Approval of high-impact products key for Lupin

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

RATING: BUY

HIGH impact approvals to drive earnings from FY16 onwards

While the number of approvals has increased for LPC in FY16 (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 FPIs. The rate of approvals should remain strong. None of the approvals in FY15 are far away to have any material impact on this. In short, more than the number of approvals, it is the approval of select high impact products—Glu-metza, Nexium, Welchol and Zolendrec—what 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 FY16E but raise by 21% for FY17E. Our FY17 EPS of $1.80 above consensus.

The earnings momentum is likely to gather pace from Q2FY16 onwards. We lift our TP (target price) to $2.149 (from $1.688) based on 25x (unchanged) FY16 average earnings of $8.6.

Valuation: TP lifted to $2.149

The stock currently trades at 26.3x one-year forward EPS of $2.3. We continue to assign the fair valuation range to be 25-30x. Significant value-accretive acquisitions and visibility to sustain growth by moving up the complexity levels (inhalers and biologics) could justify a higher valuation multiple. However, currently we have very limited visibility on the same.

Fase of approvals has increased; old backlog being cleared

While the pace of approvals has picked up in the recent past, it was for non-FPIs. 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 cut-off period, if applicable. The approvals are an even mix of first-wave and follow-on, approvals in the past two 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 113 ANDAs. The company has not received approvals for any ANDA filed after FY15. Only two ANDAs filed in FY13 have received approvals. Most of the approvals received in FY15 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 sustain high in the near-term.

Pipeline granularity

Outside the few ANDA pending approval as on July 2015, we believe 61 ANDAs are in the pipeline. This is based on litigation records and voluntary disclosures by Lupin. The 61 ANDAs have annual brand sales of $376m, 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 67% in terms of the number of ANDAs and 75% in terms of branded value of the pipeline. The pipeline presents a more attractive opportunity. The earnings momentum is likely to gather pace from Q2FY16 onwards. We expect a revival in growth in FY17 due to the specific product opportunities highlighted above. Lupin has recorded 70% of its 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 ADAs per ANDA to decline in FY16E before reviving back in FY17E. In terms of product complexity, the gains for Lupin have been limited with 50% net 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 injections. Even the pipeline is largely oral solids. Of the 61 ANDAs in the public domain, we believe that 51 ANDAs are oral solids.

A few products hold the key:

Glu-metza presents an attractive opportunity

A step-up in product approvals is positive. With the high frequency of approvals, there are possibilities of positive surprises, but such surprises 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 FY17E. These include Glumetza, Nexium, Welchol and Zolendrec. Visibility on Glumetza’s upside is high as LPC has tentative approvals for the US market. However, the regulatory challenges that the product presents. Welchol/Renagel and Nexium remain FY16E prospects, but Zolendrec is now likely only in FY17E in our view.

Attemtp to move up the value chain

After the slowdown in US revenues in FY15 and FY16, and potential single-digit growth in FY17E, we expect a revival in growth in FY17E due to the specific product opportunities highlighted above. Lupin has recorded 70% of its 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 ADAs per ANDA to decline in FY16E before reviving back in FY17E. In terms of product complexity, the gains for Lupin have been limited with 50% net 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 injections. Even the pipeline is largely oral solids. Of the 61 ANDAs in the public domain, we believe that 51 ANDAs are oral solids.