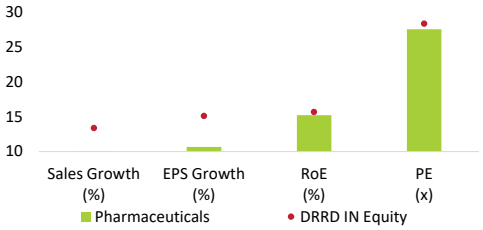
DR REDDY'S LABS

COMPANY UPDATE

KEY DATA

Rating	HOLD
Sector relative	Neutral
Price (INR)	4,663
12 month price target (INR)	5,105
Market cap (INR bn/USD bn)	776/10.3
Free float/Foreign ownership (%)	73.3/29.0
What's Changed	
Target Price	—
Rating/Risk Rating	—

INVESTMENT METRICS

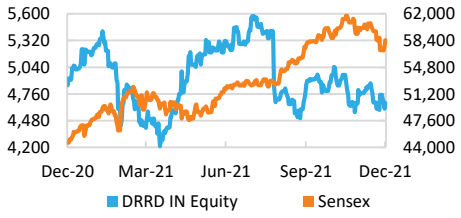


FINANCIALS

(INR mn)

Year to March	FY21A	FY22E	FY23E	FY24E
Revenue	1,89,722	2,15,027	2,48,169	2,88,849
EBITDA	44,682	46,231	63,283	84,922
Adjusted profit	23,679	27,248	41,511	57,295
Diluted EPS (INR)	142.9	164.4	250.5	345.7
EPS growth (%)	(11.2)	15.1	52.3	38.0
RoAE (%)	10.5	15.6	19.4	22.3
P/E (x)	32.6	28.3	18.6	13.5
EV/EBITDA (x)	17.3	16.2	11.7	8.3
Dividend yield (%)	0.5	0.6	0.6	0.6

PRICE PERFORMANCE



Explore:

Financial model

Podcast

Corporate access

Video

Duvvada Form 483 analysis

We analysed the Form 483 with eight observations that Dr. Reddy's (DRRD) Duvvada FTO-7 and FTO-9 received after USFDA's October inspection. Takeaways: i) There are no data integrity issues. ii) No repeat observations from Aug-19 inspection. iii) Most observations relate to deficient SOPs, potential microbial contamination and quality control. iv) We classify Observation #3 and #7 w.r.t. equipment qualification process, controls for aseptic filling and inadequate investigation as 'Serious' that could potentially lead to Official Action Indicated (OAI) classification resulting in a re-inspection and 9–12 months of remediation timeline.

We maintain the 'HOLD' rating with an unchanged TP of INR5,105.

Duvvada inspection: Not out of the woods yet

Dr. Reddy's Duvvada FTO-7 onco-injectable unit was inspected by the USFDA from 18-29 October, which resulted in a Form 483 with eight observations. The Duvvada unit was inspected twice over the last three years in Aug-19 and Jun-19, resulting in 8 and 2 observations before finally getting an EIR in Feb-20. (Refer to Exhibit 2.)

No data integrity but OAI remains a possibility

None of the observations are related to data Integrity, actual contamination, leakages or incomplete records. Observations largely relate to deficient SOPs and potential microbial contamination. We classify 2 observations as Serious (#3 and #7) and three observations as moderately serious (Obs. 1, 4 and 5) (Refer to Exhibit 1). In Obs. #3, the FDA has raised questions on areas not being tested for environmental monitoring with lack of scientific rationale. Likewise Obs#7 FDA has taken note of lack of investigation for recovered micro-organisms and fungus with no scientific rationale provided. In our view, the Duvvada inspection in Oct-18 that saw 8 observations, of which five were repeat, were far more serious (plant received EIR in Feb-19). Given the warning letter was lifted in Feb-19 and the Jun-19 inspection was also classified as NAI gives us some comfort, but since this is a sterile injectable plant, microbial contamination is the single biggest risk in our view.

Outlook and valuation: Inspections limit re-rating scope; retain 'HOLD'

Post-covid, FDA's foreign inspections have declined by ~70% and are yet to pick up pace. Among large-caps, DRRD has the second-largest export contribution, and we expect the FDA to ramp up inspection as CY22 commences. While regulatory outcomes are a zero-sum game from a sectoral perspective (loss in revenue for one company is gain for another), it could undermine multiples for the exporters at large.

We maintain **'HOLD'** on DRRD with an unchanged TP of INR5,105 considering: i) key US launches are behind and uncertainties loom on launch timelines for gRemodulin, sandostatin LAR, iron sucrose, gCopaxone and gNuvaring; ii) Sputnik opportunity is shrinking, and a ramp-up looks unlikely until a booster dose is approved; and iii) domestic remains in investment mode and acceleration is awaited.

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Financial Statements

Income Statement (INR mn)

Year to March	FY21A	FY22E	FY23E	FY24E
Total operating income	1,89,722	2,15,027	2,48,169	2,88,849
Gross profit	1,03,077	1,12,889	1,30,289	1,55,978
Employee costs	0	0	0	0
R&D cost	16,541	17,202	17,372	19,064
Other expenses	41,854	49,456	49,634	51,993
EBITDA	44,682	46,231	63,283	84,922
Depreciation	21,384	13,176	13,950	14,581
Less: Interest expense	(1,653)	(1,827)	(2,695)	(2,953)
Add: Other income	982	3,000	2,500	2,500
Profit before tax	26,413	38,482	55,128	76,393
Prov for tax	9,175	9,621	13,617	19,098
Less: Exceptional item	8,588	(2,152)	0	0
Reported profit	17,238	28,862	41,511	57,295
Adjusted profit	23,679	27,248	41,511	57,295
Diluted shares o/s	166	166	166	166
Adjusted diluted EPS	142.9	164.4	250.5	345.7
DPS (INR)	25.0	30.0	30.0	30.0
Tax rate (%)	34.7	25.0	24.7	25.0

Balance Sheet (INR mn)

Year to March	FY21A	FY22E	FY23E	FY24E
Share capital	832	832	832	832
Reserves	1,72,230	1,95,125	2,30,671	2,81,999
Shareholders funds	1,73,062	1,95,957	2,31,503	2,82,831
Minority interest	0	0	0	0
Borrowings	30,299	30,299	30,299	30,299
Trade payables	23,744	22,386	24,222	27,302
Other liabs & prov	25,355	25,527	25,707	25,896
Total liabilities	2,54,861	2,76,571	3,14,132	3,68,730
Net block	47,333	46,109	44,081	41,549
Intangible assets	40,216	40,264	38,342	36,793
Capital WIP	9,778	9,778	9,778	9,778
Total fixed assets	97,327	96,151	92,201	88,120
Non current inv	8,333	8,333	8,333	8,333
Cash/cash equivalent	34,507	55,114	63,710	1,00,064
Sundry debtors	49,641	50,075	67,991	79,137
Loans & advances	18,623	21,107	24,360	28,353
Other assets	45,412	44,773	56,518	63,705
Total assets	2,54,861	2,76,571	3,14,132	3,68,730

Important Ratios (%)

Year to March	FY21A	FY22E	FY23E	FY24E
Gross margin	54.3	52.5	52.5	54.0
R&D as a % of sales	8.7	8.0	7.0	6.6
Debt/EBITDA	0.7	0.7	0.5	0.4
EBITDA margin (%)	23.6	21.5	25.5	29.4
Net profit margin (%)	12.5	12.7	16.7	19.8
Revenue growth (% YoY)	8.7	13.3	15.4	16.4
EBITDA growth (% YoY)	9.1	3.5	36.9	34.2
Adj. profit growth (%)	(11.2)	15.1	52.3	38.0

Free Cash Flow (INR mn)

Year to March	FY21A	FY22E	FY23E	FY24E
Reported profit	26,413	38,482	55,128	76,393
Add: Depreciation	21,384	13,176	13,950	14,581
Interest (net of tax)	0	0	0	0
Others	1,819	0	0	0
Less: Changes in WC	(8,197)	(3,464)	(30,899)	(19,056)
Operating cash flow	35,703	38,573	24,562	52,820
Less: Capex	(28,075)	(12,000)	(10,000)	(10,500)
Free cash flow	7,628	26,573	14,562	42,320

Assumptions (%)

Year to March	FY21A	FY22E	FY23E	FY24E
GDP (YoY %)	(6.0)	7.0	6.0	0
Repo rate (%)	3.0	3.5	4.0	0
USD/INR (average)	74.4	73.0	72.0	0
India growth (%)	15.5	23.0	10.0	12.0
US generics (USD mn)	948.1	995.5	1,194.7	1,493.3
Russia & CIS (RUB terms)	23,200.0	26,216.0	28,313.3	30,861.5
PSAI (USD mn)	430.2	466.8	527.7	580.5
Capex (USD mn)	377.6	164.4	138.9	0

Key Ratios

Year to March	FY21A	FY22E	FY23E	FY24E
RoE (%)	10.5	15.6	19.4	22.3
RoCE (%)	12.8	16.8	21.2	25.3
Inventory days	170	161	157	165
Receivable days	96	85	87	93
Payable days	85	82	72	71
Working cap (% sales)	28.6	26.9	35.7	37.3
Gross debt/equity (x)	0.2	0.2	0.1	0.1
Net debt/equity (x)	0	(0.1)	(0.1)	(0.2)
Interest coverage (x)	14.1	18.1	18.3	23.8

Valuation Metrics

Year to March	FY21A	FY22E	FY23E	FY24E
Diluted P/E (x)	32.6	28.3	18.6	13.5
Price/BV (x)	4.5	3.9	3.3	2.7
EV/EBITDA (x)	17.3	16.2	11.7	8.3
Dividend yield (%)	0.5	0.6	0.6	0.6

Valuation Drivers

Year to March	FY21A	FY22E	FY23E	FY24E
EPS growth (%)	(11.2)	15.1	52.3	38.0
RoE (%)	10.5	15.6	19.4	22.3
EBITDA growth (%)	9.1	3.5	36.9	34.2
Payout ratio (%)	24.0	17.2	12.0	8.7

Source: Company and Edelweiss estimates

Exhibit 1: Analysis of USFDA Form 483 observations

Number	Observation	Nature of observation	Views
1	Responsibilities and procedures of Quality unit not in writing and fully followed	Quality control; Documentation	Moderately serious. Dr. Reddy's procedures w.r.t. process validation does not determine proper evaluation of viscosity (failure could be passed off as pass). The updated US pharmacoepia testing methods not followed. The handling of incidents procedures also not followed; this is a minor issue where there are no issues of inspection failures or even their classification, there was no reference to minor defects in the SAP system.
2	Lab controls do not include scientifically sound standards to ensure drug quality	Lab control systems	Benign. Specifically regarding sampling plans and test methods which the FDA have said are inadequate. FDA has pointed to lacunae in method and NOT any deviations from the current SOPs
3	Deficient aseptic procedures to monitor environmental conditions	Quality control	Serious. FDA has raised the question over a) the method of sample collection that can be exposed to microbial contamination and b) process to ensure controls for asepetically filled products. Several areas have not been tested for environmental monitoring with no rationale given, failure to perform risk evaluation for aseptic filling operators and lack of scientific rationale for not testing certain areas. The fact that this is a sterile injectable plant, microbial contamination is the single biggest risk. Company will need to re-evaluate their SOPs.
4	Procedure for microbial contamination of sterile drugs have inadequate validation of aseptic and sterilization process	Quality control	Moderately serious. Equipment qualification process and process controls for aseptic filling are inadequate. Risk assessment did not justify whether the materials used were compatible. We believe this will require new SOPs
5	Component suppliers reports are deficient as results are not validated by Dr. Reddy's	Testing	Moderately serious. Despite procedures for full testing of the suppliers inputs (API/excipients etc), Dr. Reddy's has not fully tested. However, it seems that this is not a systemic issue but rather specific to some products. While it may not be serious, these are sterile drug products and some were shipped to the US.
6	Accuracy of test methods not established	Testing	Benign. Not all drug products or drug substance testing method has been established properly. Viscosity profile, particulate matter identification and spectroscopic identification not verified; since this is for a couple of USPs we are not too worried.
7	Failure to investigate unexplained discrepancy	Environment	Serious. There are no Out-of-Specification (OOS) instances as it does not deal with finished product. Rather, there has been no investigation for recovered microorganisms and fungus, no scientific reason for inadequate investigations and inadequate CAPA for a particular incident.
8	Control system to prevent mix-ups are deficient		Benign. Looks serious optically where there are chances of cross contamination from operators to the equipment. However, in this specific instance water can be changed more frequently to minimise the risk.

Source: FDA, Edelweiss Research

Exhibit 2: Duvvada plant inspection timeline

Month and year	Details
February-March 2015	Inspection
November 2015	USFDA issued Warning Letter
February 2017	Re-inspected; Received 13 observations
November 2017	Received EIR with inspection status remaining same
October 2018	Received 8 observations
February 2019	USFDA issued EIR indicating successful closure of audit; Warning letter lifted
June 2019	Re-inspected; Received 2 observations
September 2019	USFDA issued EIR indicating successful closure of audit
August 2019	Received 8 observations
February 2020	Classified as VAI
October 2021	Re-inspected; received 8 observations

Source: Company, Edelweiss Research

Exhibit 3: USFDA plant inspection status of DRRD's manufacturing facilities

Facility	Inspection Period	No. of observations	Compliance status	Comments
Formulations:				
Bachupally-3 (OSD)	February 2020	1	Cleared, received EIR in May'20	US (~40% of US sales); ~15 out of 100 products in the pipeline are filed from this facility.
Srikakulam SEZ Unit-1	February 2020	0	Cleared	
Duvvada (Oncology) (FTO-7,9)	October'21	8	Pending	
Srikakulam SEZ Unit-2 (topicals)	November 2018	0	Cleared, EIR in Feb'2019	Commercialised in April 2019
Shreveport LA/ Lousianna (US)	August 2019	0	Cleared	Oral solid dosage
API :				
Miryalguda	March 2020	3	Cleared, classified as VAI in Apr'20	
Srikakulam CTO VI	January 2020	4	Cleared, classified as VAI in May'20	Most important API plant. Earlier under Warning Letter
Srikakulam SEZ	October 2019	4	Cleared, classified as VAI in May'20	Created for new products
Bollaram Plant-2	July 2019	5	Cleared, received EIR in October 2019	
Middleburgh, New York (US)	March 21	3	Awaiting EIR	
Mirfield (UK)	September 2017		Received 3 observations	

Source: Company, Edelweiss Research

Company Description

Dr. Reddy's is one of the largest Indian generic companies in the world with presence in more than 40 countries. The US is its largest market, contributing 40% of its revenues. It has one of the largest complex generic portfolios among Indian generic players, which has enabled it to become a prominent generic player in the US. Russia and India are the two other key geographies, where it has significant presence. Apart from strengths in developing niche generic products, vertical integration into APIs has enabled it to become a global generic powerhouse. It operates 30 facilities (10 US FDA approved) and is actively supported by an extensive R&D programme. It also has a deep biosimilar pipeline.

Investment Theme

We argue the road ahead for Dr. Reddy's (DRRD) may not be smooth. i) Key launches are behind and launch momentum is fading. ii) Uncertainty around launch timelines of key products Sandostatin LAR, Levo, gCopaxone and gNuvaring; iii) High US contribution that is exposed to price pressure; iv) Domestic business remains in investment mode; acceleration awaited. v) The Sputnik opportunity is shrinking, and its ramp-up is unlikely until domestic supplies builds up. We await evidence of US pipeline monetization before turning positive again.

Key risks

Delay in approval of key complex products

Regulatory risk from plant inspections

Failure to get approvals for biosimilars and delays in ramp up of proprietary pipeline

Currency fluctuation

Additional Data

Management

Chairman	K Satish Reddy
Co Chairman and MD	GV Prasad
CEO	Mr. Erez Israeli
CFO	Parag Agarwal
Auditor	S.R. Batliboi & Associates LLP

Holdings – Top 10*

	% Holding		% Holding
Blackrock	4.34	Aditya Birla Su	1.82
First State	3.89	Vanguard	1.68
Mitsubishi UFJ	3.54	Mirae	1.42
LIC	2.34	ICICI PruLife	1.38
SBI Funds	2.11	UTI	1.22

**Latest public data*

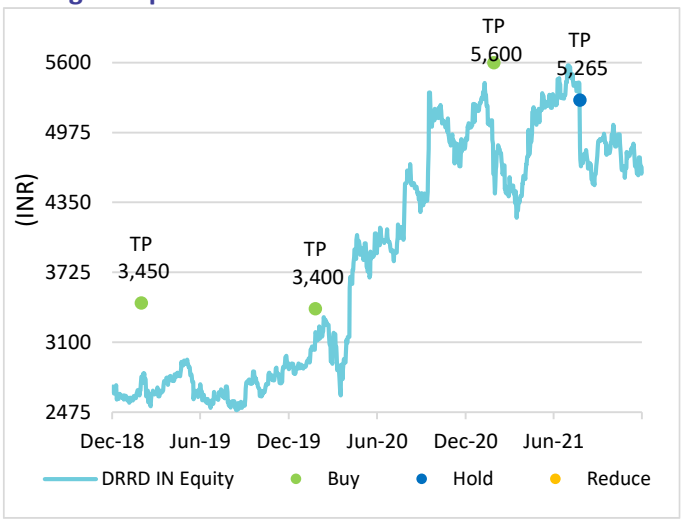
Recent Company Research

Date	Title	Price	Reco
29-Oct-21	Good showing; sustenance key; *Result Update*	4659.2	Hold
27-Jul-21	Testing times ahead ; *Result Update*	4843.35	Hold
15-Jun-21	Going from strength to strength; *Company Update*	5196.85	Buy

Recent Sector Research

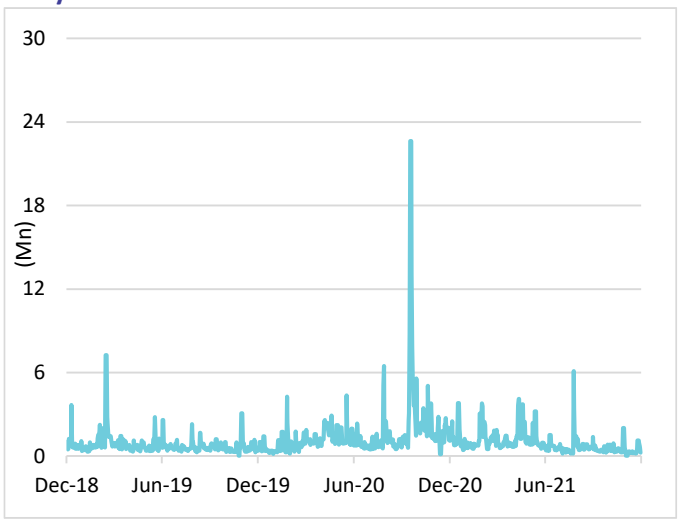
Date	Name of Co./Sector	Title
02-Dec-21	Ipca Laboratories	Long-run growth prospects intact; *Company Update*
16-Nov-21	Ipca Laboratories	Growth intact beyond near-term issues; *Result Update*
15-Nov-21	Glenmark Pharma.	Awaiting new growth trajectory; *Result Update*

Rating Interpretation



Source: Bloomberg, Edelweiss research

Daily Volume



Source: Bloomberg

Rating Distribution: Edelweiss Research Coverage

	Buy	Hold	Reduce	Total
Rating Distribution*	186	52	18	257
	>50bn	**>10bn and <50bn**	**<10bn**	**Total**
Market Cap (INR)	231	40	4	275

**1 stocks under review*

Rating Rationale

Rating	Expected absolute returns over 12 months
Buy:	>15%
Hold:	>15% and <-5%
Reduce:	<-5%

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