# Dr Reddy's Labs | DRRD IN



Price: ₹ 3,050

Product concentration risk getting serious

Teva and Antares Pharma launch of glmitrex (sumatriptan succinate) is Dr,Reddy's 3<sup>rd</sup> key limited-competition product which is facing additional competition in the last 3 months. Similar to gValcyte and gVidaza, it was among the top seller in \$183m sumatriptan injection market. While additional competition was imminent, this adds pressure on Dr.Reddy's earnings which is facing a multitude of headwinds in the form of regulatory issues resulting in US sales slowdown and a weaker industry-wide domestic outlook in the near-term. We remain comfortable with our below consensus FY17 EPS of ₹130 which had factored in additional competition for FY17 and maintain our Sell rating with ₹2,770 target price.

- What happened? Teva and Antares Pharma announced the launch of the generic equivalent to Imitrex (sumatriptan succinate) injection, 4 mg and 6 mg single-dose, prefilled syringe autoinjectors, in the US.
- **Background:** Sumatriptan injection is used to treat acute migraine with or without aura, and acute cluster headaches in adults. Dr.Reddy's launched this drug in FY14 and, in our view, holds >30% market share in the injection which translates to ~4% of its US sales. The market size for sumatriptan injection is \$183m for 12m ending March 2016.
- Dr.Reddy's and Sun to feel the heat: Along with Dr.Reddy's, sumatriptan was one of the top products from Sun's Halol plant. While the earnings impact is dependent on Teva's pricing, this will put pressure on Sun's chances of recovering market share post Halol supply resumption. In our downgrade note (dr.25-Nov), we had flagged that >25% of Dr.Reddy's EBITDA was contributed by key drugs like gValcyte, gDacogen, gVidaza, gReclast etc which were at risk from additional competition. With Dr.Reddy's grappling with regulatory issues, timing of product approvals remains uncertain which can put pressure on the base US business. We remain comfortable with our flat US revenue growth expectation for FY17.
- Downgrade cycle not over yet: With consensus downgrading FY17 estimates by 14% since Nov'15, our FY17 EPS of ₹131 is just 7% below street estimates. In the current environment, there is likely more downside than upside to the FY17 and FY18 consensus numbers. Dr.Reddy's commentary around US market mirrored its US peers; it expects price erosion to continue in high-single digit. While the price decline in FY16 was compensated by volume gains on account of issues faced by competitors, we see this unsustainable going forward. IPM has been weak in the last 3-4 months (midto-high single-digit growth) and is facing price declines and NLEM expansion which could further dent profitability.
- Warning letter resolution is the key stock catalyst: While the warning letter does not necessarily lead to an import embargo, Dr.Reddy's remains exposed to remediation requirements like third party audit, batch testing etc which may delay shipments. While the Venezuela overhang has somewhat receded given supply control (sales halved in 2016 to ~\$70m) and move to maket-linked DICOM, we see little incremental activity until things settle down. Thus, with ~2/3 of business facing pressure, resolution of warning letters is a key to recovery.

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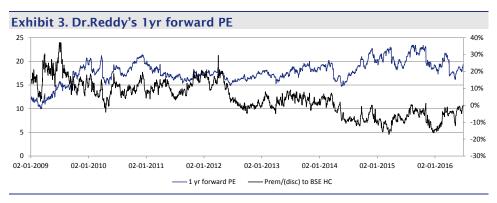
Please see Appendix I at the end of this report for Important Disclosures and Disclaimers and Research Analyst Certification.

Exhibit 1. Key US products							
Drug	Market share	Market size (\$m)	Competition	Comments			
Decitabine	72%	\$250m	2	Sun is the 3rd player but Sun's drug is not AP-rated (not directly substitutable) and hence we see little gain for Sun. Also, in our view, it manufactures from Halol w hich itself is under Form 483. Note, in the last 3 months Reddy's has lost ~10% market share, w hich could be on account of Sandoz gaining market share			
Azacitidine	51%	\$250m	2	Mylan launched in Jun'16 and became the 2nd generic after Dr.Reddy's			
Metoprolol	27%	~\$350-400m	4	However, the only other Indian player in Wockhardt which is facing issues at its Waluj plant. Cadila could enter in about 12- 15m			
Divalproex ER	21%	\$125-150m	8	2 are Indian cos – Aurobindo, Wockhardt and Cadila			
Zoledronic acid (Reclast)	51%	~\$250-300m	6	1 Indian company – Emcure w hich is privately held			
Valganciclovir hcl (Valcyte)	~45%	~\$350m	4	~45% market share pre Camber's approval in March'16. Auro recd approval in Apr'16			
Sumatriptan succinate (Imitrex)	~35%	~\$180-200m	7-8	3 major generics but Dr.Reddy's holds a high market share. With a big company like Teva entering and Sun re-entering, we see pressure on Dr.Reddy's			
Fondaparinux	51%	~\$110m market	1	No Indian company. However, Dr. Reddy's had recently purchased global IP rights from Alchmia for \$17.5m; previously it used to share 50% of US profits w ith Alchemia. It had planned to launch in EU. Teva and Auro potential entrants			
Omeprazole DR	16%		11	Indian companies like Cadila, Lupin, Kremers, Glenmark and Aurobindo. Given that it is a highly competitive market, Dr.Reddy's w ithdraw al w ill not lead to any meaningful price increase and neither w ill any single company benefit, in our view			

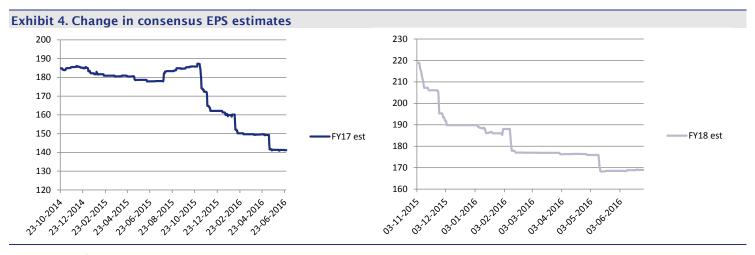
Source: Company, JM Financial

Exhibit 2. JMFe vs. Con	isensus			
		FY16	FY17	FY18
Revenue	JMFe	1,54,708	1,62,901	1,80,218
	Cons		1,63,989	1,84,014
	Variance		-0.7%	-2.1%
EBITDA	JMFe	39,088	35,937	41,243
	Cons		39,250	45,362
	Variance		-8.4%	-9.1%
EBITDA margin	JMFe	25.3%	22.1%	22.9%
	Cons Variance		23.9%	24.7%
EPS	JMFe	117	131	154
	Cons		141	169
	Variance		-7.3%	-8.6%

Source: Company, JM Financial



Source: Company, JM Financial



Source: JM Financial

### **APPENDIX I**

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Rating	Meaning			
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