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Pharmaceuticals

Asia | India

Cadila Healthcare (CADI.BO)

Alert: Successful Moraiya Inspection: A Key Bottleneck Lifted, Focus Shifts to Execution

- Compliance woes draw to a close, focus on execution We believe that the zero 483 US FDA observations at Cadila's Moraiya facility is a big positive for Cadila and removes one of the key overhangs on the company's US business. As highlighted in our recent Deep Dive (Indian Pharma Putting Pipelines Back in the Price), Cadila maps very well in terms of US pipeline optionality vs. base business risk; compliance and execution were the main drags on valuations. We believe that post this inspection, lifting of the warning letter at the site should be a formality / matter of time and the focus is likely to shift to execution viz. ability to commercialize its ANDA filings for complex generics. Maintain Buy.
- Successful inspection at Moraiya, Warning Letter may be lifted soon Cadila announced that its Moraiya facility was inspected by the US FDA during February 6 to 15 and no Form 483 observations were issued. The company had received an EIR (for the inspection that triggered the warning letter) earlier but the warning letter was not lifted, pending re-inspection. We believe that with this successful inspection, it is now only a matter of time.
- A key bottleneck lifted Moraiya is Cadila's most important facility, accounting for a large share of its pending ANDA filings (c70 out of c200), including several potential Big Guns such as transdermals (Estradiol and Clonidine), complex oral solids (Rapamune, Asacol HD, Lialda), injectables (Iron Sucrose) and nasals. The company has been working on site transfers for some of its more important filings but this is often time consuming and expensive. Getting the warning letter lifted would make it much easier for the company to commercialize its product pipeline.
- Strong pipeline, execution is the Wild Card Cadila has a strong ANDA pipeline that includes several complex products such as transdermals, topicals, complex oral solids and Injectables. Closing out the warning letter would put it a step closer to commercializing these. However, we also note that approvals for complex ANDAs have not been easy to come by and Cadila has received many CRLs in past a few key approvals could therefore meaningfully change the perception about the company. Key products to look out for include Asacol HD, Lialda, Iron Sucrose, Rapamune, Prevacid solutab, Estradiol twice weekly, among others.

Buy	1
Price (15 Feb 17 15:30)	Rs358.05
Target price	Rs410.00
Expected share price return	14.5%
Expected dividend yield	0.9%
Expected total return	15.4%
Market Cap	Rs366,551M
	US\$5,481M



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Prashant Nair, CFA AC +91-22-6175-9855 prashant.nair@citi.com

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Vivek Agrawal +91-22-6175-9875 vivek1.agrawal@citi.com

Cadila Healthcare

Valuation

We value Cadila Healthcare at Rs410. Given that pharma is a growth sector, we use P/E as our primary method to value the base business of pharma companies. We use a March 2018E P/E of 23x to value the company - this is a 15% discount to sector leaders. We place Cadila in Tier II (21-23x PE) of our valuation framework for the Indian pharma sector - in line with other mid-caps and the average for the sector.

Risks

The key upside risks that could keep the stock above our target price include: a) Better-than-expected US business and JV business performance; b) Higher-than-expected upside from acquisitions; and c) Any progress in monetizing its NCE or biosimilars pipeline. The key downside risks are: a) Complex product approvals delayed; b) any slowdown in the Indian market; c) Rising pricing pressure in the US generics business.

Appendix A-1

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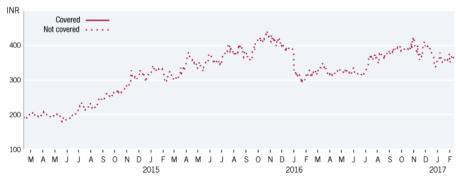
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Cadila Healthcare (CADI.BO)

Ratings and Target Price History Best Ideas Research Relative Call (3 Month)

Analyst: Prashant Nair, CFA



*Indicates Change

Rating/target price changes above reflect Eastern Time

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