# Dr Reddy's Laboratories

10 June 2016

Reuters: REDY.BO; Bloomberg: DRRD IN

Initiating Coverage

## Proprietary Business To Drive Outperformance

**Dr. Reddy's Laboratories (DRL) is India's premium generic pharmaceutical company. It is second largest pharma company in India by global revenues. DRL's revenue and adjusted earnings have grown at a phenomenal 17% and 21% CAGR respectively over the last 10 years. DRL has demonstrated industry leading product development and regulatory capabilities by successfully developing bioequivalent copies of several difficult to copy innovator products. The US, which represents the largest market for the company, will continue to lead growth driven by launch of value added and technically complex generics.**

**We initiate coverage on DRL with a Buy rating and a target price of Rs 3950 based on 21x P/E multiple on FY18E earnings. We see DRL as better poised among Indian peers to grow despite the pricing pressure in the US market. By virtue of ongoing research and development efforts, by FY-2022, the company should build a robust portfolio of value-added generics and complex generic products (sales >US$700m) that have higher endurance to competition, yield higher sales per unit capex, and have a significantly longer life cycle. We foresee DRL doubling its revenue base and trebling its net income by 2022, driven largely by its high-margin proprietary drug business. Once the manufacturing compliance issues get resolved, DRL stock should trade at a premium to its peers as the ongoing news flow on its proprietary drug pipeline should rebuild and strengthen investor confidence.**

**XP23829 is a potential blockbuster:** Psoriasis/multiple sclerosis drug XP23829 (in licensed from Xenoport) is a potential blockbuster and we expect a launch in the US in FY-20. We forecast peak sales of $1b ($400m on a risk adjusted basis) as the drug has an efficacy profile that is at least at par with Celgene's marketed drug Otezla for psoriasis. Otezla was launched recently and is currently aggregating to $700m in annual sales in the US. There is more than a good chance that XP23829 may surpass Otezla when it comes to long-term efficacy.

**DFN-02 – Intranasal Migraine Spray will expand the nasal spray market:** DFN-02 should reach the market in FY-2019. We are looking at risk adjusted peak sales of $100m. The drug should offer a notably better clinical outcome when compared to marketed nasal spray products. The penetration of nasal products is currently limited as their efficacy is moderate and it takes longer for patients to achieve pain relief. A quick onset of action is potentially the most important benefit from an unmet need perspective and DFN-02 intends to address the same.

**Other proprietary products from Promius including Xeglyze for lice infestation should add $175m to RDY sales by 2020:** Sernivo spray for psoriasis, Xeglyze for lice infestation and Zembrace symtouch (for migraine) put together should add about $175m to RDY topline by FY 2020

**Rejuvenation in ANDA approvals will support near term growth:** In the near term (FY16-FY18), abbreviated new drug application approvals in the US should support sentiment and help the company build on its growth trajectory in the US markets. We are looking at about seven important launches in the US in FY17, which should relieve the pressure because of competitors eroding sales of some of its high value products (Valcyte and Vidaza) in the US. Injectable drugs worth $16b in annual sales will lose patent protection in the US by 2020. DRL is placed well with 24 of the 79 ANDA filings that are pending approval in the US falling in this category. Of the 24 injectable filings, 13 represent complex injectables.

**A potential revival in Emerging markets:** DRL has major dependence (15% of group sales) on the emerging markets. In fact, in FY-15 emerging market sales were 21% of group sales. The contribution has declined due to near 100% erosion in Russian Ruble value and collapse of Venezuelan Bolivar. We believe with crude oil prices showing an upward trend, the worst is over and a revival in growth is on the cards. We also expect a ramp up in new product approvals in these geographies, which should fortify DRL base in these geographies.

**A favourable risk-reward profile:** Fundamentally, it is an opportune time to build position in DRL as the US Food and Drug Administration warning letter remains an overhang. The company has indicated that a healthy rate of new product approvals, in line with the previous years, in US market is expected 2HFY17 onwards. In case the warning letter escalates into an import alert, there is potential sentimental downside. However, with ongoing risk mitigation measures, we see little risk to earnings growth. The growth momentum will be mild in the near term, but should notably accelerate from FY18.

| Y/E March (Rsmn) | FY15 | FY16 | FY17E | FY18E | FY19E |
|---|---|---|---|---|---|
| Net sales | 1,48,189 | 1,54,708 | 1,69,150 | 1,88,607 | 2,21,285 |
| EBITDA | 34,581 | 37,689 | 41,752 | 48,464 | 58,599 |
| Net profit | 22,179 | 20,013 | 26,382 | 31,942 | 40,138 |
| EPS (Rs) | 130 | 117 | 155 | 187 | 235 |
| *EPS growth (%)* | *3.0* | *-9.6* | *31.8* | *21.1* | *25.7* |
| *EBITDA margin (%)* | *23.3* | *24.4* | *24.7* | *25.7* | *26.5* |
| PER (x) | 23.7 | 26.2 | 19.9 | 16.4 | 13.1 |
| P/BV (x) | 4.7 | 4.1 | 3.5 | 3.0 | 2.5 |
| EV/EBITDA (x) | 15.4 | 13.8 | 12.2 | 9.9 | 7.8 |
| *RoCE (%)* | *21.1* | *21.7* | *21.0* | *22.3* | *23.3* |
| *RoE (%)* | *19.9* | *15.7* | *17.7* | *18.1* | *19.0* |

*Source: Company, Nirmal Bang Institutional Equities Research*

## BUY

**Sector:** Pharmaceuticals

**CMP:** Rs3,071

**Target Price:** Rs3,950

**Upside:** 29%

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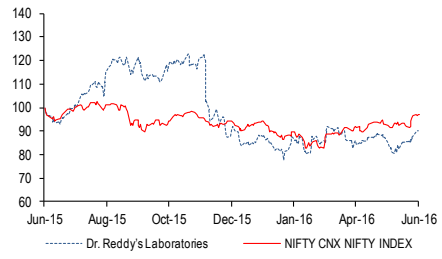
**Key Data**

| | |
|---|---|
| Current Shares O/S (mn) | 170.5 |
| Mkt Cap (Rsbn/US$bn) | 542.9/8.1 |
| 52 Wk H / L (Rs) | 4,387/2,750 |
| Daily Vol. (3M NSE Avg.) | 404,504 |

| Share holding (%) | 4QFY16 | 3QFY16 | 2QFY16 |
|---|---|---|---|
| Promoter | 25.6 | 25.6 | 25.5 |
| Public | 74.4 | 74.4 | 56.3 |
| Others | - | - | 18.2 |

**One Year Indexed Stock Performance**




**Price Performance (%)**

| | 1 M | 6 M | 1 Yr |
|---|---|---|---|
| Dr Reddy's Lab. | 10.5 | 4.8 | (5.5) |
| Nifty Index | 7.0 | 7.4 | 2.8 |

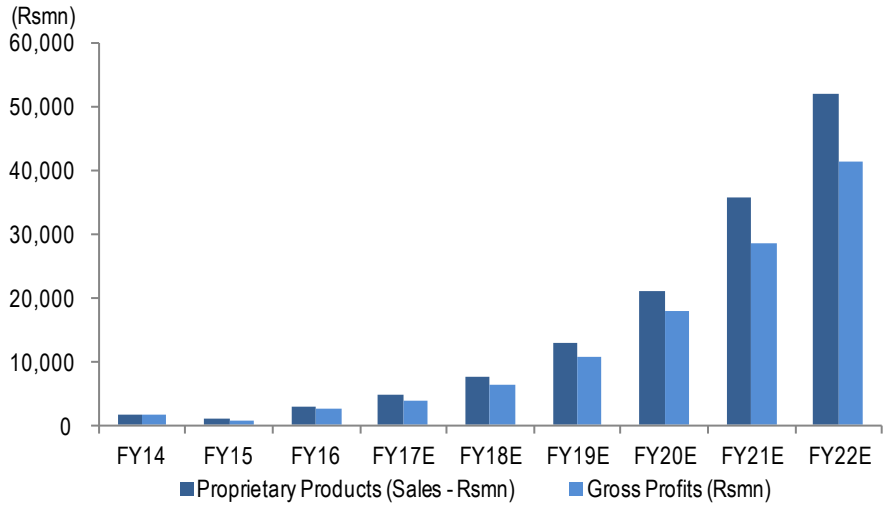
*Source: Bloomberg*

## Proprietary business of DRL (Promius Pharma) to add a new growth dimension

DRL expects revenues from Promius Pharma to touch US$500m by 2022, driven by approvals for new drug applications or NDAs. We are conservatively forecasting US$350mn (excluding in-licensed drugs) in revenues by 2022. Timely and successful approval for its first few filings (recently) adds to our confidence in successful execution of the new drug business strategy. The recently approved drugs Sernivo Spray for psoriasis and Zembrace Symtouch alone should add about US$120mn to Promius Pharma's revenues.

DRL intends to file two NDAs every year from Promius Phama. These NDAs will target the dermatology and migraine/CNS space. According to the company, each NDA approval should yield minimum annual sales of US$50mn- US$75mn, while a couple of them could be four times as large in potential peak sales. In addition to in-house developed products, DRL is also pursuing a R&D externalisation strategy to add to its NDA portfolio. In the recent past, DRL has in-licensed some high potential drugs like XP23829 (from Xenoport) and Xeglyze (from Hatchtech).

**Exhibit 1: Ramp up of Proprietary Product Portfolio of DRL**




*Source: Company, Nirmal Bang Institutional Equity Research*

### Market potential of Zembrace Symtouch

Zembrace Symtouch is a disposable auto-injector device. It is the lowest dose (3mg/0.5ml) offering among the available sumatriptan injections in the market and intended for those patients who cannot tolerate higher doses. As it has the lowest dose, those patients who have a relapse can take it as many as four times a day while the higher dose injectable versions in the market can be taken at the most twice a day. In terms of efficacy, the extent of difference between 3mg dose and 6mg dose is not significantly high (see Exhibit 2 below).

**Exhibit 2: Efficacy and safety of sumatriptan injection at various doses – 3mg vs. 6mg**

**Proportion of Patients with Migraine Relief and Incidence of Adverse Reactions by Time and by Sumatriptan Dose in Study 1**

| Dose of Sumatriptan Injection | Percent Patients With Relief* | | | | Adverse Reactions Incidence (%) |
|---|---|---|---|---|---|
| | at 10 Minutes | at 30 Minutes | at 1 Hour | at 2 Hour | |
| Placebo | 5 | 15 | 24 | 21 | 55 |
| 1 mg | 10 | 40 | 43 | 40 | 63 |
| 2 mg | 7 | 23 | 57 | 43 | 63 |
| 3 mg | 17 | 47 | 57 | 60 | 77 |
| 4 mg | 13 | 37 | 50 | 57 | 80 |
| 6 mg | 10 | 63 | 73 | 70 | 83 |
| 8 mg | 2 | 57 | 80 | 83 | 93 |

*Note: * Relief is defined as the reduction of moderate or severe pain to no or mild pain after dosing without use of rescue medication*

*Source: Prescribing information on Zembrace Symtouch*

There is a growing adoption of injectable migraine drugs as they offer a quick onset of action and effective for those who not attaining adequate control with oral triptans. The other important reason being that patients suffering from migraine develop severe nausea and vomiting and hence they are unable to retain pills.

About 70% of migraine patients are not satisfied with existing medications and with 13mn migraine prescriptions written annually in US, the potential market is huge. At current prices of injectable products, a 1% share implies annual sales of around US$50mn-US$65mn.

Including DRL, there are around five players in US, which include GlaxoSmithKline, Pfizer, Zogenix and Sun Pharmaceutical Industries or SPIL which market injectable version of Sumatriptan. Assuming DRL is able to carve a 1% share for Zembrace Symtouch, the drug should achieve peak sales of US$60mn.

### DFN-02 (intranasal sumatriptan Spray) to expand nasal spray market

DRL should file DFN-02 in FY18. DFN-02 represents an exciting opportunity as it is expected to provide much quicker pain relief for migraine patients than the existing intranasal sumatriptan spray in the market. The intranasal spray market is currently worth approximately US$140mn

Existing intranasal spray products are not widely used as they

1) Offer limited efficacy.
2) Do not provide a quick onset, which is very important from a patient perspective - **patients want quick relief from their headache. Patients consider "quick" to be one hour or less. In a survey of migraine patients, more than 90% wanted a migraine medication that can satisfactorily relieve pain within an hour.**
3) Existing nasal spray products leave an unpleasant taste.

DRL's nasal spray (DFN-02) intends address the key unmet need for the patients, which is a faster onset of action. DFN-02 should relieve headache as quickly as injectables. It has a Tmax of less than 15 minutes as against 1.15 hours for existing sumatriptan nasal spray product marketed by GSK. (Sales $65m)

A faster onset of action should also help a larger proportion of patients achieving pain freedom in a timeframe (say two hours) and lesser number of patients may need to repeat the medicine.

If successfully approved, DFN-02 may even cannibalise the share of injectable drugs in triptan market. Sales could touch anywhere between US$100mn to US$300mn. We are forecasting risk-adjusted sales of US$100mn.

## Dermatology Portfolio – Psoriasis and Rosacea drugs

**Sernivo Spray for mild-to-moderate psoriasis:** DRL has recently launched Sernivo spray in the US. Sernivo is a spray formulation of betamethasone and comes with several advantages validated through clinical trials.

Clobex spray (clobetasone), which is a directly competing spray application for psoriasis, generated annual sales of US$100mnin 2015. We forecast US$60mn in peak sales for Sernivo Spray. **Sernivo uses a less potent steroid than what is used in Clobex spray and promises better safety (lower systemic side effects - infections) and significantly lower rates of application site burning (4.5% versus 40%).**

Two multi-centre double-blind randomised clinical trials have evaluated efficacy and safety of Sernivo Spray. The primary end-point of the study was proportion of patients achieving Investigator Assessment Score (IAS) of 0 or 1 (clear or almost clear skin) on Day 15 and Day 29. Sernivo demonstrated statistically clinically significant superiority with 42.7% and 34.5% of patients on Sernivo (on Day 29 in Study 1 and 2) achieving treatment success (IAG score of 0 or 1) as compared to 11.7% and 13.6% of comparator arm (vehicle spray).

Apart from better efficacy, Sernivo Spray offers a better safety profile too. Various adverse events (application site pruritis, application site burning, application site pain and application site atrophy) associated with comparator arm were significantly reduced with Sernivo.

**XP23829 – In-licensed from Xenoport**

DRL has in-licensed US rights for XP23829 (a potential treatment for psoriasis and multiple sclerosis – Phase 2 completed) from Xenoport. The deal involves payment of US$50mn in upfront payment and US$440mn (US$190mn in regulatory milestones) on achievement of predetermined regulatory and commercial milestones. In addition, Xenoport will receive mid-teen royalty on the product. XP23829 will be developed for multiple sclerosis as well as psoriasis. **A composition-of-matter patent, which has expiry date of 2029, protects XP23829.**

**We forecast peak sales of US$1000mn ($400m on a risk-adjusted basis) for XP23829 and expect the regulatory bar to be lower for the following reasons:**

1. **XP23829 carries the same active moiety as Fumaderm whose long-term safety is validated -** XP23829 is a fumaric acid ester product on the same lines as Tecfidera and Fumaderm. All these products have a common active moiety, which is mono methyl fumarate. In fact, Tecfidera received approval for multiple sclerosis in US based on post-marketing safety evidence of Fumaderm (available only in Germany). The long-term safety profile of Fumaderm therapy is favorable and there is no evidence supporting an increased risk of infections, malignancies, or other serious adverse events in patients treated with Fumaderm.
2. **Clinical data is positive and comparable to marketed oral options:** The data seen so far is comparable to Fumaderm - a widely prescribed drug in Germany, which generates sales of US$62mn annually.
3. **Key advantage of XP23829 is build-up of efficacy with time:** The major advantage of fumaric acid compounds is that the efficacy improves with the duration of the therapy.
4. **Potential risk of Grade 3 lymphopenia is manageable through REMS** – Incidence of Grade 3 and severe lymphopenia can lead to a fatal brain infection (PML). However, the risk is manageable by monitoring lymphocyte levels in patients undergoing treatment with XP23829. Methotrexate, another treatment of psoriasis, is also associated with lymphopenia. Llymphopenia associated with Fumaderm is not associated with immuno-supression a**n**d is reversible within weeks after treatment cessation.
5. **Fumaderm has also shown efficacy in patients who have failed methotrexate and UV therapy.**
6. According to German guidelines for the treatment of psoriasis, a review of about 13 clinical studies suggests **50%-70% patients on Fumaderm achieve PASI-75 response** after 4 months of treatment, which is impressive compared to existing treatment options. The improvement in response is not associated with immunosuppressive effect or increased risk of efficacy or malignancy.
7. **GI tolerability, which is the key concern with this class of drugs, tends to improve with the duration of the therapy.**
8. **Significantly higher efficacy and faster response at a lower dose when combined with calcipotriol.**

   There are three potential advantages of using fumaric acid esters in conjunction with topical calcipotriol:

   1) **Significantly higher efficacy**: In a clinical study, involving 143 patients, those on combination of fumaric acid esters (FAE) and calcipotriol achieved a mean reduction of 80% in PASI score in 13$^{th}$ week. In comparison patients on FAE, monotherapy experienced a 60% reduction in PASI score.

   2) **Patients need a lower dose of Fumaderm:** On an average, patients on a combination of fumaric acid esters and calcipotriol need 4.5gm lower dose of fumaric acid over a 13-week course than patients treated with fumaric acid esters alone.

   3) **Significantly faster onset of action:** Patients in the combination group respond more rapidly to the treatment. A 50% reduction in PASI score was observed in combination arm after 3 weeks of treatment, compared with 9 weeks for FAE monotherapy group.

## Phase 2 Clinical data on XP23829

**Efficacy data**

In Phase 2 trials, about 40% and 22% of the patients treated with XP23829 achieved PASI-50 and PASI-75 score, respectively, in 12th week. FP-187 and Otezla demonstrated similar reduction in PASI-75 score.

**Tolerability and safety**

With regard to tolerability, the key concerns were diarrhoea, nausea and headache. Flushing, a common side effect with existing prodrugs of mono methyl fumarate was lower with XP23829. FP187 and Otezla reported similar tolerability issues.

**Competitive profiling**: The efficacy and tolerability data so far observed in Phase 2 trials is clearly inferior to biologic drug candidates. The recently approved biologic drug candidates for psoriasis have shown PASI 75 improvement in excess of 70% in 12th week.

Compared with other oral psoriasis drugs, which include recently launched Otezla (Celgene) and Forward Pharma's Phase 3 drug candidate FP187, XP 23829 has a more or less comparable profile. In Phase 2 trials, 31.3% of patients on FP-187 achieved PASI 75 score **in 20th week** while XP23829 achieved PASI75 response in 22% patients in **12th week**.

In case of Otezla, PASI-75 response was 28.8% **in 16th week**.

**XP23829 can differentiate from other oral options**

XP23829 has the potential to differentiate on efficacy vis-à-vis other oral drugs on the market by virtue of its long-term efficacy data and potential of significantly better efficacy on use in combination with topical calcipotriol

One major potential benefit of fumaric acid-based compounds is their long-term tolerability and efficacy. It has been found in long-term studies on Fumaderm that about 50%-70% of the patients achieve greater than 70% reduction in PASI score with a year of therapy. There is a good chance for XP23829 to better PASI 75 52nd week response as seen with Otezla (51%).

**Peak sales potential and launch timeline in case of psoriasis**

It has been around a year since Celgene launched its oral drug – Otezla for Psoriasis and the drug has shown an encouraging ramp up. The sales are currently running at $140m in quarterly revenues. Peak sales estimate for Otezla range anywhere between US$800mn and US$1.5bn. Forward Pharma is close to completing Phase 3 trials for FP187 in Europe and we should expect its launch in 2HFY17. The US trials have not yet kicked off, it seems the company has still not finalized its clinical strategy / priorities for the US market.

Accounting for potential competitive risks, we expect XP23829 to reach US market for psoriasis by 2019 and estimate peak sales of US$400mn (assuming a 2% market share and a 60% price discount to biologics).

**Peak sales potential and launch timeline in case of multiple sclerosis**

Multiple sclerosis represents a large market and there are potentially two competitors, which have an edge in terms of the timeline. Alkermes and Forward Pharma are also developing novel prodrug candidates for monomethyl fumarate. Alkermes has already initiated Phase 3 trial and aims to file an NDA by 2018. Likewise, Forward Pharma should also initiate a trial soon.

With Xenoport yet to freeze its Phase 3 strategy, we expect a filing by Xenoport around 2020. Tecfidera represents a US$3bn opportunity. Assuming a 15% share for XP23829 at a 30% price discount, XP23829 should garner about US$300mn in peak sales in multiple sclerosis market.

**Zenavod**: These are 40mg modified release doxycycline capsules and DRL has received a tentative approval. Zenavod is equivalent to Oracea marketed by Galderma Labs. Zenavod has an advantage over Oracea. Oracea has certain dosing restrictions. It can only be taken close to meals (one hour before meal or two hours after meals). DRL has formulated Zenavod in a way that it does away with the meal-time restrictions.

As there is an ongoing litigation with the innovator, the approval is tentative we foreacast a launch in FY 2021. The Patent Trial and Appeal Board (PTAB) recently rejected DRL's IPR petitions for Galderma's patent covering its Oracea® (doxycycline) product for the treatment of rosacea. Oracea's US sales are around US$350mn and if DRL finally prevails in the litigation, we can expect around US$50mn-US$70mn in annual sales from Zenavod.

**Xeglyze for lice infestation– In-licensed from Hatchtech**

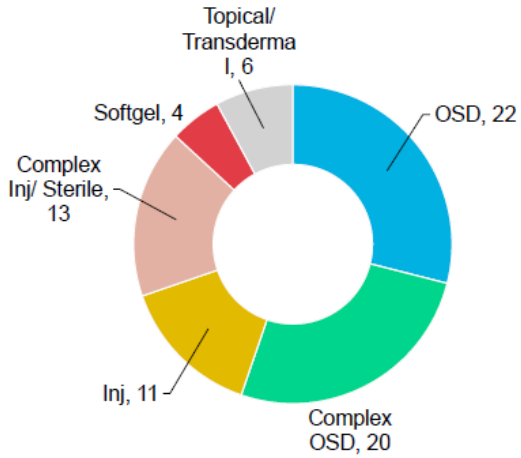
DRL has exclusive commercialisation rights in US, Canada, India, Russia, and CIS for Xeglyze lotion. Hatchtech has filed an NDA last year and assuming standard review timelines, we should expect approval by 3Q FY - 2017. Xeglyze Phase 3 data compares well with two leading lice treatments in the market - Sklice and Natroba. In Phase 3 trial, 81% of patients treated with Xeglyze were lice-free compared to 77% with Sklice and 84% with Natroba. The key benefit of Xeglyze is that patients as young as six months can use it and is a single application. Natroba can be prescribed only in patients four years of age and older.

Sklice, the largest-selling anti-lice prescription product in the US, generates around US$75mn in annual sales. With a clinical profile comparable to Sklice, we expect Xeglyze to touch US$40mn in annual sales in US by 2021.

**High-value generic drug launches in the US to help near to mid-term growth**

DRL has 79 ANDAs awaiting approval in the US. Compared to other Indian pharmaceutical companies, the number is not so encouraging. However, the sales potential of these 79 pending ANDAs is likely to be much higher as most of these ANDAs represent a complex opportunity with significant entry barriers. As many as 18 out of 79 ANDAs pending represent first-to-file opportunities.

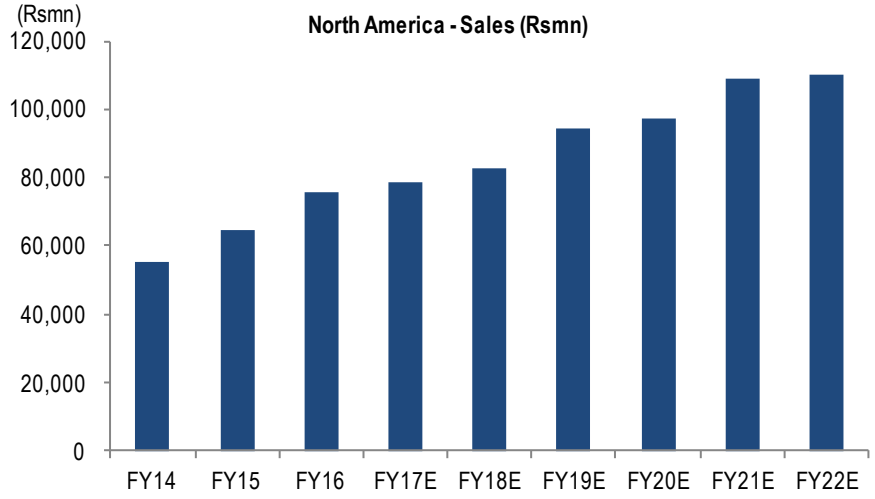
**Exhibit 3: Distribution of ANDA filings of Dr. Reddy by dosage form**




*Source: Company Presentation*

These ANDAs target US$45bn of innovator brand sales. DRL expects its sales per ANDA in 2020 to be approximately 30% higher than what it was in 2015. The realisation per ANDA in 2015 was approximately US$11mn and going forward in 2020, the same should be US$15mn.

**Exhibit 4: North America - Sales**




*Source: Company, Nirmal Bang Institutional Equity Research*

## Some high-value ANDA launches lined up over the next five years

- **Generic Diprivian (propofol):** Diprivan is a complex injectable product and expected to have low competition. Annual sales of Diprivan in the US are around US$250mn. Assuming 30% price erosion and 40% share, Diprivan should add about US$50mn to the top-line.
- **Generic Glivec (imatinib):** The approval of generic Glivec for DRL is contingent on execution of the ongoing risk mitigation measures at its facilities facing warning letter**.** Glivec could be a major contributor to DRL's earnings in FY17 in the event the competition post expiry of Sun Pharmaceutical Industries marketing exclusivity period remains limited. We expect limited competition and DRL may be the third generic player entering US market in December 2016.

  Entry of generic companies post expiry of SPIL's marketing exclusivity period in August 2016 is dependent on them either winning the ongoing litigation or entering into a settlement. So far, none of the generic companies except DRL and SPIL entered into a settlement agreement or invalidated Novartis' unexpired patents on Glivec.
- **Generic Doxil (liposomal doxorubicin):** DRL is developing the product in collaboration with Natco Pharma. We expect launch around FY18 and should be a low-competition opportunity. This is close to US$250mn to US$300mn opportunity in US. Assuming a 30% price discount and a 25% market share, the drug should add US$45mn to DRL's top-line.
- **Generic Aloxi (palonsetron hydrochloride):** This one too will be a high-value opportunity. There are two different approvals that DRL has on this compound. DRL has a final approval for an ANDA filing it made for palonsetron hyrdrochloride and the other is a tentative approval for a generic copy (bioequivalent copy) of Aloxi. For the generic version, DRL has a settlement with the innovator under which it can launch in September 2018. While DRL has final approval for the new drug application it made for palonsetron hydrochloride, it can launch the new drug any time now but is weighing potential risk of an adverse litigation outcome.

  We are expecting the launch in 2018. With brand sales of US$450mn in the US and three generic players expected in the market, we expect US$35mn in sales for DRL from this opportunity in FY19.
- **Generic Exelon patch:** The patent on Exelon patch expires in 2019. It is quite likely that DRL may launch this patch prior to patent expiry. At the 4QFY16 earnings call, the company highlighted that it is expecting approval for apatch product in FY17. We believe the product will be Exelon patch. Brand sales of Exelon patch are around US$200mn in US. Assuming DRL is able to garner a 20% share at a 35% discount, the opportunity should add US$25mn to DRL's top-line.
- **Generic Copaxone:** Copaxone represents the largest opportunity among the potential ANDA filings of DRL. Copaxone 20mg and Copaxone 40mg together generate approximately US$3bn in the US. In case of full-blown competition, we may see four or five players in the market (Natco, Sandoz, DRL, Biocon and Synthon).

Copaxone 40mg, which represents bulk of the opportunity, is subject to a favourable litigation outcome. A district court trial challenging Teva's four Orange Book-listed patents for Cpaxone 40mg (glatiramer acetate injection) is scheduled for 26 September 2016. The outcome will decide whether generic players can look to launch a generic copy of Copaxone 40mg (subject to successful approval).

## At the current run-rate, biosimilar sales should more than double by 2020

DRL's biosimilar portfolio is currently in its nascent stage, but there is tremendous growth potential. For FY15, DRL's biosimilar portfolio generated US$95mn in annual sales. The portfolio has posted a 35% CAGR over the past five years. The portfolio includes five biosimilars - darbepoetin, pegfilgrastim, trastuzumab, rituximab, and bevacizumab. The sales of innovator's brand of these biosimilar versions aggregate to US$3bn annually in emerging markets - Russia & CIS, Latam & Mexico, China, ASEAN, India and MENA.

DRL intends to file these biosimilars across major emerging markets over 2016-18. Based on these filings, biosimilar sales can more than double from the current level by 2020.

The larger part of the upside from the biosimilar portfolio would be realised when DRL launches them in developed markets. The sale of brand versions of biosimilar copies sold by DRL is around US$25bn in developed countries. The first wave of launches in developed markets is expected around 2020. As of now, DRL has two biosimilar programmes (Rituximab and Pegfilgrastim) in clinical development in US/EU. While Pegfigrastim may not be a meaningful opportunity by the time DRL would be in a position to launch, Rituximab would still be a meaningful one.

### There is immense headroom for growth of domestic pharma business and DRL is well poised

Although DRL is the second-largest pharmaceutical company in India in terms of worldwide sales, it is still a relatively small player in Indian market. The company is ranked 14th in terms of its domestic market share.

Lately DRL has intensified its sales and marketing efforts in domestic market. It has made niche acquisitions (UCB CNS portfolio) and carved collaborations (Amgen for biologics and AstraZeneca for diabetes). Growth in domestic market has now accelerated. The company's revenues are now growing at 19% against an average of 11% over FY11-FY15.

With a very strong product portfolio and presence in high-growth segments, the company has tremendous scope to build its presence in home ground. We are looking at 18% annualised growth over the next five years, but the growth should be slower in FY17 owing to inclusion of some of the large brands of DRL under price control.

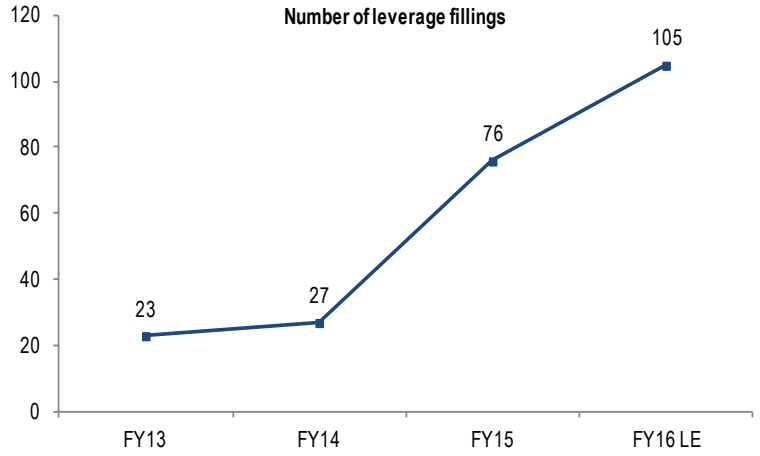
### DRL's emerging market business – How low can it go?

It remains difficult to predict the fate of emerging market currencies in view of the changing crude oil market dynamics. Nevertheless, it seems crude oil prices are staging a recovery and we have probably seen the worst in terms of currency impact.

We foresee a pick-up in emerging market sales from now onwards. The rout in emerging market currencies has already taken its toll on DRL's emerging market sales. For FY16, emerging market business of DRL is down 25% YoY. The contribution of emerging market sales to DRL's overall sales for nine months ended December 2015 was 15% compared to 21% in the same period in 2014.

Going forward, we may witness acceleration in growth as DRL is leveraging its complex generic filings in advanced markets for growth in emerging markets too. The filings have significantly shot up in the past two years and the efforts should bear fruit in the coming years.

**Exhibit 5: Filings in Emerging Markets**




*Source: DRL's presentation*

**Growth from Europe**

DRL's Europe business is back on growth trajectory. Most of DRL's revenues in Europe came from UK, Germany and out-licensing business. The EU business has now turned cash positive as DRL has moved out of competitive participation in tenders of health insurance funds/other quasi government organizations. It is focusing on launch of niche generic products that have limited competition. We expect DRL to leverage its niche portfolio in US for developing its EU business.

**Pharmaceutical service and active ingredients (PSAI) business**

PSAI business accounts for 18% of DRL's 2015 sales. The business is currently underperforming, as there is a delay in dispatches and production cuts because of ongoing remediation measures at the API facilities under warning letter. In 3QFY16 results, PSAI revenues slipped 17% YoY. We should witness renewed growth in PSAI business once the remediation measures are in place (a few quarters away from here).

**What if the USFDA warning letter escalates to an import alert**

About 10%-12% ($300m) of the consolidated turnover of DRL comes from manufacturing facilities under warning letter. The most important products that come from these facilities are generic copies of Vidaza (azacitdine) and Dacogen (decitabine). Generic Vidaza and generic Dacogen comprise 20% ($200m) of DRL's US sales (US$1bn).

Apart from manufacturing azacitidine and decitabine inhouse, DRL also relies on a third party facility for manufacturing these products. Therefore, in case of an import alert it can negotiate with the partner for a larger share of manufacturing capacity. Currently, DRL outsources 10% and 40% of Dacogen and Vidaza generic requirement, respectively. Outsourcing a larger proportion will obviously have an adverse impact on margins. The post-tax margins from these products should be around 50%. Higher outsourcing means that DRL may have to be prepared to lose on the margins front. In such a scenario, net margins should decline from 50% currently to 30%. This mean a US$20mn hit on earnings (5% of annual earnings).

Conservatively, assuming the rest of the sales (other than azacitidine and decitabine) is entirely at risk, and also assuming a 15% margin (in line with overall company margins) DRL stands to lose another US$15mn (4% of earnings).

Apart from existing products in the market, DRL is also dependent on APIs and formulations from the facilities under warning letter for the ANDAs it has already filed but are yet to be approved. In the event of an import alert, these approvals are likely to be delayed. However, DRL is actively pursuing a risk mitigation strategy which ensures that it does not miss out on important approvals.

The efforts towards de-risking are being prioritised in accordance with the expected product launch timeline. The only major product DRL has lost so far is Xeloda generic because of the warning letter. The approval has been delayed. Xeloda generic could have been a major contributor to earnings this year.

In case of an import alert, there would be a sentimental dip in DRL's stock price. However, we would rather view it as an opportunity to buy.

**Recommendation**

Resolving the USFDA warning letter concerns remains paramount for the company to regain investor confidence. Looking at its record of accomplishment in terms of regulatory execution and product development, we are positively inclined that the company should be back on a firm growth trajectory soon. The fortunes of Russia and Venezuela business hinges on the recovery in crude oil prices, but the best part of investing in DRL is that the worst is already in the numbers.

Proprietary product business of DRL is currently in a nascent stage and does not contribute to earnings. By 2022, the business should scale up several folds (from US$50mn to US$700mn). We see the next two to three years as a transition phase as the company progresses into a new growth orbit.

The ANDA pipeline is ripe too, although there may be some launch timing differences (vis-a-vis our estimates) which may lead to lower-than-expected earnings growth in the near term.

DRL's domestic business has also started growing ahead of industry growth rate. With a growing commitment of the management towards this otherwise neglected business, we expect the growth trend to continue.

## Risks

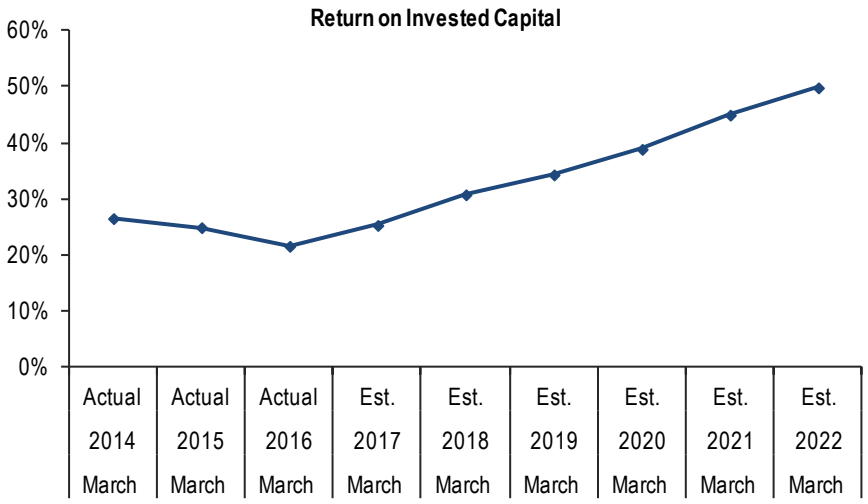
1) Promius pharma is expected to be a major contributor to DRL growth for the next five years. While DRL has so far shown exemplary capabilities in getting its new drugs approved, there is a risk that they may not be able to demonstrate the same for other products in pipeline. This may lead to a subdued growth for DRL in the medium to long term.
2) Currently DRL has 49% of its revenues coming from the US and a significant depreciation of USD vs. Indian rupee would have an adverse impact on the future earnings of the company.
3) Emerging markets which used to be 21% of DRL sales in FY-2015 have declined to 15% of sales on account of abnormal depreciation of Russian Ruble and collapse of Venezuelan Bolivar. We believe the crude oil prices should remain stable and henceforth we should start witnessing a recovery in emerging market business. However if the crude oil prices deteriorate from the current levels, we might see further harm to DRL emerging market business.
4) Dr. Reddy derives a significant part of its US revenues from a few products where the competition is currently limited. While there are entry barriers for competitors in terms of technical complexity but there is a potential chance that we might see a larger than anticipated competition for these products.
5) Regulatory changes in the US which have an adverse impact on the pricing of generic drugs also pose risk to DRL's growth prospects
6) Failure to maintain cGMP compliance for its manufacturing facilities can have an adverse impact on the potential growth of the company.

## Valuation

DRL's high value generic launches over the next five years should yield notable improvement in the return ratios and free cash flow generation. We expect DRL's return on invested capital (ROIC) which currently stands at 26% (adjusted for one time exceptional items) to double by 2022. By virtue of its enhanced free cash flow generation, DRL should also be able to leverage its balance sheet for strategic maneuvers.

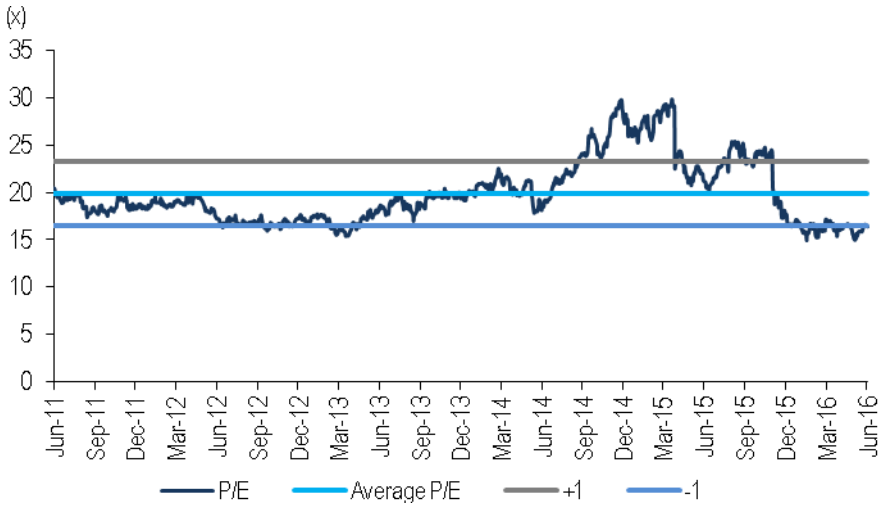
Historically DRL has traded at an average P/E ratio of 22x. We value DRL at 21x price earning multiple on 2018E earnings and arrive at a price target of Rs. 3950.

**Exhibit 6: Return on Invested Capital**




*Source: Company, Nirmal Bang Institutional Equity Research*

**Exhibit 7: P/E Chart**



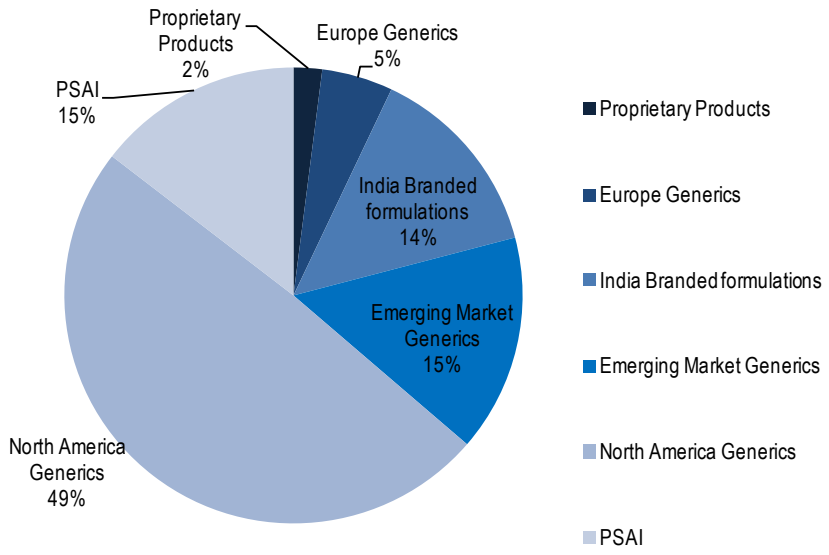

*Source: Company, Nirmal Bang Institutional Equity Research*

## Company Description

Dr. Reddy's Laboratories (DRL) is India's premium generic company. It is second largest Indian pharmaceutical company in terms of global revenues. Sales in North America represent the largest component of DRL annual revenues. Industry leading chemistry / product development / regulatory skills is the hallmark of DRL. The company operates in three segments namely –

1) **Pharmaceutical Services and Active Ingredients –** Manufactures Active pharmaceutical ingredients
2) **Global Generics** – Comprises Emerging Market, North America, India branded formulations and Europe
3) **Proprietary Products** – Develops value added generics based on incremental innovation for the US markets

**Exhibit 8: Revenue Model of Dr. Reddy based on FY-16 Numbers**




*Source: Company, Nirmal Bang Institutional Equity Research*

There is growing earning pressure in the US market, as Indian companies are on a considerably larger revenue base and the larger part of upcoming generic opportunities in the US represent complex generic products (primarily injectable, transdermals and inhalers) which is difficult to access. DRL clearly has realized this quite early and hence it has ramped up its R&D spend to transition into the innovative and complex generics space. It has a growth strategy well in place that will allow the company to not only tap the complex generic space but also grow beyond that. The company is developing novel drug candidates that should deliver meaningful benefit for patients through incremental innovations on the formulations or API front. In addition to in-house innovation, DRL is also actively pursuing R&D externalization strategy to fortify its growth prospects.

As far as the domestic market is concerned, DRL is currently a relatively small player and there is immense headroom for the company to drive growth faster than the industry.

We believe the emerging market business too has bottomed out and going forward we will see positive momentum here too.

DRL is also one of the early entrants in the biosimilar space. It has already launched 5 biosimilars in India and couple of markets outside India. A launch in major emerging markets (Russia, China, ASEAN) and developed market (US and EU) is planned and will unfold over the next five years.

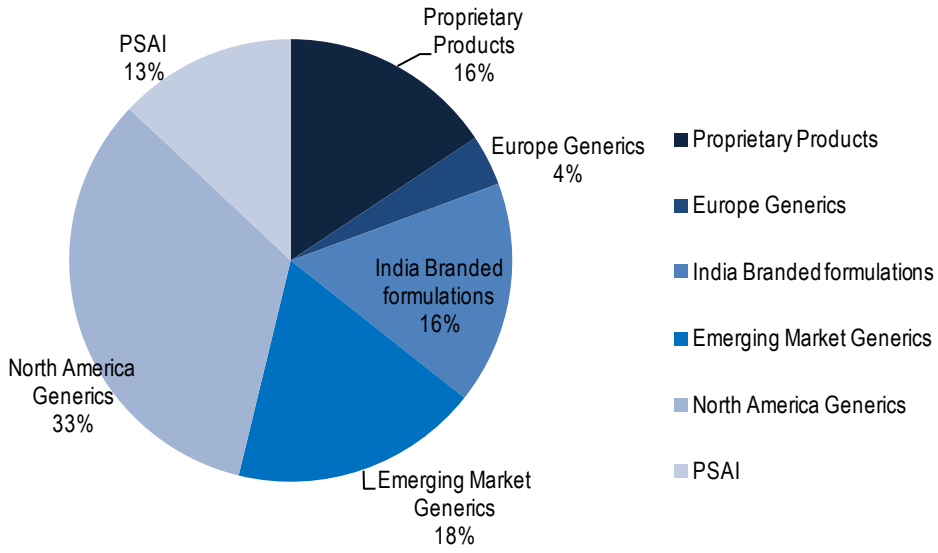
The strong fundamentals of the company are best reflected in its financial performance. The company's topline has grown at 17% CAGR over the last 10 years.

In the recent past, the stock price has corrected 35 percent from its peak. The USFDA issued a warning letter on its manufacturing facilities in India because of deviation from good manufacturing practices at its API manufacturing facilities in Srikakulam, Andhra Pradesh and Miryalaguda, Telangana, as well as regarding violations at its oncology formulation manufacturing facility at Duvvada, Visakhapatnam, Andhra Pradesh.

Apart from the warning letter related concerns, we witnessed a steep fall in value of the emerging market currencies vs.USD. Dr. Reddy has 20% of its generic formulation sales coming from Emerging markets. The larger part of RDY EM sales come from Russia / CIS and Venezuela (about 70%). The currency erosion was much steeper in both these territories

**How will the Revenue Model of DRL evolve over the next five years**

**Exhibit 9: Revenue Model of Dr. Reddy based on FY-22 Numbers**




*Source: Company, Nirmal Bang Institutional Equity Research*

## Financials

### Exhibit 10: Income statement

| Y/E March (Rsmn) | FY15 | FY16 | FY17E | FY18E | FY19E |
|---|---|---|---|---|---|
| Net sales | 1,48,189 | 1,54,708 | 1,69,150 | 1,88,607 | 2,21,285 |
| *% growth* | *12.1* | *4.4* | *9.3* | *11.5* | *17.3* |
| Raw material costs | 62,786 | 62,427 | 68,274 | 75,005 | 86,092 |
| Staff costs | 29,446 | 31,420 | 34,248 | 37,330 | 40,690 |
| R&D Costs | 17,449 | 17,834 | 19,499 | 20,747 | 23,678 |
| Other expenditure | 13,139 | 14,282 | 15,213 | 17,254 | 22,688 |
| Total expenditure | 1,22,820 | 1,25,963 | 1,37,234 | 1,50,336 | 1,73,148 |
| EBITDA | 34,581 | 37,689 | 41,752 | 48,464 | 58,599 |
| *% growth* | *3.8* | *9.0* | *10.8* | *16.1* | *20.9* |
| *EBITDA margin (%)* | *23* | *24* | *25* | *26* | *26* |
| Other income | 917 | 874 | 874 | 874 | 874 |
| Interest costs | 1,092 | 876 | 883 | 748 | 854 |
| Gross profit | 85,403 | 92,281 | 1,00,876 | 1,13,602 | 1,35,193 |
| *% growth* | *12.7* | *8.1* | *9.3* | *12.6* | *19.0* |
| Depreciation | 8,100 | 7,841 | 8,698 | 9,016 | 9,240 |
| Profit before tax | 28,163 | 27,140 | 33,823 | 40,952 | 51,459 |
| *% growth* | 6 | -4 | 25 | 21 | 26 |
| Tax | 5,984 | 7,127 | 7,441 | 9,009 | 11,321 |
| *Effective tax rate (%)* | *21.2* | *20.0* | *22.0* | *22.0* | *22.0* |
| Net profit | 22,179 | 20,013 | 26,382 | 31,942 | 40,138 |
| *% growth* | *3.1* | *(9.8)* | *31.8* | *21.1* | *25.7* |
| EPS (Rs) | 130 | 117 | 155 | 187 | 235 |
| *% growth* | *3.0* | *(9.6)* | *31.8* | *21.1* | *25.7* |
| DPS (Rs) | 20.0 | 20.0 | 22.0 | 24.2 | 26.6 |
| *Payout (%)* | *15* | *17* | *14* | *13* | *11* |
| Dividend on equity shares | 20.0 | 20.0 | 22.0 | 24.2 | 26.6 |
| Tax on dividend | 694 | 694 | 764 | 840 | 925 |

*Source: Company, Nirmal Bang Institutional Equities Research*

### Exhibit 11: Cash flow

| Y/E March (Rsmn) | FY15 | FY16 | FY17E | FY18E | FY19E |
|---|---|---|---|---|---|
| EBIT | 26,481 | 29,848 | 33,054 | 39,448 | 49,360 |
| (Inc.)/dec. in working capital | (15,040) | 3,100 | (9,430) | (4,720) | (7,460) |
| **Cash flow from operations** | **30,431** | **37,851** | **32,829** | **44,945** | **52,890** |
| Other income | 917 | 874 | 874 | 874 | 874 |
| Depreciation | (8,100) | (7,841) | (8,698) | (9,016) | (9,240) |
| Interest paid (-) | 1,092 | 876 | 883 | 748 | 854 |
| Tax paid (-) | (5,396) | (7,127) | (7,441) | (9,009) | (11,321) |
| Dividends paid (-) | (3,587) | (4,107) | (4,517) | (4,969) | (5,466) |
| **Net cash from operations** | **25,033** | **30,724** | **25,388** | **35,936** | **41,569** |
| Capital expenditure (-) | (15,155) | (10,582) | (10,454) | (10,975) | (10,178) |
| **Net cash after capex** | **9,878** | **20,142** | **14,934** | **24,961** | **31,391** |
| Inc./(dec.) in short-term borrowing | 4,068 | 746 | 2,129 | 2,461 | 3,981 |
| Inc./(dec.) in long-term borrowing | (3,716) | (6,962) | (4,177) | (1,875) | (7,500) |
| Inc./(dec.) in preference capital | - | - | - | - | - |
| Inc./(dec.) in borrowings | 352 | (6,216) | (2,048) | 586 | (3,519) |
| (Inc.)/dec. in investments | (53,466) | - | - | - | - |
| Equity issue/(buyback) | - | - | - | - | - |
| **Cash from financial activities** | **(4,118)** | **(10,322)** | **(6,565)** | **(4,383)** | **(8,985)** |
| Others | - | - | - | - | - |
| Opening cash | 8,451 | 5,394 | 15,214 | 23,582 | 44,160 |
| Closing cash | 5,394 | 15,214 | 23,582 | 44,160 | 66,567 |
| Change in cash | (1,989) | 9,820 | 8,368 | 20,578 | 22,407 |

*Source: Company, Nirmal Bang Institutional Equities Research*

### Exhibit 12: Balance sheet

| Y/E March (Rsmn) | FY15 | FY16 | FY17E | FY18E | FY19E |
|---|---|---|---|---|---|
| Equity | 852 | 852 | 852 | 852 | 852 |
| Reserves | 1,10,450 | 1,26,356 | 1,48,221 | 1,75,195 | 2,09,867 |
| Net worth | 1,11,302 | 1,27,208 | 1,49,073 | 1,76,047 | 2,10,719 |
| Net deferred tax liabilities | 1,779 | 1,779 | 1,779 | 1,779 | 1,779 |
| Short-term loans | 21,857 | 22,603 | 24,732 | 27,193 | 31,174 |
| Long-term loans | 14,307 | 10,130 | 8,255 | 755 | 755 |
| Total loans | 36,164 | 32,733 | 32,987 | 27,948 | 31,929 |
| **Liabilities** | **1,94,762** | **2,10,452** | **2,28,425** | **2,60,633** | **2,99,513** |
| Gross block | 72,011 | 81,746 | 91,364 | 1,01,461 | 1,10,824 |
| Depreciation | 30,040 | 36,220 | 43,251 | 50,696 | 58,449 |
| Net block | 5,720 | 6,180 | 7,031 | 7,445 | 7,753 |
| Capital work-in-progress | 6,119 | 6,119 | 6,119 | 6,119 | 6,119 |
| Long-term investments | 2,817 | 2,817 | 2,817 | 2,817 | 2,817 |
| Inventories | 25,529 | 27,368 | 29,922 | 33,364 | 39,145 |
| Debtors | 40,755 | 41,179 | 45,024 | 49,038 | 55,321 |
| Cash | 5,394 | 15,214 | 23,582 | 44,160 | 66,567 |
| Loans and advances | 10,989 | 10,989 | 10,989 | 10,989 | 10,989 |
| Other current assets | 37,171 | 37,808 | 38,994 | 40,907 | 44,030 |
| Total current assets | 1,19,838 | 1,32,558 | 1,48,511 | 1,78,458 | 2,16,052 |
| Creditors | 10,660 | 11,129 | 12,168 | 13,567 | 15,918 |
| Other current liabilities | 53,335 | 56,827 | 53,770 | 65,105 | 66,964 |
| Total current liabilities | 63,995 | 67,956 | 65,938 | 78,673 | 82,882 |
| Net current assets | 55,843 | 64,602 | 82,573 | 99,785 | 1,33,171 |
| Misc. expenses | - | - | - | - | - |
| **Total assets** | **1,94,762** | **2,10,452** | **2,28,425** | **2,60,633** | **2,99,513** |

*Source: Company, Nirmal Bang Institutional Equities Research*

### Exhibit 13: Key ratios

| Y/E March | FY15 | FY16 | FY17E | FY18E | FY19E |
|---|---|---|---|---|---|
| **Profitability & return ratios** | | | | | |
| EBITDA margin (%) | 23.3 | 24.4 | 24.7 | 25.7 | 26.5 |
| EBIT margin (%) | 17.9 | 19.3 | 19.5 | 20.9 | 22.3 |
| Net profit margin (%) | 15.0 | 12.9 | 15.6 | 16.9 | 18.1 |
| RoE (%) | 19.9 | 15.7 | 17.7 | 18.1 | 19.0 |
| RoCE (%) | 21.1 | 21.7 | 21.0 | 22.3 | 23.3 |
| **Working capital & liquidity ratios** | | | | | |
| Receivables (days) | 100.4 | 97.2 | 94.9 | 91.3 | 87.6 |
| Inventory (days) | 148.4 | 160.0 | 160.0 | 162.4 | 166.0 |
| Payables (days) | 62.0 | 65.1 | 65.1 | 66.0 | 67.5 |
| Current ratio (x) | 1.87 | 1.95 | 2.25 | 2.27 | 2.61 |
| Quick ratio (x) | 1.5 | 1.5 | 1.8 | 1.8 | 2.1 |
| **Valuation ratios** | | | | | |
| EV/sales (x) | 3.6 | 3.4 | 3.0 | 2.5 | 2.1 |
| EV/EBITDA (x) | 15.4 | 13.8 | 12.2 | 9.9 | 7.8 |
| P/E (x) | 23.7 | 26.2 | 19.9 | 16.4 | 13.1 |
| P/BV (x) | 4.7 | 4.1 | 3.5 | 3.0 | 2.5 |

*Source: Company, Nirmal Bang Institutional Equities Research*

## Disclaimer

### Stock Ratings Absolute Returns

BUY > 15%

ACCUMULATE -5% to15%

SELL < -5%

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