

October 13, 2020

Event Update

■ Change in Estimates | ■ Target | ■ Reco

Change in Estimates

	Current		Previous	
	FY22E	FY23E	FY22E	FY23E
Rating	REDUCE		REDUCE	
Target Price	657		657	
Sales (Rs. m)	1,84,748	1,98,423	1,84,748	1,98,423
% Chng.	-	-	-	-
EBITDA (Rs. m)	38,894	42,760	38,894	42,760
% Chng.	-	-	-	-
EPS (Rs.)	29.9	37.4	29.9	37.4
% Chng.	-	-	-	-

Key Financials - Consolidated

Y/e Mar	FY20	FY21E	FY22E	FY23E
Sales (Rs. m)	1,66,949	1,72,639	1,84,748	1,98,423
EBITDA (Rs. m)	27,689	34,684	38,894	42,760
Margin (%)	16.6	20.1	21.1	21.6
PAT (Rs. m)	15,940	21,722	24,072	30,144
EPS (Rs.)	19.8	26.9	29.9	37.4
Gr. (%)	3.1	36.3	10.8	25.2
DPS (Rs.)	7.0	2.0	2.0	2.0
Yield (%)	0.9	0.3	0.3	0.3
RoE (%)	10.4	13.6	14.8	18.2
RoCE (%)	12.5	16.0	17.8	22.2
EV/Sales (x)	3.8	3.7	3.5	3.2
EV/EBITDA (x)	23.2	18.5	16.4	15.0
PE (x)	39.8	29.2	26.4	21.1
P/BV (x)	4.0	3.9	3.9	3.8

Key Data

CIPLA.BO | CIPLA IN

52-W High / Low	Rs.829 / Rs.354
Sensex / Nifty	40,626 / 11,935
Market Cap	Rs.635bn/ \$ 8,654m
Shares Outstanding	806m
3M Avg. Daily Value	Rs.13674.44m

Shareholding Pattern (%)

Promoter's	36.68
Foreign	18.63
Domestic Institution	22.00
Public & Others	22.69
Promoter Pledge (Rs bn)	-

Stock Performance (%)

	1M	6M	12M
Absolute	8.4	32.8	78.8
Relative	3.7	0.3	67.8

Surajit Pal

surajitpal@plindia.com | 91-22-66322259

Tausif Shaikh

tausifshaikh@plindia.com | 91-22-66322246

FDA issues CRL to IV Tramadol ; Setback for specialty portfolio in US

Quick Pointers:

- CRL would delay Tramadol approval by at least 3-6 months
- Option for resolution: Black box warning and/or additional data generation

While CIPLA's US business is struggling with growth issues since last 12 months, it has received an additional setback because of CRL issued (Complete Response Letter) against NDA application for its specialty product IV Tramadol. We believe CRL would delay the approval for at least 3-6 months and final launch may perhaps be in 2HFY22E. Our earnings estimate has not discounted potential benefits from IV Tramadol as we await better clarity of CIPLA's strategy to market/monetize the products in global markets including US and EU. The product being a specialty medicine, it would take 12-18 months to breakeven, post which it would start contributing in operating profit. However, we prefer to have further clarity post FDA refusal of approval along with issue of CRL and marketing/monetizing strategy of CIPLA in US and ROW. We maintain 'REDUCE' with TP of Rs657 based on 22x (PE) of FY22E.

Options for resolution: CIPLA will have two options to achieve resolution of CRL it received from USFDA:

Option 1: It may choose the option of Black Box warning and remove the drug from use in acute therapy treatment. While this may help to get faster approval but it may take away revenue from large part of the US market. Nevertheless, CIPLA may compensate the loss of US acute therapy market with wider reach of IV Tramadol in ROW hospital markets of Nigeria and South Africa. This option may lead to lower payment to the shareholders of Avenue Therapeutics than current contract of US\$180m.

Option 2: To avoid the loss of acute therapy treatment in US, CIPLA may choose the path of additional data generation that may take 2-3 months where it has to show no staking of opioid (or no opioid overdose). In case it being successful, CIPLA may tap large acute therapy market of IV Tramadol in US. In this scenario, Avenue Therapeutics shareholders will receive US\$180m as contracted if the whole process completes by Apr CY21E.

Details of the CRL: Phase-3 trials demonstrated statistically significant outcomes for all primary and many secondary endpoints, FDA concluded that it cannot approve the application in its present form. FDA highlighted two important points:

- CRL cited that IV tramadol is not safe, especially in cases wherein a patient "requires an analgesic between the first dose of IV tramadol and an onset of analgesia". As choice may be for a different opioid, it may potentially result in opioid "stacking" and increase the likelihood of opioid-related adverse effects.
- FDA also requires that renewed filing of IV Tramadol should have an adequate terminal sterilization validation prior to NDA approval, which is planned for later in Q3FY21E.

Key takeaways from the conference call of the Avenue Therapeutics:

- To submit the response to the regulator in 1QCY22E (Q4FY21E)
- Around 2% from patients group showed lack of efficacy during trials and discontinued/dropped out from the clinical trials
- CRL of the USFDA resolution does not require additional data nor is has it been requested
- CIPLA's contract with the Avenue Therapeutics is expected to close by (stage-2) April CY-21 if the core criterion is met, however Cipla has an option to negotiate for lower payment on the contract.

Genesis about IV Tramadol: Tramadol is a strong painkiller. It's used to treat moderate to severe pain after an operation or a serious injury. It's also used to treat long-standing pain when weaker painkillers no longer work.

Value proposition offered by Cipla/Invagen to Avenue Therapeutics: Cipla offered value proposition to Avenue Therapeutics in Nov-CY18 for stage-wise investment in the company that included offering CVR (Contingent Value rights) to current shareholders of Avenue Therapeutics Inc. The proposal included partial investment by Cipla/Invagen post closure of stage-1 and agreement to complete buyout post closure of stage-2 in April CY-21.

Cipla invested US\$35m post closure of stage-1(Feb FY19). It acquired 5.8m shares @US\$6/share for 33.3% stake in the Avenue Therapeutics on a fully diluted basis. Post the closure stage-2, CIPLA will invest US\$180m for acquiring remaining shares in the Avenue Therapeutics and plan for REVERSE TRIANGULAR merger with Avenue, so as to still remain a surviving entity. The offer of US\$180m investment represents a shareholder value of US\$13.92/share (11m non-Cipla shares o/s in Jun CY20), subject to meeting certain major milestones.

CIPLA also offered upside to the current shareholders of the Avenue Therapeutics though CVR based of IV Tramadol sales. Avenue believes that strong IP of its proprietary dosing regimen of IV Tramadol will protect its exclusivity in the US till mid 2030's (roughly 15 years). Each shareholders of Avenue will receive CVR at 1:1 for shares it holds, during the Stage-2 closure.

CVR payments are on annual IV tramadol net sales (from product launch to CY28):

- 10% of all gross profits if net sales >US\$325M
- 12.5% of all gross profits if net sales >US\$400M
- 15% of all gross profits if net sales >US\$500M

From the beginning in 2029, if cumulative net sales of IV Tramadol are at least US\$1.5bn AND annual net sales are >US\$100M, then annual payment of CVR is 20% of all gross profits.

Financials

Income Statement (Rs m)

Y/e Mar	FY20	FY21E	FY22E	FY23E
Net Revenues	1,66,949	1,72,639	1,84,748	1,98,423
YoY gr. (%)	4.5	3.4	7.0	7.4
Cost of Goods Sold	59,914	67,153	71,964	69,349
Gross Profit	1,07,034	1,05,486	1,12,784	1,29,074
Margin (%)	64.1	61.1	61.0	65.1
Employee Cost	30,270	31,095	33,245	35,716
Other Expenses	12,061	13,810	13,856	14,882
EBITDA	27,689	34,684	38,894	42,760
YoY gr. (%)	2.3	25.3	12.1	9.9
Margin (%)	16.6	20.1	21.1	21.6
Depreciation and Amortization	11,747	13,400	15,311	11,566
EBIT	15,942	21,285	23,583	31,195
Margin (%)	9.5	12.3	12.8	15.7
Net Interest	1,974	1,218	785	760
Other Income	7,813	8,353	8,776	9,214
Profit Before Tax	21,782	28,420	31,573	39,649
Margin (%)	13.0	16.5	17.1	20.0
Total Tax	6,312	7,245	8,051	10,110
Effective tax rate (%)	29.0	25.5	25.5	25.5
Profit after tax	15,470	21,176	23,522	29,539
Minority interest	(470)	(546)	(550)	(605)
Share Profit from Associate	-	-	-	-
Adjusted PAT	15,940	21,722	24,072	30,144
YoY gr. (%)	3.2	36.3	10.8	25.2
Margin (%)	9.5	12.6	13.0	15.2
Extra Ord. Income / (Exp)	-	-	-	-
Reported PAT	15,940	21,722	24,072	30,144
YoY gr. (%)	3.2	36.3	10.8	25.2
Margin (%)	9.5	12.6	13.0	15.2
Other Comprehensive Income	-	-	-	-
Total Comprehensive Income	15,940	21,722	24,072	30,144
Equity Shares O/s (m)	806	806	806	806
EPS (Rs)	19.8	26.9	29.9	37.4

Source: Company Data, PL Research

Balance Sheet Abstract (Rs m)

Y/e Mar	FY20	FY21E	FY22E	FY23E
Non-Current Assets				
Gross Block	1,17,813	1,26,813	1,35,813	1,45,813
Tangibles	79,536	85,536	91,536	98,536
Intangibles	38,277	41,277	44,277	47,277
Acc: Dep / Amortization	53,551	67,518	82,490	94,055
Tangibles	30,240	36,983	44,206	51,990
Intangibles	23,311	30,535	38,283	42,065
Net fixed assets	64,262	59,295	53,323	51,757
Tangibles	49,296	48,553	47,329	46,546
Intangibles	14,965	10,742	5,994	5,211
Capital Work In Progress	8,245	8,366	8,491	8,277
Goodwill	32,567	32,567	32,567	32,567
Non-Current Investments	5,489	5,682	5,883	5,364
Net Deferred tax assets	(1,254)	(110)	1,153	2,739
Other Non-Current Assets	6,603	5,977	5,661	4,888
Current Assets				
Investments	10,165	8,132	6,506	5,205
Inventories	43,776	41,623	45,554	48,926
Trade receivables	38,913	42,569	44,542	47,839
Cash & Bank Balance	10,039	6,063	6,314	6,724
Other Current Assets	8,866	9,044	8,139	8,953
Total Assets	2,36,625	2,27,673	2,24,906	2,29,648
Equity				
Equity Share Capital	1,613	1,613	1,613	1,613
Other Equity	1,56,018	1,60,665	1,61,406	1,65,869
Total Networkth	1,57,630	1,62,277	1,63,019	1,67,481
Non-Current Liabilities				
Long Term borrowings	23,693	17,770	14,216	13,505
Provisions	1,333	1,133	963	818
Other non current liabilities	675	484	321	183
Current Liabilities				
ST Debt / Current of LT Debt	4,472	3,577	3,219	3,380
Trade payables	22,818	21,284	22,777	24,463
Other current liabilities	16,642	13,318	14,095	15,219
Total Equity & Liabilities	2,36,626	2,27,673	2,24,906	2,29,648

Source: Company Data, PL Research

Cash Flow (Rs m)

Y/e Mar	FY20	FY21E	FY22E	FY23E
PBT	21,782	28,420	31,573	39,649
Add. Depreciation	11,747	13,400	15,311	11,566
Add. Interest	1,974	1,218	785	760
Less Financial Other Income	7,813	8,353	8,776	9,214
Add. Other	2,425	(10,052)	(19,512)	(20,492)
Op. profit before WC changes	37,927	32,986	28,157	31,482
Net Changes-WC	5,747	(5,569)	(2,077)	(5,649)
Direct tax	(6,312)	(7,245)	(8,051)	(10,110)
Net cash from Op. activities	37,363	20,172	18,029	15,722
Capital expenditures	(9,465)	(9,121)	(9,125)	(9,786)
Interest / Dividend Income	-	-	-	-
Others	10,836	1,989	1,582	1,530
Net Cash from Inv. activities	1,371	(7,132)	(7,543)	(8,256)
Issue of share cap. / premium	-	-	-	-
Debt changes	(14,998)	(6,818)	(3,912)	(550)
Dividend paid	(5,650)	(1,609)	(1,609)	(1,609)
Interest paid	(1,974)	(1,218)	(785)	(760)
Others	-	-	-	-
Net cash from Fin. activities	(22,622)	(9,644)	(6,306)	(2,919)
Net change in cash	16,112	3,396	4,180	4,547
Free Cash Flow	27,898	11,051	8,904	5,936

Source: Company Data, PL Research

Quarterly Financials (Rs m)

Y/e Mar	Q3FY20	Q4FY20	Q1FY21	Q2FY21E
Net Revenue	42,346	43,016	42,769	43,917
YoY gr. (%)	8.4	0.7	9.8	3.0
Raw Material Expenses	16,450	16,889	15,895	17,260
Gross Profit	25,896	26,127	26,874	26,658
Margin (%)	61.2	60.7	62.8	60.7
EBITDA	6,219	5,590	9,795	8,388
YoY gr. (%)	2.6	(32.5)	20.9	7.8
Margin (%)	14.7	13.0	22.9	19.1
Depreciation / Depletion	2,779	3,458	2,690	2,959
EBIT	3,440	2,132	7,105	5,429
Margin (%)	8.1	5.0	16.6	12.4
Net Interest	462	530	460	469
Other Income	2,086	1,678	1,347	2,635
Profit before Tax	5,064	3,280	7,992	7,595
Margin (%)	12.0	7.6	18.7	17.3
Total Tax	1,528	856	2,278	1,747
Effective tax rate (%)	30.2	26.1	28.5	23.0
Profit after Tax	3,536	2,424	5,714	5,848
Minority interest	26	38	54	(200)
Share Profit from Associates	-	-	-	-
Adjusted PAT	3,510	2,385	5,661	6,048
YoY gr. (%)	5.7	(35.0)	26.6	28.3
Margin (%)	8.3	5.5	13.2	13.8
Extra Ord. Income / (Exp)	-	-	-	-
Reported PAT	3,510	2,385	5,661	6,048
YoY gr. (%)	5.7	(35.0)	26.6	28.3
Margin (%)	8.3	5.5	13.2	13.8
Other Comprehensive Income	-	-	-	-
Total Comprehensive Income	3,510	2,385	5,661	6,048
Avg. Shares O/s (m)	806	806	806	806
EPS (Rs)	4.4	3.0	7.0	7.5

Source: Company Data, PL Research

Key Financial Metrics

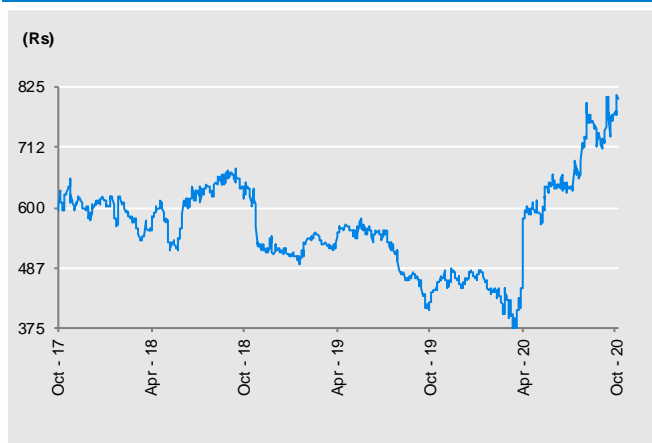
Y/e Mar	FY20	FY21E	FY22E	FY23E
Per Share(Rs)				
EPS	19.8	26.9	29.9	37.4
CEPS	34.3	43.6	48.8	51.7
BVPS	195.5	201.3	202.2	207.7
FCF	34.6	13.7	11.0	7.4
DPS	7.0	2.0	2.0	2.0
Return Ratio(%)				
RoCE	12.5	16.0	17.8	22.2
ROIC	11.7	15.2	17.3	18.6
RoE	10.4	13.6	14.8	18.2
Balance Sheet				
Net Debt : Equity (x)	0.1	0.0	0.0	0.0
Net Working Capital (Days)	131	133	133	133
Valuation(x)				
PER	39.8	29.2	26.4	21.1
P/B	4.0	3.9	3.9	3.8
P/CEPS	22.9	18.1	16.1	15.2
EV/EBITDA	23.2	18.5	16.4	15.0
EV/Sales	3.8	3.7	3.5	3.2
Dividend Yield (%)	0.9	0.3	0.3	0.3

Source: Company Data, PL Research

Key Operating Metrics

Y/e Mar	FY20	FY21E	FY22E	FY23E
India Formulations	65,856	70,466	76,103	82,191
Exports	94,313	98,469	1,04,275	1,11,125
APIs	7,711	7,865	8,652	9,517

Source: Company Data, PL Research

Price Chart
Recommendation History


No.	Date	Rating	TP (Rs.)	Share Price (Rs.)
1	13-Oct-20	Reduce	657	814
2	09-Aug-20	Reduce	657	729
3	08-Jul-20	Reduce	542	634
4	16-May-20	Reduce	542	570
5	18-Apr-20	Reduce	542	598
6	14-Apr-20	Reduce	460	580
7	05-Feb-20	Reduce	460	448
8	03-Jan-20	Reduce	439	470
9	06-Nov-19	Reduce	439	481

Analyst Coverage Universe

Sr. No.	Company Name	Rating	TP (Rs)	Share Price (Rs)
1	Aurobindo Pharma	Hold	808	834
2	Cadila Healthcare	Sell	310	442
3	Cipla	Reduce	657	814
4	Dr. Lal PathLabs	UR	-	2,179
5	Dr. Reddy's Laboratories	Accumulate	5,648	5,221
6	Eris Lifesciences	BUY	615	510
7	Glenmark Pharmaceuticals	Sell	349	496
8	Indoco Remedies	Hold	239	252
9	Ipca Laboratories	Hold	1,886	2,113
10	Jubilant Life Sciences	Sell	455	708
11	Lupin	BUY	1,085	1,047
12	Sun Pharmaceutical Industries	Reduce	476	514
13	Thyrocare Technologies	UR	-	1,102

PL's Recommendation Nomenclature (Absolute Performance)

Buy	: > 15%
Accumulate	: 5% to 15%
Hold	: +5% to -5%
Reduce	: -5% to -15%
Sell	: < -15%
Not Rated (NR)	: No specific call on the stock
Under Review (UR)	: Rating likely to change shortly

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3rd Floor, Sadhana House, 570, P. B. Marg, Worli, Mumbai-400 018, India | Tel: (91 22) 6632 2222 Fax: (91 22) 6632 2209

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