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Approval of high-impact products key for Lupin

Earnings momentum should gather pace towards the end of this financial year

LUPIN

RATING: BUY

HIGH impact approvals to drive earnings from Q4FY16F onwards: While the number of approvals has increased for LPC in FY16 (14 so far vs. 10 in FY15), the average time for an approval has also risen to more than 60 months. Most of the recent approvals were for pre-FY13 filings. With 43% of pending filings more than three years old, the rate of approvals should remain strong. None of the approvals in FY16 so far are likely to have any material impact on growth. In our opinion, more than the number of approvals, it is the approval of select high impact products—gGlumetza, gNexium, gWelchol and gRenvela/Renagel—that matter most for growth. We incorporate the recent currency movements, acquisitions by Lupin and the prospect of new launches into our financial projections. We lower our earnings by 7% for FY16F, but raise by 21% for FY17F. Our FY17F EPS is 18% above consensus.

The earnings momentum is likely to gather pace from 4QFY16F. We lift our TP (target price to ₹2,149 (from ₹1,698), based on 23x (unchanged) FY17-18F average EPS of ₹93.4.

Valuation: TP lifted to ₹2,149

The stock currently trades at 26.3x one-year forward EPS of ₹72.3. We continue to assess the fair valuation range to be 20-25x. Significant value-accretive acquisitions and visibility to sustain growth by moving up the complexity levels (inhalers and biosimilars) could justify a higher valuation multiple. However, currently we have very limited visibility on the same.

Pace of approvals has increased; old backlog being cleared

Lupin's pace of approvals has picked up in the recent past. In **Fig 1** we highlight the first wave of ANDA approvals for Lupin separately. The first-wave approvals consist of products in which Lupin is among the first set of companies to receive generic approvals or receive approvals just after the generic exclusivity period, if applicable. The approvals are an even mix of first-wave and follow-on approvals in the past three years as shown on **Fig 1**.

Large fraction of old ANDAs implies approval momentum to sustain in the near-term

Fig 2 shows the ANDA approval timeline and we map it with the filing period. So far Lupin has received approvals for 106 ANDAs. The company has not received approvals for any ANDA filed after FY13. Only two ANDAs filed in FY13 have received approvals. Most of the approvals received in FY16 were filed in FY11 and FY12. Approvals that are coming through now are more than three year old filings.

The average time for approval has been rising for Lupin, as is the case with the rest of the industry. The average time for approval for ANDAs approved in FY16 is 66 months compared with 51 months for approvals in FY15. With approximately 36 ANDAs which are more than 50 months old, the momentum for new approvals is likely to remain high in the near term.

Pipeline granularity

Out of the 106 ANDAs pending approval as on July 2015, we believe 61 ANDAs are in the public domain. This is based on litigation records and voluntary disclosure by Lupin. The 61 ANDAs have annual brand sales of $40bn, according to our estimates. Thus, we believe that 46 ANDAs with sales of $15bn are not in the public domain. Therefore, the pipeline visibility is high at 57% in terms of the number of ANDAs and 73% in terms of brand value of the pending pipeline. The pipeline presents a lot more visibility in the near term and we see a lean patch again in FY18F (**Fig 2**). New filings from FY16F onwards are unlikely to have any material impact in FY18F given the timeline for product approvals, in our view. In general, we find that the value of the pipeline is growing at 10-11%. The FY19 portfolio is recording a stronger growth on the back of a 125% growth y-o-y in Lyrica.

A few products hold the key: Glumetza presents an attractive opportunity

A step-up in product approvals is a positive. With the high frequency of approvals, there are possibilities of positive surprises, but such upsides are unpredictable and may not be sustainable, we believe. Thus, we think a few high-impact products are key for the revival of Lupin's US growth starting 4QFY16F. These include Glumetza, Nexium, Welchol and Renvela/Renagel for growth. Visibility on Glumetza's upside is high as LPC has tentative approval and the recent price increase in Glumetza adds to the upside. The visibility on the approval timing is limited on the rest given the regulatory challenges that the product presents. Renvela/Renagel and Nexium remain FY16F prospects, but Welchol is now likely only in FY17F, in our view.

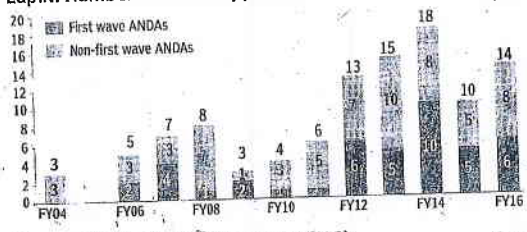
Attempt to move up the value chain

After the slowdown in US revenues in FY14 and FY15, and potential single-digit growth in FY16F, we expect a revival in growth in FY17F due to the specific product opportunities highlighted above. Lupin has recorded $8.76 m of generic sales per approved ANDA in FY15, which is ahead of peers. Lupin's strong execution, in terms of the timely approval and strong customer service, has led to market share gains, supporting higher sales per ANDA. With a step-up in approvals and not a proportionate rise in revenue, we expect sales per ANDA to decline in FY16F, before reviving back in FY17F.

In terms of product complexity, the gains for Lupin have been limited with gFortamet being an exception. In **Fig 3**, we present the sales split based on product formulations. LPC's portfolio is largely oral solids at the moment, with little presence in other formulation segments like derm and injectables. Even the pipeline is largely oral solids. Of the 61 ANDAs in the public domain, we believe that 51 ANDAs are oral solids.

—Nomura

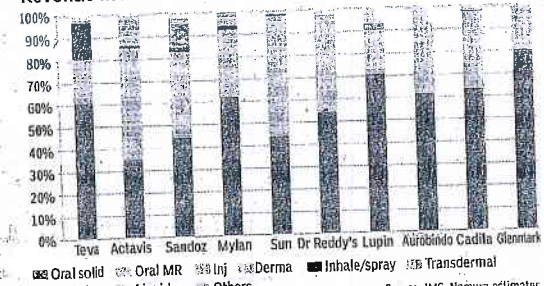
Lupin: Number of ANDA approvals — Fig 1



Known ANDA pipeline (post-Q1FY16) — Fig 2

	FY16	FY17	FY18	FY19	FY20	>FY20	Total
No of ANDAs	12	10	8	6	4	21	61
Value ($ bn)	10.1	11.3	2.4	7	0.9	7.8	40
Growth (y-o-y)	9%	10%	11%	46%	10%	11%	15%

Revenue mix based on formulations — Fig 3



Source: IMS, Nomura estimates