBITDA |       |       | EV/Sales |       |       |
|                                    |          |                |                        |                     | FY11F | FY12F | FY13F | FY11F     | FY12F | FY13F | FY11F    | FY12F | FY13F |
| Sun Pharma                         | SUNP IN  | NEUTRAL        | 514,953                | 500                 | 28.5  | 24.7  | 21.5  | 25.4      | 20.3  | 17.3  | 8.7      | 6.5   | 5.5   |
| Cipla                              | CIPLA IN | NEUTRAL        | 264,001                | 329                 | 27.3  | 22.8  | 19.7  | 20.3      | 15.9  | 13.7  | 4.3      | 3.7   | 3.2   |
| Ranbaxy                            | RBXY IN  | REDUCE         | 166,500                | 395                 | 11.1  | 10.8  | 9.1   | 7.8       | 8.0   | 3.7   | 1.9      | 1.7   | 1.2   |
| Dr. Reddy's                        | DRRD IN  | BUY            | 265,713                | 1,568               | 24.0  | 17.3  | 16.0  | 16.5      | 11.3  | 10.2  | 3.7      | 2.9   | 2.5   |
| GlaxoSmithKline                    | GLXO IN  | NEUTRAL        | 156,658                | 1,850               | 28.0  | 24.4  | 21.6  | 17.6      | 15.6  | 13.6  | 6.3      | 5.5   | 4.8   |
| Lupin                              | LPC IN   | BUY            | 190,782                | 427                 | 22.0  | 18.8  | 16.2  | 16.5      | 13.3  | 11.0  | 3.5      | 2.9   | 2.3   |
| Glenmark                           | GNP IN   | BUY            | 74,850                 | 277                 | 16.3  | 14.3  | 12.5  | 15.7      | 8.8   | 9.8   | 3.2      | 2.3   | 2.2   |
| Cadila Healthcare                  | CDH IN   | BUY            | 145,259                | 711                 | 21.9  | 17.8  | 14.5  | 15.3      | 12.8  | 10.5  | 3.5      | 2.9   | 2.4   |
| Jubilant Organosys                 | JOL IN   | BUY            | 26,202                 | 165                 | 6.0   | 10.9  | 9.7   | 8.0       | 10.1  | 7.5   | 1.5      | 1.6   | 1.4   |

| Current trading multiples - Adjusted |          |                |                        |                          |       |       |       |           |       |       |          |       |       |
|--------------------------------------|----------|----------------|------------------------|--------------------------|-------|-------|-------|-----------|-------|-------|----------|-------|-------|
| Company                              | Ticker   | Recommendation | Market Cap<br>(INR mn) | Adj. CMP<br>(INR/share)* | P/E   |       |       | EV/EBITDA |       |       | EV/Sales |       |       |
|                                      |          |                |                        |                          | FY11F | FY12F | FY13F | FY11F     | FY12F | FY13F | FY11F    | FY12F | FY13F |
| Sun Pharma                           | SUNP IN  | NEUTRAL        | 514,953                | 495                      | 41.5  | 28.9  | 21.9  | 36.7      | 23.4  | 19.0  | 9.9      | 6.8   | 5.9   |
| Cipla                                | CIPLA IN | NEUTRAL        | 264,001                | 329                      | 27.7  | 22.8  | 19.7  | 20.3      | 15.9  | 14.0  | 4.3      | 3.7   | 3.3   |
| Ranbaxy                              | RBXY IN  | REDUCE         | 166,500                | 287                      | 108.8 | 41.8  | 18.4  | 52.5      | 22.0  | 11.2  | 1.8      | 1.6   | 1.2   |
| Dr. Reddy's                          | DRRD IN  | BUY            | 265,713                | 1,496                    | 23.9  | 22.8  | 18.4  | 15.8      | 10.8  | 9.7   | 3.9      | 3.2   | 2.6   |
| GlaxoSmithKline                      | GLXO IN  | NEUTRAL        | 156,658                | 1,850                    | 27.1  | 24.4  | 21.6  | 17.6      | 15.6  | 13.6  | 6.3      | 5.5   | 4.8   |
| Lupin                                | LPC IN   | BUY            | 190,782                | 427                      | 22.0  | 18.8  | 16.2  | 19.6      | 15.6  | 12.0  | 3.5      | 2.9   | 2.4   |
| Glenmark                             | GNP IN   | BUY            | 74,850                 | 250                      | 45.7  | 11.9  | 11.3  | 17.1      | 10.8  | 9.0   | 3.0      | 2.3   | 2.0   |
| Cadila Healthcare                    | CDH IN   | BUY            | 145,259                | 711                      | 21.9  | 17.8  | 14.5  | 15.3      | 12.8  | 10.5  | 3.5      | 2.9   | 2.4   |
| Jubilant Organosys                   | JOL IN   | BUY            | 26,202                 | 165                      | 6.0   | 10.9  | 9.7   | 8.0       | 10.1  | 7.5   | 1.5      | 1.6   | 1.4   |

\*Note: Pricing as of 20<sup>th</sup> December 2011; Adj. CMP is adjusted for one off opportunities and innovative R&D value

Source: Nomura estimates, Bloomberg

# Appendix A-1

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