BUY
TP: Rs 555 | ▲ 31%

CIPLA | Pharmaceuticals | 12 October 2019

Goa 483s – no data integrity concerns but many procedurals; BUY

Cipla has received 12 observation from the USFDA's inspection of its Goa facility over 16-27 Sep. The inspectors were June P Page, Thomas Arista and Rajiv R Srivastava. Their observations mostly centered around the injectable unit. We believe these are largely procedurals with no data integrity issues. Escalation risk to OAI is very low. The facility accounts for 25-30% of US sales and 6% of FY19 sales (~3% based on single source product, per company). Cipla expects to reply to the FDA on its proposed CAPA within 15 days. Retain BUY, TP Rs 555.

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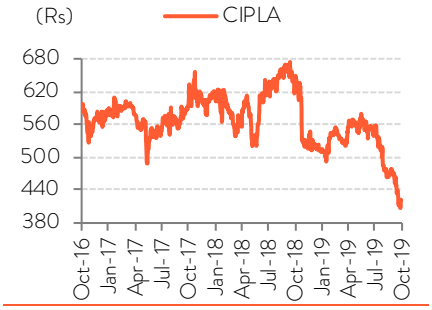
Many procedurals – earnings won't be impacted: We believe chances of official action indicated (OAI) classification are low in the absence of quality integrity and data integrity issues in Form 483. However, there are several procedural issues where resolution could take time. Cipla clarified that dependence on the Goa unit for existing sales based on a single sourced product would be ~US$ 50mn-60mn or 2.5% of FY19 sales (6% on total product basis). Also, none of the pending files from this site are due for approval in the next 15 months. Hence, we don't think earning growth should be affected.

Observations centre on aseptic fill area: The FDA has pointed out: (1) multiple instances of a thick layer of product residual being present on the air exhaust duct; (2) unclean production equipment; (3) deficiency in non-viable particle (NVP) monitoring in the sterile filtration area, evaluation of airflow pattern and equipment qualification; and (4) need for inclusion of SOPs on sanitisation efficacy around the production area and sampling procedures for in-process material testing (details on Page 2).

Ticker/Price	CIPLA IN/Rs 422
Market cap	US$ 4.8bn
Shares o/s	806mn
3M ADV	US$ 15.4mn
52wk high/low	Rs 652/Rs 403
Promoter/FPI/DII	37%/26%/13%

Source: NSE

STOCK PERFORMANCE



Source: NSE

KEY FINANCIALS

Y/E 31 Mar	FY18A	FY19A	FY20E	FY21E	FY22E
Total revenue (Rs mn)	152,181	163,604	164,283	173,998	187,695
EBITDA (Rs mn)	28,254	30,955	31,122	33,681	37,480
Adj. net profit (Rs mn)	12,340	13,409	14,515	16,400	19,037
Adj. EPS (Rs)	15.3	16.6	18.0	20.4	23.6
Adj. EPS growth (%)	(0.2)	8.7	8.2	13.0	16.1
Adj. ROAE (%)	8.9	9.0	9.2	9.6	10.2
Adj. P/E (x)	27.6	25.4	23.4	20.7	17.9
EV/EBITDA (x)	13.0	11.6	11.4	9.9	8.4

Source: Company, BOBCAPS Research

Key USFDA observations for Goa facility

#1 Equipment is not being cleaned, maintained and sanitised at proper intervals to prevent contamination. Also, SOPs do not contain a provision on cleaning of the air exhaust ducts that are contaminated and which are integral to the manufacturing system. The FDA mentioned instances of the presence of a thick, coloured product residue on the inside surface of air exhaust ducts of multiple machines. Cleaning on a periodic basis is required and should be included in the SOP. Cipla has also been using non-dedicated equipment to manufacture and ship drugs to the US and ROW markets over 2017-19.

#2 Non-viable particle monitoring for Grade-A classification is not performed on a routine and dynamic basis during aseptic filling processing. Plus there are no SOPs established for testing and ensuring control mechanism functions. This was across two units in Goa.

#3 An air-flow pattern evaluation does not completely demonstrate that acceptance criteria within the filling room have been achieved.

#4 There are limitations on visual monitoring of the aseptic filling operation due to large batch size and poor viewing angles. Although the CCTV was functioning, the FDA recommended using cGMP CCTV technology to observe the filling area.

#5 Quality assurance impact assessment review was deficient with regards to conducting a check of the particulate count in the sterile filtration area.

#6 Written SOPs on procedures to be followed when microbial limits are exceeded (for personal and surface monitoring) were not being adhered to.

#7 Equipment used for drug manufacturing was not validated for the cleaning process. Written procedures for cleaning and maintenance were not exhaustive.

#8 Investigations of an unexplained discrepancy or failure of a batch to meet any of its specifications did not extend to other batches of the same drug product or other drug products that may have been associated with the specific failure or discrepancy.

#9 Certain equipment was exposed to the outside atmosphere, leading to air flow into the unit from outside. There were no records/verification to ensure that the gaps were covered/sealed to prevent foreign particles entering the area. Deficiency in equipment qualification was noted.

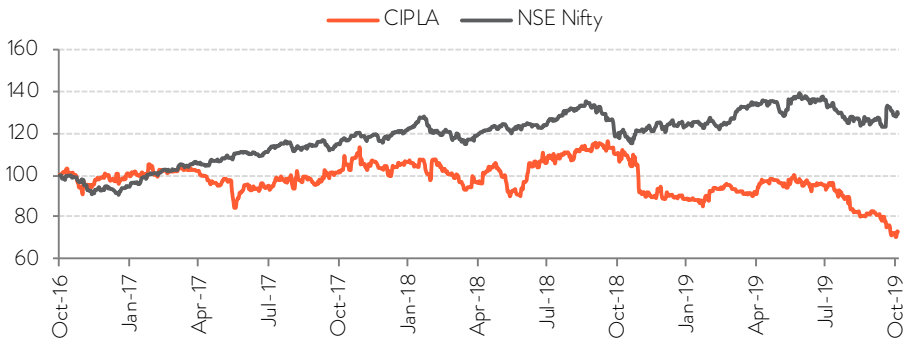
Valuation methodology

We like Cipla for its strong India franchise, rich US pipeline and low risk of price erosion in the US market (due to a benign base and low concentration). Operating leverage in the US business will be a key margin driver in the next two years. So far, Cipla has had a good compliance track record with the USFDA. We believe the Goa 483s are largely procedurals and carry no data integrity issues. Escalation risk to OAI is very low and we see limited earnings impact from the observations.

Post the recent correction, the stock is pricing in headwinds from a sharp contraction in the India trade generics business, weak ROW sales and generic competition in large US assets such as gSensipar, Pulmicort and gVoltaren gel. Valuations are comfortable at 22x P/E on FY21E. We retain our Sep'20 target price of Rs 555, based on 12x one-year forward EV/EBITDA (25x implied P/E).

We continue to expect a core EPS CAGR of 18-20% over FY19-FY21. Advair approval represents an upside risk to our EPS estimates. We have valued one-time gSensipar at non-core business multiples. Maintain BUY.

FIG 1 – RELATIVE STOCK PERFORMANCE



Source: NSE

Key risks

- **US execution critical:** We expect the US market to contribute meaningfully to profitability in the coming years. Any delay in key launches (Proventil HFA, Flonase) can potentially erode 4-5% of FY20E/FY21E EPS.
- **Reduction in Global Access funding:** A decline in the tender-facing Global Access business due to challenges in the funding environment poses a risk to our estimates.
- **Above-expected increase in R&D costs:** Should R&D costs increase beyond the current 7-8% of sales, the savings from other cost optimisation measures would be nullified.
- **Weak drug price hikes in South Africa**

FINANCIALS

Income Statement

Y/E 31 Mar (Rs mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Total revenue	**152,181**	**163,604**	**164,283**	**173,998**	**187,695**
EBITDA	28,254	30,955	31,122	33,681	37,480
Depreciation	13,228	13,263	13,359	14,428	15,582
EBIT	15,026	17,692	17,763	19,253	21,898
Net interest income/(expenses)	(1,142)	(1,684)	(1,480)	(1,002)	(626)
Other income/(expenses)	984	2,915	3,331	3,910	4,454
Exceptional items	0	0	0	0	0
EBT	14,868	18,924	19,614	22,162	25,726
Income taxes	2,501	5,696	5,100	5,762	6,689
Extraordinary items	1,817	1,850	0	0	0
Min. int./Inc. from associates	27	(181)	0	0	0
Reported net profit	**14,157**	**15,259**	**14,515**	**16,400**	**19,037**
Adjustments	1,817	1,850	0	0	0
Adjusted net profit	**12,340**	**13,409**	**14,515**	**16,400**	**19,037**

Balance Sheet

Y/E 31 Mar (Rs mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Accounts payables	21,191	19,480	21,938	23,263	25,125
Other current liabilities	7,904	10,126	9,609	10,189	11,005
Provisions	7,650	8,582	8,606	9,126	9,856
Debt funds	40,980	43,161	30,829	19,268	12,043
Other liabilities	0	0	0	0	0
Equity capital	1,610	1,611	1,611	1,611	1,611
Reserves & surplus	147,378	154,016	166,114	180,096	196,716
Shareholders' fund	148,988	155,627	167,725	181,707	198,327
Total liabilities and equities	**226,713**	**236,976**	**238,707**	**243,553**	**256,355**
Cash and cash eq.	9,655	6,188	17,908	23,946	34,251
Accounts receivables	31,020	41,507	33,784	33,964	36,682
Inventories	40,450	39,648	41,682	44,199	47,737
Other current assets	23,697	21,866	22,420	23,774	25,677
Investments	12,586	25,539	25,539	25,539	25,539
Net fixed assets	53,154	51,144	48,717	46,096	43,265
CWIP	9,813	6,762	6,762	6,762	6,762
Intangible assets	46,337	44,322	41,895	39,274	36,443
Deferred tax assets, net	0	0	0	0	0
Other assets	0	0	0	0	0
Total assets	**226,712**	**236,975**	**238,707**	**243,553**	**256,355**

Source: Company, BOBCAPS Research

Cash Flows

Y/E 31 Mar (Rs mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Net income + Depreciation	27,385	28,522	27,874	30,827	34,619
Interest expenses	1,142	1,684	1,480	1,002	626
Non-cash adjustments	0	0	0	0	0
Changes in working capital	(9,765)	(6,412)	7,100	(1,626)	(4,751)
Other operating cash flows	0	0	0	0	0
Cash flow from operations	**18,761**	**23,794**	**36,453**	**30,204**	**30,494**
Capital expenditures	(17,369)	(6,228)	(10,932)	(11,807)	(12,751)
Change in investments	(2,856)	(12,953)	0	0	0
Other investing cash flows	0	0	0	0	0
Cash flow from investing	**(20,225)**	**(19,181)**	**(10,932)**	**(11,807)**	**(12,751)**
Equities issued/Others	1	1	0	0	0
Debt raised/repaid	(146)	2,181	(12,332)	(11,561)	(7,226)
Interest expenses	(1,142)	(1,684)	(1,480)	(1,002)	(626)
Dividends paid	(1,609)	(2,417)	(2,417)	(2,417)	(2,417)
Other financing cash flows	7,775	(6,163)	2,427	2,621	2,831
Cash flow from financing	**4,879**	**(8,082)**	**(13,802)**	**(12,359)**	**(7,438)**
Changes in cash and cash eq.	**3,415**	**(3,468)**	**11,720**	**6,038**	**10,305**
Closing cash and cash eq.	**9,656**	**6,187**	**17,908**	**23,946**	**34,251**

Per Share

Y/E 31 Mar (Rs)	FY18A	FY19A	FY20E	FY21E	FY22E
Reported EPS	17.6	18.9	18.0	20.4	23.6
Adjusted EPS	15.3	16.6	18.0	20.4	23.6
Dividend per share	3.0	3.0	3.0	3.0	3.0
Book value per share	180.8	189.3	204.6	222.0	242.7

Valuations Ratios

Y/E 31 Mar (x)	FY18A	FY19A	FY20E	FY21E	FY22E
EV/Sales	2.4	2.2	2.2	1.9	1.7
EV/EBITDA	13.0	11.6	11.4	9.9	8.4
Adjusted P/E	27.6	25.4	23.4	20.7	17.9
P/BV	2.3	2.2	2.1	1.9	1.7

DuPont Analysis

Y/E 31 Mar (%)	FY18A	FY19A	FY20E	FY21E	FY22E
Tax burden (Net profit/PBT)	83.0	70.9	74.0	74.0	74.0
Interest burden (PBT/EBIT)	98.9	107.0	110.4	115.1	117.5
EBIT margin (EBIT/Revenue)	9.9	10.8	10.8	11.1	11.7
Asset turnover (Revenue/Avg TA)	20.8	21.0	20.7	21.8	22.8
Leverage (Avg TA/Avg Equity)	1.3	1.3	1.3	1.2	1.1
Adjusted ROAE	8.9	9.0	9.2	9.6	10.2

Source: Company, BOBCAPS Research | Note: TA = Total Assets

Ratio Analysis

Y/E 31 Mar	FY18A	FY19A	FY20E	FY21E	FY22E
YoY growth (%)					
Revenue	4.1	7.5	0.4	5.9	7.9
EBITDA	14.9	9.6	0.5	8.2	11.3
Adjusted EPS	(0.2)	8.7	8.2	13.0	16.1
Profitability & Return ratios (%)					
EBITDA margin	18.6	18.9	18.9	19.4	20.0
EBIT margin	9.9	10.8	10.8	11.1	11.7
Adjusted profit margin	8.1	8.2	8.8	9.4	10.1
Adjusted ROAE	8.9	9.0	9.2	9.6	10.2
ROCE	8.7	10.6	10.6	11.6	12.8
Working capital days (days)					
Receivables	77	95	77	73	73
Inventory	100	91	95	95	95
Payables	52	45	50	50	50
Ratios (x)					
Gross asset turnover	1.2	1.2	1.1	1.1	1.1
Current ratio	2.9	2.9	2.9	3.0	3.1
Net interest coverage ratio	13.2	10.5	12.0	19.2	35.0
Adjusted debt/equity	0.1	0.1	(0.1)	(0.1)	(0.2)

Source: Company, BOBCAPS Research

Disclaimer

Recommendations and Absolute returns (%) over 12 months

BUY – Expected return >+15%

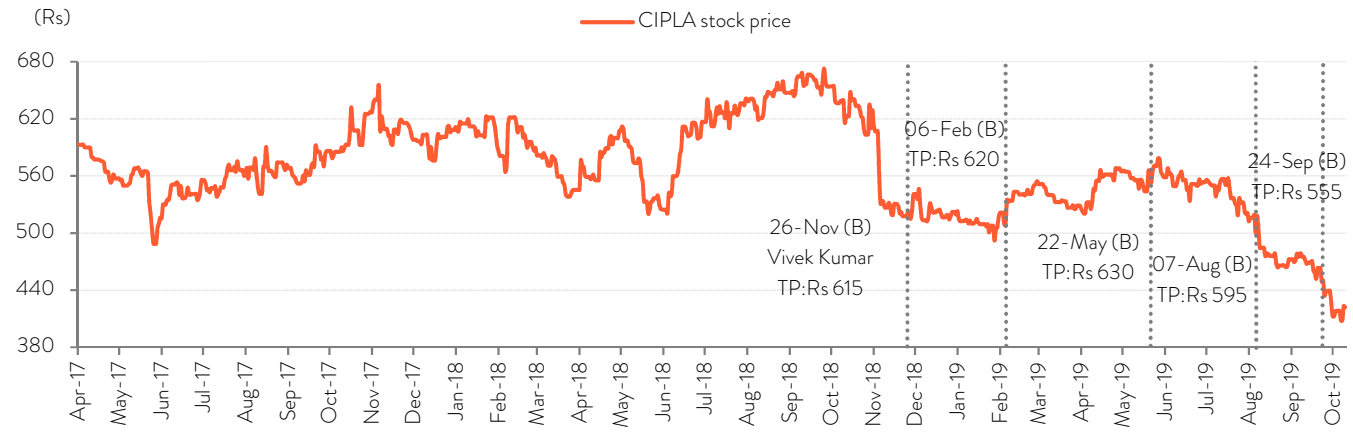
ADD – Expected return from >+5% to +15%

REDUCE – Expected return from -5% to +5%

SELL – Expected return <-5%

Note: Recommendation structure changed with effect from 1 January 2018 (Hold rating discontinued and replaced by Add / Reduce)

HISTORICAL RATINGS AND TARGET PRICE: CIPLA (CIPLA IN)



B – Buy, A – Add, R – Reduce, S – Sell

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